

# National Institutes of Health Consensus Development Conference on Surgical Treatment of Morbid Obesity\*

ON DECEMBER 4–5, 1978, about 200 surgeons, internists, basic scientists, psychiatrists, psychologists, legal experts, patients and representatives from health insurance companies convened under the sponsorship of the National Institute of Arthritis, Metabolism, and Digestive Diseases of The National Institutes of Health in Bethesda, Maryland, to discuss the current status of surgical treatments for very severe or "morbid obesity." This meeting was one of an ongoing series of consensus development conferences through which The National Institutes of Health seek to establish agreement among knowledgeable experts in different relevant disciplines concerning the soundness, feasibility, selective applicability and desirability of utilizing various newly developed and emerging medical technologies in clinical treatment and care.

To provide a framework within which to consider the problem, the prevalence of severe obesity in the United States and the hazards it poses to life, health and well-being were first assessed. The "morbid" form of severe obesity has been variably defined as "100 pounds overweight" or, more acceptably, 200% or more of desirable weight as defined by the Metropolitan Life Insurance Company. One useful way of defining morbid obesity would seem to be in terms of Body Mass Index (BMI) or weight in kg/height in meters<sup>2</sup>. When this index is used, morbid obesity would constitute a BMI of about 47 or higher. The effectiveness of non-surgical treatments for this disabling condition was also evaluated. On the basis of body measurement data obtained from the Health and Nutrition Examination Survey (Hanes) 1971–1974, a representative from the National Center for Health Statistics of the United States Public Health Service reported that among men aged 20 to 74 years of age in the United States, 4.9% or an estimated 2.8 million men were "severely obese" (30% above "relative desirable" weight). The corresponding percentage for women (more than 50% above relative desirable weight) was 7.2% or an estimated 4.5 million.

A survey of currently available information on mor-

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tality among severely obese persons showed that the death rate among such individuals may range up to 11 times that of non-obese persons of the same age and sex. Of course, the risks associated with moderate obesity (115–130% of desirable weight) are much lower. Severe obesity predisposes a person to a variety of serious disorders ranging from coronary heart disease, hypertension and diabetes mellitus to marked osteoarthritis of the weight-bearing joints, respiratory distress, gallbladder disease and psychosocial incapacity. Such individuals are also subject to social and economic discrimination. Although a variety of drastic medical treatments has been tried in the treatment of morbid obesity, including prolonged fasting and very low calorie diets consisting principally of protein, only one-third to two-thirds of morbidly obese persons who seek such treatment will remain on these regimens for sufficient periods of time to lose a significant proportion (up to two-thirds) of their excess weight. Of those who are successful in losing a substantial quantity of weight, it is estimated that only about 10–20% are able to maintain the loss for more than a few years. In view of this very high recidivism rate, it was concluded that for most persons with morbid obesity, current modalities of medical treatment are ineffective. Accordingly, the potential benefits and risks of surgical interventions designed to deal with this problem were thoroughly explored.

The surgical procedures that were intensively reviewed and compared were the jejunoileal bypass and the gastric bypass. Gastroplasty, vagotomy and jaw-wiring also were discussed. Other procedures that are in still earlier stages of development; for example, the biliopancreatic bypass and some as yet limited to laboratory animals, were considered as well.

The benefits and hazards of the more commonly used operations, namely, jejunoileal and gastric bypass were analyzed in terms of their short- and long-term physical, physiological and psychosocial effects. It was

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generally agreed that, in contrast to the more established jejunoileal bypass, the new gastric bypass operation has fewer long-term side effects: however, follow-up has been only two to three years compared to five to seven years for the jejunoileal bypass. Moreover, it appears to be a technically more demanding procedure. It is still not known whether patients with gastric bypass will lose as much weight or maintain substantial weight loss for as long a period of time as those receiving intestinal bypass. It appears that some patients learn to "out-eat" the gastric bypass operation by consuming very frequent small meals. Gastroplasty, a new variant of gastric bypass, is promising, but follow-up studies of sufficient duration are not available to permit an assessment of its long-term effect on weight loss. It was evident that the techniques designed to reduce the gastric reservoir are still evolving rapidly.

The most common, serious complications of jejunoileal bypass include a high incidence of oxalate-containing kidney stones, unremitting diarrhea, development of various nutritional deficiencies, including protein malnutrition, and possibly accelerated gallstone formation. Serious kidney problems may also develop. Unless they also receive long-term dietary and behavioral management, a few patients will regain much or all of their lost weight. Other long-term complications include a sometimes fatal liver cirrhosis (probably related to bacterial overgrowth in the excluded intestinal segment), and depletion of fat-soluble vitamins and trace elements, arthritis and metabolic bone disease. Many, but not necessarily all, of these complications can be prevented or mitigated by meticulous follow-up care.

Benefits associated with weight loss, regardless of the procedure used, include frequent amelioration of hypertension, reversal of cardiorespiratory impairment, reduction of hypertriglyceridemia, improvement and sometimes disappearance of maturity-onset diabetes, greater agility and mobility, and frequently a striking psychosocial rehabilitation. Earning capacity and ability to return to maintain a regular occupation are similarly enhanced. Two separate issues about the psychosocial rehabilitation are worthy of emphasis. One is that the greatly improved social function is not actually rehabilitation for many (perhaps most) patients since they had never functioned adequately before. The second is that far fewer untoward emotional responses occur with surgical treatment (either jejunoileal or gastric bypass) than occur in the course of weight reduction by "conservative" treatments. It is also noteworthy that despite certain distressing complications, a majority of patients who have received the jejunoileal bypass say that they are satisfied with the overall results and would "do it again."

Consensus was reached that surgical interventions

should be limited to morbidly obese patients (as defined earlier) with serious physical health or psychosocial problems and who have given suitable nonsurgical treatments, such as calorie restriction and behavioral therapy, a fair trial (preferably on repeated occasions) and who have failed to improve adequately, or who have always relapsed within a relatively short time after initial periods of successful weight loss.

It was acknowledged that some patients do not do well following either gastric or jejunoileal bypass; however, no criteria are currently available to predict reliably whether surgical intervention will be successful in a given individual. Thus, for the patient who undergoes a bypass procedure, the outcome is likely to be less predictable than it is for many other, more established operations. Also, a patient who submits to such surgery, as would be the case whenever major surgery is performed, undertakes a calculated risk. Because of these uncertainties, it was agreed that the development and use of a truly informed consent mechanism would be essential. It was emphasized that the patient should receive all the relevant information that he would need to make an informed judgment and that such information should be presented in an objective and readily understandable fashion. Patients should also receive a thorough explanation about the risks, benefits and uncertainties, short- and long-term, of both the gastric and the jejunoileal bypass procedures and, if a choice is available, be permitted to choose between them. If possible, they should have an opportunity to talk to other patients who have already experienced each procedure.

Comparison of the different surgical procedures was found difficult because of constantly changing surgical techniques and follow-up data of insufficient size and duration, particularly among the more recently developed operations. One point of view held that jaw-wiring (and the subsequent weight loss) could be a relatively safe and effective method for preparing patients for bypass surgery at a later time on grounds that, first of all, continued compliance with this procedure would be a useful test of the patient's level of motivation and, if successful, it would reduce the subsequent risks of anesthesia and abdominal surgery.

It was agreed that careful follow-up studies of gastric bypass and gastroplasty will be needed to determine whether long-term weight reduction can be maintained in a majority of subjects by means of these procedures. In this regard, it is essential to develop standardized methods for case selection, surgical techniques and follow-up; otherwise, comparative assessment of the different surgical approaches will be difficult, if not impossible. Bypass operations should only be performed in a setting that provides a multidisciplinary team committed to careful diagnosis and long-term follow-up.

Such a team should include a gastroenterologist, clinical nutritionist and psychiatrist, as well as one or more surgeons experienced in the conduct of the operations that have been selected as being most safe and effective.

It must be emphasized that many of the differing results reported for jejunoileal or gastric bypass operations depend on variations in surgical technique; thus, in the former operation, weight will not be lost if too much intestine is left in continuity. On the other hand, intractable diarrhea and electrolyte imbalance persist if too little intestine is left. Also, judgment about results may depend upon the degree to which medical or non-surgical help is provided before reversal of the shunt is deemed advisable. By the same token, results with the gastric bypass are significantly enhanced if the gastric reservoir is reduced to about 50ml and the outlet to 12mm. Finally, clinical trials of the most promising new techniques and improvements of existing procedures should be encouraged, so long as they are theoretically well-grounded, are thoroughly tested in animal models, when appropriate, and adhere to carefully thought-out protocols that have been approved by an independent institutional peer review committee.

It was agreed that a number of important research concerns remain with respect to surgical treatment of morbid obesity. First, more attention needs to be paid to the "taxonomy" of obesity; namely, the acquisition of a better understanding of the different types of obesity and their implications for health and response to treatment. Next, more data are needed concerning

the incidence of massive obesity and the degree of risk associated with such severe obesity. Also required are better techniques to identify early in life those individuals who are destined to become "super-obese." The mechanism of the effects of the surgical therapies—particularly on the control of food intake—needs much more attention. For example, the changes that occur in gut hormones and their responses to food ingestion require further study. In particular, the possible role as satiety signals of gut hormones and neural stimuli arising from the gastrointestinal tract deserves elucidation. The behavioral effects of the various surgical treatments should be studied in greater detail. Finally, the ethical issues involved in such surgery, particularly as they can be dealt with by use of properly designed informed consent procedures require further thoughtful consideration.

This report reflects the attempt of the authors to identify points of view expressed at the conference concerning which a reasonable consensus was reached.

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