General Assembly

Raised Bill No. 579

February Session, 2006

LCO No. **2651**

Referred to Committee on

Introduced by: PUBLIC HEALTH
(PH)

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2006*) (a) Subject to the limitations set forth in subsection (b) of this section, each individual health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, amended, renewed or continued in this state on or after October 1, 2006, shall provide coverage for the medically necessary expenses of the diagnosis and treatment of morbid obesity, including, but not limited to, bariatric surgery, physician office visits, health and behavior assessments, nutrition education, patient self-management education and training and therapeutic exercises. Such coverage shall have durational limits, dollar limits, deductibles, copayments and coinsurance factors that are no less favorable than for physical illness generally. Access to surgery for morbid obesity shall not be restricted based upon dietary or any other criteria not recommended by the National Institutes of Health. For the purposes of this section, (1) "morbid obesity" means (A) a

weight that is at least one hundred pounds over or twice the ideal weight for frame, age, height and gender as specified in the 1983 Metropolitan Life Insurance tables, (B) a BMI equal to or greater than thirty-five kilograms per meter squared with comorbidity or coexisting medical conditions related to morbid obesity such as hypertension, cardiopulmonary conditions, sleep apnea or diabetes, or (C) a BMI of forty kilograms per meter squared without such comorbidity, and (2) "BMI" means body mass index that equals weight in kilograms divided by height in meters squared.

(b) Such policy may:

(1) Limit such coverage to an individual until the date of such individual's eighteenth birthday;

(2) Limit such coverage to include up to four physician-office visits per year and related testing for the evaluation and treatment of morbid obesity;

(3) Limit such coverage to include up to four visits per year, prescribed by a physician and performed by a physician or qualified nonphysician including, but not limited to, a dietician, nutritionist or exercise physiologist supplying, but not limited to, health and behavior assessment, nutrition education, education and training for patient self-management;

(4) Limit coverage for bariatric surgery to those individuals who have a documented history of an inadequate nonsurgical weight loss attempt under the direction of a physician and who demonstrate a willingness to overcome morbid obesity or seek an improvement in health status;

(5) Limit coverage for bariatric surgery to those individuals who have received pre-operative and postoperative medical and nutritional education, as well as psychological assessment and clearance prior to surgery;

(6) Require that providers of surgical services be: (A) Certified by the American College of Surgeons as a level 1a Bariatric Surgery Center; or (B) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence;

(7) Require that the following minimum standards be maintained by providers of bariatric surgery services who do not meet the criteria of subdivision (6) of this subsection:

(A) An institutional commitment of the medical staff and the institution's administration to excellence in bariatric surgical care that is demonstrated by ongoing, regularly scheduled, in-service education programs in bariatric surgery and the adoption of credentialing guidelines for bariatric surgery;

(B) Performance of at least one hundred twenty-five bariatric surgical cases each year by institutions, and at least fifty bariatric surgical cases each year by surgeons, for a period of at least two years;

(C) A designated physician medical director for bariatric surgery who participates in relevant decision-making and medical and administrative meetings of the institution;

(D) A full staff of the various consultative services required for the care of bariatric surgical patients, available upon thirty minutes notice, including the immediate on-site availability of a physician qualified in advanced cardiac life support;

(E) A full-line of equipment and instruments for the care of bariatric surgical patients, including furniture, wheelchairs, operating room tables, beds, radiologic capabilities, surgical instruments and other facilities suitable for morbidly obese patients;

(F) A bariatric surgeon certified by the American Board of Surgery, the American Osteopathic Board of Surgery, or the Royal College of Surgeons of Australia, United Kingdom or Canada who spends a significant portion of his or her efforts in the field of bariatric surgery

and who has qualified coverage entailing full care of a bariatric patient in the absence of the primary surgeon and support for patient care;

(G) Clinical pathways and orders by providers that facilitate the standardization of perioperative care for the relevant procedure chosen by the provider;

(H) Designated licensed nurses or nonphysician extenders who are dedicated to serving bariatric surgical patients and who are involved in continuing education in the care of bariatric patients;

(I) Organized, supervised and documented support groups for patients who have undergone bariatric surgery at the institution;

(J) Documentation of a program dedicated to a goal of long-term patient follow-up of at least seventy-five per cent for bariatric procedures at five years with a monitoring and tracking system for outcomes, and an agreement to make available annual outcome summaries to the reviewing professionally directed accrediting organization in a manner consistent with Health Insurance Portability and Accountability Act regulations;

(8) Require coverage of the long-term postoperative follow-up care following bariatric surgery. Such follow-up care shall be prescribed by a physician and performed by a physician or qualified nonphysician, including, but not limited to, a dietician, nutritionist or exercise physiologist supplying services beyond the normal surgical postoperative care period; and

(9) Limit coverage to individuals who have maintained coverage under such policy for at least twelve months, provided such policy provides written notice to each insured or prospective insured that benefits exclude coverage pursuant to this subdivision. Such notice shall appear in the policy, application and sales brochure for such policy in not less than ten-point type.

Sec. 2. (NEW) (*Effective October 1, 2006*) (a) Any insurance company,

hospital service corporation or medical service corporation authorized to do the business of health insurance in this state shall offer to any individual, partnership, corporation or unincorporated association providing group hospital or medical insurance coverage for its employees a group hospital or medical service plan or contract providing coverage for the medically necessary expenses of the diagnosis and treatment of morbid obesity.

(b) Subject to the limitations set forth in subsection (c) of this section, each group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, amended, renewed or continued in this state on or after October 1, 2006, shall provide coverage for medically necessary expenses of the diagnosis and treatment of morbid obesity, including, but not limited to, bariatric surgery, physician office visits, health and behavior assessments, nutrition education, patient self-management education and training and therapeutic exercises. Such coverage shall have durational limits, dollar limits, deductibles, copayments and coinsurance factors that are no less favorable than for physical illness generally. Access to surgery for morbid obesity shall not be restricted based upon dietary or any other criteria not recommended by the National Institutes of Health. For the purposes of this section, (1) "morbid obesity" means (A) a weight that is at least one hundred pounds over or twice the ideal weight for frame, age, height and gender as specified in the 1983 Metropolitan Life Insurance tables, (B) a BMI equal to or greater than thirty-five kilograms per meter squared with comorbidity or coexisting medical conditions related to morbid obesity such as hypertension, cardiopulmonary conditions, sleep apnea or diabetes, or (C) a BMI of forty kilograms per meter squared without such comorbidity, and (2) "BMI" means body mass index that equals weight in kilograms divided by height in meters squared.

(c) Such policy may:

(1) Limit such coverage to an individual until the date of such individual's eighteenth birthday;

(2) Limit such coverage to include up to four physician-office visits per year and related testing for the evaluation and treatment of morbid obesity;

(3) Limit such coverage to include up to four visits per year, prescribed by a physician and performed by a physician or qualified nonphysician including, but not limited to, a dietician, nutritionist or exercise physiologist supplying, but not limited to, health and behavior assessment, nutrition education, education and training for patient self-management;

(4) Limit coverage for bariatric surgery to those individuals who have a documented history of an inadequate nonsurgical weight loss attempt under the direction of a physician and who demonstrate a willingness to overcome morbid obesity or seek an improvement in health status;

(5) Limit coverage for bariatric surgery to those individuals who have received pre-operative and postoperative medical and nutritional education, as well as psychological assessment and clearance prior to surgery;

(6) Require that providers of surgical services be (A): Certified by the American College of Surgeons as a level 1a Bariatric Surgery Center; or (B) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence;

(7) Require that the following minimum standards be maintained by providers of bariatric surgery services who do not meet the criteria of Subdivision (6) of this subsection:

(A) An institutional commitment of the medical staff and the institution's administration to excellence in bariatric surgical care that is demonstrated by ongoing, regularly scheduled, in-service education

programs in bariatric surgery and the adoption of credentialing guidelines for bariatric surgery;

(B) Performance of at least one hundred twenty-five bariatric surgical cases each year by institutions, and at least fifty bariatric surgical cases each year by surgeons, for a period of at least two years;

(C) A designated physician medical director for bariatric surgery who participates in relevant decision-making and medical and administrative meetings of the institution;

(D) A full staff of the various consultative services required for the care of bariatric surgical patients, available upon thirty minutes notice, including the immediate on-site availability of a physician qualified in advanced cardiac life support;

(E) A full-line of equipment and instruments for the care of bariatric surgical patients, including furniture, wheelchairs, operating room tables, beds, radiologic capabilities, surgical instruments and other facilities suitable for morbidly obese patients;

(F) A bariatric surgeon certified by the American Board of Surgery, the American Osteopathic Board of Surgery, or the Royal College of Surgeons of Australia, United Kingdom or Canada who spends a significant portion of his or her efforts in the field of bariatric surgery and who has qualified coverage entailing full care of a bariatric patient in the absence of the primary surgeon and support for patient care;

(G) Clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure chosen by the provider;

(H) Designated licensed nurses or nonphysician extenders who are dedicated to serving bariatric surgical patients and who are involved in continuing education in the care of bariatric patients;

(I) Organized, supervised and documented support groups for

patients who have undergone bariatric surgery at the institution;

(J) Documentation of a program dedicated to a goal of long-term patient follow-up of at least seventy-five per cent for bariatric procedures at five years with a monitoring and tracking system for outcomes, and an agreement to make available annual outcome summaries to the reviewing professionally directed accrediting organization in a manner consistent with Health Insurance Portability and Accountability Act regulations;

(8) Require coverage of the long-term postoperative follow-up care following bariatric surgery. Such follow-up care shall be prescribed by a physician and performed by a physician or qualified nonphysician, including, but not limited to, a dietician, nutritionist or exercise physiologist supplying services beyond the normal surgical postoperative care period; and

(9) Limit coverage to individuals who have maintained coverage under such policy for at least twelve months, provided such policy provides written notice to each insured or prospective insured that benefits exclude coverage pursuant to this subdivision. Such notice shall appear in the policy, application and sales brochure for such policy in not less than ten-point type.

Sec. 3. (NEW) (*Effective October 1, 2006*) Each health care provider licensed in this state who performs a bariatric surgery procedure shall submit a report to the Department of Public Health that specifies comprehensive standardized data, including the methods of collection of such data, in order to determine the success of such procedure and the impact of such procedure on the lives of such provider's patients, not later than April first following any year in which such procedure is performed. The standardized data shall include the patient's age, gender, height, pre-bariatric surgery weight, pre-bariatric surgery BMI, pre-bariatric surgery comorbidities, and comprehensive pre-surgical history, the type of surgical procedure, the length of stay of bariatric surgery admission, any complications reported during bariatric

surgery and any readmissions up to one year after the surgery that were related to complications of primary bariatric surgery. Such data shall be submitted on such forms as the department prescribes.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2006*	New section
Sec. 2	*October 1, 2006*	New section
Sec. 3	*October 1, 2006*	New section

Statement of Purpose:

To require individual and group health insurance policies to provide coverage for medically necessary expenses associated with the diagnosis and treatment of morbid obesity, including, bariatric surgery and associated physician office visits, health and behavior assessments, nutrition education, patient self-management education and training and therapeutic exercises.

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]

General Assembly

Proposed Substitute Bill No. 579

February Session, 2006

LCO No. **3428**

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective from passage*) (a) As used in this section:

(1) "Morbid obesity" means (A) a weight that is at least one hundred pounds over or twice the ideal weight for frame, age, height and gender as specified in the 1983 Metropolitan Life Insurance tables, (B) a BMI equal to or greater than thirty-five kilograms per meter squared with comorbidity or coexisting medical conditions related to morbid obesity such as hypertension, cardiopulmonary conditions, sleep apnea or diabetes, or (C) a BMI of forty kilograms per meter squared without such comorbidity; and

(2) "BMI" means body mass index that equals weight in kilograms divided by height in meters squared.

(b) On or before October 1, 2007, the Insurance Commissioner shall adopt regulations, in accordance with chapter 54 of the general

statutes, establishing guidelines for health insurance coverage for medical services and treatment for morbid obesity. Such regulations shall:

(1) Require that each individual and group health insurance policy providing coverage of the type specified in subdivisions (1), (2), (4), (11) and (12) of section 38a-469 of the general statutes delivered, issued for delivery, amended, renewed or continued in this state on or after October 1, 2007, provide coverage for the medically necessary expenses of the diagnosis and treatment of morbid obesity, including, but not limited to, bariatric surgery, physician office visits, health and behavior assessments, nutrition education, patient self-management education and training and therapeutic exercises.

(2) Limit coverage of bariatric surgery to providers of surgical services that are: (A) Certified by the American College of Surgeons as a level 1a Bariatric Surgery Center; or (B) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence.

(c) The regulations adopted pursuant to subsection (b) of this section do not apply to any health insurer that obtains approval from the Insurance Department on or before October 1, 2007, to provide coverage for the medically necessary expenses of the diagnosis and treatment of morbid obesity, including, but not limited to, bariatric surgery, physician office visits, health and behavior assessments, nutrition education, patient self-management education and training and therapeutic exercises.

Sec. 2. (NEW) (*Effective October 1, 2007*) Each health insurer, as defined in section 38a-478n of the 2006 supplement to the general statutes, hospital service corporation, as defined in section 38a-199 of the general statutes, or medical service corporation licensed to conduct health insurance business in this state shall offer to any individual, partnership, corporation or unincorporated association providing group hospital or medical insurance coverage for its employees a

group hospital or medical service plan or contract providing coverage for the medically necessary expenses of the diagnosis and treatment of morbid obesity.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*from passage*	New section
Sec. 2	*October 1, 2007*	New section

Senate

General Assembly

File No. 338

February Session, 2006

Substitute Senate Bill No. 579

Senate, April 4, 2006

The Committee on Public Health reported through SEN. MURPHY of the 16th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

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Section 1. (NEW) (*Effective from passage*) (a) As used in this section:

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group hospital or medical service plan or contract providing coverage for the medically necessary expenses of the diagnosis and treatment of morbid obesity.

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PH *Joint Favorable Subst.*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 07 $	FY 08 $
State Comptroller - Miscellaneous	Various - Cost	None	700,000

Municipal Impact:

Municipalities	Effect	FY 07 $	FY 08 $
Various Municipalities	Cost	Potential	Potential

Explanation

Since the bill requires coverage that slightly exceeds the protocols of the existing state health plans, a cost increase of less than 0.10% would occur when new contracts are entered into in FY 08. This would translate into approximately $700,000 annually for FY 08 for all medical plans. However it should be noted that the state should save in future years. If the treatment is successful, the often attendant medical conditions of high blood pressure, diabetes and heart disease, etc. would improve and could produce a reduction in the state's medical costs for the treatment of the related conditions.

The bill's impact on municipal health insurance costs will vary based on existing municipal coverage. To the extent the coverage required under the bill is greater than is currently provided; there would be increased costs and the potential for future savings.

The bill also requires the commissioner of the Department of Insurance to adopt certain regulations. This does not have a fiscal impact.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

OLR Bill Analysis

sSB 579

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

SUMMARY:

This bill requires certain health insurers, beginning October 1, 2007, to offer individual and group coverage for the medically necessary expenses of diagnosing and treating morbid obesity. It requires the insurance commissioner to adopt regulatory guidelines requiring coverage for certain items and limiting coverage for bariatric surgery to procedures performed in certified locations. Insurers who obtain Insurance Department approval to cover diagnosis and treatment of morbid obesity before October 1, 2007 are not subject to these regulations.

EFFECTIVE DATE: Upon passage for insurance commissioner regulatory guidelines and October 1, 2007 for the mandatory offer.

MORBID OBESITY DEFINED

The bill defines "morbid obesity" as:

1. being at least 100 pounds over, or double, the ideal weight for frame, height, age, and gender listed in the 1983 Metropolitan Life Insurance table (the last revision);

2. having both a "body mass index" (BMI) of 35 or more kilograms per square meter and a related disease or condition such as hypertension, cardiopulmonary conditions, sleep apnea, or diabetes; or

3. a BMI of 40 without related diseases or conditions.

BMI is derived by dividing weight (in kilograms) by height (in meters squared).

Insurance Regulation Requirements and Limitations

The bill requires the insurance commissioner to adopt regulations by October 1, 2007 that establish coverage guidelines for medical services and treatment of morbid obesity. The regulations must require certain individual and group policies to cover the medically necessary expenses of diagnosing and treating morbid obesity. The policies must cover, at least, bariatric surgery, physician office visits, health and behavior assessments, nutrition education, patient self-management education and training, and therapeutic exercise. This requirement applies to basic hospital, basic medical-surgical, major medical, hospital or medical service plan contract, and HMO policies delivered, issued, amended, renewed, or continued after September 30, 2007.

The regulations must limit coverage for bariatric surgery to providers certified as (1) level 1a bariatric surgery centers by the American College of Surgeons or (2) bariatric surgery centers of excellence by the American Society for Bariatric Surgery.

Mandatory Offer of Coverage

The bill requires all "health insurers" (whose definition excludes managed care organizations), hospital service corporations, and medical service corporations licensed in Connecticut to offer individual and group policies that cover medically necessary expenses of diagnosing and treating morbid obesity. They must do so beginning October 1, 2007.

BACKGROUND

Bariatric Surgery

The term bariatric surgery includes a variety of operations, such as gastric bypass and adjustable banding, that either reduce the absorption of nutrients into the body or restrict food intake and promote a feeling of fullness after meals.

Related Bill

sSB 552, reported favorably by the Insurance Committee, requires the committee's chairmen to convene a working group to study the feasibility of requiring coverage of morbid obesity. The bill requires the group to report to the committee by January 1, 2007.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute
Yea 22 Nay 0 (03/17/2006)

Senate

General Assembly

File No. 338

February Session, 2006

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Senate, April 4, 2006

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PH *Joint Favorable Subst.*

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Explanation

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OLR Bill Analysis

sSB 579

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

SUMMARY:

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EFFECTIVE DATE: Upon passage for insurance commissioner regulatory guidelines and October 1, 2007 for the mandatory offer.

MORBID OBESITY DEFINED

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3. a BMI of 40 without related diseases or conditions.

BMI is derived by dividing weight (in kilograms) by height (in meters squared).

Insurance Regulation Requirements and Limitations

The bill requires the insurance commissioner to adopt regulations by October 1, 2007 that establish coverage guidelines for medical services and treatment of morbid obesity. The regulations must require certain individual and group policies to cover the medically necessary expenses of diagnosing and treating morbid obesity. The policies must cover, at least, bariatric surgery, physician office visits, health and behavior assessments, nutrition education, patient self-management education and training, and therapeutic exercise. This requirement applies to basic hospital, basic medical-surgical, major medical, hospital or medical service plan contract, and HMO policies delivered, issued, amended, renewed, or continued after September 30, 2007.

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Mandatory Offer of Coverage

The bill requires all "health insurers" (whose definition excludes managed care organizations), hospital service corporations, and medical service corporations licensed in Connecticut to offer individual and group policies that cover medically necessary expenses of diagnosing and treating morbid obesity. They must do so beginning October 1, 2007.

BACKGROUND

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COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute
Yea 22 Nay 0 (03/17/2006)

PUBLIC HEALTH COMMITTEE
VOTE TALLY SHEET

Bill No.: SB-579 **Amendment Letter:**

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

Chair: **Motion:** **Second:**

Action: Joint Favorable Substitute

Language Change:

TOTALS	Voting	Yea	Nay	Abstain	Absent and Not Voting	Voice Vote
	22	22	0	1	3	

	yea	nay	abstain	absent
Sen. **Murphy**, C. S16	X			
Rep. **Sayers**, P. 060	X			
Rep. **Olson**, M. 046	X			
Sen. **Slossberg**, G. S14	X			
Sen. **Gunther**, G. S21	X			
Rep. **Wasserman**, J. 106				X
Rep. **Aldarondo**, D. 075	X			
Rep. **Carson**, M. 108	X			
Rep. **Christ**, M. 011	X			
Sen. **Coleman**, E. S02	X			
Sen. **Cook**, C. S18	X			
Rep. **Fahrbach**, R. 061	X			
Rep. **Giegler**, J. 138	X			
Rep. **Heinrich**, D. 101			X	
Rep. **Keeley**, R. 129	X			
Rep. **Klarides**, T. 114				X
Rep. **Malone**, J. 047				X
Rep. **Nardello**, V. 089	X			
Rep. **Orange**, L. 048	X			
Rep. **Ritter**, E. 038	X			
Rep. **Ryan**, K. 139	X			
Sen. **Stillman**, A. S20	X			
Rep. **Stone**, J. 134	X			
Rep. **Tercyak**, P. 026	X			
Rep. **Widlitz**, P. 098	X			
Rep. **Winkler**, L. 041	X			

	yea	nay	abstain	absent

Vote date: 3/17/2006 4:49:00 PM Correction date:

REPORT ON BILLS FAVORABLY REPORTED BY COMMITTEE

COMMITTEE: **Public Health Committee**

File No.: 338
Bill No.: SB-579
PH Date: 3/13/2006
Action/Date: 3/17/2006
Reference Change: JFS to Floor

TITLE OF BILL:

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

SPONSORS OF BILL:

Public Health Committee

REASONS FOR BILL:

To require individual and group health insurance policies to provide coverage for medically necessary expenses associated with the diagnosis and treatment of morbid obesity, including, bariatric surgery and associated physician office visits, health and behavior assessments, nutrition education, patient self-management education and training and therapeutic exercises.

RESPONSE FROM ADMINISTRATION/AGENCY:

J. Robert Galvin, M.D., M.P.H., Commissioner Department of Public Health:
The Department of Public health provides the following information with regard to Senate Bill 579.

Obesity is a growing public health crisis in Connecticut. It is second only to smoking in its contribution to total morbidity and mortality rates in the United States and is a risk factor for a variety of chronic diseases including: arthritis, asthma, cancer, cardiovascular disease and stroke, depression, and diabetes.

In Connecticut, over half of all adults (56%) are either overweight or obese, and in Hartford public schools, nearly one-quarter of sixth-graders are at risk for learning impairment and health conditions because of excess body weight.

In Connecticut, an estimated 4.3% of adult medical costs -- $856 million dollars annually – are attributable to obesity. Medicare and Medicaid finance approximately 78% of these costs.

Statistical Analysis has proven that there is a marked reduction in morbidity and mortality in individuals who have undergone successful bariatric surgery in an approved hospital program. This program should consist of comprehensive services that include: nutrition education, psychological counseling, medical evaluation and the services of a certified bariatric surgical team.

Ultimately, the successful diagnosis and treatment of morbid obesity will reduce overall health care costs over a patients' lifetime, and will provide significant improvements in the individual's health, morale, and lifestyle.

Leslie J. Gabel-Brett, Executive Director, the Permanent Commission on the Status of Women:
We urge you to support SB 579 that would provide limited coverage for diagnosis and treatment of morbid obesity including dietetic consultations, nutrition education and health and behavioral assessments. Obesity is of concern to women and girls, especially women of color. Obesity is more common among African-American and Hispanic women and children and low-income women.

Obesity is associated with significant health problems and is an early risk factor for disease and, ultimately, death. Nationally, 15% of girls 6-19 are considered overweight. In Connecticut, 25% of children between the ages of 6-17 are considered overweight. Women are disproportionately obese: 33% of adult women are obese compared to 28% of adult men. Within Connecticut, 19% of the adult population is obese.

In 2003, direct health costs associated with the treatment of obesity-related diseases amounted to $75 billion, and health cost associated with obesity-related illnesses amounted to $856 million in Connecticut.

NATURE AND SOURCES OF SUPPORT:

Bernadette McBride, RN, Andover, CT:
I have been overweight for 30 years. I have been on various diets since the age of 12. I have never been successful at keeping the weight off, and have been "morbidly obese" for a good 12-15 years.

I had weight loss surgery three days before my Insurer ceased to cover gastric bypass surgery. I got my life back. Three days later and I wouldn't be here today freed from the clutches of a disease that has plagued me most of my life.

I urge you to vote for this legislation and mandate the insurance companies to cover the NIH recommended Weight Loss Surgery procedures. The efficacy, safety and benefits of these procedures are well documented. This surgery creates successful, permanently sustainable, major weight loss for the morbidly obese patient.

Please do not allow insurers to continue to discriminate against the morbidly obese patient by denying coverage for this surgery when it has been deemed medically necessary by the treating physician.

Nancy Dennehy, Nursing program Director for the bariatric program at Middlesex Hospital:
I am here today to speak in support of Raised Bill #579.

The decision for undergoing weight loss surgery is not an easy one. Individuals must go through an informational program provided by the surgeon, attend an informational session by the psychologist and dietician, attend individual mandatory nutritional and psychological counseling sessions, attend support groups, and undergo required medical testing based on individual needs such as endoscopy and sleep apnea studies. This process can take up to a year.

After many years of unsuccessful weight loss maintenance, I chose to undergo gastric bypass surgery. As a nurse, I understood and had witnessed the devastating sequelae associated with morbid obesity.

Professionally, since 2001, I have witnessed, the success of bariatric surgery on the patients that have come through our bariatric surgical program at Middlesex Hospital. For patients that have come through the program, bariatric surgery is their last hope for life versus death. They have tried everything else without success. There is no reason why this life saving surgical intervention should be denied anyone. The current exclusion policy by insurance companies is preventing patients from their last chance to lose weight and a chance to live healthier lives.

Patricia Mancini, Columbia, CT:
I have been morbidly obese a good part of my adult years. I worked in the nursing profession until I could no longer stand or get around. I was forced to retire early on social security disability. Finally, at age 63 I had a gastric lap band. I am doing well and some of my medical problems have already improved and as I lose more weight my hopes are that I will be independent again.

I hope that this legislation will make it possible for other people to have this life saving surgery.

[SB 579, 1067]

Judith B. Mitrowski, South Windsor, CT:
This legislation is very important to morbidly obese people like me. Morbid obesity is just as much a life threatening disease as cancer, heart disease, and diabetes as well as alcoholism and drug addition. Coverage for this surgery is vitally important. My health today is due to the gastric bypass surgery I had. To deny a morbid obese person this surgery is giving them a death sentence instead of a chance for a better healthier life.

Karen Winkler Weiss, Chester, CT:
I am a successful patient of gastric bypass surgery. Fortunately, I had a good health insurance policy. As unhealthy as I was, weight loss surgery would never have been an option for me if my insurance company had not been willing to pay.

I urge you to pass Senate Bill 579 so that more lives like mine can be saved by this effective cure for obesity and the many other illnesses from which these people suffer.

David Giles, M.D., Assistant Professor of Clinical Surgery, UCHC and Surgical Director of Weigh Your Options, Clinical Weight Loss Center, New Britain General Hospital:

Six years ago as a UCONN faculty member with responsibilities teaching and administering the surgical curriculum for the medical students, teaching surgical residents, practicing general surgery and intensive care medicine, I was asked to start an obesity surgery program at UCONN. I initially refused this request, but agreed under pressure. I attended courses and workshops, visited multiple well regarded programs, obtained a mentor, and began a program at UCONN. The last five years have been an education to me in the life-transforming power of this operation. I have learned a great deal while maintaining a high quality program whose results received the praise of my superiors. After several years, I was invited to move the program to a different hospital to better align this program with the goals and interest of the two respective hospitals.

Today is both exciting as it champions obesity surgery, and sad that we are forced to move toward mandates for these procedures. With a three year perspective, insurance companies do not realize the financial rewards of their investment into the surgery. Meanwhile, obesity and diabetes grow as epidemics of increasing seriousness, epidemics that have no answer currently. There is only one known proven cure, an obesity surgery operation. Returning individuals to the workforce and/or increasing their productivity has no financial reward for our insurance companies.

However, I come concerned about the structure and tone of this bill. I urge caution in moving down the centers of excellence path. The centers program is the product of fears about economic self-preservation of a group of large volume obesity surgeons. Their effort has produced good fruit with the articulation and insistence on best practice processes. But the codifying of this program into law means we also partake of their intentional ploughing under of smaller quality programs that have good results.

Personally, my program will not meet the requirements of these centers program because of its volume and time requirements. I would prefer the state pursue a more flexible approach that promotes best practice processes and accountability, without the straight-jacket effect that these proposed formulas create. This centers approach will be used to stifle growth, limit citizen choices and put hospitals out of the obesity surgery business uncecessarily.

Jessie Moore, Advanced Practice Registered Nurse at the Hospital of Saint Raphael, Center for Obesity Surgery and I am representing the Connecticut Advanced Practice Nurse Society:

I strongly support this bill. As written, it incorporates a standard of care that includes both preoperative and postoperative multidisciplinary care. For the morbidly obese individual, bariatric surgery is a life-changing and often life-saving event. The surgery itself is a "tool" to help achieve the-necessary weight loss, and is just the beginning step in the process.

This bill requires surgery to be performed in designated centers which have achieved quality care standards. Insurers and leaders in the surgical field have endorsed the concept of Bariatric Surgery Centers of Excellence. Surgery done in such a facility reduces the risk and improves the outcomes of the surgery. If we require the insurers to provide coverage, it is only reasonable to require that a standard of care be established.

Morbid obesity affects 9 million adult Americans. The cause is multifactorial: genetic and environmental. It affects all body systems, and the only currently effective treatment is bariatric surgery.

The general benefits of obesity surgery include: weight loss, this occurs soon after surgery and continues for 18 months to two years; at five years studies report a sustained weight loss of 60% of excess body weight; improvements in diabetes, cholesterol, hypertension and sleep apnea; and provides significant quality of life improvements.

Recent trends in health insurance have led to a reduction in coverage for surgical treatment of morbid obesity. Benefits have been changed to exclude coverage, with no notice to subscribers. I have seen patients who have spent months in preparation for their surgery have their coverage dropped during the process, preventing them from having the surgery.

No other health condition is treated this way.

Ms. Anahid Kachoyan, West Hartford, CT:

I was formerly a 343 lb woman who suffered from medical conditions as a direct result of morbid obesity. Had gastric bypass not been an option for me, I would have incurred many more claims related to arthritic and joint ailments, and diabetes. To date, I've lost 210 lbs and have incurred **NO** medical claims pertinent to any ongoing or newly emerged ailments. I feel strongly about availing this surgical option to all eligible individuals.

My prognosis for longevity is no longer limited to 5 years and not health-driven. Without surgery, I may not have been here to issue this appeal. I urge you to give strong consideration to the passage of this legislation.

Gary M. Pratt, Chief Executive Officer, Surgical Review Corporation (SRC):
On behalf of SRC, we support the general tenants of SB 579. SRC is an independent, not-for-profit corporation under contract to administer the Bariatric Surgery Centers of Excellence (BSCOE) program offered by the American Society for Bariatric Surgery (ASBS). SRC wants to comment on two issues: 1) facility selection criteria and 2) outcomes tracking.

SRC highly supports Section 1 (6) which requires that providers of bariatric services be designated as a BSCOE by the ASBS. SRC also supports the provider requirements listed in Section 1 given they match the ASBS' criteria. Our only concern is the listing of specific criteria because this could limit SRC and ASBS' ability to modify criteria based on data analysis.

SRC supports the language in Section 1 (J). The decision to track outcomes data will benefit many patients, as long as the data remains confidential to encourage accurate reporting and is utilized to improve quality. In order to conserve resources and maintain consistency, SRC requests that the state consider utilizing SRC's services to administer the requirements in SB 579.

The ASBS, SRC and State of Connecticut share common goals to promote bariatric surgical excellence with efficiency, efficacy and safety. Developing a program other than the one developed by the ASBS would be detrimental to the industry. Variation in analysis will create confusion to the consumer wondering whose care was actually excellent.

In summary, the ASBS BSCOE is the only center of excellence program approved and endorsed by bariatric surgeons. This program already has tremendous participation for over 500 hospitals and more than 900 surgeons. The information derived from its program is used to spearhead continuous improvement in bariatric surgery.

Christine Gerritt, Middletown, CT:
Having Bariatric surgery has completely changed my life for the better. It has given me a new, healthy and productive life. I am forever grateful for this opportunity.

She provided self testimony of her case similar to the others.

Bariatric surgery is a life saver and in the long run a money saver. It is imperative, especially given all the public attention to obesity, that bariatric surgery be covered by insurance to cure patients of life threatening complications due to obesity.

Donna Salomon:
Last year I was a very sick woman and doctors recommended I have gastric bypass surgery. I was under anesthesia to have the surgery when a complication arose and the surgery was aborted. The very next day my insurance company's plan changed, and the surgery was no longer covered. I felt hopeless.

It was suggested that I contact an attorney that specialized in gastric bypass patients that needed help with their insurance companies. I hired an attorney that understood the problem, having had gastric surgery himself. He went to bat for me and I finally got approved for the surgery.

I had the surgery, during which the doctors found that I was suffering from cirrhosis of the liver as a result of my weight, and therefore, the surgery was even more necessary. Since then, I have lost forty-four pounds, no longer need a wheel chair and have great expectations for the rest of my life.

Jonathan S. Aranow, M.D., F.A.C.S., Shoreline Surgical Associates, P.C.:
I am here to testify in support of Senate Bill 579. I am here representing the Bariatric surgeons of the state, and more importantly, their patients. I am a member of the American Society of Bariatric Surgery and a fellow of the American College of Surgeons. I am chairman of the Connecticut chapter of the ACS Bariatric committee. My testimony is endorsed by the Connecticut State Medical Society.

The bill being discussed today is not seeking expanded health insurance coverage but rather is designed to restore the coverage that was available to all insured clients until January of 2005. Up until that point in time, all major carriers included coverage for weight loss surgery in their general policies. The criteria utilized medical necessity in this bill is identical to those criteria utilized under those policies.

Beginning in January 2005, all of our state's insurance providers revoked coverage for these procedures from their general policies. The exceptions being Medicare and Medicaid and other federally backed insurance programs which nationally mandate coverage for these procedures.

Insurers, however, continue to recognize the medical validity of these procedures. Despite revoking these procedures from the general policies, riders have been made available to large employer groups. This unfortunately leaves about 50% of our population without access to coverage.

These surgeries save lives and the procedures can be done safely despite the exceptionally high risk individuals whom we are referring. The risks of surgery are outweighed by the risk inherent to morbid obesity. The following are benefits documented for those that under go surgery:

- They have a nine-fold reduction of the risk of dying in the five years following surgery.

- Diabetes is completely resolved in 78-82% of patients with dramatic improvements in an additional 20%.
- High blood pressure is completely resolved in 62% of patients with an additional 20% of patients seeing substantial improvement.
- Sleep apnea is resolved in 86% of patients.
- Weight loss is maintained beyond 14 years in over 89% of patients.

The rationale promoted by insurers for these exclusions has been to save costs. This is a clear contradiction to the cost-effectiveness of the results of this surgery. Upfront costs of Bariatric surgery are paid off within 3 years by the reduction in medical care needs and pharmaceutical savings.

Dr. Aranow submitted 22 medical articles and fact sheets in support of his testimony and they are on file.

Cory Weiss, Rabbi of Temple Beth Torah, Wethersfield:
Gastric bypass surgery saved my life.

Rabbi Weiss outlined his personal battle with morbid obesity and attempts at weight loss. After the realization that without a solution he might not live to see his grandchildren or his own boys grow to manhood, he sought out the help of Dr. Aranow, who specializes in Bariatric Surgery. He had gastric bypass surgery which was covered by his medical insurer. He has lost 110 pounds and his medical maladies have been reversed.

I urge the legislature to pass this very important health care bill. This bill will not only save insurance companies a great deal of money over time, but it will save countless lives as well.

Judy Szwaya:
I am 62 years old and three years ago I was morbidly obese. I had gastric by-pass surgery without which I would probably not be here today.

I have lost 200 pounds and no longer take any prescription drugs.

Bariatric surgery is neither a quick fix, nor an easy one. I still have to maintain a very low-calorie diet, and I have to tell myself daily that I can keep doing this. There is a real commitment needed on the part of the patient.

Derek Sloane Jennings:
Thank you for raising SB 579. I am a gastric by-pass patient.

At my annual physical in 2003 I was 366 lbs. My doctor told me that "you never see any overweight older men. Women yes, but not men. When it comes to black men, you never, ever, see ANY!" Well this hit home.

Today, I'm here before you at 180 lbs with normal blood pressure. I am no longer a candidate for multiple surgeries. No more sleep apnea.

Having had insurance to help cover my surgery has, hopefully, added additional years back to my life.

So I am here today in support of having laws requiring the insurance industry to cover gastric by-pass surgery for morbidly obese people. It makes good business sense. The costs are less for both short and long term health issues. The state gains by having its citizens live longer, earn more and pay more taxes. So it's a win – win situation.

NATURE AND SOURCES OF OPPOSITION:

Christine Cappiello, Director of Government Relations, Anthem Blue Cross and Blue Shield:
I am here today to speak against SB 579.

Anthem Blue Cross and Blue Shield is opposed to this bill for a number of reasons, particularly from a quality perspective. While we think it is laudable that the legislature has included many quality incentives into the proposal, like creation of Centers of Excellence, we still remain concerned about this legislation because it may drive people to a very dangerous surgery whose outcomes are not proven for all individuals who have the procedure. Gastric bypass surgery is not just about reducing weight, there are other components that have to be considered including the impact on a person's mental well being prior to and following the surgery.

We also are concerned about the section which requires a person to maintain insurance with a carrier for 12 months prior to the surgery. This notion is in direct conflict with the federal HIPPAA laws.

Finally, we are opposed to this bill because it is important to remind ourselves of the role mandated benefits play in this critical problem. Each time the Legislature passes a bill mandating another benefit, the cost of insurance increases, making it even more difficult for a customer, particularly small employers to purchase insurance.

Connecticut Association of Health Plans:
The Connecticut Association of Health Plans respectfully urges rejection of SB 579. There has been a dramatic increase in the number of individuals seeking gastric bypass surgery for obesity and, unfortunately, a dramatic increase in severe, even deadly complications associated with the inappropriate use of this surgery for weight reduction. Passing a mandate of this type will result in a dramatic increase in utilization of this surgery, a potentially dangerous thing for Connecticut's citizens.

[SB 579, 1067]

The number of grave complications from this surgery leads us to urge rejection primarily on the grounds of patient safety.

There are also significant cost implications. Proposals of this nature have a negative impact on the affordability of health insurance and thereby impede, rather than expand, access to health care.

Randall Graff	March 28, 2006
Reported by	Date

P067

OLR Bill Analysis

sSB 579

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

SUMMARY:

This bill requires certain health insurers, beginning October 1, 2007, to offer individual and group coverage for the medically necessary expenses of diagnosing and treating morbid obesity. It requires the insurance commissioner to adopt regulatory guidelines requiring coverage for certain items and limiting coverage for bariatric surgery to procedures performed in certified locations. Insurers who obtain Insurance Department approval to cover diagnosis and treatment of morbid obesity before October 1, 2007 are not subject to these regulations.

EFFECTIVE DATE: Upon passage for insurance commissioner regulatory guidelines and October 1, 2007 for the mandatory offer.

MORBID OBESITY DEFINED

The bill defines "morbid obesity" as:

1. being at least 100 pounds over, or double, the ideal weight for frame, height, age, and gender listed in the 1983 Metropolitan Life Insurance table (the last revision);

2. having both a "body mass index" (BMI) of 35 or more kilograms per square meter and a related disease or condition such as hypertension, cardiopulmonary conditions, sleep apnea, or diabetes; or

3. a BMI of 40 without related diseases or conditions.

BMI is derived by dividing weight (in kilograms) by height (in meters squared).

Insurance Regulation Requirements and Limitations

The bill requires the insurance commissioner to adopt regulations by October 1, 2007 that establish coverage guidelines for medical services and treatment of morbid obesity. The regulations must require certain individual and group policies to cover the medically necessary expenses of diagnosing and treating morbid obesity. The policies must cover, at least, bariatric surgery, physician office visits, health and behavior assessments, nutrition education, patient self-management education and training, and therapeutic exercise. This requirement applies to basic hospital, basic medical-surgical, major medical, hospital or medical service plan contract, and HMO policies delivered, issued, amended, renewed, or continued after September 30, 2007.

The regulations must limit coverage for bariatric surgery to providers certified as (1) level 1a bariatric surgery centers by the American College of Surgeons or (2) bariatric surgery centers of excellence by the American Society for Bariatric Surgery.

Mandatory Offer of Coverage

The bill requires all "health insurers" (whose definition excludes managed care organizations), hospital service corporations, and medical service corporations licensed in Connecticut to offer individual and group policies that cover medically necessary expenses of diagnosing and treating morbid obesity. They must do so beginning October 1, 2007.

BACKGROUND

Bariatric Surgery

The term bariatric surgery includes a variety of operations, such as gastric bypass and adjustable banding, that either reduce the absorption of nutrients into the body or restrict food intake and promote a feeling of fullness after meals.

Related Bill

sSB 552, reported favorably by the Insurance Committee, requires the committee's chairmen to convene a working group to study the feasibility of requiring coverage of morbid obesity. The bill requires the group to report to the committee by January 1, 2007.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute

Yea 22 Nay 0 (03/17/2006)

C'067

OFFICE OF FISCAL ANALYSIS

Legislative Office Building, Room 5200

Hartford, CT 06106 ◇ (860) 240-0200

http: //www. cga. ct. gov/ofa

sSB-579

AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR MEDICAL SERVICES AND TREATMENT FOR MORBID OBESITY.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 07 $	FY 08 $
State Comptroller - Miscellaneous	Various - Cost	None	700,000

Municipal Impact:

Municipalities	Effect	FY 07 $	FY 08 $
Various Municipalities	Cost	Potential	Potential

Explanation

Since the bill requires coverage that slightly exceeds the protocols of the existing state health plans, a cost increase of less than 0. 10% would occur when new contracts are entered into in FY 08. This would translate into approximately $700,000 annually for FY 08 for all medical plans. However it should be noted that the state should save in future years. If the treatment is successful, the often attendant medical conditions of high blood pressure, diabetes and heart disease, etc. would improve and could produce a reduction in the state's medical costs for the treatment of the related conditions.

The bill's impact on municipal health insurance costs will vary based on existing municipal coverage. To the extent the coverage required under the bill is greater than is currently provided; there would be increased costs and the potential for future savings.

The bill also requires the commissioner of the Department of Insurance to adopt certain regulations. This does not have a fiscal impact.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation.

Shoreline Surgical Associates, P.C.
GENERAL, BARIATRIC, VASCULAR & THORACIC SURGERY

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Jonathan D. Blancaflor, M.D., F.A.C.S.

Testimony on Raised Bill # 579 An Act Concerning Health Insurance Coverage for Medical Services and Treatment for Morbid Obesity

Good afternoon Senator Murphy, Representative Sayer, and members of the Committee. My name is Dr. Jonathan Aranow and I am here to testify in support of senate bill #579. I am here representing the bariatric surgeons of this state, and more importantly, their patients. I am a member of the American Society of Bariatric Surgery and a fellow of the American College of Surgeons. I am chairman of the Connecticut chapter of the ACS bariatric committee. My testimony is endorsed by the Connecticut State Medical Society from whom you will receive additional written testimony.

This is not my first time before members of our state assembly regarding the matter of weight-loss, or bariatric, surgery. Last year I testified before the Insurance and Real Estate committee regarding the need for ***restoration*** of insurance coverage for the surgical treatment of obesity.

The bill being discussed today is not seeking expanded health insurance coverage but rather is designed to restore the coverage that was available to all insured clients until January of 2005. Up until that point in time, all major carriers included coverage for weight loss surgery in their general policies. In fact, the criteria utilized to describe medical necessity in this bill is identical to those criteria utilized under those policies which in turn were drawn directly from the consensus statement published by the National Institutes of Health in 1991.

Beginning in January 2005, all of our state's insurance providers revoked coverage for these procedures from their general policies. The exceptions being medicare and Medicaid and other federally backed insurance programs which nationally mandate coverage for these procedures. The reasons for the exclusionary policies I have included with my written testimony.

Insurers, however, continue to recognize the medical validity of these procedures. Despite revoking these procedures from the general policies, riders have been made available to large employer groups (having at least 50 employees on health plan). This unfortunately leaves about 50% of our population without access to coverage. The individual policies, small group plans, and "mom and pop" employers have no means to achieve health insurance coverage for potentially curable obesity related issues including--but by no means limited to-- diabetes, hypertension, and sleep apnea.

[SB 579, '06]

These surgeries save lives. In the literature I have provided you will see documentation of the following:

- Those who undergo surgery have a nine-fold reduction in the risk of dying in the 5 years following surgery (Christou, 2004).
- Diabetes is completely resolved in 78-82% of patient with dramatic improvements seen in an additional 20% (Buchwald, 2004; Pories 1995).
- High Blood Pressure is completely resolved in 62% of patients with an additional 20% of patients seeing substantial improvements (Buchwald, 2004).
- Sleep apnea is resolved in 86% of patients (Buchwald, 2004).
- Weight loss is maintained beyond 14 years in over 89% of patients (Pories 1995).

These procedures can be done safely despite the exceptionally high risk individuals to whom we are referring. The NIH clearly states in their 1991 consensus. that the risks of surgery are outweighed by the risk inherent to morbid obesity. By utilizing a "center of excellence" approach similar to that adopted by the recent medicare policy statement, we can further ensure patient safety and quality outcomes. The ASBS/SRC program reports that of the 42,282 procedures performed inpatient mortality, 30 day mortality, and 90 day mortality are 0.11%, 0.14%, and 0.04%. Reoperation and hospital readmission were at an incredibly low 2.16% and 4.65%. To get a true sense of these numbers, compare them to the 0.3% mortality rate of elective gallbladder surgery in the general surgery population!

The rationale promoted by insurers for these exclusions has been to save costs. This is in clear contradiction to the cost-effectiveness literature which I have provided. Upfront costs of bariatric surgery are paid off within 3 years by the reduction in medical care needs and pharmaceutical savings (Sampalis, 2004; Potteiger, 2004). The philosophy of pay for it now or pay for it later must be given credence. The end result would be beneficial to the public both physically and fiscally.

I recognize that your time is valuable and I will defer further comments to any questions you may wish to ask. I thank you again for your time and patience.

Respectfully,

Jonathan Aranow, M.D., F.A.C.S.

[SB 579, 667

Reasons for Mandated coverage for Bariatric Surgery

Jonathan Aranow, M.D., F.A.C.S.
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Item 1: Are these surgeries safe?

It is an incontrovertible fact that the safety of these procedures far exceeds the risks of conservative weight loss management. This was proven and substantiated by the National Institutes of Health (see previously provided literature - 1991 consensus statement by NIH). Yes, major complications and even death can result from these procedures as they can from any surgical procedure. One must remember that these surgical candidates are exceptionally high risk patients with numerous illnesses including diabetes, sleep apnea, restrictive lung disease, and accelerated coronary disease. However the statewide and national incidence of death and major morbidity is very low (see Buchwald's metaanalysis previously provided). When one compares these surgical risks against the dangers of progression of weight related illnesses, the weight related limitations on quality of life, and obesity reduced longevity, the literature and data speaks for itself. A patient undergoing weight loss sugery is more likely to live longer, healthier, and happier than if they remain morbidly obese despite conservative efforts of weight loss management. Furthermore, the mandate that is being considered would require surgery to be done at "centers of excellence". These are programs that are nationally supervised for consistent, safe outcomes (overall surgical mortality is comparable to the results from routine gallbladder surgery). In these centers, surgical mortality is 0.11% in over 42,000 cases performed.

Item 2: How do we define "medically necessary"?

These procedures are medically necessary in appropriately chosen patients. The definition has been made by the NIH., the American College of Surgeons, and by the American Society of Bariatric Surgeons.

In regards to the definition of medically necessary, the NIH proposed the following:

1. BMI of 35 (approximately 80 lbs overweight) with weight associated comorbidities,
2. BMI of 40 (approximately 100 lbs overweight) regardless of the presence of Comorbidities,
3. A history of failed conservative weight loss attempts,
4. Psychological stability with a documented support system, a clear understanding of the proposed procedures, preoperative education, and long-term follow-up.

Item 3: Are further studies of cost-effectiveness needed?

I have previously testified to the well established cost effectiveness of these procedures. This is well documented in the scientific literature. You heard in public testimony of several individual experiences of dramatic cost savings-a patient who no longer needs a heart transplant, a patient who no longer needs diabetes medications or their $6,000 CPAP device, and others who are free of innumerable medications and prescription costs.

A lobbyist from the insurance coalition has proposed we hold off on deliberating on this bill until cost effectiveness data can be obtained. This delaying tactic is clearly unnecessary in this situation where the data has been so abundant and conclusive. I have attatched numerous peer reviewed papers that strongly demonstrate that these surgical procedures reduce healthcare

[SB 379, 067

costs substantially by curing and/or dramatically improving weight related illnesses. Prescription cost drop by over 60% (a yield of $250,000/year in a study of 72 patients) and the incidence and costs of future hospitalization drop so dramatically that the surgery pays for itself in under 3.5 years (in the study by Christou) and within 1 year in the VA system.

By requiring that surgery be performed at Centers of Excellence where complications are very rare and volume is high, we can improve the cost efficiency of these procedures as well.

Item 4: If the cost benefit is so clear then why are insurers currently excluding coverage?

Connecticut health insurance thrives by market competition. Furthermore, client retention per policy is on average 19 months before the client changes to another provider's policy. One argument that insurers will make is that if it takes 3.5 years to see a financial benefit to these procedures then the short client retention makes paying for these procedures unprofitable. In contrast, when self insured employers offer coverage for these procedures, the cost benefits are realized since client/employee retention is prolonged. Public testimony has been given by Tyco International, a self-insured Connecticut based company, regarding their internal findings that private based insurance coverage is cost effective.

Item 5: Have other avenues of securing coverage been addressed with the Insurance companies?

Throughout the past year and a half, the advocates of this bill have tried to negotiate with the state HMO's and Anthem for broader coverage for our patients. Many of these meetings have been overseen by Commissioner Cogswell and members of her staff.. At our last meeting with anthem in February 2006, we were informed that they "can find no middle ground". Thus seeking a mandate is our route of last resort.

Item 6: Is there a precedent for such a healthcare mandate?

The federal government and medicare maintain that these procedures are mewdically necessary. The language for this bill comes directly from the recent policy statement made by medicare (CMS) which confirms ongoing coverage for these procedures at centers of excellence. Maryland and Georgia have legislative mandates. New York and Massachusettes also require insurer to cover these procedures when done at COEs. Currently Connecticut mandates coverage for diabetes treatment yet insurers exclude coverage for bariatric surgery despite it being the *only known cure* for diabetes (outside of pancreatic transplantation). Similarly, treatment for sleep apnea is mandated yet weight loss surgery is excluded by insurers despite its near 100% cure rate for this disease. When I have approached the state insurance commission regarding these conflicts I was told that this is a matter for the state legislature to resolve.

Item 7: Why must all insurers, statewide, offer policy coverage for weight loss procedures?

Aetna was the first of our statewide insurers to exclude coverage for weight loss surgery in their general policies, presumably due to their short duration of client retention. This shifted patients seeking these procedures to competitors such as Anthem BC/BS. The increased patient burden led them to adopt similar exclusionary policies. The effect has snowballed to include nearly all of our major health insurers (eg. healthnet, cigna, connecticare). This is a direct result of market competition. The problem develops that now the majority of patients in need have no access to these surgical procedures.

If only a limited number of health insurers provide coverage, they will be subject to financial risk dependent on the duration of their client retention. However, if we universally require coverage for this procedure then the effects of client retention will be negated since the long-term, cost-saving effects of comorbidity resolution will be felt by all. The net result would be a healthier populace with fewer prescription costs, fewer and less costly hospitalizations.

CHIME Data Fiscal Year (Oct - Sept)

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DRG 288 OR Procedures for Obesity	Discharges					Days					Average Length of Stay				
	2001	2002	2003	2004	2005	2001	2002	2003	2004	2005	2001	2002	2003	2004	2005
Inpatient															
HOSPITAL OF SAINT RAPHAEL	228	361	414	477	497	936	1,373	1,470	1,528	1,343	4.1	3.8	3.6	3.2	2.7
SAINT FRANCIS HOSPITAL AND MEDICAL CE	98	134	223	312	377	521	543	726	961	1,149	5.3	4.1	3.3	3.1	3.0
NORWALK HOSPITAL	11	74	239	356	312	69	268	631	893	661	6.3	3.6	2.6	2.5	2.1
MIDDLESEX HOSPITAL	11	102	193	210	187	45	423	644	651	576	4.1	4.1	3.3	3.1	3.1
DANBURY HOSPITAL	4	45	134	140	184	9	175	472	529	495	2.3	3.9	3.5	3.8	2.7
ST. VINCENT'S MEDICAL CENTER	1	-	-	19	148	1	-	-	36	253	1.0	-	-	1.9	1.7
YALE-NEW HAVEN HOSPITAL	3	4	102	153	140	5	38	295	495	350	1.7	9.5	2.9	3.2	2.5
BRIDGEPORT HOSPITAL	2	1	22	48	63	9	1	134	169	165	4.5	1.0	6.1	3.5	2.6
HARTFORD HOSPITAL	14	21	12	17	59	45	52	44	57	144	3.2	2.5	3.7	3.4	2.4
SAINT MARY'S HOSPITAL	4	23	111	99	31	34	68	332	281	70	8.5	3.0	3.0	2.8	2.3
NEW BRITAIN GENERAL HOSPITAL	-	-	-	-	22	-	-	-	-	89	-	-	-	-	4.0
MIDSTATE MEDICAL CENTER	-	1	-	9	17	-	1	-	42	81	-	1.0	-	4.7	4.8
GREENWICH HOSPITAL	9	12	20	28	14	18	16	83	69	34	2.0	1.3	4.2	2.5	2.4
THE STAMFORD HOSPITAL	14	33	57	6	10	41	179	113	24	30	2.9	5.4	2.0	4.0	3.0
WATERBURY HOSPITAL	-	2	12	11	8	-	20	14	12	9	-	10.0	1.2	1.1	1.1
JOHN DEMPSEY HOSPITAL	8	23	35	44	4	24	79	156	153	11	3.0	3.4	4.5	3.5	2.8
THE WILLIAM W. BACKUS HOSPITAL	3	1	2	-	4	6	1	48	-	17	2.0	1.0	24.0	-	4.3
MANCHESTER MEMORIAL HOSPITAL	1	2	3	3	3	1	4	3	12	3	1.0	2.0	1.0	4.0	1.0
BRISTOL HOSPITAL	5	18	23	20	2	22	83	102	97	10	4.4	4.6	4.4	4.9	5.0
MILFORD HOSPITAL	-	-	-	3	2	-	-	-	8	4	-	-	-	2.7	2.0
ROCKVILLE GENERAL HOSPITAL	-	-	-	-	1	-	-	-	-	26	-	-	-	-	26.0
THE CHARLOTTE HUNGERFORD HOSPITAL	-	-	-	-	1	-	-	-	-	1	-	-	-	-	1.0
GRIFFIN HOSPITAL	-	1	-	1	-	-	1	-	1	-	-	1.0	-	1.0	-
LAWRENCE & MEMORIAL HOSPITAL	12	4	1	1	-	48	54	15	3	-	4.0	13.5	15.0	3.0	-
NEW MILFORD HOSPITAL	3	2	-	-	-	14	13	-	-	-	4.7	6.5	-	-	-
	431	864	1,603	1,957	2,086	1,848	3,392	5,282	6,021	5,521	4.3	3.9	3.3	3.1	2.6
Ambulatory Surgery															
HARTFORD HOSPITAL	34	22	40	49	77										
YALE-NEW HAVEN HOSPITAL	38	53	51	48	57										
GREENWICH HOSPITAL	28	25	57	43	43										
MILFORD HOSPITAL	6	27	36	34	43										
MIDDLESEX HOSPITAL	2	5	3	16	32										
HOSPITAL OF SAINT RAPHAEL	4	5	3	13	22										
SAINT FRANCIS HOSPITAL AND MEDICAL CE	1	4	7	10	18										
LAWRENCE & MEMORIAL HOSPITAL	14	6	14	13	15										
SAINT MARY'S HOSPITAL	5	14	12	18	13										
THE WILLIAM W. BACKUS HOSPITAL	14	7	4	7	13										
ST. VINCENT'S MEDICAL CENTER	-	2	-	2	11										
JOHN DEMPSEY HOSPITAL	17	10	15	5	10										
NORWALK HOSPITAL	-	2	-	2	8										
BRIDGEPORT HOSPITAL	1	2	2	4	7										
THE CHARLOTTE HUNGERFORD HOSPITAL	-	1	-	1	3										
THE STAMFORD HOSPITAL	2	3	1	2	3										
WATERBURY HOSPITAL	-	-	1	2	3										
DANBURY HOSPITAL	-	-	2	-	2										
CONNECTICUT CHILDREN'S MEDICAL CENTI	-	-	-	-	1										
MANCHESTER MEMORIAL HOSPITAL	5	1	2	-	1										
MIDSTATE MEDICAL CENTER	-	-	2	-	1										
NEW BRITAIN GENERAL HOSPITAL	-	-	-	-	1										
BRISTOL HOSPITAL	-	-	2	-	-										
GRIFFIN HOSPITAL	2	-	-	-	-										
	173	190	254	269	384										

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Fact Sheet: Why it makes sense to provide treatment for obesity through bariatric surgery

Reason	Evidence/Details
Obesity is widespread, deadly and expensive	• 30.5% of Americans are obese with 4.7% morbidly obese (more than 100 pounds overweight).[1] • Approximately 75% of the morbidly obese have at least one co-morbid condition (diabetes, hypertension, sleep apnea, etc.) which significantly increases the risk of premature death.[2] • Life expectancy for a 20 year-old morbidly obese male is 13 years shorter than a normal weight male of the same age.[3] • Annual direct medical expenditures attributable to obesity are $75 billion.[4]
Obesity disproportionately affects minority and poor populations	• African-Americans are disproportionately affected by obesity. Caucasians make up 75% of the U.S. population, but only 64% of the morbidly obese population. In contrast, African-Americans make up 12% of the population but 23% of the morbidly obese population.[5] • Poor populations (those making less than $20,000 annually) show a similar increase in likelihood of being morbidly obese.[5]
Bariatric surgery is a life-saving procedure as it is proven to increase life expectancy	• Christou study compared morbidly obese patients who were treated with surgery versus those who were not. It found an 89% reduction in the risk of death throughout five years in the surgery group. **In other words, those who received surgery were nine times less likely to die over the next five years.**[6] • MacDonald study in North Carolina found 68% reduction in risk of death after mean follow-up time of six years.[7] • Flum study found that adjusted hazard for death was 33% lower for patients who received surgery than for non-operated patients.[8]
Bariatric surgery resolves potentially fatal co-morbid conditions	• A meta-analysis study including more than 22,000 patients showed the following effects of surgery on co-morbidities: ° Diabetes was completely resolved in 76.8% of patients. ° High cholesterol was resolved or improved in more than 70% of patients. ° High blood pressure was resolved in 61.7% of patients. ° Sleep apnea was resolved in 85.7% of patients.[9] • Other studies have shown even higher (82%) resolution of diabetes[10] and "profound improvement in obstructive sleep apnea."[11]
Weight-loss post-surgery is extensive and durable	• A long term study following patients for up to 14 years after surgery found that 89% of weight-loss was maintained.[12]
The risk-benefit tradeoff for bariatric surgery is favorable	• The mortality rate for bariatric surgery varies by surgeon. Experienced surgeons have mortality rates ranging from 0.5%-2% (averaging the rate for all types of procedures). The risks of not receiving surgery is far higher as demonstrated by the Christou study where those who did not receive surgery were almost nine times more likely to die.[13]
Coverage for bariatric surgery makes economic sense	• Upfront costs of bariatric surgery are paid off in three and a half years due to hospitalization cost savings.[14] • Post surgery drug costs for diabetic and anti-hypertensive medications decrease dramatically. Potteiger study found a 77.3% savings.[15]

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The Impact of Weight Reduction Surgery on Health-Care Costs in Morbidly Obese Patients

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Background: The treatment of obesity and related co-morbidities are significant financial burdens and sources of resource expenditure. This study was conducted in order to assess the impact of weight-reduction surgery on health-related costs.

Methods: This was an observational two-cohort study. The treatment cohort included patients having undergone weight-reduction (bariatric) surgery at the McGill University Health Centre (MUHC) between 1986 and 2002. The control group included age and gender matched obese patients who had not undergone weight-reduction surgery from the Quebec provincial health insurance database (RAMQ). The cohorts were followed for a maximum of 5 years from inception. The primary outcome measure was overall direct health-care costs. Secondary outcomes included cost analysis by diagnostic category for the treatment of new medical conditions following cohort inception.

Results: The cohorts were well-matched for age, gender and duration of follow-up. Patients having undergone bariatric surgery had significant reductions in mean percent initial excess weight loss (67.1%, $P<0.001$) and in percent change in initial body mass index (34.6%, $P<0.001$). Bariatric surgery patients had higher total costs for hospitalizations (per 1,000 patients) in the first year following cohort inception (surgery cohort = CDN $12,461,938; control cohort = CDN $3,609,680). At 5 years after cohort inception, average cumulative costs for operated patients were CDN $19,516,667 versus CDN $25,264,608, for an absolute difference of almost CDN $6,000,000 per 1,000 patients.

Conclusion: Weight-reduction surgery in morbidly obese patients produces effective weight loss and decreases long-term direct health-care costs. The initial costs of surgery can be amortized over 3.5 years.

Key words: Bariatric surgery, morbid obesity, health care, health-care costs, resource utilization, pharmacoeconomics

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Introduction

During recent years, obesity has emerged as a major public health problem and is second to smoking as a leading cause of preventable, premature death in the United States and the Western World.[1] According to the World Health Organization (WHO), there is a growing epidemic of obesity throughout most of the developed and developing world.[2] The prevalence of obesity in Canada has increased from 5.6% in 1985 to 14.8% in 1998.

Morbid obesity is independently associated with an increased risk for mortality[3,4] and increased physical and psychological dysfunction.[5-8] The associations between morbid obesity and increased risk for the development of hypertension, coronary artery disease, diabetes, cancer and respiratory conditions have been well-documented.[9-15] The data in the literature have shown that bariatric surgery is effective in producing short- and long-term weight loss in obese patients[16-20] and is more effective than dieting in producing sustained weight loss.

In addition to the increased risk for mortality and morbidity, obesity consumes a large portion of health-care expenditures through both direct and

indirect costs related to the management of obesity and its sequelae.[22-27] Obesity has been shown to be associated with a 36% independent increase in inpatient and outpatient spending and a 77% increase in medication use.[28] In view of the impact of obesity on health status and quality of life, it is anticipated that weight loss in obese patients will be associated with both health and economic benefits.[29] However, to our knowledge there have not been any reports of the economic effects of weight-reduction surgery in morbidly obese patients compared to non-operated individuals.

This study was undertaken with the goal of evaluating the effect of weight-loss (bariatric) surgery on health-care costs. The current study addresses this issue by comparing the direct health-care costs related to hospitalization for two cohorts of obese patients: one cohort that underwent weight-reduction surgery and one that did not.

Methods

Study Design

This was an observational two-cohort study that compared the health-care costs of a cohort of morbidly obese patients treated with bariatric surgery at the Center for Bariatric Surgery, McGill University Health Centre (MUHC) to that of matched morbidly obese controls that had not been treated surgically. The inception time of the bariatric cohort was the time of admission for surgery. The inception time for the control group was the date of surgery of their matched bariatric patients. A maximum of six controls were identified for each bariatric subject. The two cohorts were followed for 5 years.

Assembly of Study Cohorts

A total of 1,118 patients underwent bariatric surgery for the treatment of morbid obesity at the MUHC between January 7, 1986 and June 8, 2002. The unique health insurance numbers of these patients were used to retrieve their information from the provincial health insurance database of the Regie de l'assurance maladie du Quebec (RAMQ). The RAMQ database includes information regarding all health-care utilization claims, including those for hospitalizations, physician visits, prescription medications and other paramedical services. Database linkage was conducted using encrypted provincial health insurance numbers to ensure anonymity of the patient. Data concerning weight loss parameters for these patients were extracted from the MUHC bariatric surgery patient registry.

Of the 1,118 patients in the bariatric surgery cohort, 83 patients were excluded because they were treated for one of the outcome conditions listed in Table 1 prior to their operation. If a patient had a repeat bariatric surgery, the index surgery was used as the point of entry into the cohort and the subsequent surgery was included in the follow-up morbidity assessment.

The RAMQ database was queried to identify a maximum of six control subjects for each bariatric patient. The inclusion criteria for the controls were a diagnosis of morbid obesity according to the ICD9 codes for treatment in a hospital, treatment by a physician or as an indication for a prescription, as well as never having had surgery for the treatment of obesity, and never having been treated for one of the outcome conditions listed in Table 1 prior to the date of surgery for the matched bariatric subject. Each bariatric patient was caliper-matched to controls with respect to the date of the first diagnosis of morbid obesity within 2 years, age within 5 years, and gender. There were a total of 6,210 controls identified, of which 464 were excluded because they had been hospitalized for one of the chronic conditions listed in Table 1 prior to the surgery date of their matched bariatric patient.

The final study sample included 1,035 bariatric

Table 1. Exclusion Criteria – Chronic Conditions

Diseases of the Blood and Blood-Forming Organs
Cancer
Cardiovascular and Circulatory Diseases
Digestive Diseases
Endocrinological Diseases including Diabetes
Genito-urinary Diseases
Infectious Diseases
Musculoskeletal Disorders including Arthritis
Nervous System Diseases
Psychiatric and Mental Diseases
Respiratory Diseases
Skin Diseases

surgery patients and 5,746 matched controls.

Weight loss for the bariatric surgery cohort was estimated using the percent change in body mass index (BMI) and percent excess weight loss. The percent change in BMI was calculated as: 100% x{(BMI_0–BMI_i)/BMI_0} where BMI_i=the BMI at the last follow-up and BMI_0 is the BMI at the time of surgery. The percent excess weight loss was calculated as: 100% x{(W_0–W_i)/EW_0} where W_0=the weight (kg) at the time of surgery, W_i=the weight (kg) at the last follow-up and EW_0=the excess weight at the time of surgery. Excess weight was estimated according to the formula described by Deitel and Greenstein[30] and are based on the Metropolitan Tables for middle frame individuals.

Surgical Procedures

Roux-en-Y Gastric Bypass (RYGBP)

Patients were given 2 gm sodium cephazolin i.v. and 7,500 units of unfractionated heparin s.c. with induction of anesthesia. Exposure was obtained through an upper midline incision. Blunt finger dissection was used to encircle the cardia of the stomach at the angle of His and the lesser curvature of the stomach approximately 2 cm distal to the gastroesophageal junction. At this point, a 2 cm window was made along the lesser curvature of the stomach. A previously placed 32-Fr bougie was held against the lesser curvature and a 25-mm EEA® (Ethicon Endo-Surgery) was used to create a circular opening into the stomach.

The PI-90® instrument (US Surgical Corp) was passed through this opening (with the help of a No. 28 chest tube), positioned in a vertical orientation against the bougie, and fired. A second firing of the PI-90 created a quadruple row of staples, and the stomach was completely divided between the staple-lines. A Roux limb of jejunum (50-300 cm long depending on the BMI and the date of the surgery) was brought up in a retrocolic, retrogastric fashion, and an end-to-side gastrojejunostomy was fashioned using a 3-0 PDS® (Ethicon Endo-Surgery) single continuous suture around an 18-gauge nasogastric tube. The end result was a gastric pouch 1.2 cm in diameter and 4-5 cm long with a calculated volume (πr^2 x height) of ~4.5-6 cc (approximately the size of a thumb). The jejunojejunostomy was completed, and the mesenteric defects were closed. The nasogastric tube was removed after a satisfactory methylene blue and air bubble leak test. A small suction drain was placed next the gastrojejunostomy and brought out through a separate stab-wound incision up to 1998. No drains were used afterwards. The fascia was closed with a No. 2 Maxon® double suture in a continuous fashion. The subcutaneous tissue was irrigated and carefully dried with clean sterile sponges that had not touched skin.

Clips were used to close the skin, and an occlusive dressing was applied. Two more doses of cephazolin were given after surgery and 7,500 units of s.c. heparin was continued until patient discharge. Patients were placed on a cardiac monitor after surgery and ambulated later on the day of surgery. Ice chips and water were given orally the night of the operation, initially limited to no more than 60 mL per hour. The following morning, if there was no tachycardia >120 bpm, tachypnia or fever, the patients were given a clear fluid diet and advanced to full fluid diet as tolerated. Discharge followed on the 3rd-4th postoperative day. The first appointment to the bariatric clinic was scheduled for 2 weeks after surgery.

Since February 2002, we have been performing RYGBP laparoscopically using 5 ports. We perform a hand-sewn gastrojejunostomy using a modification of Higa's technique.[31] This ensures that the operation is very similar to the open RYGBP, especially the creation of the very small vertically oriented gastric pouch. The time-frame of this study captured the first 21 laparoscopic RYGBP patients for this analysis.

Vertical Banded Gastroplasty (VBG)

Exposure was obtained through an upper midline incision. Blunt finger dissection was used to encircle the cardia of the stomach at the angle of His and the lesser curvature of the stomach approximately 2 cm distal to the gastroesophageal junction. At this point, a 2 cm window was made along the lesser curvature of the stomach. A 28-Fr Maloney bougie was placed along the lesser curvature of the stomach as a guide for the placement of the EEA stapler and for the placement of the vertical staple-lines. The EEA device used was either Auto-Suture (United States Surgical Corp) or the Ethicon Proximate intraluminal stapler. Pouch size was measured in the

first 20 patients and intermittently thereafter with a 70-cm water head of pressure and was never larger than 30 ml.

The vertical staple-lines were made with a TA 90 instrument (United States Surgical Corp, Norwalk, CT) with 4.8-mm staples. In all patients, at least two applications of the stapler were made with close approximation of the staple-lines in most. In a few patients, a third set of staple-lines was added and in some patients there was a separation of the staple-lines by 1 cm of stomach wall. The staple-lines were not reinforced with sutures. The VBG was made with an outlet of 40 to 45 mm external circumference. Either a single or double layer of polypropylene mesh 60 mm in length and 15 mm in width was used to construct the band. The mesh was sutured in place with four 3-0 polypropylene sutures at a premeasured length to correspond to the above circumferences. A gastrostomy with a 14-Fr catheter was routinely placed in the stomach below the gastroplasty and removed after 6 weeks if the patient tolerated oral feeds. An 18-Fr nasogastric tube was also placed into the gastroplasty pouch for 24 hours.

Estimation of Health-Care Costs

The RAMQ database was searched for all claims for health-care services utilized by subjects in both cohorts for the 5-year period following the date of entry into the study. The ICD9 codes were used to classify the primary conditions leading to the utilization of health-care services.[32] Direct health-care costs were presented in 1996 Canadian dollars. For each subject, the total direct health-care cost was estimated on the basis of the information in the RAMQ database. Hospital costs included the costs for hospital bed use, intensive care unit stay, nursing, medications, food, operating-room costs, diagnostic procedures including all radiology and laboratory tests, disposable equipment, physician's fees, surgeon's fees, anesthesiologist's fee, preoperative evaluation fees, dietetics consultation fees, psychiatric evaluation fees and all paramedical services including physiotherapy. The costs for the bariatric surgery and subsequent related care including the management of complications were included in the total cost estimates of the bariatric surgery cohort. The RAMQ costs reflect the value of the claim and are not necessarily equivalent to the costs for the services in the private sector.

The statistical significance of weight loss in the bariatric surgery cohort was assessed using the paired Student's t-test and was described using the mean change and 95% confidence intervals for the cohort. Differences between the bariatric surgery and control cohorts with respect to health-care costs were assessed for statistical significance with the Student's t-test.

The study was submitted and approved by the McGill University Health Centre Ethics Review Board.

Results

Seven different surgeons affiliated with the MUHC treated the 1,035 bariatric patients in two hospitals over 16.4 years. One surgeon carried out half these procedures. Table 2 describes the patient demographics of the two cohorts. There were no differences with respect to age and gender of the two cohorts. The majority of the procedures were open Roux-en-Y isolated gastric bypasses: 820 (79.2%), followed by VBG: 194 (18.7%), and laparoscopic Roux-en-Y isolated gastric bypass: 21 (2.2%). Fifty-six per cent were in the BMI range 38-49, 32% in the BMI range 50-59, 8% in the BMI range 60-69, and the rest had a BMI >70 (highest 98). Thirty-five per cent of the VBG patients were subsequently converted to open RYGBP because of complications which included outlet obstruction (58%), failure to lose weight (33%) and miscellaneous reasons (9%). There were no significant differences in age, gender or follow-up.

The data in Table 3 describe the weight loss

Table 2 Patient Demographics

		Bariatric Surgery	Controls
Number of Subjects		1,035	5,746
Age (years)	Mean (SD)	45.1 (11.6)	46.7 (13.1)
	Median	44.8	47.0
Gender N (%)	Male	356 (34.4)	2,068 (36.0)
	Female	679 (65.6)	3,678 (64.0)

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Table 3. Weight Loss - Bariatric Surgery Cohort

Parameter	Mean	SD	Min-Max
Initial Weight (kg)	136.4	28.4	77 - 284
Initial BMI (kg/m²)	50.0	8.2	36 - 90
Ideal Body Weight (kg)	64.1	8.4	45 - 114
Initial Excess Weight (kg)	72.4	23.8	29 - 205
Excess BMI (kg/m²)	26.5	7.8	12 - 66
Final Weight (kg)	88.8	22.9	42 - 199
Final BMI (kg/m²)	32.6	7.3	16 - 62
% Initial Excess Weight Loss	67.1	23.7	1 - 130
% Initial BMI Reduction	34.6	12.1	1 - 65
Overall Follow-up (years)	5.3	3.8	1 - 16

achieved in the bariatric surgery cohort. There were significant reductions in mean percent excess weight loss (67.1%, $P<0.001$) and in the percent change in BMI (34.6%, $P<0.001$).

Table 4 summarizes the average total costs per 1,000 patients for the 5 years following cohort inception. In the first year, total costs for hospitalizations in the surgery cohort were higher by over 8 million Canadian dollars per 1,000 patients, when compared to the controls. This difference is reversed for the subsequent years, reaching a maximum during the fifth year when the costs for the control cohort were more than 4 million dollars higher on the average for the control cohort when compared to the bariatric cohort. After 5 years, the total cost per 1,000 patients for hospitalizations in the control cohort was 29% higher when compared to the bariatric patients (Absolute Difference = 5.7 million 1996 CDN dollars in favor of weight-reduction surgery).

Table 5 and Figures 1 and 2 demonstrate the annual cumulative costs over the 5-year study period. For the first 3½, the cumulative average cost is higher for the bariatric cohort. However, in the next 1½ the difference in costs was in favor of the patients who underwent surgery. After 3.5 years, the initial investment for the weight-reduction surgery and related hospital care was compensated by a reduction in total costs. This corresponds to an expected amortization period of 3.5 years of the initial investment for bariatric surgery.

Table 6 outlines the annual costs per hospitalization per 1,000 patients by primary diagnosis of hospitalization. The costs of the bariatric surgery are included in the first year. The cost for the surgery and admissions due to digestive system problems were higher in the first year in the surgery cohort when compared to controls. For all subsequent years, these costs were higher in the controls when compared to the surgery cohort. For all other diagnoses, the costs in the bariatric cohort were less than the controls for the 5-year follow-up period.

Discussion

This was an observational study utilizing a combination of hospital and provincial insurance administrative databases to assess the direct health-care costs in morbidly obese patients treated with bariatric surgery and matched controls that were not treated surgically.

The direct cost of obesity is between 2 and 5% of most developed countries' health-care expenditures.[33] In 1995, the total cost of obesity in the USA was estimated to be 99 billion US dollars with 52 billion dollars representing direct health costs. This is equivalent to 5.7% of the total health costs.[34] If the direct cost of physical inactivity is combined with that of obesity, the estimated cost in the USA is 9.4% of the national health budget.[35] The direct

Table 4. Average total cost per 1,000 patients for hospitalization by group, year of follow-up

Year of Follow Up	Bariatric	Control	Absolute Difference	Cost Ratio: Control/Bariatric
1	$12,461,938	$3,609,680	$-8,852,258	0.29
2	$3,398,835	$4,846,794	$1,447,959	1.43
3	$1,362,408	$5,831,456	$4,469,048	4.28
4	$1,318,323	$5,895,988	$4,577,666	4.47
5	$975,163	$5,080,690	$4,105,526	5.21
Total	$19,516,667	$25,264,608	$5,747,941	1.29

Table 5. Average cumulative costs per 1,000 patients for hospitalization by group and year of follow-up

Year of Follow-Up	Bariatric	Control	Absolute Difference	Cost Ratio; Control/Bariatric
1	$12,461,938	$3,609,680	$-8,852,258	0.29
2	$15,860,773	$8,456,474	$-7,404,299	0.53
3	$17,223,181	$14,287,930	$-2,935,251	0.83
4	$18,541,503	$20,183,918	$1,642,415	1.09

medical costs attributable to adult obesity in Canada are estimated to have been $1.8 billion in 1997 or 2.4% of total direct medical costs.[36] The highest cost drivers are those of managing the co-morbidities associated with obesity.[37,38] It is estimated that obesity accounts for 85% of the total cost of treating type II diabetes and 45% of the cost of treating hypertension.[39]

Medical interventions for weight loss in severely obese patients are ineffective.[40-44] In 1991, an NIH consensus conference reviewed the long-term data on safety and efficacy of medical and surgical weight loss therapies and concluded that surgical therapy should be offered to morbidly or severely obese patients who are unresponsive to non-surgical therapy.[45] In 2000, the NIH published evidence-based guidelines stating that surgical therapy should be offered to obese patients (BMI >35) who have experienced obesity-related co-morbidities.[46]

Narbro et al[47] compared the pharmaceutical costs in a group of 510 obese individuals who underwent weight-reduction surgery to a group of 455 randomly selected obese individuals who did not undergo weight-reduction surgery for 6 years following surgery. She found that surgery lowered the usage and costs of diabetes and cardiovascular medications, but was associated with increased costs for other medications including gastrointestinal, anemia and vitamin deficiency medications. This resulted in similar total overall medication costs for both groups. Potteiger et al[48] found a 77.3% reduction in total cost of diabetic and antihypertensive medications with surgically induced weight loss (RYGBP).

We found that when compared to a cohort of matched controls, the patients having undergone bariatric surgery had significantly reduced total direct health-care costs. This finding is significant from a societal and health-economic point of view, because the health-care services and costs associated with surgery were included in the total costs for the bariatric surgery patients. These results have shown that on the average, the total direct health-care costs for managing a morbidly obese patient may be reduced by 29% within 5 years following surgery. In absolute terms, this is equivalent to a total reduction of approximately CDN $5,700 in direct health-care costs per patient. The total benefit would be greater if indirect costs were considered.

The strengths of the current study are related to the design and the selection of the cohorts. The

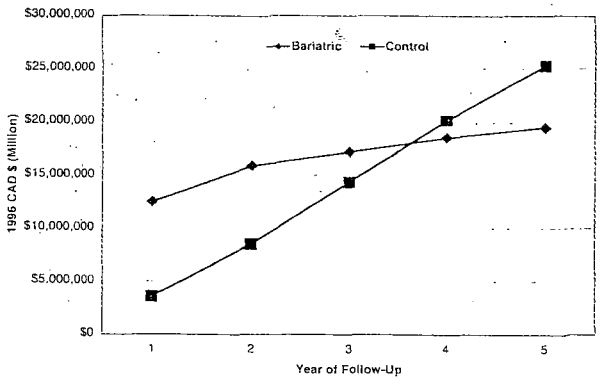

Figure 1. Average cumulative costs per 1,000 patients for hospitalization by group and year of follow-up.

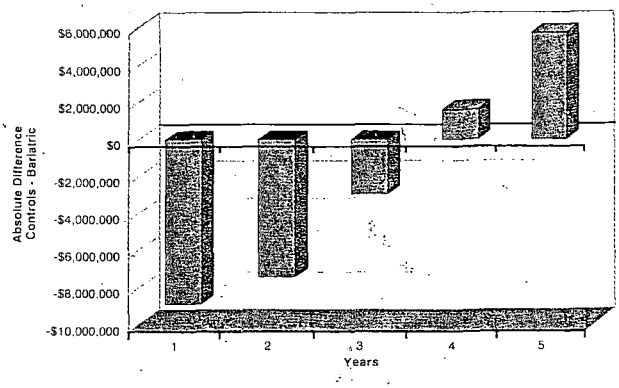

Figure 2. Average cumulative costs per 1,000 patients for years of follow-up: Controls minus surgery patients.

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Table 6. Average costs per 1,000 patients for hospitalization by primary diagnosis, group and year of follow-up

	Bariatric	Control	Bariatric	Control	Bariatric	Control	Bariatric	Control	Bariatric	Control
Bariatric Surgery	$8,718,000	$0	$0	$0	$0	$0	$0	$0	$0	$0
Hematological	$2,126	$1,532	$4,251	$2,297	$0	$5,743	$0	$5,360	$2,126	$4,595
Cancer	$128,357	$226,580	$148,895	$312,588	$46,209	$707,485	$56,477	$677,891	$46,209	$457,785
Digestive	$1,340,033	$251,525	$1,321,247	$289,874	$513,471	$625,993	$444,590	$664,342	$394,496	$431,991
Cardiovascular	$885,872	$1,767,764	$477,676	$2,797,134	$442,936	$1,148,264	$425,566	$1,104,461	$251,866	$1,756,813
Endocrinological	$302,458	$129,032	$270,620	$107,527	$71,635	$288,172	$55,716	$263,800	$63,675	$197,850
Genito-urinary	$216,155	$361,183	$262,145	$407,574	$87,382	$917,870	$55,188	$954,320	$59,787	$685,089
Infections	$347,589	$274,675	$437,290	$349,402	$67,275	$694,765	$123,338	$745,257	$22,425	$506,936
Musculoskeletal	$130,788	$130,641	$101,064	$132,783	$59,449	$340,525	$41,614	$320,179	$47,559	$240,937
Nervous System	$164,754	$273,022	$164,754	$281,925	$16,475	$658,814	$65,901	$718,166	$49,426	$510,432
Psychiatric	$107,374	$58,022	$130,383	$44,207	$53,687	$120,189	$30,678	$120,189	$23,009	$85,652
Respiratory	$102,099	$127,858	$68,066	$115,598	$0	$307,385	$14,586	$302,130	$14,586	$196,166
Skin	$16,333	$7,845	$12,444	$5,884	$3,889	$16,251	$4,667	$19,894	$0	$6,444
Total:	$12,461,938	$3,609,680	$3,398,835	$4,846,794	$1,362,408	$5,831,456	$1,318,323	$5,895,988	$975,163	$5,080,690

exclusion of patients with a history of the ascertained outcomes allows the estimation of the true incidence and removes potential selection bias and confounding. Matching the cases and controls with respect to age, gender and duration of disease, further reduces the possibility of confounding from these factors, because both are potentially associated with increased health-care utilization and costs. The random selection of controls from an administrative database reduces selection bias and bias by indication that would have been introduced if hospital-based controls were used.

In conclusion, weight reduction surgery in this cohort of Canadian patients is associated with a net reduction of more than 5.7 million Canadian dollars for health-related hospitalizations per 1,000 patients treated, within 5 years after surgery. Weight-reduction surgery appears to be cost minimizing over the long-term, and further reductions in costs over longer periods of follow-up could be expected. Although more extensive risk-benefit assessments may be useful in providing more detailed data regarding the impact of bariatric surgery, the current study has produced evidence supporting the implementation of weight-reduction surgery in the management of the morbidly obese patient from a health-economic perspective.

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The Cost-Effectiveness of Bariatric Surgery

Craig BM, Tseng DS.

Cost-Effectiveness of Gastric Bypass for Severe Obesity
Am J Intern Med 2002;113:491–8

ABSTRACT

The purpose of the study was to estimate the cost-effectiveness of gastric bypass in the treatment of severe obesity (body mass index > 40). A deterministic decision analysis that compared the lifetime expected costs and outcomes between open gastric bypass and no treatment of severe obesity from the payer perspective was performed. Men and women between the ages of 35 and 55 yr, with body mass index between 40 and 50 kg/m^2, who did not have cardiac disease and who failed conservative treatment, including pharmacotherapy, were included. Cost-effectiveness ratio of the base case conditions was made with parameter estimates from the literature and expert discussion and expressed as cost per quality-adjusted life-years (QALY). One- and two-way sensitivity analyses were performed on selected variables.

Gastric bypass was not cost-saving, because the reduction in lifetime medical costs was less than the cost of treatment in any subgroup. The base case cost-effectiveness ratios ranged from $5,400 to $16,100 for women and from $10,700 to $35,600 per QALY for men. Sensitivity analysis demonstrated that in older, less obese men, the cost effectiveness ratio was responsive to the amount of weight lost, obesity-related quality of life, and complication rates. Parameter variation did not significantly affect cost-effectiveness ratios in the remaining patients. The authors concluded that gastric bypass is a cost-effective alternative to no treatment in the severely obese, at less than $50,000 per QALY. (Am J Gastroenterol 2003;98:2097–2098. © 2003 by Am. Coll. of Gastroenterology)

COMMENTS

In the United States, more than 60% of adults are overweight, and the prevalence of obesity has doubled since 1960. It is estimated that obesity results in approximately 300,000 deaths and more than $100 billion in costs per year (1). Results of conservative treatment, including pharmacotherapy, have been disappointing. Bariatric surgery, specifically gastric bypass, is effective; however, there are no randomized, long-term cost analyses of gastric bypass compared with no treatment. Decision analysis is a useful tool to determine the most cost-effective strategy in this situation.

The authors model a clinically important and common scenario of a severely obese patient who has failed conservative therapy. They exhaustively included both early (surgical mortality, deep vein thrombosis, wound infection) and late outcomes (reversal surgery, incisional hernia, cholelithiasis, and even long-term vitamin and mineral supplementation). Costs for treatment for many obesity-related diseases were included, but costs for sleep apnea, certain cancers, nonalcoholic steatohepatitis, gastroesophageal reflux disease, and degenerative joint disease were not calculated. Including these would result in surgical therapy being favored, because the morbidity and mortality from these conditions would be decreased with significant weight loss. In the sensitivity analysis, the authors varied the amount of weight loss, life expectancy, quality of life, lifetime medical costs, mortality, and complication rates over reasonable ranges. Gastric bypass remained cost-effective (<$50,000 per QALY) for all base case scenarios except for older, less obese men (*i.e.*, aged 55 yr with a body mass index of 40).

The analysis did not show that gastric bypass was cost-saving under any scenario. However, in all base case conditions it was cost-effective at less than the commonly accepted amount of $50,000 per QALY. This finding was also relatively robust, with cost-effectiveness ratios greater than $50,000 only in older, less obese men at the lower estimated range of weight loss from gastric bypass.

The decision analysis models patients who have already failed conservative therapy; therefore, applying these results to patients who present without having attempted such treatment might not be appropriate. It includes only severely obese patients with no comorbid conditions associated with obesity. Inclusion of these would increase complications, cost, and mortality of surgery, but likely result in even greater long-term improvements in QALY. In addition, the model assumes that patients who lose weight have the same quality of life as those who have always been at the lower weight, despite reports that quality of life after successful

weight loss is increased compared with the general population (2). Finally, the authors have modeled outcomes with the use of open gastric bypass. Laparoscopic bypass is becoming more common, with decreased morbidity and costs (3). Inclusion of these variables in the analysis would likely further increase the cost-effectiveness of gastric bypass. These results are consistent with other recent analyses demonstrating that surgical therapy is more cost-effective than either diet/exercise or medical treatment (4, 5). Gastric bypass does seem to be cost-effective in the treatment of severe obesity.

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The Agony and the Ecstasy

From the Centers for Disease Control and Prevention
Outbreaks of Gastroenteritis Associated With Noroviruses on Cruise Ships—United States 2002
MMWR Morb Mortal Wkly Rep 2002;51:1112–5

Table 1. Norovirus: Clinical Aspects

Epidemiology
- Distributed throughout the United States
- Affects all age groups
- Multiple modes of transmission: direct person-to-person contact, consumption of contaminated food or water, airborne droplets of vomitus, and contact with contaminated environmental surfaces
- Infectious dose of as few as 10 viral particles

Clinical findings
- 30% of infections might be asymptomatic
- Incubation period: 24–48 h
- Disease characterized most frequently by
  - — Acute-onset vomiting
  - — Watery nonbloody diarrhea and one or more of the following:
    - — Abdominal cramps
    - — Nausea
    - — Fever
    - — Headache
- Dehydration most common complication in young and elderly
- Duration of illness: 12–60 h
- Immunity short-lived and type-specific

Laboratory testing (difficult for practicing physician)
- Diagnosis made by detection of norovirus by reverse transcriptase polymerase chain testing of stool or emesis specimens
  - — Sequencing of norovirus for genotype and cluster identification
- Older methods for diagnosis include:
  - — Direct and immune electron microscopy of fecal samples
  - — Demonstration of 4-fold increase in IgG antibodies in paired acute- and convalescent-phase serum samples

Treatment
- No specific therapy for norovirus illness
- Symptomatic therapy consisting of replacement of fluids and electrolytes

Prevention
- Provision of safe food and water
- Frequent hand washing. Ensuring that ill food-handlers do not work until well
  Disinfection by using at least a 1:50 solution of domestic bleach

Adapted from (4).

ABSTRACT

The authors, who are from the Vessel Sanitation Program of the Centers for Disease Control and Prevention (CDC), summarize the recent outbreaks of acute gastroenteritis (AGE), which occurred on five different cruise ships. Attack rates among passengers ranged from 4% to 13% and among crew members from 0.2% to 3.3%. Subsequent epidemiological investigations by the CDC suggested that the incidence was higher, approaching 19–41% of passengers. Overall there were 21 outbreaks of AGE on 17 cruise ships, of which nine were documented to be due to norovirus, three due to bacterial agents, and nine of unknown cause. In general, subsequent outbreaks on each cruise ship were of the identical strain of norovirus by reverse transcriptase polymerase reaction, which suggests an embedded source. The authors conclude that in addition to emphasizing basic food and water sanitation measures, control efforts should include thorough and prompt disinfection of ships during cruises and isolation of ill crew-members and passengers for 72 hours. (Am J Gastroenterol 2003;98:2098–2099. © 2003 by Am. Coll. of Gastroenterology)

COMMENT

The advertisements are so seductive. An impossibly attractive couple over-represents the rich and famous. Scantily clad, the perfection of their sculptured bodies is only eclipsed by their flawless dentition. A gibbous moon is a backdrop to a distant tropical island paradise, where the natives are presumably eager to adopt any potential stranger. But for a ticket on a cruise liner, we, too, could be part of this elite group. Hurry, accommodation is limited.

So much for anticipation—what about reality? On this same cruise liner, our glamorous couple has a high probability of contracting norovirus and spending a substantial time below decks dealing with gastroenteritis. The fluted champagne glass is exchanged for either the stainless steel receptacle or the porcelain bowl, depending on whether diarrhea or vomiting is the more pressing.

The abstracted article describes five norovirus outbreaks that occurred during July–December, 2002 on cruise ships. Noroviruses (previously Norwalk-like virus), a member of the family *Caliciviridae*, are the commonest cause of AGE in the United States, causing approximately 23 million illnesses per year (1). Although outbreaks on cruise ships have had the most publicity, at least 60–80% of all cases occur on land (2), particularly where there is a high density of people (summer camps and military encampments). As an aside, norovirus was the most common cause of disability among U.S. troops in Desert Shield/Desert Storm. The multiple modes of transmission of this virus, coupled with its relative environmental stability and a prolonged period of asymptomatic stool excretion, make norovirus difficult to control. Up to a quarter of infected patients might continue to excrete the virus 3 wk after illness, and as many as one third might be asymptomatic excreters (3). The epidemiology and clinical aspects of norovirus are summarized in the accompanying table (Table 1).

We live in a world where someone or something is always to blame, so who is culpable? Big industry is always an attractive scapegoat, and the cruise ship industry is an $11 billion/year potential target. However, environmental health inspections conducted by the CDC on one of the cruise ships revealed no sanitary deficiencies, and no association between illness and water, specific meals, or offshore excursions was found. Quarantine of infected crew members and passengers and improved sanitation was not enough to prevent subsequent epidemics, in some instances. If blame must be assigned, then it is to the crowded human condition and not lapses in cruise ship sanitation. The authors noted that on one ship 41% of passengers prospectively surveyed had evidence of AGE, although only 8% of passengers and 2% of crew sought medical attention—another "tip of the iceberg"?

This negative publicity has not caused a significant decrease in bookings for future cruises, although one report suggested there has been a significant fall in stock prices of several major cruise companies (5). It can be anticipated that many of our patients will still take cruises and want our advice about how to keep well. Bringing copious amounts of electrolyte solutions and obsessing about hand washing might make for a more enjoyable vacation than the video camera, suntan lotion, and an elegantly tailored swimsuit.

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Obesity Surgery, 14, 13-15

Pharmaceutical Savings after Gastric Bypass Surgery

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Background: Clinically severe obesity (CSO) is a surgically treated disease. The Roux-en-Y gastric bypass (RYGBP) has been used to treat patients with CSO and has resulted in an improvement in co-morbidities. We speculated that after a period of weight loss, patients would require less medication, resulting in cost-savings to both the patient and the insurance company, as well as an overall gain in health.

Method: A retrospective study was performed which involved the first 100 patients who had undergone RYGBP at a community-teaching hospital. Analysis of the data was conducted by the Wilcoxon signed rank test.

Results: 64 patients met our inclusion criteria and had adequate follow-up data available. The mean BMI was 57 kg/m^2 (range 36.6 - 85.4 kg/m^2), the female to male ratio was 4:1 (51:13), and the mean age was 44 years (range 27-64). The average monthly medication expenditure was reduced from $317 (SEM 47.25, range $23.12-$1801.19) preoperatively, to $135 (SEM 35.35, range $0.00-$1122.72) postoperatively. This reduction is significant (P <0.01).

Conclusion: Weight loss after RYGBP leads to a significant reduction in medication expenses. These medication savings offset the costs of the initial procedure and represent permanent financial savings for the patient and society.

Key words: Morbid obesity, bariatric surgery, pharmaceutical savings

Introduction

In the United States, 97 million adults are obese or overweight. The treatment of obesity and obesity-related co-morbidities costs yearly over 50 billion US dollars (NIH, 1998).[1] It is estimated that medical care costs for obesity and its associated co-morbidities consume 5.5% of US health dollars.[2,3] Clinically Severe Obesity (CSO) has a significant impact on the patient's physical, psychosocial, social and economic health, as well as long-term implications for future health-care policies of the USA.[4] CSO is defined by a body mass index (BMI) ≥40 kg/m^2.

Surgical therapy for CSO has been found to be significantly more effective at producing and maintaining weight loss than dietary measures.[5] One of the most effective surgical treatments for CSO is Roux-en-Y gastric bypass (RYGBP). Studies have suggested that losing one-third of excess weight is associated with significant medical benefits.[6,7] Losing weight has been shown to result in decrease in co-morbidities.[2,8-11] For example, RYGBP is the most effective therapy for type 2 diabetes.[12] Patients with CSO are commonly prescribed a number of medications to treat their co-morbidities, and the amount of medication decreases with weight loss.[6] Previous studies have not addressed the issue of corresponding financial savings following RYGBP and successful weight loss. Decreasing medication costs could be used as a barometer of improved health for the patient.

Methods

Institutional Review Board approval was obtained. The charts of the first 100 patients who underwent RYGBP at York hospital by the same surgeon were reviewed. Study inclusion criteria were: 1) use of prescription medication preoperatively; 2) follow-up of at least 6 months after RYGBP. Medication

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consumption was analyzed both preoperatively and at the time of most recent follow-up. Costs of medications were determined based on figures supplied by the hospital pharmacy, which has an average pricing profile among most pharmacies. Statistical analysis was performed by the Wilcoxon signed rank test.

Results

The operative series included 100 patients, 87 of whom were on medications preoperatively for a variety of co-morbid conditions. Because of relocation or incomplete documentation of medications and dosages, 23 patients were lost to follow-up. Complete data sets were obtained for 64 patients (a 73.6% follow-up rate). Mean follow-up time was 16 months (6-60 months)

Demographics

The population included 51 females and 13 males (ratio 4:1). Mean age was 44 years (range 27-64). Mean BMI was 57 kg/m^2 (range 36.6-85.4).

Co-morbidities

Sleep apnea preoperatively had been diagnosed in 38 patients, 25 of whom used continuous positive airway pressure (CPAP) at night. Postoperatively, only two continued CPAP use. Savings for CPAP equipment and oxygen tank refills in this group totaled $207.00/month (Table 1).

Preoperatively, 23 patients had been treated for diabetes type 2, and 21 (91%) of these patients discontinued anti-diabetic medication postoperatively. The remaining two patients decreased their dosage by one-half. Mean preoperative expenses of $75.60 per month were reduced to <$5.00.

Hypertension had been diagnosed preoperatively in 31 patients; 11 (35%) were able to discontinue all medications postoperatively, and 15 (48%) decreased their antihypertensive medications. This resulted in average saving of $16.26 per patient per month.

Gastro-esophageal reflux disease (GERD) had been diagnosed in 21 patients, 8 of whom were treated with pharmaceuticals before RYGBP. Postoperatively, 5 (62.5%) of the 8 patients discontinued all medications for GERD.

Preoperatively, 23 patients were prescribed at least one treatment for asthma; postoperatively, 18 (78%) reduced the dosage or discontinued at least one of the pharmaceuticals (Table 1). Other co-morbidities in our study population, including anxiety, hypothyroidism, insomnia, psychosis and arthritic pain, did not show significant changes in medication expenses.

When all co-morbidities are included in the analysis, the median monthly expenditure of preoperative medications per patient was $317.00 (SEM 47.25, range $23.12-$1801.19). Postoperatively this was reduced to $135.00 (SEM 35.35, range $0.00-$1,122.72). These monthly savings of $182.00 add up to yearly savings of $2,184.00 per patient. Wilcoxon signed rank test provided a significant *P*-value <0.01 (Figure 1).

Table 1. Co-morbidity-related medical expenses and savings

Co-morbidity	n	preoperative	postoperative	monthly savings
Sleep Apnea				
CPAP	20	$225.00	$18.00	$207.00
Diabetes				
type 2	23	$75.60	$4.60	$71.00
Hypertension	31	$26.59	$10.33	$16.26
GERD	21	$81.73	$47.86	$33.87
Asthma	23	$52.45	$32.79	$19.66
All co-morbidities	64	$317.30	$135.20	$182.10

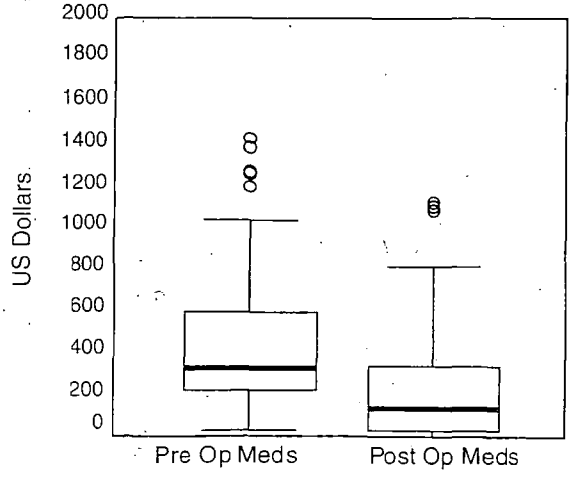

Figure 1. Medication expenses for all co-morbidities pre and postoperatively.

[SB579, 06]

This study has three weak points: 1) mean follow-up of only 16 months; 2) exclusion of patients without preoperative medications; 3) incomplete data for 23 patients. Nonetheless, the statistical analysis does show a highly significant result. With this in mind, if we extrapolate from our results of $2,184.00 savings per patient per year to the nearly 75 million US citizens, the total savings on medication expenses would amount to over 100 billion US dollars per year.

Discussion

Improvement in co-morbidities following gastric bypass surgery and subsequent weight loss has been widely reported,[4,7-11] but financial savings have not been addressed. Our data confirms the hypothesis that medical expenses for the treatment of co-morbidities of massive obesity decrease significantly with weight loss after RYGBP. Decreased medication requirements for sleep apnea, diabetes, cardiovascular and gastrointestinal co-morbidities appear to be the biggest contributors to these savings.

However, not all conditions are directly subject to improvement following surgical treatment and weight loss. For example, we found no reduction in pain medication, nor was there a decrease in medication for the treatment of hypothyroidism or anxiety.

Long-term follow-up of these patients is needed to further analyze the evolution of their co-morbidities and the associated medication expenses after RYGBP. However, we can conclude that financial savings represent yet another way of expressing the benefits of bariatric surgery. The patients are losing weight, improving their co-morbidities and requiring less medication. This could lead to nationwide yearly savings of over 100 billion US dollars.

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The Impact of Bariatric Surgery on the Veterans Administration Healthcare System: A Cost Analysis

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Background: The economic burden of caring for veterans with clinically severe obesity and its comorbidities is straining the Veterans Administration (VA) healthcare system. The authors determined the cost of Roux-en-Y Gastric Bypass (RYGBP) in the VA's single-payor healthcare system.

Methods: The records of all 25 patients who underwent RYGBP from May 1999 to October 2001 were reviewed. All obesity-related health-care costs including hospitalizations as well as outpatient visits, medications and home health devices were calculated for 12 months before and after the RYGBP.

Results: Age was 52±2 yr and preoperative BMI was 52±2 kg/m^2; ASA score was III (21 patients) and II (4 patients). Mean follow-up was 18 months. Total cost of care for these patients preoperatively was $10,778±2,460/patient (outpatient visits=$5,476±682, hospital admissions=$12,221±6,062, and home health devices=$1,383±349). Postoperative length of stay was 8±0.5 days. Cost of the gastric bypass was $8,976±497/pt (OR fixed cost=$1,900/patient + ICU and ward=$7,076±497/patient). For the first postoperative year, 6 patients had 12 admissions, but routine outpatient visits were significantly reduced from 55±6 to 18±2 postoperatively ($P<0.001$). The cost of all care excluding peri-operative charges for 1 year after gastric bypass was $2,840±622/patient ($P=0.005$ vs preop).

Conclusions: Operative treatment of clinically severe obesity reduces obesity-related expenditures and utilization of healthcare resources. The cost of undertaking RYGBP at the VA is offset by reduction of health-care costs within the first year after surgery. These data support allocation of resources to support existing bariatric surgery programs throughout the VA system.

Key words: Bariatric surgery, morbid obesity, cost analysis, veterans administration (VA), Roux-en-Y gastric bypass

Introduction

Throughout the Western world, the prevalence of obesity, as defined by body mass index (BMI>30 kg/m^2), is increasing in all age groups.[1,2] It is estimated that more than one-fifth of U.S. adults are clinically obese.[3] Obesity has become a healthcare crisis in the United States, not only because of its healthcare consequences, but also because of the ever-increasing financial burden and expenditure secondary to weight-related morbidites.[4,5] It is estimated that 7% of the total healthcare expenditures in the United States is utilized toward the treatment of clinically significant obesity and its associated comorbidities.[6]

In most patients, weight loss induced by bariatric surgery will correct or ameliorate most of the weight-related comorbid conditions associated with clinically severe obesity, including diabetes mellitus, mechanical arthropathy, sleep apnea, obesity hypoventilation, hypertension, gastroesophageal reflux (GERD), urinary stress incontinence, pseudotumor cerebri, dyslipidemia, asthma, and congestive heart failure as well as improve the quality of life.[7-9]

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The Veterans Administration (VA) healthcare system has several unique attributes. The VA system has a fixed budget and therefore a fixed allocation for the healthcare of each veteran. Consequently, it is necessary for new treatment modalities to be cost-effective and to be justified through proven cost-savings analysis. Our hypothesis is that the amelioration of comorbid conditions following bariatric surgery would be reflected in cost-savings for the VA healthcare system. Therefore, we undertook a study to evaluate the cost of bariatric surgery and its impact on the VA healthcare system.

Methods

The medical records of all consecutive patients who underwent RYGBP for clinically severe obesity from May 1999 through October 2001 were reviewed. All operations were completed by the same surgeon (DHS) at The Bay Pines Veterans Administration Medical Center (VAMC), one of five teaching Dean's hospitals affiliated with The University of South Florida Surgical Residency Program.

The VA's Computerized Medical Records System (CPRS) was abstracted for patient characteristics; all preoperative outpatient clinic visits for 1 year before the RYGBP, obesity-related hospital admissions for 3 years before RYGBP, all postoperative outpatient clinic visits for 1 year after RYGBP, and hospital admissions up to 3 years following RYGBP were analyzed. Hospital admissions and outpatient visits not related to obesity or its comorbidities were similarly excluded (i.e. dental clinic and eye clinic). Distribution and use of scooters, walkers, continuous positive airway pressure (CPAP) machines, glucometers, syringes, and other special accommodations were also recorded.

The costs used in this analysis were based on information and data from Bay Pines VAMC Department of Surgery Administrative Financial Office. In addition, the Decision Support Systems Committee also collects and analyzes data within the said Department of Surgery. The reported costs of inpatient and outpatient care as calculated/reported by the Department of Surgery Administrative Financial Officer are: outpatient clinic visits=$100/visit, ICU=$1,620/day, inpatient ward=$680/day, and OR cost=$1,900 / operation / patient (RYGBP). The cost of medical devices were: scooter=$6,000/unit, CPAP machine=$600/unit, Glucometer=$500/unit, diabetic supplies and syringes=$30/month/patient.

Statistical Analysis

Data are reported as mean ± standard error of the mean (sem). Means were compared using Student's t-test. Significance was at $P<0.05$.

Results

The clinical characteristics of 25 patients who underwent RYGBP from May 1999 to October 2001 are summarized in Table 1. The mean postoperative length of stay was 8±0.5 days. The average stay in the ICU was 1.4±0.5 days. The mean cost of perioperative hospitalization was $7,076±497 per patient. The total cost of open RYGBP (including OR costs and hospitalization) was $8,976±497 per patient (Table 2).

Healthcare cost prior to RYGBP was $10,558±2,470 per patient incurred as follows: outpatient clinic visits=$5,476±682 per patient; hospital admissions=$13,211±6,906 per patient; and home health devices=$1,383±349 per patient (Table 2).

Costs for preoperative hospitalizations included 11 separate admissions for eight patients with obesity-related conditions (psychiatric=3, chest pain/coronary artery disease=2, congestive heart failure/sleep apnea=2, diabetic ketoacidosis=2, fall/hip fracture=1, and preoperative evaluation=1) for a total of 141 inpatient days; the preoperative evaluation in the last patient was for assessment of

Table 1 Characteristics of 25 veterans who underwent RYGBP (mean±sem)

Age	52±2 years
Sex	M (72%)
	F (28%)
BMI	52±2 kg/m²
ASA	III (84%)
	II (16%)

a veteran who was new to the Bay Pines VAMC. In total, six patients were new to the Bay Pines VAMC; their preoperative outpatient visits to the VA Healthcare System were initiated for surgical consultation in consideration for RYGBP.

Postoperative admissions in the first year following surgery included six patients who had 12 admissions (wound infection=5, tubo-ovarian abscess=1, alcohol abuse/depression=1, shortness of breath=2, panniculectomy with/without hernia repair=3, and fatal pulmonary embolism in the emergency room=1) for a total of 59 days (Table 2). An emergency-room visit at Bay Pines is equivalent to an outpatient clinic visit. Mean follow-up was 18 months.

After RYGBP, the number of outpatient clinic visits was dramatically reduced from 55±6 to 18±2 per veteran ($P<0.001$). Thereby, the cost of care was reduced to $2,840±622 per patient ($P=0.005$ vs. preop).

Discussion

Clinically significant obesity has become an epidemic with monumental socio-economic and healthcare implications. As a result, healthcare expenditures for patients with clinically significant obesity will continue to escalate. In a national healthcare system whose resources are continually being limited, cost-savings are crucial to maintain optimal healthcare availability and coverage for all veterans including the patients with clinically severe obesity. To that end, bariatric surgery is the only modality for the treatment of patients with clinically severe obesity (BMI ≥40 kg/m^2) that has resulted in significant and durable weight loss.[12]

Table 2. The costs of preoperative, peri-operative, post-operative and total care including outpatient visits, hospitalizations, and home health devices in 25 veterans who underwent RYGBP, (mean±sem). *P=0.005 vs preoperative

Pre-op expenses	*Units*	*x $1,000*
Outpatient	$100/visit	5.5±0.7
Inpatient	($680/ward day & $1620/ICU day)	12.2±6.0
Home health devices	individual	1.4±0.3
Total		**10.8±2.5**
Peri-op expenses	*Units*	*x $1,000*
Fixed OR cost	per operation	1.9
ICU & ward cost	($680/ward day & $1620/ICU day)	7.1±0.5
Total		**9.0±0.5**
Post-op expenses	*Units*	*x $1,000*
Outpatient	$100/visit	1.8±0.3
Inpatient	($680/ward day & $1620/ICU day)	5.0±1.6
Total		**2.8±0.6***

The widespread acceptance of bariatric surgery by patients and healthcare providers has challenged the resources of third party payors and, to some extent, those VA hospitals that have initiated small-scale bariatric surgery programs. Healthcare administrators and policy makers have long evaluated emerging treatments through cost-benefit analysis. While hospital charges for bariatric surgery have been studied,[11] data on actual cost has not been reported. In addition, hospital administrators may not be able to extract these data as a result of the inherent and convoluted inflation that is built into hospital charges and budgets. These inaccuracies are subsequently amplified by the fact that hospitals are reimbursed by different insurance companies, who in turn utilize complicated schemes and restrictions.

On the other hand, the VA healthcare system is a not-for-profit system where facilities and providers operate within the same budget. Therefore, reported costs reflect actual costs most realistically. In addition, the VA's mandatory CPRS eliminates reporting bias and errors. As a consequence, the VA system has been the subject of many seminal clinical trials and outcomes projects. The cost and healthcare expenses were calculated based on data provided by the Financial Office at Bay Pines VAMC. Although these data are derived from the VA's budget, regional differences are not included.

Our cohort consists primarily of middle-aged men, as expected, who have a moderate risk for postoperative complications (ASA class). The impact of comorbid conditions is evident from the expense incurred during the period before definitive treatment by RYGBP. Although the utilization of outpatient visits and inpatient care may be falsely increased in a setting where patients traditionally have no fiscal responsibility (i.e. co-pay, deductible, secondary insurance, etc...), the VA's practice climate has not been immune to utilization changes

[SB579, 106]

that have occurred in the private sector. Nevertheless, these same factors are operative in the postoperative setting, thereby eliminating any bias for the purpose of this comparison.

In spite of this, there was a dramatic reduction in the healthcare expenditure for obesity-related conditions in the first year following RYGBP. This was primarily due to the decrease in utilization of outpatient clinic visits that dropped precipitously from 55±6 to 18±2 per patient ($P<0.001$). This reduction in outpatient visits was expected as a result of the documented improvement in diabetes, sleep apnea, GERD, and hypertension following RYGBP.[9-11] Similarly, the utilization of inpatient days was reduced after RYGBP, further demonstrating the amelioration of underlying comorbid conditions.

Although these data are based on the VA cost structure and influenced by practice dynamics at the VA, which is exemplified by routine ICU admissions and a mean LOS of 8±0.5 days per patient, important corollaries are apparent. In the VA's capitated, single-payor system, the cost of RYGBP is clearly offset by reductions in expenses incurred in the treatment of obesity-related comorbid conditions.

The implications of cost reduction and improvement in quality of life after RYGBP are very significant. To date, very little data exists on cost analysis of RYGBP; and although the VA model is unique, it can also be extrapolated to non-VA settings.

Conclusions

The operative treatment of clinically severe obesity is cost-effective in the Veterans Administration Healthcare System based on this cost analysis. Bariatric surgery reduces clinic visits and hospital resource utilization by reducing obesity-related cost of care. These data support the allocation of resources to initiate and maintain bariatric surgery centers throughout the VA Healthcare System.

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Cost-effectiveness of Gastric Bypass for Severe Obesity

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PURPOSE: To estimate the cost-effectiveness of gastric bypass in the treatment of severe obesity.

SUBJECTS AND METHODS: We performed a cost-effectiveness analysis of gastric bypass versus no treatment from the payer perspective. We discounted quality-adjusted life-years (QALYs), life-years, and cost during the patient's lifetime. Our target group comprised women and men aged 35 to 55 years with a body mass index between 40 and 50 kg/m^2, and who did not have cardiovascular disease and in whom conservative bariatric therapies had been unsuccessful.

RESULTS: The base case cost-effectiveness ratios ranged from $5000 to $16,100 per QALY for women and from $10,000 to $35,600 per QALY for men, depending on age and initial body mass index. In a few subgroups of older, less obese men, variation in parameters such as loss of excess weight, obesity-related quality of life, complication rates, and perioperative mortality affected the cost-effectiveness ratios. Parameter variation did not result in meaningful changes in the remaining patients.

CONCLUSION: Gastric bypass is a cost-effective alternative to no treatment, providing substantial lifetime benefits in patients who are severely obese. **Am J Med. 2002;113:491–498.** ©2002 by Excerpta Medica, Inc.

In the United States, the prevalence of severe obesity in men and women aged 18 to 64 years increased by 114% between 1991 and 1999 (1,2). Yet few treatments have been effective in severely obese patients, typically identified as having a body mass index >40 kg/m^2. Dietary therapy, even together with exercise and behavior therapy, is rarely successful in these patients (3). Weight loss medications such as orlistat and sibutramine have shown modest efficacy (4,5), and their effects on long-term maintenance of weight loss are unknown. Frequent complications and severe adverse effects characterized early surgical procedures such as jejunoileal bypass.

Gastric bypass is one of two main forms of bariatric surgery (6) that is tolerated better and performed widely. It limits food intake by dividing the stomach to form a small gastric pouch, and induces malabsorption by creating an anastomosis from the pouch to the jejunum. The alternative surgical procedure, vertical banded gastroplasty, has similar costs as gastric bypass but is less effective (7–11) and was not considered in our analysis. We sought to determine the cost-effectiveness of gastric bypass in the treatment of severe obesity in patients without cardiovascular disease in whom conservative bariatric therapies were repeatedly unsuccessful.

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METHODS

Decision Model and Sample

We used a deterministic decision model (12) to compare the lifetime expected costs and outcomes between gastric bypass and no treatment of severe obesity from the payer perspective (Figure 1). Patients in each arm were assigned to health outcomes by rates, instead of drawn from distributions. The cost-effectiveness ratio was determined by dividing the difference in total lifetime medical cost by the difference in quality-adjusted life-years (QALYs). Cost and QALYs were discounted at 3% to reflect the principle that events in the future are less valuable than immediate costs and benefits. Base case parameter estimates represent our best judgment from the literature and discussions with experts. When ambiguous, we chose model attributes and estimates that favored no treatment.

The target group comprised a relatively healthy subset of men and women who were severely obese (class 3), defined as having a body mass index >40 kg/m^2. Subjects were 35 to 55 years in age, and body mass index was between 40 and 50 kg/m^2. We limited analysis to nonsmoking patients who did not have cardiovascular disease, drug addictions, and major psychological disorders. As recommended by treatment guidelines (6), we included only those subjects who had been unable to maintain clinically meaningful weight loss despite several attempts at conservative therapies (e.g., dieting, exercise, behavior therapy, and pharmacotherapy). To assess variation within this group, we characterized risk subgroups by age, sex, and initial body mass index. Differences in longevity and average cost and length of stay motivated the differentiation.

Gastric Bypass Probabilities and Rates

Gastric bypass is associated with the risk of perioperative death and complications such as deep venous thrombosis

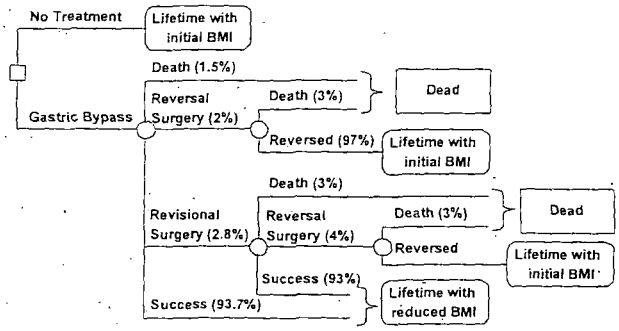

Figure 1. Deterministic decision model comparing lifetime expected costs and outcomes between gastric bypass and no treatment of severe obesity from the payer perspective. If no treatment was chosen, we estimated the patient's lifetime medical costs for the treatment of selected obesity-related diseases, life expectancy, and quality-adjusted life expectancy conditional on age, sex, and initial body mass index (see Tables 3 and 4). If surgery was chosen, the patient bore the cost and burden of the initial surgery and its complications. Surviving patients may require corrective surgery within a year of the initial surgery. We assumed that at the end of that year, the patient had died, returned to the original weight, or lost weight. If the procedure was reversed, we further accumulated lifetime cost and health outcomes as in the no-treatment group, except that quality of life was halved for the remainder of the patient's life because of the psychological burden of treatment failure. Successful patients incurred additional costs and burden from weight loss–related events, namely treatment for cholelithiasis and abdominoplasty. We assumed that 5 years after the initial surgery, the weight loss of successful patients stabilized, and we similarly estimated lifetime cost and health outcomes based on age, sex, and reduced body mass index. BMI = body mass index.

and wound infection (Figure 1, Table 1). Rarely, patients cannot restrict their diet sufficiently following the procedure and develop intractable dumping syndrome requiring reversal surgery. Revisional surgery is necessary with complications such as staple line disruption or dehiscence and may sometimes need to be followed with reversal surgery. Nearly a quarter of patients require treatment for incisional hernia within 2 years after hospital discharge. Revisional and reversal procedures are associated with higher complication rates (13,14). Therefore, we set the complication rates following corrective procedures to be twice that of rates after initial surgery. The modeling of each arm incorporated the rates of complications and their timing.

We considered gastric bypass to be successful if the patient survived and did not undergo a reversal procedure, regardless of complications. Some successful patients require treatment for cholelithiasis 2 years after discharge and abdominoplasty 5 years after discharge. Each patient was assumed to return for follow-up care with a general practitioner and a dietitian three times a year for 3 years if the surgical procedure was successful, and for 1 year if the procedure was reversed. Because malabsorption increases the risk of nutritional deficiencies, successful patients take two multivitamins, two tablets of $FeSO_4$ (325 mg), and 1000 mg of calcium carbonate every day, and vitamin B_{12} 1000 μg intramuscularly every month, for the rest of their lives. Some studies recommend taking ursodiol during the weight loss period to prevent cholelithiasis (15,16), which we did not follow because of limited evidence.

We based our estimates for weight loss and complication rates on those from a study by Pories et al. (17), which involved a large sample (608 patients) and 14 years of follow-up with a 96.3% follow-up rate. Loss of excess weight was the amount of weight lost divided by the total amount of excess weight before the intervention, and was expressed as a percentage. Excess weight was defined as the weight above a body mass index of 22 kg/m^2. Pories et al. estimated a mean percentage loss of excess weight of about 58% five years after surgery. We abstracted the rates of deep venous thrombosis and pulmonary embolism from the International Bariatric Surgery Registry, given that their estimation required a large sample (18,19). The rates of abdominoplasty and reversal surgery were obtained from the Adelaide Study (9), a randomized clinical trial that compared the outcomes of gastric bypass with those of vertical banded gastroplasty over 5 years. These two rates were unavailable elsewhere in the literature.

Life Expectancy

Using data from the Framingham Heart Study, Thompson et al. estimated life expectancy across age, sex, and body mass index (20), considering only mortality associated with coronary heart disease and stroke, and excluding patients with an initial history of these conditions. We applied a simple linear approximation to their estimates to assess the effects of obesity on life expectancy.

Costs

We included medical costs (in U.S. 2001 dollars) associated with the initial surgery, treatment of complications, follow-up care, and treatment of obesity-related diseases, such as coronary heart disease, stroke, type 2 diabetes, hypercholesterolemia, and hypertension. All cost estimates were adjusted for inflation; the Medical Care Component of the Consumer Price Index for All Urban Consumers was used to adjust prices, when necessary. Expected lifetime medical cost estimates were obtained from the published literature (20). For the majority of the remaining costs, estimates of nationally representative hospital charges (Table 1) were obtained from the Healthcare Cost and Utilization Project (21). These sex-specific estimates were consistently higher in men, except for perioperative death. We overestimated treatment

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Table 1. Input Variables and Sources* Used in the Model

Procedure or Outcome (ICD-9-CM Code)	Rate (%)	Charges ($)		Length of Stay (days)		Length of Recovery (days)	Reference
		Men	Women	Men	Women		
Gastric bypass (44.31)	–	26,100	20,500	5.20	4.40	45	–
Minor wound infection†	8.7	192	192	0	0	0	17
Major wound infection (998.6)	3.0	20,600	19,200	7.80	8.00	14	17
Deep venous thrombosis (128)	2.6	8700	8100	5.70	5.36	14	19
Pulmonary embolism (78)	1.0	14,700	13,900	6.47	6.34	14	19
Cholelithiasis (51.22)	11.4	27,100	22,700	8.10	7.00	14	17
Incisional hernia (53.51)	24.0	13,200	12,500	4.10	4.10	14	17
Abdominoplasty (86.83)	39.0	13,600	12,200	3.90	2.50	14	9
Revision surgery (44.69)	2.8	38,500	25,600	10.40	7.60	30	17
Reversal surgery (44.69)	2.0	38,500	25,600	10.40	7.60	∞	9
Perioperative death (249)	1.5	27,600	29,000	6.90	6.80	14	17
Follow-up visit‡	–	150	150	–	–	–	–
Supplements†§	–	68	68	–	–	–	–

* Charges and lengths of stay were mostly taken from the Healthcare Cost and Utilization Project database derived from the 1997 medical claims survey (21). Codes indicate the ICD-9-CM number for each procedure, except for deep venous thrombosis and pulmonary embolism, which are Clinical Classification Software codes, a tool developed at the Centers for Medicare and Medicaid Services for clustering patient diagnoses and procedures into a manageable number of clinically meaningful categories, and for perioperative death, which is a diagnosis-related group code. Length of recovery was assessed by expert opinion.

† From reference (22).

‡ From R. Atkinson, MD, Clinical Nutrition Clinic, written communication, 2001.

§ Refers to the annual supply of multivitamins, iron supplements ($FeSO_4$ 320 mg), calcium supplements, and vitamin B_{12} injections.

ICD-9-CM = *International Classification of Diseases, Ninth Revision, Clinical Modification.*

costs because charge reimbursement rates were usually less than 100%. We obtained the cost of medications and follow-up visits from a source on wholesale drug prices (22) and a local source (R. Atkinson, MD, Clinical Nutrition Clinic, written communication, 2001).

Quality of Life

We assumed that a person who loses weight has the same quality of life as someone who is at that reduced weight. To estimate the effects of obesity on quality of life, we stratified a nationally representative sample of nonsmoking adults by sex (23). Within each stratum, we used a multivariate linear regression model to estimate years of healthy life (24), which revealed the negative relation between health-related quality of life and body mass index (Table 2) and provided the basis for QALY estimates. Quality-adjusted life expectancy was also adjusted for treatment burden and perioperative mortality.

We reduced quality of life by 200% for time spent in the hospital and by 50% for time spent in recovery, assuming that being in hospital was a state "worse than death," represented by a quality of life less than zero, and that recovery time decreased quality of life by half. We also assumed that patients never recovered completely from reversal surgery because of its psychological effects. For successful procedures, the 6-week recovery period was associated with adverse effects of dietary adjustment, often characterized by vomiting and dumping syndrome.

Table 2. Health-Related Quality of Life, by Sex, Age, and Body Mass Index*

Body Mass Index (kg/m^2)	Age (years)									
	Men					Women				
	35	45	55	65	75	35	45	55	65	75
25	0.929	0.912	0.886	0.85	0.805	0.908	0.889	0.857	0.813	0.755
30	0.903	0.88	0.853	0.823	0.79	0.875	0.846	0.811	0.77	0.722
35	0.877	0.848	0.821	0.797	0.775	0.842	0.804	0.765	0.727	0.688
40	0.851	0.816	0.789	0.77	0.76	0.809	0.761	0.719	0.684	0.654
45	0.825	0.784	0.756	0.743	0.745	0.775	0.718	0.673	0.641	0.621
50	0.799	0.752	0.724	0.717	0.73	0.742	0.675	0.627	0.598	0.587

* On a 0 (death) to 1 (perfect health) scale.

RESULTS

Base Case Analysis

In all risk subgroups, the cost-effectiveness ratios of gastric bypass versus no treatment were favorable, at less than $50,000 per QALY. In four risk subgroups representing the upper and lower bounds of the cost-effectiveness ratios (Tables 3 and 4, Figure 2), the ratios ranged from about $5000 to $16,100 per QALY for women and from about $10,000 to $35,600 per QALY for men, depending on age and initial body mass index. These variations suggest that gastric bypass is more cost-effective among women and those with a higher initial body mass index. However, because the reduction in lifetime medical cost was not greater than the cost of treatment in any risk subgroup, this analysis did not show that gastric bypass was cost saving.

Sensitivity Analysis

Because estimates of treatment effectiveness were based on case series and subject to patient selection bias, we set the lower bound of percentage loss of excess weight to 38%, more than one-third less than the base case estimate. Thus, the cost-effectiveness ratio for a 45-year-old man with a body mass index of 40 kg/m^2 was $57,200 per QALY and for a woman of the same age and body mass index was $28,000 per QALY (Figure 3). Further analysis suggested that the 38% estimate increased the cost-effectiveness ratio beyond $50,000 per QALY for a few subgroups of older, less obese men.

Most insurers reimburse a fraction of charges. For example, the median reimbursement rate at the University of Wisconsin Hospitals and Clinics is 67%, which, in a 45-year-old woman with a body mass index of 40 kg/m^2, would lower the cost-effectiveness ratio from $14,000 to $7300 per QALY. Such a shift is intuitive because a decrease in the reimbursement rate reduces all charge-based cost estimates for gastric bypass surgery but has no effect on the lifetime cost estimates derived from the literature.

Long-term severe obesity may have residual effects on health. Consequently, the risk of obesity-related disease for a person who loses weight may not equal the risk for someone who is less obese. Because the estimations of life expectancy and expected lifetime medical costs did not account for such residual effects, our base case estimates may have favored weight loss. To investigate the sensitivity of our results to residual effects, we incorporated these effects into the model. We performed one-way and two-way sensitivity analyses that assumed that weight loss did not affect life expectancy or the onset of obesity-related disease. To assess the sensitivity of the cost-effectiveness ratios to a decrease in the effect of obesity on quality of life, we decreased the obesity-related regression coefficients by 25%. In each analysis, the resulting ratios remained below $50,000 per QALY, except in a few subgroups of older, less obese men.

Table 3. Effectiveness and Costs in Base Case Estimates, by Risk Subgroup at Age 35 Years*

Body Mass Index (kg/m^2)	Life Expectancy (years)				Quality-Adjusted Life Expectancy (QALY)				Total Cost ($)				Cost-effectiveness Ratio			
	Gastric Bypass		No Treatment		Gastric Bypass		No Treatment		Gastric Bypass		No Treatment		Cost Per Life-Year ($)		Cost Per QALY ($)	
	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women
40	23.00	24.63	22.97	24.72	19.56	19.82	18.51	18.21	68,600	59,000	38,500	35,300	844,700	—	28,600	14,700
50	22.83	24.46	22.52	24.46	18.87	18.88	16.83	16.03	75,000	64,800	53,200	48,500	70,300	9,130,000	10,700	5700

* Absent values indicate that the cost-effectiveness ratio (cost per life-year) is negative, signifying that gastric bypass incurred higher cost with lower effectiveness than did no treatment of severe obesity. All values are discounted at 3%.
QALY = quality-adjusted life-year.

Table 4. Effectiveness and Costs in Base Case Estimates, by Risk Subgroup at Age 55 Years*

Body Mass Index (kg/m²)	Life Expectancy (years)				Quality-Adjusted Life Expectancy (QALY)				Total Cost ($)				Cost-effectiveness Ratio			
	Gastric Bypass		No Treatment		Gastric Bypass		No Treatment		Gastric Bypass		No Treatment		Cost Per Life-Year ($)		Cost Per QALY ($)	
	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women	Men	Women
40	16.44	18.58	16.15	18.49	13.32	13.94	12.48	12.62	77,600	69,600	47,900	48,200	100,200	248,500	35,600	16,100
50	16.22	18.41	15.51	18.08	12.81	13.23	11.17	10.88	85,300	77,000	63,500	64,100	30,700	38,900	13,300	5400

* All values are discounted at 3%.
QALY = quality-adjusted life-year.

According to the International Bariatric Surgery Registry, mortality is 0.17% in severely obese patients. Regardless of this discrepancy, gastric bypass remained cost-effective, except in some older, less obese men, even after doubling the base case estimate to 3% and after increasing all complication rates by 25%.

In the sensitivity analysis of the discount rate, we removed lifetime medical costs from the model, which was equivalent to assuming that weight loss had no effect on lifetime medical costs, and increased the discount rate from 3% to 5%. The cost-effectiveness ratio remained favorable in all women and in some men in the upper body mass index ranges, suggesting that the significance of discount rate variation was concentrated among less obese men, if present.

Given the repeated finding of sensitivity among older, less obese men, we assessed how variation in loss of excess weight and the reimbursement rate altered the cost-effectiveness ratio among 55-year-old men with a body mass index of 40 kg/m^2, the oldest and least obese male risk subgroup. The two-way analysis (Figure 4) showed that a loss of excess weight greater than 46% was sufficient for a $50,000 per QALY cutoff under the base case reimbursement rate. If the reimbursement rate was less than 67%, the ratio was less than the cutoff for all loss of excess weight estimates considered. Therefore, the cost-effectiveness of gastric bypass among older, less obese men depended on whether loss of excess weight was greater than 46% or the reimbursement rate was less than 67%.

Gastric bypass was not cost-effective in patients under all potential parameter estimates. Parameter variation increased the cost-effectiveness ratio among some older, less obese men. This sensitivity to parameter variation was attributed to increased cost and length of treatment, and lower disutility associated with obesity. Variation in parameters did not have a noteworthy effect on the cost-effectiveness ratio among women.

DISCUSSION

Our results suggest that gastric bypass is not cost saving from the payer perspective. However, the cost-effectiveness ratio estimates compare favorably with those of other accepted interventions and appear robust to parameter variation, especially among women and younger, more obese men (25). In comparison with no treatment, gastric bypass is a cost-effective alternative.

Our study sample comprised subjects who were severely obese but who did not have the chronic medical conditions typically associated with obesity. Results may have been different if we had included patients with comorbid conditions such as diabetes, heart disease, and hypertension. Among such patients, the perioperative risks would be greater, but so would the benefits of weight

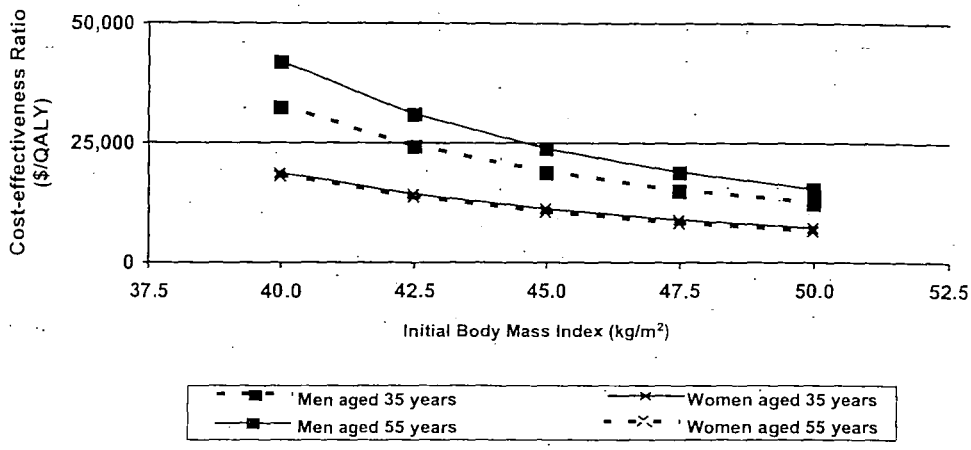

Figure 2. Analysis of four risk subgroups representing the upper and lower bounds of the cost-effectiveness ratios. These results suggest that gastric bypass is more cost-effective among women and those with a higher initial body mass index. QALY = quality-adjusted life-year.

loss. The importance of weight loss in patients with chronic conditions is appreciated by the National Institutes of Health Consensus Development Conference Panel (1), which lowered the recommended threshold for surgery from a body mass index of 40 kg/m^2 to 35 kg/m^2 in these patients.

We also included only patients who had been repeatedly unsuccessful at conservative interventions, which is in agreement with clinical guidelines (6) that failure of diet, exercise, and behavior therapy is an eligibility requirement for bariatric surgery. Failure of pharmacotherapy, however, is not a requirement, although it is common practice to attempt all conservative treatments before undergoing invasive procedures.

Laparoscopic forms of gastric bypass are becoming more common (26,27) and are potentially more effective, albeit more costly. However, more long-term follow-up data are needed on safety and effectiveness.

Our analysis had several limitations. Several obesity-related costs were excluded because of insufficient evidence. We applied the payer perspective, which ignores nonmedical costs such as decreased productivity, lost wages, and other indirect costs associated with comorbid conditions. We incorporated medical costs associated with treatment and with the lifelong treatment of obesity-related diseases such as coronary heart disease, stroke, type 2 diabetes, hypercholesterolemia, and hypertension. Some obesity-related diseases such as cancer and musculoskeletal conditions were also excluded from our analysis, as were nonobesity-related medical costs incurred by increased longevity and the effects of weight loss on conception and childbirth. Beyond patient outcomes, we dis-

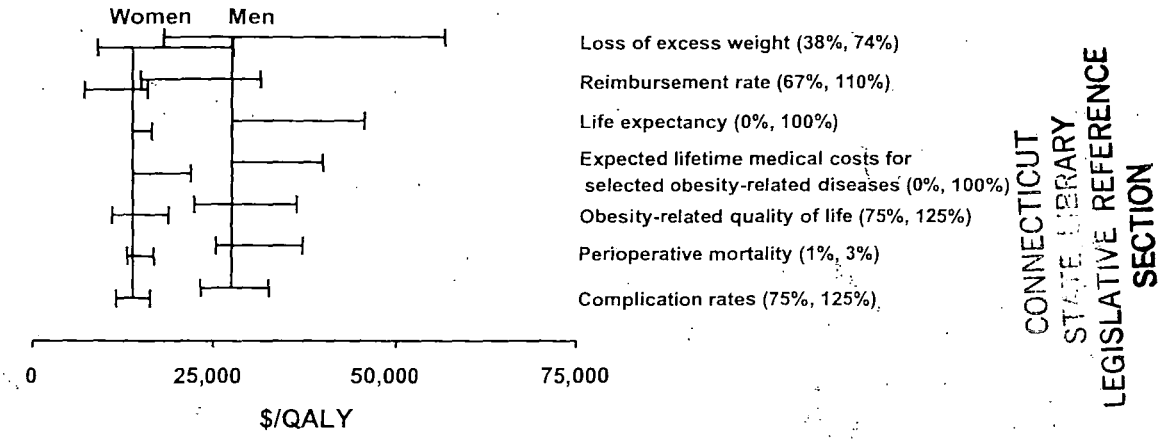

Figure 3. One-way analysis of 45-year-old men and women with body mass index of 40 kg/m^2. For all parameters, we conducted a bidirectional analysis, except for life expectancy and expected lifetime medical costs. Gains in life expectancy and savings of expected lifetime medical costs were potentially less because of residual effects. Obesity-related quality of life refers to the obesity parameters in the regression analysis. QALY = quality-adjusted life-year.

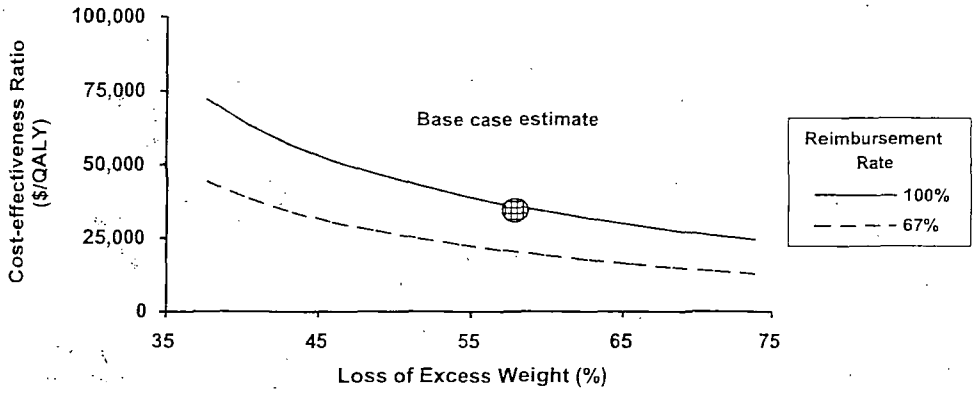

Figure 4. Two-way analysis of 55-year-old men with body mass index of 40 kg/m^2. QALY = quality-adjusted life-year.

regarded the effects of treatment on family members and the community. The inclusion of these factors would likely have strengthened the importance of weight loss and increased the cost-effectiveness of gastric bypass.

In our model, the effectiveness of gastric bypass to induce weight loss was based on published results estimated using case series. Patient selection bias and potential publication bias may have inflated the loss of excess weight estimate. In response, we chose a conservative base case estimate from the literature (17) and applied a much-reduced loss of excess weight estimate in the sensitivity analysis. We also assumed that those who had lost weight had the same quality of life as did those who had always been at that lower weight, even though some have reported that quality of life after weight loss surpassed that of the general population (28,29).

In conclusion, gastric bypass is a cost-effective alternative to no treatment of severe obesity from the payer perspective. However, bariatric surgery is often considered a cosmetic procedure by health maintenance organizations. We recognize that the decision to undergo bariatric surgery must be individualized because of the associated risks, and patients should understand the long-term commitment that the treatment entails. Given the numerous health consequences of severe obesity and its increasing prevalence, gastric bypass has the potential to improve health dramatically and at a reasonable cost.

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Bariatric Surgery: Shedding the Monetary Weight of Prescription Costs in the Managed Care Arena

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Background: Prescription costs for treatment of co-morbidities associated with morbid obesity is a considerable annual health-care expenditure. This study addressed the effect of Roux-en-Y gastric bypass (RYGBP) on diabetic and anti-hypertensive pharmaceutical utilization and cost savings at our institution.

Methods: Retrospective data from the electronic database of 51 consecutive patients, who underwent RYGBP from March 2001 to May 2002 were studied. Patients had BMI >40 associated with obesity-related diabetes and hypertension. Prescription medications utilized by this cohort were reviewed preoperatively and at 3- and 9-month intervals postoperatively. Significance was analyzed by paired t-test.

Results: Prevalence of diabetes and hypertension was 55.7% (29/53) and 44.3% (24/53) respectively, and 34% (18/53) patients had both co-morbidities. Preoperatively, patients were on an average of 2.44 ± 1.86 medications at a cost of $187.24 ± $237.41 per month. Postoperatively, the mean number of medications was reduced to 0.56 ± 0.81 agents ($P<0.001$) at a monthly cost of $42.53 ± 116.60 ($P<0.001$).

Conclusions: RYGBP can decrease the prescription medication requirements, resulting in significant cost-savings in the treatment of obesity-related hypertension and diabetes. This study found a 77.3% reduction in total cost of diabetic and anti-hypertensive medications.

Key words: Morbid obesity, bariatric surgery, gastric bypass, costs, medications, diabetes, hypertension

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Introduction

Obesity continues to be one of the most significant medical problems in the United States. From 2000 to 2001, the prevalence of obesity in the U.S.A. increased by 5.6%, with an overall prevalence of 20.9%.[1] Prescription costs related to obesity and its co-morbidities are a significant burden to patients and the health-care system.

Over the past several years, prescription drug expenditures have accounted for >15% of annual health-care spending[2-5] and account for nearly 10% of the total health-care expenditure in the U.S.A.[6] Obese individuals younger than 65 years had 36% higher expenditure for medications than those of normal weight.[7] Per capita annual medical spending for obesity has increased by an estimated 37.4% ($732). Increases were 26.1% ($125) for out-of-pocket expenses, 36.8% ($1486) for Medicare and 39.1% ($864) for Medicaid patients. The U.S. adult population as a whole had only a 5.3% increase in medical spending during the same period.[8]

Morbid obesity has been strongly associated with diabetes, hypertension, and early mortality.[1,9-13] The Swedish obesity study reported a baseline incidence of diabetes of 15% in the obese individuals.[8] Sixty-nine percent of patients with type II diabetes were cured following gastric bypass and subsequent weight loss, and only 0.5% of those who did not have diabetes at baseline developed the disorder. In comparison, obese subjects who did not lose weight had a much lower cure-rate (16%) and an increase in the incidence of type II diabetes (8%).[14]

Higher BMIs are associated with an increased number and cost of medications, primarily for treatment of hypertension, diabetes and congestive heart disease.[15-17] Increased body mass index (BMI) has also been associated with decreased utilization of preventive health-care services among women, thereby increasing their exposure to the co-morbidities associated with obesity[18] and indirectly contributing to higher health-care costs.

Various studies have reported that weight loss in obese individuals improves their health status and also reduces the costs involved in the treatment of the co-morbidities such as diabetes and hypertension.[19-21]

The authors designed a study to evaluate the impact of Roux-en-Y gastric bypass (RYGBP) on specifically diabetic and anti-hypertensive pharmaceutical utilization and costs at our institution.

Methods and Materials

Patients were prospectively entered into an electronic database upon enrollment at the Geisinger Center for Nutrition and Weight Management. This study retrospectively analyzed data on 51 consecutive patients from this program who underwent either open or laparoscopic distal RYGBP (alimentary or Roux limb >100 cm).

All patients in the study underwent 6 months of evaluation and treatment at our Center. The Center provides comprehensive evaluation by the medical director, a psychologist, a bariatric surgeon, nutritionists, and nurse specialists. Medical treatment of all obesity-related co-morbidities was optimized. Patients who completed the program were referred for RYGBP surgery if their BMI was >40 with an associated co-morbidity or if their BMI was >45 alone. Both open and laparoscopic approaches were used to create a 30-cc gastric pouch and a malabsorptive jejunal limb of at least 100 cm. Patients with diabetes and hypertension or both were considered for the study.

Following RYGBP, patients were evaluated every 3 months for 1 year and every 6 months thereafter. Postoperative evaluation included clinical examination, record of postoperative weight loss, prescription medications for co-morbidities, and laboratory investigations to identify and manage any nutritional or other abnormalities related to the bariatric surgery.

The number and average cost for diabetic and anti-hypertensive medications was tabulated preoperatively and at 9 months postoperatively. Diabetic patients who were prescribed angiotensin-converting enzyme (ACE) inhibitors for their renal protective effects were included in the hypertensive group irrespective of blood pressure. Prescription costs were referenced individually, based on average national wholesale pricing.[22]

The cost to the medical center of providing RYGBP was calculated. The hospital costs included all laboratory, materials and hospital-based services utilized by the patients during their surgical hospitalization. The clinician costs include the costs to the clinic of physician-providers including the surgeon. All clinicians are health-system employees, enabling us to capture 100% of these costs. These values reflect the real cost to the medical center and do not represent charges or reimbursement.

Statistical Methods

The means of the number of prescription medications (RxN) consumed and the cost incurred every month (Rx$) were calculated. Comparison between pre- and postoperative follow-up for the number of medications, and the average cost involved in treating diabetes and hypertension, were calculated and compared by paired t-test.

Results

The study enrolled 51 consecutive patients who underwent RYGBP with a male:female ratio of 1:2.3 and a mean age of 45 years (range 27 to 63). Surgical complications were seen in 13 patients (25.5%), and there was no 30-day or same-hospitalization mortality (Table 1). Mean length of hospital stay was 3.29 ±1.17 days. Two patients were excluded from length-of-stay data. One patient had severe sleep apnea and chronic obstructive pulmonary disease (COPD) with a 50-day hospital-stay for recurrent pneumonia and pulmonary rehabilitation. Another patient with an anastomotic leak com-

Table 1. Morbidity and mortality after RYGBP

Complication	RYGBP Open (n=30)	RYGBP Laparoscopic (n=21)
Death	0	0
Respiratory Failure	2	0
Anastomotic Leak	2	1
Bleeding	1	1
Deep Vein Thrombosis	1	0
Obstruction/Internal Hernia	0	2
Wound Infection		
Hospitalized	3	0
Outpatient	10	2
Ventral Hernia	4	0

plicated by acute respiratory distress syndrome (ARDS) had a 136-day hospital-stay.

All patients were included in the analysis of pharmaceutical costs. Both diabetes and hypertension were present in 34% of patients, with diabetes alone in 55.7% (29 out of 53) and hypertension alone in 44.3% (24 out of 53) of the patients. Diabetes and hypertension had resolved or improved in 92% (n=47) and 78% (n=40) of patients respectively at 9 months after RYGBP.

Patients initially utilized a total of 2.44 ±1.86 medications at a monthly cost of $187.24 ± $237.41 (Table 2). Postoperatively, the mean number of medications was reduced to 0.56 ± 0.81 agents ($P<0.001$), with a monthly cost of $42.53 ± 116.60 ($P<0.001$) (Figure 1).

Analysis of the diabetic medication usage revealed a preoperative monthly mean use of 1.12 ± 1.15 agents, costing $136.89 ± $206.60. After RYGBP, the medication number and cost fell to 0.12 ± 0.48 ($P<0.001$) and $26.58 ± $107.05 ($P<0.001$), respectively. Similarly, there was a decline in the anti-hypertensive agents used from 1.32±1.25 to 0.44 ± 0.64 ($P<0.001$), associated with a cost reduction from $50.35 ± $59.91 to $15.97 ± $24.56 ($P<0.001$) (Figure 2).

The mean cost of RYGBP to the medical center was $14,676 ± 5,299 per patient. Hospital costs included all hospital-based services and materials, and were $10,508 ± 3,704 per patient. Clinician costs were $4,168 ± 1,595 per patient. These include any physician expenses related to the surgery, procedures or consultations for this group of patients. The cost to the medical center to provide the surgeon's service to perform the procedure was $2,340 ± 1031, which represents 56% of the total clinician costs (Figure 3). This data excludes the two outlying patients. The patient with a 50-day hospital-stay had a hospital cost of $112,151 and a total clinician cost of $23, 240. The other had a hospital stay of 105 days, with hospital costs of $284,534 and total clinician costs of $49,322.

Discussion

Numerous studies have documented substantial savings in prescription medication costs following weight loss by drugs,[23] diet[20] and RYGBP.[24] This study demonstrates that RYGB results in significant pharmaceutical cost-savings for both obesity-related diabetes and hypertension. For diabetic treatment, there was an average reduction in the monthly pharmaceutical expenditure of $109 and for the treatment of hypertension costs were reduced by $34 per month. This results in a total monthly saving of $144. Monk et al[25] recently reported a pharmaceutical cost-saving of $182 per month for all medications after RYGBP. Resolution or improvement of both diabetes and hypertension in our series was similar to other series.

Table 2. Reduction in number and cost of medications

	RxN		Rx$	
	Preoperative	Postoperative	Preoperative	Postoperative
Diabetes	1.12 ± 1.15	0.12± 0.48*	$136.9 ±$206.6	$26.6± $107.1*
Hypertension	1.32 ± 1.25	0.44 ±0.64*	$50.4 ± $59.91	$15.97 ± $24.6*

*($P<0.001$); RxN = number of medications; Rx$ = prescription costs (±SE)

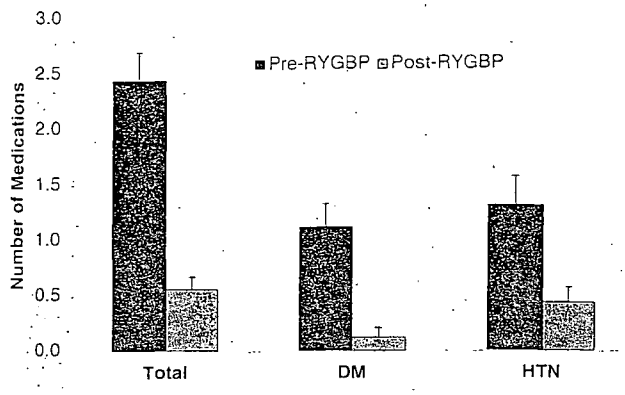

Figure 1. Number of medications (with standard error, SE). DM= diabetes type II, HTN = hypertension.

We reviewed all costs of the procedure to the medical center independent of charges or reimbursement. Hospital costs related to the RYGBP were about $14,700 per patient, with success and complication rates similar to other large series.[26]

Overall cost-effectiveness analysis of health-care interventions is complex and beyond the objectives of this study. However, our results can help piece together the overall cost-effectiveness of gastric bypass surgery. Craig et al[24] studied morbidly obese patients with no co-morbidities and concluded that gastric bypass was not cost-saving from the payer perspective, but was cost-effective compared with no treatment at all.

The cost-effectiveness of gastric bypass versus no treatment demonstrated base case cost-effectiveness ratios from $5,000 to $16,100 versus $10,000 to $35,600 per quality-adjusted life-year (QALY).[24] Similarly, Clegl et al[27] found gastric bypass surgery to be cost-effective compared with nonsurgical

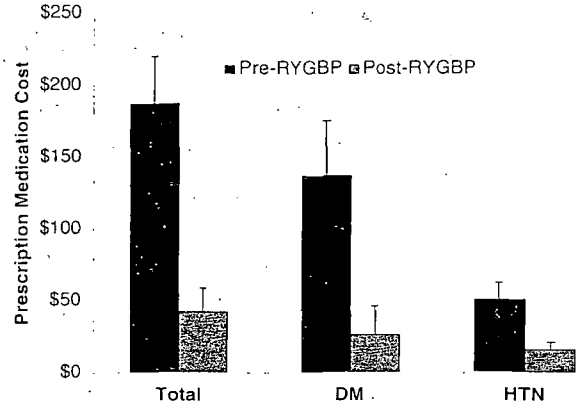

Figure 2. Prescription medication costs (± SE).

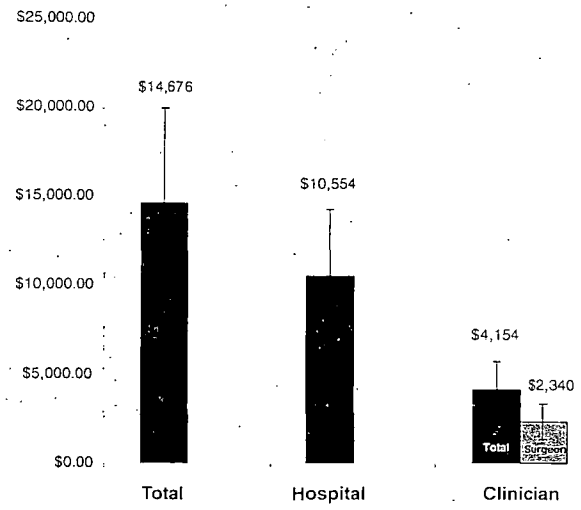

Figure 3. Cost of RYGBP (with SE).

management at about $19,500 per QALY. Comparing the long-term costs and outcomes of gastric bypass versus medical therapy (very low-calorie diet plus weekly behavioral modification therapy) for obese patients has found that surgical treatment was more cost-effective in reducing and maintaining weight loss at 5-year follow-up.[28]

Patients in this study had an annualized pharmaceutical savings of $1,736. The mean age of our patients was 45; therefore, the real saving in prescription costs over 30 years for diabetes and hypertension alone is about $52,080. These savings are independent of QALY, progression of disease and subsequent obesity-related co-morbidities, and compare favorably to the $14,700 mean cost of RYGBP.

This study demonstrates a significant reduction in number of medications and cost of medications for the treatment of obesity-related diabetes and hypertension after RYGBP. Patients studied represent those with optimal management of the obesity and obesity-related co-morbidities preoperatively, and all patients were included in the study end-points. Surgical costs were as high as $333,856 in a patient with more severe medical problems and significant surgical complications. However, this study population represents our initial experience with the RYGBP at Geisinger Medical Center.

Even at a relatively short follow-up, this retrospective pilot study found that the pharmaceutical

cost-savings are significant and compare favorably to the cost of RYGBP. We have performed more than 500 RYGBPs in the Center for Nutrition and Weight Management, and more than 96% of the patients have completed our preoperative program. We are in the processes of a review of all our patients to date with a more detailed cost-analysis and longer follow-up of more extensive obesity-related co-morbidities[9,29,30] and surgical complications.

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Cost-benefit Analysis for the Treatment of Severe Obesity

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Abstract. Cost-benefit and cost-effectiveness analyses (CEAs) are only now beginning to be used by business, government, and policymakers to evaluate various medical treatments. The evolution of why CEAs are being demanded is reviewed. To date, a formal CEA of obesity treatments has not been published. This article outlines how a CEA is performed, reviews data relevant to setting up a formal CEA of medical and surgical obesity treatments, and lists published reports that demonstrate the effectiveness of surgical obesity treatments. The general level of discrimination that society allows the obese to suffer also allows medical insurance companies, businesses, and government to not provide many obese Americans with obesity treatments that have established a level of effectiveness far surpassing many other forms of medical therapy. CEAs of obesity treatments, by themselves, cannot be expected to reverse this discrimination. This type of data, however, provides individual obese patients and their physicians with evidence to challenge policymakers' decisions, especially when cost-effective obesity treatments are excluded or placed at a lower priority than treatments with less proven effectiveness.

The cost of health care in most countries continues to rise faster than the rate of inflation largely because the public is demanding and obtaining an ever-increasing volume and intensity of medical services [1, 2]. Increases in health care costs have led the groups that pay these costs (the payers), usually governments and businesses, to develop a number of strategies to control the costs. Surgically related services account for approximately one-third of the costs of the United States (U.S.) Medicare and Medicaid programs [1]. This causes surgical therapies to undergo more intensive examination than less expensive therapies or services. The payers have attempted to reduce the cost of surgical therapies by demanding second opinions before agreeing to pay for a procedure, reducing referrals in managed care settings by increasing incentives to primary care physicians who do not recommend surgical therapies, limiting the number of surgeons on panels of approved physicians, or refusing to reimburse surgeons for a wide array of procedures that the payers themselves decide are ineffective, investigational, experimental, or otherwise inappropriate and therefore are noncovered services [1, 3, 4].

Unfortunately, a large portion of what constitutes "standard" medical practice is not firmly based on scientific evidence but has instead evolved empirically from trial and error scenarios. Medical insurance companies would like to reduce costs by eliminating reimbursement for many procedures not considered "evidence based" treatments. The U.S. federal government has been a leader in the drive to establish the relative merits of various treatments, attempting to develop means to determine medical effectiveness [2, 5]. A large part of this effort, however, is directed at determining what medical services are unnecessary or inappropriate so reimbursement can be denied. Studies showing variability among the rates of use of certain surgical procedures by different medical communities have driven these efforts [6, 7]. Brook et al. [8] stated that "perhaps one fourth of hospital days, one fourth of procedures, and two fifths of medications could be done without." Phelps [9] has argued that "flawed estimates of the rates of inappropriate treatment may account for these findings" because often the appropriate rate for initiating a treatment has not been determined. Variability among regions for the use of procedures such as prostatectomy or carotid endarterectomy [6, 7] "cannot substitute for careful analysis of the actual effectiveness of medical treatment" [9]. Phelps and his associates [9–11] have pointed out that the payers would save enormous sums of money if they would agree to fund studies on the effectiveness of medical treatments that attempt to control for poor specificity, a major concern for physicians where appropriate interventions are labeled inappropriate, and poor sensitivity, a major problem for patients and payers where treatments are considered appropriate when in fact they are inappropriate.

Regardless of whether the U.S. federal government and other payers decide to spend money to determine which medical treatments are effective and which are not, specialty areas of medicine are beginning to understand that the total dollars to be spent on medical care are limited. This means, increasingly, that physicians and their patients will be fighting over how these dollars will be spent. Bariatric surgeons believe that they provide an effective medical therapy that prolongs life and decreases co-morbidities [12]. Yet bariatric operations are less frequently reimbursed by the payers than many other therapies that have far less evidence demonstrating their medical effectiveness. Physician groups will be fighting among themselves to keep reimbursement rates for their specialist services as high as possible. Bariatric surgeons are already at the back of the pack for what looks to

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a competitive race to receive fair reimbursement for effective medical services.

This article outlines why the U.S. government is attempting to use cost-effectiveness analyses (CEAs) to help define what constitutes appropriate medical care. It then reviews studies that suggest that surgical therapy of morbid obesity meets guidelines as a medically effective treatment, especially if formally evaluated. Even before such studies are available, patients and their legal representation can use available information to demand medical treatment for the problem of morbid obesity and its co-morbid conditions. Finally, all physicians should be encouraged to participate in debates that will decide how our health care dollars will be spent during our lifetimes. As the debate becomes more contentious, it is important to find criteria on which society can base these important decisions. Hopefully, data-based criteria will be used.

State and Federal Insurance Laws

Most state governments in the United States do not attempt to mandate health care coverage benefits legislatively for their citizens because medical treatments are considered a constantly shifting area of expertise. Businesses also generally resist governmental regulations regarding health care coverage, viewing them in general as restrictive, mandating added expenses whenever compliance has to be demonstrated, and a source of litigation to interrupt the meaning and determine whether compliance has been achieved.

Recent decisions by certain managed care companies to limit benefits severely, such as "drive-through" births, which limits hospitalization benefits to under 24 hours for uncomplicated births, and outpatient mastectomies are changing these legislative attitudes [3, 4, 13]. Companies remind employees that health care coverage is a voluntary benefit extended to employees, not a right of employment.

Federal and state governments regulate their Medicaid and Medicare health programs by determining how they will reimburse physicians and other health care providers for interventions based on procedure codes (current procedural terminology, or CPT) [14]. These procedure codes are a list of medical, surgical, and diagnostic services converted to five-digit numbers that form an agreed-upon nomenclature for administrative purposes. The list was initially collected by the American Medical Association (AMA) and first published in 1966 but regularly is reviewed and updated with input from the AMA member organizations plus government, insurance, and hospital associations. The list is copyrighted as intellectual property and is in its fourth edition [14].

A specific five-digit identifying code number for a medical service generally indicates a contemporary, identifiable, medical practice that has been supported for inclusion by an AMA member organization. Each revision eliminates codes and produces new codes. Inclusion in the list does not represent endorsement by the AMA or guarantee reimbursement. Medicaid and Medicare programs choose the CPT codes for which they will provide reimbursement, and these choices are often not identical for the two programs, as Medicare has national guidelines to follow whereas Medicaid is administered under individual choices made by each state.

The procedure codes have also recently been scrutinized extensively to place relative values for the amount of work (time), skill (training), and malpractice risk required to perform each activity in an attempt to ensure that physicians are reimbursed fairly across different specialties for the services they perform [15]. The units of work are listed on the Relative Value Scale. Assignment of charges for these services directly pits the various specialities against one another as each vies to obtain the maximal amount of reimbursement for their activities while the government attempts to change reimbursement levels for various codes (both up and down) without changing the yearly amount paid for physician services.

The U.S. government's tracking system for the Medicaid and Medicare programs registers how much the Health Care Financing Agency pays per procedure code, which allows it to analyze trends especially in surgical therapies. The government does not want any type of surgical therapy to increase in volume without attempting to determine why it has occurred and whether the trend can be reversed or slowed. Common surgical procedures, such as coronary bypass grafts, cholecystectomy, cataract removal, and gastric bypass, draw attention as areas where costs could be reduced by limiting these procedures or decreasing reimbursement rates [5].

The Medicare and Medicaid programs provide reimbursement only for medical services for patients who have an identifiable medical problem (i.e., a history and physical examination performed to exclude the presence of serious diseases is rarely reimbursed). Since April 1, 1989 the U.S. Health Care Financing Agency (HCFA) has required all physicians billing for services provided to Medicare beneficiaries to include diagnoses using codes established by the World Health Organization's (WHO) ninth revision of its International Classification of Diseases (ICD-9), which was published in January 1979 [16]. This practice was established by the Medicare Catastrophic Coverage Act of 1988.

During the 1950s various hospitals led by the Veterans Administration hospitals began using the eighth edition of the International Classification of Diseases (ICD-8) for hospital indexing purposes. The American Hospital Association and the American Medical Record Association both studied the relative efficiencies of various coding systems for diagnostic indexing during the 1950s, leading to revisions in ICD-8 first published in December 1959. During the 1960s and early 1970s the Commission on Professional and Hospital Activities of Ann Arbor, MI, the American Hospital Association, and the U.S. Public Health Service all made modifications in the ICD-9, attempting to make it easier for hospitals to use [16]. Clinical organizations (including the American College of Surgeons), hospital organizations, and government all had input between 1977 and 1978 that was incorporated into the ICD-9 Clinical Modification (CM), which was accepted as the single classification system for the United States in 1979. The WHO has now published the ICD-10 (1993), which includes 5500 more codes than the ICD-9 [16]. The ICD-10 is already being used in some European countries, and its implementation in the United States is expected after the year 2000. Clinicians continue to contribute to these efforts because of their importance for reimbursement policies.

Physicians who treat obese patients, especially those who limit their practice to bariatrics, have numerous problems obtaining fair reimbursement for their services related to these tracking systems for procedures and diseases. First, obesity is classified in the ICD-9-CM and ICD-10 as a variety of diagnoses that do not

reflect current scientific knowledge [17]. These disease classifications distinguish endogenous obesity, interpreted as the result of bad habits or overfeeding, from endogenous obesity, considered a genetic or endocrine condition (e.g., Cushing's disease) [16]. Many medical insurance programs refuse to provide payment for treatment of obesity unless it can be documented that it is the result of adrenal, thyroid, or pituitary dysfunction. Even leading state health officials include the obese in the category of individuals with illnesses associated with life style. In 1997 the Louisiana Secretary of the Department of Health and Hospitals listed the obese with smokers, sufferers of sport injuries, alcoholics, drug addicts, and those who participate in unprotected sex in an article discussing ways society would have the citizens pay the increased health care costs associated with risky life style choices [18].

New knowledge relating obesity to specific genetic abnormalities identified in rodents and humans not associated with these endocrine organ dysfunctions and life style choices may need another decade or two to be incorporated into the disease classification system [17]. Meanwhile bariatric physicians and their patients are left to argue with medical reimbursement systems, which by refusing to classify endogenous obesity as a true disease feel justified in denying reimbursement because it would be an invalid use of medical services. Recent evidence demonstrating that surgery reduces the risk of death for diabetics who are also morbidly obese compared to those who are denied this benefit by their insurance company over a 5- to 10-year period is ignored [19].

Most physicians therefore are careful to list one of obesity's co-morbid conditions as the reason for providing medical service to obese patients, although this practice does not guarantee reimbursement. The Louisiana Medicaid program's attempts to pay only for treatments that are effective has eliminated all physicians from being reimbursed for any service provided to patients where a diagnosis of endogenous obesity (ICD-9-CM codes, 278.00 or 278.01) is listed even if it is not the primary diagnosis (personal communication, Larry Hebert, Medicare Director, Louisiana Medicaid Program, June 1996). This was the result of a Medicaid patient winning an appeal to be reimbursed for a 4-week in-hospital, low-calorie-diet program with psychiatric support during the 1980s. This type of program has been widely discredited because patients regain the weight they lose once released from the hospital [12, 17].

The state's legal counsel advised the Medicaid Program that if they wanted to avoid being charged for ineffective obesity treatments the program's reimbursement computer software should be designed to deny payment for any CPT code which listed endogenous obesity (ICD-9-CM codes 278.00 or 278.01) as one of the three diagnoses that can be listed in the reimbursement request form. This extreme measure eliminates a cardiovascular surgeon from being reimbursed for performing coronary artery bypass grafting if obesity is listed with coronary artery disease, a fact Mr. Jindal, the Secretary of Health and Hospitals did not appreciate when he recently suggested it would be wrong to deny "heart surgery to the obese" [18].

The Louisiana Medicaid program states, however, that this policy is fair because obesity is rarely listed as a diagnosis, and denial is spread fairly among most physicians (B. Jindal, personal communication). When a physician group limits its practice to bariatrics, however, this policy no longer remains fair. The Medicaid program states that it is willing to modify its computer software to allow a specific physician to be able to bill for specific CPT codes to treat obesity if that physician can produce data demonstrating in Medicaid patients that their treatment for obesity is effective long term. Producing this type of medical effectiveness data to guarantee reimbursement will become more common as medical insurance companies demand proof of effectiveness before paying for controversial treatments or for diseases where treatment failures are common.

The key to obtaining reimbursement for bariatric treatments is to show which of these treatments is cost-effective, under what conditions the treatments are cost-effective, and to help the payers develop reimbursement schemes that can guarantee that they will have to pay only for treatments that have a high chance of success. Bariatric treatments must undergo a standardized, cost-effectiveness analysis for this scenario to begin.

A related but independent issue that was the focus of Jindal's article [18] is whether taxes on specific activities should be used as supplemental insurance premiums to help states pay health care costs associated with citizens whose behaviors or life styles result in them needing state-supported health care services some day. Several health care personnel have advocated taxes on alcohol, ammunition, motorcycles, cigarettes, hang gliders, and so on that would be used to defray state health care costs and potentially decrease the use of such activities as a means of saving society money [18–20]. Others, including ourselves, have suggested using a tax on the percentage of fat in all foods as another type of tax [21]. Taxes dependent on usage are more ethical than denying people with an underlying biologic defect health care benefits as a means for society to decrease shared public expenses. Regarding the financing of health care, bariatric physicians and hopefully most other physicians would like to see separation of the issue of the effectiveness of various treatments from the underlying causes of diseases as a criterion for reimbursement. This would include whether a medical disability is the result of underlying genetic defects or inappropriate life style, which in many cases such as obesity, alcoholism, and drug addiction, the scientific evidence is incomplete [17, 22].

Cost-benefit and Cost-effective Analyses

Beginning in the early 1970s the federal government began attempting to apply cost-benefit analysis (CBA) techniques to health care issues [5, 23] to estimate medical effectiveness and costs. Despite more than 20 years of evolution, Weinstein and Stason's statement from an initial review article in 1977 [24] still applies: "the available database on the effectiveness of most clinical procedures is distressly limited."

In general, the effectiveness of medical therapies are assessed in terms of length and quality of life. CEA is more applicable to medical treatments than CBA because a CBA demands that all outcomes be valued in economic (e.g., dollar) terms, whereas CEA examines the relative expenditures of different treatment options using number of life-years saved without requiring that a specific dollar value be placed on each year of life. Arguments over how lives should be valued [25] (attaching a dollar value to human life) has limited the use of the CBA. Any change in such an estimate affects the outcome, and standards have been impossible to establish in our argumentative society. This article focuses on CEAs to eliminate the need to review these value judgments.

Although the methods for producing a CEA were well de-

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scribed in the medical literature by the late 1970s [24], reviews of the medical literature through the last of the 1980s show that few articles claiming to have conducted a CEA or CBA met even minimum analytic principles for performing such an economic analysis [26]. This lack of rigor and the lack of standards by which medical journal editorial boards could judge these articles were a major concern to the U.S. government, especially the HCFA, which hoped to use CEAs to establish reimbursement policies for its Medicare and Medicaid programs. These concerns led in 1993 to the U.S. Public Health Service recruiting 13 nongovernmental scientists and economists with expertise in CEA to convene a panel on cost-effectiveness in health and medicine. The panel published their recommendations for standardizing CEAs in 1996 [27] and summarized their book in three consensus statements published in the *Journal of the American Medical Association* that same year [28–30].

These recommendations or standards can be summarized into four major principles, and the framework for how to report a CEA in the medical literature is summarized in a table presented by Siegel et al. [30]. (Others have chosen to summarize standards into six [26] or eight [29] categories.) First, all analyses of event or treatment pathways must be presented from a societal perspective using a "reference case" to describe what is included in the analysis. Therefore the treatment pathway of a morbidly obese patient undergoing gastric bypass must consider what would happen to this patient without surgery, including the additional use of anorectic medications, psychotherapy, dietary advice, and so on, to patients who choose surgery and those who do not. The cost of complications from each of these treatments must be included, as must the current and future treatment of co-morbid medical conditions associated with obesity. A CEA had always required an explicit statement of a perspective from which the analysis arose (i.e., hospital, Medicare program, patient). These recommendations discourage the use of limiting the prospective to a specific group, such as hospital costs or private insurance costs. This recommendation allows all CEAs to be comparable because the analyses would be conducted from one perspective: the cost to our society of these interventions.

An important issue when measuring the benefits of a treatment is whether patient preferences for quality improvement in life due to the elimination of a disease are used or preferences of a representative community sample are used [27, 28]. The panel recognized that community preferences can discriminate against people who are disabled or ill. Issues of discrimination, including discrimination against the obese, were raised when Oregon used community preferences to decide which diseases were to be treated by their Medicaid program [27, 28]. The panel still chose to endorse the community as the source of preferences for the reference case but encouraged the use of sensitivity analyses (explained below) to determine if there were important differences in preferences between a diseased population and the community that would affect the CEA [31, 32]. The panel emphasized that CEAs are presented to policymakers not as a *fait accompli* but as a tool to be used with criteria such as expected benefit, standards of evidence and the issues of fairness, help for those worst off, and the feasibility to arrive at decisions on priority of treatments.

The second major area the panel clarified was what was to be placed in each part of the C/E ratio [27, 29]. It has been especially important to adhere to the accounting principle that no cost should be counted twice and that no health effect, even in monetary form, could be included in the numerator. Costs for each treatment are measured in dollars. This includes all direct medical costs [24, 27, 30] including hospitalizations, physician time, medications, laboratory and other ancillary services, costs associated with the adverse side effects of treatment, and costs of treating diseases that would not have occurred if the patient had not lived longer as a result of the original treatment. Costs associated with diseases a treatment prevents are subtracted from these costs.

Additionally, costs of patient time expended for the treatment must be included and the costs associated with care given by the family or others. These costs are included regardless of whether the patient and the other caregivers are paid or unpaid, so all "disability or leave" time is accounted for [27, 29]. These costs are priced out using only age and gender as variables. Child care, travel expenses, and economic costs borne by employers or other employees and the rest of society are also included in costs. These include disability insurance payments, "friction costs" such as those associated with absenteeism and employee turnover [27, 29], and non-health-care costs that result from the intervention, such as educational costs, legal/criminal costs, and environmental costs.

Importantly, the panel forbid the inclusion of transfer payments (i.e., cash transfers from taxpayers to welfare recipients), stating that this was a redistribution of resources from one individual to another, not a cost to society [29]. Administrator costs secondary to the transfer are included; but because the impact from the societal perspective (the wealthy lose money while the poor gain it) is an exact cancellation, these funds are not a cost. They would become an issue only if a treatment prolonged life so productivity and consumption were extended or if there was a switch in status due to a treatment; that is, someone on welfare (consuming resources) obtained a job and began producing an income and paying taxes.

Medical effectiveness or health benefits are measured in differences in years of life provided by different therapies, termed life-years or now more commonly called quality-adjusted life-years (QALY) [24, 27, 29]. QALYs include measures of quality of life in the extra years provided by a treatment. Therefore the ratio of costs to health benefits in a CEA is measured as cost per QALY saved. Time spent sick is considered morbidity time and is placed in the denominator. Alternative medical treatment (including lack of treatment) can then be ranked using QALYs. Additionally, the measure can be used to prioritize which diseases will be treated with available resources or to what degree a disease will be treated. Stason and Weinstein [33] provided an initial example of a CEA by pricing out the cost of treating hypertension at different diastolic blood pressures, which helped shape the recommendations for the diastolic value at which consensus panels recommended treatment should be initiated.

A medical CEA asks the patients, rather than their physicians, to place values on different treatments. Nonsurgeons are a risk-adverse lot, in general, so patient groups often place vastly different values on eliminating certain symptoms or societal reactions. Surgeons, on the other hand, can place more value on anatomic correction of a problem but fail to understand that patients are more concerned about symptomatic improvement than anatomic improvements.

The QALYs are calculated by asking patients to weight subjec-

tively the quality of time they still wish to live by answering the following question: "Taking into account your age, pain and suffering, immobility, and lost earnings, what fraction, P, of a year would you be willing to give up to be completely healthy for the remaining fraction of year instead of your present level of health status for the full year?" [24]. The probability of death as the result of a treatment can be used rather than the symptom-free interval. The ability of the patient to evaluate an intervention such as cataract removal, which may improve quality of life but have almost no impact (positive or negative) on length of life, versus congestive heart failure, where the immediate risk of death to reopen a blocked coronary artery using angioplasty is twice that of surgical revascularization using grafts but has almost no periprocedural pain, is limited [5].

To classify how disabling obese patients believe their disease is to them, scales such as the Health Utilities Index [34–37], Quality of Well-Being Scale [38], or EuroQol [39], each of which includes premeasured preferences for defined health states, must be collected for patients whose body mass index (a measure of their obesity) and co-morbid conditions is known. Russell et al. [28] explained that "these premeasured values come in part from direct measurement of some preferences (using standard gamble, time trade-off, or category rating) and in part from application to those preferences of multiattribute utility theory or statistical inference to fill in values not measured directly." Premeasured values have been determined for each of these health classification systems by questioning large, random samples from various communities. Whether these community standards are similar to the preferences of the obese still must be determined. This concept of allowing different individuals with different diseases to assign different weights to how they value their lives is an important concept in our democratic society but obviously complicates the analysis when the alternative is to just measure a change in life expectancy.

A third major problem complicating CEAs is that neither the costs nor the benefits of different medical treatments occur at the same time. Surgical treatment of obesity may cost $25,000 this week, which makes each pound lost over the next 5 years more expensive than the corresponding medical treatment [40]. Medical treatment failures, which approach 100% at 6 years [17, 40], lead to more joint replacements being performed in 10 to 20 years. If the treatment dollars saved today by not performing a surgical treatment for obesity are wisely invested, enough money may be saved to pay for two joint replacements but probably not for four joint replacements.

Arguments abound regarding how much future costs should be discontinued because when a discount rate is used we assume that the rate of annual return on these invested dollars can be accurately predicted. Policymakers also assume that medical therapies will constantly improve, allowing them to predict that the costs to save a QALY 10 years from today will be less expensive than it is today [24, 27]. Not all of us agree with these assumptions. The panel recommended that costs and health care outcomes during different time periods be discounted to their present value, and that this rate always be a real, 3% discount rate in the reference case [27, 29]. Before discounting, all costs should be adjusted for inflation.

The fourth major principle is that all CEAs are based on certain estimates and that the quality of the underlying data varies widely because the prediction of health benefits from our various medical therapies are not based on a large enough database to be accurate [24, 27]. CEAs are not that accurate, and a great deal of uncertainty is associated with their use. Sensitivity analysis, variations over a range of each of the uncertain features in a CEA help determine how confident one can be in the conclusions drawn from it. If varying many of the estimates individually do not change the overall conclusions of the CEA, one can be more certain of the CEA [24, 27, 29]. For important parameters, multivariate sensitivity analyses should also be conducted. These analyses should test alternative data and assumptions.

Finally, the panel discouraged any report from labeling a specific treatment or intervention cost-effective [27, 30]. Rather, they suggested describing each intervention as being more or less cost-effective than others.

How Effective Are Obesity Treatments?

The effectiveness of obesity treatments have been extensively reviewed [12, 17, 21, 40], and many aspects of these treatments have been updated in this issue of the *World Journal of Surgery*. Americans and most other industrialized nations are seeing a rapid rise in the percentage of their population that the health care community is labeling obese. More worrisome, children in industrialized nations are becoming more obese as high-fat, inexpensive food becomes readily available in "drive-through" restaurants and childrens' daily energy expenditures decrease. These facts suggest an ever-increasing crisis, as obesity-related medical care costs already consume at least 5.5% of U.S. health care dollars [12]. Obesity is now also considered the second leading cause of death in America. Only tobacco-related costs, estimated between 7.3% and 12.5% of medical expenses [18] and mortality rates [41], are higher.

Several National Institutes of Health (NIH) consensus conferences have endorsed the use of surgical treatments of our most obese citizens as the only effective long-term treatment available [12]. Yet state Medicaid programs and the medical insurance programs covering most U.S. citizens do not routinely pay for surgical obesity treatments. Why? First, the average U.S. citizen currently remains with the same medical insurance company less than three continuous years. Therefore insurance companies have no incentive to attempt comprehensive, long-term care plans because they do not reap the long-term benefits of a carefully planned preventive program today, only its immediate expense.

Yet medical insurance companies pay for other expensive treatments for malignancies, heart disease, and diabetes. Why not obesity treatments? Here, two additional problems emerge. First, no medical treatment of obesity has shown that weight loss remains stable for 5 years even in 10% of those treated [17, 40]. Therefore nonsurgical treatments of obesity are not permanent and may have to be applied again and again without necessarily increasing the chance they will work. Insurance companies are worried that without a true CEA of obesity treatments, if they reimburse for surgical treatments they will also have to reimburse for medical treatments.

Finally, the obese are routinely discriminated against without society noticing [31, 42]. Employers, insurance companies, and even physicians [43] have singled out obesity as a disease for which they blame the patient, and they have not incurred legal consequences from not providing treatment, as they would for not treating sexually transmitted disease or breast cancer. Nor has

obesity received the same media attention. The cost savings are often more important than their individual employee's health, especially if the supply of employees is large enough to easily replace those lost to the ravages of obesity.

Obtaining Surgical Treatment of Obesity for Individual Patients

There is a growing tendency to seek legal redress for discrimination based on obesity. A close examination of the modest number of court opinions dealing with this issue and the times that these decisions have helped the morbidly obese person access treatment have not yet generated much enthusiasm for this approach.

A major problem is that treatment for morbid obesity is often contractually excluded in insurance plans and health service agreements [1]. Patients who examine their coverage are often dissuaded from seeking treatment because of their perception (correct or incorrect) that the exclusion bars insurance reimbursement. Most patients are financially precluded from self-funding bariatric surgery.

Faced with the challenge of overcoming policy language, policyholders and their counsel are further dissuaded from accepting the challenges of such claims because of the absence of meaningful remedial measures available under the current Employee Retirement Income Security Act (ERISA) [3, 4]. This Act is the U.S. federal statutory scheme that generally governs claims for benefits for group health insurance, the mechanism under which most patients are seeking insurance coverage for the surgical treatment of their morbid obesity. ERISA preempts state law insurance remedies, and claimants are limited to obtaining the medical benefits due under the policy and, under certain circumstances, recovery of attorneys' fees. There is no extracontractual recovery (i.e., emotional distress or punitive damage) in the context of an ERISA plan [44].

Few cases have addressed claims for benefits for the surgical treatment of morbid obesity, and these cases do not provide substantial help. In *Exbom v. Central States, Southeast and Southwest Areas Health and Welfare Fund* [45], plaintiff Leilani Exbom was morbidly obese. In addition, she suffered from backache and low self-esteem with indications of depression. Her treating physician recommended gastroplasty. However, her self-insured plan (governed by ERISA) included an exclusion statement that included "surgery for obesity, including gastric bypass, gastric stapling, intestinal bypass, lipectomy, suction lipectomy, and any other surgical procedures, the purpose and result of which is simply to remove adipose" [45]. In the *Exbom* case, the trustees of the self-insured plan denied her claim on the basis of this exclusion after several internal levels of appeal and use of an "outside" medical consultant [1]. The medical consultant choose to label the proposed surgery "experimental in nature" when he conducted his review in 1987 [45]. He also believed that the surgery was "cosmetic" [45]. It was his opinion "the proposed surgery does not cure diseases related to obesity," and therefore the surgery was not medically necessary [45].

In cases under ERISA, the court does not necessarily review whether the medical decision was correct [1] but, rather, whether the plan acted in an arbitrary and capricious manner. In the above cases, because there were multiple levels of review including the use of a medical consultant the court upheld the denial of treatment because the plan did not act arbitrarily. A court does not set aside the denial of a claim if the denial is based on a reasonable interpretation of the relevant plan documents [46] even if the medical opinions are not consistent with current knowledge [1, 12, 17, 19, 21, 22].

A similar result occurred in the case of *Livington v. Central States, Southeast and Southwest Health and Welfare Fund* [47]. The plaintiff, Barbara Livingston, was suffering from bleeding and gastritis that resulted from a torn staple line from a gastrojejunostomy in 1981. In May 1993 her surgeon converted the earlier operation to a vertical banded gastroplasty.

The patient had policy language identical to that in the *Exbom* case. The same medical consultant, a Dr. Buckingham, determined that the surgery was excluded because it was a revision resulting from a complication from a prior noncovered procedure [47]. Once again, the courts focused on the denial *process* and, because there were multiple levels of review utilized by the insurance plan to evaluate the claim and because there was no bad motive or bad faith in the reviewing process, the denial of the procedure was upheld.

As these two cases demonstrate, at least in the context of an ERISA plan, patients often have a considerable hill to climb when attempting to obtain benefits for the surgical treatment of morbid obesity. A natural question is whether statutory schemes other than ERISA may be applied to these claims. Although there are no reported completed court cases analyzing obesity surgery in other contexts, there has been litigation concerning whether morbid obesity is covered under the Americans with Disabilities Act (ADA), Rehabilitation Act, or state antidiscrimination laws. Several health-related cases are now before federal or state judges.

Cook v. Rhode Island [48] was the first federal case to recognize obesity as a protected disability. This case was brought under Section 504 of the Rehabilitation Act of 1973, a precursor to the much more familiar ADA. The definitions of "disability" are essentially identical under the two statues. Bonnie Cook weighed 320 pounds and had worked for the Rhode Island Department of Mental Health, Retardation and Hospitals. After voluntarily leaving her position, she was refused rehiring because her morbid obesity purportedly compromised her ability to evacuate patients in an emergency and put her in at a greater risk of developing serious health problems [49].

Cook's claim proceeded to trial on a "regarded as disabled" theory of liability. Instead of claiming she *was* disabled under the statute but otherwise qualified to do the job (with or without a reasonable accommodation), Cook had to show she did not suffer from a statutorily prescribed physical or mental impairment but that the state *regarded her* as being impaired and substantially limited in one or more of her major life activities. The most important legacy of the *Cook* case is that the court determined that morbid obesity, in certain circumstances, is protected under the Rehabilitation Act. Because the definitions are similar, morbid obesity can be considered a protected disability under the ADA.

As Judge Selya, the author of the *Cook* opinions, stated, "In a society that all too often confuses 'slim' with 'beautiful' or 'good,' morbid obesity can present formidable barriers to employment. Where, as here, the barriers transgress federal law, those who erect and seek to preserve them must suffer the consequences."

Unfortunately, the holding in *Cook* represents a position that is

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not always embraced by other courts. For instance, in *Hazeldine v. Beverage Media, Ltd.* [50] the plaintiff sued for wrongful termination and discrimination under the ADA and the New York State Human Rights Law based on her morbid obesity. The district court dismissed her claim under the ADA, holding that she failed to meet the threshold of establishing "substantial impairment with major life activities." This was despite her testimony that she could not walk long distances, lift heavy objects, or engage in heavy physical exercise due to her weighing almost 300 pounds. The court held that to be a *substantial* limitation under the ADA an individual must be "unable to perform a major life activity that the average person in the general population can perform" or be "significantly restricted as to the condition, manner of duration under which an individual can perform a particular major life activity" compared to the average person [50]. The court held in *Hazeldine* that, although her obesity affected her ability to engage in everyday activities, these did not rise to the level of a "substantial limitation" of the degree or character required to invoke the protection of the ADA [50]. These arguments ignore criteria for disability established by the Social Security Administration of the U.S. Department of Health and Human Services [51].

Arguments can also be advanced utilizing the ADA in the context of employer-provided insurance policies or health maintenance organization (HMO) contracts containing exclusions specifically directed at the condition of "morbid obesity." Title I of the ADA [52] prohibits discrimination on the basis of disability with respect to terms, conditions, and privileges of employment. The ADA prohibits discrimination against individuals with disabilities with regard to fringe benefits provided to employees [53]. In particular, an employer may not participate in a contract or other arrangement, such as an insurance contract, HMO contract, or a third party administration contract, that has the effect of discriminating against individuals with disabilities [54].

The term "disability" includes an individual with "a physical or mental impairment that substantially limits one or more major life activities." Morbid obesity is such a physical impairment because 42 U.S.C. §12102(2) defines the term "impairment" to include "any physiological disorder or condition affecting one or more bodily systems." The interpretive guidelines established by the Equal Employment Opportunity Commission (EEOC), the agency that administers Title I claims under the Act, clearly states that morbid obesity is always considered an impairment: "On the other hand, severe obesity which has been defined as body weight more than 100% over the norm . . . is clearly an impairment . . . "[55].

In June 1993 the EEOC issued interim guidelines describing its interpretation of the ADA restrictions on disability-based classification (the Guidelines) [56]. The Guidelines establish four general principles for analyzing the application of the ADA to employer-provided health insurance. Disability-based distinctions are permitted only if they fall within the risk classification exception to the general principles of nondiscrimination. These general principles include the following. (1) Decisions about employment cannot be motivated by concerns of the impact of the individual's disability on the employer's health insurance plan. (2) Employees with disabilities must be accorded equal access to whatever health insurance the employer provides to employees without disabilities. (3) The employer may not make an employment decision about any person or family member, regardless of whether that person has a disability, because of concerns about the impact on the health insurance plan of the disability of someone else with whom that person has a relationship.

If a plan contains a disability-based distinction, that distinction must qualify under the special risk classification rules or it violates the ADA. Specifically, mental/nervous limits, preexisting condition limits, and universal limits on drugs or procedures are permitted. Limits on specific conditions or on disabilities in general are suspect. For example, exclusions or limitations on coverage for a specific disability (e.g., acquired immunodeficiency syndrome or schizophrenia), a group of disabilities (e.g., cancers), or disability in general are disability-based distinctions.

Independent of any liability the insurer may have under Title I, there are differences in opinions concerning whether Title III of the Act, which governs access to facilities, includes insurance policies. The argument against Title III application is that its provisions are limited to physical access [57]. The countering argument states that "insurance offices" are "places of public accommodation" covered under Title III of the Act. As such, insurance providers are prohibited from discriminating on the basis of disability regarding "the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations" they provide. The Department of Justice, which enforces ADA Title III regulations, has stated that insurance offices are covered as public accommodations and that the prohibition of discrimination applies to "all types of insurance" [58].

The Department of Justice's view of what constitutes discrimination and the terms or conditions of insurance are generally consistent with that of the EEOC. The Department of Justice has declared that insurance providers "may offer a plan that limits certain kinds of coverage based on classification of risk, but may not refuse to insure, or refuse to continue to insure, or limit the amount, extent, or kind of coverage available to an individual, or charge a different rate for the same coverage solely because of a physical or mental impairment, except where the refusal, limitation, or rate differential is based on sound actuarial principles or is related to actual or reasonably anticipated experience" [59].

In summary, the liability of insurers, HMOs, and employers for issuing policies with exclusions specifically aimed at "morbid obesity" is still being resolved and is likely to be the focus of litigation in the future as patient policyholders attempt to enforce their rights to access equal medical treatment as the "normal" weighted population. With the federal government being pressured to change the ERISA sections on health care policies, litigation will likely increase [3, 4]. This point underscores the importance of utilizing CEAs as an approach to justifying surgical intervention for morbid obesity.

While these issues are evolving and until more CEAs are available to compare the costs of treating various diseases, patients and their advocates must learn to use the elements of a CEA to argue for fair treatment for the obese. First, the overall level of disability associated with various levels of obesity must be documented and compared to population norms and that of other disease or disability groups. Recently, the Medical Outcomes Study Short-Form Health Survey (SA-36) [60] has been completed by more than 1000 morbidly obese preoperative surgical candidates and compared to population norms [61]. The obese patients showed statistically poorer scores on all 10 subtests evaluating such aspects of health as physical functioning, social functioning, mental health, and pain than did the population norms. Furthermore, a surgical obesity treatment, gastric banding,

which has been shown to help these patients lose weight (an average 23.7 kg during the first year of treatment) results in significant increases in physical functioning, energy/fatigue, social functioning, general health, pain, and the role limitations due to health scores even within the first year after treatment [62].

Unfortunately, because the SF-36 is not a preference-weighed health status scale, it is not a suitable instrument for conducting a CEA [29]. The Health Utilities Index [34–37], EuroQol [39], Quality of Well-Being Scale [38], or Years of Health Life measure [63] must be given to large numbers of obese patients and compared to community norms to help evaluate the effectiveness of surgical obesity treatments. The fact that obese individuals score significantly lower on the SF-36 but come up to normative values within a year suggest that obesity treatments will show significant changes in QALYs. Other review articles comparing obesity to other disabilities suggest that obese people suffer significant decreases in quality of life due to morbid obesity's co-morbid conditions that are largely reversed by surgical therapy [12, 64, 65, this issue].

The dangers of not undergoing surgical obesity treatments have not been well documented in the morbidly obese. Mortality is suspected to be much higher for the morbidly obese, especially at young ages [66], but this point is documented with a minimum data set. MacDonald and colleagues [19] showed that morbidly obese diabetics have less chance of dying if they undergo surgical treatment, but there are no published data regarding obesity's other co-morbid conditions. This lack of data may not change until the Swedish Obese Subjects (SOS) study reports its initial results. This study has followed 2000 patients who underwent operation and another 12,000 who did not [67]. This report, when published, will allow obesity advocates to ask insurance companies why they specifically deny obese patients life-saving treatment options that also decrease the changes in those developing or continuing-to-be-affected by obesity's co-morbid conditions: hypertension, type II diabetes mellitus, heart disease, respiratory disease, osteoarthritis, and venous stasis. The incidence figures for these events will provide adequate estimates for a CEA in the population studied. Unfortunately, medication treatments of obesity were not studied, and only patients at least 85% over ideal body weight were included in the study. It is also not clear how many surgical approaches are identified separately with enough information on side effects to make accurate estimates for a CEA comparison.

The Swedish population is not directly comparable to the more racially and ethnically diverse population of the United States. Different systems of social support also will confound comparisons. Identifying questions that still need to be studied are an important component of conducting a CEA of obesity treatments in the United States.

Conclusions

Because bariatric surgeons and physicians have encountered difficulty receiving fair reimbursement for their services, they have more incentive than nephrologists, neurosurgeons, transplant surgeons, cardiovascular surgeons, cardiologists, orthopedists, or other specialty groups to conduct a CEA of their obesity treatments than do these other groups. The HCFA has already begun to carefully evaluate treatments for the Medicare population. The HCFA is similarly interested in CEAs for benign prostatic hypertrophy, end-stage renal disease, carotid artery obstruction, and cataracts for the same reasons [5]. Figures will soon be available to begin comparing treatments. All physicians must follow these developments to help their patients receive the best care possible with the money available for policymakers to distribute. Bariatric surgeons and their patients can expect that this information will make it easier to obtain reimbursement for surgical treatment of severe obesity.

Résumé

L'analyse des coûts-bénéfices et du coût-efficacité sont à leur début d'utilisation par des sociétés, des institutions du gouvernement et les hommes de la loi pour évaluer de différents traitements. L'évolution de la demande d'analyse est passée en revue. Jusqu'à présent, cette forme d'évaluation pour les traitements de l'obésité n'a jamais été publiée. Ce travail indique comment la faire, souligne les conditions nécessaires pour réaliser formellement ce travail concernant les traitements médicaux et chirurgicaux de l'obésité et enfin cite les travaux déjà publiés qui démontrent l'efficacité des traitements chirurgicaux de l'obésité. Le niveau général de discrimination que la société permet à l'égard de l'obèse est une des raisons pour lesquelles les traitements chirurgicaux reconnus pour être les plus efficaces (par rapport aux traitements médicaux) ne sont pas accordés aux obèses par des compagnies d'assurance médicale, des sociétés et des instances de santé aux Etats-Unis. Il ne faut pas s'attendre à ce que l'analyse des coûts-bénéfices et du coût-efficacité des traitements de l'obèse change cette discrimination en elle-même. Ce type d'information, cependant, fourni au patient obèse et à son médecin traitant, est nécessaire pour leur permettre de s'opposer aux politiciens surtout lorsque les traitements dont le coût-efficacité ont déjà fait leurs épreuves sont exclus ou placés en deuxième ligne en favorisant les autres traitements dont on connaît l'efficacité moindre.

Resumen

Sólo en época reciente se inició la implementación de los análisis de costo-beneficio y costo-efectividad (ACEs) en la evaluación de los tratamientos médicos en los sectores de los negocios, de los gobiernos y de quienes definen políticas. En el presente artículo se analiza la evolución del por qué hoy existe demanda de ACEs. Hasta la fecha no aparecen publicados ACEs de los tratamientos de la obesidad. También se describe la forma de efectuar ACE, se revisan los datos pertinentes al establecimiento de ACE de los métodos médicos y quirúrgicos en el tratamiento de la obesidad y se enumeran las publicaciones que demuestran qué tan efectivos son los tratamientos quirúrgicos. El nivel general de discriminación que la sociedad impone al individuo obeso también lleva a que las compañías de seguros médicos, el sector de los negocios y el gobierno no provean a los norteamericanos obesos aquellos tratamientos que han probado su efectividad y que sobrepasan en beneficio a cualquier forma de tratamiento médico. Pero no se puede esperar que los ACEs de los tratamientos para la obesidad, de por sí, lleguen a revertir tal forma de discriminación. Sin embargo, la información obtenida aporta a los pacientes y a sus médicos la evidencia para confrontar a quienes definen las políticas, especialmente en lo referente al por qué los tratamientos de comprobado costo-efectividad, son excluidos o ubicados en

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un nivel inferior de prioridad, frente a tratamientos que han probado ser menos eficaces.

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The Effect of Roux-en-Y Gastric Bypass on Prescription Drug Costs

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Background: This study examines the effect of weight loss following laparoscopic Roux-en-Y gastric bypass (RYGBP) for morbid obesity on prescription drug costs in patients over the age of 54.

Methods: 78 patients aged 55 to 75 who met the inclusion criteria were identified in a database of 1,060 morbidly obese patients undergoing LRYGBP between March 2001 and March 2003. All prescription drugs and dosages were recorded preoperatively and postoperatively at 6 months, 1 year, and yearly thereafter. Drug history was obtained from the patient and verified by records from referring physicians' offices. The cost of a 30-day supply of each drug was obtained from 3 retail sources and averaged.

Results: The average pre-LRYGBP cost of prescription drugs was $368.65 per month per patient. The average annualized cost at 6 months after LRYGBP was $119.10 per month (down 68%), at 1 year $118.67 (down 68%) and at 2 years $104.68 per month (down 72%).

Conclusions: Weight loss resulting from LRYGBP significantly reduces obesity-related morbidities, resulting in a substantial reduction in medication needs in patients over the age of 54. The projected cost savings realized in the 78 patients in this study amounts to approximately $240,566.04 annually.

Key words: Morbid obesity, bariatric surgery, gastric bypass, benefits, costs, drug costs

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Introduction

Because of increase in the rate of morbid obesity and the introduction of the laparoscopic Roux-en-Y gastric bypass (LRYGBP),[1] the demand for bariatric surgery has dramatically increased in recent years. Approximately 100,000 bariatric procedures were performed in the United States in 2003, and an estimated 144,000 will be performed in 2004. Ostensibly, this has placed an economic burden on private and public health-care insurers, resulting in efforts to compensate for the additional costs of surgery. The options are to raise premiums, reduce reimbursements, increase patient co-payments or deny coverage for the procedure. Rather than raising premiums, the trend has been to shift costs to providers by reducing allowable charges and to the morbidly obese patient by denying coverage or raising co-payments. The medical costs to treat obesity and obesity-related morbidities have also risen. According to the Centers for Disease Control and Prevention, the direct and indirect annual medical cost to treat obesity and obesity-related morbidities in the U.S.A. in 1998 was 78.5 billion dollars, which would be equivalent to 92.6 billion in 2002 dollars.[2]

These economic issues generated two related hypotheses: The first hypothesis was that surgery is more effective therapeutically and economically for the treatment of both obesity and obesity-related morbidities than drugs. The second hypothesis was that the benefits of bariatric surgery pay for the costs of surgery in a reasonable period of time.

A narrow study was designed to test these hypotheses by comparing the cost and effectiveness of surgery in the patients studied, using the methods described against the cost and effectiveness of medical treatment using a single surgical benefit – savings in prescription drug costs.

Materials and Methods

All patients over the age of 54 in a database of 1,060 patients in whom a LRYGBP was attempted between March, 2001 and March, 2003 with a minimum of 6 months follow-up were included. Patients who died or were lost to follow-up within 6 months of surgery were excluded.

Pertinent data including patient's age, weight, body mass index (BMI), morbidities and lists of prescription drugs and dosages were prospectively recorded preoperatively and postoperatively at 6 months and yearly thereafter. Prescription drug data were obtained from the patient and later verified by the patient's primary care and other physicians' recorded history and office records. The cost of a 30-day supply of each drug was obtained from three retail sources and averaged. The average drug cost-savings was calculated on a monthly and yearly basis, by subtracting the average cost at each postoperative time interval from the average preoperative cost. The mean cost per episode for a LRYGBP during the study period was obtained from the data bank of a single insurer that insured over 75% of the patients in our database. Costs included the average of all payments including patient co-payments to the surgeon, assistant surgeon, consultants, anesthesiologist, pathologist, radiologist and the hospital.

Results were analyzed for statistical significance using one or two way analysis of variance where appropriate, using SPSS v.11 (SPSS Inc. Chicago, IL). Significance was set at $P < .05$.

Results

There were 82 patients over the age of 54 identified in a database of 1,060 LRYGBP operations performed from April 15, 2001 through April 15, 2003. Of these, 78 patients met the inclusion criteria. Age ranged from 55 to 75, with a mean of 60 years. There were 17 males (22%) and 61 females (78%). Weight ranged from 85 to 226 kg with a mean of 136 kg. BMI ranged from 36 to 70, with a mean of 48 kg/m^2. There was an average of 3 obesity-related co-morbidities per patient, versus 1 per patient in the 977 patients below the age of 55 years. Morbidities are listed in Table 1. Mean operating time was 124 minutes. Ten patients (12.4%) were converted to open. Mean estimated blood loss

Table 1. Co-morbidities requiring prescription drugs. Number of drugs, number of patients taking drugs and percentage decrease in number of drugs for each morbidity at each time interval.

	Preop 78 patients		6 months postop 78 patients			1 year postop 78 patients			2 years postop 26 patients (93 Drugs preop)		
Morbidity	No. Drugs	No. Pts.	No. Drugs	% Drugs	No. Pts	No. Drugs	% Drugs	No. Pts	No. Drugs	% Drugs	No. Pts
HT / HT CVD	96	51	34	65	25	44	49	27	13	32	9
Type 2 Diabetes	46	28	4	91	3	4	91	3	1	94	1
Pulmonary Insufficiency	40	24	20	50	11	15	63	9	7	56	3
Osteoarthritis	47	32	12	75	11	16	66	14	5	62	5
Anxiety / Depression	46	34	22	52	17	20	57	17	9	44	7
Hyperlipidemia	23	20	10	57	9	9	61	8	1	80	1
GERD	23	21	6	74	6	6	74	6	2	75	2
Urinary incontinence	3	3	0	100	0	0	-	0	0		0
Total	324	70	112	67	49	113	65	53	38	59	18

HT=hypertension, CVD=cardiovascular disease, GERD=gastroesophageal reflux disease, Pts=patients.

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(EBL) was 132 cc. There were no surgical deaths.

Four patients were excluded. There were three late deaths between 30 and 180 days following surgery. All three were discharged doing well by the fourth day after surgery. A 59-year-old male on anticoagulant therapy for lower extremity deep vein thrombosis died 32 days after surgery from massive intestinal bleeding. A 74-year-old female died 135 days after surgery and a 61-year-old female died 70 days after surgery, both from an unknown cause clinically consistent with a pulmonary embolus or cardiac event. One patient was lost to follow-up after the 1-month postoperative visit. Of the remaining 78 patients, follow-up was 100% at 6 months, 100% at 1 year, and 94% at 2 years.

Preoperatively, 70 of 78 patients were taking 324 prescription drugs or 4.2 drugs per patient per day. Six months postoperatively, 53 of 78 patients were taking 112 prescription drugs or 1.4 drugs per patient per day. At 1 year, 49 of 78 patients were taking 113 prescription drugs or 1.4 drugs per patient per day, and at 2 years 18 of 26 patients were taking 38 prescription drugs or 1.5 drugs per patient per day (Table 2). The average cost of prescription drugs preoperatively was $369 per patient per month. The average cost 6 months postoperatively was $119.10 (down 68%), at 1 year $118.67 (down 68%) and at 2 years $104.66 (down 72%) (Table 3). The annual cost for all 78 patients preoperatively was $345,056. The annualized cost 6 months postoperatively was $111,478 (down $233,579), at 1 year $111,057.00 (down $233,981) and at 2 years $97,962 (down $247,151) for an average annual savings of approximately $240,000 (Table 4). The total cost of surgery was $631,000 based on an average cost of $8,090 per LRYGBP.

Table 2. Total number of drugs prescribed and number of drugs taken per patient at each interval studied

Interval	Number of Drugs	Drugs per Patient
Preoperative	324	4.2
6 months postop	112	1.4
1 year postop	113	1.4
2 years postop (25 patients)	38	1.5

Table 3. Average prescription drug cost, drug cost savings and percentage decrease per patient per month at intervals studied

	Preop	6 Mos	1 Yr	2 Yrs
Drug cost	$369	$119	$119	$105
Savings in drug costs		$250	$250	$264
Percentage decrease		68%	68%	72%

Discussion

The first hypothesis was that surgery was more effective in the treatment of obesity and related co-morbidities than drugs. There are two distinct categories in the treatment of obesity: treatment for weight loss, and treatment of obesity-related morbidities. There is currently no known long-term medical cure for morbid obesity. Weight loss following medical treatment for morbid obesity in the form of drugs, diets, exercise and behavior modification has only been minimally successful in the short-term and uniformly unsuccessful in the long-term. Unsuccessful medical treatment only adds to the cost of obesity. The only treatment modality that affords a reasonable degree of immediate and long-term weight loss success is surgery. The standard Roux-en-Y gastric bypass results in significant long-term weight loss of ≥50% of excess weight in over 60% of morbidly obese patients undergoing the operation. Prescription drugs do not cure the co-morbidities; they only moderate the severity and alleviate the symptoms while the diseases progress. Surgery, however, cures or improves the co-morbidities while retarding their progression.[3-17]

Support for the first hypothesis is illustrated in

Table 4. Annualized prescription drug cost and drug cost savings at each interval studied

Interval	Annualized Drug Costs	Annualized Savings
Preop	$345,056.40	
6 Months	$111,477.60	$233,578.80
1 Year	$111,057.12	$233,981.28
2 Years	$97,961.76	$247,150.80
Average Annual Savings	$240,566.04	

Figure 1. This compares the accumulated costs of prescription drugs alone in the patients without surgery, to the cost of surgery. The cost of drugs to treat morbidities surpasses the cost of surgery at 22 months and continues to escalate thereafter.

The second hypothesis was that a single surgical benefit, savings in prescription drug costs, would pay for the cost of the surgery. Support for this hypothesis is illustrated in Figure 2 which compares the accumulated savings in prescription drug costs over time to the cost of surgery. The savings in drug costs would pay for the cost of surgery in 32 months.

Recent reports have corroborated the cost savings after bariatric surgery. Monk et al[18] and Potteiger et al[19] documented a significant reduction in co-morbidities and in pharmaceutical expenses after gastric bypass. These financial savings offset the cost of surgery, and represent permanent economic benefits for the patients and society. Furthermore, Christou's group,[20] using obese well-matched controls, found significant reductions in overall direct long-term health-care costs following weight-reduction surgery.

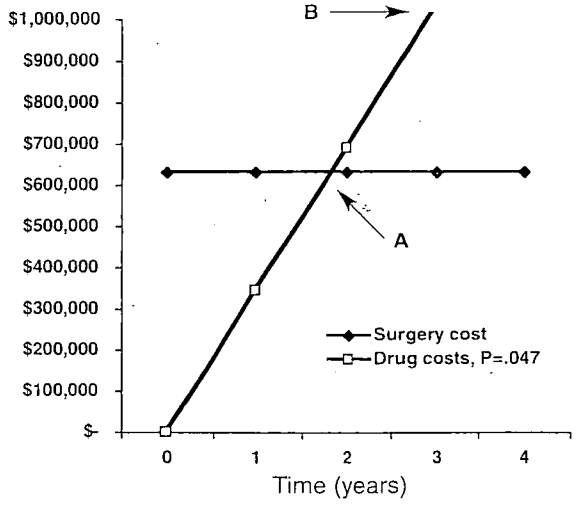

Figure 1. Cost of surgery versus accumulated prescription drug cost (medical costs): The cost of drugs surpassed the cost of surgery at 22 months (A) and reached $1,000,000 at 34 months (B) (U.S. Dollars).

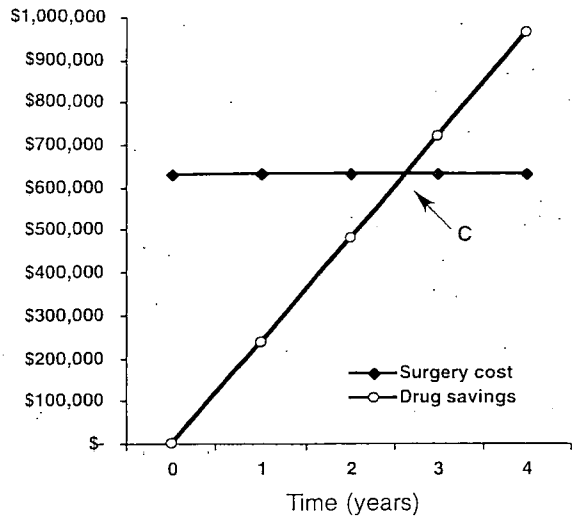

Figure 2. Cost of gastric bypass surgery versus accumulated savings in drug costs (U.S. Dollars). The savings in drug costs paid for the cost of surgery in 32 months (C).

Conclusions

In the patients studied, using the methods described, LRYGBP is significantly more effective therapeutically and economically than prescription drugs for the treatment of obesity and obesity-related morbidities ($P < .05$). LRYGBP significantly affects prescription drug costs, resulting in cost savings that pay for the operation in a reasonably short period of time.

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Lifestyle, Diabetes, and Cardiovascular Risk Factors 10 Years after Bariatric Surgery

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ABSTRACT

BACKGROUND

Weight loss is associated with short-term amelioration and prevention of metabolic and cardiovascular risk, but whether these benefits persist over time is unknown.

METHODS

The prospective, controlled Swedish Obese Subjects Study involved obese subjects who underwent gastric surgery and contemporaneously matched, conventionally treated obese control subjects. We now report follow-up data for subjects (mean age, 48 years; mean body-mass index, 41) who had been enrolled for at least 2 years (4047 subjects) or 10 years (1703 subjects) before the analysis (January 1, 2004). The follow-up rate for laboratory examinations was 86.6 percent at 2 years and 74.5 percent at 10 years.

RESULTS

After two years, the weight had increased by 0.1 percent in the control group and had decreased by 23.4 percent in the surgery group ($P<0.001$). After 10 years, the weight had increased by 1.6 percent and decreased by 16.1 percent, respectively ($P<0.001$). Energy intake was lower and the proportion of physically active subjects higher in the surgery group than in the control group throughout the observation period. Two- and 10-year rates of recovery from diabetes, hypertriglyceridemia, low levels of high-density lipoprotein cholesterol, hypertension, and hyperuricemia were more favorable in the surgery group than in the control group, whereas recovery from hypercholesterolemia did not differ between the groups. The surgery group had lower 2- and 10-year incidence rates of diabetes, hypertriglyceridemia, and hyperuricemia than the control group; differences between the groups in the incidence of hypercholesterolemia and hypertension were undetectable.

CONCLUSIONS

As compared with conventional therapy, bariatric surgery appears to be a viable option for the treatment of severe obesity, resulting in long-term weight loss, improved lifestyle, and, except for hypercholesterolemia, amelioration in risk factors that were elevated at baseline.

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OBESITY IS ASSOCIATED WITH INcreased morbidity and mortality.[1] The increased morbidity is assumed to be mediated mainly by insulin resistance, diabetes, hypertension, and lipid disturbances — conditions that affect one quarter of the North American population.[2,3] Over the short term (one to three years), lifestyle changes resulting in weight loss result in improvements in insulin resistance,[4] diabetes,[5-7] hypertension,[8] and lipid disturbances[9-11] or in the prevention of these conditions. In contrast, several (but not all[12]) observational epidemiologic studies have suggested that weight loss is associated with increased overall mortality and mortality from cardiovascular causes, not only among thin[13] and normal-weight[14] subjects, but also among obese subjects.[15-17]

One overall aim of the Swedish Obese Subjects (SOS) Study was to address this apparent discrepancy between the effects of weight loss on risk factors and hard end points. In the current study, we assessed changes in cardiovascular risk factors over follow-up periods of 2 and 10 years in surgically treated subjects and contemporaneously matched, conventionally treated control subjects. Changes in energy intake and physical activity over the 10-year period were also evaluated.

METHODS

STUDY DESIGN

The SOS Study was a prospective, nonrandomized, intervention trial involving 4047 obese subjects. The outcomes in a surgically treated group were compared with those in a contemporaneously matched, conventionally treated control group.[18] For the purposes of this report, all subjects who had been enrolled at least 2 years (4047 subjects) or 10 years (1703 subjects) before the date of the analysis (January 1, 2004) were included. The 4047 subjects were all those who were finally enrolled in the SOS intervention study.

The seven ethics review boards involved in the SOS Study approved the protocol. Informed consent was obtained both from the subjects in the registry study and from those in the intervention study.

Registry Examination

As a result of recruitment campaigns through the mass media and at 480 primary health care centers in Sweden, 11,453 subjects living in participating counties (18 of the 24 counties in Sweden) sent standardized application forms to the SOS secretariat between September 1987 and November 2000. All 8966 applicants who fulfilled age and weight-for-height criteria were provided written information about the surgical and nonsurgical treatments offered by the SOS Study. They also completed questionnaires and were asked whether they wanted to participate as surgically treated or medically treated subjects. All 7593 subjects who returned their questionnaires were offered participation in the registry examination, and 6905 completed that examination. According to individual treatment preferences and data obtained from the registry examination, eligible subjects were assigned either to the surgery group of the intervention study or to a pool of potential control subjects.

Surgical Visit

The eligibility of candidates for surgery was determined by computer, and the result was manually checked by the examining surgeon. If a candidate was eligible, an operation was scheduled. On average, the surgical visit occurred eight months after the registry examination and five months before the operation itself, which marked the start of the intervention study. Eight weeks before a subject underwent surgery, an optimal matched control was selected, on the basis of variables described below, from among the subjects in the pool of potential controls. Thus, matching was contemporaneous and was based on registry data, both for the surgically treated subjects and for the control subjects.

Inclusion Examination

The inclusion examination for subjects for whom surgery was planned and for their matched controls was undertaken 4 weeks before surgery (i.e., 4 weeks before the start of the intervention study), on average 13 months after the registry examination. This delay was a consequence of the waiting time for surgery at the 25 participating surgical departments. The controls underwent their manual eligibility check at the time of the inclusion examination.

Intervention Study

The intervention study for a surgically treated subject and his or her matched control began on the day of the surgically treated subject's operation. The dates of all subsequent examinations (at 0.5, 1.0, 2.0, 3.0, 4.0, 6.0, 8.0, and 10.0 years) for both sub-

jects were calculated in relation to the date of surgery. Inclusion criteria for the intervention study were a body-mass index (calculated as the weight in kilograms divided by the square of the height in meters) of 34 or more (for men) or 38 or more (for women) and an age of 37 to 60 years. Exclusion criteria, described elsewhere,[18] were minimal and were aimed at ensuring that the subjects in the surgery group could tolerate the operation. Identical inclusion and exclusion criteria were used in the two study groups. Subjects with diabetes, hypertension, or lipid disturbances were not excluded, nor were subjects who had had a myocardial infarction or a stroke more than six months before inclusion.

Matching

The SOS Study was not randomized; rather, subjects were matched according to the method of sequential treatment assignment,[19] with balancing of confounding factors measured at baseline in prospective, nonrandomized intervention trials. The following 18 matching variables were considered[18]: sex, age, weight, height, waist and hip circumferences, systolic blood pressure, serum cholesterol and triglyceride levels, smoking status, diabetes, menopausal status, four psychosocial variables with documented associations with the risk of death, and two personality traits related to treatment preferences. The investigators had no influence on the computerized matching process.

Clinical and Biochemical Assessments

At each visit, measurements of weight, height, waist circumference, and blood pressure were obtained. In addition, energy intake (in kilocalories per day) was estimated with use of the validated SOS Dietary Questionnaire.[20,21] Subjects were also asked to rate their physical activity during leisure and work time on a scale from 1 to 4, in which 1 denotes sedentary activity and 4 regular strenuous exercise.[20,22] In the current report, ratings were dichotomized; a rating of 1 corresponded to physically inactive and ratings of 2, 3, or 4 to physically active.

Biochemical variables were measured at the registry examination, at the inclusion examination (year 0 of the intervention study), and at years 2 and 10 of the intervention study (Table 1). All blood samples, which were obtained in the morning after a 10-to-12-hour fast, were analyzed at the Central Laboratory of Sahlgrenska University Hospital (accredited according to European Norm EN45001). The schedule, questionnaires, blood pressure and anthropometric measurements, and laboratory examinations were identical for surgically treated subjects and their matched controls.

TREATMENTS

The surgically treated subjects underwent fixed or variable banding, vertical banded gastroplasty, or gastric bypass.[23] The contemporaneously matched controls received the nonsurgical treatment for obesity that was customary for the center at which they were registered. No attempt was made to standardize the nonsurgical treatment, which ranged from sophisticated lifestyle intervention and behavior modification to, in some practices, no treatment whatsoever. No antiobesity drugs were approved in Sweden until 1998.

CRITERIA FOR HEALTH AND DISEASE

Criteria for health and disease were based on cutoff values or the use of medication for the condition in question, according to principles specified elsewhere.[11] However, in the course of the study, the criterion for diagnosing diabetes decreased to a fasting blood glucose level of 110 mg per deciliter (6.1 mmol per liter) or greater, corresponding to a fasting plasma glucose level of 126 mg per deciliter (7.0 mmol per liter) or greater, in accordance with the new criteria of the American Diabetes Association.[24] Similarly, the criterion for diagnosing hypertension decreased to a systolic pressure of 140 mm Hg or greater or a diastolic pressure of 90 mm Hg or greater.[25] Other criteria included the following: hypercholesterolemia (cholesterol level, 201 mg per deciliter [5.2 mmol per liter] or greater[26]); hypertriglyceridemia (triglyceride level, 150 mg per deciliter [1.7 mmol per liter] or greater[26]); a low level of high-density-lipoprotein (HDL) cholesterol (less than 39 mg per deciliter [1.0 mmol per liter][26]); and hyperuricemia (uric acid level, 7.6 mg per deciliter [450 μmol per liter] or greater in men and 5.7 mg per deciliter [340 μmol per liter] or greater in women).

OUTCOME VARIABLES

The primary outcome variable in the SOS Study as a whole was overall mortality. Three secondary outcome variables are described in this report. The first was the difference between the surgery group and the control group with respect to changes in body weight, risk factors, energy intake, and the propor-

Table 1. Characteristics of the Subjects at the Time of Matching and at the Time of the Inclusion Examination of the Intervention Study.*

Characteristic	Matching Data, Subjects Who Completed 10 Yr		Matching Data, Subjects Who Did Not Complete 10 Yr†		Inclusion Data, Subjects Who Completed 2 Yr		Inclusion Data, Subjects Who Completed 10 Yr	
	Control Group (N=627)	Surgery Group (N=641)‡	Control Group (N=225)§	Surgery Group (N=210)¶	Control Group (N=1660)	Surgery Group (N=1845)‡	Control Group (N=627)	Surgery Group (N=641)‡
Age (yr)	47.3±6.1	46.1±5.6‖	47.7±6.2**	46.3±6.0**	48.8±6.2	47.4±5.9‖	48.4±6.3	47.0±5.6‖
Male sex (%)	31.4	30.6**	32.0**	34.8**	29.7	29.3**	31.4	30.6**
Smoker (%)	19.5	25.4††	31.6‖	39.5‖	19.5	24.4‖	21.1	24.7**
Weight (kg)	115.7±15.7	118.4±15.7††	117.1±17.1**	121.4±16.7††	114.6±16.4	120.6±16.4‖	113.9±16.7	120.0±16.4‖
Height (m)	1.69±0.09	1.69±0.09**	1.69±0.09**	1.69±0.09**	1.69±0.09	1.69±0.09**	1.69±0.09	1.69±0.09**
Body-mass index	40.5±4.2	41.3±4.0‖	40.8±4.8**	42.3±4.9††	40.0±4.6	42.3±4.4‖	39.9±4.6	41.9±4.2‖
Waist (cm)	120.9±10.0	123.2±10.5‖	123.5±11.8††	126.5±10.6‖	120.0±11.0	125.5±10.8‖	119.3±11.2	124.0±10.9‖
Blood pressure (mm Hg)								
Systolic	140.1±18.8	140.6±19.1**	144.0±20.5††	139.9±17.1**	137.5±17.9	143.5±18.8‖	138.4±17.6	143.8±19.3‖
Diastolic	87.3±10.6	88.4±11.4**	89.3±11.4††	87.8±11.1**	84.7±10.5	88.7±11.2‖	85.8±10.6	89.6±11.3‖
Glucose (mmol/liter)	5.3±1.8	5.4±2.0**	5.7±2.3††	5.6±2.1**	5.2±1.9	5.4±2.1‖	5.1±1.7	5.5±2.1‖
Insulin (mU/liter)	20.7±12.6	22.1±12.7**	21.5±12.7**	24.9±23.3**	18.0±11.5	21.2±12.6‖	18.3±11.2	21.2±11.4‖
Uric acid (μmol/liter)	354.7±84.1	358.1±84.0**	360.1±83.1**	357.5±83.3**	353.3±79.3	359.4±80.1††	357.7±78.9	366.2±84.2**
Triglycerides (mmol/liter)	2.18±1.47	2.27±1.76**	2.58±2.45††	2.32±1.23**	2.01±1.35	2.23±1.52‖	2.12±1.49	2.30±1.56††
Serum cholesterol (mmol/liter)								
HDL	1.23±0.34	1.22±0.30**	1.22±0.30**	1.19±0.28**	1.19±0.29	1.20±0.28‖	1.18±0.29	1.19±0.28**
Total	5.84±1.12	5.97±1.13††	6.07±1.22††	6.05±1.13**	5.60±1.06	5.85±1.12‖	5.76±1.10	6.02±1.13‖

* Plus–minus values are means ±SD. To convert the values for glucose to milligrams per deciliter, divide by 0.05551. To convert the values for insulin to picomoles per liter, multiply by 7.175. To convert the values for uric acid to milligrams per deciliter, divide by 59.48. To convert the values for triglycerides to milligrams per deciliter, divide by 0.01129. To convert the values for cholesterol to milligrams per deciliter, divide by 0.02586. HDL denotes high-density lipoprotein.

† Among the subjects who did not complete 10 years of the study, the controls were older and had higher systolic blood pressure than the surgically treated subjects, whereas the surgically treated subjects were heavier and had a larger waist circumference (P values not shown).

‡ P values are for the comparison with data for subjects in the control group under the indicated conditions.

§ P values are for the comparison with matching data for subjects in the control group who completed the 10-year examination.

¶ P values are for the comparison with matching data for subjects in the surgically treated group who completed the 10-year examination.

‖ P<0.001.

** P values indicate that the difference is not significant.

†† P<0.05.

tion of subjects who were physically active. These calculations included all the subjects and did not take medication use or baseline disease into account. The next secondary outcome was the difference between the two groups in the incidence of risk conditions over 2- and 10-year periods among the subjects unaffected by those risk conditions at baseline (i.e., the primary preventive effect of weight loss). The final secondary outcome was the difference between the two groups in the rate of recovery from risk conditions over 2- and 10-year periods among those who had been affected by those conditions at baseline.

STATISTICAL ANALYSIS

The intervention study had 80 percent power (at an alpha level of 0.05) to detect a difference in total mortality between a group of 2000 surgically treat-

ed subjects and a group of 2000 controls followed for 10 years.[18] To evaluate the originally chosen treatment strategy according to pragmatic clinical-treatment principles,[27] subjects in the surgery group who completed 10 years of the study and who underwent reoperation (band removal in 15 subjects and conversion to another type of surgical treatment in 62) or who had a spontaneous band disruption (in 2 subjects) were considered surgically treated and remained in their original treatment subgroup. Similarly, control subjects who later underwent bariatric surgery (34 subjects) were considered controls throughout the study. All analyses presented here are based on data from subjects who completed 2 or 10 years of the study. However, for confirmatory reasons, additional calculations were performed by replacing all missing data with baseline data, according to the "baseline observation carried forward" method.[28]

Mean values and standard deviations are used to describe the baseline characteristics of the two treatment groups. Analysis of covariance was used to test for differences in changes in risk factors between the two treatment groups. Treatment group was included as a covariate, as were sex, age, body-mass index, and the baseline level of each studied variable. Adjusted differences, with 95 percent confidence intervals, are reported. Logistic regression was used to compare the incidence of disease and rates of recovery. The data were adjusted for sex, age, and body-mass index at baseline, and the resulting differences in risk are reported as odds ratios with 95 percent confidence intervals. All reported P values are two-sided. Statistical analyses were carried out with use of the Stata statistical package (version 7.0).[29]

RESULTS

SUBJECTS

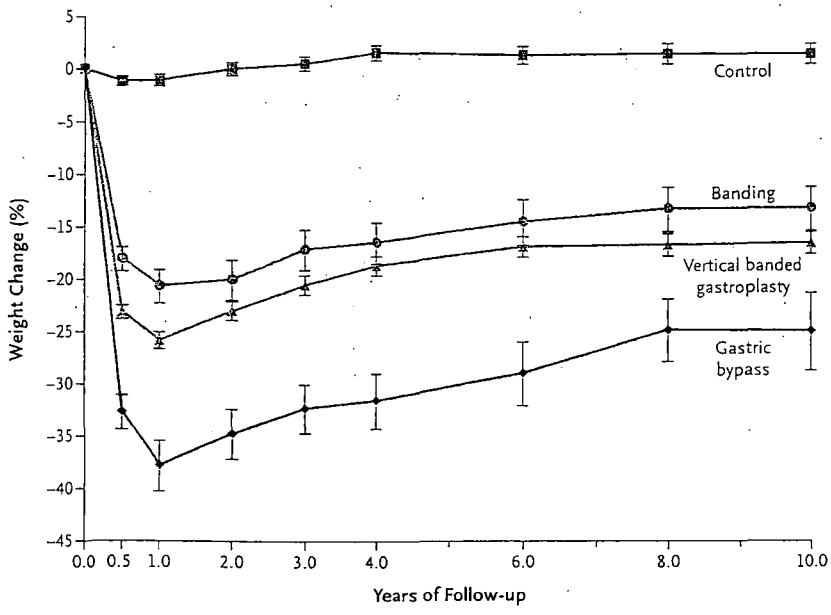
At least 10 years before the date of the current analysis, 851 surgically treated subjects had been enrolled in the SOS Study. The surgically treated subjects had been contemporaneously matched with 852 obese control subjects. The matching resulted in two groups that were not significantly different with respect to sex distribution, height, blood pressure, blood glucose level, serum lipid levels, or serum uric acid level (data not shown). At the time of matching, the surgically treated subjects were slightly younger than the control subjects (46.1 vs. 47.4 years of age, P=0.005), were heavier (119.2 vs. 116.1 kg, P<0.001), and had a slightly higher plasma insulin level (22.8 vs. 20.9 mU per liter, P=0.009).

Of the 851 surgically treated subjects, 210 (24.7 percent) had been lost to follow-up by the time of the 10-year laboratory examination; of the 852 controls, 225 (26.4 percent) had been lost to follow-up by that time (this difference was not significant). Thus, 641 surgically treated subjects and 627 controls completed the 10-year examination. Of the 2010 surgically treated subjects and the 2037 controls who participated in the SOS Study, 165 (8.2 percent) and 377 (18.5 percent), respectively, did not participate in the two-year examination (P<0.001). Thus, 1845 surgically treated subjects and 1660 controls completed the two-year examination.

Table 1 shows matching data from the registry examination for surgically treated and control subjects, according to whether they completed or did not complete 10 years of the study. In general, those who completed 10 years and those who dropped out before 10 years had similar matching values, although some differences between them reached statistical significance, both among the surgically treated subjects and among the controls. Table 1 also shows data obtained at the inclusion examination of the intervention study for subjects who completed 2 and 10 years of the study.

CHANGES IN WEIGHT

The changes in weight among the subjects followed for 10 years are shown in Figure 1. Weight change was maximal after six months in the control group (mean [±SD] change, −1±6 percent [where the minus sign denotes a decrease]) and maximal after one year in the three surgical subgroups (gastric bypass, −38±7 percent; vertical banded gastroplasty, −26±9 percent; and banding, −21±10 percent). After two years, weight had increased by 0.1 percent in the control group and had decreased by 23.4 percent in the surgical group (P<0.001) (Table 2). After 10 years, the controls had increased by 1.6±12 percent over the inclusion weight, whereas the maintained weight change was −25±11 percent in the gastric-bypass subgroup, −16.5±11 percent in the subgroup that underwent vertical banded gastroplasty, and −13.2±13 percent in the banding subgroup. The average weight changes in the entire group of surgically treated subjects are listed in Table 2 and were almost identical to those shown in the curve for the subgroup that underwent vertical banded



No. of Subjects									
Control	627	585	594	587	577	563	542	535	627
Banding	156	150	154	153	149	150	147	144	156
Vertical banded gastroplasty	451	438	438	438	429	417	412	401	451
Gastric bypass	34	34	34	34	33	32	32	29	34

Figure 1. Weight Changes among Subjects in the SOS Study over a 10-Year Period.

All data are for subjects who completed 10 years of the study. The average weight change in the entire group of surgically treated subjects was almost identical to that in the subgroup of subjects who underwent vertical banded gastroplasty. The I bars represent the 95 percent confidence intervals.

gastroplasty (Fig. 1). The fractions of subjects who, after completing 10 years of the study, had a loss of less than 5 percent of their initial weight were 72.7 percent (control group), 8.8 percent (gastric-bypass subgroup), 13.8 percent (vertical-banded-gastroplasty subgroup), and 25.0 percent (banding subgroup). The fractions of subjects achieving 20 percent weight loss or more over the 10-year period were 3.8 percent (control group), 73.5 percent (gastric-bypass subgroup), 35.2 percent (vertical-banded-gastroplasty subgroup), and 27.6 percent (banding subgroup).

LIFESTYLE CHANGES

Mean energy intake at the time of inclusion in the intervention study was 2882 kcal per day among the surgically treated subjects, as compared with 2526 kcal per day among the controls. As Figure 2 and Table 2 indicate, the baseline adjusted energy intake was significantly lower in the surgery group than in the control group over the 10-year period. Similarly, the fraction of subjects physically active during leisure time was higher in the surgery group over the 10-year period, and the fraction of those physically active during work time was higher in the surgery group for the first 6 years of the intervention.

EFFECTS ON ANTHROPOMETRIC VARIABLES AND MEAN RISK-FACTOR VALUES

Table 2 shows the changes in risk factors for all available subjects, independent of baseline status and medication use. The waist circumference was reduced more in the surgery group than in the control group after 2 and 10 years. Glucose and insulin levels increased in the control group, whereas substantial decreases were seen in the surgically treated group after both 2 and 10 years of observation. Similarly, changes in uric acid, triglyceride, and HDL cholesterol levels were more favorable in the surgically treated group than in the control group after 2 and 10 years. Systolic blood pressure was reduced by more in the surgery group at two years only. Diastolic blood pressure and total cholesterol were reduced by more in the surgery group than in

Table 2. Percentage Changes in Weight, Anthropometric Variables, Risk Factors, and Energy Intake at 2 and 10 Years.*

Variable	Changes at 2 Yr†			Changes at 10 Yr†			Changes at 10 Yr in Surgery Subgroups		
	Control Group (N=1660)	Surgery Group (N=1845)	Difference (95% CI)	Control Group (N=627)	Surgery Group (N=641)	Difference (95% CI)	Banding (N=156)	Vertical Banded Gastroplasty‡ (N=451)	Gastric Bypass‡ (N=34)
	percent			*percent*				*percent*	
Weight	0.1	−23.4	22.2 (21.6 to 22.8)§	1.6	−16.1	16.3 (14.9 to 17.6)§	−13.2	−16.5¶	−25.0§
Height	−0.01	−0.06	0.06 (0.02 to 0.10)¶	−0.3	−0.3	−0.01 (−0.12 to 0.10)	−0.2	−0.3	−0.8§
BMI	0.1	−23.3	22.1 (21.5 to 22.7)§	2.3	−15.7	16.5 (15.1 to 17.8)§	−12.8	−16.0¶	−23.8§
Waist	0.2	−16.9	16.0 (15.4 to 16.5)§	2.8	−10.1	11.3 (10.3 to 12.4)§	−7.6	−10.2¶	−19.3§
Systolic blood pressure	0.5	−4.4	2.8 (2.1 to 3.6)§	4.4	0.5	1.1 (−0.3 to 2.6)	2.1	0.4	−4.7
Diastolic blood pressure	0.3	−5.2	3.2 (2.4 to 3.9)§	−2.0	−2.6	−2.3 (−3.5 to −1.0)§	−1.4	−2.5	−10.4‖
Pulse pressure	3.2	0.6	−0.5 (−2.3 to 1.3)	18.0	10.8	3.5 (0.1 to 6.9)¶	13.8	10.1	6.3
Glucose	5.1	−13.6	16.6 (15.0 to 18.3)§	18.7	−2.5	18.4 (14.7 to 22.1)§	−0.8	−2.5	−10.0
Insulin	10.3	−46.2	51.4 (48.0 to 54.8)§	12.3	−28.2	30.3 (23.9 to 36.6)§	−25.3	−27.2	−54.0§
Uric acid	−0.4	−14.9	13.5 (12.5 to 14.6)§	3.9	−6.2	8.8 (6.4 to 11.1)§	−5.2	−6.1	−12.3
Triglycerides	6.3	−27.2	29.9 (27.4 to 32.5)§	2.2	−16.3	14.8 (10.4 to 19.1)§	−18.0	−14.9	−28.0¶
HDL cholesterol	3.5	22.0	−18.7 (−20.1 to −17.3)§	10.8	24.0	−13.6 (−16.5 to −10.6)§	20.4	23.5	47.5¶
Total cholesterol	0.1	−2.9	1.0 (0.1 to 1.9)¶	−6.0	−5.4	−2.0 (−0.2 to −3.8)¶	−5.0	−5.0	−12.6§
Energy intake	−2.8	−28.6	19.1 (16.0 to 22.2)§	−1.0	−20.7	11.6 (8.1 to 15.0)§	−19.7	−21.6	−12.6

* Data are for all subjects who completed 2 and 10 years of the study and are independent of diagnosis and medications at or after baseline. The changes within each treatment group are unadjusted, whereas the differences between the groups in the changes have been adjusted for sex, age, body-mass index (BMI), and the baseline level of the respective variable. CI denotes confidence interval, and HDL high-density lipoprotein.

† For values within each group, minus signs denote decreases; for differences between the groups, minus signs denote smaller reductions or (in the case of HDL cholesterol) larger increases in the surgical group than in the control group.

‡ P values are for the comparison with the banding subgroup.

§ P<0.001.

¶ P<0.05.

‖ P<0.10.

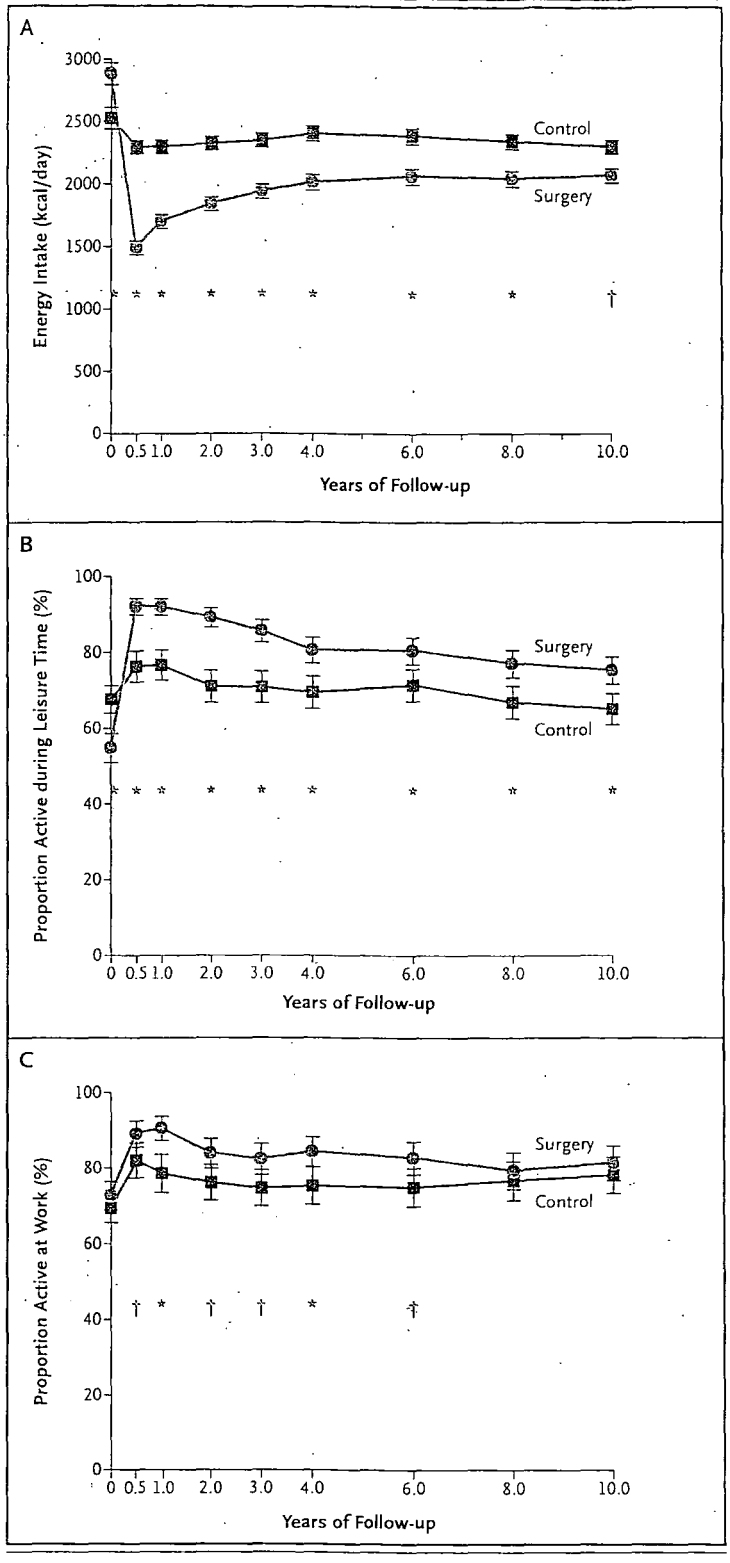


Figure 2. Lifestyle Changes among the Subjects in the SOS Study over a 10-Year Period.

Mean energy intake (in kilocalories per day) (Panel A) and the percentage of subjects who were physically active during leisure time and at work (Panels B and C, respectively) are shown. Energy intake and the proportion of active subjects at baseline (year 0) are unadjusted values, whereas the values during the follow-up have been adjusted for sex, age, body-mass index, and energy intake or physical activity at baseline. All data are from subjects who completed 10 years of the study. The numbers of subjects at each time point are the same as those shown in Figure 1. Asterisks denote $P<0.01$ and daggers $P<0.05$ for the comparison between the groups (by tests for equality). I bars represent the 95 percent confidence intervals.

the control group after 2 years but less reduced after 10 years. The pulse-pressure increase was less pronounced in the surgery group than in the control group after 10 years (Table 2).

The 10-year changes in weight, body-mass index, and waist circumference were larger for subjects who underwent vertical banded gastroplasty and gastric bypass than for those who underwent banding. Insulin, triglyceride, HDL cholesterol, and total cholesterol levels were more improved among the subjects who underwent gastric bypass than among those who underwent banding (Table 2).

EFFECTS ON INCIDENCE OF AND RECOVERY FROM RISK CONDITIONS

As Figure 3 shows, the incidence rates of hypertriglyceridemia, diabetes, and hyperuricemia were markedly lower in the surgically treated group than in the control group after 2 and 10 years. The incidence of low HDL cholesterol was significantly lower in the surgical group after 2 years but not after 10 years. The incidence of hypertension and hypercholesterolemia did not differ between the groups over the 2- and 10-year periods (Fig. 3).

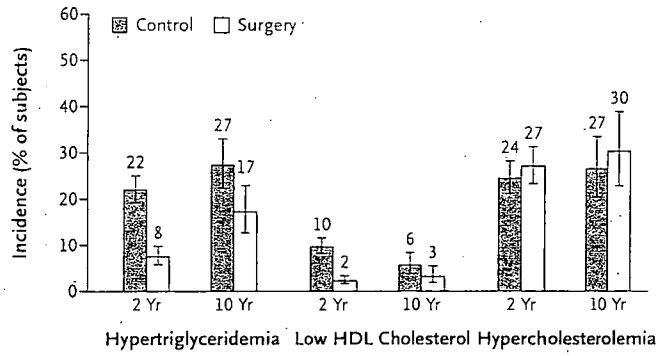
Recovery from hypertension, diabetes, hypertriglyceridemia, a low HDL cholesterol level, and hyperuricemia was more frequent in the surgical group than in the control group, both at 2 and 10 years (Fig. 4). The rates of recovery from hypercholesterolemia did not differ between the two groups after either 2 or 10 years.

BASELINE OBSERVATIONS CARRIED FORWARD

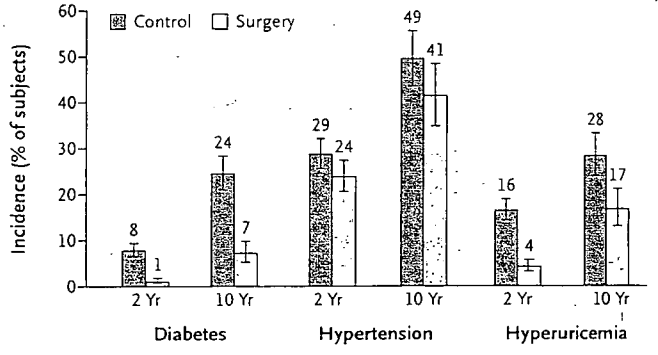
In additional calculations, all missing observations were replaced by baseline observations. The conclusions with respect to mean risk-factor values, incidence rates, and rates of recovery for subjects who completed the study remained the same in the analysis in which baseline observations were carried forward (data not shown).

DEATH AND OTHER ADVERSE EVENTS

Five of the 2010 subjects who underwent surgery (0.25 percent) died postoperatively. As reported elsewhere for 1164 patients,[23] 151 (13.0 percent) had 193 postoperative complications (bleeding in 0.5 percent, embolism or thrombosis in 0.8 percent, wound complications in 1.8 percent, deep infections [leakage or abscess] in 2.1 percent, pulmonary complications in 6.1 percent, and other complications in 4.8 percent). In 26 patients (2.2 percent), the postoperative complications were serious enough to require reoperation. The study is ongoing with respect to analyses of mortality and the incidence of myocardial infarction, stroke, and cancer. The safety monitoring committee found no reason to interrupt the study prematurely because of positive effects or harm.



	Hypertriglyceridemia		Low HDL Cholesterol		Hypercholesterolemia	
No. of subjects						
Control	801	281	1174	440	596	188
Surgery	731	225	1293	431	504	135
Odds ratio	0.29	0.61	0.21	0.57	1.27	1.16
95% CI	0.21–0.41	0.39–0.95	0.14–0.32	0.29–1.15	0.95–1.69	0.69–1.95
P value	<0.001	0.03	<0.001	0.12	0.11	0.57



	Diabetes		Hypertension		Hyperuricemia	
No. of subjects						
Control	1402	539	770	279	1017	382
Surgery	1489	517	623	215	1044	342
Odds ratio	0.14	0.25	0.78	0.75	0.22	0.49
95% CI	0.08–0.24	0.17–0.38	0.60–1.01	0.52–1.08	0.15–0.31	0.34–0.71
P value	<0.001	<0.001	0.06	0.13	<0.001	<0.001

Figure 3. Incidence of Diabetes, Lipid Disturbances, Hypertension, and Hyperuricemia among Subjects in the SOS Study over 2- and 10-Year Periods.

Data are for subjects who completed 2 years and 10 years of the study. The bars and the values above the bars indicate unadjusted incidence rates; I bars represent the corresponding 95 percent confidence intervals (CIs). The odds ratios, 95 percent CIs for the odds ratios, and P values have been adjusted for sex, age, and body-mass index at the time of inclusion in the intervention study.

DISCUSSION

The surgically treated subjects in this study had greater weight loss, more physical activity, and lower energy intake than the control subjects over a 10-year period. Furthermore, the 2- and 10-year rates of recovery from all the studied risk factors, except hypercholesterolemia, were more favorable in the surgery group than in the control group, as were the 2- and 10-year incidence rates of hypertriglyceridemia, diabetes, and hyperuricemia. All reported results are based on subjects who completed 2 or 10 years of the study. However, the conclusions remained the same when data from all included subjects were used and missing follow-up data were replaced by baseline data, according to the conservative "baseline observation carried forward" procedure.[28]

The mean changes in weight and risk factors were more favorable among the subjects treated by gastric bypass than among those treated by banding or vertical banded gastroplasty. The low number of subjects who were followed for 10 years after gastric bypass prohibited incidence and recovery calculations, but the technique appears to be a current method of choice. The large weight loss after gastric bypass, as compared with that after the other types of surgery, may be related to altered gut-to-brain signaling.[30,31]

Most intervention studies with one to three years of follow-up are in agreement with our two-year ob-

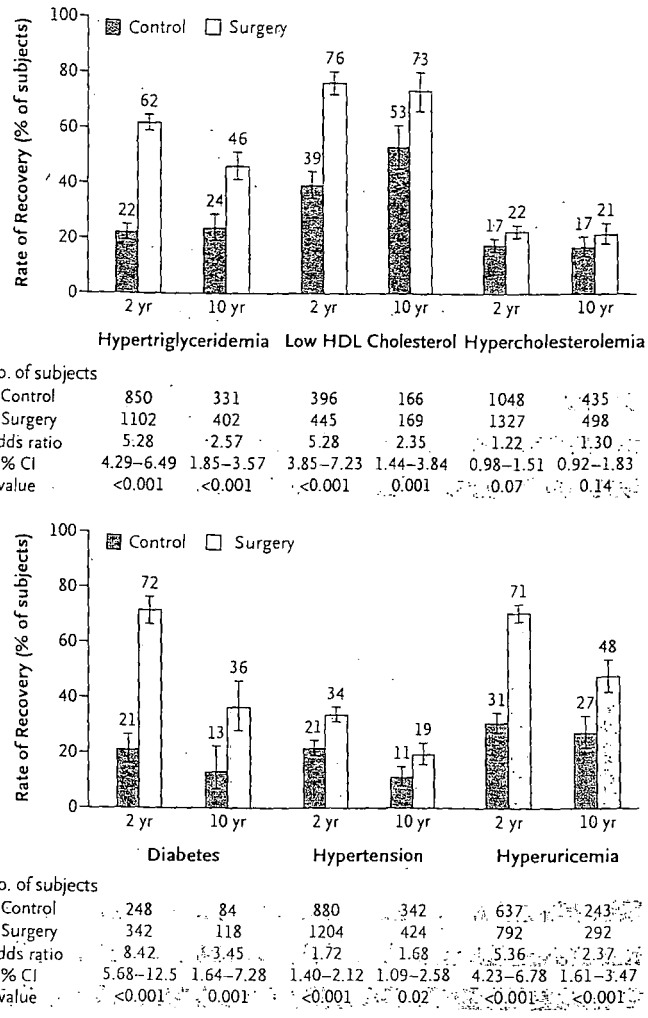


Figure 4. Recovery from Diabetes, Lipid Disturbances, Hypertension, and Hyperuricemia over 2 and 10 Years in Surgically Treated Subjects and Their Obese Controls.

Data are for subjects who completed 2 years and 10 years of the study. The bars and the values above the bars indicate unadjusted rates of recovery; I bars represent the corresponding 95 percent confidence intervals (CIs). The odds ratios, 95 percent CIs for the odds ratios, and P values have been adjusted for sex, age, and body-mass index at the time of inclusion in the intervention study.

servations concerning the effects of weight loss on blood pressure,[8,32,33] lipids,[9,34,35] uric acid,[36] and diabetes.[5-7] In contrast, to our knowledge there have been no controlled, prospective intervention trials against which our long-term results can be compared. In a retrospective, nine-year analysis, gastric bypass surgery was found to have a dramatic effect on the incidence of type 2 diabetes and overall mortality.[37] Sixteen-year observational data on weight loss from the Framingham Study[38] are in agreement with the primary preventive effect on diabetes that we found over a 10-year period. In contrast, observational, epidemiologic 12-to-15-year data on weight loss indicated a primary preventive effect on hypertension in the Nurses' Health Study,[39] but this finding could not be confirmed in our controlled 10-year intervention. Our results indicate that the long-term effects (effects at 10 years) of maintained weight loss on risk factors cannot always be estimated from short-term observations (up to 2 years).

The main limitation of the SOS Study is that it was not randomized. When it was approved as a matched, prospective intervention study in 1987, six of the seven involved ethics review boards in Sweden considered the high mortality rate after gastric surgery for obesity (1 to 5 percent in the 1970s and 1980s[40]) unacceptable for randomization.

In summary, this study indicates that bariatric surgery is a favorable option in the treatment of severe obesity. That not all obesity-associated risk factors were improved by sustained weight loss underscores the importance of obtaining long-term data concerning the effect of weight loss on overall mortality and on the incidence rates of myocardial infarction, stroke, and cancer.

Supported by a grant (05239) from the Swedish Medical Research Council and by grants from Hoffmann–La Roche, Basel, Switzerland (to Dr. Sjöström), and Bristol-Myers Squibb (to Dr. Bouchard).

Dr. Carlsson reports holding equity in AstraZeneca.

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APPENDIX

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JOURNAL INDEX

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The Gastric Bypass Operation Reduces the Progression and Mortality of Non–Insulin-Dependent Diabetes Mellitus

Kenneth G. MacDonald, Jr., M.D., Stuart D. Long, B.S., Melvin S. Swanson, Ph.D., Brenda M. Brown, M.R.A., Patricia Morris, R.N., G. Lynis Dohm, Ph.D., Walter J. Pories, M.D.

Of 232 morbidly obese patients with non–insulin-dependent diabetes mellitus referred to East Carolina University between March 5, 1979, and January 1, 1994, 154 had a Roux-en-Y gastric bypass operation and 78 did not undergo surgery because of personal preference or their insurance company's refusal to pay for the procedure. The surgical and the nonoperative (control) groups were comparable in terms of age, weight, body mass index, sex, and percentage with hypertension. The two groups were compared retrospectively to determine differences in survival and the need for medical management of their diabetes. Mean length of follow-up was 9 years in the surgical group and 6.2 years in the control group. The mean glucose levels in the surgical group fell from 187 mg/dl preoperatively and remained less than 140 mg/dl for up to 10 years of follow-up. The percentage of control subjects being treated with oral hypoglycemics or insulin increased from 56.4% at initial contact to 87.5% at last contact ($P = 0.0003$), whereas the percentage of surgical patients requiring medical management fell from 31.8% preoperatively to 8.6% at last contact ($P = 0.0001$). The mortality rate in the control group was 28% compared to 9% in the surgical group (including perioperative deaths). For every year of follow-up, patients in the control group had a 4.5% chance of dying vs. a 1.0% chance for those in the surgical group. The improvement in the mortality rate in the surgical group was primarily due to a decrease in the number of cardiovascular deaths. (J GASTROINTEST SURG 1997;1:213-220.)

Morbid obesity is a serious health problem that is associated with significant morbidity and mortality,[1-3] much of which is secondary to conditions either caused by or exacerbated by the obesity; this is commonly referred to as "comorbidity." These comorbid conditions include non–insulin-dependent diabetes mellitus (NIDDM), hypertension,[4,5] obstructive sleep apnea and obesity hypoventilation syndrome,[6] hyperlipidemia, degenerative joint disease, cardiovascular disease,[7] cholelithiasis, and increased incidence of certain cancers. Psychosocial impairments, most frequently depression and feelings of insecurity and inadequacy, occur often and may be disabling.[7]

NIDDM, the subject of this report, is a devastating disease and a major cause of atherosclerotic cardiovascular disease, renal disease, retinopathy, and neuropathy. Of the estimated 10 million Americans with diabetes, approximately 95% have NIDDM,[8] much of which can be attributed to obesity. Previous reports from our studies at East Carolina University have shown that 82.9% to 88.7% of obese patients with diabetes became euglycemic following Roux-en-Y gastric bypass.[8,9] Patients whose glucose metabolism failed to return to normal were older and had had diabetes for longer than those who became euglycemic. We have also demonstrated amelioration of hyperinsulinemia, which is characteristic of NIDDM, following gastric bypass.[8] We have previously published data showing that gastric bypass prevents the progression of subclinical diabetes, or impaired glucose tolerance, to overt diabetes.[9,10]

Despite this documented control of NIDDM after gastric bypass, there is still little documentation of improved morbidity and mortality in comparison to

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morbidly obese patients with diabetes who do not undergo surgery. In a recent review, Benotti and Forse [11] concluded that "future longitudinal studies of patients who have undergone surgical therapy for obesity should be conducted in order to assess whether long-term weight control in these patients will result in improved health risks." This article represents our ongoing attempt to provide long-term follow-up data that could answer this question.

MATERIAL AND METHODS

Design

From March 5, 1979, to January 1, 1994, a total of 1309 patients were referred to the Obesity Research Program at East Carolina University where they were evaluated for possible gastric restrictive surgery for obesity. Of this group, 603 patients ultimately had an initial gastric bypass procedure performed at East Carolina University. Five hundred sixty-nine of these patients met the strict criteria for morbid obesity; that is, they weighed more than 100 pounds over their ideal body weight, as defined by the median weight of the 1983 Metropolitian Life Insurance Tables, at the time of their surgery. One hundred fifty-four of these morbidly obese patients were diagnosed with NIDDM either before or during their preoperative evaluation for gastric bypass; these patients form the surgical group for this study. Seven hundred six patients seen by project investigators for initial consultation ultimately did not undergo gastric bypass. Among this group, 127 patients considered possible candidates for surgery were diagnosed with NIDDM either before or during their preoperative evaluations. Forty-nine of these 127 patients were excluded from this analysis for the following reasons: weight inadequate for a diagnosis of morbid obesity (22 patients), surgery denied for medical reasons (15patients), age greater than 64 years (2 patients), going elsewhere for surgery (8 patients), or lost to follow-up (2 patients). The remaining 78 patients were termed the control group for the purposes of this study.

Data on the patients in the surgical group were collected by reviewing the charts from the Obesity Research Clinic, where patients are followed at regular intervals after surgery. Data on the control group at the time of their initial presentation were obtained from their clinic records. Current follow-up data on survival and medical management of diabetes were obtained by phone interviews with the patients, their families, or their physicians for all 78 patients in this group. When patients were found to be deceased, the cause of death was obtained from the death certificate in all but two cases.

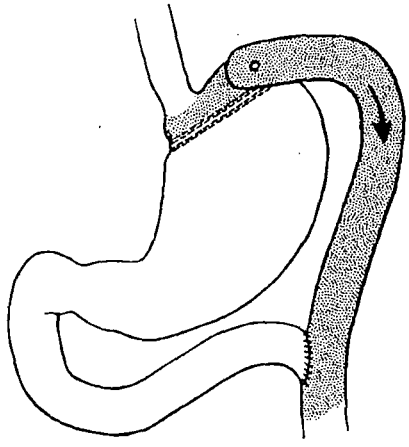

Fig. 1. Roux-en-Y gastric bypass.

Statistical Analysis

Statistical analysis was conducted using the SAS software with graphics supplied by the Plot-It program (Plot-It Scientific Programming Enterprises, Haslett, Mich.). Descriptive statistics such as means, standard deviations, counts of events, and totals were calculated for both the control and surgical groups. Student's *t* test for independent samples was used to test for differences between continuous variables, and the chi-square test was used to test for differences between proportions. The incidence densities (events divided by time of exposure to risk), incidence density ratios, and tests of hypothesis were also calculated. Confidence intervals (CI of 95%) were conducted under an exponential model, following a previously described approach.

The Gastric Bypass

Between March 5, 1979 and July 1, 1990, a standardized Roux-en-Y gastric bypass, as described by Pories et al.,[12] was performed in all patients (Fig. 1). A small proximal gastric pouch of approximately 30 ml was created by placing four rows of staples using a (double-armed PI-90 stapler, 3M Company, St. Paul, Minn.) from the angle of His to a point on the lesser curvature approximately 3 cm distal to the cardia. Much of the volume of the pouch was created by pulling up the anterior wall of the stomach. No vessels to the stomach were routinely divided during construction of the pouch. The jejunum was then divided at its apex, approximately 30 cm from the ligament of Treitz, with a GIA stapling instrument (Ethicon, Inc., Somerville, N.J.). The distal jejunal limb was then brought through the transverse meso-

Table I. Characteristics of surgical and control groups

Characteristics	Group: Surgical (n = 154)	Group: Control (n = 78)	*P* value
Mean baseline age (yr)	41.9	43.5	NS
Mean BMI	50.6	48.8	NS
Mean weight (pounds)	313.9	303.3	NS
Mean length of follow-up (yr)	9.0	6.2	<0.0001
% with hypertension	80.5	76.9	NS
Race (% white)	76.6	50.0	<0.001
Sex (% female)	76.6	73.1	NS

BMI = body mass index; NS = not significant.

colon and around the greater curvature to lie adjacent to the proximal gastric pouch. A side-to-side gastrojejunostomy was then performed in two layers with a running 3-0 polypropylene suture around an 18 F sump nasogastric tube, providing an internal diameter of approximately 0.8 cm. The Roux anastomosis, or jejunojejunostomy, was then constructed approximately 40 cm from the gastrojejunostomy.

With the use of this technique of partitioning the pouch with four parallel staple lines, we found an 11.8% incidence of staple line dehiscence over 11 years of follow-up.[13] The larger breakdowns usually were associated with a regain of lost weight and, in the diabetic patients, a return to abnormal glucose metabolism. In response to these findings, in July 1990, we modified our technique and began to perform a divided gastric bypass for primary as well as revision procedures. By dividing the proximal gastric pouch from the distal stomach, we hoped to eliminate the problem of staple line breakdowns; the gastrojejunostomy was constructed in a manner identical to the original procedure. In 100 consecutive divided gastric bypass operations, both primary and revision procedures, we encountered a 6% incidence of gastrogastric fistulas, or a fistulous communication between the proximal pouch and the distal stomach.[14] In five of the six patients these were revision operations. Although it appeared that minor variations in technique could lower the incidence of this complication, we wished to find a simpler, more reliable alternative. Since February 25, 1994, we have partitioned the stomach in our last 100 procedures with three superimposed applications of the PI-90 stapler without division. Only one of these 100 patients has thus far demonstrated a staple line breakdown on routine barium upper gastrointestinal studies obtained 6 months postoperatively. Except for the above-mentioned differences in construction of the partition, the operations have been identical and have been evaluated as one cohort in this study.

RESULTS

Group Characteristics

Table I lists the characteristics of the surgical and control groups, which were not significantly different in terms of age, weight, body mass index, sex, or the percentage with hypertension (80.5% of the surgical group vs. 76.9% of the control group). FIfty-six percent of the control group were being treated with antihypertensive drugs vs. 47% of the surgical group, again not a significant difference. The mean length of follow-up was significantly higher in the surgical group (9 years) compared to the control group (6.2 years). Follow-up for the surgical patients began at the time of the gastric bypass operation, whereas follow-up for the control subjects began at the time of the initial evaluation or when the diabetes was first diagnosed. There was a significantly higher percentage of white patients in the surgical group (76.6%) compared to the control group (50%). Fifty-six percent of the control group were on either oral hypoglycemic medication or insulin for treatment of their diabetes at the begining of the study, which was significantly greater than the 32% of the surgical patients whose diabetes was medically treated prior to gastric bypass surgery (Fig. 2).

Weight Loss and Glucose Levels After Gastric Bypass

Fig. 3 shows the mean percentage of excess body weight lost in the surgical group. After reaching a maximum 62.4% loss of excess body weight at 1 year after gastric bypass, the group demonstrated a slight regaining of weight over time with the mean loss re-

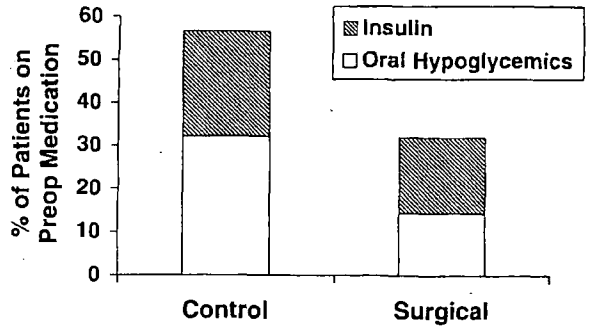

Fig. 2. Fifty-six percent of the control patients were treated with either insulin or oral hypoglycemics at the beginning of the study period, whereas only 32% of those in the surgical group were medically managed preoperatively.

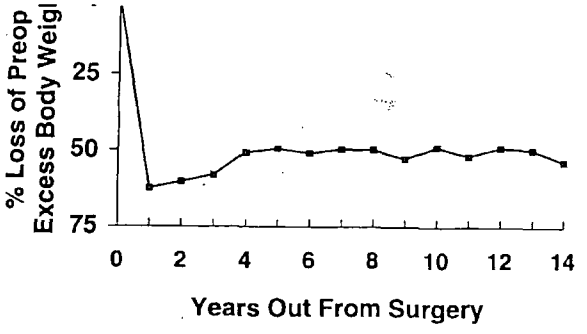

Fig. 3. Percentage of excess body weight lost in the surgical group (n = 154). The mean percentage loss of excess body weight reached a maximum of 62.4% 1 year after gastric bypass and remained at approximately 50% out to 14 years.

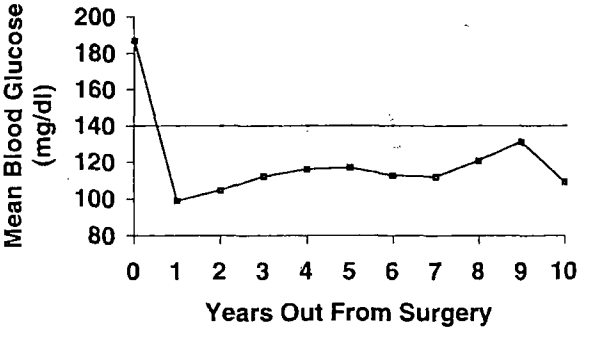

Fig. 4. The mean blood glucose level fell from 187 mg/dl (all fasting) to a minimum of 98.9 mg/dl (combination of random and fasting) at 1 year after surgery, and then remained less than 140 mg/dl out to 10 years.

maining at approximately 50% for up to 14 years of follow-up. In terms of actual weight, the group ranged from a preoperative mean weight of 314 pounds to a minimum of 206 pounds at 1 year after surgery. The mean weight then remained within a stable range of 199 to 224 pounds for up to 14 years.

Fig. 4 shows the mean blood glucose levels in the surgical group after gastric bypass. The preoperative glucose levels were all fasting values, whereas the mean values from the postoperative period were a combination of fasting and random glucose levels. Therefore these postoperative means should be skewed toward higher levels. Regardless, the mean blood glucose level fell from 187 mg/dl preoperatively to a low of 98.9 mg/dl at 1 year after surgery. The mean values then remained less than 140 mg/dl for up to 10 years of follow-up. Unfortunately, similar data were not available for a sufficient number of the control patients to allow a significant comparison.

Surgical vs. Control Groups

Diabetes. One method of comparing control of diabetes in the two groups with the data that were available to us was to compare the percentage of patients being treated with either oral hypoglycemics or insulin at the initiation of the study with the percentage of those requiring medical management at the time of our last contact with them. As shown in Fig. 5, the percentage of patients in the control group who were taking either oral hypoglycemics or insulin increased from 56.4% at the initiation of the study to 87.5% at the time of last contact, a significant increase (P = 0.0003). Conversely, the percentage of surgical

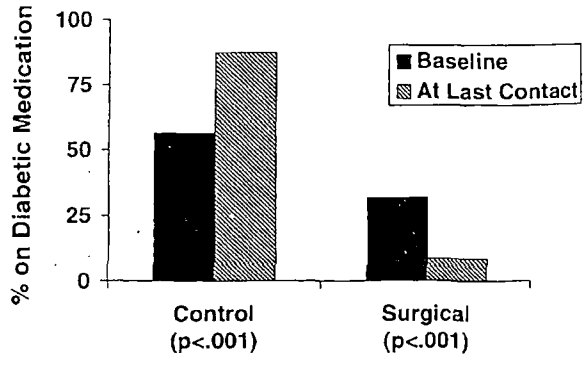

Fig. 5. The percentage of control patients being treated with insulin or oral hypoglycemics increased from 56.4% at first contact to 87.5% at last contact. The percentage of surgical patients requiring medical management fell from 31.8% preoperatively to 8.6% at last contact.

patients requiring medical management of diabetes fell from 31.8% preoperatively to only 8.6% at time of last contact, a significant decrease ($P = 0.0001$).

Death. Analysis of the number of deaths in each group (Fig. 6) revealed that 22 of the 78 control patients had died, compared to only 14 of the 154 surgical patients. This difference in mortality rates—28% for the control group vs. 9% for the surgical group—was highly significant ($P < 0.0003$) and was further emphasized by the fact that the mean follow-up in the surgical group was longer at 9 years than the 6.2 years in the control group. When this difference in length of follow-up was included in the equation to calculate the incidence of death per patient-year of follow-up (Fig. 7), the incidence in the control group was 4.5 times that of the surgical group ($P < 0.0001$). Based on the 95% confidence interval of the control group, we would expect to have observed between 46 and 58 deaths in the surgical group rather than the 14 deaths actually recorded.

Causes of Death

Table II lists the causes of death in the surgical and control groups. Most notable was the markedly increased incidence of cardiovascular death in the control group, which was responsible for 54.5% of the deaths among control subjects compared to only 14.3% of the deaths in the surgical group. The 12 cardiovascular deaths in the control group included eight myocardial infarctions, one sudden cardiac death, one case of congestive heart failure, one dissecting aneurysm, and one cerebrovascular accident. The single most common cause of death in the surgical group (4 patients) was perioperative mortality, which was responsible for 28% of the deaths in this group. These deaths included two cases of pulmonary emboli, one case of sepsis secondary to a leak, and one patient who died of unknown causes after being discharged from the hospital. The overall perioperative mortality rate for the entire group of 154 diabetic patients was 2.6%.

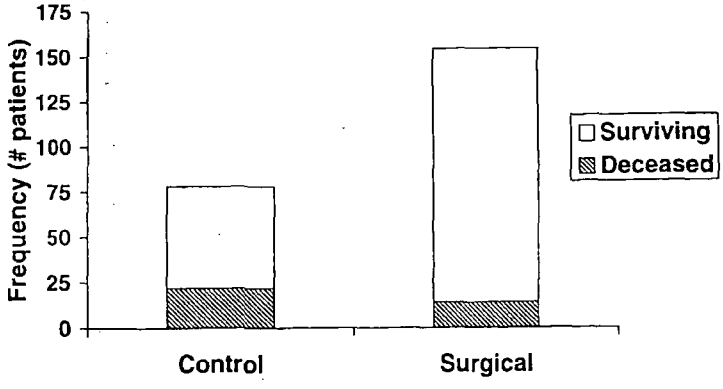

Fig. 6. The mortality rate in the control group was 28% (22 of 78 patients) compared to 9% (14 of 154 patients) in the surgical group ($P < 0.0003$).

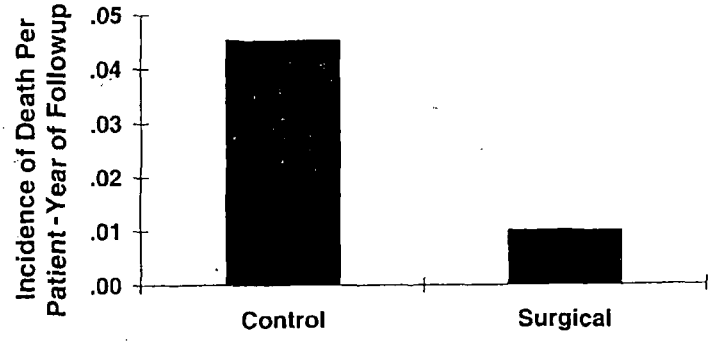

Fig. 7. Patients in the control group had 4.5 times the incidence of death of patients in the surgical group ($P < 0.0001$).

[SB 579, 1067]

Table II. Causes of death in control and surgical groups

Cause of death	No.
Control group	
Cardiovascular	12
Pulmonary embolism	1
Cancer	2
Sepsis	2
Acute respiratory distress	1
End-stage renal disease	1
Trauma	1
Suicide	1
Unknown	1
Total deaths	22
Surgical group	
Perioperative	4
Pulmonary embolism (subsequent revision)	1
Non–gastric bypass-related sepsis	1
Anemia	1
Asphyxia	1
Cardiovascular	2
Malnutrition	1
Auto accident	2
Suicide	1
Total deaths	14

Effect of Race on Mortality

Characteristics of the surgical and control groups that differed significantly were examined to determine those that were possibly responsible for the difference in mortality rates between the two groups. As shown earlier, black patients comprised 50% of the control group compared to only 23% of the surgical group, a significant difference. Fig. 8 shows that the statistically significant improvement in the mortality rate in the surgical group compared to the control group was maintained for both black and white patients. Although there was no difference in the incidence of death per patient-year of follow-up between black and white patients in the control group, there was a significant difference in the surgical group (0.024 in blacks vs. 0.006 in whites).

Effect of Diabetes Treatment on Mortality

Inasmuch as there was also a significant difference in the percentage of patients being treated with oral hypoglycemics or insulin at the beginning of the study period between the control and surgical groups (56% vs. 32%, respectively), we looked for a possible association with the difference in mortality rates between the two groups. It could be assumed, for example, that those requiring medical management had diabetes of longer duration or greater severity. We found, however, that there was a significant improvement in the mortality rate in the surgical group regardless of the initial treatment status of the patients (Fig. 9).

DISCUSSION

Although we have long had evidence that gastric bypass effectively controls NIDDM in most morbidly obese patients,[1,2] these are the first data from our group to demonstrate a decrease in the number of deaths after surgery as compared to a similar group of obese patients with diabetes who did not have surgery for nonmedical reasons. This improvement in the mortality rate was unrelated to differences in race or in the percentage of patients requiring oral hypoglycemics or insulin between the two groups.

We realize there are significant limitations to this retrospective study; although we were able to adequately determine the cause of death and type of medical management of diabetes in all control patients, we did not have adequate follow-up data regarding weight, blood glucose levels, or other comorbid conditions such as cardiac, pulmonary, or renal disease, which may have had an impact on survival. We do not believe a randomized, prospective trial of surgical vs. medical management would be possible, because most patients who are referred for surgery have exhausted all other options for weight loss and surgery represents the last resort. To suggest alternatives known not to be effective would raise ethical questions.

Acknowledging these limitations, we still believe this report strongly infers that gastric bypass surgery significantly improves the long-term mortality rate in morbidly obese diabetic patients, largely by reducing the number of deaths from cardiovascular causes. This improvement in cardiovascular disease could be due to other benefits of the surgery, in addition to control of diabetes, such as improvement in pulmonary artery hypertension due to obstructive sleep apnea and improvement in hypertension. Inasmuch as the hyperinsulinemia associated with NIDDM has been associated with the progression of coronary artery disease,[15] the greater reduction in insulin levels achieved with gastric bypass compared to operations that do not bypass the foregut, such as vertical banded gastroplasty,[16] may confer an additional benefit.

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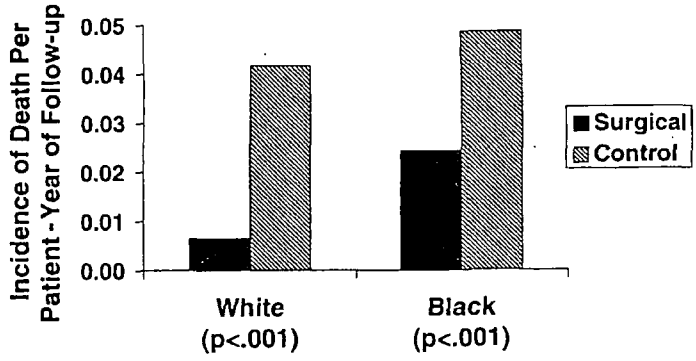

Fig. 8. The decrease in the mortality rate in the surgical group vs. the control group was significant for both white and black patients, although within the surgical group, black patients had a significantly higher mortality rate compared to white patients.

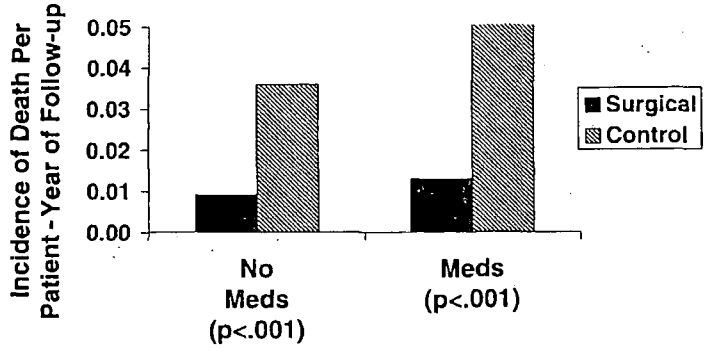

Fig. 9. The improvement in the mortality rate in the surgical group as compared to the control group was maintained whether or not diabetes was medically managed preoperatively *(Meds)*.

The percentage of control patients requiring medical management of their diabetes increases significantly over the follow-up period, from 56.4% to 87.5%, whereas among surgical patients on medication for diabetes the percentage droppped from 31.8% preoperatively to 8.6% at the time of the last contact. These results demonstrate the progressive nature of the disease when obesity is not treated and reconfirm the effective control of diabetes with gastric bypass in the majority of patients. In a previous study[9] we reported that 9% of 298 patients with either NIDDM or impaired glucose tolerance failed to become euglycemic after gastric bypass. Thirty-seven percent of this group were found to have mechanical failure of the gastric bypass, such as breakdown of the staple line or dilatation of the gastrojejunostomy. The remaining patients with intact gastric bypasses were found to be on average 7.3 years older and had had diabetes for 3 years longer than those patients who became euglycemic, again suggesting that NIDDM is a progressive disease that becomes more irreversible with time. Fortunately gastric bypass can prevent this progression in the majority of patients if it is performed in a timely fashion, before irreversible destruction of the function of the islets.

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Discussion

Dr. J. Kral (Brooklyn, N.Y.). From a public health perspective, this is one of the most important papers ever written by surgeons, given the enormity of the epidemic of obesity not only in industrialized nations but increasingly in third world countries as well. It is a credit to the authors and to the SSAT.

This report presents a whole new concept in surgery — that is, the notion that surgery can be used as a preventive measure. With early intervention in identifiable at-risk individuals, substantial morbidity and mortality can be prevented. Within a relatively short period of time, given the young age of these patients (mean of 42 to 44 years), it is extraordinary to achieve a fivefold decrease in mortality just by operating.

Equally spectacular is the 28% mortality rate in the control group, which is sufficient evidence of how devastating this disease is without effective treatment. There are two scientific flaws in this important work, and the authors are aware of both: the difference in race and the difference in severity of disease between the two groups. That is part of the problem of a retrospective study. Larger numbers are naturally needed. A prospective study, or at least a case-control or matching study, is necessary to be more conclusive. Such data are being gathered in the Swedish Obese Subject study. The major weakness in this present report is the source of information; that is, telephone interviews with patients or family do not provide the precision needed for this type of study. Finally, did you notice any gender difference in the deaths? I would predict that there might be an increased prevalence of death and poor outcome among men.

Dr. K.G. MacDonald. Unfortunately we do not know the sex of the patients who died. We were aware of the limitations of this study, but believed it was the best we could do. We tried to make the best possible use of the telephone interviews. The most accurate information we were able to obtain was whether or not the patients were taking medication for their diabetes and whether or not they had died. For the patients who died, we obtained the cause of death from the death certificate in all but two patients, so we thought it reasonable to at least try to use these data.

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Heart disease and hypertension in severe obesity: the benefits of weight reduction[1,2]

Peter N Benotti, Bruce Bistrian, Joseph R Benotti, George Blackburn, R Armour Forse

ABSTRACT Severe obesity is associated with abnormalities of cardiac structure and function. These include an increased cardiac workload and ventricular hypertrophy. Hypertension in combination with severe obesity seriously burdens the heart because the increased preload and afterload compound cardiac work. Weight reduction induced by gastric operations for severe obesity is associated with resolution of hypertension, reduction in ventricular wall thickness and cardiac chamber size, as well as improved systolic function. Additional data are needed to predict when in the course of development of obese cardiomyopathy the changes in contractile function become irreversible. Additionally, the impact of coronary artery disease on the progression of obese cardiomyopathy and the effects of surgical weight reduction on cardiac structure and function need to be further clarified. Studies of the association between obesity, its treatment, and modification of cardiovascular risk are a major focus of preventive cardiology today. *Am J Clin Nutr* 1992;55:586S–90S.

KEY WORDS Obese cardiomyopathy, gastric surgery for morbid obesity, hypertension

Introduction

The association between severe obesity, defined as twice, or 50 kg above, ideal weight, and serious health risk is well established (1, 2). The premature morbidity and mortality in severely obese patients is related to the adverse effects of obesity on heart and lung function as well as the association between obesity and metabolic abnormalities like diabetes and hyperlipidemia, which are major cardiovascular risk factors. The purpose of this paper is to define the specific alterations in cardiac structure and function that are associated with severe obesity and to review the data regarding the effect of gastric-restrictive surgery and its associated weight loss on cardiac structure and function.

The initial observations of abnormalities of the heart in severe obesity derive from autopsy studies of massively obese patients dying of congestive heart failure without clinical evidence of hypertension or cardiac disease. These early studies indicated that in severe obesity the heart weight is significantly increased above normal and is directly related to body weight up to a weight of 105 kg (3). A subsequent postmortem study of 12 patients dying of severe obesity without obvious cardiovascular disease revealed increases in myocardial weight and left ventricular wall thickness. This study demonstrated that ventricular hypertrophy is the cause of the increased heart weight in obesity (4). In a Veterans Administration study of nine severely obese patients at autopsy, increased heart weight and left ventricular thickness was noted in all patients (5). Left ventricular hypertrophy in the absence of significant coronary atherosclerosis was found in all patients even though 56% of the patients were > 60 y of age (5).

Fatty infiltration of the heart was originally thought to be a major contributor to the increased heart weight noted in the severely obese. This occurs primarily as an extension of epicardial adipose tissue into the myocardium. The right ventricle is the most commonly involved site for fatty infiltration. However, studies indicate that this occurs relatively infrequently in severely obese patients coming to autopsy, and its clinical significance involving arrhythmias and sudden death is related to fatty infiltration of the conduction system (6).

Hemodynamic changes in obesity

Severe obesity is associated with major increases in total-body-fat mass, which require increased blood flow to support the active metabolism of adipose tissue. It has been estimated that 2–3 mL of blood is necessary to perfuse every 100 g of adipose tissue at rest. In the patient with 100 kg of fat, this would require up to a 3 L/min increase in blood flow (6). Gross obesity is also associated with significant increases in the size of the skeletal muscle compartment and skin. Expansion of these body compartments requires additional increments in circulatory demand. The expanded fat compartment and, to a lesser extent, lean body mass result in an increased total body oxygen consumption at any given degree of exercise (6). Because arteriovenous oxygen differences are normal in obesity, the increase in body oxygen consumption associated with obesity requires an increase in cardiac output. Resting heart rate does not change in obesity and thus stroke volume increases to provide the increased cardiac output. The increase in stroke volume is associated with increases in total blood and plasma volume, which seem to correlate with increases in body weight over ideal (7). In severe obesity the increased cardiac output is associated with a reduced systemic vascular resistance as mean blood pressure is maintained within

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TABLE 1
Hemodynamic data obtained via right (10) or left (8) heart catheterization in severely obese patients

Variable	Severe obesity		Normal
	Alud-din et al (10)	Divitiis et al (8)	
Heart rate (beats/min)	84 ± 2*	84.6 ± 13*	80–120
Blood pressure (mm Hg)	132/79	145/93	90–140/60–90
Oxygen consumption (mL/min)	—	311.5 ± 77*	250
Cardiac output (L/min)	8.3 ± 0.4*	7.56 ± 1.3*	4.8–8.9
Cardiac index ($L \cdot min^{-1} \cdot m^{-2}$)	3.61 ± 0.16*	3.45 ± 0.40*	2.8–4.2
Left ventricular stroke work (g-m/beat)	162 ± 9*	116.3 ± 21*	—
Subjects (n)	29	10	

* $\bar{x}$ ± SD.

normal limits. At rest or any level of activity, an obese patient demonstrates a greater total body oxygen consumption, cardiac output, plasma volume, and left ventricular stroke work in comparison with lean controls (6, 8–11) (**Table 1**).

In normotensive severe obesity, major increases in total blood and plasma volumes occur in association with increases in cardiac output. Systemic vascular resistance is reduced because of the increased circulatory demand. The increased stroke volume results in an increased left ventricular cavitary size to accommodate the increased preload. With an increased left ventricular dimension, the left ventricular wall thickness increases proportionately to maintain myocardial wall stress (6). Therefore, obesity is a major stimulus for left ventricular hypertrophy. In obesity, left ventricular mass increases in proportion to ventricular cavitary size to maintain cardiovascular reserve (6) (**Table 2**).

In severe obesity complicated by hypertension, cardiac output is increased, preload is increased, and mean blood pressure is increased. Thus, systemic vascular resistance is not as low as it is in uncomplicated obesity, but normal (13). The increased afterload associated with hypertension will increase the wall tension in the left ventricle as normal ejection is maintained. To maintain ventricular performance in the face of sustained increases in afterload, ventricular hypertrophy develops. In hypertension with obesity, systemic vascular resistance is higher, increasing the afterload on the ventricle. This requires increased ventricular pressure generation, which adds to myocardial work. Hypertension and obesity combine to increase cardiac work significantly. Myocardial work is the product of stroke volume and mean left ventricular pressure generated. In hypertension the increased myocardial work stems from an increased left ventricular pressure generated whereas in obese patients the increased myocardial work is secondary to an increased stroke volume. Thus the obese hypertensive patient suffers from markedly increased stroke work because of a combination of volume and pressure overload state (13) (**Table 3**).

Often in states of cardiac hypertrophy, coronary blood flow reserve may become limiting as ventricular mass increases and metabolic demands of the myocardium increase. With time the ability of the overburdened ventricle to maintain adequate function declines and the severely obese hypertensive patient is predisposed to develop congestive heart failure (6, 13). The increases in left ventricular hypertrophy are also associated with an increased risk and complexity of ventricular ectopy (6, 13). This ventricular ectopy may be an explanation for the significant incidence of sudden death in these patients (14) and may be a manifestation of left ventricular hypertrophy exceeding a critical mass beyond which myocardial blood supply becomes limiting or progressive interstitial fibrosis causing progressive discontinuity of myocardial tissue.

TABLE 2
Data obtained by echocardiography in severely obese patients*

Variable	Alud-din et al (10)†	Alpert et al (12)†	Normal
Left atrium (cm)	3.47 ± 0.11	3.6 ± 0.2	2–3.5
Left ventricle (systolic) (cm)	2.98 ± 0.04	3.7 ± 0.2	2–3.5
Left ventricle (diastolic) (cm)	4.74 ± 0.95	5.7 ± 0.3	4–5.2
Posterior wall (cm)	1.05 ± 0.09	1.1 ± 0.1	0.8–1
Intraventricular septum (cm)	1.05 ± 0.02	1.1 ± 0.1	0.6–1
Left ventricular mass (g)	430 ± 14	—	300
Subjects (n)	30	34	

* The data demonstrate increase in cavitary size as well as wall and septal thickness.

The cardiomyopathy of obesity is often accompanied by signs of systemic congestion. The state of chronic fluid overload is necessary to maintain ventricular performance as the ventricle hypertrophies and loses its compliance (6, 13). Salt and water retention occurs to sustain the enhanced preload. Pulmonary artery mean pressures and pulmonary artery wedge pressures have been shown to be elevated and may exceed 12–15 mm of mercury (6, 8, 10). The cardiovascular response to exercise will eventually become abnormal with an increase in pulmonary artery wedge pressure and pulmonary artery mean pressure, as well as an increase in heart rate with a decline in ejection fraction (6, 10).

Alpert et al (15) studied 23 severely obese patients with radionuclide ventriculography before and during exercise. More than one-half of the patients had a depressed left ventricular ejection fraction. Ten of 23 patients had an expanded left ventricular mass. The patients were restudied after a graded exercise period. A normal increase in ejection fraction was observed only in those patients with normal ventricular mass. The change in ejection fraction with exercise was significantly different in those patients with normal ventricular mass and those with increased

TABLE 3
Summary of the additive effects of severe obesity and hypertension on cardiac work*

Parameter	Severe obesity	Severe obesity and hypertension
Vascular resistance	↓	Normal
Blood pressure	Normal	↑
Afterload	↓	↑
Preload	↑	↑
Stroke work	↑	↑↑

* ↓, lower; ↑, greater; ↑↑, much greater.

left ventricular mass. Thus, ventricular mass, which correlated with body weight, (r = 0.912) was a good predictor of systolic reserve in that the exercise response in this study had a strong negative correlation (r = 0.829) with left ventricular mass.

With time and progression of severe obesity, the ability of the ventricle to maintain performance declines. This begins a vicious cycle that results in diminished ventricular performance with corresponding enhanced fluid retention. The result is further weight gain in conjunction with edema of pannus, legs, and scrotum. When ventricular performance declines sufficiently, the augmented preload originally necessary to maintain performance eventually evolves into frank congestive heart failure. Many recent noninvasive studies of heart function in severe obesity have confirmed the presence of left ventricular hypertrophy and abnormalities of systolic function (10, 12, 15–17). Zarich et al (18) also demonstrated abnormalities in diastolic filling in 50% of asymptomatic severely obese patients in a noninvasive study.

Obesity and coronary artery disease

Obesity is a known risk factor for the development of premature cardiovascular disease (1, 19, 20). The association between obesity and major coronary artery disease risk factors, including hypertension, diabetes, and hypercholesterolemia, is well established. The exact influence of coronary artery disease on the progression of the obese cardiomyopathic state is not clear. Autopsy data involving the study of large numbers of patients with severe obesity dying of congestive heart failure consistently demonstrate little in the way of gross coronary artery disease. There is limited coronary angiographic data published in patients with severe obesity. The exact influence of large and small vessel disease on the coronary reserve necessary to support the overworked hypertrophied ventricle of the severely obese patient is not known. One can speculate that diabetes and hyperlipidemia, which are common in obese patients, should adversely effect the microperfusion in the subendocardium of the hypertrophied ventricle.

Clinical studies suggest an association between body size and risk of clinical events related to coronary artery disease such as angina, myocardial infarction, etc (20). Additional data suggest that the distribution of obesity, in particular, in the abdomen is a better predictor of premature cardiovascular morbidity than the body mass index or other indicators of total body fat (21, 22).

There is little information addressing the effect of weight loss on the progression of coronary artery disease. There is an abundance of inferential information regarding the effect of gastric surgery for weight reduction on the specific cardiovascular risk factors. This information is presented elsewhere in this supplement (23, 24).

Severe obesity and hypertension

There is a large body of evidence linking obesity to the prevalence of hypertension (25, 26). The largest community screening study of over a million people demonstrates that the prevalence of arterial hypertension is twice as high in overweight people between the ages of 20 and 39 y as in people with normal weight. In this study the incidence of hypertension among persons aged 40–64 y was increased by 50% in obesity as compared with normal-weight control subjects (27). In addition, MacMahon et al (28) estimated that ~30% of arterial hypertension can be attributed to obesity. The link to hypertension is related not merely to excess body fat but to the waist-hip ratio and other indicators of abdominal or truncal adiposity. Longitudinal population studies such as the Framingham study indicate that interim weight gain also increases the risk of hypertension (26).

The impact on myocardial function of obesity and hypertension has been reviewed previously. The adverse effect of obesity and hypertension on cardiac workload is additive (Table 3). Autopsy studies reveal the greatest heart weight in patients in whom obesity is associated with hypertension (3). The combination of obesity and hypertension significantly increases the risk of congestive heart failure as well as ventricular ectopy and sudden death (6, 13, 14). Of interest is the fact that obese hypertensive patients seem to be slightly less prone to other cardiovascular morbidity common to hypertension, namely cerebrovascular accidents and nephrosclerosis. This may be related to the protective effect of a relative reduction in total peripheral resistance on the pathogenesis and progression of arteriolar injury for a given level of hypertension in severely obese patients (13).

Effects of weight reduction

Numerous studies of medical weight reduction have confirmed that weight loss is associated with a fall in blood pressure in obese hypertensive patients (29–31). The maximum fall in blood pressure occurs well before normal weight is achieved (32). The mechanism is thought to relate to diuresis and contraction of blood volume, with possible reductions in sympathetic drive (29–31). If systemic vascular resistance remains constant, a decline in blood volume is associated with a reduction in cardiac output.

TABLE 4
Summary of the clinical data demonstrating ventricular dysfunction in severely obese patients

Author	Manner of study	No. subjects	Findings
Divitiis et al (8)	Left heart catheterization	10	Impaired ventricular function in 80%
Alpert et al (15)	Radionuclide left ventriculography, echocardiography	23	Resting ventricular function depressed in 13
Alud-din et al (10)	Radionuclide left ventriculography, right heart catheterization	30	Abnormal response to exercise
Garavaglia et al (16)	Echocardiography	23	Depressed contractility related to ventricular mass (obesity and hypertension)

TABLE 5
Summary of available data demonstrating favorable changes in cardiac structure and function after gastric surgery for severe obesity

Author	Manner of study	No. subjects	Findings
Alpert et al (12)	Echocardiography	34	Significant improvement in fractional shortening associated with significant fall in LV internal dimension, fall in mean BP.
Alud-din et al (10)	Echocardiography		Reduced atrial dimension
	Radionuclide ventriculography	12	Reduced ventricular wall and septal size
	Right heart catherization		Improved response to exercise

In severely obese patients undergoing gastric-restrictive surgery, Foley et al (33) surveyed 289 consecutive patients over a 6-y period. Seventy-four (26%) were hypertensive preoperatively. Preoperative hypertension resolved in 66% of these patients, with 91% follow-up at 4.25 ± 0.2 y. The amount of weight loss significantly predicted hypertension reduction, whereas final weight achieved did not correlate with hypertension reduction. For those whose hypertension resolved, weight loss was 40.1 ± 2.7 kg pounds, and for those whose hypertension persisted after gastric surgery, weight loss was 30 ± 4 kg ($P < 0.02$). The final weight for those whose hypertension resolved after surgery was 133 ± 4% of ideal for the severely obese and 170 ± 7% of ideal for the superobese patients. This study shows that gastric surgery for obesity is an effective therapy for hypertension and that the usual weight reduction associated with these procedures can be expected to provide hypertension control even though the final weight achieved may be well in excess of ideal body weight (33).

In addition to resolving hypertension, the weight reduction associated with severe obesity surgery has been shown to favorably affect cardiac structure and function. MacMahon et al (17) studied moderately obese subjects (body mass index 31.8) undergoing medical weight reduction ($\bar{x}$ weight loss 8.3 kg). They noted significant reductions in systolic blood pressure, interventricular septal thickness, and in left ventricular mass with weight loss.

Alpert et al (12) studied 64 severely obese patients all twice ideal body weight with no clinical signs of organic heart disease or hypertension. These patients underwent gastric-stapling procedures to control severe obesity. Preoperatively 32–56% of the patients had enlarged ventricular internal dimension in diastole, as well as increases in ventricular septal and posterior wall thickness. Thirty-four patients were studied after 73% of excess weight was lost. Body weight fell from 135 ± 8 kg to 79 ± 6 kg. In 13 patients with reduced preoperative left ventricular fractional shortening, there was a significant increase in left ventricular fractional shortening measured after weight reduction. These changes were associated with significant reduction in left ventricular internal dimension in systole and diastole and significant reduction in mean blood pressure. This study demonstrates a systolic dysfunction in severe obesity that seems to improve after surgically induced weight loss.

Alaud-din and co-workers (10) studied 30 patients before bariatric surgery and 12 patients 13 ± 4 mo after surgery. Cardiac function was studied by echocardiography, radionuclide angiography, and right heart catheterization. These patients were studied before and after exercise and fluid challenges to better detect ventricular function reserve. These authors confirmed previous findings as they demonstrated, by ultrasound, myocardial thickening with an increase in interventricular septal thickness and left ventricular mass in 32–53% of patients. After weight loss, wall and interventricular septal thickness was reduced. Radionuclide scan demonstrated increased end diastolic volume and diminished left ventricular ejection fraction in comparison to normal control subjects. After exercise, the control group increased cardiac rate, end diastolic volume, and stroke volume, thus increasing cardiac output significantly. The severely obese patients increased heart rate only. In the severely obese patients after weight loss, exercise resulted in increases in stroke volume and cardiac output.

In addition, the right heart catheterization studies revealed filling pressures in the high normal range. Exercise produced significant increases in pulse rate and pulmonary capillary wedge pressure. Cardiac output increased primarily because of an increase in heart rate. Stroke volume did not increase with exercise. Fourteen of the 29 patients had an abnormal response to exercise, with a fall in left ventricular stroke work index with exercise. Six patients were studied with right heart catheterization after surgical weight loss. A more normal response to exercise was demonstrated in these patients, namely an increase in stroke volume, a fall in filling pressures, and an increase in left ventricular stroke work index (10).

This detailed study provides further evidence of systolic dysfunction and limited systolic reserve in association with severe obesity (**Table 4**). The authors also present evidence that systolic function and cardiac reserve seem to improve with weight reduction after gastric-restrictive surgery for severe obesity (10) (**Table 5**).

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Effect of Surgically Induced Weight Loss on Asthma in the Morbidly Obese

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Forty morbidly obese asthmatic patients who underwent gastric restrictive surgery more than 2 years earlier were evaluated to determine the influence of weight loss on asthma outcome. Mean percentage excess weight loss in this group was 68% and body mass index (BMI) fell from a mean of 46 to 30. Following surgery, 90% showed improvement in asthma symptoms. Complete remission of asthma occurred in 48% and a further 12.5% became asthma free on reduced medications dosage. Of those taking daily medications for asthma before surgery, 42% were completely off medication following weight loss surgery, and another 18.5% experienced fewer asthma attacks on reduced medication dosage. Of the 22 patients with severe asthma (>10 attacks per year) on routine daily medications for asthma preoperatively, 8(36%) required no medication after surgery, 7(32%) used medication only on an 'as-needed' basis, and 7(32%) controlled their asthma on reduced medication dosage. Five patients gained weight during the follow-up period. All developed an increased incidence of asthma attacks, which again abated after successfully losing weight following revisional surgery. Coexistent factors of smoking and clinically apparent esophageal reflux were evaluated, but no statistically significant correlation was shown with either smoking or reflux and improvement in asthma. Possible etiologies of the improvement in asthma with weight loss are discussed

Key words: Asthma, gastric restrictive surgery, gastro-esophageal reflux, morbid obesity, smoking, weight loss.

Introduction

Obesity is a major health problem in the USA.[1] Approximately 30% of the population is overweight, to a degree sufficient to adversely affect health.[2] Obesity-related health problems include hypertension, adult onset diabetes mellitus, and pulmonary restriction most dramatically illustrated by life-threatening sleep apnea and Pickwickian syndrome.[3] The effects of obesity on pulmonary function have recently been reviewed[4] and the benefits of surgically induced weight loss on morbid obesity and its related medical conditions including pulmonary sequelae have been reported.[5–8] Two authors make reference to the beneficial effect of weight loss in morbidly obese asthmatics,[9,10] but there are no detailed evaluations of this phenomenon in the literature.

This paper reviews the results of surgically induced weight loss in a series of morbidly obese asthmatics with particular attention to the changes in frequency and severity of asthma attacks following weight change.

Patients and Methods

Forty morbidly obese patients with severe or moderately severe asthma who have been subjected to either gastric bypass or vertical banded gastroplasty by one surgeon (A.M.) were reviewed. Only patients whose surgery occurred more than 2 years previously were included in this study. The average duration of follow-up was 4 years (range 2–11 years). There were 32 females and eight males, a F:M ratio of 4:1. Of the 40 patients, five had vertical banded gastroplasty and 35 had gastric bypass with Roux-Y jejuno-jejunostomy. Average patient age at surgery was 45 years (range 23–68 years), 45 years for females and 44 years for males. The mean body weight at surgery was 129 kg. Mean BMI was 46.

Patients were graded for severity of disease by two parameters (Table 1): (1) frequency of asthmatic attacks and (2) intensity of drug therapy. Prior to surgery, 28 patients had severe asthma (>10 attacks per year), and 12 had moderate asthma (>six but <10 attacks per year). Of the patients, 29 (72.5%) were on routine

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Table 1. Preoperative status: 40 patients

Frequency		
>10 attacks/year ('severe')	28	(70%)
>6 attacks/year ('moderate')	12	(30%)
Severity		
Daily bronchodilators	29	(72.5%)
Medications 'as needed'	11	(27.5%)
Combination		
>10 attacks/year in spite of routine medication	22	(55%)

bronchodilators, and 11 (27.5%) took medication on an 'as-needed' basis. Of the 28 patients who had more than 10 asthma attacks yearly, 22 were on routine bronchodilator therapy.

In addition to weight loss, other factors which might affect asthmatic symptoms were taken into consideration, particularly the presence or absence of acid reflux before and after the weight loss procedure, and smoking history. Of the 40 patients, 20 complained of heartburn prior to surgery, and 20 did not. Since this was a retrospective study, no acid or esophageal studies were performed. The diagnosis of reflux was made primarily on a symptomatic basis. Of the total series of 40 patients, 22 have never smoked. Nine patients smoked prior to their surgery and continue to do so. Nine smoked in the past but have not smoked since their gastric restrictive surgery.

Results

Weight Loss

Mean weight loss at follow-up an average of 4 years later (range 2–11 years) was 45 kg. Mean percent excess body weight loss (%EBWL) was 68%. Mean postoperative BMI was 30, a reduction of 16.

Symptom Change

Following surgically induced weight loss, 36 (90%) patients showed some degree of improvement. Three (7.5%) were unchanged and one (2.5%) was worse. Of the 36 improved patients, 19 (49%) reported complete remission of their asthma and were off all asthma medication. Five (12.5%) patients reported no attacks, but continued medication at reduced dosage. Seven (18.5%) had fewer attacks but required to continue medication, though at reduced dosage, while five (12.5%) reported attacks only on a seasonal/allergy-related basis.

Medication Change

Bronchodilators were used by 29 patients on a daily, routine basis prior to surgery. Of these, 12 (42%) no longer use medications for asthma. Seven (24%) use them on an 'as-needed' basis, and 10 (34%) continue on daily medications, but at reduced dosage.

Most Severe Group

Out of the group of 22 patients with the most severe disease, who suffered more than 10 attacks yearly in spite of routine bronchodilators, eight (36%) no longer use asthma medications, seven (32%) use medications only on an 'as-needed' basis, and the remaining seven (32%) continue with medication, but at reduced dosage.

Weight Regain

Of the total of 40 patients followed up for 11 years, eight had revisional surgery during the course of their follow-up. Of these, two were revised for reasons other than weight gain, and reported no change in their asthma. Five gained weight and all five again noted an increased incidence of asthmatic attacks, which resolved following successful revisional surgery with subsequent weight loss. One patient failed to lose weight following revision and his asthma failed to improve.

Smoking

In the 90% of patients whose asthma improved following bariatric surgery, 22 of 36 (61%) never smoked, either before or after the surgery. Six smoked preoperatively but subsequently stopped smoking, and eight smoked before surgery, and continued to do so postoperatively (Table 2).

Table 2. Smoking history

	Improved	Unchanged	Worse
Smoked in past, not currently	6	1	1
Smoked in past, currently smoking	8	2	
Never smoked	22		
Total	36	3	1

Table 3. Heartburn

	Improved	Unchanged	Worse
Present pre-op, none post-op	18	1	1
None pre-op, none post-op	13	1	
Present pre-op and post-op	3	1	
None pre-op, present post-op	2		
Total	36	3	1

Of the three whose asthma remained unaffected by weight loss, two smoked preoperatively but subsequently ceased. The other continues to smoke cigarettes. The one patient whose asthma worsened following weight loss, gave a history of smoking prior to surgery only.

Acid Reflux

Eighteen (50%) of the 36 patients whose asthma was improved by weight loss complained of heartburn preoperatively which completely resolved postoperatively. Another 13 (36%) denied symptoms either before or subsequently. In three (8%) patients asthma improved but heartburn did not, and two patients complained of onset of heartburn after surgery which was not present preoperatively (Table 3).

Of the three patients whose asthma failed to improve with weight loss, one complained of heartburn preoperatively which resolved following surgery, one of heartburn which came on after surgery, never having been present previously, and one continued with heartburn which had been present before surgery. In the one patient whose asthma worsened, preoperative heartburn existed, which, unlike the asthma, completely resolved following weight loss.

Data Analysis

Data were analysed by Pearson's product moment correlation and analysis of variants (ANOVA). Significant correlation between weight loss and improvement in asthma symptoms was found ($p = 0.0093$ with a 0.01 level of significance). No statistically significant association was found to exist between smoking and improvement in asthma symptoms or between reflux and improvement in asthma symptoms.

Discussion

Asthma is a disease of the airways characterized by increased responsiveness of the tracheobronchial tree to a multiplicity of stimuli including allergens, drugs such as aspirin and related substances, environmental and occupational factors, infections, exercise and emotional stress. Asthma is manifest clinically by paroxysms of dyspnoea, cough, and wheezing. It is an episodic disease, acute exacerbations being interspersed with symptom-free periods. The pathologic hallmark of asthma is reduction in airway diameter brought about by contraction of smooth muscle, edema of the bronchial wall and thick tenacious secretions.[11] The natural course of adult onset asthma has been little investigated, but some studies suggest that spontaneous remissions occur in approximately 20% of those who develop the disease as an adult and that 40% or so can be expected to improve with less frequent and severe attacks as they grow older.

Reduction in the incidence and severity of asthmatic attacks in previously obese patients following weight loss has been briefly reported in the literature.[9,10] Brolin[9] describes a 56% resolution rate in 25 asthmatic bronchitics following gastric bypass, an additional 40% were improved, and 4% were unchanged. The Adelaide group also mentions the beneficial effect of weight loss in the asthmatic obese, with six of 12 patients (50%) being off medication 3 years after surgery.[10]

Consideration must be given to the possibility that the dietary changes induced by gastric restrictive surgery, rather than the weight loss, underlie the beneficial effects. There are a few patients with asthma who develop bronchospasm after ingestion of certain foods, notably shellfish. Although food allergy has not been clearly shown to cause asthma, many physicians believe that elimination diets are of therapeutic value and employ such an approach, advocating avoidance of certain foods, particularly shellfish, poultry, dairy products, nuts and chocolates. Metabisulfites, widely used in food processing and as additives to beer, wine, salads and vegetables, may rarely cause explosive asthma.[12] Following gastric bypass, considerable dietary changes ensue, with avoidance of many dairy products by the 40% of patients who become intolerant of lactose, avoidance of chocolate, and marked reduction of red meat intake. It is possible that these changes may be significant in a few individuals.

Gastroesophageal reflux (GER) is defined as the movement of gastric contents into the esophagus. This material, which may contain acid, pepsin, bile acids and

pancreatic enzymes, has the ability to irritate or injure tissue not adapted to the presence of the potentially noxious material. The use of 24-h pH monitoring has shown that almost all individuals have regular episodes of reflux as part of their normal digestion, occurring in the upright position (physiologic reflux).[13–15]

Acid sensitivity of the esophagus without esophagitis, as manifested by heartburn, is extremely common. Conversely pathologic reflux leading to esophageal and/or extraesophageal manifestations with tissue injury may occur without pain or the sensation of heartburn.[16,17] Many individuals are not aware of the presence of refluxed gastric contents, even with the development of the most severe form of esophageal injury (e.g. as many as one-third of those with Barretts esophagus are unaware of reflux symptoms).[18]

An association between GER and asthma has long been recognized and recently confirmed.[19] Osler, in his 1892 text, noted the risk of asthma in the overfilled stomach, stating that asthmatic patients learn to take their large daily meal at noon to avoid night-time asthma which occurred if they ate a full supper.[20] In 1934, Bray[21] suggested that vagal reflexes from the gastrointestinal tract were responsible for asthma attacks in patients when they overindulged. Clemencon[22] in 1961 first recognized the increased incidence of hiatal hernia and GER in asthmatics. Kjellen *et al.*[23] reported that conservative treatment of esophageal dysfunction was associated with a reduction in asthma symptoms and medication. Cooper *et al.*[24] have reported that treatment of such patients with cimetidine causes a decrease in nocturnal asthma. This association seems most significant in nocturnal asthmatics, and it is logical that acid-induced asthma would occur at night while the patient is asleep and supine.

There are two postulated mechanisms leading to reflux-induced symptoms. One is microaspiration of gastric contents, resulting in bronchial irritation, wheezing and coughing. This has been demonstrated by radionuclide scanning in patients with GER, a study which may be more predictive of a good response to H_2 blockers than 24-h esophageal pH monitoring.[25] The second mechanism involves reflex changes induced by the presence of acid in the esophagus. Wright[26] recently reported significant reduction in arterial oxygen saturations and 1-s forced expiratory volumes during esophageal acid infusion, suggesting a reflex increase in airway resistance, and therefore a potential tendency toward asthma. Mansfield and Stein[27] demonstrated that intraesophageal acid infusion increased pulmonary airflow resistance in 15 asthmatic patients and that such increased resistance was reversed by antacid therapy. These reflexes appear to be vagal in origin.[27,28] Bronchodilators commonly used in the treatment of asthma may decrease the lower esophageal sphincter pressure and encourage reflux.[29,30] In a randomized controlled trial, Larrain *et al.*[31] treated eight patients with cimetidine, surgery or placebo. At 6 months, 36% of the placebo group remained improved compared with 77% of the surgical and 74% of those treated with H_2 blockers and anti-reflux regimen. Others have published similar findings (Table 4).

Table 4. Effect of anti-reflux medical therapy on pulmonary symptoms in adults

Author	Subjects number	Pulmonary symptoms				GER symptoms			
		C	VI	I	NI	C	VI	I	NI
Mays[32]	28			28				28	
Larrain *et al.*[31]	27			20	7				
Goodall *et al.*[33]	18			18				18	
Harper *et al.*[34]	15		15				15		

C, complete; VI, very improved; I, improved; NI, not improved.
Modified from: Mansfield LE, *Ann Allergy* 1989; **62**: 158–63.

Aggressive surgeons have utilized anti-reflux operative procedures in the management of nocturnal asthma. Sontag *et al.*[35] published the results of anti-reflux surgery in 13 asthmatics with symptoms refractory to H_2 blockers. Six patients were relieved of all symptoms, and were able to stop all bronchodilators, while six others had marked reduction in symptoms and bronchodilator dose. Perrin-Fayolle *et al.*[36] treated 44 patients with severe asthma and GER by Nissen fundoplication and followed them for a mean of 8 years. They found that 25% of asthmatics were totally cured, 41% had moderate to marked improvement in their asthmatic symptoms and 34% were unchanged. These results are included in the list of published results of anti-reflux surgery on pulmonary symptoms (Table 5).

Gastric restrictive procedures have anti-reflux effects. Deitel *et al.*[44] described the physiologic changes which follow vertical banded gastroplasty and its effects on lower esophageal sphincter pressures with improvement in GER. Roux-Y gastric bypass has recently been reported as an effective anti-reflux procedure.[45] This is not unexpected in a procedure which is functionally a subtotal gastrectomy with simultaneous diversion of the duodenal bile, a principle which has been utilized successfully in the past with

Table 5. Effect of anti-reflux surgery on pulmonary symptoms in adults

Author	Subjects number	Pulmonary symptoms				GER symptoms			
		C	VI	I	NI	C	VI	I	NI
Kennedy[37]	15	15				15			
Babb *et al.*[38]		2	2			2			
Overholt and Ashraf[39]	28	6	17	2	3	14	7		
Urschel and Paulson[40]	27	24							
Klotz and Moeller[41]	3		2		1				
Sternlieb and Kashan[42]	1	1				1			
Sontag *et al.*[35]	13	6	6		1	13			
Zaloga *et al.*[43]	1	1					1		
Perrin-Fayolle *et al.*[36]	44	11	7	11	15	42			2

C, complete; VI, very improved; I, improved; NI, not improved.
Modified from: Mansfield LE, *Ann Allergy* 1989; **62**: 158–63.

Table 6. Effect of gastric restrictive surgery on asthma

Author	Subjects number	Pulmonary symptoms				GER symptoms			
		C	VI	I	NI	C	VI	I	NI
Brolin[9]	25	14	10		1				
Hall *et al.*[10a]	12	6							
Macgregor[4]	40	19	5	12	4	34			6
Total	77	39	15	12	5				

C, complete; VI, very improved; I, improved; NI, not improved.
[a]No details of six patients who were not totally off medications post-operatively.

use of antrectomy plus Roux-Y diversion to treat reflux esophagitis[46].

In our series, half the patients whose asthma improved following weight loss complained of heartburn preoperatively which totally resolved following surgery. However, another third of those whose asthma improved following surgery did not have preoperative heartburn, and in three patients asthma improved following weight loss but heartburn did not. There was no statistical correlation between GER, defined in our series by clinical heartburn, and resolution of asthmatic symptoms. However, the known effects of asymptomatic acid reflux on pulmonary performance leaves this conclusion in question. It is of interest to note the symptomatic deterioration with weight gain and subsequent improvement in asthma with successful revisional surgery (see Tables 6 and 7).

Additional prospective studies with quantitation of acid reflux and its pulmonary effects before and after weight loss surgery will be necessary to separate the roles of weight loss and of acid reflux in the clearly beneficial effects of bariatric surgery in the obese asthmatic.

Table 7. Summary of effects of therapeutic anti-reflux measures on asthma

	Subjects number	Pulmonary symptoms (%)				GER symptoms			
		C	VI	I	NI	C	VI	I	NI
Medical therapy[a]	88	0(0)	15(12)	66(75)	7(8)	0	15	46	0
Anti-reflux surgery[b]	134	66(49)	32(24)	13(1)	20(15)	88	7		2
Bariatric surgery[c]	77	39(51)	15(19)	12(16)	5(6)	18	13	3	2

C, complete; VI, very improved; I, improved; NI, not improved.
[a]Sum of four published series.[31–34]
[b]Sum of nine published series.[35–43]
[c]Sum of three series[9,10] and present series.

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Assessment of quality of life before and after surgery for severe obesity[1,2]

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ABSTRACT Quality of life is poor in obese people because of poor physical health and mental well-being and impaired psychosocial functioning. Obese people perceive discrimination and prejudice against them as their heaviest burden. Reports of absence of psychopathology in obese people reflect adaptation to chronic disease or failure of assessment instruments to detect disturbances. We present information on the extraordinary suffering and perceived discrimination of obese people and discuss econometric assessment of quality of life. The Swedish national population study of obese subjects (SOS) is presented as well as studies of effects of surgical weight loss on quality of life. Most studies lack adequate controls and extrapolations from surgical populations are uncertain. Psychosocial factors are important predictors of outcome in terms of physical as well as mental health. Operated patients with significant weight loss after surgery demonstrate dramatic improvement in quality of life. This alone justifies treating severely obese patients surgically. *Am J Clin Nutr* 1992;55:611S–4S.

KEY WORDS Quality of life, severe obesity, psychosocial functioning, mental well-being, surgical treatment, employment status

Introduction

Severe obesity causes impaired quality of life above and beyond the impact of medical complications of the disease. Increases in the prevalence of psychological disturbances or frank psychopathology compared with the general (nonobese) population have been reported not to occur in obese candidates for surgery. Nevertheless, it is likely that emotional disturbances caused by discrimination and prejudice against obese people underlie both perpetuation of the obese state and significant impairment of quality of life in many obese patients.

Surveys of mental health and general well-being, functional capacity, social interaction, and intellectual performance have demonstrated substantial reductions in obese subjects with varying degrees of obesity. There are few studies on the effects of weight loss on these various measures of quality of life, among other reasons, from lack of sustained weight loss after nonsurgical treatment. Though surgical candidates might not represent the general obese population (1), the dramatic improvement in some quality-of-life parameters with surgically induced weight loss seem relevant for evaluating the impact of obesity on quality of life.

Definition and measurement

Quality of life is intrinsically both subjective and situational and thus can only be truly defined by each individual in relative terms and based on personal history. Social, physical, and psychological functioning are the principal components of most definitions (2) as summarized in **Table 1**. The terms mental health, psychosocial functioning, well-being, or simply health or adjustment are inextricably related to, if not synonymous with, quality of life, but they are not adequately operationalized. Presence of psychological symptoms, such as depression or anxiety, measured by standardized questionnaires may also reflect quality of life and are indeed included in many studies. Surveys of representative populations can be normative and serve to develop basic criteria for objective definitions of quality of life. Methods of assessment rely on interviews or questionnaires both for subjective evaluations (self-assessment) and for the more objective ratings by professionals or significant others. Self-assessment in its most subjective form demonstrates the individual's opinion about personal health. More objectively, self-assessment can rate performance in predetermined functions assigned weights by judges and/or based on normative data. Among severely obese people there are many disturbances of natural body functions that nonobese people take for granted that have been overlooked in conventional analyses of health or quality of life (**Table 2**). Such items are often included in measures of health designed for specific organ-related diseases. It is difficult to strike a balance between practicability and thoroughness of evaluation when constructing or choosing an instrument.

Objective techniques are frequently econometric, based on level of income, working hours, or amount of sick leave, or on utilization of medical, psychological, and social services. Acceptance of such objective techniques as true or relevant measurements of quality of life represents one particular political or ideological bias, which obviously is open to controversy.

Baseline data

Sources of information are large population surveys, insurance statistics, and for severely obese individuals, surgical series stud-

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TABLE 1
Core dimensions of health-related quality of life in clinical research

Concepts	Examples
Physical complaints/ well-being	Disease- and treatment-related symptoms, general symptoms, fitness
Psychological distress/ well-being	Anxiety and depressive symptoms, positive affect, cognitive disturbance
Functional status	Activities of daily living, mobility
Role functioning	Occupational/domestic activities
Social functioning/ well-being	Interpersonal relations, quantity and quality of social interaction, leisure
Health/perceived quality of life	Global assessment

ied pre- and postoperatively. The Danish population study of > 330 000 young men demonstrated reduced intellectual performance in men with BMI > 31, correcting for socioeconomic status (3). In a sample of 5817 persons participating in the Health Insurance Study of the Rand Corporation, 15% of women and 9% of men were > 130% of life-insurance weight standards [body mass index (BMI) > 29.3]. Eighty-eight percent of these persons worried about their weight, 18% reported pain, and 18% had restricted their activities because of their weight (4).

In a similar Dutch study from four general practices, BMI correlated with health complaints in men and women with differential effects of age (5). Significantly more complaints were recorded in women and men with a BMI > 30 than in those with a BMI < 27. The specific complaints that were related to BMI in both sexes, independent of age, social class, or smoking, were complaints of the digestive tract, skeletal-muscular system, and shortness of breath (5). It is interesting to note that the cluster of complaints with increasing BMI in these Dutch patients is remarkably similar to the conditions having the greatest impact on functional status and well-being in the extensive Medical Outcomes Study (6). Although that study did not analyze the obesity or the impact of weight on well-being (AL Stewart, personal communication, 1990), it is not unreasonable to expect similar findings as in the Dutch study. In a study of a random population of 226 men aged 50 y and 787 men aged 60 y in Goteborg, Sweden, an increased amount of body fat by skinfold thickness discriminated between men with symptoms such as shortness of breath, inability to relax, dizziness, and sweating and those lacking these complaints (7).

An ongoing national survey of severely obese subjects in Sweden (Swedish Obese Subjects, SOS) is a unique population study of very obese patients (BMI ≥ 34), which includes baseline characterization (Register study) and an intervention arm to evaluate surgical treatment and effects of weight loss (8). Numerous objective and subjective scales are employed in SOS, with attention paid to patient burden and feasibility with respect to the numbers of items in questionnaires. The first 1743 (943 female, 800 male) subjects entered into the Register study demonstrated poorer perceived health, had less positive mood, and exhibited more anxiety and depression than appropriate nonobese reference subjects. By using the Hospital Anxiety and Depression scale (9), which identifies psychiatric morbidity according to Diagnostic and Statistic Manual of the American Psychiatric Association, 3rd edition (DSM-III) criteria, 11% of the 943 women and 9% of the 800 men qualified as cases of depression. Eighteen percent and 14%, respectively, were borderline. Anxiety, according to the scale, was scored as borderline or above in 40% of women and 30% of men. In SOS, multiple-regression procedures identified history of psychiatric symptoms, presence of angina pectoris or joint symptoms, dieting attempts, physical activity level during leisure, and body image as prominent indicators of quality-of-life parameters.

Studies of surgical populations

The majority of studies on the psychosocial consequences of obesity and the effects of weight loss from surgery have been performed on patients undergoing intestinal bypass. Even though eligibility criteria have been refined and there are significant improvements in patient management, candidates for surgical treatment of obesity by gastric operations should be grossly similar to those who underwent intestinal bypass in the 1970s. Postoperative effects are also expected to be similar though intestinal bypass caused more complications of greater severity than the current gastric operations. Such complications would, if anything, tend to diminish quality of life in the intestinal bypass patients compared with those patients with gastric procedures.

The lack of psychological disturbance in severely obese subjects has been confirmed in numerous studies, though many others have demonstrated elevations of Minnesota Multiphasic Personality Inventory (MMPI) scores indicative of psychopathological traits. It has been suggested that the reported lack of psychopathology reflects an inability of standard tests to detect emotional disturbance peculiar to the obese (10). An alternative interpretation is the remarkably effective psychological adaptation to chronic illness that has been demonstrated in other groups of physically ill patients (11). The majority of severely obese patients have childhood onset of their disease, qualifying obesity as a truly chronic disease. Two of the chronic diseases in the study by Cassileth et al (11) (arthritis and diabetes) that did not differ in psychological status from the general public, are highly associated with obesity. Depression, on the other hand, which also is related to obesity, significantly reduced the score for psychological status.

Psychosocial changes postoperatively

After the Solow et al (12) report in 1974 of beneficial psychosocial effects of intestinal bypass, numerous reports have confirmed similar effects maintained for 6 y or more (for review *see* reference 13). Studies showing psychological maladaptation after surgical weight loss have mostly been performed during the dynamic phase of weight loss when metabolic stress and side

TABLE 2
Disturbances of natural body functions in the obese

Shortness of breath
Disordered sleep
Pathological hunger
Sexual impairment
Excessive perspiration
Urinary incontinence (women)
Inability to clean oneself
Limited locomotion

effects are the greatest. Those studies also failed to provide appropriate controls.

Dieting has been linked to depressive symptoms in obese people in several reports and is considered to be a significant factor underlying impaired quality of life for such patients. A few studies have compared the impact of weight loss through dieting with that of gastric surgery, revealing dramatic differences in favor of surgical treatment (14, 15).

The intervention arm of the SOS study has accumulated data from the first 193 operated patients and their matched control patients followed for 1 y. Weight loss in 60 men and 132 women (one death) is in the order of 10 units of BMI, or 35 kg in men and 31 kg in women. Interestingly, before the operation, the subjects having surgery exhibited more impairment of social interaction, had more obesity-related problems, anxiety, depression, and decreased mental well-being than the weight-matched (obese) control subjects, particularly among the men. This clearly demonstrates that surgical candidates differ from the general obese population as predicted (1). All parameters had improved, compared with preoperative, by 6 mo postoperative and were statistically significantly improved compared with the control subjects after 12 mo. The first 48 women, followed for ≥ 2 y, demonstrated maintenance of these improvements compared with before the operations, with significantly higher scores for mental well-being, perceived health, and social interaction than the control cases.

Waters et al (16), in North Carolina, showed in a study of 157 gastric bypass patients that significant improvements in mental-health indices measured at 6 and 12 mo after surgery with the Health Insurance Study—General Well Being Battery deteriorated to preoperative values in the 31 patients studied after 24 mo and the 11 patients included at 36 mo. Not only is the number of patients small (11/157) but also only 35% of questionnaires were completed, severely jeopardizing the validity of the findings. It is reasonable to assume that a fair number of severely obese people have mood disorders or depression. In a subset of 11 242 patients from the Medical Outcomes Study of patients with normal weight distribution in three health-care provision systems, 22% had depressive symptoms (17). Without debating whether a population restricted to obese patients would be more or less likely to be depressed, one can assume that a proportion of severely obese candidates for surgery would have preexisting depression unrelated to their obesity. Such depression would be unlikely to be affected by surgical treatment of obesity. This is not addressed in the study by Waters et al (16).

Another recent study clearly demonstrates the importance of pre-operative socio-economic status as a predictor for developing medical as well as psychiatric complications post-operatively (18). This study also demonstrates the need for having appropriate control groups when evaluating the effects of surgery.

A Norwegian study of 66 women and 24 men with a mean BMI of 42 kg/m^2 rated the patients by using DSM-III criteria and several clinical scales before and 1 and 3 y after horizontal gastric banding (19). Between 20% and 40% of patients received DSM-III diagnoses and 37% had sought treatment for psychiatric problems one or more times preoperatively. There were highly statistically significant improvements in psychosocial functioning maintained 3 y after the operation. These effects were explained by the degree of weight loss. Patients with insufficient weight loss had significantly more diagnoses of personality disorders before the operation then the successful patients. It is noteworthy that 43% of the patients cited psychosocial reasons for having surgery (19).

Further evidence of psychosocial reasons for patients seeking surgical treatment is found in a study of 57 consecutive patients (50 female, 7 male) interviewed before and after undergoing gastric bypass (20). More than 80% indicated that they always or usually experienced prejudice and discrimination, particularly at work or when seen in public. Especially disturbing was the patients' perception that physicians were disrespectful in 75% of cases. All of the patients demonstrated characteristic self-disparagement with poor body image, claiming that they felt unattractive. Dramatic improvement was experienced 14 mo after the operation, after a mean weight loss of 50 kg (20).

Table 3 presents dysfunction scores on the Sickness Impact Profile (21) administered to a small group (n = 9) of massively obese (BMI = 52) patients (6 female) before, and a mean 30 mo after, malasorptive or gastric-restrictive operations. Before the operations the total dysfunction score of 24% in the obese patients exceeded scores of populations of patients with cirrhosis (20%), Crohn's disease (15%), or myocardial infarction (10%), demonstrating the serious impact of obesity (22). The postoperative scores demonstrate clear improvements in all categories, with a mean total dysfunction score of 5.8 ± 1.3%.

Econometric changes

Among studies of econometric techniques for assessing quality of life, 240 patients in South Australia revealed an increase in full-time or part-time employment from 38%, before, to 60%, 3 y after the gastric operations, having lost 53% of excess weight (23). There were also significant improvements in self-image, social life, sex, and emotional relationships compared with preoperatively. A preliminary report from Sweden recently demonstrated a mean 20% increase in yearly income (from $16 000 to $19 000) and a 17% increased employment rate (from 64% to 81%) among patients studied after gastric-restrictive surgery (24). These obese Swedish surgical patients had a mean income above the Swedish general population mean. This is contrary to most obese populations who usually are poorer than national standards. Once again, this challenges the representativity of surgical populations. Nevertheless, the operated patients consumed less medical services and rated their general health status higher than appropriate untreated obese candidates for surgery acting as control subjects (24). A remarkably similar increase in employment, from 60% preoperatively to 78% after gastric bypass, was reported from Pennsylvania (18).

TABLE 3
Sickness Impact Profile dysfunction scores in nine severely obese patients (BMI = 52) before and a mean 30 mo after antiobesity surgery, having lost a mean 72 kg of weight*

	Before	After
	%	
Social interaction	31	4
Work status	30	16
Emotional behavior	29	9
Recreation	28	12
Ambulation	24	1

* High scores indicate greater impairment.

[SB579, 1067]

Conclusion

Quality of life, however it is measured, is severely impaired with increasing degree of obesity according to unanimous reports in the literature. Long-term follow-up studies after intestinal bypass operations have clearly demonstrated beneficial effects on quality of life even in the face of serious side effects of the operations. Available data from the more benign gastric operations confirm these findings. Because of significant differences within and between populations and between surgical candidates and matched obese subjects it is particularly important to include appropriate controls in studying this multifaceted problem.

Because obesity is associated with significant comorbidity as well as problems specific to obesity it is necessary to construct and validate obesity-specific instruments for assessment of quality of life in severely obese people. Obesity qualifies as a chronic disease and thus long-term studies are necessary to evaluate treatment effects. Because of differences between patients opting for surgery and those electing other modalities and the inherent inequality of different interventions, it is exceedingly difficult if not impossible to design randomized studies with equivalent treatment arms (1). Respecting the patients' right to choose defeats the scientific validity of a randomized study in this context, where the surgical option appears more frightening to most patients.

No studies of treatment of obesity so far have taken into account the importance of duration of disease or the impact of hereditary factors in influencing outcome. A frequency of 30% of nonresponders might well represent the proportion of patients with irreversible disease, either acquired or inherited.

Most obese patients consider quality-of-life impairment to be the most serious concomitant of their crippling disease. According to the patients themselves, improved quality of life is the most important benefit of surgical treatment. It remains to be seen whether other treatments can achieve similar results over the long term.

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Bariatric surgery in morbidly obese sleep-apnea patients: short- and long-term follow-up[1,2]

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ABSTRACT Forty-seven obese sleep-apnea patients were investigated in the sleep laboratory before and after a massive weight reduction achieved by bariatric surgery. The first postoperative sleep investigations were performed ~1 y after surgery and revealed a highly significant decrease in the number of apneic episodes per hour of sleep and a significant improvement in all sleep-quality–related measures. A second postoperative sleep study was performed ~7 y postoperatively and revealed that regaining of weight was associated with the reappearance of sleep apnea syndrome, although the great majority of the patients still felt, subjectively, that they were well and did not suffer from recurrence of the sleep apnea syndrome. *Am J Clin Nutr* 1992;55:594S–6S

KEY WORDS Obesity, bariatric surgery, sleep apnea syndrome

Introduction

Sleep apnea syndrome (SAS) and obesity hypoventilation syndrome are well-recognized complications of morbid obesity. Whereas the incidence of SAS in the general population is ~1% (1), it is 12–30-fold higher in the morbidly obese (2, 3). Complications of SAS, such as severe cardiac decompensation and cardiac arrhythmias, may contribute to the increased mortality rate in the morbidly obese (4–6).

Previously, we (3, 7–9) and others (2) demonstrated that bariatric surgical procedures that achieved a considerable weight loss were associated with dramatic improvement in the severity of SAS and consequently in sleep quality. In some patients, weight loss was associated with the complete disappearance of the syndrome. The present work summarizes the results of our short- and long-term follow-up of obese SAS patients who underwent a bariatric surgical procedure in our department.

Materials and methods

From 1978 to 1986, 798 morbidly obese patients [199 male (25%) and 599 female (75%)] underwent bariatric surgical procedures for morbid obesity in the Department of Surgery C, Soroka Medical Center. All patients were selected for surgery after several unsuccessful dietary trials to reduce weight. All met the criteria of the Metropolitan Life Insurance Company for Morbid Obesity. Before surgery all patients were screened for SAS; this was done in two stages. First, patients were interviewed by use of the Technion Sleep Questionnaire for symptoms characteristic of SAS (10). This questionnaire was found to have 88% specificity and 86% sensitivity with respect to the diagnosis of SAS (11). Second, patients suspected of SAS underwent whole-night polysomnographic recordings.

The surgical procedures performed were the Roux-en-Y gastric bypass and the vertical banded gastroplasty (11, 12).

Results

Short-term follow-up

The study population consisted of 51 patients (44 males and 7 females) aged 24–59 y ($\bar{x}$ 41.2 ± 9.5 y). The weight of the patients at the preoperative sleep study ranged from 96 to 197 kg ($\bar{x}$ 138.9 ± 24.6 kg) with percent excess body weight over ideal body weight ranging from 65% to 211% ($\bar{x}$ 116.2 ± 35.7%). Except for one, none of the patients met the criteria for obesity hypoventilation syndrome (6).

The postoperative sleep study was done from 5 wk to 2.5 y after the operation ($\bar{x}$ 42.6 ± 30.9 wk).

Complete pre- and postoperative data were available from 47 patients. Weight reduction achieved by surgery was associated with a significant reduction in sleep apneas. Mean apnea index was reduced from 60 to 8/h of sleep ($P < 0.001$). Almost three-quarters (72.3%) of the patients had an apnea index < 10; 40.4% of the patients did not have any apneas at all. The reduction in the postoperative apnea index was associated with significant improvements in all quality-related sleep parameters (Table 1).

Step-wise multiple regression analysis revealed that 19% of the variance in the postoperative apnea index was accounted for by the following variables: percent body weight lost postoperatively, preoperative apnea index, and time interval elapsed between surgery and the postoperative sleep study.

Long-term follow-up

Long-term follow-up was conducted in two stages. First all patients operated upon during 1980–1985 were contacted and

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TABLE 1
Values for percent excess body weight, apnea index, and sleep-related measures from the pre- and postsurgical sleep studies

	Presurgery (n = 47)	Postsurgery* (n = 47)	Significance of difference
Apnea index	60.8 ± 35.5	8.0 ± 11.8	<0.001
Percent excess body weight	117.4 ± 36.4	44.4 ± 35.1	<0.001
Sleep efficiency	83.0 ± 13.2	87.4 ± 7.3	<0.05
Sleep latency	14.1 ± 25.6	9.1 ± 7.3	NS
Rapid eye movement latency	161.1 ± 93.9	82.9 ± 41.0	<0.001
Sleep stages (%)			
Stage 0	4.8 ± 8.9	1.9 ± 3.0	<0.05
Motion time	2.2 ± 3.4	2.0 ± 2.3	NS
Stage 1	1.8 ± 2.8	1.8 ± 2.3	NS
Stage 2	69.7 ± 15.8	53.2 ± 12.3	<0.001
Stage 3/4	10.9 ± 11.6	21.8 ± 11.5	<0.001
Rapid eye movement	10.5 ± 7.2	19.1 ± 7.5	<0.001

* $\bar{x}$ ± SD.

requested to complete a sleep and health questionnaire. Subsequently, whole-night sleep recordings were scheduled. Here, we report the results of the first phase and preliminary results of the second phase.

Forty-two patients with a mean age of 48.43 ± 9.49 y (37 males and 5 females) completed the sleep and health questionnaire. Mean follow-up period to the first phase was 6.3 ± 1.79 y; sleep recordings were conducted ~8 mo later. Mean weight of the patients who completed the questionnaire was 101.52 ± 17.9 kg and mean excess body weight was 56.83 ± 27.88%. Twenty-two patients (64.7%) increased their body weight in comparison with their weight at the time of the first postoperative sleep recordings. The vast majority of the patients (92.9%) had an improvement in their general condition since the operation. Three patients (7.1%) reported that there was no change. Seventy-nine and a half percent of the responding patients reported less snoring; 66.7% reported better breathing during sleep; 85.7% reported less daytime fatigue, and 88.1% reported less daytime somnolence.

At this time, only six patients have been recorded in the sleep laboratory. Table 2 presents their data regarding percent excess body weight and apnea index in the preoperative and two postoperative evaluations.

Discussion

Our present results show that weight reduction achieved by bariatric surgery was associated with a complete disappearance of the sleep apneas in 40% of the patients and with a marked reduction in apneas in 72% of the patients. These were associated with a marked improvement in general feeling and in normalization of sleep quality. The questionnaire study revealed that most patients still considered their condition 6 y after the operation to be better than before the operation. However, although preliminary, sleep laboratory recordings showed that objective improvement was maintained only in patients who did not regain excess weight.

Although the beneficial effect of bariatric surgery on weight loss and SAS have been demonstrated before (6–9), the direct association between excess weight and SAS severity has not been firmly established. Here we show that percent excess weight is of primary importance in SAS. It was found to be the main contributing factor to the severity of the syndrome before and after the surgical intervention.

Taking the preoperative and postoperative data together, there is a clear indication that the optimal treatment for obese SAS patients is a massive weight reduction. Because most morbidly obese patients are unwilling, or unable, to lose weight by dietary means, it leaves surgically achieved weight reduction as the treatment of choice. In view of our long-term follow-up, a word of caution seems necessary. Despite an initial impressive weight loss 6 y postoperatively, 22 of 44 patients were found to regain considerable weight. Of the six patients recorded so far in the laboratory, all three patients who had a considerable weight gain since the first postoperative recording were found to have severe SAS. This clearly indicates that bariatric surgery cannot be considered as a miraculous treatment for excessive weight. Postoperative guidance of patients' behavior and diet is essential to ensure effective outcome of the surgical procedure. Patients should be explicitly informed that regaining extra weight means the reappearance of full-blown SAS.

TABLE 2
Data of percent excessive body weight and sleep recordings obtained preoperatively and twice postoperatively

	Preoperative		1 y postoperatively		7 y postoperatively	
Patient	Excessive body weight	Apnea index*	Excessive body weight	Apnea index*	Excessive body weight	Apnea index*
	%		%		%	
1	72	72	18	24	43	46
2	97	66	41	1	86	58
3	125	54	52	3	65	18
4	118	71	55	12	41	15
5	104	69	58	22	84	61
6	85	30	—	—	22	9
$\bar{x}$ ± SD	100.1 ± 19.9	60.3 ± 16.2	44.8 ± 16.3	12.4 ± 10.5	56.8 ± 25.7	34.5 ± 23.1

* Total number of apneic episodes per hour of sleep.

[SB 579, 106]

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Marked Improvement in Asthma after Lap-Band® Surgery for Morbid Obesity

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Background: Asthma and morbid obesity are common chronic conditions that may be related. Laparoscopic banding provides effective weight control of morbid obesity. The aim of this study was to evaluate the prevalence of asthma in the morbidly obese and the changes in asthma after laparoscopic adjustable gastric banding (LAGB) (Lap-Band®) surgery for morbid obesity.

Methods: Asthma was assessed preoperatively in all patients presenting for LAGB. 32 consecutive asthmatic patients were followed up clinically and by a standard questionnaire at least 12 months after surgery, and any change in asthma impact was recorded.

Results: The prevalence of the doctors' diagnosis of asthma was 24.6% (73 of 296 consecutive patients). This was significantly higher than the prevalence in the Australian community of 12% to 13% ($P < 0.001$).

The 32 patients who were followed up had a mean body weight of 125.2 kg and a body mass index (BMI) of 45.7 kg/m2 prior to operation, and a weight of 89.3 kg (BMI 32.9 kg/m2) at follow-up. All 32 patients recorded a lower asthma score postoperatively. There were significant improvements in all aspects of asthma assessed. These included severity, daily impact, medications needed, hospitalization, sleep, and exercise. The mean preoperative scaled asthma score was 44.5 ± 16. There was a highly significant reduction at follow-up to a mean value of 14.3 ± 11 ($P < 0.001$).

Conclusions: There is a high prevalence of asthma in morbidly obese adults, and major reductions in asthma severity occur after Lap-Band(r) surgery and weight loss. Mechanisms other than direct weight loss appear to play a part in this improvement. Prevention of gastroesophageal reflux may be an important factor.

Key words: Morbid obesity, asthma, obesity surgery, gastric banding (adjustable), gastroesophageal reflux, laparoscopy.

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Introduction

Asthma is a common chronic illness in the Australian community, having a prevalence in adults of 12% to 13%.[1] It is the direct cause of considerable morbidity and mortality. It places a considerable burden on health services at many levels and is one of the conditions that commonly leads to hospital admission. Obesity is also one of the most common chronic conditions of the Western world. Its prevalence in Australia is about 16% to 17% and is increasing.[2] Obesity is associated with serious physical disability; exacerbates many illnesses including hypertension, dyslipidemia, and non–insulin-dependent diabetes mellitus; and is a major cause of psychosocial problems.[3,4]

Evidence suggests that these two common chronic conditions are associated. There is an increased prevalence and severity of asthma in obese children. Unger showed that the prevalence of both obesity and asthma in children was rising and the prevalence of asthma in obese children of 30% was significantly greater than the 5% to 12% reported in that community as a whole.[5] Exercise-induced bronchoconstriction is more common in nonasthmatic obese children.[6] Asthma tends to be more severe in obese children than in a comparable group of nonobese children with asthma.[7] In adults, a strong link has been shown between obesity and respiratory conditions such as reduced lung volume, reduced ventilation, and sleep apnea.[9] However, to our knowledge there are no studies specifically of the relationship between morbid obesity and asthma in adults.

We have had the opportunity of studying the prevalence of asthma in obesity and the effects of weight loss on asthma in a group of patients having the laparoscopic adjustable gastric banding (LAGB)

(Lap-Band®, Bioenterics, Carpinteria, CA) procedure for the management of morbid obesity. This procedure is performed laparoscopically and involves the placement of an adjustable silicone band around the upper stomach, thereby creating an early sense of satiety after eating. The procedure has been associated with minimal morbidity and effective weight loss.[9]

Patients and Methods

Patients with a body mass index (BMI) >35 kg/m2; who had significant medical, physical, or psychosocial disabilities; and who had attempted weight reduction by other means for at least 5 years were considered for entry into the Lap-Band® program. After 2 consultations with the surgeon, during which clinical evaluation was made and the procedure was discussed extensively, patients who elected to proceed underwent an extensive preoperative assessment. This included clinical assessment by a consultant physician and laboratory tests. Any history of doctor's diagnosis of asthma was noted, and an assessment was made of its severity, specific problems, and treatment. The patients with asthma continued to have the disease managed by the their general practitioner and/or respiratory physician.

Patients were selected for this study if they gave a history of asthma as an adult, a medical practitioner had confirmed the diagnosis, and the patient had been followed up for at least 12 months following surgery. Asthma was assessed preoperatively by a consultant physician, at regular follow-up visits, and by standard questionnaire sent by mail to all asthmatic patients.

The questionnaire was a self-reporting instrument designed to collect information about the subject's asthma history, asthma triggers, and smoking. However, its main focus was to assess any change in the severity of asthma and its impact on day-to-day living. The study included the effects on sleep, exercise, asthma treatment required, and admissions to hospital due to asthma. The questionnaire asked subjects to tick boxes or choose the most appropriate response to a series of questions. The only written response required was to list medications taken the weeks prior to surgery and those taken in the last weeks. Patients who did not return their questionnaires promptly were phoned and reminded, and in a small number of cases, the questionnaire was completed by telephone interview. Accurate weight recordings were kept on all patients at regular follow-up visits.

Data Analysis

The respondents' demographic details and history of asthma were analyzed, and the mean characteristics of the group were determined. Asthma was assessed and graded according to impact or severity: asthma severity, daily impact, sleep disturbance, exercise, treatment required, and need for hospitalization. Summation of these values provided a global score of asthma severity (range 0–100) and was expressed as a percentage. In addition, all patients were classified according to the National Asthma Campaign criteria[10] into "mild," "moderate," and "severe" asthma in adults. Grading was based on the severity in the last 3 months. Responses to individual questions were averaged within each domain and compared preoperatively and postoperatively. The significance of differences was measured using a paired Student's t test. A P value of <0.05 was considered to be significant. Pearson correlation coefficients were used to compare change in asthma with weight loss, age, and asthma history.

Results

Between July 1994 and July 1998, 380 patients were treated. The median age was 39 (17–69), and 88% were female. Mean weight prior to operation was 128 ± 24 kg, and BMI was 45.1 ± 7 kg/m2. A laparoscopic approach was used for 348 patients (92%), and only 2 significant complications (0.6%) occurred in these patients. A further 32 patients had an open surgical approach, mainly because prior gastric stapling surgery precluded the laparoscopic approach, and 9 significant complications (34%) occurred in this group. Overall there was a median loss of 49% of excess weight at 12 months after operation, 63% at 2 years, and 67% at 4 years.

The prevalence of doctors' diagnosis of asthma in the patients with morbid obesity presenting for laparoscopic banding was 24.6% (73 of 296 patients). The prevalence in the adult Australian community is 12% to 13%.[1] The difference is highly significant ($P < 0.001$)

A total of 33 patients with asthma fulfilled the entry criteria for the study; 32 (M:F 2:30) attended follow-up reviews and responded to the questionnaire. One patient was being followed up at another center and did not respond to the survey. The mean age was 38.9 (23–57) years. The mean age at asthma onset was 16 (2–42) years. Mean age at onset of obesity was 20 (7–42) years.

These subjects had an initial mean BMI of 45.7 ±

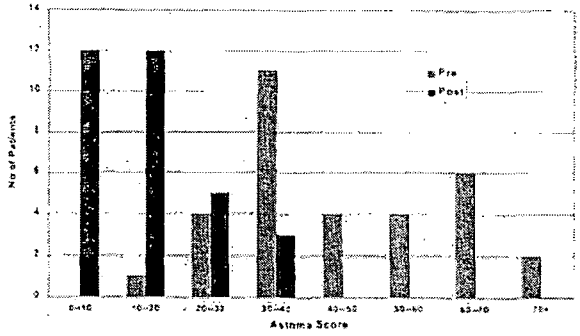

Figure 1. Scaled asthma score preoperatively and at follow-up.

7.5 kg /m2 and an initial mean weight of 125.2 ± 26 kg. At the time of review, the group had a mean BMI of 32.9 ± 4.7 kg/m2 and a mean weight of 89.3 ± 14 kg. Thus, 58 ± 18% of excess weight had been lost (% EWL) at the time of completion of the follow-up study.

For 63% of the patients, the asthma was triggered by allergy, 55% by viral infections, 45% by exercise, 40% by emotional factors and stress, and 35% by active or passive smoking. Less common triggers included air pollution, weather changes, and chemical irritants. Patients often had more than one trigger for their asthma. None listed gastroesophageal reflux as triggers.

All 32 of the subjects recorded a lower scaled score for the postoperative period. There were also significant improvements in all the specific categories that the questionnaire covered. The mean scaled asthma score was 44.5 before operation and 14.3 after at least 12 months follow-up. The mean difference was 30.2 ± 14 ($P < 0.001$). Pre- and post-scaled asthma scores are shown in Figure 1. The 20 patients who listed allergy as a significant trigger for their asthma had a mean fall in scaled asthma score of 30.9 at follow-up. This was a similar improvement to the group as a whole.

Asthma severity based on National Asthma Campaign classification prior to surgery and at follow-up are shown in Figure 2. There were 10 patients with a severe classification prior to surgery and none at follow-up. There were none in the "no asthma" classification initially and 8 at follow-up.

Patient-assessed asthma severity was graded 1–6 (1 = no asthma, 6 = very severe asthma). The mean score was 3.66 (±1.29) preoperatively and 2.03 (± 0.97) postoperatively ($P < 0.001$). Only one patient had a score of 1 before surgery, but 11 of the 32 scored 1 at follow-up. Six patients scored severe or very severe before surgery, but none scored above moderate at follow-up.

The daily impact of asthma on the activities of everyday living was assessed in another question (graded 1–5; 1 = no apparent effect day to day, 5 = severe restriction of most activities every day). The mean preoperative score was 2.08 (SD 0.7) and postoperative score was 1.21 ($P < 0.001$). Six patients had no day-to-day effect preoperatively, and 23 postoperatively. There were also significant improvements in the impact of exercise-induced asthma and sleep disturbance due to asthma. Ability to exercise was rated as "much improved" by 25, "improved" by 6, and "unchanged" by 1.

There was a weak positive correlation between percentage weight loss and fall in asthma score ($r = 0.21$). There was no correlation between age and asthma improvement ($r = 0.09$) or age at asthma onset and asthma improvement ($r = 0.05$).

Changes in Asthma Treatment

Medication used to treat asthma was significantly reduced in all treatment medication groups: 20 were using "much less," 6 were using "less," and 6 were "the same." None was using more medication. Medications used to treat asthma were grouped into 6 categories. Figure 3 shows the changes of the category for the last 2 weeks before surgery and at follow-up. There was a highly significant difference ($P < 0.001$).

Before surgery, 14 patients took daily medication for asthma; at follow-up there were 6. At follow-up no patients required continuous oral steroids, and only one was using them intermittently. Fewer were using inhaled steroids for asthma prevention.

Seven patients were admitted to the hospital on one or more occasions for severe asthma in the year

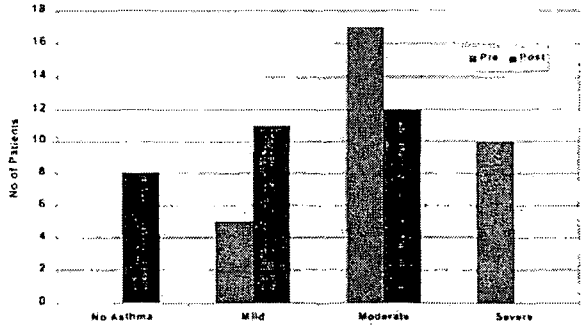

Figure 2. Severity based on National Asthma Campaign, before and after laparoscopic banding.

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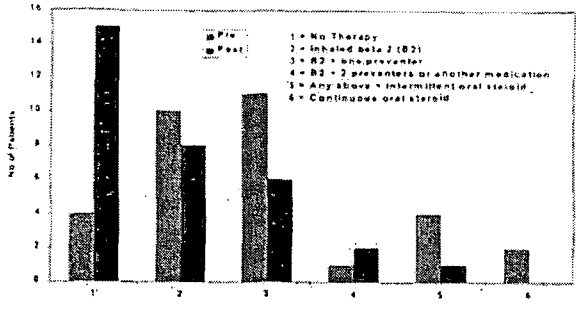

Figure 3. Medication used in last 2 weeks to treat asthma, before and after laparoscopic banding.

prior to surgery. None required hospitalization for asthma during the follow-up period after surgery.

Overall, 24 patients rated their asthma "much improved" after the surgery with its subsequent weight loss, 6 were "improved," and 2 were "unchanged." Eleven (34%) of the respondents had complete resolution of all asthma symptoms and felt that it no longer affected their day-to-day living in any way.

Discussion

This study indicates that the morbidly obese have a significantly higher prevalence of doctors' diagnosis of asthma and report very significant improvements in their asthma following LapBand® surgery. The improvements affected all measured aspects of the patient's asthma, including severity, effect on day-to-day activities, medication usage, and hospital admissions. Asthma improved in all asthmatic patients, including those with allergy conditions. In 34%, the disease had resolved completely (no impact over the last month). "Asthma is a chronic inflammatory disorder in which many cells play a role. In susceptible individuals this inflammation causes symptoms which are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment, and it also causes an associated increase in airways responsiveness to a variety of stimuli."[1] It is highly unlikely for these to improve dramatically over 12–24 months.

The mechanism for this effect is not clear, and there are many possible hypotheses. The cause of asthma is often multifactorial in an individual patient, and it is possible any improvement is multifactorial. Our study shows that the prevalence of asthma in obese adults may well be similar in pattern to that reported in obese children.[5] Morbidly obese adults may have increased bronchial activity, as found by Kaplan et al. in children.[6] Exercise-induced bronchial reactivity may lead to exercise avoidance, thus aggravating obesity. Bronchial reactivity in adults may be increased with weight gain and decreased with weight loss after surgery.

Morbidly obese patients often suffer from gastroesophageal reflux.[12] Placement of the Lap-Band® probably prevents acid reflux because of its position high near the gastroesophageal junction. Patients with severe reflux symptoms report rapid relief of reflux symptoms after Lap-Band® placement. There has been recent evidence of asthma improvement with the use of proton pump inhibitors and after surgery for gastroesophageal reflux.[13–15]

The improvement in exercise tolerance with weight loss may lead to the improvement in asthma symptoms and reduced exercise induced asthma. The ability to exercise was improved in all patients except one. This may have biased our asthma score, as a question about the ability to exercise was included. Therefore a small fall in "asthma score" would occur with improved exercise tolerance alone.

Improvement may be related to changes in upper body and abdominal fat distribution and the associated restrictions in lung volumes and chest wall mechanics.[16] Some improvement may be associated with an improved sleep pattern, as persistent snoring and sleep apnea are commonly associated with morbid obesity.[17] Improvement in sleep with weight loss may be a confounder in our results, as nocturnal asthma may improve with less upper airway obstruction.[18] Improved confidence, self-esteem, and body image as well as a new feeling of control can have a positive effect on the psychosomatic components of adult asthma.

This study has shown a major increase in prevalence of asthma in the morbidly obese and has shown that a major reduction in the severity of asthma occurs in association with the placement of a Lap-Band® and loss of excess weight. Better understanding of the mechanisms for this important effect will come from documenting pulmonary function and bronchial reactivity before surgery and during the process of weight loss after surgery.

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Reduction in Incidence of Diabetes, Hypertension and Lipid Disturbances after Intentional Weight Loss Induced by Bariatric Surgery: the SOS Intervention Study

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Abstract

SJÖSTRÖM, C. DAVID, LAUREN LISSNER, HANS WEDEL, and LARS SJÖSTRÖM. Reduction in incidence of diabetes, hypertension and lipid disturbances after intentional weight loss induced by bariatric surgery: the SOS Intervention Study. *Obes Res.* 1999;7:477–484.

Objective: To examine the effect of a large, long standing and intentional weight reduction on the incidence of diabetes, hypertension and lipid disturbances in severely obese individuals as compared to weight-stable obese controls.

Research Methods and Procedures: The ongoing prospective SOS (Swedish Obese Subjects) intervention consists of a surgically treated group and a matched control group obtaining conventional obesity treatment. This report is based on 845 surgically treated patients and 845 controls (BMI 41.0±4.6 kg/m^2 (mean±standard deviation [S])) followed for 2 years.

Results: Surgically treated patients lost 28±15 kg and controls 0.5±8.9 kg (p<0.0001). Two-year incidence of hypertension, diabetes, hyperinsulinemia, and lipid disturbances was compared in the two treatment groups. Adjusted odds ratios (95% CI) for the surgically treated group versus controls were 0.38 (0.22, 0.65) for hypertension, 0.02 (0.00, 0.16) for diabetes, 0.10 (0.03, 0.28) for hyperinsulinemia, 0.10 (0.04, 0.25) for hypertriglyceridemia, 0.28 (0.16, 0.49) for low HDL-cholesterol and 1.24 (0.84, 1.8) for hypercholesterolemia. Compared to controls, the 2-year recovery rates from hypertension, diabetes, hypo-HDL, and hypertriglyceridemia were significantly higher in the surgically treated group.

Discussion: Intentional weight loss in the obese causes a marked reduction in the 2-year incidence of hypertension, diabetes and some lipid disturbances. The results suggest that severe obesity can and should be treated.

Key words: morbid obesity, gastric surgery, controlled intervention study, intentional weight loss, diabetes mellitus, lipids, hypertension

Introduction

Obesity is a fast growing worldwide epidemic (1) with enormous secondary health-care costs. Recent editorials in leading medical journals have debated for as well as against the relevance of obesity treatment (2,3).

The understanding of the impact of weight change is complicated by several observational studies indicating that weight loss predicts increased mortality (4–6) even in subjects who were initially obese. In contrast, several studies have demonstrated that diabetes, hypertension, and other cardiovascular risk factors are improved by weight reduction (7–12), although mostly studied over a relatively short period of time. This contradictory situation may be related to unintentional weight loss among subjects in observational studies (13,14). There is also a great uncertainty about how large the sustained weight loss must be in order to have any effect on morbidity. One way, and perhaps the only valid one, to elucidate this controversy may be to conduct controlled intervention studies of obesity. These interventions should produce weight losses that are not only intentional but also large and sustained over time. Therefore, the intervention study Swedish Obese Subjects (SOS) was started (15).

Although it is too early to use SOS-data for studying hard endpoints such as mortality or myocardial infarction in response to weight reduction, this controlled 2-year report describes marked reductions in incidence of hypertension, diabetes and other endpoints based on staging of severity of functional measurements.

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Methods

General Design

SOS is an ongoing project consisting of a registry (in which 6000 to 10,000 obese subjects will be examined) and a prospective intervention study. From the registry, eligible patients are recruited into the intervention study. This consists of two groups, one surgically treated group and one matched, conventionally treated control group. The two groups will contain 2000 subjects each and the follow-up period will be 10 years. All details of the study design have been published before (15). Inclusion criteria for the intervention study are age 37–60 and BMI≥38 for women and BMI≥34 kg/m^2 for men.

The SOS-study has a non-randomised matched design. The matching procedure is based on a computerised matching program that can not be manually influenced by the investigators. When selecting eligible controls from potential controls of the registry the program is taking the following 18 variables into account: sex (absolute match), age, weight, height, waist circumference, hip circumference, systolic blood pressure, s-cholesterol, s-triglycerides, smoking, diabetes, pre-/post-menopausal state among women, four psychosocial variables known to be associated with mortality (current health, availability of social interaction, availability of attachment, stressful life events) and two personality traits related to treatment preferences (psychastenia, monotony avoidance) (16).

Study Group

For the purpose of the current report, 2-year results from the first 845 patients included in the surgically treated group and their 845 matched controls were used. Due to mortality, drop outs, pending data, and pregnancies, 2-year data were not available in 133 controls (16%) and in 78 surgically treated patients (9.2%) when the data file was compiled. Table 1 shows age, anthropometric variables, and cardiovascular risk factors at baseline as well as changes after 2 years for those patients who were available at the 2-year examination.

For various reasons, 15 surgically treated patients had their operations reversed during the first 2 years of the intervention study. Conversely, 6 controls demanded and received gastric surgery during this period of time. According to the intention to treat principle these 21 subjects have been

Table 1. Age, anthropometric variables and cardiovascular risk factors in 767 surgically treated patients and 712 controls examined at inclusion and after 2 years. Unadjusted means±S. Significance level of difference between groups is given at baseline (column II). Columns III and IV give within group changes after 2 years and significance levels (column IV) for differences between changes in the control group and changes in the surgically treated group.

	Baseline		Changes: 2 years–baseline	
	I Controls	II Surgery	III Controls	IV Surgery
n	712	767		
Women, percent	68	69		
Age, years	48.6±6.3	47.0±5.8**		
Height, m	1.69±0.09	1.69±0.09	0±0	−0.0±0.01
Weight, kg	114.1±17	120.5±16**	−0.5±8.9	−28±15**
BMI, kg/m^2	39.8±4.6	42.1±4.3**	0±3	−9.7±5**
Waist/hip	0.98±0.07	0.99±0.08*	0±0.06	−0.05±0.08**
SBP, mmHg	139±18	144±19**	0±15	−7±18**
DBP, mmHg	86±11	90±11**	−1±9	−6±11**
TG, mmol/l	2.2±1.7	2.3±1.4*	−0.1±1.2	−0.7±1.3**
Glu, mmol/l	5.2±1.8	5.5±2.1**	0.1±1.4	−1.1±1.8**
Ins, mmol/l	18.5±11	21.8±13**	−0.7±10	−11.4±12**
Uric, umol/l	358±80	365±84	−12±60	−62±72**
Chol, mmol/l	5.8±1.1	6.0±1.1**	−0.06±0.8	−0.25±1**
HDL, mmol/l	1.17±0.28	1.19±0.29	0.01±0.2	0.18±0.3**

* = $p<0.05$, ** = $p\leq 0.001$

considered as belonging to their original treatment groups in all calculations.

Treatment

Among the 767 surgically treated patients available at 2 years, 191 had originally received gastric banding, 534 vertical banded gastroplasty (VBG), and 42 gastric bypass (17). These operations were performed at 25 surgical departments located throughout Sweden. Within 2 years, 5 patients operated with gastric banding were converted to gastric bypass and one patient to VBG. Seven patients operated with VBG had their operations converted to gastric bypass.

It was neither feasible nor scientifically desirable to introduce a standardized treatment for the controls at the 480 primary health care centers. Instead, SOS controls received usual treatment as obese patients at the different centers. These treatments ranged from dietary advice, behavior modification, very-low-calorie diets, and physical training to no treatment at all. No anti-obesity drugs were registered in Sweden during the study period. Given the poor long-term results after traditional obesity management (18), poor weight loss effects were anticipated following non-surgical treatment. Thus these patients were expected to constitute a control group which would not, on average, experience intentional weight loss.

Measurements

The following anthropometric measurements have been used in this report: body weight to the nearest 0.1 kg without shoes in indoor clothing; body height to the nearest 0.01 m. Waist and hip circumferences in cm were measured without clothes in the recumbent position. Systolic and phase 5 diastolic blood pressures were adjusted for arm circumference and cuff size when appropriate (19).

Serum, EDTA, and heparin fluoride blood samples were sent by overnight mail to the Central laboratory at Sahlgrenska University Hospital, Göteborg. The laboratory is accredited according to Europe norm EN 45 001. Hemoglobin was analyzed by photometry and s-insulin radioimmunochemically. Blood glucose and the remaining serum tests reported here were analyzed by enzymatic techniques.

Criteria for Health and Disease

The appendix gives all criteria used for incidence and recovery calculations with respect to hypertension, diabetes, hyperinsulinemia, hypertriglyceridemia, hypo-HDL cholesterolemia, and hypercholesterolemia. The criteria are in accordance with internationally accepted recommendations (20–22).

With respect to incidence calculations of hypertension all subjects with blood pressure lowering drugs at baseline were excluded. The diagnosis hypertension required elevated blood pressure or medication prescribed specifically against hypertension. Fifty-seven subjects with normal blood pressure and blood pressure lowering drugs for other indications than hypertension were not used for any calculations. The relatively high number of missing data points with respect to HDL-cholesterol (n = 45) was explained by hypertriglyceridemia, making it impossible to determine HDL-cholesterol in most of these specimens.

Statistical Methods

The statistical calculations were performed with SAS. Logistic analyses were used to adjust for imbalances in the following baseline factors: sex, age, baseline weight, smoking, and perception of current health. With the exception of sex and smoking these factors differed significantly between groups at baseline. In order to be consistent with the logistic model, OR (odds ratio) rather than relative risk was used for risk comparisons, except when the incidence was higher than 15% (23). In the latter case, RR (relative risk) was used to avoid over-estimation of treatment effects.

Log transformed values of triglycerides, glucose, and insulin have been used for calculating p-values in the t-test calculations. Other variables were normally or close to normally distributed.

Human Subjects

The study was performed according to the declaration of Helsinki and was approved by the Ethical committees of all universities in Sweden. Patients gave their written informed consent.

Results

Baseline and 2-year data of completers are described in Table 1. Baseline values of the 211 subjects not available at 2 years (not shown) were not significantly different from baseline values of completers (Table 1). The baseline examination of the intervention study was undertaken 0.9±1.0 years (mean±S) after the registry examination. During this initial period between matching and inclusion, the control group lost some weight while the group that was to be surgically treated gained weight resulting in an average difference in body weight of 6.4 kg at inclusion (Table 1).

At the 2-year follow-up, body weight was unchanged in the control group and reduced to 92.7 kg in the surgically treated group. The difference between the two groups was 20.8 kg (95% CI: -22.6, -19.1 kg). Similarly, BMI was unchanged in the control group but reduced to 32.4 kg/m^2 in the surgically treated group. In the latter group the waist/hip ratio was also reduced.

Figure 1 shows average weight changes in percent over 2 years in the control group and in the three surgically treated subgroups. At 2 years, gastric bypass (n = 42) resulted in 33±10% (mean±S) weight reduction. Corresponding figures for VBG (n = 534) and banding (n = 191) were 23±10% and 21±12%, respectively.

All risk factors except uric acid and HDL-cholesterol

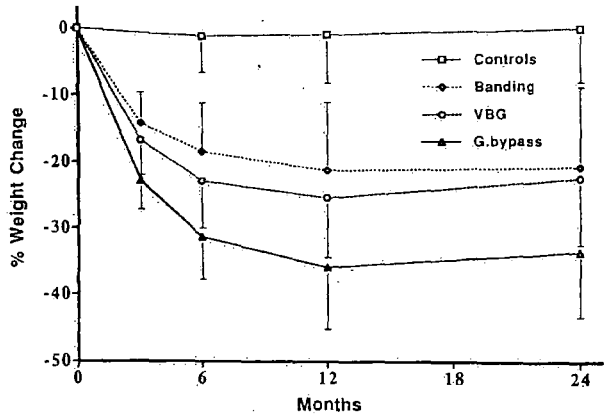

Figure 1: Percent weight change (S) in 712 controls and 767 surgically treated patients from baseline until end of year 2 in the SOS intervention study. Each one of the three surgical groups had a significantly ($p<0.0001$) larger weight reduction than the controls.

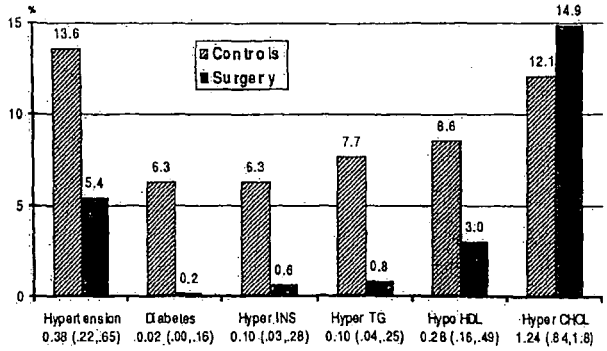

Figure 2: Two year unadjusted incidence of indicated conditions in controls (striped bars) and in surgically treated patients (filled bars). Below bars, Odds Ratios (95% CI) are adjusted for baseline values of age, sex, weight, smoking, and matching values of perceived health. $P<0.001$ except for hypercholesterolemia (NS). The following abbreviations were used: insulin, INS; triglyceridemia, TG; HDL-cholesterol, HDL; cholesterol, CHOL. Number of subjects used for different incidence calculations is shown in appendix.

were slightly but significantly higher in the surgical group at baseline (Table 1). Nevertheless, all risk factors except systolic blood pressure and total cholesterol were much more favorable in the surgical group at 2 years (Table 1).

The 2-year incidence of hypertension, diabetes, hyperinsulinemia, hypertriglyceridemia, and hypo HDL-cholesterolemia was lower in the surgically treated group (Figure 2). In the case of diabetes mellitus, the 2-year incidence was reduced 30-fold. The incidence of hypercholesterolemia was not significantly different between the two groups, while the incidence of other risk conditions were reduced 2.6- to 10-fold (Figure 2).

Figure 1 indicates that most patients were weight stable over the second year of the study. Therefore, the 767 surgically treated patients and the 712 controls were pooled in order to examine what degree of weight reduction at the end of year one predicted reduced incidence of risk factors at the end of year 2. Weight change over the first year was used to divide all individuals in three subgroups (legend to Table 2). When compared with subjects increasing their body weight on average by 4% (0%–26% weight increase) over the first year, a maintained weight decrease of 9% (19.9–0.1% weight loss) was sufficient to decrease the 2-year incidence of diabetes, hyperinsulinemia, hypertriglyceridemia, and hypo-HDL-cholesterolemia. In order to detect a significant effect on the incidence of hypertension after 2 years, an average weight reduction of 30% (56%–20% weight loss) was required after 1 year. Concerning incidence of hypercholesterolemia, no significant differences were obtained between the three categories of weight change.

In patients with disease or risk factors at baseline, recoveries from disease at 2 years were significantly more common in the surgically treated group as compared to the control group. The following relative risks (with 95% CI and number of diseased at baseline) were observed with respect to diabetes (RR = 3.7; 2.3–6.0; 195), hyperinsulinemia (RR = 1.4; 1.2–1.7; 221), hypertriglyceridemia (RR = 1.9; 1.5–2.4; 314), hypo-HDL-cholesterolemia (RR = 1.7; 1.4–2.1; 216), and hypertension (RR = 2.0; 1.5–2.7; 589), (in all cases $p<0.00001$). With respect to reversal of hypercholesterolemia no significant difference was observed between surgically treated patients and controls (RR = 1.2; 0.95–1.5; 531).

Discussion

This prospective, controlled, non-randomized study of severely obese subjects demonstrates that large intentional weight losses in the obese cause marked reductions in 2-year incidence of hypertension, diabetes and some lipid disturbances. This report as well as pharmacological 2-year trials (24) demonstrate that obesity can and should be treated.

One unique feature of this study is that the surgical intervention group is undergoing intentional weight loss, making it possible to compare incidences among this well-characterized group versus controls. Never the less, there remains an evident weakness in the present study, which is that the surgical intervention is not randomly assigned. The necessity of this design was based on the decision of six of the seven Ethics committees in Sweden not to approve a randomized design for this particular study. The rationale for this decision was the comparatively high postoperative mortality after gastric surgery (1%–5%) in 1987 when the

Table 2. Two-year incidence and odds ratios of indicated conditions by weight change after 1 year in the pooled study group consisting of controls plus surgically treated patients. Stable and weight gaining patients were used as reference group (III), with a 1-year percent weight change range of ≥0% to +26%. The remaining, weight losing patients were divided into two groups (I and II) with the following weight change ranges, >−56 to −20 and >−20 to <0%, respectively. Means±S of 1-year percent weight changes are given as well as OR (95% CI) adjusted for baseline values of age, sex, weight and smoking. Number of observations varies (10%–17%) from those given, due to different prevalence of the studied conditions at baseline.

		I	II	III
Mean weight change, percent		−30±7	−9±7	4±4
n, condition 1–4		454	488	333
n, condition 5–6		325	358	240
1. Diabetes	Incidence (%)	0.2	2.8	8.1
	OR	0.02	0.32	1
	95% CI	(0.00, 0.19)	(0.16, 0.64)	
	p	0.0003	0.0012	
2. Hyper Ins	Incidence (%)	0.2	4.0	6.8
	OR	0.03	0.50	1
	95% CI	(0.00, 0.23)	(0.26, 0.97)	
	p	0.0007	0.040	
3. Hyper TG	Incidence (%)	0.2	4.3	9.5
	OR	0.02	0.43	1
	95% CI	(0.00, 0.16)	(0.23, 0.80)	
	p	0.0002	0.007	
4. Hyper HDL	Incidence (%)	2.4	5.7	11
	OR	0.17	0.46	1
	95% CI	(0.08, 0.36)	(0.26, 0.80)	
	p	0.0001	0.007	
5. Hypertension	Incidence (%)	5.1	10	14
	OR	0.34	0.65	1
	95% CI	(0.17, 0.68)	(0.38, 1.1)	
	p	0.0025	0.130	
6. Hyper Chol	Incidence (%)	13	15	11
	OR	1.20	1.33	1
	95% CI	(0.71, 2.0)	(0.81, 2.2)	
	p	0.50	0.260	

SOS study was planned. The current postoperative mortality is 0.22% (4 of 1815).

Our results are both in agreement and in contrast to those obtained in observational epidemiology. Several studies have demonstrated that cardiovascular risk factors are elevated in the obese (for review 15, 25) and that these risk factor levels decrease in parallel with body weight reductions (7–12). The controlled incidence data of the current report is confirmatory of previous work relating weight change to changes in cardiovascular risk factors. In contrast, our results are not consistent with several carefully performed epidemiological studies suggesting increased mortality and morbidity endpoint rates after weight reduction, even among those individuals who were obese at baseline (4–6).

It is not fully understood why the effects of weight reduction on cardiovascular risk factors and endpoints are not in agreement. With two exceptions (14,26), epidemiological studies on weight loss in relation to survival include no information on whether the weight loss was intentional or not. While intentional weight loss seems to be beneficial in women (14), this may not necessarily be the case in men (26). Poor long-term treatment results (18) suggest that long lasting weight reductions in the obese are often involuntary

and, in fact, it has been shown that unintentional weight loss is at least as common as intentional weight loss among randomly sampled women (13). Thus, observational epidemiological studies might be flawed by a "reversed causality," i.e., weight loss could be the consequence rather than the cause of illness. Attempts have usually been made to exclude subjects with subclinical disease at baseline from analysis by not taking early mortality into account. However, this procedure has been suggested to be insufficient (27) and residual confounding by undetected illness may remain making it impossible to attribute observed associations between weight reduction and mortality specifically to intentional weight loss in observational epidemiology.

An alternative explanation for differential weight reduction effects on risk factors and on hard endpoints might be that the risk factor improvements are temporary. Most studies of risk factors in relation to weight reduction have been of short duration (28) while survival is usually examined on a long-term basis. As recently demonstrated, a 5% maintained weight reduction gives risk factor improvements at 6 and 12 months but not after 2 years, while an 8% maintained weight reduction resulted in risk factor improvements up to 2 years (24). In the current 2-year study, a 20% weight reduction resulted in marked effects on average risk factor levels and on the incidence of hypertension, diabetes and some lipid disturbances. However, it must be remembered that the patients are still obese (BMI = 32±4.8). Although one retrospective bariatric study suggests that diabetes is prevented long-term (29) it is still an open question whether some or all risk factors may return to baseline in a longer perspective (10–20 years).

These considerations underscore the need for intervention trials in obesity rather than more observational studies. The interventions should produce weight losses that are not only voluntary but also large and sustained over time. Approved anti-obesity drugs and drugs in phase III trials result in average weight losses of 10% or less. So far, only two controlled 2-year studies (24,30) on such drugs have been published. Some drugs or drug combinations may result in pulmonary hypertension and heart valve damages (31). When Swedish Obese Subjects was planned (15), surgery was the only available treatment resulting in large (>20%) and maintained (>2 years) weight losses. As indicated above the situation is very much the same today. While surgery is an efficient tool to achieve long-term weight reduction it can hardly be the single answer to the ongoing global epidemic of obesity (1), which creates an enormous challenge for public health authorities as well as the pharmaceutical industry.

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Appendix. Criteria for incidence and recovery calculations

			2 Year			
Risk factor	**Type of calc.**	**Baseline n=1479**	**Healthy**	**Sick**	**Excl. from calc.**	**Missing**
Hypertension:	Incidence:	SBP <160 and DBP <95 and no drugs. n=810	SBP <160 and DBP <95 and no drugs. n=716	SBP ≥160 or DBP ≥95 or spec. antihypertensive drug treatment. n=76	SBP <160 and DBP <95 and drugs for non antihypertensive reasons. n=16	n=2

Appendix. Continued

			2 Year			
Risk factor	**Type of calc.**	**Baseline n=1479**	**Healthy**	**Sick**	**Excl. from calc.**	**Missing**
	Recovery:	SBP ≥160 or DBP ≥95 or spec. antihypertensive drug treatment n=604	SBP <160 and DBP <95 and no drugs n=191	SBP ≥160 or DBP ≥95 or spec. antihypertensive drug treatment n=398	SBP <160 and DBP <95 and drugs for non antihypertensive reasons n=14	n=1
	Excl from calc:	SBP <160 and DBP <95 and drugs for non antihypertensive reasons n=57				
	Missing:	n=8				
Diabetes:	Incidence:	Glu <6.7 no drugs n=1281	Glu <6.7 no drugs n=1238	Glu ≥6.7 or drugs n=41		n=2
	Recovery:	Glu ≥6.7 or drugs n=196	Glu <6.7 no drugs n=101	Glu ≥6.7 or drugs n=94		n=1
	Missing:	n=2				
Hyper Ins:	Incidence:	Ins <30 n=1254	Ins <30 n=1208	Ins ≥30 n=44		n=2
	Recovery:	Ins ≥30 n=221	Ins <30 n=186	Ins ≥30 n=35		
	Missing:	n=4				
Hyper TG:	Incidence:	TG <2.8 no drugs n=1158	TG <2.8 no drugs n=1107	TG ≥2.8 n=48	TG <2.8 and drugs n=2	n=1
	Recovery:	TG ≥2.8 n=315	TG <2.8 no drugs n=169	TG ≥2.8 or TG <2.8 and drugs n=145		n=1
	Excl from calc:	TG <2.8 and drugs n=4				
	Missing:	n=2				
Hypo HDL:	Incidence:	HDL ≥0.9 n=1182	HDL ≥0.9 n=1087	HDL <0.9 n=65		n=30
	Recovery:	HDL <0.9 n=231	HDL ≥0.9 n=136	HDL <0.9 n=80		n=15
	Missing:	n=66				
Hyper Chol:	Incidence:	Chol <6.2 no drugs n=943	Chol <6.2 no drugs n=813	Chol ≥6.2 n=127	Chol <6.2 and drugs n=2	n=1
	Recovery:	Chol ≥6.2 n=531	Chol <6.2 no drugs n=206	Chol ≥6.2 or Chol <6.2 and drugs n=325		
	Excl from calc:	Chol <6.2 and drugs n=3				
	Missing:	n=2				

Anti-lipidemic drugs: HMG-CoA reductase inhibitors, fibric acid derivatives, bile acid sequestrants and nicotinic acid with derivatives
Anti-diabetic drugs: Insulin and oral hypoglycemic drugs
Blood pressure lowering drugs: Metyldopa, imidazolin receptor agonists, alfa-1-receptor blockers, hydralazin, bensotiadiazin derivatives, ACE-inhibitors, beta blockers, Ca antagonists and all diuretics

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Long-term effects of gastric surgery for treating respiratory insufficiency of obesity[1-3]

Harvey J Sugerman, R Paul Fairman, Rakesh K Sood, Kathryn Engle, Luke Wolfe, and John M Kellum

ABSTRACT The Pickwickian syndrome can be divided into two primary breathing disorders, which can affect patients alone or in combination: sleep apnea syndrome (SAS) and obesity hypoventilation syndrome (OHS). Between 1980 and 1990, 126 patients with respiratory insufficiency underwent gastric surgery for morbid obesity, 12.5% of the entire series. These patients weighed more (164 ± 36 vs 135 ± 25 kg, $P < 0.0001$) and were more often men (62% vs 14%, $P < 0.001$) than those without pulmonary dysfunction. Sixteen had OHS alone, 65 had SAS alone, and 45 had both. Of those with OHS, 38 have been followed for 5.8 ± 2.4 y since surgery and 29 are currently asymptomatic. In the 12 patients in whom arterial blood gases were available > 5 y since surgery, the PaO_2 increased from 54 ± 10 to 68 ± 20 mm Hg ($P < 0.0001$) and $PaCO_2$ fell from 53 ± 9 to 47 ± 11 mm Hg ($P = 0.05$). Of the 110 patients with SAS, 57 were available for follow-up an average of 4.5 ± 2.3 y since surgery and 38 were completely asymptomatic, 15 had mild SAS, and 4 had both SAS and OHS. In 40 patients with pre- and post-weight reduction sleep polysomnograms, the sleep apnea index fell from 64 ± 39 to 26 ± 26 ($P < 0.0001$). Although respiratory insufficiency of obesity patients had a higher operative mortality than did patients wtihout pulmonary dysfunction (2.4% vs 0.2% after gastric bypass), weight loss was associated with significant improvements in sleep apnea, arterial blood gases, pulmonary hypertension, left ventricular dysfunction, lung volumes, and polycythemia. *Am J Clin Nutr* 1992;55:597S–601S.

KEY WORDS Pickwickian, sleep apnea, obesity hypoventilation, blood gas, heart failure, lung volumes, pulmonary hypertension, polysomnography

Introduction

Morbid obesity may be associated with severe respiratory insufficiency, commonly known as the Pickwickian syndrome (1). This can be divided into the following two primary breathing disorders, which can affect patients alone or in combination: obstructive sleep apnea syndrome and obesity hypoventilation syndrome.

Sleep apnea syndrome entails recurrent episodes of upper glottic airway obstruction. There may be a mixed obstructive and central component to the apneas, as severe hypoxemia will often produce periodic respirations, as in Cheynes-Stokes breathing. This interferes with Stage III, IV, and REM sleep and is associated with severe daytime somnolence (2). Sleep apnea can lead to falling asleep while driving or at work, which can be especially dangerous in certain occupations. We have had two taxi cab drivers, two interstate truck drivers, and two state prison guards with morbid obesity and severe sleep apnea syndrome.

Obesity hypoventilation syndrome is associated with hypoxemia and hypercarbia while awake and is secondary to decreased lung volumes, probably secondary to an elevated diaphragm and heavy chest wall (3, 4). The lung volume most affected is the expiratory reserve volume, leading to arteriovenous shunting at end-expiration. Forced vital capacity and other spirometric values are often only mildly reduced. Obesity hypoventilation syndrome is often accompanied by cardiac dysfunction with either right or biventricular failure (3, 4). We have defined obesity hypoventilation syndrome as an arterial oxygen tension (PaO_2) ≤ 55 mm Hg and/or a $PaCO_2$ ≥ 47 mm Hg (5–7).

Over the past decade, 126 of 1010 (12.5%) morbidly obese patients who underwent gastric surgery for the treatment of morbid obesity at the Medical College of Virginia had respiratory insufficiency of obesity. Men constituted 62% of patients with pulmonary dysfunction but only 14% of patients without respiratory impairment ($P < 0.001$). Sixteen had obesity hypoventilation alone (94% women), 65 had sleep apnea alone (69% men), and 45 had both sleep apnea and obesity hypoventilation syndromes (71% men). Patients with respiratory insufficiency had a higher percent ideal body weight (IBW) [244 ± 53% vs 215 ± 37% ($\bar{x}$ ± SD), $P < 0.0001$] and weighed more (164 ± 36 vs 135 ± 25 kg, $P < 0.0001$) than those without breathing dysfunction. Although these differences were statistically significant, the standard deviations were large, so that a number of very heavy patients, weighing as much as 232 kg, did not suffer from respiratory insufficiency and several patients who were just 45 kg above IBW were affected. Morbidly obese patients with pulmonary dysfunction often suffered from an additional underlying pulmonary problem: 25% smoked more than one pack of cigarettes per day and 11% suffered from asthma. These patients

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TABLE 1
Effect of weight loss on obesity hypoventilation syndrome*

	Preoperative (n = 61)	1 year (n = 31)	Last visit† (n = 38)
PaO_2 (mm Hg)‡	53 ± 10	73 ± 15§	68 ± 20§
$PaCO_2$ (mm Hg)‡	53 ± 9	44 ± 8§	47 ± 12‖
Asymptomatic (%)	0	66§	76§
Body mass index (kg/m²)	56 ± 13	38 ± 9§	40 ± 10§
Weight (kg)	163 ± 39	113 ± 30§	115 ± 30§
Ideal body weight (%)	242 ± 55	163 ± 40§	172 ± 43§
Weight loss (%)		33 ± 14§	26 ± 18§
Excess weight loss (%)		58 ± 25§	45 ± 34§

* $\bar{x}$ ± SD.
† Average time of last visit = 5.8 ± 2.4 y.
‡ Arterial blood gases only obtained in 12 patients at time of last visit.
§ $P < 0.0001$.
‖ $P < 0.05$.

suffered primarily from obesity hypoventilation syndrome, 72% in smokers and 66% in asthmatics. Additional problems were seen on occasion, such as sarcoidosis (2), idiopathic pulmonary fibrosis (2), and recurrent pulmonary emboli (1).

Several different obesity procedures were performed over the decade, including various types of horizontal gastroplasty in 15, vertical banded gastroplasty in 16, proximal gastric bypass in 83, and distal gastric bypass in 12 patients. Eighteen patients are known to have failed their gastroplasty procedures and 14 were converted to gastric bypass. Ten patients failed their proximal gastric bypass and six were converted to the malabsorptive distal gastric bypass. There were five operative (< 30 d after surgery) deaths in the 126 patients with respiratory insufficiency of obesity for an operative mortality of 4%, as compared with 0.7% ($P < 0.01$) for the entire series of 1010 patients or 0.2% in the patients without respiratory insufficiency. These five deaths were due to one fatal pulmonary embolus, three cases of peritonitis from leaks, and one patient with both peritonitis and pulmonary embolus. In the respiratory insufficiency of obesity patients who underwent proximal gastric bypass, the operative mortality was 2.4%, in contrast to 0.4% of the entire group of 672 patients who underwent gastric bypass, or 0.2% ($P < 0.01$) of the gastric bypass patients without pulmonary dysfunction. Although the mortality is relatively low, these patients have little reserve should a postoperative complication develop. Furthermore, respiratory insufficiency patients tend to be superobese (> 225% IBW), which makes the operation technically more difficult and the risk of postoperative complications greater.

The respiratory insufficiency patient followed the longest in our series underwent a Gomez horizontal gastroplasty in 1980 when he was 30 y old and weighed 172 kg. His sleep apnea was so incapacitating that he had to sell his convenience store. He was involved in several automobile accidents from falling asleep at the wheel. His arterial blood gases (ABGs) were PaO_2 53 mm Hg and $PaCO_2$ 39 mm Hg. He lost 47 kg within 3 mo of surgery, with complete resolution of both sleep apnea syndrome and obesity hypoventilation syndrome (5). He has been asymptomatic for the past 10 y and is currently in an executive training program. His weight has been stable at 100 kg for the past 5 y. A recent sleep study reveals no apneic or hypopneic events; his PaO_2 is 95 mm Hg and his $PaCO_2$ is 40 mm Hg.

Long-term follow-up

Thirty-eight obesity hypoventilation syndrome patients have been followed for 5.8 ± 2.4 y since gastric surgery (**Table 1**).Their preoperative percent ideal body weight (% IBW) was 242 ± 55 and they weighed 163 ± 39 kg with a 56 ± 13 kg/m² body mass index (BMI). These patients lost 44 ± 34 kg or 45 ± 34% of their excess weight or 26 ± 18% of their preoperative weight to a BMI of 40 ± 10 m/kg² or 172 ± 43% IBW. Most of these patients were superobese and have been noted to have a significantly lower percent excess weight loss than those who are simply morbidly obese, who lose on the average 60% of their excess weight at 5 y after gastric surgery for obesity (8). Their preoperative PaO_2 was 53 ± 10 mm Hg and their $PaCO_2$ was 53 ± 9 mm Hg. Of these 38 patients, 29 were asymptomatic at follow-up evaluation. ABGs were available in 31 patients at 6 mo–1 y after surgery, with a rise in PaO_2 to 73 ± 15 mm Hg and fall in $PaCO_2$ to 44 ± 8 mm Hg ($P < 0.0001$) and, in 12 patients at 5.8 ± 2.4 y postoperatively, with a rise in PaO_2 to 68 ± 20 mm Hg ($P < 0.0001$ compared with preoperative) and a fall in $PaCO_2$ to 47 ± 11 mm Hg ($P = 0.05$ compared with preoperative).

Most of the 110 patients with sleep apnea syndrome underwent sleep polysomnography. Twenty-four patients were diagnosed with sleep capneography. An apneic event was defined as absence of ventilatory effort for 10 s or longer; a hypopneic event was defined as a reduction of air flow by at least 50% for 10 s or more. The sleep apnea index was defined as the combination of apneic and hypopneic events per hour of sleep. Sleep apnea was defined as mild, moderate, or severe with sleep apnea indices of 6–20, 21–40, and > 41, respectively. Two-thirds of the patients had severe sleep apnea.

Fifty-seven of the 110 patients with sleep apnea were available for follow-up an average of 4.5 ± 2.3 y since their gastric operation. These patients had lost 54 ± 32 kg, 53 ± 29% of their excess weight or 31 ± 16% of their preoperative weight. Their BMI had fallen from 56 ± 12 to 38 ± 9 m/kg² and their % IBW had fallen from 243 ± 53 to 165 ± 38. As in the obesity hypoventilation group, the majority of these patients were superobese. Each of these parameters had changed significantly ($P < 0.0001$). Of these 57 patients, 38, or two-thirds, were completely asymptomatic, 15 had mild persistent sleep apnea syndrome, and 4 had both sleep apnea and obesity hypoventilation syndromes.

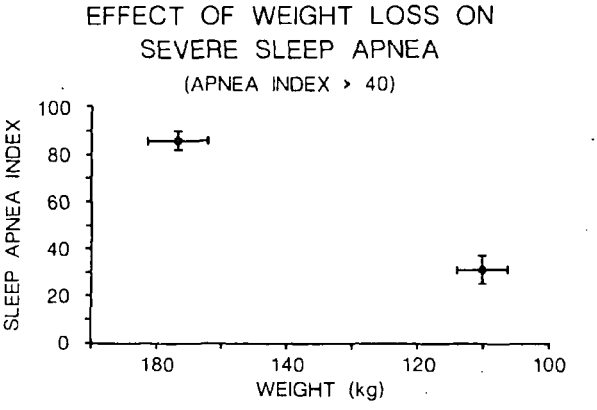

FIG 1. Decrease in sleep apnea index ($P < 0.0001$) associated with decrease in weight ($P < 0.0001$) after gastric surgery for obesity in patients with severe obstructive sleep apnea syndrome (apnea index > 40).

TABLE 2
Effect of weight loss on severity of sleep apnea syndrome*

	Preoperative (n = 110)	1 year (n = 63)	Last visit† (n = 57)
Apnea index	64 ± 39‡	33 ± 27§	32 ± 32§
Asymptomatic (%)	0	60§	66§
BMI (kg/m^2)	56 ± 12	37 ± 8§	38 ± 9§
Weight (kg)	166 ± 35	110 ± 23§	114 ± 28§
IBW (%)	244 ± 53	162 ± 33§	165 ± 39§
Weight loss (%)		33 ± 11§	31 ± 16§
Excess weight loss (%)		58 ± 18§	53 ± 29§

* $\bar{x}$ ± SD.
† Average time of last visit = 4.5 ± 2.3 y.
‡ Sleep polysomnograms performed in 86 preoperatively, 20 at 1 y and 7 at last visit.
§ $P < 0.0001$ compared with preoperative value.

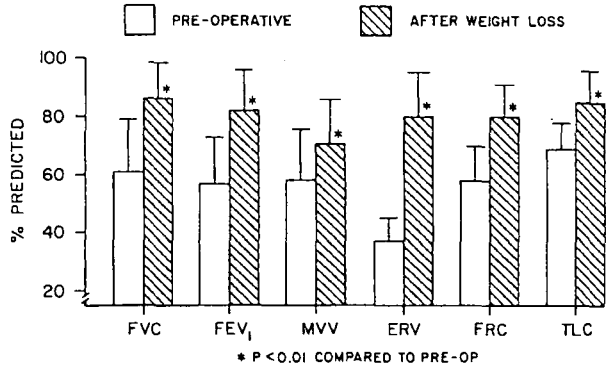

FIG 3. Improved pulmonary function in 26 patients with obesity hypoventilation syndrome after weight loss after gastric surgery for obesity. Reproduced with permission from reference 6.

Follow-up sleep polysomnography was extremely difficult to obtain because of the expense, inconvenience, and discomfort of the procedure. Pre- and postweight reduction sleep polysomnograms were obtained in 40 patients with a decrease ($P < 0.0001$) in sleep apnea index from 64 ± 39 to 26 ± 26. In the patients with severe sleep apnea, the apnea index fell from 86 ± 28 to 32 ± 29 ($P < 0.0001$) at 1 y after surgery in the 21 patients who underwent repeat study (**Fig 1**). At an average of 3.2 ± 1.3 y after surgery, two-thirds of these patients were clinically asymptomatic (**Table 2**). They no longer felt the need for nocturnal nasal continuous positive airway pressure (nasal CPAP) nor did they feel tired during the day. These patients had lost 57 ± 30 kg or 54% of their excess weight or 32 ± 13% of their preoperative weight ($P < 0.0001$). Their BMI fell from 58 ± 13 to 39 ± 8 kg/m^2 and their % IBW fell from 256 ± 58 to 171 ± 34 ($P < 0.0001$). Other investigators have also noted significant improvement in sleep apnea syndrome with surgically induced weight loss (9–11).

Respiratory insufficiency of obesity returned in those patients (mostly gastroplasty) who regained weight after obesity surgery. Patients who failed a gastroplasty (14 patients) or gastric bypass (2 patients) and lost weight after conversion to a proximal gastric bypass or malabsorptive distal gastric bypass, respectively, again corrected their respiratory insufficiency problem. One patient with severe sleep apnea and obesity hypoventilation syndromes initially lost 55 kg after his gastric bypass with resolution of his respiratory insufficiency problems only to regain all of his lost weight and die 7 y later of cardiorespiratory failure.

In our previous studies (5–7), significant improvements were noted in ABGs and lung volumes after surgically induced weight loss (**Figs 2 and 3**). Most lung volumes are moderately reduced in patients with obesity hypoventilation syndrome, as this is primarily a restrictive disease; the expiratory reserve volume is markedly depressed, suggesting alveolar collapse and shunting during expiration. This lung volume is the most significantly improved after surgically induced weight loss (Fig 3). Similar results have also been noted by other investigators who noted that the obstructive component of lung function in smokers was masked in morbidly obese patients before weight loss by the opposing effects on residual volume and functional residual capacity (12).

Effect of weight loss on cardiac filling pressures and function

We performed right heart catheterization in 46 morbidly obese patients before gastric surgery, 26 with and 20 without obesity

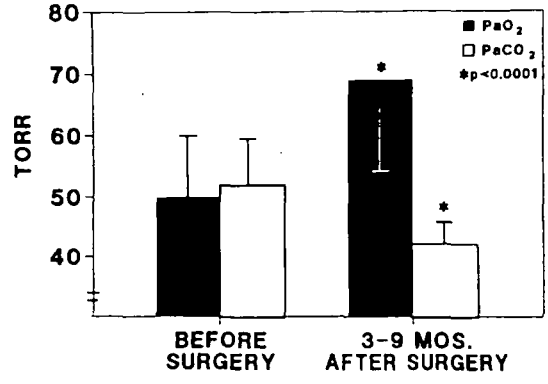

FIG 2. Significantly improved PaO_2 and $PaCO_2$ in 18 patients 3–9 mo after gastric-surgery–induced loss of 42 ± 19% excess weight. Reproduced with permission from reference 7.

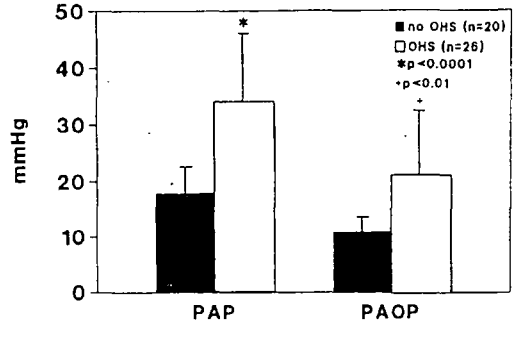

FIG 4. Significantly higher mean pulmonary artery pressure (PAP) and mean pulmonary artery occlusion pressure (PAOP), also known as wedge pressure, in morbidly obese patients with, than in morbidly obese control subjects without, obesity hypoventilation syndrome (OHS). Reproduced with permission from reference 7.

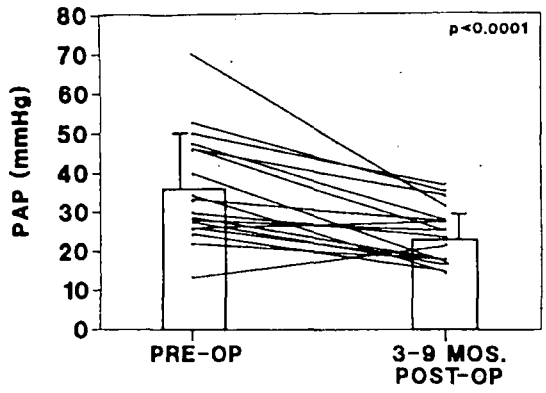

FIG 5. Significantly improved pulmonary artery pressure (PAP) in 18 patients 3–9 mo after gastric-surgery–induced loss of 42 ± 19% excess weight. Reproduced with permission from reference 7.

hypoventilation syndrome (7). Significantly higher pulmonary artery pressures (PAP) and pulmonary artery occlusion pressures (PAOP), commonly called pulmonary capillary wedge pressures, were noted in the patients with OHS (**Fig 4**). Four to nine months after surgically induced weight loss, there were clinically significant improvements in ABGs, PAP (**Fig 5**), and PAOP.

One patient (7) with both sleep apnea and obesity hypoventilation syndromes (PaO_2 55 mm Hg, $PaCO_2$ 50 mm Hg) had a PAP of 105/55 mm Hg and PAOP of 45 mm Hg with chronic cardiac insufficiency and marked cardiomegaly on chest roentgenogram when she weighed 182 kg with a 55 BMI kg/m^2 (**Fig 6**). Three years after gastric bypass she had lost 67 kg, which was associated with markedly improved ABGs: PaO_2 95 mm Hg and $PaCO_2$ 39 mm Hg. Her PAP had decreased to 20/12 mm Hg, her PAOP decreased to 10 mm Hg, and her cardiac silhouette normalized (Fig 7). Six years after gastric bypass she regained 23 kg with recurrence of mild sleep apnea syndrome and a slight deterioration in ABGs (PaO_2 75 mm Hg, $PaCO_2$ 42 mm Hg), but no clinical cardiac dysfunction. Her cardiac silhouette on chest roentgenogram was unchanged.

Preoperative evaluation

Morbidly obese patients with suspected sleep apnea syndrome (restless sleep, daytime somnolence, morning headaches) should undergo preoperative sleep polysomnography. If moderate to severe sleep apnea is present, treatment with nocturnal nasal CPAP should be attempted (13). If the patient does not tolerate nasal CPAP and has severe sleep apnea, the patient should probably undergo tracheostomy at the time of gastric surgery for obesity.

Patients with symptoms suggestive of obesity hypoventilation syndrome (severe shortness of breath, marked leg edema, congestive heart failure) should have preoperative measurement of ABGs. If the PaO_2 is $\leq$ 55 mm Hg and/or the $PaCO_2$ is $\geq$ 47 mm Hg, it has been our policy to perform right heart catheterization. If the PAOP is high, the patient should be given therapeutic doses of digoxin and diuresis with furosemide should be attempted. However, many of these patients require high cardiac filling pressures to maintain an adequate cardiac output. The high filling pressures may be partially secondary to an elevated intrathoracic pressure so that transmyocardial pressures may be much lower. Nevertheless, the nonthoracic venous system must overcome the intrathoracic pressure burden. If the mean PAP is high (> 40 mm Hg), one should consider prophylactic Greenfield vena caval filter insertion to prevent a fatal pulmonary embolus. If hypoxemic-induced polycythemia is present, the patient should probably be bled to a hemoglobin < 15 g/dL to reduce the risk of venous thrombosis. Other investigators have

FIG 6. Markedly enlarged cardiac silhouette on anterior-posterior portable chest roentgenogram before surgery in a 39-y-old, 1.8-m tall, 182 kg (56 BMI) black female with severe sleep apnea and awake PaO_2 55 mm Hg, $PaCO_2$ 50 mm Hg, PAP 105/55 mm Hg, PAOP 40 mm Hg, and cardiac output 13 L/min. Reproduced with permission from reference 7.

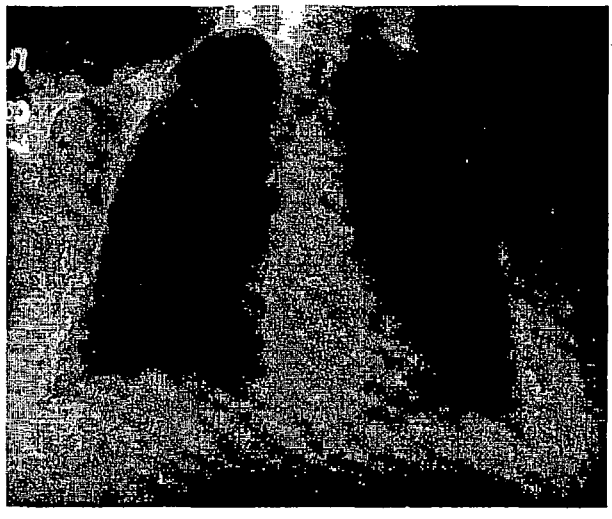

FIG 7. Markedly improved cardiac silhouette on posterior-anterior chest roentgenogram 3 y after gastric-surgery–induced 69-kg weight loss in patient from Figure 6 with correction of obesity hypoventilation: PaO_2 95 mm Hg, $PaCO_2$ 39 mm Hg, PAP 20/12 mm Hg, PAOP 10 mm Hg, and cardiac output 7 L/min. Reproduced with permission from reference 7.

noted that routine spirometry has not been of clinical value before surgery in morbidly obese patients (14). We would extend this to patients with obesity hypoventilation, unless one is interested in research evaluation of the effect of weight reduction.

Anesthesia

Anesthetic induction may be dangerous. Three anesthesia personnel should be present: one to insert an oral airway, hyperextend the jaw, and maintain a tight face-mask fit; one to squeeze the ventilation bag, using both hands because these patients have low compliant chests; and one to administer medications. Should intubation be difficult, one can return to bag-and-mask ventilation and attempt reintubation after adequate reoxygenation. A digital pulse oximeter and end-tidal CO_2 monitor are mandatory. With this approach we have not had an anesthetic complication. Intermittent compression boots should be used during surgery and until the patient is fully ambulatory to minimize venous thrombosis and pulmonary embolism.

Postoperative management

Postoperatively, patients with sleep apnea should remain intubated and ventilated overnight; they can usually be weaned from the ventilator and extubated the next day and monitored overnight while they are treated with nasal CPAP. Patients with obesity hypoventilation require mechanical ventilation for 1–5 d until their incisional pain resolves and the ABGs return to their preoperative values, at which time they can be safely weaned from the ventilator and extubated. They should be nursed in a reverse Trendelenburg position to maximize diaphragmatic excursion.

The duration of postoperative hospitalization for our average patient without complications is 4–5 d. Patients with respiratory insufficiency of obesity usually require an additional 3–4 d of hospitalization. Clinical resolution of sleep apnea syndrome, permitting removal of the tracheostomy tube or discontinuance of nasal CPAP, is usually seen within 2–3 months, although complete correction may require much longer (5, 6, 9–11). Improved ABGs, ventilatory function, and cardiac filling pressures are also seen within several months after gastric-surgery–induced weight loss in patients with obesity hypoventilation syndrome (5–7).

Conclusion

Although gastric-surgery–induced weight loss for the respiratory insufficiency of obesity patients has a slightly higher operative risk than patients without pulmonary dysfunction, the procedure is relatively safe and effective. Weight loss after gastric bypass is significant and, in most instances, long-lasting and is associated with marked improvements in arterial blood gases, lung volumes, polycythemia, cardiac dysfunction, and sleep apnea index, permitting the return of these severely incapacitated individuals to productive lives in society, possibly with a net long-term reduction in medical costs and mortality.

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Who Would Have Thought It?

An Operation Proves to Be the Most Effective Therapy for Adult-Onset Diabetes Mellitus

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Objective

This report documents that the gastric bypass operation provides long-term control for obesity and diabetes.

Summary Background Data

Obesity and diabetes, both notoriously resistant to medical therapy, continue to be two of our most common and serious diseases.

Methods

Over the last 14 years, 608 morbidly obese patients underwent gastric bypass, an operation that restricts caloric intake by (1) reducing the functional stomach to approximately 30 mL, (2) delaying gastric emptying with a c. 0.8 to 1.0 cm gastric outlet, and (3) excluding foregut with a 40 to 60 cm Roux-en-Y gastrojejunostomy. Even though many of the patients were seriously ill, the operation was performed with a perioperative mortality and complication rate of 1.5% and 8.5%, respectively. Seventeen of the 608 patients (<3%) were lost to follow-up.

Results

Gastric bypass provides durable weight control. Weights fell from a preoperative mean of 304.4 lb (range, 198 to 615 lb) to 192.2 lb (range, 104 to 466) by 1 year and were maintained at 205.4 lb (range, 107 to 512 lb) at 5 years, 206.5 lb (130 to 388 lb) at 10 years, and 204.7 lb (158 to 270 lb) at 14 years.

The operation provides long-term control of non–insulin-dependent diabetes mellitus (NIDDM). In those patients with adequate follow-up, 121 of 146 patients (82.9%) with NIDDM and 150 of 152 patients (98.7%) with glucose impairment maintained normal levels of plasma glucose, glycosylated hemoglobin, and insulin. These antidiabetic effects appear to be due primarily to a reduction in caloric intake, suggesting that insulin resistance is a secondary protective effect rather than the initial lesion. In addition to the control of weight and NIDDM, gastric bypass also corrected or alleviated a number of other comorbidities of obesity, including hypertension, sleep apnea, cardiopulmonary failure, arthritis, and infertility.

Conclusions

Gastric bypass is now established as an effective and safe therapy for morbid obesity and its associated morbidities. No other therapy has produced such durable and complete control of diabetes mellitus.

Non-insulin-dependent diabetes mellitus (NIDDM), the form of diabetes that afflicts more than 90% of the 14 million diabetic Americans, is notoriously resistant to treatment. The current therapies, including insulin, diet, exercise, behavior modification, and oral agents, rarely return patients to long-term euglycemia. Further, these therapies have not been shown to reduce the incidence of the complications of diabetes, including stroke, myocardial infarction, loss of vision, renal failure, amputations, and neuropathies.

This report details our experience with the gastric bypass operation in a series of 330 of 608 (54.3%) morbidly obese patients who had either NIDDM or impaired glucose tolerance (IGT). Operative management restored and maintained normal levels of glucose, insulin, and glycosylated hemoglobin in 91% of the patients for as long as 14 years. This degree of diabetic control is far better than any reported by medical means.

METHODS

Since 1980, 608 morbidly obese patients were treated with the Greenville modification of Mason's gastric bypass operation. The operations were performed on 404 white (66.4%) and 102 African American (16.8%) women and on 87 white (14.3%) and 15 African American (2.5%) men. The average age at the time of surgery was 37.3 years (range, 14 to 64 years). Preoperative weights of the group ranged from 198 to 615 lb, with a mean of 304.4 lb. Of these 608 individuals, 364 (59.9%) were employed: two as executives or major professionals; 52 as managers, professionals, or owners of medium businesses; 46 as administrators, semiprofessionals, or small business owners; 122 as technicians or clerical/sales workers; 79 as skilled workers; 42 as semiskilled workers; and 21 as laborers. Two hundred forty-four (40.1%) were not employed. Marital status inquiries revealed that 418 (68.8%) were married, 54 (8.9%) were divorced, 25 (4.1%) were separated, 11 were (1.8%) widowed, and 100 (16.4%) had never married.

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Of these 608 morbidly obese patients, 165 (27%) had NIDDM, and another 165 (27%) had IGT. Before surgery, 353 (58.1%) of the patients had hypertension.

Of the initial 608 patients who underwent surgery, 553 of the 574 living patients maintained contact over the 14 years, a follow-up rate of 96.3%. After surgery, 599 (98.5%) survived the perioperative period and 574 (94.4%) are currently alive. Of these, 281 (49%) were examined in the clinic and 272 (47%) were interviewed by phone over the last year. Information was received from the family for 4 (1%) patients, and 17 patients (3%) were lost to follow-up.

Patient Selection

Patients between the ages of 14 and 65 years were accepted for evaluation for bariatric surgery if they had a body mass index (BMI, kg/m^2) of ≥ 35 if comorbidities such as diabetes, cardiopulmonary failure, or arthritis existed or ≥ 40 if no comorbidities existed. Table 1 shows ideal body weights and BMIs at each height as well as the weights for these heights when BMI values are 24 (considered normal weight by some), 35, and 40. Contraindications to surgery included a history of unresolved alcohol or substance abuse in the previous 5 years, depression, an inability or unwillingness to cooperate in long-term follow-up, a lack of understanding of the operation and its consequences, an unrealistic expectation of outcome, and failure to correct the medical conditions to a degree to permit safe surgery. Strong immutable opposition from the family was a relative contraindication.

Preoperative Evaluation and Preparation

The evaluation of these patients as candidates for bariatric surgery was simplified as we gained experience. Even so, we continue to prefer a slow evaluation, that is, over 2 to 3 months, to be certain that the patient and the family are well educated about the operation and its consequences. The first visit is used for the initial evaluation, for the first screening to determine whether the patient is a candidate for bariatric surgery, for the distribution of educational materials, and, if the patient is deemed suitable, for ordering of a psychologic evaluation as well as a chest roentgenogram, upper gastrointestinal series, complete blood count, SMA-17, thyroid-stimulating hormone levels, urinalysis, electrocardio-

Table 1. IDEAL BODY WEIGHTS FOR MEN AND WOMEN WITH COMPARISONS TO WEIGHTS WITH BMIS AT 24, 35, AND 40*

Height (ft./in.)	Height (cm)	Weight (lb)	Weight (kg)	BMI	BMI = 24 (lb)	BMI = 35 (lb)	BMI = 40 (lb)
Women							
4'10"	147	115	52.2	24	114	166	190
4'11"	150	117	53.1	24	119	173	198
5'0"	152	120	54.2	23	122	178	203
5'1"	155	122	55.3	23	127	185	211
5'2"	158	125	56.7	23	132	192	220
5'3"	160	128	58.1	23	135	197	225
5'4"	163	131	59.4	22	140	205	234
5'5"	165	134	60.8	22	144	210	240
5'6"	168	137	62.1	22	149	217	248
5'7"	170	140	63.5	22	153	223	254
5'8"	173	143	64.9	22	158	230	263
5'9"	175	146	66.2	22	162	236	270
5'10"	178	149	67.6	21	167	244	279
5'11"	180	152	68.9	21	171	249	285
6'0"	183	155	70.3	21	177	258	295
Men							
5'2"	158	136	61.7	25	132	192	220
5'3"	160	138	62.6	24	135	197	225
5'4"	163	140	63.5	24	140	205	234
5'5"	165	143	64.6	24	144	210	240
5'6"	168	145	65.8	23	149	217	248
5'7"	170	149	67.6	23	153	223	254
5'8"	172	151	68.5	23	156	228	260
5'9"	175	154	69.8	23	162	236	270
5'10"	178	157	71.2	22	167	244	279
5'11"	180	160	72.6	22	171	249	285
6'0"	183	164	74.2	22	177	258	295
6'1"	185	167	75.7	22	181	264	301
6'2"	188	171	77.6	22	187	272	311
6'3"	191	175	79.2	22	193	281	321
6'4"	193	179	81.2	22	197	287	328

BMI = body mass index.

* Based on the 1983 tables from the Metropolitan Life Insurance Company, New York, New York. Surgery is the therapy of choice for weight control when the BMI ≥35 in a patient with comorbidities such as diabetes and hypertension or when the BMI ≥40 in a patient without such comorbidities.

gram, and pregnancy test in women younger than age 50. Every patient is seen by the project psychologist, because depression and other emotional disorders are common in the morbidly obese population. The decision to proceed with bariatric surgery is made on the second visit, usually a month later, after the review of the various study outcomes and another counseling session with the patient. If the patient then requests the operation, additional consultations to evaluate and stabilize cardiac failure, pickwickian syndrome, sleep apnea, anemia, or pulmonary function are requested if needed. Morbidly obese patients who select surgical therapy have often exhausted all other treatment options. They must be regarded as chronically ill individuals with complex medical problems, often burdened with 50 to 100 lb of excess water, chronic malnutrition, and complex social conflicts. Insurance approval, occasionally difficult to obtain, is also requested at this visit. The third visit occurs within a week before surgery, at which time the operation, risks, alternatives, and benefits are again reviewed and the preadmission hospital workup is completed.

Preoperative Preparation

Serious health problems need to be stabilized before surgery. Skin lesions need to clear as much as possible, and chronic problems, such as asthma, chronic pulmonary infections, diabetes, and hypertension need to be stabilized; if the patient is receiving medications, these need to be reviewed and adjusted to appropriate levels. Patients are generally admitted on the morning of surgery. Complicated cases, however, such as those involv-

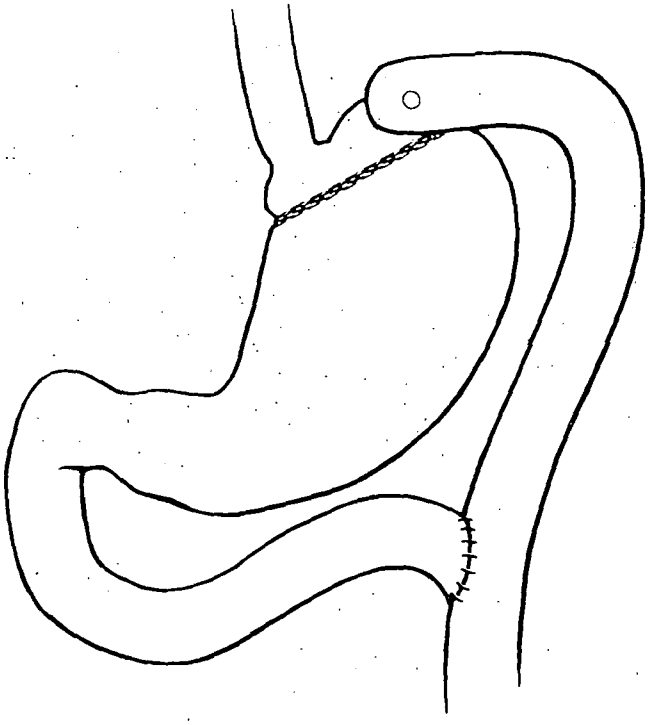

Figure 1. The Greenville modification of the gastric bypass. The stomach is partitioned to form a 20 to 30 mL proximal pouch that is connected to a 40 to 60 cm Roux-en-Y loop with an 8 to 10 mm double-layered gastroenterostomy. The biliopancreatic limb also measures 40 to 60 cm, depending on the mobility of the gut.

ing patients with cardiorespiratory failure, may require several days of preparation in the hospital to bring them to an optimal preoperative status. A cephalosporin is given intravenously for prophylaxis the morning of surgery and for 2 days thereafter.

Special equipment must be available for the care of the morbidly obese. The clinics require seats, couches, examining tables, and wheelchairs designed for individuals who may weigh over 600 lb. In addition, sturdy beds, strong gurneys, and X-ray that can accommodate these patients are required in the hospital.

Description of the Operation

A diagram of the operation is shown in Figure 1. The abdomen is entered through a high midline incision, and exposure is provided by a mechanical retractor, such as the Omni models (Omni-trak, St. Paul, MN). If the exploration demonstrates no contraindications, the upper stomach is isolated by inserting the index finger gently into the angle at the cardia to the left of the esophagus. At this point, there is a weak, thin area of the posterior peritoneum that is easily entered by the dissecting finger. The dissection is gently continued behind the esophagus and cardia and the finger brought out, not at the right side of the esophagus but between the ascending branches of the left gastric artery, 2.5 to 3.0 cm below the esophagogastric junction. A No. 36 Malecot catheter, from which the bulbous end has been cut, is used to pull a TA90 stapling instrument through the passage. A proximal pouch measuring 4 cm in width and 1.5 cm in height, approximately the size of a thumb, is then prepared by firing the staples. Two additional layers of similar TA90 staples are then superimposed and fired over the first set. A figure-of-eight suture is placed at each end of the staple line to close the ends securely and to serve as guy sutures. To prepare the Roux-en-Y, the jejunum is divided 40 to 60 cm from the ligament of Treitz with the GIA stapling instrument (Ethicon, Somerville, NJ) and then threaded through the mesocolon and the lesser sac and taken back out by the bare area of the greater curvature. The proximal end of the distal jejunum is then sutured to the gastric pouch. The anastomosis is sewn to fit loosely around a 0.8-cm Salem SUMP tube (Sherwood Medical Co., St. Louis, MO) in two layers with continuous polypropylene. The Roux-en-Y enteroenterostomy is then completed by joining the proximal jejunum end-to-side to the distal jejunum 60 cm below the gastroenterostomy with GIA and TA55 stapling devices. It is important to ensure that the intestine is not constricted in its passage through the lesser sac, that the Roux loop is attached to the mesocolon with three sutures to prevent an internal hernia, and that the enteroenterostomy is not bleeding from the internal staple line before applying the TA55. The abdomen is closed with a running double-stranded 0 PDS absorbable suture (Ethicon, Somerville, NJ). The skin is stapled. The operation can usually be performed in 60 to 75 minutes; blood loss rarely exceeds 300 mL. The first 519 gastric partitions were done with a four-row TA90 stapling device. Since then, to avoid further staple line failures, we have either divided the stomach or used the triple superimposed layers of double-row TA90 staples. Except for the different approaches for partition, the operations were identical and can therefore be evaluated as one cohort.

Postoperative Care

The postoperative care of bariatric patients demands close attention. The first 24 hours are particularly critical because of the great seriousness of a leak or intra-abdominal infection in these individuals. If the pulse remains over 120, if there is a rise in temperature over 39 C., or if the patient looks ill despite normal vital signs, emergency exploration and additional types of antibiotics may be needed. In such cases, swallow of a small amount of a

water-soluble radiopaque agent followed by barium may be helpful to detect an anastomotic leak. (Such tests are not always reliable; we have several patients with leaks who, on the first examination, demonstrated normal passage of barium without extravasation.) Neglect of a perforation or intra-abdominal infection is associated with a high mortality rate. If there is doubt, it is best to proceed with surgery; an unnecessary exploration is a lot safer than a missed perforation.

Patients usually spend the first night on an intermediate unit with nurses who are familiar with bariatric care. Patients are kept on nothing-by-mouth status until they pass flatus, usually on the 3rd day, begun on half-strength Ensure Plus (30 mL four times daily) with water (30 mL every hour) on the 4th day, and full-strength Ensure Plus with water, in the same doses, on the 5th or 6th day, when they are sent home. After discharge, the patients are maintained on full fluids for 2 weeks and then cautiously progress to a full diet by the end of 6 weeks. Most patients gradually return to their previous diet in terms of variety but with a marked reduction in quantity, because they fill up quickly and because the gastric pouch empties slowly. Most patients cannot tolerate simple carbohydrates, such as candy, because of the dumping induced by the gastroenterostomy. Meats may present difficulties: we start slowly with fish, then progress to chicken, and finally, after some months, introduce red meat. By the end of 3 months, most patients eat a limited but well-balanced diet. Considerable counseling may be needed during the initial adjustment to the operation so that the patients understand that the emesis after overeating and the dumping after the ingestion of candy are desirable side effects of the operation and that these symptoms can be avoided by adherence to the dietary limitations.

The most common early complications seen in the clinic are wound abscesses, and these, as might be expected, occur most commonly in the diabetic patients. The wound infections generally present as red bulges that drain spontaneously or that can be drained through a small 1- to 2-cm opening of the incision. It is not necessary to open the whole wound or significant lengths of the incision; such interventions may lead to long-term wound care and delays in healing. Late subphrenic abscesses can usually be drained percutaneously with interventional radiologic techniques.

Long-Term Follow-up

Patients generally do remarkably well and are delighted with their new body image, their freedom from diabetes, and their new life. Daily long-term intake of liquid or chewable total mineral and vitamin product is essential; 600 μg/day of B_{12} is the recommended minimum dose.[1] Omission of this may lead to severe anemia, Wernicke-Korsakoff syndrome, or other neuropathies. Weight gain exceeding 12% above the lowest postoperative weight is generally the result of staple line breakdown, pouch or anastomotic dilatation, or compulsive snacking. Abdominal pain is most commonly due to cholecystitis, although some patients may develop marginal ulcers that clear quickly with histamine blockers and, when indicated, with therapy for *Helicobacter pylori*. Recurrent vomiting usually signals overeating but may be due to stenosis of the gastrojejunostomy. Such strictures can almost always be relieved with one or two dilatations of the anastomosis. Finally, these patients require considerable emotional support from their referring physician, the surgical staff, and their families. We have found monthly support groups useful.

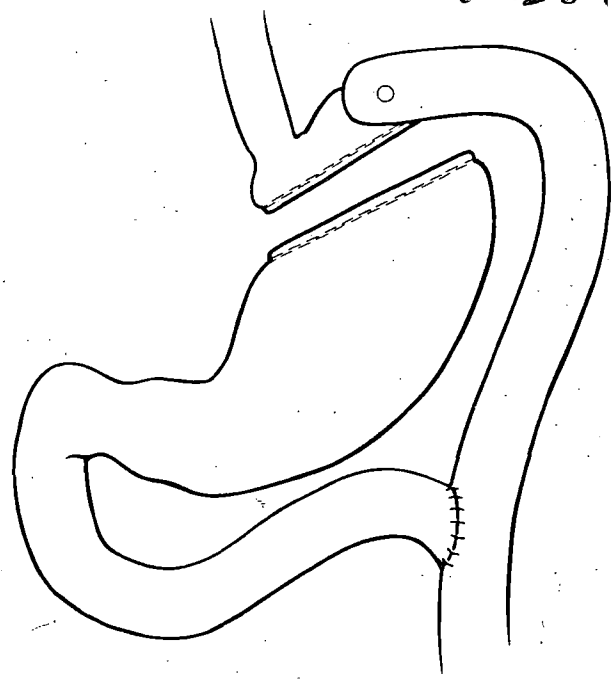

Figure 2. Revision of a failed gastric bypass. The pouch is restored to the original 20- to 30-cm size by dividing the stomach and resecting the previous staple line *en bloc* with the gastroenterostomy. A new anastomosis is then constructed to restore the 8- 10-mm gastric outlet. The formation of a fistula between the two gastric segments can be minimized by oversewing the two staple lines and interposing a tongue of omentum.

Revision of Failed Bariatric Procedures

All bariatric procedures have a failure rate, ranging from 80% or more for horizontal gastroplasties to about 5% to 10% for the vertical banded gastroplasties and gastric bypasses. Most of the failures are due to failed staple

Table 2. WEIGHT LOSS IN 608 MORBIDLY OBESE PATIENTS AFTER THE GASTRIC BYPASS OVER 14 YEARS WITH 97% FOLLOW-UP

	Mean Weights (lb) (range)	% Excess Weight Loss (range)	Body Mass Index
Preoperation	304.4 (198–615)	0.0	49.7 (33.9–101.6)
1 yr	192.2 (104–466)	68.9 (10.3–124)	31.5 (19.1–69.3)
5 yr	205.4 (107–512)	57.7 (−14.6–115.9)	33.7 (19.6–7.16)
10 yr	206.2 (130–388)	54.7 (−0.9–103.1)	34.7 (22.5–64.7)
14 yr	204.7 (158–270)	49.2 (7.2–80.9)	34.9 (25.9–54.6)

lines, stenosis of the gastric outlets, distended gastric pouches, or dilated gastrojejunostomies. Revision of these failures is technically challenging and associated with a high complication and second failure rate. Our most useful approach has been to (1) define the stomach and the alimentary limb, (2) expose the pouch and previous anastomosis, (3) resect the old staple line and the gastroenterostomy, and (4) reanastomose the jejunal limb to the now-divided gastric pouch (Fig. 2).

RESULTS

Control of Disease

The operation produced significant and durable weight loss. Table 2 demonstrates that the mean preoperative weight of 304.4 lb (range, 198 to 615 lb) drops to 192.2 lb (range, 104 to 466 lb) by the 1st year, a decrease of 112 lb. Usually there is some additional loss by 18 months, followed by a remarkable stability of weight for almost a decade and a half: 205.4 lb (range, 107 to 512 lb) at 5 years, 206.2 lb (range, 130 to 388 lb) at 10 years, and 204.7 lb (range, 158 to 270 lb) at 14 years. Not only has the mean weight of these patients at 14 years dropped 100 lb below their operative weights, but also, the maximum weights have diminished even more significantly, from 615 lb to 270 lb. An average maximum weight loss of 70% of excess body weight occurred approximately 2 years after surgery. At the end of 5 years, mean weight loss was 58% of excess body weight; after 10 years, 55%; and after 14 years, 49%. Similarly, the mean BMI levels fell from 49.7 to 31.5, 33.7, 34.7, and 34.9 at 1, 5, 10, and 14 years, respectively. The durability of the weight loss is graphically illustrated in Figure 3.

Gastric bypass effectively reduced the proportion of body fat. Measurements of body composition with hydrodensitometry (underwater immersion weighing) in 220 randomly selected patients demonstrated that the percentage of fat in females fell from a preoperative mean of 50.92% to 38.46% and in males from 46.70% to 31.93%.

Even more striking is the control of adult-onset diabetes. Before surgery, 165 of 608 patients (27%) had NIDDM and another 165 patients (27%) had IGT, however, a full set of data was not available for 19 of the 608 patients for technical reasons. Adequate follow-up data are available on 298 glucose-intolerant patients following surgery, 146 of 165 (88.5%) with NIDDM and 152 of 165 (92.1%) with IGT. Of these 298 patients, 271 (91%) have maintained normal values of fasting blood glucose and glycosylated hemoglobin, whereas 27 (9%) continue to be diabetic. Among these 27 diabetic patients, 25 originally presented with NIDDM and 2 with IGT. As of September 12, 1994, the date of the last annual summary, 121 of 146 patients (82.9%) who presented with NIDDM maintained normal values of blood glucose and glycosylated hemoglobin.

The 165 patients with IGT were followed until death

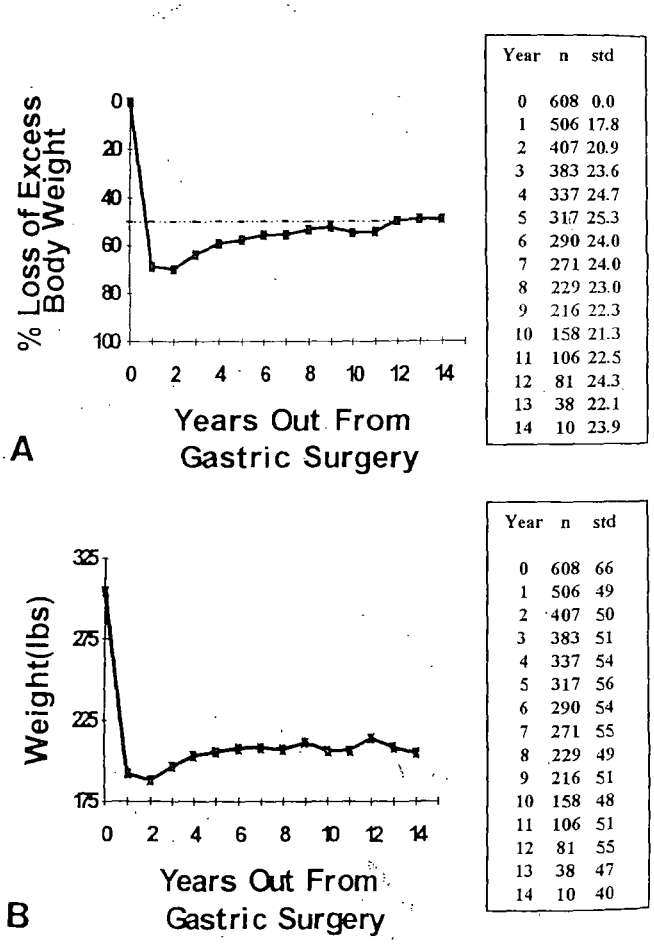

Figure 3. The gastric bypass produces durable weight loss. Weight loss of the entire cohort of 608 patients is shown in terms of pounds and percentage loss of excess body weight. If the patients with failed staple lines and stretched anastomoses are removed, the line is virtually straight.

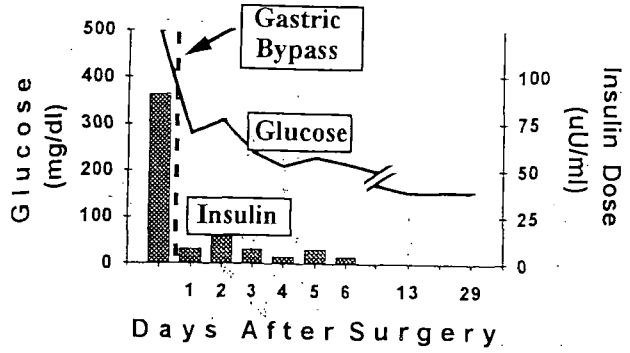

Figure 4. The correction of the hyperglycemia occurs rapidly. Patient 1 had an fasting blood glucose level of 495 mg/dL on the day before surgery despite the administration of 90 U of insulin. By the end of the 1st postoperative day, her fasting blood glucose level fell to 281 mg/dL and her insulin requirement dropped to 8 U. By the 6th postoperative day, she no longer required insulin.

or until September 12, 1994, for an average of 7.6 years after gastric bypass surgery, for a total of 1254 patient years of follow-up. Two patients (1.2%) who presented with IGT progressed to NIDDM; of the others available for study, 150 of 152 (98.7%) reverted to euglycemia. (Compared with a similar IGT population who did not undergo surgery, between 43 and 75 would have been expected to progress to NIDDM[2] within the same time frame [95% confidence interval].)

The normalization of glucose metabolism occurred with surprising speed, even before there was significant weight loss. Figure 4 demonstrates the response in patient 1, whose blood sugar levels were almost uncontrollable, with a fasting blood glucose of 495 mg/dL, despite administration of 90 U of insulin on the day before surgery. By the 6th postoperative day, she no longer required insulin, and by the end of the first month, her fasting blood glucose fell to 155 mg/dL. Within 3 months, her fasting blood glucose and glycosylated hemoglobin levels returned to normal. Figure 5 compares the changes in glucose and insulin levels in three groups: morbidly obese patients with NIDDM, morbidly obese non-NIDDM patients, and lean control subjects. The rapid fall in glucose levels in the patients with NIDDM contrasts sharply with the mild elevation of both of these indices in the nondiabetic group after surgery, thus fasting alone may not account for the euglycemia in the NIDDM and IGT groups. The differences in insulin levels among the three groups are also shown.

A review of the 27 failed operations in which the patients did not return to euglycemia revealed that 10 of these failures were due to staple line breakdowns, that is, technical failures prevented their correction. When the 17 nonresponders with intact operations, that is, without staple line breakdowns or anastomotic dilatation, were compared with those patients with full control of diabetic indices, the data showed that the patients who failed to revert to full euglycemia were older (48.0 *vs.* 40.7 years; $p < 0.01$) and their diabetes was of longer duration (4.6 *vs.* 1.6 years; $p < 0.04$) than those with successful control of glucose and insulin levels.

It is also of interest that the gastric bypass can overcorrect the hyperglycemia. We have documented 43 episodes of hypoglycemia in 35 patients, 6 of whom were from the NIDDM cohort, 1 from those with insulin-dependent diabetes mellitus, 8 from those who presented with IGT, and 20 from those with normal oral glucose tolerance curves. Postgastric bypass hypoglycemia can

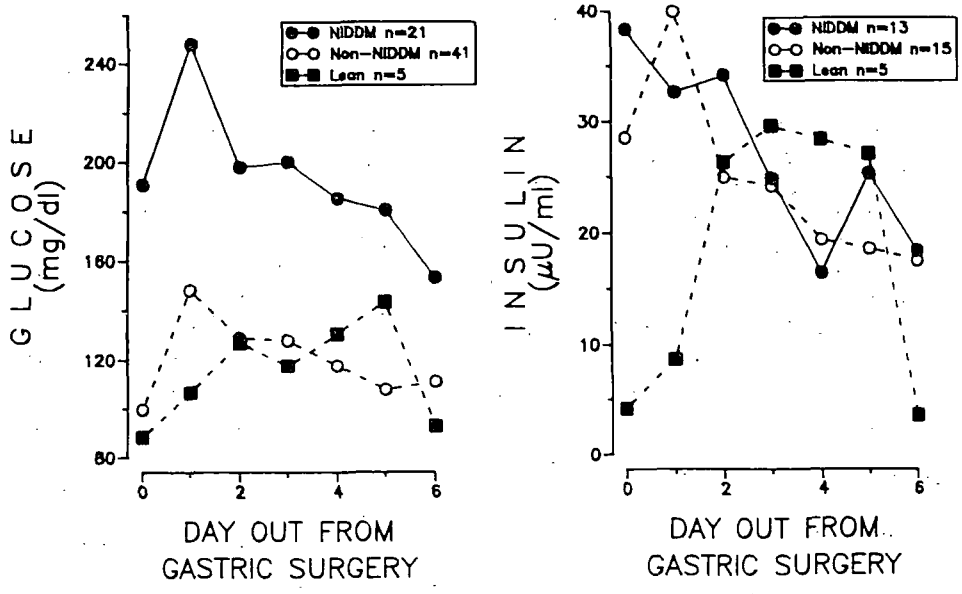

Figure 5. A comparison of blood glucose values and insulin levels after surgery in two cohorts, one with euglycemia and the other with NIDDM. The insulin and glucose levels rise slightly during the postoperative period in the euglycemic patients but fall sharply in those with NIDDM.

be troublesome, with blood glucose levels as low as 27 mg/dL. We have treated these without therapeutic intervention, urging these patients to carry sugar, and most were self-limited, with corrections occurring usually within 1 year.

Before surgery, 353 of the 608 patients (58.1%) had hypertension. After surgery, this rate has been reduced to 14%. In addition to these improvements, patients almost always demonstrated improvement of cardiopulmonary function, clearance of sleep apnea, cessation of snoring, control of asthma, clearance of peptic reflux, fewer limitations of physical activity from arthritis, and restoration of fertility. Mental health evaluations revealed marked overall improvement in mood and mental health indicators during the first 2 years after surgery. These gains, however, eroded by the 3rd year, with a return to their previous mood status, perhaps because some of their personal dreams in terms of mates or socioeconomic success were unrealized.

Complications

Complications diminished with increasing experience and rose with the severity of the comorbidities. For the whole series, including some patients with daunting risks, perioperative mortality was 9 of 608 (1.5%), with 5 dying of sepsis, 3 of pulmonary embolism, and 1 of an unknown cause (perhaps dysrhythmias) shortly after discharge. Perioperative morbidity, that is, during the first 30 days, included the following complications: minor wound infections, 8.7%; wound seromas, 5.8%; severe wound infections, 3.0%; anastomotic stenosis, 3.0%; splenic tears, 2.5%; and subphrenic abscesses, 2.5%. Hospital readmissions were required for 8.2% of the patients, and 2.8% of the patients needed reoperations during the early postoperative period. The total mortality over the 14 years was 34 of 608, with 9 perioperative and 25 late deaths. The latter were divided into two groups, 13 from emotionally related causes and 12 due to "more natural" causes. The emotionally related deaths involved three suicides, three cases of cirrhosis due to a return to drinking, one case of bulimia, one case of pernicious anemia due to a refusal to take vitamin B_{12}, one case of alcoholic hepatitis, and four, perhaps more questionable, cases of auto accidents. (Even though we have begun a regular support group, there have been three such deaths in the 3 years since its commencement.) The other late "natural" deaths included four of cardiac causes, two of cancer, and one each of atherosclerosis, pneumonia, acquired immunodeficiency syndrome, peritonitis, pulmonary embolus, and sepsis from a later operation.

The most frequent late complications were B_{12} deficiency (40%), anemia (39%), hospital readmission (38.1%), incisional hernia (23.9%), depression (23.4%), staple line failure (15.1%), gastritis (13.2%), cholelithiasis (11.4%), and bile reflux (8.7%). Dumping syndrome developed in 70.6% of the patients, but although this syndrome is sometimes listed as a complication, it is easily controlled by the avoidance of sweets and is actually a desired side effect.

DISCUSSION

The importance of our findings is not that gastric bypass can control diabetes in the morbidly obese, but that NIDDM, previously considered a progressive and inexorable disease, can be controlled for as long as 14 years.

What is the explanation for this remarkable control? We can immediately rule out several of the traditional approaches used in the treatment of NIDDM: exercise, sulfonylureas, and insulin. None of these play a role in the operative correction of diabetes. Morbidly obese patients do not exercise immediately after surgery, sulfonylureas are never given after the operation, and insulin, even when required initially for the 1st few postoperative days, is rarely needed after the 1st week. The reason for success must be associated with one of the changes induced by surgery:

1. Limitation of total caloric intake.
2. Decrease of carbohydrates in the diet (sweets cause dumping).
3. Exclusion of food from the hormonally active antrum, duodenum, and proximal jejunum by the bypass.
4. Delayed transit time from the stomach to the small bowel because of the small gastric outlet.
5. Presentation of the midjejunum with undigested food directly from the stomach.

There are several observations that offer clues in sorting out the role of each of these changes:

1. The correction of NIDDM occurs within days, long before significant weight loss has occurred and long before there is a significant reduction in the mass of adipocytes.
2. The correction of NIDDM is durable even though most of these patients remain obese. (Although the morbid obesity is almost always "cured," most patients do not return to an ideal body weight, but remain, on the average, 50% above their ideal body weight.)
3. The operation prevents the progression of IGT to NIDDM in 97.8% of the patients and, instead, returns them to euglycemia.
4. The correction of the NIDDM is less likely in pa-

tients who are older (48.0 *vs.* 40.7 years; $p < 0.01$) and who have had the disease longer (4.6 *vs.* 1.6 years; $p < 0.04$), probably due to a lower cell reserve.

5. In the three morbidly obese patients with NIDDM who underwent the vertical banded gastroplasty, an operation that also limits food intake but does not bypass any section of the foregut, the diabetes was also corrected.
6. In a unique patient who had a sham operation, the NIDDM also resolved rapidly when the patient was given the same postoperative diet as the patients who were treated with the gastric bypass. (The patient, a 48-year-old morbidly obese man with NIDDM, was scheduled for a gastric bypass but during surgery was found to have a stomach full of food. We did not, therefore, proceed with the procedure but closed his incision and then requested that he stay on the identical postoperative regimen as if he had undergone the bypass. His levels of blood glucose fell rapidly, similar to the correction seen in the gastric bypass patients, but rose again to preoperative levels as soon as he was unable to maintain the diet, 4 weeks after the procedure.)

Accordingly, based on these observations, it is reasonable to conclude that the gastric bypass controls NIDDM through the reduction of caloric intake. Whether the realignment of intestinal flow with the exclusion of the antrum, duodenum, and proximal jejunum as well as the presentation of undigested food to the midjejunum plays an additional role is not known, because we lack a definitive comparison between the effects of the gastric bypass and the gastroplasty. The observation by Sugerman's group[3] that gut hormone changes are more profound with the bypass than with the vertical banded gastroplasty suggests that such a comparison may demonstrate additional effects of the bypass on glucose metabolism.

The relationship between obesity, that is, the increased intake of food, and diabetes and the improvement of diabetes with weight control was noted even in the earliest descriptions of the disease. Most patients older than age 50 with NIDDM are overweight.[4] However, dietary control of NIDDM has generally been disappointing. Although diets can improve glucose metabolism in the obese, the improvement usually represents only a partial and usually brief return to euglycemia, even when patients appear to comply. In the study of the effect of diet on diabetes by Doar et al.,[5] 118 obese patients with newly diagnosed NIDDM were subjected to a rigorous diet that produced a significant weight loss of 5.1 ± 4.0 kg within 2 months. Even so, the average reduction in the fasting plasma glucose was only from approximately 250 to 170 mg/dL, and random blood glucose levels were below 140 mg/dL in only 59% of the group. Although these values reflect improvement, the reversal of NIDDM is not nearly so complete as it is after the gastric bypass.

Our studies of insulin resistance at the cellular level also support the theory that NIDDM is the result of obesity, that is, increased food intake. Because muscle is the site of utilization of approximately 80% of the glucose ingested in a meal, we studied the mechanism(s) causing insulin resistance in rectus abdominis muscle of lean and obese patients undergoing abdominal surgery. Very thin muscle fiber strips were incubated *in vitro* to make metabolic measurements, including rates of glucose transport, glycogen synthesis, and glycolysis.[6] With this preparation, we demonstrated that insulin stimulation of glucose transport, which is the limiting step in glucose utilization, is depressed in muscle[7] of morbidly obese patients with or without diabetes. The degree of insulin resistance is correlated with the degree of obesity up to a body mass index of approximately 30,[8] after which there is little further change.

If NIDDM can be controlled so completely by the reduction of caloric intake followed by a rapid decrease in insulin levels and insulin resistance long before there is any significant reduction in the mass of adipose tissue, it is also reasonable to conclude that the lesion of NIDDM must be related to food intake and the signaling mechanisms stimulated by that food. If that hypothesis is true, it follows that the increased insulin resistance of NIDDM may not be the cause, but rather, an effect of the disease. What are these signaling mechanisms? The gastrointestinal tract, on contact with food and especially with carbohydrates, stimulates insulin secretion through the release of endocrine transmitters, also known as incretins. The incretin effect denotes the phenomenon that glucose elicits a higher β-cell secretory response when administered through the gut as compared with the intravenous route. Increting hormones, then, are endocrine insulinotropic factors released from the gut in response to glucose (or, less strictly, nutrient) ingestion. Two gut peptides have been identified as incretins: glucagon-like peptide-1 (7 to 36) amide (glucagon-like insulinotropic peptide) and glucose-dependent insulinotropic polypeptide (gastric inhibitory peptide).[9–12] (None of the other peptides from the gut, that is, cholecystokinin, gastrin, or secretin, are thought to be involved in the regulation of insulin in humans.) There may be other incretins that are unidentified. For further information, refer to Creutzfeldt and Nauck.[12]

The errors in signaling probably are not confined to the gut. Further evidence of a broader faulty glucose metabolism signaling system is our finding that decreased

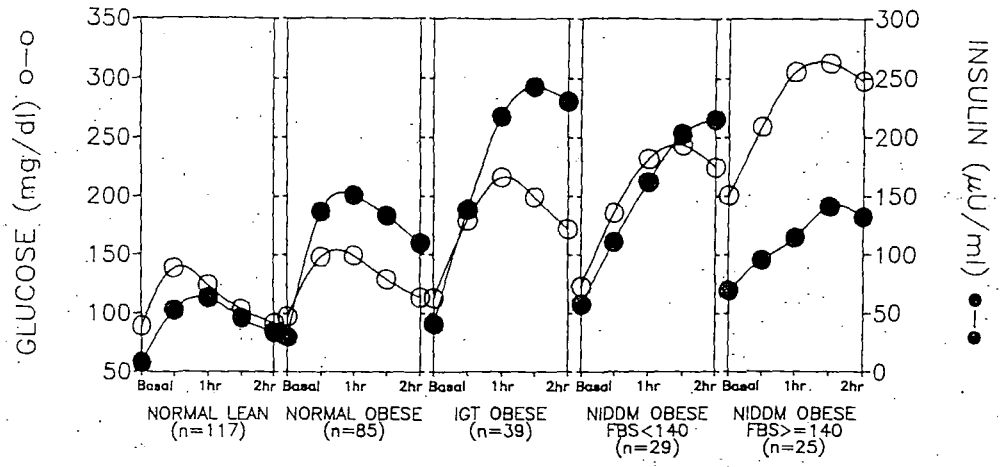

Figure 6. The progression of NIDDM. In lean subjects, the glucose level is maintained by low levels of insulin secretion. With increasing obesity, that is, increasing food intake, the maintenance of glucose at normal levels requires increasing amounts of insulin. Non-insulin-dependent diabetes mellitus occurs when the islets are no longer capable of secreting enough insulin, more than three times the normal output, to keep glucose under control.

tissue content of glucose transport protein[13] is not the cause for this decrease in transport.[14] In addition, the glucose transport effector system operates normally in insulin-resistant muscle of obese individuals if an appropriate signal is generated.[15,16] These results suggest that the defect causing insulin resistance is in the insulin signaling system of muscle. To confirm this conclusion, we have shown that the tyrosine kinase activity of the insulin receptor is decreased in morbidly obese individuals with or without diabetes[17] and that this change in receptor kinase activity is the most likely cause of the decreased phosphorylation of insulin receptor substrate-1 and activation of phosphatidylinositol 3-kinase in obese muscle.[18]

Our clinical observations do not support the belief that the islets are sick in the early stages of NIDDM. In fact, as shown in Figure 6, the islets in the morbidly obese patients with NIDDM are initially normal and are able to produce three times as much insulin as those of healthy control subjects before finally failing under the continued stimulation, perhaps due to accumulation of amylin faster than it can be cleared.

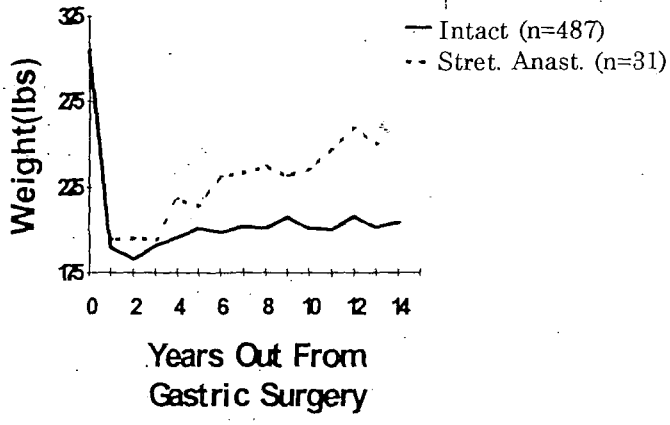

Figure 7. The importance of the size of the gastric outlet. A comparison of weight loss achieved by patients with stomas of approximately 1 cm compared with that seen in individuals with stretched anastomoses.

The lesion of NIDDM, however, is not based on high food intake alone. Genetics clearly plays an important, but still undefined, role. One third of our morbidly obese patients have normal glucose metabolism, despite massive obesity. These patients appear to have a different distribution of fat as well, with a greater tendency to be pear-shaped than apple-shaped, that is, the patients without diabetes have a gynecoid appearance, with the fat distributed to hips and breasts, rather than the android conformation, with a large concentration of abdominal fat. Most of our patients with NIDDM have strong family histories of diabetes.

Differences in the characteristics and genetic expressions of the adipocytes from the NIDDM and non-NIDDM morbidly obese patients are being studied in several centers, including ours. We have conducted studies that revealed differences in the physical, chemical, and biologic properties of plasma lipoproteins in insulin-resistant patients compared with that of insulin-responsive subjects. Plasma low-density lipoprotein (LDL) molecules of insulin-resistant patients tended to be smaller and more dense than LDL of control patients. These changes in the physical properties of LDL could be attributed to changes in the chemical composition of LDL, which included a decrease in the cholesterol ester content and an increase in the protein content of these particles.[19] The changes in the physical and chemical properties of the lipoproteins appear to affect the biologic function of LDL, as is evident from our studies. We have shown that cells that depend on exogenous cholesterol for growth and proliferation did not grow as fast when cultured in the presence of LDL of insulin-resistant patients, compared with cells grown in the presence of LDL

of control patients.[20] We confirmed these findings with a comparison of the properties of LDL in morbidly obese patients with NIDDM before and after gastric bypass surgery.

Study Limitations

There are several limitations to our study and our hypothesis. First, the claim that NIDDM is controlled by the gastric bypass needs to be supported with evidence that the complications of diabetes are also avoided. We are encouraged by our finding in these patients that LDL reverted to a more normal pattern with respect to physical, chemical, and biologic properties.[21] There is also some evidence in patients with NIDDM that the level of glycemic control is a major predictor of the early development of proliferative retinopathy and that hyperinsulinemia is a factor in the progression of coronary artery disease.[22] (Whether these conclusions can be extrapolated to patients with NIDDM remain unclear.) Even so, although it is true that none of our 608 patients have suffered renal failure, progressed to blindness, or required an amputation, our group is too small in terms of statistical power for us to claim that the gastric bypass prevents diabetic system failures.

The second limitation is the lack of assays of glucose-dependent insulinotropic polypeptide and glucagon-like insulinotropic peptide to support the hypothesis (1) that these incretin levels are high in the morbidly obese, (2) that high incretin levels can cause exhaustion of the islets, and (3) that these levels fall after bariatric procedures. We have recently sent specimens, drawn from NIDDM subjects before and after bariatric surgery, for analysis to Gutniak in Vällingby, Sweden, but the results are not yet available. Even that study is limited by the fact that there may be other incretins, perhaps even more powerful, that have not been identified.

The third limitation is the lack of a prospective, rigorous comparison between the gastric bypass and one of the gastric banding procedures in terms of the efficacy of diabetic control. Kuzmak's[23] adjustable gastric banding procedure would be an excellent choice for such a study.

CONCLUSION

Non–insulin-dependent diabetes mellitus is no longer an uncontrollable disease. A return to normal levels of plasma glucose, insulin, and glycosylated hemoglobin are now attainable with gastric bypass in the majority of morbidly obese diabetic patients, especially if the therapy can be initiated in the first 2 years after the diagnosis of the disease. Whether the other bariatric procedures, such as the gastroplasties, produce similar levels of control remains to be determined.

Why the operation controls diabetes so well is not clear, but the major reason appears to be the reduction of caloric intake. There is some evidence that changes in the incretin stimulation of the islets by the gut may also play a role.

These studies provide new insights and opportunities to understand NIDDM and predict, with control of obesity, that this devastating disease may be curable.

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Discussion

DR. LLOYD D. MACLEAN (Montreal, Quebec): I agree that surgery for obesity is gaining acceptance within the medical profession. This is in no small measure, I think, due to the efforts of Dr. Pories and his colleagues. It is also due to the willingness of the American Surgical Association to hear of the interests of its members, no matter how controversial. The first paper on this was given by Arnold Kremen in 1954. Some of you will remember that.

Dr. Pories has reported a large series with impressive results, and an even more remarkable follow-up, which he did not emphasize during his presentation.

We perform a similar operation with a small pouch, 10 to 15 mL. It is isolated from the rest of the stomach and the fundic side is inverted so there can be no mucosa-to-mucosa approximation. The operation is not dependent on staples. It is placed in the dependent position along the lesser curve of the stomach so there is no enlargement of the pouch over time. In contrast to Dr. Pories, we have made the anastomosis initially with a running nonabsorbable Prolene suture (Ethicon, Somerville, NJ). But when we rescoped those people 1 or 2 years later, we invariably found the Prolene in the lumen. The anastomosis was the size of the jejunum and not confined by the running suture.

We have gone on to perform this operation without any attempt at narrowing the anastomosis using an absorbable suture. On 160 patients who have been followed between 3 and 7 years, 95% have a satisfactory result; that is, they are within 50% of ideal weight.

This only held for morbid obesity, that is, a body mass index between 40 and 50 and when a primary operation was performed. If it was a redo or revision operation, or if the patient was super obese with a body mass index over 50, our results were only 63% satisfactory. I wonder if Dr. Pories could comment on that.

I have four very brief questions.

How many of your patients do return to within 50% of ideal? You give your results as means with a wide variation around the mean; it is a little difficult to tell how many patients got a satisfactory result.

You have made a very good point that visceral obesity is associated with insulin resistance, hyperinsulinemia, and impaired glucose intolerance. In addition, I think you have data that are not in the paper on the dyslipedemic state, which is the strongest, after smoking, predisposing factor for coronary artery disease. I would be very interested in the incidence of coronary artery disease in your 600 patients. Is this less than might be expected in this group? Do they have to lose more weight than you have found so effective in the treatment of type 2 diabetes? There is a genetic predisposition to severe obesity and its distribution. I wonder, does a strong family history influence the likelihood of a successful result?

Finally, fewer super obese patients in our experience return to normal. I wonder if this has been your experience? And I wonder why that is? Do they eat more despite the operation than morbidly obese people?

The suggestion has been made by the recent cloning of an obesity gene that the product of that is a satiety substance released from fat cells throughout the body. This works in an exceedingly efficient manner for most of us, who gain approximately 10 kg over 20 years of adulthood, which is equivalent to about one too many carrot sticks a day.

I suspect this is a central defect in these people and they could have all the satiety hormone floating around that they would need, but it will not help and you will still have to operate on those people.

DR. HARVEY J. SUGERMAN (Richmond, Virginia): A recent publication in last month's *New England Journal of Medicine* (Leibel R, Rosenbaum M, Hirsch J. Changes in energy expenditure resulting from altered body weight. N Engl J Med 1995; 332:621–628) stated in the opening line of the abstract that, "No current treatment for obesity reliably sustains weight loss."

In the accompanying editorial, there is no mention of gastric surgery for obesity, but the possibility of brain surgery is raised (Bennett W. Beyond overeating. N Engl J Med 1995: 332:673–674).

The 14-year follow-up of gastric bypass patients from the Greenville, North Carolina group under the leadership of Dr. Pories emphasizes the dramatic long-term success this operation can provide. In addition to diabetes, it effectively reverses in most patients hypertension, sleep apnea, obesity hyperventilation, pseudo-tumor cerebri, venous stasis ulcers, gastroesophageal reflux, etc.

There are several other published studies, including our own, documenting the long-term efficacy of gastric bypass for this "intractable" problem.

In a previous study of glucose tolerance tests before and 1 year after vertical-banded gastroplasty or gastric bypass in severely obese patients who did not require medication for diabetes, we noted that the gastric bypass was associated with the loss of 65% of excess weight, and vertical-banded gastroplasty,

42%. This was associated with a significant decrease in the area under the curve for glucose and insulin following gastric bypass, but not after vertical-banded gastroplasty. Several patients who required insulin before vertical-banded gastroplasty still required it, albeit at a lower dose, 1 year after surgery. And this was much less likely to occur after gastric bypass. This and the less effective weight loss have led us to abandon the vertical-banded gastroplasty procedure.

Although you presume the decreased insulin need was primarily due to a decreased caloric intake, both of these groups of patients that I presented drank the same quantity of glucose for their glucose tolerance test. Could the differences be due to total weight loss, as well as a difference in gut peptide release? By the way, we had to pay our gastric bypass patients $100 to drink the 100 grams of glucose because they knew that they were going to get severe dumping syndrome symptoms with it.

The loss of excess weight in your patients averaged 66% at 2 years, 50% at 10 years, and 47% 14 years after surgery, far better than anything reported for dietary management, which only achieves a 20% loss of excess weight at 2 years and almost a 100% weight regain at 5 years.

Still, some of your patients must have maintained an excellent weight loss while, as Dr. MacLean pointed out, others probably regained all of their lost weight despite an intact staple line and slightly enlarged stoma.

We have found that our patients have to keep—and listen to this number—their caloric intake to around 1100 kcal per day for the rest of their life after the surgery. If they start nibbling a little bit of high-fat junk food, such as potato or corn chips, and increase their caloric intake to 1500 calories per day, they will gradually, but inexorably, regain their weight, consistent with a decreased total energy expenditure noted in the *New England Journal of Medicine* article, following weight loss.

What do you do for these gastric bypass failures who have had recurrence of their comorbidity, such as need for insulin or obesity hypoventilation?

This study suggests that patients who have required insulin for a number of years before gastric bypass have a higher failure rate. We have had a number of older patients on 50 to 120 units of insulin a day for 10 to 20 years before gastric bypass who became euglycemic 3 to 9 months after surgery. Have you had a similar experience? If so, could there be another reason why patients fail? Could it be related to their weight loss?

One half of your patients were evaluated at office visits, whereas half were via telephone contact. Were these self-reported weights or were they weights obtained from their primary care physicians? Self-reported weights can be very inaccurate.

Finally, for those of you who run surgical training programs where we rarely do ulcer surgery anymore, this operation provides a wonderful educational opportunity. Our third-year residents perform, with guidance, 20 to 30 of these procedures during a 2-month rotation. And from my perspective, it is one of the most rewarding experiences I have ever had.

DR. EDWARD MASON (Iowa City, Iowa): In May of 1969, at a meeting of this Society, and after I presented a paper on gastric bypass, Dr. Nyhus discussed the paper and observed that, "Antral exclusion for the treatment of duodenal ulcer has been of interest since Von Eiselberg's paper in 1895." Dr. Nyhus stated that, ". . . in addition to possible development of stomal ulcer, there are other undesirable side effects which will result from the high, gastric transection—dumping syndrome, etc. . . . The procedure suggested today, devised for the treatment of a psychological metabolic problem probably should be extended cautiously to the human patient, if at all."

The first gastric bypass was performed at the University of Iowa in 1966. It was 10 years before papers by others began to appear in the surgical literature but before long gastric bypass replaced intestinal bypass for the treatment of obesity.

The concern of Nyhus did not go unheeded. In 1980, vertical-banded gastroplasty was introduced with the expectation that it would replace gastric bypass. If constructed with a measured pouch of less than 20 mL, a four-row stapler, and an outlet stabilized with a 5.0 cm collar, vertical-banded gastroplasty will reduce weight and maintain that weight reduction without the side effects and complications peculiar to Billroth II gastrectomy and the analogous operations used for treating obesity.

All bypass operations have the potential for causing iron deficiency anemia and osteopenia, as well as occasional stomal ulcers, duodenal ulcers, and closed segment obstruction. Stretching of the unsupported outlet can cause failure to control weight over time.

Pories has provided an excellent illustration of what can be accomplished in the treatment of the most prevalent form of diabetes with operations designed for control of caloric intake.

Colditz at the National Institutes of Health consensus conference on surgical treatment of obesity, estimated that the 1986 cost of treatment of obesity was $56.5 billion or 7.8% of the total cost of illness in the United States. This did not include the cost of loss of ability to work and premature loss of life from severe obesity.

We knew about the deleterious effects of a too rapid absorption of glucose from the small bowel after Billroth II gastrectomy 29 years ago when gastric bypass was introduced. It was one of the side effects that led to the replacement of Roux-gastric-bypass with vertical-banded gastroplasty at the University of Iowa since 1980.

In a study of the first 787 patients who were treated with vertical-banded gastroplasty for obesity at the University of Iowa, there were 83 who had diabetes. Diabetes was corrected or greatly improved in most of these patients. Insulin causes hypertension. Hypertension was present in 72%. The hypertensive diabetics required medication to control their blood pressure preoperatively in 85%, but this need decreased to 35% of patients after vertical-banded gastroplasty.

Dr. Pories started a randomized prospective comparison of RGB and vertical-banded gastroplasty and had about 30 patients in each arm. There were three with diabetes who had an excellent control of their diabetes with vertical-banded gastroplasty. I would recommend vertical-banded gastroplasty over any form of bypass in the interests of long-term health of the patient, but the vertical-banded gastroplasty must be performed with measurement of pouch and collar and must ad-

here to the techniques that we have learned in the 14 years of using the operation.

And now a question for Dr. Pories: Is there a special advantage of the Greenville gastric bypass that warrants a life-long increased risk to patients of a bypass type of operation?

I am grateful to the American Surgical Association for the opportunity to present a paper on this subject in 1969 and to hear and discuss a fine paper on the subject in 1995.

DR. WALTER J. PORIES (Closing Discussion): Slide 23 addresses the question of the anastomoses, because there has been some concern about unexplained weight gain. We believe that some of it may be that it is due to a stretched anastomosis in the area that has not been given enough emphasis.

As you can see, 31 patients whose anastomoses have stretched. We believe that this makes up for some of the reason why patients who snack appear to suddenly gain weight. We believe that all patients snack to some degree.

Many of the questions are answered in the manuscript. I am particularly intrigued by the question of gastric bypass *versus* vertical-banded gastroplasty. We have also switched totally to the gastric bypass. However, there are some advantages to gastroplasty. There is a particularly good one now being tested by Dr. Kuzmark, and as soon as that passes Food and Drug Administration review, we plan to do a prospective randomized study, and in that study gastric inhibitory polypeptide and glucose-dependent insulinotropic polypeptide.

Do the super obese go all the way down? They do not. So someone who weighs 500 pounds may go down to 280. I have no idea why they do not go all the way down. We have not had a chance to do caloric studies on these patients.

I would like to just show you Slide 20 as I thought you ought to see what a wonderful operation this can be. (Showing slide of "Mona Lisa" fat and skinny.)

Dr. Aranow
[SB S 79, /06]

Gastric Bypass Surgery for Obesity: Weight Loss, Psychosocial Outcome, and Morbidity One and Three Years Later

COLLEEN S. W. RAND, PhD, ALEX MACGREGOR, MD, and GARY HANKINS, MD, Gainesville, Fla

ABSTRACT: In two nonoverlapping cohorts of consecutive patients receiving gastric bypass for obesity, we interviewed 100 patients one year after operation and 60 patients at three years. Weight loss among patients in both cohorts averaged 45 kg; all had improved physical and emotional health, had stable marriages, and had made satisfactory eating adjustments. Factors contributing to successful outcome include the technical skill and experience of the surgical team, adequate preoperative patient preparation, extensive postoperative instruction, medical and dietary follow-up, and patient support groups. Gastric bypass was found to be a safe, effective procedure without the medical morbidity associated with jejunoileal bypass.

ADULTS are considered morbidly obese when they are 45 kg (100 lb), or 100%, above their ideal weight. Typically, adults elect surgery for obesity when dietary and exercise regimens have repeatedly failed and medical and psychosocial problems related to obesity become overwhelming.[1,2] Concern over excessive morbidity associated with the jejunoileal bypass operation for obesity prompted development of gastric bypass, gastric partition, and vertical banded gastroplasty.[3-6]

Many studies describe medical and psychosocial outcomes of patients receiving the jejunoileal bypass.[2,7-9] Most report excellent weight loss, improved self-esteem and emotional well-being, a higher divorce rate than the general population (though most marriages are stable), and very substantial medical morbidity.[10] Serious sequelae of the jejunoileal bypass include progressive liver damage, malnutrition, and persistent electrolyte problems. Follow-up studies indicate that more than half of the patients receiving jejunoileal bypass may require revision of the anastomosis.

Far fewer studies provide follow-up evaluation of gastric partition for obesity.[11-15] Weight loss and psychosocial adjustment are reported to be good. Failure to lose weight and postoperative complications are frequently associated with persistence of improper eating behavior.[12,14] Medical morbidity is relatively benign.[16] The conclusions regarding the superiority of the gastric bypass over the jejunoileal bypass have been challenged, however, on the basis of relatively short follow-up, inadequate information on patient weight loss, and high dropout rate.[17,18] Our study avoids these limitations.

METHOD

Background

All patients were from a private practice. The same surgeon (A.M.), assistant, and technician performed the operations (Roux-en-Y procedure[19]). The surgical team had worked together since 1973. Operations were done at North Florida Regional Hospital and Alachua General Hospital. Before surgery, patients were evaluated to assess their general fitness for surgery, to detect peptic ulcer or gallstones, and to exclude a hormonal cause for obesity; fewer than 0.5% of the applicants were refused surgery.

Preparation for surgery included extensive instruction by a dietitian about necessary changes in eating behavior. Patients shared experiences with an individual who had had a successful gastric bypass, and were given a booklet detailing the procedure, required postoperative eating behavior, and medical sequelae. Postoperatively, patients were advised to telephone the dietitian for food/eating problems and the surgeon's office for other concerns, and to participate in meetings of the Gastric Bypass Association of Florida (a self-help patient organization established and encouraged by one of us [A.M.]). These supports were well used by patients (Table 1). Patients

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[S3579,06]

TABLE 1. Services for Patients

1. Patient and family interviews with surgeon preoperatively and discussions with a nutritionist and successful bypass patient.
2. Booklet prepared by A. Macgregor, MD, *Patient Information, Surgery for Obesity*. Contents include information on health risks of obesity, surgical procedures for obesity, eating changes, dietary guides, medical sequelae and follow-up, and postoperative support services.
3. Access to 21 support groups (the Gastric Bypass Association of Florida) in Florida and Georgia. Toll free number for the Gastric Bypass Association.
4. Bimonthly magazine, *The Thinner Circle*, with medical and nutritional updates on the gastric bypass, and patient contributions.
5. A full-time nutritionist working with all patients before surgery, in the hospital, and after surgery.
6. Photographs taken before surgery and one year later.
7. Monthly visits to support groups by surgeon to educate and motivate.
8. Biweekly visits to support groups by nutritionist to educate and motivate.
9. Annual bypass reunion with panel of specialists (nutritionist, plastic surgeon, psychiatrist).
10. Annual meeting with surgeon, nutritionist, and support group leaders.
11. Cards given to patients to be used in restaurants entitling patient to reduced portions.

returned to the surgeon's office for routine check-ups at 1, 3, 6, and 12 months postoperatively. They had the option of returning to the office for vitamin B_{12} shots every three months thereafter or going to their local physician.

Procedure

One hundred consecutive patients receiving the gastric bypass were interviewed by telephone at one year after operation (average of 14 ± 2 months), and a second nonoverlapping cohort, of 60 consecutive patients at three years (average of 35 ± 3 months). The one patient lost to follow-up (three-year group) was replaced by the 61st consecutive patient. We excluded patients who had had previous procedures for obesity (eg, jejunoileal bypass takedown and conversion to gastric bypass).

The same trained nurse conducted a structured one-hour interview with all patients. The nurse was not personally acquainted with any patient. Questions, derived from previous research in this area, covered weight, emotional functioning, marital satisfaction, eating behavior, and morbidity.[9,20] The purpose of the interview, the voluntary nature of participation, and confidentiality of responses were explained. Special care was taken to encourage patients to report "the good, the bad, and the ugly." Most of the questions were about current functioning and postoperative changes. Preoperative demographic and weight data were obtained from office records; psychosocial data were available only from postoperative interviews.

Validity of Reported Weight

Excellent agreement was observed between patients' report of their current weight and the weights recorded on office records. Maximal discrepancies (2 to 5 kg) occurred among one-year patients who were interviewed one to two months after their office visit and who were still losing weight.

TABLE 2. Preoperative Patient Characteristics

	1-Year Group	3-Year Group
Number of men	24 (24%)	9 (15%)
Number of women	76 (76%)	51 (85%)
Mean age	38 ± 10	39 ± 9
Married	75%	83%
Middle- and upper-middle class	74%	74%
Men: average weight (kg)	152 ± 23	146 ± 17
% Overweight	91%	89%
Women: average weight (kg)	118 ± 15	120 ± 19
% Overweight	87%	96%

RESULTS

Patient Characteristics

More than 75% of the patients in both groups were women. Most patients were in their 30s at the time of operation, were middle- or upper-middle class (as defined by the Hollingshed-Redlich index[21]), and were married (Table 2).

Weight Loss

Patients lost between 69% and 81% of their excess weight, and weighed approximately 45 kg less (Table 3). More than half of the patients in both groups, however, wanted to lose more weight. A third of the one-year group were still losing weight, whereas weight had stabilized for the three-year group down to an average of 20% over the "standard weight for height." Three-year patients, with one exception, had had minimal weight regain (0 to 5 kg). The single patient with substantial weight regain (21.4 kg from the nadir of weight loss) was a potential candidate for revisional surgery.

Emotional Adjustment

Patients reported being in good spirits and were no longer embarrassed about being seen in public. They felt more self-confident and hopeful about the future than before surgery (Table 3). Only two patients (both in the one-year group) reported being more depressed since surgery.

Marital Adjustment

All patients married at the time of follow-up wanted to stay married, although two (both in the one-year group) were unsure about their spouse's commitment (Table 3). Two one-year patients and three three-year patients had obtained a divorce. About half the patients in both groups reported that surgery had improved both their marriage and sexual life, and 92% described their marital relationship as harmonious.

(SB 879, 106)

TABLE 3. Weight Loss, Emotions, Marital Relationships, and Consumption After Gastric Bypass

	1-Year Group	3-Year Group
Weight Loss		
Men: % of excess weight lost	74%	69%
Maximal weight (kg) lost	55 ± 13	53 ± 13
Women: % of excess weight lost	80%	81%
Maximal weight (kg) lost	44 ± 10	51 ± 12
Still losing weight	30%	2%
Desire to lose more weight	69%	75%
Weight loss desired (kg)	12 ± 8	11 ± 5
Psychosocial Outcome		
Emotional:		
More often in good spirits	94%	97%
More hopeful about future	92%	98%
Increased depression	2%	0
Increased self-confidence	84%	92%
Less self-conscious about appearance	91%	92%
Marital:		
Improved relationship	59%	49%
Divorce prevalence	3%	6%
Improved sexual relations	50%	71%
Worsened sexual relations	0	3%
Consumption:		
Marked preoccupation with food	3%	2%
Eating binges	14%	3%
Decreased alcohol use	54%	44%

TABLE 4. Medical Morbidity

	1-Year Group	3-Year Group
Abdominal or stomach pain	8%	10%
Nausea	10%	3%
Vomiting	8%	2%
Diarrhea (not present preop)	12%	1%
Constipation (not present preop)	7%	15%
Excessive thirst	4%	5%
Excessive hunger	1%	0

Eating Behavior

Most patients had regular eating habits and were not preoccupied with thoughts about food (Table 3). Approximately two thirds of patients in both groups reported sometimes wanting to eat more food than physically permissible; two one-year patients considered this a daily problem, but few patients actually went on eating binges. Those who did reported that the amount they could eat was very limited compared to quantities consumed before surgery. Although many patients hoped to lose more weight, only one patient (three-year group) reported dieting.

Alcohol Use

Consistent with the gastric bypass surgical changes that facilitate rapid entry of alcohol into the blood stream, patients reported feeling "high" with significantly less alcohol (Wilcoxon matched-pairs signed ranks test, $P \leq .001$ for both groups) (Table 3). Two patients in the one-year and one in the three-year group reported that they had, at some time in their life, abused alcohol; one of them was currently under treatment for alcoholism.

Medical and Surgical Morbidity

Few patients were still having undesirable side effects at follow-up (Table 4). The most frequently reported were nausea, vomiting, and bowel dysfunction. Three one-year patients and one three-year patient required corrective surgery (one ruptured wound, one incisional hernia, two obstructions with adhesions). Panniculectomies were requested by one one-year and two three-year patients, and a smaller pouch (to lose more weight) by one three-year patient. About 10% of patients are expected eventually to experience late complications (iron deficiency and vitamin B_{12} deficiency anemia) associated with the gastric bypass.

DISCUSSION

Concern has been voiced that gastric bypass will not produce adequate weight loss for morbidly obese adults because they gorge on food.[3] In fact, improper eating behavior can cause failure to lose or sustain weight loss.[12,14] Our study shows, however, that almost all patients can adjust to the drastic eating changes when the surgical procedure is accompanied by adequate preoperative and postoperative instruction and support. The weight loss reported here is consistent with the overall revisional surgery rate of 3.5% in the total experience of 800 gastric bypass procedures done by one of us (A.M.).

Medical sequelae of the jejunoileal bypass have sensitized both surgeons and referring physicians to high rates of morbidity and mortality associated with obesity surgery.[7,10] Complications reported for the gastric bypass are less serious and less common.[16,22,23] The most dangerous complication unique to gastric bypass is a leak from the stomach or anastomosis; no patient in our series had this complication. Obstruction of the stoma may also require reoperation. Vomiting and stomach pain are routine when patients begin to eat solid food. Adherence to recommended eating behavior and diet effectively mitigates these problems, however. Multivitamins, iron, vitamin B_{12}, and calcium supplements are recommended to minimize late hematopoietic complications.[16,29]

Improved emotional well-being accompanied weight loss in almost all gastric bypass patients. Patients reported that the support groups helped them cope with difficulties that did arise (eg, food intolerance, conversing during meals, spouse's

jealousy). Weight loss also appeared to enhance marital relationships. Some patients reported that feeling better about themselves made them easier to live with, while others, for the first time in years, were willing to go out socially with their spouse. The high prevalence of divorce reported in other series was not observed.[9]

Until recently, patients have had the option of remaining morbidly obese or risking major medical problems associated with the jejunoileal bypass. Our study demonstrates that gastric bypass surgery can produce excellent weight loss without sacrificing health. This outcome does not result from selective follow-up; in this series of consecutive patients, only one could not be located. Factors contributing to the successful outcome include experience and skill of the surgical team, adequate preoperative patient preparation, and extensive postoperative instruction, support, and medical follow-up.

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