



RATIONALE FOR THE SURGICAL TREATMENT OF MORBID OBESITY

Updated 04/06/98
Reviewed 04/08/98

- [**Introduction**](#)
- [**Rationale for the surgical treatment of morbid obesity**](#)
- [**Non-operative patient**](#)
- [**Treatment goals**](#)
- [**Patient selection**](#)
- [**Risks of surgical treatment**](#)
- [**Results**](#)
- [**Childbearing**](#)
- [**Nutritional consequences of gastric restrictive surgery for obesity**](#)
- [**What specific recommendations can be made for the treatment of morbid obesity?**](#)
- [**Preoperative psychological testing**](#)
- [**References**](#)
- [**Further enquiries**](#)
-

INTRODUCTION

There is considerable misinformation concerning the validity of bariatric surgery in the management of morbid obesity. The following "Rationale for Surgery" covers the field in general. References are provided to allow the interested reader to obtain more detailed information along with the opportunity to examine the original data on which these statements are based.

Bariatric surgery is a recognized sub-interest in the field of General Surgery. It has been endorsed by the National Institutes of Health Consensus Conference, 1992.

(1) The American Society for Bariatric Surgery is recognized by the American College of Surgeons and a specialty surgical society in the Specialty & Service Society section of the American Medical Association. Regular members of the A.S.B.S. are all Board Certified Surgeons who have a special interest in surgical treatment of hugely obese patients. It must be emphasized that these procedures are in no way to be considered as cosmetic surgery, and, as you read on, this should become abundantly clear.

Among recent articles of interest included in the references are the paper from Pories et al from the University of East Carolina, a group with the finances and personnel to enable follow-up of their entire obesity surgery population, some 600 patients, achieving a patient follow-up of 96% at 14 years after surgery. This paper, while particularly emphasizing the beneficial effects of surgically induced weight loss in Type II diabetics, also includes follow-up data on other aspects of their series.(2) Other papers detailing the results of bariatric surgery in the younger and older age groups and noting improvement in co-morbidities not generally appreciated include results in adolescents,(3) those over 55 years of age,(4) and the remarkable improvements in asthmatics which follows surgically induced weight loss.(5)

[Return to top of page](#)

RATIONALE FOR THE SURGICAL TREATMENT OF MORBID OBESITY

Clinically morbid obesity (this term is now preferred over morbid obesity) is a disease of excess energy stores in the form of fat. Clinically morbid obesity correlates with a Body Mass Index (BMI) of 40 kg/m² or with being 100 pounds overweight. Being overweight is associated with real physical problems which are now well recognized. The most obvious is an increased mortality rate directly related to weight increase.(6) In a 12 year follow-up of 336,442 men and 419,060 women, it was found that the mortality rates for men 50% above average weight were increased approximately two fold. In the same weight group the mortality was increased five fold for diabetics and four fold for those with digestive tract disease. In women, the mortality was also increased two fold, while in female diabetics the mortality risk increased eight fold and three fold in those with digestive tract disease. It is clear that overweight people of both sexes, especially young overweight people, tend to die sooner than their lean contemporaries.(7-9) While obesity, of itself, is a risk factor,(10) most associated mortality and morbidity is associated with the co-morbid conditions. This applies to non-operated as well as peri-operative mortality and morbidity. These conditions have been outlined in the 1985 National Institutes of Health Consensus Conference and include hypertension, hypertrophic cardiomyopathy, hyperlipidemia, diabetes, cholelithiasis, obstructive sleep apnea, hypoventilation, degenerative arthritis and psychosocial impairments.(10, 11)

A Veterans Administration study of 200 morbidly obese men aged 23 to 70 years, with an average weight of 316 lbs (143.5 kg) showed a twelve fold increase in mortality in the 25-34 year age group and a six fold increase in the 35-44 year age group. During the average follow-up period of 7 _ years, 50 of the original group had died.(12) An interesting ongoing study in this regard is the Swedish Obesity Study (SOS) in which 2000 patients have been randomized to diet therapy and gastric restrictive surgery.(13) The study is still incomplete, but at this time, 6 years into the study, 3 "surgical" patients had died, and 27 "diet" patients had died, a 9 fold difference.

The Nurses Health Study has reported obesity related health risks in women at much less impressive degrees of obesity. Weight gain after the age of 18 years was shown to be a strong predictor of cardiovascular risk. This large prospective cohort study involving 115,886 women apparently healthy at baseline, showed a strong association between BMI and cardiovascular disease. As compared with women whose BMI was less than 21 kg/m², the age and smoking adjusted relative risk of non fatal myocardial infarction and fatal coronary artery disease for women with BMI of 25-29 was 1.8 (95%CI: 1.2-2.5), and that for women with BMI 29 was 3.3 (95%CI:2.3-4.5).(14)

The Framingham study noted that the first cohort to terminate because of demise of all participants was the morbidly obese. Finally, in this litany of risk, the Guinness Book of Records memorializes the worlds heaviest individuals. Note that none of these lived over 40 years of age. Recent work suggests that the significantly increased mortality risk of morbid obesity reverts to normal following successful weight loss surgery.(15)

Obesity is dangerous to health because of the associated increased prevalence of cardiovascular risk factors such as hypertension, diabetes mellitus, hypertriglyceridemia, hyperinsulinemia and low levels of high density lipoprotein (HDL) cholesterol. Cardiovascular risk factors are reduced significantly by sustained weight reduction. Data from the Framingham study support the estimate that a ten percent reduction in body weight corresponds to a twenty percent reduction in the risk of developing coronary heart disease.(16) Serious consequences of morbid obesity are well documented and include cardiac dysfunction, pulmonary problems, digestive diseases, and endocrine disorders as well as obstetric, orthopedic, and dermatologic complications.

The association between average weight of population groups and the prevalence of non-insulin-dependent diabetes has been repeatedly observed.(17, 18) The risk for diabetes has been reported to be about twofold in the mildly obese, fivefold in moderately obese and tenfold in morbidly obese persons.(19) The duration of obesity is also an important determinant of the risk for developing diabetes.(20) In cross-sectional studies, obesity has been shown to be associated with an increased prevalence of non-insulin-dependent diabetes in both men and women.(21) The NHANES II data found that the overall relative risk of developing diabetes was 2.9

times higher for obese persons who are 20-75 years old.(22) The risk of developing diabetes also increases with age,(23, 24) if a family history is present (25) and if the obesity is central.(26) A prospective study in Scandinavia showed that moderate obesity was associated with a 10 fold increase in the risk of diabetes. This risk increased sharply as obesity became more morbid.(26) Even in patients who are morbidly obese and candidates for surgical treatment, diabetes and hypertension are highly correlated with body weight and waist hip ratio.(27)

Cancer mortality rates are increased in morbidly obese females; e.g. endometrium (5.4 times), gallbladder (3.6 times), uterine cervix (2.4 times), ovary (1.6 times), breast (1.5 times). Cancer mortality rates are increased in morbidly obese males; e.g. colorectum (1.7 times), and prostate (1.3 times).(28)

Health care for the four million morbidly obese adults in the United States of America (eighty percent of whom are women of childbearing age)(29) has been hampered by the misconception that body weight is not a physiologically regulated variable, but rather determined by acquired food habits and conscious and unconscious desires. Obesity represents a management challenge for physicians and a psychological and biological challenge for patients.

Lack of respect for the morbidly obese is an issue of concern. A survey of morbidly obese individuals found that nearly eighty percent reported being treated disrespectfully by the medical profession.(30, 31) There are widespread negative attitudes that the morbidly obese adult is weak-willed, ugly, awkward, self-indulgent and immoral. This intense prejudice cuts across age, sex, religion, race, and socioeconomic status. Numerous studies have documented the stigmatization of obese persons in most areas of social functioning. This can promote psychological distress and increase the risk of developing a psychological disorder. The morbidly obese patient is at risk for affective, anxiety and substance abuse disorders. The obese often consider their condition as a greater handicap than deafness, dyslexia or blindness.(32, 33)

[Return to top of page](#)

NON-OPERATIVE TREATMENT:

Published scientific reports document that non operative methods alone have not been effective in achieving a medically significant long term weight loss in morbidly obese adults. The average medical weight reduction trial is a 10-12 week study with average weight loss of 2.5 kg.(34) The use of anorectic medications has recently been advocated as a long term therapeutic modality in management of what is clearly a chronic disease. In a nearly four year study, utilizing a two drug regimen of Phentermine and Fenfluramine, behavior modification, diet and exercise, the initial optimistic results have not been sustained, with a one third drop out rate and a final average weight loss of only three pounds in those who

were followed for the four years of the study.(35) This drug combination appears to have an unacceptably high association with cardiac valvular disease and is no longer recommended. Dietary weight loss attempts often cause depression, anxiety, irritability, weakness and preoccupation with food. The treatment goal for morbid obesity should be an improvement in health achieved by a durable weight loss that reduces life threatening risk factors and improves performance of activities of daily living. Temporary fluctuations of body weight from effective calorie restricted diets should be avoided.

[Return to top of page](#)

TREATMENT GOALS:

Surgical treatment is medically necessary because it is the only proven method of achieving long term weight control for the morbidly obese. Surgical treatment is not a cosmetic procedure. Surgical treatment of morbid obesity does not involve the removal of adipose tissue (fat) by suction or excision. Bariatric surgery involves reducing the size of the gastric reservoir, with or without a degree of associated malabsorption. Eating behavior improves dramatically.(36) This reduces caloric intake and ensures that the patient practices behavior modification by eating small amounts slowly, and chews each mouthful well. Success of surgical treatment must begin with realistic goals and progress through the best possible use of well designed and tested operations. These have been worked out over the last thirty years, and are now standardized, clearly defined procedures, with well recognized and documented outcome results.

Prevention of secondary complications of morbid obesity is an important goal of management. Therefore, the option of surgical treatment is a rational one supported by the time honored principle that diseases that harm call for therapeutic intervention that is less harmful than the disease being treated. The biological basis for morbid obesity is unknown, though recent work has demonstrated a genetic component of between 25 and 50%, and several studies confirm the influence of genetically determined proteins produced by the fat cell which have a place in the control of satiety. This confirms that morbid obesity is a disease, not a disorder of willpower, as sometimes implied. The physiologic, biochemical and genetic evidence is overwhelming that clinically morbid obesity is a complex disorder. Contributing causes are inheritance, environmental, cultural, socioeconomic and psychological.

[Return to top of page](#)

PATIENT SELECTION:

The option of surgical treatment should be offered to patients who are morbidly obese, well informed, motivated, and acceptable operative risks. The patient should be able to participate in treatment and long term follow-up. Some patients with manifest psychopathology that jeopardizes an informed consent and cooperation with long term follow up may need to be excluded. A decision to elect surgical treatment requires an assessment of the risk and benefit in each case. Increased abdominal fat or "central obesity" (apple shaped as opposed to pear shaped) is an important risk factor associated with the major complications of obesity. Functional impairments associated with obesity are also important deciding factors for surgical treatment. An important conclusion of the 1991 National Institutes Consensus Development Conference Statement on the surgical treatment of obesity was that "patients judged by experienced clinicians to have a low probability of success with non-surgical measures, as demonstrated, for example, by failure in established weight control programs or reluctance by the patient to enter such a program, may be considered for surgical treatment."(1)

Patients whose BMI exceeds 40 are potential candidates for surgery if they strongly desire substantial weight loss, because obesity morbidly impairs the quality of their lives. They must clearly and realistically understand how their lives may change after operation.

In certain circumstances, less morbidly obese patients (with BMI's between 35 and 40) also may be considered for surgery. Included in this category are patients with high risk co-morbid conditions such as life threatening cardiopulmonary problems (e.g. morbid sleep apnea, Pickwickian syndrome, obesity related cardiomyopathy, or morbid diabetes mellitus). Other possible indications for patients with BMI's between 35 and 40 include obesity-induced physical problems that are interfering with lifestyle (e.g. musculoskeletal or neurologic or body size problems precluding or morbidly interfering with employment, family function and ambulation).

End stage obesity syndrome: Some candidates for surgical treatment of morbid obesity have such impaired health that they must be hospitalized pre-operatively and undergo treatment to improve their operative risk.

[Return to top of page](#)

RISKS OF SURGICAL TREATMENT:

Assessing the risks of surgical treatment of obesity involves operative, perioperative and long term complications. Available published series report that the immediate operative mortality rate for both vertical banded gastroplasty and

Roux-en-y gastric bypass is relatively low. Morbidity in the early postoperative period, i.e. wound infections, dehiscence, leaks from staple breakdown, stomal stenosis, marginal ulcers, various pulmonary problems, and deep thrombophlebitis may be as high as ten percent or more. Splenectomy is necessary in 0.3% of patients to control operative bleeding. However, the aggregate risk of the most serious complications of gastrointestinal leak and deep venous thrombosis is less than one per cent. In the late postoperative period, other problems may arise and may require reoperation. The mortality and morbidity rates of reoperation are higher than those of primary operations.

THE INTERNATIONAL BARIATRIC SURGERY REGISTRY (IBSR)

The purpose of the International bariatric Surgery Registry (IBSR), formerly known as the National Bariatric Surgery Registry (NBSR), is to promote optimum care of patients undergoing surgical treatment of morbid obesity. Development of the centralized IBSR data base has provided standardized clinical data collection and analysis for the surgical treatment of obesity. One goal of the IBSR is to enable bariatric surgeons to evaluate and improve his/her expertise and benefit from the combined experience of all participants.

In 1997, the IBSR published 10 year results.(37) Males comprised 13% of 14,641 patient records in the data set. Mean age at operation was 37 ± 9.4 years. Operative weight was 127 ± 27.4 kilograms and the Body Mass Index was 46 ± 8.3 kg/m².

Vertical Banded Gastroplasty (VBG) was the most frequently reported bariatric procedure performed (36.3%). VBG was followed by the Roux-en-Y Gastric Bypass (RGB) with 29.5%; Silastic Ring Gastroplasty was 9.9%; and Distal Roux-en-Y gastric Bypass (DRGB) 9.0%. The remaining 15.3% of the procedures were grouped according to the degree of operative complexity. An increase in variation and complexity of procedures was noted in the last quarter of the decade which began January 1, 1986

A subset of records with complete information for perioperative complications and postoperative hospital stay was analyzed for *dominant complication*. (38) Mean postoperative hospital stay was reported to be 4.7 days (± 2.7). Within 30 days of operation, no perioperative complications were reported for 93.37% of the patients. Major (1.35%) and minor (5.28%) perioperative complications were defined according to length of postoperative stay (Table 1.

| Table 1: PERIOPERATIVE COMPLICATIONS- within 30 days of operations | |
|--|---|
| MINOR (postoperative hospital stay was less than 7 days) | MAJOR (postoperative hospital stay equal or greater than 7 days) |

| | |
|------------------------------------|--|
| N, Percent | Hepatic or Cardiac 23 (0.25%) |
| Respiratory 216 (2.35%) | Pulmonary Embolism 19 (0.21%) |
| Other 156 (1.70%) | Subphrenic Abscess 17 (0.19%) |
| Wound Infection 94 (1.02%) | Gastrointestinal Leak 15 (0.16%) |
| Splenic Injury 19 (0.21%) | Evisceration, Dehiscence 12 (0.13%) |
| | G-I Bleeding 12 (0.13%) |
| | Deep Venous Thrombosis 10 (0.11%) |
| | Neurologic, Renal 10 (0.11%) |
| | Wound Seroma 4 (0.04%) |
| No Complications 8,570 (93.37%) | Small Bowel Obstruction 2 (0.02%) |

Twenty-five deaths were reported to have occurred within 30 days of operation, for an operative mortality rate of 0.17%. Pulmonary embolism was the most frequent reported cause of operative death (n=9)

Risk and efficacy of operations for obesity must be understood in the context that morbid obesity is a chronic, frequently progressive, life threatening disease. The therapeutic program applied should be designed to last throughout the lifetime of the patient. Adequate long term follow-up is essential before additional measures of treatment effectiveness can be reported.

[Return to top of page](#)

RESULTS:

Weight loss usually reaches a maximum between 18 and 24 months postoperatively.

Mean percent excess weight loss at five years ranged from 48 to 74 % after gastric bypass and from 50 to 60% after vertical banded gastroplasty. In a study of over 600 patients following gastric bypass, with 96% follow up, mean percent excess weight loss still exceeds 50% fourteen years.(2) Another 10 year follow-up series from the University of Virginia reports weight loss of 60% of excess weight at 5 years and in the mid 50's between years 6 and 10.(39) Multiple other authors have reported 5 and 6 year follow-up of their patient series with similar weight loss results. (2, 15, 40-44)

Weight reduction surgery has been reported to improve several comorbid conditions such as glucose intolerance and frank diabetes mellitus,(2) sleep apnea and obesity associated hypoventilation,(45, 46) hypertension,(47) and serum lipid abnormalities.(48, 49) A recent study showed that Type II diabetics treated medically had a mortality rate three times that of a comparable group who underwent gastric bypass surgery.(50) Also preliminary data indicate improved heart function with decreased ventricular wall thickness and decreased chamber size with sustained weight loss. Other benefits observed in some patients after surgical treatment include improved mobility and stamina. Many patients note a better mood, self esteem, interpersonal effectiveness, and an enhanced quality of life. They have lessened self consciousness.(51) They are able to explore social and vocational activities formerly inaccessible to them. Self body image disparagement decreases. Marital satisfaction increases, but only if a measure of satisfaction existed before surgery. If marital discord exists preoperatively, the improved self image may lead to divorce postoperatively. (51)

Evolving surgical techniques have resulted in progressive improvement in both the safety and long term integrity of bariatric surgical procedures. Previous reports of staple line failures of 15% or more in ten years (2, 43) has resulted in increasing use of gastric transection. In consequence, the need for revisional surgery to correct this problem (52, 53) has all but disappeared.

Only the further accumulation of long term follow up data will answer the question of what magnitude of weight loss is necessary to achieve the greatest benefit in terms of longevity. Data from medical weight reduction studies suggest that a small weight loss will favorably affect obesity comorbidity. Similarly, data in patients over 55 years of age at the time of surgery, followed at least 6 years after gastric bypass, reflect significant sustained improvement in morbidity.(4)

[Return to top of page](#)

CHILDBEARING:

Women of childbearing age who elect to have weight reduction operations must use secure birth control methods during the period of rapid weight loss. They should be informed that maternal malnutrition may impair normal fetal development. This is particularly important to those who may have previously failed to conceive, since fertility may increase following weight loss. Indeed, failure to conceive in the face of morbid obesity is yet another positive indication for weight loss surgery. Women who become pregnant after these surgical procedures need specific attention from the surgical care team. However, there are several reports in the literature of pregnancy outcomes following gastric bypass without evidence of fetal impairment.(54)

[Return to top of page](#)

NUTRITIONAL CONSEQUENCES OF GASTRIC RESTRICTIVE SURGERY FOR OBESITY:

Gastric restrictive surgery in the motivated, cooperative patient, who has been educated in the nutritional requirements to maintain adequate protein/calorie/mineral/vitamin intake, routinely results in a smooth post-operative course, with some protein deficit in the first 3 postoperative months, which is completely restored 18 months after surgery, by which time the patient will have re-established a lean body mass appropriate to the total body weight.

Pure gastric restrictive procedures such as vertical banded gastroplasty (VBG), silicone ring vertical gastroplasty (SRG), adjustable silicone gastric banding (ASGB) all achieve weight loss by restricting volume of intake. Intake becomes a function of the patients motivation to chew well and eat slowly. Failure to do so may result in repeated vomiting and isolated cases of protein and vitamin deficiency have been reported in these circumstances. Careful patient follow up is therefore mandatory, with particular emphasis on the first three postoperative months. Adjustable silicone gastric banding remains in FDA trials and is not generally available in the USA at this time.

Gastric bypass with Roux-y results in ingested food bypassing the gastric fundus, body, antrum, duodenum and a variable length of proximal jejunum. In consequence, these patients are at risk to develop iron deficiency secondary to lack of contact of food iron with gastric acid and consequent reduced conversion of iron from the relatively insoluble ferrous to the more absorbable ferric form. In addition, vitamin B12 deficiency may result in consequence of food no longer

coming in contact with gastric intrinsic factor. Vitamin D and calcium absorption may also be reduced since the duodenum and proximal jejunum, which are the preferential sites of absorption, are bypassed by this procedure. Life long supplements of multivitamins, vitamin B12 and calcium are mandatory following this procedure. A corollary of this is the need for long term follow up for physical, nutritional and metabolic evaluation and counseling.

[Return to top of page](#)

WHAT SPECIFIC RECOMMENDATIONS CAN BE MADE FOR THE TREATMENT OF MORBID OBESITY?

Patients seeking therapy for the first time should be evaluated by a knowledgeable physician and provided with sufficient information on which to make a reasonable choice for therapy.

In spite of the failure of medical therapy by drugs, diet, behaviour modification and exercise to achieve documented long term weight loss in the morbidly obese, it is accepted practice to require that the potential candidate for surgical treatment have made good faith attempts to achieve weight loss by dietary means. Although the segment of the morbidly obese population able to lose significant weight by non-surgical means is miniscule, candidates for surgery must be given the opportunity to try, a proposition which justifies insistence on at least one attempt at dietary weight loss prior to acceptance into a bariatric surgery program.

Decisions on what therapy to recommend to patients with clinically morbid obesity should depend on their wishes for outcomes, on the need for therapy, and on the physicians explanation of options for therapy and the current information on probable safety, efficacy, advantages and risks. The need for close nutritional monitoring during rapid weight loss and the need for lifelong medical surveillance after surgical therapy should be made clear to the prospective patient and their relatives.

The operation should be carried out by a surgeon substantially experienced with the appropriate procedures and working in a clinical setting with adequate support for all aspects of perioperative assessment and management. These include hospital facilities geared to care for the morbidly obese patient, medical specialty availability, psychological support, dietary and nutritional counseling, and patient support groups.

[Return to top of page](#)

PREOPERATIVE PSYCHOLOGICAL TESTING:

There are two possible reasons for pre operative psychological testing prior to bariatric surgery. One is to weed out those with significant psychopathology in whom surgery would be contra-indicated, the other to pre-select those in whom the surgery is likely to be a success. Unfortunately psychologic evaluation has proven of limited value in both these situations.

Studies of morbidly overweight persons conducted before their undergoing anti-obesity surgery have shown a) that there is no single personality type that characterizes the morbidly obese. b) that this population does not report greater levels of psychopathology than do average-weight control subjects; and c) that the complications specific to morbid obesity include body image disparagement and binge eating. Studies conducted after surgical treatment and weight loss have shown 1) that self esteem and positive emotions increase; 2) that body image disparagement decreases; 3) that marital satisfaction increases, but only if a measure of satisfaction existed before surgery; and 4) that eating behavior is improved dramatically. The results of surgical treatment are superior to those of dietary treatment alone. Practitioners should be aware that morbidly obese persons are subjected to prejudice and discrimination and should be treated with an extra measure of compassion and concern to help alleviate their feelings of rejection and shame.(55)

In addition, numerous studies in the literature attempting to identify patient characteristics related to outcome have been reported, but no reliable psychological predictors of success have been identified. (See Vallis and Ross 1993 (56) for a comprehensive review of this area). Only two general recommendations emerge from this study. (1) The more distressed patients are by their obesity , (reflected by exogenous depression) the more likely they are to lose weight and (2) Serious psychiatric disturbance, to the extent that psychiatric treatment or admission is required, appears to be a negative predictor of outcome. While other psychological variables have been shown to be associated with post-surgical weight loss, none have been replicated in independent studies.(56)

Accordingly, routine pre-operative psychological evaluation should be required in patients who have a history of severe psychiatric disturbance or who are currently under the care of a psychologist/psychiatrist. Such patients, and those under the age of 18 years, should be required either to have psychiatric clearance in writing from their counselor or to undergo psychiatric evaluation before surgery. Other patients who wish to have the benefit of psychologic counseling before surgery should be encouraged to do so. Post-operative support can be extremely important, especially for those with preoperative psychological difficulties, and should be actively pursued by patient, surgeon and psychologist/psychiatrist.

"Weight reduction may be life saving for patients with extreme obesity, arbitrarily defined as weight twice the desirable weight or 45 kg (100 pounds) over desirable weight"(10)

[Return to top of page](#)

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[Return to top of page](#)

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