

Gastrointestinal Surgery for Severe Obesity

Consensus Statement

NIH Consensus Development Conference
March 25–27, 1991

Volume 9, Number 1

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This statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.



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Abstract

The National Institutes of Health Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity brought together surgeons, gastroenterologists, endocrinologists, psychiatrists, nutritionists, and other health care professionals as well as the public to address: the nonsurgical treatment options for severe obesity, the surgical treatments for severe obesity and the criteria for selection, the efficacy and risks of surgical treatments for severe obesity, and the need for future research on and epidemiological evaluation of these therapies. Following 2 days of presentations by experts and discussion by the audience, a consensus panel weighed the evidence and prepared their consensus statement.

Among their findings, the panel recommended that (1) patients seeking therapy for severe obesity for the first time should be considered for treatment in a nonsurgical program with integrated components of a dietary regimen, appropriate exercise, and behavioral modification and support, (2) gastric restrictive or bypass procedures could be considered for well-informed and motivated patients with acceptable operative risks, (3) patients who are candidates for surgical procedures should be selected carefully after evaluation by a multidisciplinary team with medical, surgical, psychiatric, and nutritional expertise, (4) the operation be performed by a surgeon substantially experienced with the appropriate procedures and working in a clinical setting with adequate support for all aspects of management and assessment, and (5) lifelong medical surveillance after surgical therapy is a necessity.

The full text of the consensus panel's statement follows.

Introduction

In a 1985 National Institutes of Health (NIH) consensus conference, the health implications of obesity were established as including increased risk for cardiovascular disease (especially hypertension), dyslipidemia, diabetes mellitus, gallbladder disease, increased prevalences and mortality ratios of selected types of cancer, and socioeconomic and psychosocial impairment.

Risk for morbidity and mortality accompanying obesity is proportional to the degree of overweight. A simple means to define overweight is by the body mass index (BMI): [weight (kilograms)/height (meters)²]. The BMI associated with lowest mortality is between 20 and 25 kg/m². Approximately 4 million Americans have BMI's between 35 and 40 kg/m², and another 1.5 million have BMI's over 40 kg/m². A BMI of 40 kg/m² is roughly equivalent to 100 pounds overweight for an average adult male. Persons at the highest risk of morbidity and mortality can be categorized as having "clinically severe obesity," a term that is preferred to "morbid obesity." Patients with severe obesity are potential candidates for treatment by surgical procedures.

The ultimate biologic basis of severe obesity is unknown, and specific therapy directed to it, therefore, is not available. This disorder, nevertheless, is accompanied by a reduction in life expectancy, which is due in large part to significant comorbid associations in the form of metabolic abnormalities and several serious cardiopulmonary disorders. In addition, significant psychosocial and economic problems frequently are experienced by persons with severe obesity. These facts lend urgency to the effort to provide rational care for those seeking relief from effects of this condition.

A 1978 NIH consensus conference on surgery for obesity considered primarily intestinal (jejunoileal) bypass, which exerts its weight-loss effects through malabsorption, decreased food intake, and possibly other mechanisms. This operation was shown to be effective in some reported series of cases, but in many patients it was accompanied by serious complications. The 1978 conference highlighted the undesirable side effects of this operation, and its use has all but disappeared. In the

past 10 to 15 years, other types of surgical procedures have been developed; these use reduction in gastric volume, gastric bypass, and other procedures. Mechanisms of weight loss with newer procedures, which may include both food aversion and malabsorption, have not been determined with certainty. Refinements in such procedures have led to reports of results superior to those seen with the earlier operation; however, side effects sometimes do occur, and in spite of weight loss, ideal body weight is rarely attained. The time has come to evaluate the objective evidence for these new surgical therapies.

To resolve questions relating to surgery for severe obesity, the National Institute of Diabetes and Digestive and Kidney Disease and the Office of Medical Applications of Research of the NIH convened a consensus development conference March 25-27, 1991. After 2 days of presentations by experts in the field, a consensus panel representing the professional fields of surgery, general medicine, gastroenterology, nutrition, epidemiology, psychiatry, endocrinology, and including representatives from medical literature and the public, considered the evidence and agreed on answers to the questions that follow.

What Are the Nonsurgical Treatment Options for Severe Obesity and Their Consequences?

Nonsurgical approaches to treatment of clinically severe obesity include various combinations of low- or very low-calorie diets, behavioral modification, exercise, and pharmacologic agents. In addition to weight reduction regimens, co-morbid factors such as hypertension, dyslipidemia, and diabetes mellitus can be treated by usual medical methods. Published studies of medical approaches to the treatment of obesity include few reports or indications of efficacy in persons with clinically severe obesity. The potential efficacy of these approaches in persons with this degree of obesity, therefore, must be inferred from evidence of their efficacy in less obese persons.

Nonsurgical treatment of clinically severe obesity aims to create a caloric deficit sufficient to result in both permanent weight loss and reduction of weight-related risk factors or comorbidity. The specific amount of targeted weight loss is defined on a case-by-case basis and does not necessarily require reduction to ideal body weight.

Very low-calorie diets (VLCD's) have been widely publicized as having dramatic success in the treatment of clinically severe obesity. Typically, these diets contain 400 to 800 kilocalories per day with increased protein and minimal fat in a solid or liquid form. Significant weight reduction, for example 20 kg over 12 weeks, can be expected. However, in the absence of successful behavior modification, most patients regain their lost weight within 1 year. Thus, although VLCD's used under close medical supervision often are effective in short-term treatment of clinically severe obesity, these diets alone generally have not been successful for achieving permanent weight loss. Combining a VLCD with intensive behavioral modification may be more effective than a VLCD alone for treating the severely obese patient. Although data on the use of this approach are few, some evidence suggests that initial treatment with a VLCD followed by intensive behavioral modification may result in sustained weight loss in highly motivated patients with clinically severe obesity.

Behavioral modification is a therapeutic approach based on the assumption that habitual eating and physical activity behaviors must be relearned to promote long-term weight change. Behavioral treatment also can be combined with a lesser degree of caloric restriction, although evidence of long-term efficacy of this more conservative approach in persons with clinically severe obesity is lacking. Although increased physical activity is recommended as a component of weight-loss programs, the role of exercise in promoting and sustaining weight loss has never been established.

Experience with drug therapy for clinically severe obesity has been disappointing. Although pharmacologic studies with anorexigenic drugs suggest short-term benefit, prolonged and sustained weight loss has not been proved with these agents. Drugs such as amphetamines and thyroid derivatives are unsafe and unapproved.

Medical complications of rapid weight loss may occur and are usually treatable. Electrolyte abnormalities and cardiac arrhythmias during administration of VLCD's generally can be avoided or corrected by the inclusion of high-quality protein and frequent physician surveillance. Recent studies have recognized that rapid weight loss may be associated with a substantial incidence of gallstones. Although there are no specific complications of behavior therapy, failure to achieve sustained weight reduction may heighten the patient's sense of personal failure and decrease the motivation for further medical therapy.

Limited success has been achieved by various techniques that include medically supervised dieting and intensive behavior modification. During such a treatment program, comorbidity factors such as hypertension, dyslipidemia, and diabetes mellitus can be treated by conventional medical therapy in the patient with clinically severe obesity. Although weight may be reduced acceptably, a major drawback to the nonsurgical approach is failure to maintain reduced body weight in most patients. The possibility should not be excluded that the highly motivated patient can achieve sustained weight reduction by a combination of supervised low-calorie diets and prolonged, intensive behavior modification therapy.

What Are the Surgical Treatments and Criteria for Selection?

A number of operations have been tried and discarded as inefficient or because of complications. Two procedures dominate practice in the early 1990's and have advanced beyond the experimental stage.

Vertical banded gastroplasty (see figure 1) and related techniques consist of constructing a small pouch with a restricted outlet along the lesser curvature of the stomach. The outlet may be externally reinforced to prevent disruption or dilation.

Gastric bypass procedures (see figure 2) involve constructing a proximal gastric pouch whose outlet is a Y-shaped limb of small bowel of varying lengths (Roux-en-Y gastric bypass).

Choosing between these procedures involves the surgeon's preference and consideration of the patient's eating habits. The somewhat greater weight loss after the gastric bypass procedure must be balanced against its higher risk of nutritional deficiencies, especially of micronutrients.

Biliary-pancreatic bypass includes a gastric restriction and diverts bile and pancreatic juice into the distal ileum. Experience with the procedure in the United States is limited.

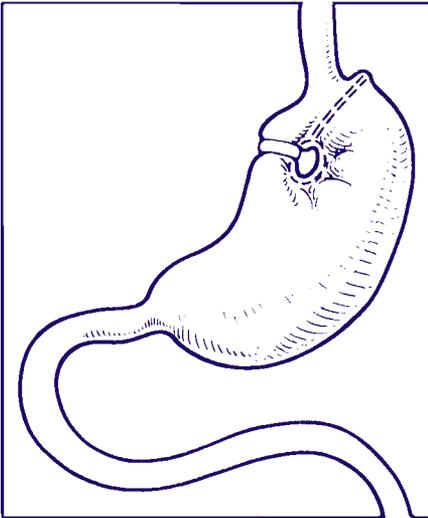


Figure 1. Vertical banded gastroplasty

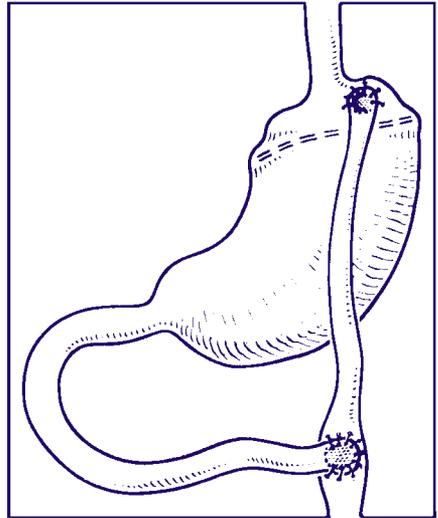


Figure 2. Roux-en-Y gastric bypass

Patient Selection

These surgical procedures are major operations with short- and long-term complications, some of which remain to be completely elucidated. There are insufficient data on which to base recommendations for patient selection using objective clinical features alone. However, while data accumulate, it may be possible in certain cases to consider surgery on the basis of limited information from the uncontrolled or short-term followup studies available. A decision to use surgery requires assessing the risk-benefit ratio in each case. Those patients judged by experienced clinicians to have a low probability of success with non-surgical measures, as demonstrated for example by failures in established weight control programs or reluctance by the patient to enter such a program, may be considered for surgery.

A gastric restrictive or bypass procedure should be considered only for well-informed and motivated patients with acceptable operative risks. The patient should be able to participate in treatment and long-term followup.

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

In certain instances less severely obese patients (with BMI's between 35 and 40) also may be considered for surgery. Included in this category are patients with high-risk comorbid conditions such as life-threatening cardiopulmonary problems (e.g. severe sleep apnea, Pickwickian syndrome, and obesity-related cardiomyopathy) or severe diabetes mellitus. Other possible indications for patients with BMI's between 35 and 40 include obesity-induced *physical* problems interfering with lifestyle (e.g., joint disease treatable but for the obesity, or body size problems precluding or severely interfering with employment, family function, and ambulation).

Children and adolescents have not been sufficiently studied to allow a recommendation for surgery for them even in the face of obesity associated with BMI over 40.

What Are the Efficacy and Risks of Surgical Treatments for Obesity?

Issues of efficacy and risk in bariatric surgical procedures must be viewed in light of the fact that severe obesity is a chronic intractable disorder; any therapeutic program must, therefore, be lifelong.

While definitive therapy for severe obesity is not available, the surgical procedures in use can induce substantial weight loss, and this, in turn, may ameliorate comorbid conditions. Since short- and intermediate-term effects observed in several studies may relate to long-term benefits, further application and investigation of these operations are justified. It must be kept in mind, however, that long-term results are of critical importance and must be delineated. Of special note, many patient cohorts studied to date are not representative of the distribution of race, ethnic and cultural factors, and socio-economic status among the severely obese population.

Efficacy of Surgical Treatments for Obesity

Weight Loss. The two major types of present operations for severe obesity are vertical banded gastroplasty and Roux-en-Y gastric bypass. The success rate for weight loss has been reported to be slightly higher with the Roux-en-Y operation. Substantial weight loss generally occurs, with the weight nadir occurring in 18 to 24 months. Some regain of weight is common by 2 to 5 years after operation. A third operation, biliopancreatic bypass, about which there are only limited data, also has been reported to produce weight loss but with a higher frequency of metabolic complications.

Comorbid Conditions. Weight reduction surgery has been reported to improve several comorbid conditions such as sleep apnea and obesity-associated hypoventilation, glucose intolerance, frank diabetes mellitus, hypertension, and serum lipid abnormalities. Whether beneficial effects in the various metabolic disorders are maintained long enough to prevent end-organ damage (e.g., renal disease, stroke, myocardial infarction and heart failure) is not known.

Psychosocial Effects. Many patients report improvement in mood and other aspects of psychosocial functioning after these operative procedures. The degree to which these improvements are sustained is unknown.

Risk

Assessing the risks in the surgical treatment of obesity involves evaluating both 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. On the other hand, morbidity in the early postoperative period, i.e. wound infections, dehiscence, leaks from staple line breakdown, stomal stenosis, marginal ulcers, various pulmonary problems, and deep thrombophlebitis in the aggregate, may be as high as 10 percent or more. In the later postoperative period, other problems may arise and may require reoperation. These are pouch and distal esophageal dilation, persistent vomiting (with or without stomal obstruction), cholecystitis, or failure to lose weight. Moreover, mortality and morbidity rates with reoperation are higher than those of primary operations.

In the long term, micronutrient deficiencies, particularly of vitamin B₁₂, folate, and iron, are common after gastric bypass and must be sought and treated. Another potential result of this operation is the so-called “dumping syndrome,” which is characterized by gastrointestinal distress and other symptoms. Occasionally, these symptoms may not respond to conservative measures and may be troublesome to the patient.

Many data suggest that deficient nutrition in pregnancy carries with it a high risk of fetal damage or loss. This is of particular concern because as many as 80 percent of patients having weight reduction surgery are women of childbearing age. In view of the uncertain frequency and effects on fetal development of rapid weight loss, micro- or macronutrient deficiency, or other metabolic sequelae of these procedures, secure birth control methods should be provided for these patients during this period of weight loss. They should be informed that maternal malnutrition may impair normal fetal development. Women who become pregnant after these surgical procedures need special attention from the clinical care team.

The increased nutritional requirements for energy, protein, and specific micronutrients as well as the normal need for weight gain during pregnancy must be emphasized as part of the obstetrical management of these patients.

Quality-of-life considerations in patients undergoing surgical treatment for obesity must be considered, as there must be reorientation and adjustment to the side effects of surgery and the effect of a changing body image. Euphoria can be seen in patients during the early postoperative period. Some patients, however, may experience significant late postoperative depression. Some patients have depressive symptoms that are not improved by surgically-induced weight loss.

What Specific Recommendations Can Be Made for the Treatment of Severe Obesity?

Decisions on what therapy to recommend to patients with clinically severe obesity should depend on their wishes for outcomes, on the physician's judgment of the urgency of the need for therapy, and on the physician's judgment of possible options for therapy and their probable efficacy.

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 most cases, patients should first be considered for treatment in a nonsurgical program with integrated components of a dietary regimen, appropriate exercise, and behavioral support and modification. Possible comorbidities such as hypertension and diabetes should be sought and treated if not already under treatment. The desired outcomes may vary among patients and include such indices as a gain in the quality of life as judged by the patient, reduction of hypertension, and amelioration of glucose intolerance. A judgment of failed nonsurgical therapy should be followed by a decision for nonsurgical therapy in a different kind of program or with a different therapist, for no further therapy if significant comorbidities do not exist, or for surgical therapy.

Patients who are candidates for the surgical procedures reviewed during this conference should be selected carefully after evaluation by a multidisciplinary team with access to medical, surgical, psychiatric, and nutritional expertise. Patients should have an opportunity to explore with the physician any previously unconsidered treatment options and the advantages and disadvantages of each. The need for lifelong medical surveillance after surgical therapy should be made clear. With all of these considerations, the patient should be helped to arrive at a fully informed, independent decision concerning his or her therapy.

A decision for surgical therapy should be reached only after assessment of the probability that the patient will be able to tolerate surgery without excessive risk and to comply adequately with the postoperative regimen. There must be full discussion with the patient of the probable outcome of the

surgery, of the probable extent to which it will eliminate the patient's problems, of the compliance that will be needed in the postoperative regimen, and of the possible complications from the surgery, both short- and long-term. Women with reproductive potential would be well advised to avoid pregnancy until weight has stabilized postoperatively and potential micronutrient deficiencies have been identified and treated.

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 management and assessment. Postoperative care, nutritional counseling, and surveillance should continue for an indefinitely long period. The surveillance should include the monitoring of indices of inadequate nutrition and of amelioration of any preoperative disorders such as diabetes, hypertension, and dyslipidemia. The monitoring should include not only indices of macronutrients but also of mineral and vitamin nutrition.

What Are the Future Directions for Basic Science, Clinical Research, and Epidemiological Evaluation of Therapy?

The panel recognized the need to develop safe and effective means to treat patients with clinically severe obesity. In the view of the panel, none of the available therapies, including surgery, has been adequately evaluated. For this reason, it is recommended that centers be developed that can manage patients with clinically severe obesity, using a multidisciplinary approach, and, at the same time, can enter these patients into controlled investigations with long-term followup. The research will need to involve a team that includes professionals trained in fields such as epidemiology, nutrition, surgery, general medicine, gastroenterology, cardiovascular-pulmonary medicine, psychiatry, and endocrinology. Only if in-depth investigations are carried out over long periods will needed information be obtained to care for obese patients more effectively in the future.

A series of issues arose during the conference that need additional investigation. These issues include the following:

- The balance of efficacy and risk between surgical treatment and nontreatment or alternative treatments of severe obesity is difficult to evaluate with available information. Lacking are studies that use well-defined groups of subjects and standard protocols, with adequate power to define long-term outcomes. Nevertheless, the current reports from case series are sufficiently encouraging to indicate that well-organized clinical trials that address the critical issues surrounding surgical procedures are now in order.
- A better vocabulary and nomenclature are critically needed to define clearly terms related to obesity, especially terms defining outcomes. These will improve communication between investigators.
- A definition of the natural history of severe obesity is required that can serve as a baseline to evaluate the long-term effects of any form of therapy.
- Various surgical procedures should be compared for complication rates, weight loss, long-term weight maintenance, and improvement in secondary complications of obesity.

- Several specific issues were identified for better definition of the efficacy and risks of surgical therapy for severe obesity.
 - The mechanisms whereby surgical treatment produces weight reduction (i.e., malabsorption of nutrients, food aversion, decreased intake, altered metabolism) deserve further investigation.
 - Further investigation is needed of mechanisms whereby comorbidity factors are reduced by these surgical procedures.
 - The effects of surgical therapy should be defined in various subgroups stratified for gender, age, ethnicity, socioeconomic status, comorbidity, and fat distribution.
 - The effects of surgical treatment of mothers on their developing fetuses and whether it is safe for women to get pregnant after such operations must be determined.
 - Better statistical reporting of surgical results is urgently needed for clearer assessments of outcomes.
- In addition, more effective alternate forms of weight-reduction therapy need to be developed and evaluated. Specifically, the following needs were identified:
 - Development of more effective behavioral techniques for producing long-term changes in eating and exercise behaviors is needed. Further, there is a need to determine the types of behavioral strategies that are most effective in treating various subgroups of overweight populations and to define the roles of physician, clinical psychologist, and dietitian in the behavioral approach.
 - Research is needed on how best to maintain weight reduction for a long term, with clarification of the roles of reduced caloric intake and increased energy expenditure (e.g., exercise). Consideration should be given to use of combined approaches, for example, low-calorie diets, behavior therapy, and drug therapy.
 - The potential for pharmacologic therapy needs further evaluation. The possibility that long-term drug therapy can be used successfully deserves exploration. Especially important are efficacy of therapy, long-term safety, and enhanced efficacy of drugs in combination.

- One of the key problems in evaluating the current reports of case series in surgical therapy is the lack of standards for comparison. The present practice is to compare postoperative indicators of comorbidity to the same patient's own preoperative status. Although this approach may give some useful information on short-term effects of surgical therapy, it is insufficient for evaluation of long-term effects and of survival. An alternative approach for evaluating surgical therapy is to compare levels of morbidity and mortality in the surgical group with an appropriate comparison group. The establishment of a meaningful comparison group presents a challenge to future research.
- Evaluation of the psychosocial changes that occur during weight reduction is needed. Standardized, reliable, and valid questionnaires and structured interviews should be developed to evaluate the patient's expectations about changes and the psychosocial changes they actually experience during weight loss and maintenance.

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"Effect of Surgically Induced
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George A. Bray, M.D.
"Pathophysiology of
Severe Obesity"
"Pharmacologic Intervention and
Control of Food Intake for
Treatment of Severe Obesity"

Robert E. Brolin, M.D.
"Critical Analysis of Results:
Weight Loss and Quality of
Data"

Jorge Calles, M.D.
"Nonsurgical Treatment of
Severe Obesity"

Ilan Charuzi, M.D.
"Bariatric Surgery in Morbidly
Obese Sleep Apnea Patients:
Short- and Long-Term
Followup"

**Graham A. Colditz, M.D.,
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"Economic Costs of Severe
Obesity"

John J. Gleysteen, M.D.
"Results of Surgery: Long-Term
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"Gastric Restriction Procedures
for the Treatment of Severe
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"Metabolic Risk of Obesity
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"Overview of Surgical
Techniques for Treating
Obesity"
"Assessment of Quality of Life
Before and After Surgery for
Severe Obesity"

**Robert J. Kuczmarski
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"Prevalence of Overweight
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"Reoperative Surgery –
Indications, Efficacy, and
Long-Term Followup"

Edward E. Mason, M.D., Ph.D.
"Perioperative Risks and Safety
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"Physiological Implications
of Gastrointestinal Surgery"

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"Surgical Treatment of Obesity
and Its Effect on Diabetes:
10-Year Followup"

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"Morbidity and Mortality of
Severely Obese Subjects"
"Mortality of Obese Subjects"

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