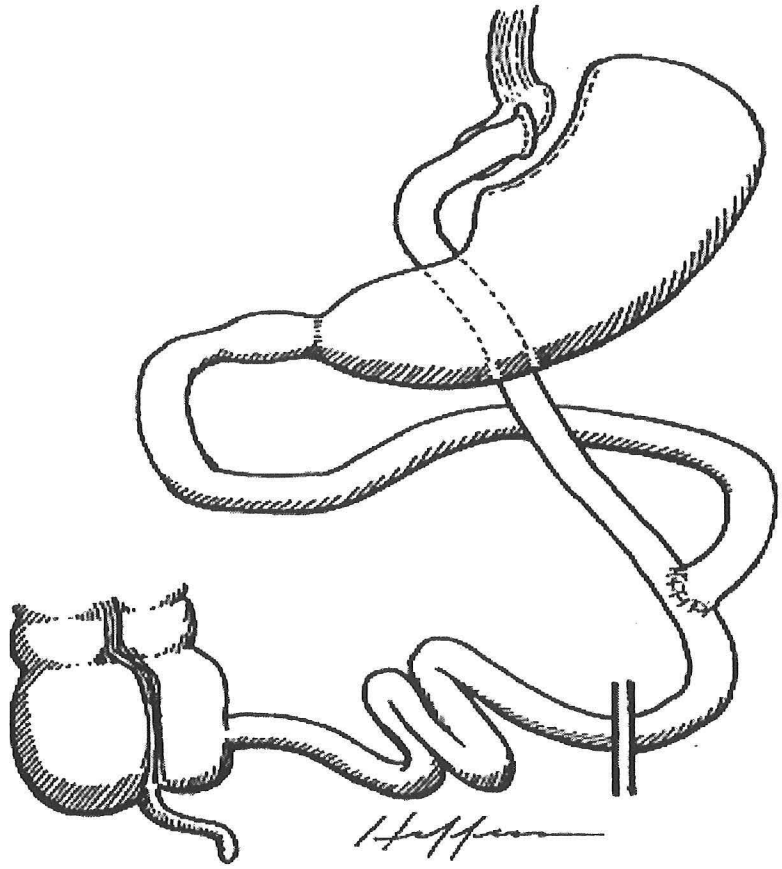

SURGICAL TREATMENT OF OBESITY
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This is to acknowledge that Dr. William Harford has not disclosed any financial interests or other relationships with commercial concerns related directly to this program. Dr. Harford will not be discussing off-label uses in his presentation

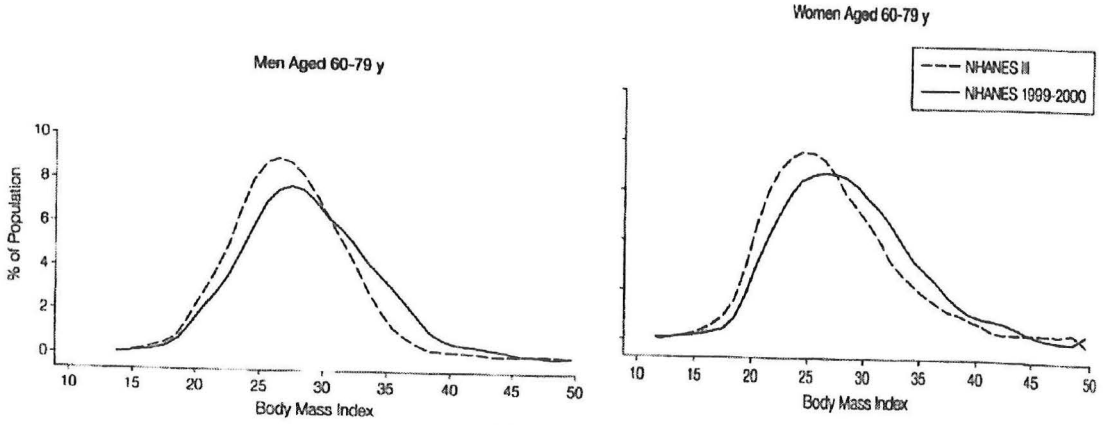
Outline

- The prevalence of morbid obesity in the US is increasing significantly.
- Serious health problems associated with morbid obesity are increasing.
- Current medical therapy for morbid obesity is ineffective.
- Weight loss surgery is the only currently effective therapy for morbid obesity.
- Internists should be well informed about weight loss surgery, including
    - The varieties of surgical procedures available;
    - The physiology of weight loss surgery;
    - The benefits, risks, and complications of weight loss surgery;
    - Patient selection and preparation for weight loss surgery;
    - Patient follow-up after weight loss surgery.
- As physicians we have a responsibility to respond to the Surgeon General's Call to Action to prevent and decrease overweight and obesity.

The Increasing Prevalence of Obesity and Morbid Obesity In The US

The prevalence of overweight and obesity has increased markedly in the United States during the past 3 decades.

Using data from the National Health and Nutrition Examination Survey (NHANES), it can be shown that the age-adjusted prevalence of overweight (BMI greater than 25) in the adult population increased from 56% in the period 1988-1994 to 64.5% in the period 1999-2000. During the same period the prevalence of obesity increased from 23% to 30.5% and the prevalence of extreme obesity (BMI greater than 40) increased from 3% to 5% (1). Using NHANES data and assuming an adult US population of 185 million, it can be calculated that there are about 10 million adults with a BMI between 35 and 40, and about 6 million with a BMI >40. The prevalence of overweight and obesity is also increasing rapidly in children. The prevalence of obesity among children in 2000 was estimated to be 16% (2).



Increased Prevalence of Obesity

How Did We Get So Fat?

This increase in overweight and obesity is being caused by a complex set of environmental and behavioral changes in our society.

In general, the amount of physical activity we engage in has substantially decreased. This can be attributed to

1) a reduction in the amount of physical labor required in many occupations;
2) a reduction in the amount of walking for personal transportation;
3) an increase in sedentary leisure activities, such as television viewing, video games, and Internet-based activities, compared to activities requiring exertion;
4) a reduction in exercise among children, due to
    a) under funding of schools, requiring cuts in budgets for physical education and sports;
    b) budget shortfalls in communities, requiring cuts in budgets for safe recreational programs and facilities.

The amount and type of food we eat has changed for a variety of reasons.

1) Many families have 2 wage earners. Because of this, eating habits had become less regular, and many families increasingly rely on fast foods rather than home-cooked meals.
2) Under funding of schools has lead to substitution of fast foods for previously available cafeteria foods. Many schools allow vending machines and promotion of soft drinks, snack foods, and fast foods in return for financial considerations that aid the schools in dealing with budget reductions.
3) The corporate food industry has been extremely successful in developing inexpensive, convenient, and appealing snack food and fast food. The industry has also been extremely successful in marketing their products. Much of the marketing is directed at children. Unfortunately, a major part of the marketing effort has promoted large portions of high-calorie, high-fat food.

An informative review of factors leading to increased obesity in the United States can be found in the book "Fat Land", by Greg Critser, cited in the bibliography (3).

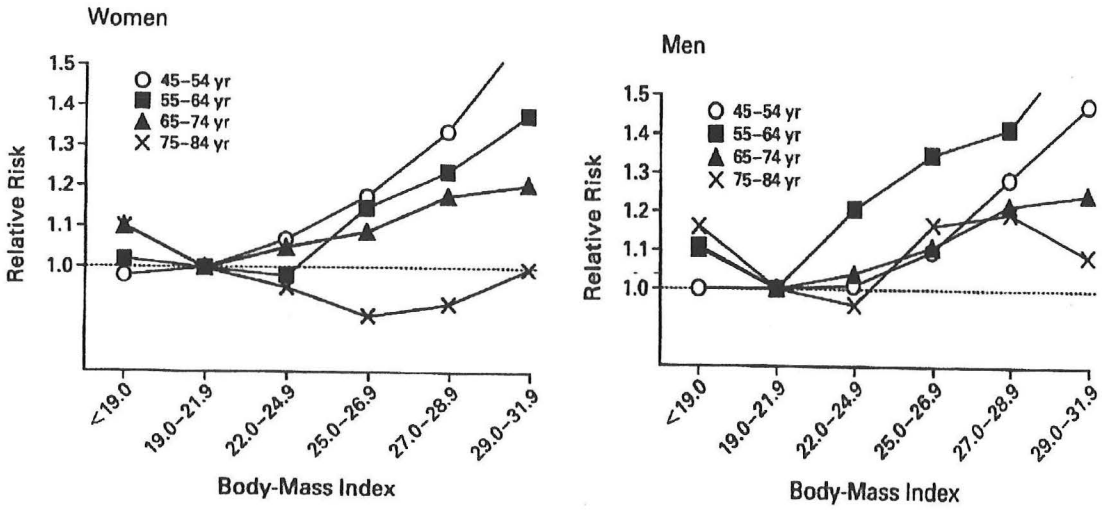
Obesity is not a problem only in the US. The prevalence of obesity is also increasing in many other countries, such as China and Japan.

Health Problems Associated with Obesity

Mortality

Overweight and obesity are associated with increased mortality

In the 30 year follow-up of the Framingham Heart Study, overweight non-smoking men were found to have a mortality rate about four fold higher than that of non-overweight men (4). In the NHANES III study (using data from 1988 to 1994) obesity was associated with increased mortality, including mortality from cardiovascular disease and cancer (5). In a study of 200 obese male Veterans 23 to 70 years old with an average weight of 316 lbs, mortality in the group aged 34 to 44 years was increased six fold, while mortality in the group aged 25 to 34 years was increased 12 fold (6). Much of the increased mortality is due to increased prevalence of diabetes, cardiovascular disease, and certain cancers (7). It is estimated that about U.S. 280,000 deaths per year are attributable to obesity.



Relative Risk of Mortality By Body Mass Index in Women and Men

Medical Conditions Associated with Obesity
Insulin resistance and adult onset diabetes mellitus
Hyperlipidemia
Hypertension
Coronary artery disease, congestive heart failure
Obstructive sleep apnea, hypoventilation syndrome, cor pulmonale
Venous stasis disease, deep venous thrombosis, pulmonary embolus
Dysmenorrhea, infertility, polycystic ovary syndrome, stress incontinence
Non-alcoholic fatty liver disease
Gallstones
Gastroesophageal reflux
Abdominal hernias
Osteoarthritis
Cancers
Depression, low self esteem, social disability and discrimination

In a study using data from and the Framingham Heart Study, the risks of 5 obesity-related diseases were estimated. Moderate obesity was found to increase the lifetime risk of stroke from 14 to 17.5%, of coronary artery disease from 35% to 46%, hypertension from 18% to 51, hypercholesterolemia 25% to 345% and adult onset diabetes mellitus from 3% to 13% (8).

Diabetes

In the Nurses Health Study the relative risk of developing diabetes was increased ninety fold for women with a BMI greater than 35 compared to those with a BMI of 22 or lower (9). The NHANES II survey found an overall relative risk of developing diabetes of about 3 for obese persons compared to normal persons (10). The 1975 report of US National Commission on Diabetes estimated a two-fold risk of diabetes for mild obesity, five-fold for moderate obesity, and ten-fold for severe obesity.

Hypercholesterolemia

In the NHANES II survey, the relative risk of hypercholesterolemia was twice normal in obese patients younger than 45 years old. In older patients, the difference was not significant (10).

Hypertension

The risk of hypertension is substantially increased in obesity, particularly for younger persons. In the NHANES II survey, the relative risk was increase five-fold for persons less than 45 years old, and two fold for older persons (10). In another study the prevalence of hypertension was 60% in persons with a BMI of over 35 (11).

Coronary Heart Disease

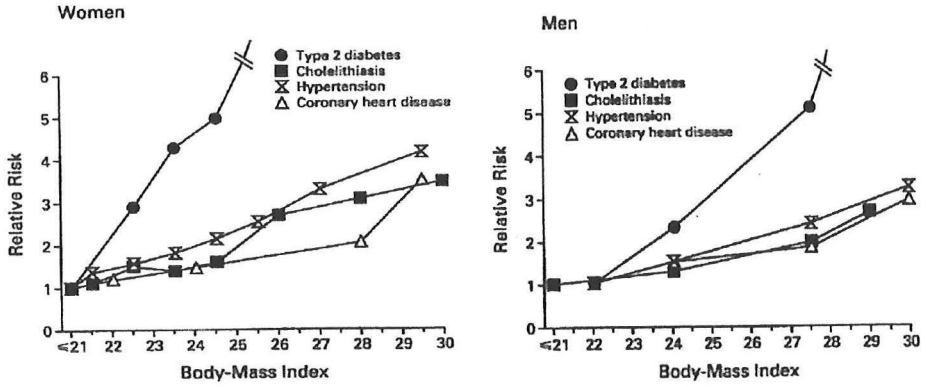
In the Health Professionals Follow-Up Study the relative risk of coronary artery disease was increased three fold for persons with a BMI over 33, compared to those with a BMI less than 23 (12). In the Nurses Health Study, the relative risk of coronary artery disease was also increased about three fold by obesity in women (13). Using data from the Framingham Heart Study, the risk of congestive heart failure was estimated to be increased by 5% in men and 7% in women for each unit increment in BMI (14)

Cancers associated with obesity

The Cancer Prevention Study II is a prospective mortality study sponsored by the American Cancer Society, and includes over a million individuals. In a 2003 report, BMI greater than 40 was associated with death rate from all cancer of 52% over normal for men and 62% over normal for women. Increased deaths were found for cancer of the esophagus, colon (RR 1.7), rectum, liver, gallbladder (RR 3.5), pancreas and kidney, as well as for non-Hodkins lymphoma and multiple myeloma. Obese men had increased rates of stomach and prostate cancer (RR 1.3), and obese women had higher rates of postmenopausal breast (RR 1.5), uterine (RR 5), cervical (RR 2.5), and ovarian cancer. Approximately 14% of all deaths from cancer in men and 20% of all deaths from cancer in women could be attributed to obesity (2;15).

Gallstones

In the NHANES III the risk of gallstones increased from 9% for women in the lowest quartile of BMI to 25% for those in the highest quartile. The risk for men increased from 5% to 11%.



Relative Risk of Comorbities by Body Mass Index in Women and Men
From the Nurses' Health Study and the Health Professionals Follow-Up Study (16)

Non-alcoholic fatty liver disease
Obese patients are at greatly increased risk of non-alcoholic fatty liver disease, which is associated with insulin resistance.

Obstructive Sleep Apnea
The development of obstructive sleep apnea, with all its potential sequelae, is greatly increased by obesity (17).

Social and psychological disability
The social and psychological disability associated with obesity is very important (18). Many people consider obesity a moral deficiency, due to a lack of willpower or determination to exercise and avoid overeating. Obese persons are subject to social and professional discrimination. Unfortunately, even medical professionals are guilty of discrimination. Up to 80% of obese persons reported being treated disrespectfully by the medical profession in one survey (19). Obese persons have a higher prevalence of depression and poor self-esteem, which can be exacerbated by repeated unsuccessful attempts to achieve and maintain weight loss.

Healthcare costs of obesity
The healthcare costs of obesity are very high in the US. Direct costs are over $50 billion and total costs over $100 billion per year. This amounts to close to 6% of the total annual health care expenditure (20;21). Consumers spend at least $30 billion a year on commercial weight loss programs. In a study of managed care patients, every unit increase in BMI lead to a 2% increase in health care costs (22). In a workplace study, workers with a BMI over 27 had a $700 per year increase in health care costs compared to workers with a lower BMI (23).

Benefits of weight loss
There is evidence that even moderate weight loss can achieve improve obesity-related co morbidities. Modest to moderate loss of excess weight achieved by diet and lifestyle changes can reduce hypertension, glucose intolerance, and hyperlipidemia. A 5 to 10 pound weight loss may decrease LDL by 5 to 20 mg/dl, increase HDL by 1 to 6 mg, lower HbA1c by 0.8 to 2.2 % and decrease insulin levels by 18 to 30% (24). In the

Framingham study, a 10% weight loss corresponded to 20% reduction in risk of coronary artery disease. In a recently published study it was projected that a 10% weight loss would reduce number of years of life with diabetes, hypertension, and hypercholesterolemia, reduce lifetime incidence of coronary artery disease and stroke, increase life expectancy 2-7 months, and reduce lifetime medical costs related to these illnesses by $2200 to $5300 (25).

Medical treatment of obesity

Diet, exercise, and medications often result in modest weight loss.

The Expert Panel on the Identification, Evaluation, and Treatment of Obesity in Adults of the National Institute of Health found that low calorie diets can reduce total body weight by an average of 8% over 3-12 months. In a recent trial comparing low-carbohydrate to the low-fat diets, mean weight loss was only 6 lbs after 1 year. Many subjects dropped out (26). In a 1993 review, Wadden concluded that moderate and severe caloric restriction is ineffective for weight loss, because 90-95% of pts regain their weight in the long term (27).

Medications may increase weight loss when added to diet and exercise. Weight loss is still modest, averaging about 10%, and weight is usually regained when medication is stopped. In the 4 year Phen-Fen study the final average weight loss was only 3 kg in patients who completed follow-up (28). In a study of siburamine and behavior therapy versus behavior alone in obese adolescents, weight with medication was about 8 kg at 6 months. Weight loss did not continue during the next 6 months even if medication was continued (29). Our understanding of the regulation of appetite and weight is improving rapidly, and new medications are being development, but no major developments are on the immediate horizon.

However, for severely obese patients, no program of medical therapy alone, with or without medications, has been effective in achieving medically significant long-term weight loss.

THE EVOLUTION OF SURGERY FOR OBESITY

Surgery for obesity has been performed since about 1970. In the past 3 decades the indications for surgery have been defined and surgical procedures have improved. Because of the increasing number of obese patients, the increasing awareness of the health risks of obesity and improvements in surgical procedures, the number of surgical weight loss procedures performed has greatly increased, particularly in the last few years. The American Society for Bariatric Surgery estimates that 47,000 procedures were done in 2001, 63,000 in 2002, and estimates that 98, 000 will be done in 2003. The program at Baylor University Medical Center in Dallas is currently doing about 15-20 weight loss procedures per week. The demand for weight loss surgery is greater than our current capacity to provide it. Some programs have long waiting lists. There are not enough well-trained surgeons and established comprehensive programs.

In 1978 the NIH issued a consensus statement on surgery for obesity, but it addressed primarily the jejunoileal bypass. It highlighted the complications of this operation, which was largely abandoned. In 1985 the NIH published a second Consensus Development Conference Statement on the health implications of obesity, but this statement did not address surgery. At that time there was little clinical data on surgical procedures that had been developed since the jejunoileal bypass.

In 1991 the NIH issued a third Consensus Development Statement which specifically addressed gastrointestinal surgery for severe obesity (30). The panel reviewed the evidence for the effectiveness of diet, behavior modification, and drug treatment of severe obesity. It found that these treatments had very limited success for the majority of severely obese patients. It reviewed the clinical data on the two surgical procedures most commonly performed at that time, the vertical banded gastroplasty and the gastric bypass.

It recommended weight loss surgery be considered for patients failing one or more medical weight loss programs and who have

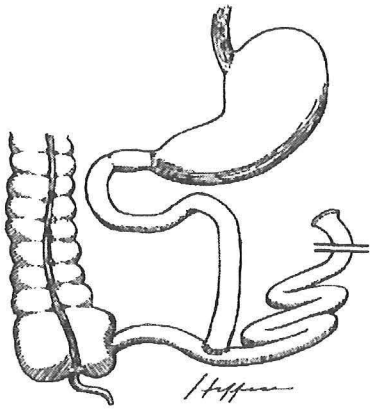
1) BMIs exceeding 40 if they strongly desire weight loss to improve their quality of life, as well as for patients
2) BMIs between 35 and 40 and with high-risk comorbidities or obesity-induced physical problems interfering with lifestyle.

The committee recommended that patients considered for weight loss surgery be selected carefully after evaluation by a multidisciplinary team. Patients should be fully informed about the risks of surgery, the probable outcomes, and the need for lifelong changes in diet and lifestyle, as well as the need for lifetime follow-up. These recommendations are the generally accepted clinical guidelines for weight loss surgery.

Surgical procedures for weight loss

Malabsorptive surgical procedures

The first surgical procedure introduced for weight loss was the jejunoileal bypass (JIB), introduced by Payne in 1969 (31). The idea for this procedure was based on the observation that patients who had major small bowel resections for ischemia often had profound malabsorption and weight loss. Payne described bypassing the greatest part of the jejunum, by joining the proximal 35 cm of jejunum to distal 10 of ileum. The stomach was not modified

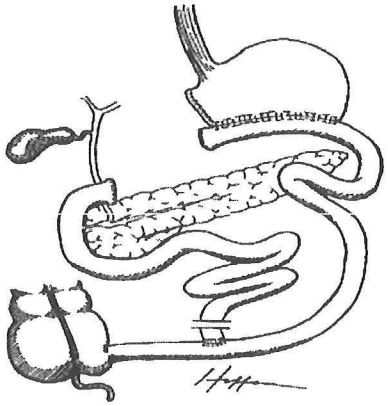


Jejunoileal Bypass

About 100,000 patients had the JIB bypass done for weight loss during the 1970s. The procedure resulted in marked weight loss. Unfortunately, it was associated with a very high morbidity, Problems included severe diarrhea, fluid and electrolyte depletion, vitamin and mineral deficiencies, blind loop syndrome, metabolic bone disease, renal abnormalities, and liver failure due to hepatic steatosis (32). For all these reasons, jejunoileal bypass was abandoned about 20 years ago. Patients who had the procedure were advised to have it taken down and converted to a more acceptable procedure, such as gastric bypass. There are few survivors of JI bypass at this time, but if such a patient is encountered, they should be evaluated for liver and renal disease and urged to consider conversion to another procedure.

Biliopancreatic Diversion

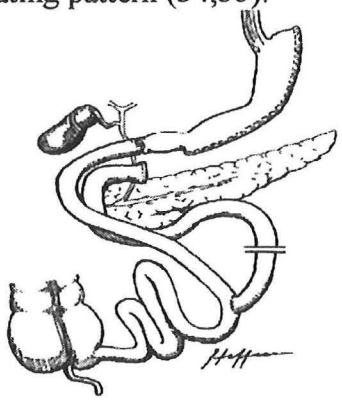
The biliopancreatic diversion (BPD) is a contemporary malabsorptive procedure introduced by Scopinaro and his Italian colleagues in 1979 (33). In this procedure the ileum is joined to the stomach. Biliary and pancreatic secretions are diverted to the distal 50-100 of the ileum. A partial gastric resection is often included, producing a moderate reduction in the capacity of the stomach. Functional shortening of the bowel and diversion of the pancreatic and biliary secretions produces a major degree of malabsorption. One advantage of this procedure is that patients can eat moderate quantities of food at each meal, since the gastric pouch is not much reduced.



Biliopancreatic diversion

Biliopancreatic diversion with duodenal switch

In a variation of the BPD, the jejunum, rather than the ileum, is connected to the proximal duodenum. This leads to dumping physiology if the patients overeat high sugar foods, which discourages this type of eating pattern (34;35).



Biliopancreatic diversion with duodenal switch

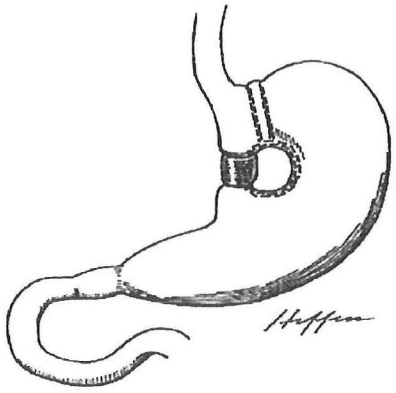
BPD is very effective in producing weight loss in superobese patients (BMI >50). Mean losses of 75% to 80% of excess weight have been reported in several series (36;37). The problem of blind loop and bacterial overgrowth that characterized JIB does not occur. However, complications related to malabsorption are very common, including a 30% incidence of anemia and a 30% to 50% incidence of fat-soluble vitamin deficiency (36;38). Serious long term consequences of malnutrition, such as metabolic bone disease, may occur. Meticulous lifelong follow-up is essential. There are very few US surgeons who perform biliopancreatic diversion.

Restrictive surgical procedures

Restrictive surgical procedures are designed to reduce the ability of patients to ingest more than a small amount of food at a time. These procedures include gastroplasty and gastric banding.

Gastroplasty

Gastroplasty was introduced by Mason in about 1971 (39). Mason's first procedure consisted in placing a transverse row of staples across the proximal stomach, leaving a small stoma. He soon found that stretching of the pouch and staple line disruptions were common. By 1982 he had developed a modification termed the vertical banded gastroplasty (VBG) (40). In this procedure the staple line is oriented from a point on the lesser curve to the angle of His. The thicker gastric wall along the lesser curve reduced pouch stretching. He reinforced the stoma with a mesh band to prevent disruption.

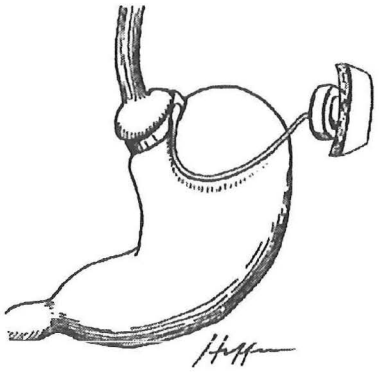


Vertical Banded Gastroplasty

A major advantage of VBG is preservation of gastrointestinal continuity. Malabsorption does not occur. Patients cannot eat more than a few ounces of food at a time. Attempts to overeat produce fullness, discomfort, or vomiting. Some patients have lost up to 50% of excess weight with VBG. Unfortunately, it is possible to "cheat" by taking large amounts of high calorie liquid or soft foods, such as milk shakes or ice cream. Long-term weight loss has been disappointing. In one series, mean excess weight loss at three years was 38%. In another, no patient was able to maintain at least 50% of weight loss by 5 years (41). Disadvantages include a high incidence of staple line dehiscence or stenosis of the stoma. VBG can be done laparoscopically (42).

Gastric banding

Gastric banding was introduced by Bo and Kuzmak in the mid 1980s (43;44). Like VBG, gastric banding is intended to be purely restrictive. A prosthetic band is placed around proximal stomach to make a small pouch. In 1992 Kuzmak introduced the adjustable band. A balloon was built into the band which can be filled from a subcutaneous reservoir, making it possible to tighten or loosen the band (45).



Adjustable Gastric Band

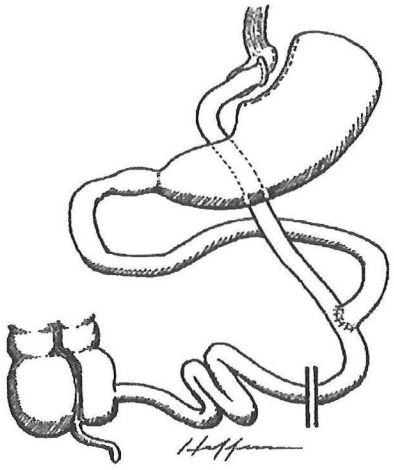
There are two brands of gastric banding device, the Lap-Band and the Swedish Adjustable Gastric Banding System (SAGB). The Lap-Band Adjustable Gastric Banding

System (LAGB) (INAMED Health) is the only device available in the US. It was licensed by the FDA in June of 2001. The SAGB has been in use in Europe for a number of years. Distribution rights for the SAGB were recently purchased by Ethicon.

The major appeal of gastric banding is its simplicity. Gastric bands are easy to place laparoscopically. In addition, there are no staple lines, and thus no risk of staple line breakdown or leakage.

Laparoscopic adjustable gastric banding is the most commonly performed weight loss procedure in Europe and Australia. More than 70,000 procedures had been done by 2002 (46). In some series the results have been comparable to those of VBG and other surgical weight loss procedures. Mittermair reported his 5 year experience with 450 Austrian patients. Mean follow-up was 30 months. The mean excess weight loss was 72% at 3 years. Complications requiring re-operation occurred in 8% of patients (47).
In a recent report of the Swedish Obese Subject project the mean excess weight loss 6 years after surgery was about 17%. In this project about 90% of patients had either gastroplasty or gastric banding (12). Suter reported his results in 300 Swiss patients. Mean excess weight loss was 60%. He reported complications of band erosion, slippage, infection, and port displacement and dysfunction. It was necessary to remove the band in 9% of patients (48). Westling reported a mean 56% excess weight loss at 2 years, but 35% of his patients required band removal and conversion to gastric bypass (49).
Others have reported a high prevalence of similar problems, as well as erosive esophagitis, esophageal dilation, and gastric prolapse (50). European results with the LAP-BAND were not reproduced by FDA-monitored clinical trials in the United States (51). Over 1000 adverse events related to adjustable gastric banding devices have been reported to the FDA to date.
Laparoscopic adjustable gastric banding is popular in the United States, if judged by the number of programs advertising Lap-Band placement on the Internet. However, a number of bariatric surgeons from established programs are skeptical of gastric banding, and will not recommend the procedure except in a few cases.

Roux-Y-Gastric Bypass
Mason first introduced the Roux-Y gastric bypass (RGB) procedure for weight loss in 1967 (52). The idea for the RGB was based on the observation that patients left with small gastric remnant after gastric resection for peptic ulcer disease almost invariably lost weight.
A number of surgical techniques have been used. All current versions create a small (15 to 30 ml) proximal gastric pouch drained by a Roux-Y limb of jejunum. The distal stomach, duodenum, and the first 15 to 20 cm of the proximal jejunum are bypassed, and connected to the Roux-Y limb approximately 75 cm from the gastrojejunal anastomosis. .

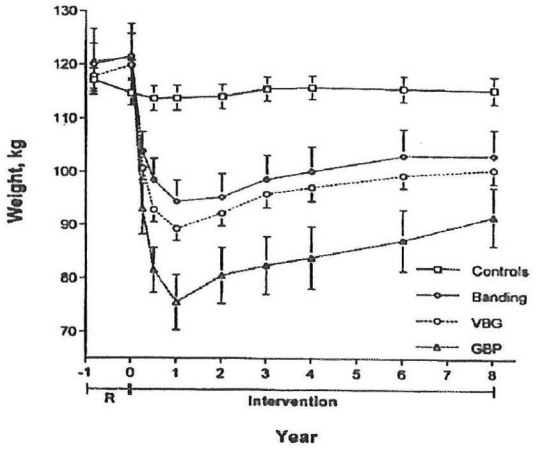


Roux-Y Gastric Bypass

RGB is primarily a restrictive procedure. The small gastric pouch prevents patients from eating more than a very small quantity of food at a time, much like VBG and gastric banding. RGB also produces symptoms of "dumping" when high carbohydrate foods are eating. Some degree of malabsorption occurs because part of the proximal bowel is bypassed and because mixing with bile and pancreatic secretions is delayed.

Initial weight loss is very good, averaging 65% to 75% of excess weight (53). More importantly, weight loss is maintained long term. In a large series, Pories reported mean excess weight loss of 58%, 55%, and 49% at 5, 10, and 14 years after surgery (54). Jones reported a mean of 62% excess weight loss maintained at 10 yrs (55). Other studies have confirmed that patients maintain a weight loss of 55-60% of excess weight for 5 to 10 years after surgery (56-62).

In several trials, including 3 randomized controlled studies, RBG has been shown to result in greater weight loss than VBG and gastric banding (41;57;63;64). In data from the International Bariatric Surgery Registry the mean excess weight loss at one year after VBG ranged from 53% to 58% compared to from 71% to 80% after RGB.
The graph below, taken from the large Swedish Obese Subjects (SOS), project shows results for controls, and after vertical banded gastroplasty, gastric banding, and Roux-en-Y gastric bypass.



Comparison of vertical banded gastroplasty, gastric banding, and gastric bypass

Because of the documented good long-term results and acceptable complication rate, many surgeons consider Roux-Y gastric bypass the gold standard for weight loss surgery.

Open versus Laparoscopic Surgery

VBG, gastric banding, and RGB can be performed be performed laparoscopically. Laparoscopic VBG and RBG require advanced laparoscopic skills. The learning curve is long. Laparoscopic procedures can take substantially more operating room time to perform than open procedures, particularly while surgeons are acquiring experience and proficiency. Large series of laparoscopic RGBs have been published (42;65). Some centers, such as the weight loss surgery program at Baylor Medical Center in Dallas, perform more than 90% of RGBs laparoscopically (66). Laparoscopic surgery has a number of advantages. Post-operative recovery time is substantially less than recovery time with open procedures. Patients can often be discharged within 24 hours of laparoscopic procedures. The time to return to normal activities is reduced. The incidence of wound infections and incisional hernias is also markedly reduced. There is little difference in other complication rates between laparoscopic and open procedures (67).

How Does Weight Loss Surgery Work?

Weight loss surgery should be regarded as an aid to lifelong dieting. Without permanent changes in diet, surgery will not produce weight loss.

Creation of a small gastric pouch produces a conditioned aversive change in eating behavior. Patients experience discomfort and vomiting if they attempt to eat large portions. Patients who have had RGB also learn to avoid high carbohydrate foods because of the development of dumping symptoms. One disadvantage of VBG and gastric banding is that patients can overcome the restriction of the small gastric pouch by taking high calorie liquids such as milk shakes without having dumping symptoms. Patients who have had procedures that produce substantial malabsorption may experience increased diarrhea if they overeat. This additional aversive experience may contribute as much to weight loss with these procedures as the malabsorption itself.

On the basis of our current understanding of the regulation of appetite, weight loss after surgery might be expected increase hunger and food-seeking behavior. Interestingly, most patients have reduced appetite after surgery. They relate that after they feel hungry less often, think less about food, find it much easier to stop after eating a modest amount, and rarely finish all the food on their plate, even though their enjoyment of food is preserved (68;69).

The mechanism for this reduced appetite is not clear. Ghrelin, the recently described regulatory hormone that stimulates appetite and increases energy conservation, usually rises markedly with fasting, but ghrelin levels are markedly suppressed after weight loss surgery (70). It is possible that weight loss surgery changes hormonal regulation of appetite in ways that are not yet understood.

Complications of Weight Loss Surgery

Weight loss surgery entails substantial mortality and morbidity. The figures often quoted to prospective patients are a mortality rate of 1% and a major morbidity rate of 10%. Reported mortality and morbidity rates have been lower in some large established programs.

Complications can be classified as early or late. These include:

Early complications

- Splenic injury
- Anastomotic leak, peritonitis, abscess
- Gastrointestinal bleeding
- Bowel obstruction
- Wound infection, dehiscence
- Deep venous thrombosis, pulmonary embolus
- Post-operative respiratory failure
- Depression

Late complications

- Stomal stenosis, persistent vomiting, food plugging
- Reflux esophagitis
- Incisional hernia
- Sympomatic biliary tract disease
- Bowel obstruction
- Iron deficiency
- Calcium malabsorption, osteopenia
- Vitamin B12 deficiency
- Malnutrition

As discussed above, VBG and gastric banding preserve gastrointestinal continuity and do not lead to iron, calcium, or vitamin B12 malabsorption. Gastric banding has complications unique to that procedure, such as band slippage, leakage, and erosion.

Complication Rates From Large Series

In a series of Roux-Y gastric bypass procedures reported in 1995, Pories recorded the complications rates listed below (54).

Perioperative mortality 1.5%

Early complications

- Wound infection 12%
- Wound seromas 6%
- Stomal stenosis 3%
- Splenic laceration 3%
- Subphrenic abscess 2.5%
- Readmission 8%
- Re-operation 3%

Late complications

- Staple line dehiscence 15%
- Incisional hernia 24%
- Gastritis 13%
- Gallstones 11%
- Bile reflux 9%
- Vitamin B12 def 40%
- Anemia 39%
- Readmission 38%
- Depression 23%

The International Bariatric Surgery Registry was initiated by the American Society of Bariatric Surgeons in 1986. In 1997 Mason reported complications in 14,600 cases done by 75 surgeons. The most commonly performed procedures were VBG (36%), RGB (39%), and silastic ring gastroplasty (10%). In that report the 30 day perioperative mortality was 0.17%, representing a total of 25 deaths. Nine deaths were due to pulmonary embolus, 5 to anastomotic leaks, and 6 to cardiac causes. The overall perioperative complication rate was 7%. Respiratory complications occurred in 216 patients (2.4%). Other serious complications were anastomotic leaks or abscess (32 patients), wound infections (94 patients), pulmonary emboli (19 patients) and gastrointestinal bleeding (12 patients) (71).

Anastomotic leak is potentially the most serious complication associated with RGB. Leaks may be very difficult to diagnose, particularly if they occur in excluded stomach. Delay in recognition and repair can lead to catastrophic consequences such as peritonitis and intra-abdominal abscess. In reported studies the incidence ranges from 1% to 2% (67).

DVT and pulmonary embolism are serious post-operative threats that can be reduced by prophylactic measures. The reported incidence has varied from 0.35 to 3.0% (67).

Respiratory Complications

Atelectasis and pneumonia are relatively common after weight loss surgery, but can be reduced by early mobilization. A few patients develop respiratory failure requiring ventilatory surgery after surgery. The risk seems to be increased in those with very high BMI (e.g. 55 or greater) and those with asthma (Flancbaum L, abstract presented at Digestive Disease Week 2003). Patients with obstructive sleep apnea may also be at increased risk. Some investigators have suggested that these patients should be treated with CPAP for several months before surgery (Bowers SP, abstract Digestive Disease Week 2003).

Wound infections occur after 12% to 16% of open procedures, and incisional hernias after 8% to 20% of open procedures. These complications are reduced to about 1% to 2% after laparoscopic procedures.

Stenosis of the gastrojejunostomy may occur both early and late after surgery, and after both open and laparoscopic RGB. This is one of the more common complications of weight loss surgery, with a reported incidence of between 3 and 12%. Many cases of stenosis can be managed by endoscopic dilation.

Gallstones are a common complication of rapid weight loss, whether occurring with medical or surgical therapy. The incidence of symptomatic biliary disease after weight loss surgery has been reported to be up to 30%, but this can be reduced to 5% by prophylactic treatment with ursodiol for 6 months after surgery.

Bowel obstruction may also occur both early and late after surgery. The obstruction may result from anastomotic stenosis, adhesions, or internal hernias. The reported incidence is about 1%.

Vomiting and "plugging" are common symptoms related to the small stoma and gastric pouch. In one series of 100 patients followed for about 15 years after RGB, about 70% had intermittent vomiting and 40% had intermittent "plugging" (transient lodging of food in the gastric pouch). Most patients accepted these symptoms and are were not concerned (72).

Dumping may occur after RGB. Patients with RGB who ingest a substantial amount of high sugar or high osmolarity food will note symptoms due to rapid emptying into the small bowel, resulting in reactive hypoglycemia and/or symptoms of hypovolemia due to osmotic loss of intravascular fluid into the small bowel lumen. Like vomiting, dumping symptoms act as a behavioral deterrent to overeating.

Esophageal complications include heartburn and esophageal distention. Severe gastroesophageal reflux disease may occur after VGB and gastric banding (46). Relief has been reported by conversion to RGB (46;73).
Bile reflux esophagitis was reported after some of the early RGB procedures in which a loop gastroenterostomy was used, rather than a Roux-Y gastrojejunostomy. Bile reflux is still possible if the Roux-Y limb is too short, but it is very uncommon.

Esophageal distention has been reported after gastric banding, presumably because of chronic esophageal obstruction.

Nutritional complications

Nutritional complications are rare after VBG and gastric banding. Gastrointestinal continuity is preserved and malabsorption does not occur. RGB and BPD both cause malabsorption. In the standard RGB, more than 90% of the stomach is excluded from contact with food. This reduces iron and vitamin B12 absorption. The duodenal loop is also excluded, which further reduces iron absorption and contributes to calcium malabsorption. The afferent limb is about 75 cm long, so that biliary and pancreatic secretion mixing is delayed along this length of bowel, producing some degree of fat malabsorption. This can lead to further calcium malabsorption as well as fat-soluble vitamin malabsorption. BPD has the potential for much more significant malabsorption since more of the bowel is bypassed.

Iron, vitamin B12 and Calcium

Iron deficiency is the most common nutritional complication of RGB. Iron malabsorption occurs because of decreased exposure of ingested iron stomach acid and because of bypass of the duodenum, the site of normal iron absorption. Vitamin B12 malabsorption occurs because of limited exposure of food to gastric intrinsic factor. In a 10 year follow-up of 350 RGB patients treated with multivitamins, 47% became iron deficient. About 90% of the patients who developed clinically significant iron deficiency anemia were young women. Iron deficiency was easily correctable with oral iron supplements. Vitamin B12 deficiency developed in 37% of patients, none of whom developed macrocytic anemia or symptoms. Vitamin B12 deficiency could be corrected by oral supplementation of 350 micrograms per day. Folate deficiency did not occur in any of the patients (74). There is also a risk of calcium malabsorption. The long-term risk of osteopenia is not clear, but severe metabolic bone disease has been reported in a patient not properly supplemented (16). Bariatric surgeons routinely prescribe supplemental oral iron, vitamin B12, and calcium (75).

Depression

Depression is common in the first months after weight loss surgery, in part because of the difficulties of adapting to the dramatic changes in eating habits required. These and other difficulties can be ameliorated by providing counseling and group support.

The risk of early pregnancy

All bariatric surgeons strongly recommend that women avoid pregnancy during the period of rapid weight loss after surgery because of the risk of maternal and fetal malnutrition. Successful outcomes have been reported with early pregnancy, but women becoming pregnant soon after weight loss surgery are at high risk, and should be treated by experts in high-risk pregnancy (76).

The Benefits of Weight Loss Surgery

Do the benefits of weight loss surgery outweigh the risk? There is strong evidence that they do.

Diabetes

Weight loss surgery markedly reduces the risk of developing overt diabetes for obese patients. In an 8 year follow-up of the Swedish Obese Subjects patients, the incidence of diabetes was 18.5% in medically treated matched controls, compared to 3.5% in surgically treated subjects (77). This occurred even though the mean weight loss at 8 years was a modest 16%, Most patients had VGB or gastric banding rather than RGB.

Glucose intolerance and diabetes are markedly improved after successful weight loss surgery. In a large series reported by Pories of East Carolina University School of Medicine, more than 90% of patients with overt adult onset diabetes mellitus or impaired glucose tolerance became euglycemic after RGB (54;78). In another study obese diabetic patients treated medically had a mortality 3-fold higher than those treated surgically (79).

Improvement in diabetes after weight loss surgery may result from bypass of the proximal part of gastrointestinal tract as well as from weight loss. In a recent study two groups of six women were matched for weight, age, per cent body fat, BMI, waist circumference, and aerobic capacity. Six had undergone RGB and the other six were controls. All had stable weight. Serum leptin, fasting glucose and fasting insulin were lower in the women who had undergone RGB than in the unoperated matched controls (80).

Hypertension

Information on improvement in hypertension after weight loss surgery is conflicting. Several studies have shown modest reduced incidence or improvement in established hypertension after surgery (81-83). However, data from the Swedish Obese Subjects Study showed no significant difference in hypertension in surgical patients compared to controls at 8 years (84).

Cardiac

There are no long term clinical studies on the effect of weight loss surgery on the development or progression of heart disease, but physiological data suggest a possible benefit. In a small group of patients studied before and after surgery, cardiac chamber enlargement, left ventricular hypertrophy, and left ventricular systolic dysfunction improved following substantial wt loss (85).

Hyperlipidemia

Several studies have shown improvement in hyperlipidemia after weight loss surgery (77;86;87).

Non-alcoholic steatohepatitis (NASH)

Preliminary findings presented at Digestive Disease week this year showed substantial improvement in liver biopsy findings in patients with NASH after RGB.

Obstructive Sleep Apnea, Hypoventilation, and Asthma

Obstructive sleep apnea, chronic obesity-related hypoventilation, and asthma have all been reported to improve following weight loss surgery (88-90)

Fertility, menstrual irregularities

Many women resume normal menstrual function and are able to become pregnant after successful weight loss surgery (76;91-93).

Quality of Life

The first few months after surgery are stressful. Many patients become somewhat depressed because of the difficulty in adjusting to their new eating patterns. However self esteem, body image, and self-confidence improve quickly after surgery, even before major weight loss. Sexual functioning and enjoyment generally improve. Marital satisfaction improves if the relationship was positive to begin with. Weight loss surgery often leads to divorce in dysfunctional marriages (18;94-96). In a study of the Swedish Obese Subjects, patients undergoing surgery had more disability and sick leave days in the first year after surgery than medically treated patients, but 10% to 14% fewer during the second and third year (97).

Is Weight Loss Surgery Cost Effective?

Whether weight loss surgery is cost effective for treatment of morbid obesity is difficult to determine. In the Swedish Obese Subjects Study total cost of inpatient care were no different in surgically obese patients compared to medically treated controls at six years, if initial surgical costs were excluded, but higher if initial surgery costs were included. On the other hand, in a study from LSU Medical Center comparing the cost per pound lost for medical therapy (about $250) exceeded that of surgical therapy after 6 years, primarily because 89% of surgical patients had maintained weight loss, compared to only 21% of medically treated patients (98).

Selection and Preparation for of Patients for Weight Loss Surgery

Criteria for Patient Selection

- BMI >40, or BMI >35 and significant obesity related co morbidity, e.g. DM, OSA, hypertension, OA
- Age 16-65
- Acceptable medical/operative risks; psychologically stable.
- Documented failure to loss weight in a medically supervised program that includes diet counseling, behavioral therapy, and an exercise program.
- Realistic expectations regarding surgery, including understanding of the risks and consequences
- Understanding, motivation and ability to make lifelong changes in diet and lifestyle
- Good family/social support
- Willingness to participate in lifelong medical follow-up.

Patients are ineligible for weight loss surgery if they have a history of

- Current alcohol or substance abuse
- Severe mental illness
- Hostile & uncooperative behavior or seriously dysfunctional family support system
- Medical conditions, such as advanced heart disease, that pose unacceptable risk for major surgery

Preparation of patients for weight loss surgery

Patients considering weight loss surgery should receive a thorough education in all aspects of the procedure. They should learn how the procedure is done, what the risks are, and how it will affect them. They must understand that the months after surgery will be stressful and they will need support. In particular, they should understand the radical and lifelong changes in eating behavior that will be required.

Diet after weight loss surgery

After RGB or gastric banding, patients generally can eat no more than one-half cup of food at each meal. They must eat four to six meals a day. Food must be thoroughly chewed and taken very slowly. Carbonated drinks are not allowed. They cannot eat high sugar foods and may become lactose intolerant. They cannot drink large amounts of liquids quickly. Thus they must learn to must sip liquids throughout the day.

Patients must understand the possible long-term risks, including vitamin and mineral deficiencies, and the need for lifelong medical follow-up.

Good weight loss surgery programs include a formal, medically supervised pre-operative program that includes instruction in the issues mentioned above. The programs require that patients complete the program before proceeding with surgery. The programs should include instruction from an experienced dietitian and an exercise therapist. Psychological counseling should be available. The goal of a good pre-operative program is to make sure that patients are familiar with the diet and lifestyle changes that will be required, and to demonstrate they have the ability and commitment to make the changes by attending sessions and following instructions.

Selection of An Appropriate Weight Loss Surgery Program

Selection of an appropriate weight loss surgery program is very important. Weight loss surgery is well remunerated, and the incentive to offer it is strong. However, it requires time, effort, and resources to acquire the skills and experience required to evaluate patients appropriately, perform the surgery competently, and offer appropriate follow-up. Not all surgeons are willing to invest the time and effort required. The ease of laparoscopic banding both for patients and for surgeons may offer a temptation to offer a deceptively easy solution for the complex and difficult problem of severe obesity.

An appropriate weight loss surgery program should have well trained and experienced surgeons who can perform Roux-Y gastric bypass. The program should have a comprehensive preoperative and postoperative program that includes dieticians, exercise

therapists, availability of counseling, and support groups. The program should be committed to lifelong follow-up of their patients.

Insurance requirements for reimbursement for weight loss surgery
Insurance requirements vary among plans. Most follow the NIH recommendations. Other conditions may be imposed.

Aetna US Healthcare guidelines are among the most stringent. Aetna requires:

- Documentation in physician record (chart notes) of a weight indicating morbid obesity of the past 5 years.
- Documentation of failure to respond to lose adequate weight in a medically-supervised program within the previous 2 years. The program must be at least 6 months in duration and include monthly weighing, counseling from a licensed dietician, and exercise therapy.
- The program cannot be supervised by a bariatric surgeon.

If a physician is considering referring a patient for weight loss surgery, the insurance company pre-conditions should be considered. If the patient has not met the conditions, the patient should be referred to a medically supervised program that meets the requirements, or the physician should undertake to supervise and document a program for the patient.

Follow-up of patients after weight loss surgery
Patients should have surgery in a program dedicated to lifelong follow-up. If a physician encounters a patient who has had weight loss surgery that physician should find out if the patient attends a follow-up program regularly. If not, the patient should be encouraged to do so. If the patient cannot or will not attend such a program, the primary care physician must undertake the appropriate follow-up. This should include regular weights and assessments of nutritional status. Iron, vitamin B12, and calcium supplements should be prescribed, and the patient should be monitored for iron and B12 deficiency, as well as for the development of metabolic bone disease.

What Can We Do As Physicians To Combat Obesity?
In 2001, the Surgeon General's issued a Call to Action to Prevent and Decrease Overweight and Obesity (99). The call to action included the suggestions outlined below:

Education

- Everyone should educate themselves in healthy diet and lifestyle and provide an example for their children
- Promote education in healthy diet and lifestyle in schools and the public media.

Diet

- Provide healthy meals and snack choices at home. Reduce fast food consumption.
- Promote healthy diets in schools and workplaces.
- Reduce the promotion and availability of unhealthy fast foods and snacks in schools and workplaces.

- Promote responsible changes by the fast food industry, such as improved labeling of meal content, more healthy meal choices, reduced portion sizes, and socially responsible advertising.

Physical activity

- Be physically active. Adults should engage in at least 30 minutes and children 60 minutes of physical activity daily.
- Plan regular family activities which provide enjoyable exercise.
- Reduce the amount of time spent watching TV or engaging in other sedentary activities.
- Promote education in healthy lifestyles and daily exercise in schools for all children.
- Provide safe environments in the home for children to play actively.
- Promote safe facilities for exercise in schools, communities and worksites.

Research

- Increase research on behavioral and environmental causes of overweight and obesity.
- Increase research and evaluation regarding prevention and treatment interventions for overweight and obesity. Develop and disseminate best practice guidelines.
- Increase research on disparities in the prevalence of overweight and obesity among racial and ethnic, gender, socioeconomic, and age groups, and use the research to identify effective and culturally appropriate interventions.

Like smoking, obesity is considered to be a lifestyle, behavioral and social problem, not a medical disease, and, like smoking, there is little evidence of the effectiveness of medical treatments of obesity. These factors contribute to reluctance of payors to cover treatment of medical treatment of obesity. We should promote controlled trials of interventions for producing long-term weight loss and improvement in health outcomes, as well as the cost-effectiveness of weight loss interventions. Information from research trials can be used in developing clinical guidelines and implementing public policies to prevent, reduce obesity.

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American Society for Bariatric Surgery @ www.asbs.org

Overweight and Obesity: The Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity. 2001 @ www.surgeongeneral.gov.library

Weight Loss Surgery Databases

International Bariatric Surgery Registry

This registry was established by the American Society of Bariatric Surgeons. It includes information from surgeons in private practice surgeons in US and Canada, as well as Europe and other areas of the world. Since 1986, information from over 26000 patients has been collected.

Swedish Obese Subjects Study-SOS

This ongoing project includes both a registry and an intervention study. The registry consists of health examination and follow-up of obese pts at 480 primary care centers in Sweden. Patients are assigned to either conventional or surgical treatment of obesity. Assignment is not randomized, but the groups are matched for 18 relevant variables. The goal is to accumulate 2000 subjects in each arm, all followed for 10 years. Inclusion criteria include age between 37 and 60 years old, and BMI of at least for 38 women and 34 for men; Patients are excluded for severe illness, drug and alcohol abuse, and previous bariatric surgery. At last report, about 90% of surgically treated patients received either gastroplasty or gastric banding (100)

The National Institute of Diabetes, Digestive, and Kidney Disease (NIDDK) Bariatric Surgery Clinical Research Consortium will be announced this fall. It is intended to include 4 to 6 centers generating data by treating large number of bariatric patients.

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