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Selecting the optimal patient for LAP-BAND placement

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Abstract

Optimal patient selection for laparoscopic adjustable gastric banding with the LAP-BAND (INAMED Health, Santa Barbara, CA) enables maximization of results for patients most suited to the procedure and avoidance of unsatisfactory outcomes for inappropriate candidates. We have investigated potential predictors of outcomes in our patients to look for associations with weight loss. We have also reviewed published data for additional predictors. This analysis has revealed a number of conditions associated with a significantly lower percent excess weight loss (%EWL) than experienced in the overall group. These include increasing age, increasing body mass index (BMI), hyperinsulinemia, insulin resistance, type 2 diabetes, and polycystic ovary syndrome. There was also less weight loss if the SF-36 quality-of-life measure showed a poor physical activity score, high pain score, or poor general health score. However, in all these conditions, the effect was small in comparison with the benefits achieved by these patients, and was judged insufficient to preclude this approach to treatment of their obesity. A number of conditions were found to have no relation to weight loss after LAP-BAND placement. These included sex, presence of mental illness, most comorbidities except those linked to insulin resistance, previous bariatric surgery, and sweet-eating behavior. The value of psychologic assessment to predict outcomes could not be established. The superobese (BMI >50) achieved a lower %EWL at 1 year after LAP-BAND placement compared with those with BMI <50, but there were no differences at the 2-, 3-, and 4-year follow-ups. © 2002 Excerpta Medica Inc. All rights reserved.

The selection of appropriate patients for bariatric surgery is a serious responsibility. On one hand, we should avoid operating on those in whom there is a significant chance that we can do more harm than good, either because the positive outcomes (eg, weight loss, improved health, and improved quality of life) are likely to be modest or because the bad outcomes (eg, death or serious complications) are more probable. On the other hand, we must recognize the benefits of weight loss to health and quality of life and should be reluctant to exclude someone from those benefits on unproven grounds. Using the mantra of evidence-based medicine, we should "do what is known to be right and not do what is known to be wrong." This still leaves a large middle ground where we have insufficient data; we then have to make a judgment while striving always to do no harm.

Studies of predictors of outcomes

To refine our selection criteria and, in particular, identify subgroups who are likely to do so poorly that they should not be permitted to proceed, we analyzed the data we had collected related to predictors of outcome for 440 of our patients who received the LAP-BAND (INAMED Health, Santa Barbara, CA) [1]. We used the percent excess weight loss (%EWL) at the end of 1 year as the outcome measure and performed linear regression multivariate analysis on the data to identify predictors of better or worse %EWL at 1 year.

Negative predictors

A number of negative predictors were identified (Table 1). These included increasing age, increasing body mass index (BMI), hyperinsulinemia, insulin resistance and diseases associated with insulin resistance (type 2 diabetes, polycystic ovary syndrome), poor physical activity, high pain score, and poor general health. However, the differences in outcomes, although statistically significant, were small and, when compared with the benefits that these patients achieved through weight loss, were judged insufficient to conclude that the procedure should not be performed in these patients.

Positive predictor

There was only 1 positive predictor that emerged from this analysis. Those patients who consumed alcohol regu-

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Table 1
Percentage of excess weight loss in 1 year (%EWL1) for specific groups when compared with those not in the group

Group	n	%EWL1 in group	%EWL1 not in group	*P*-value*
Type 2 diabetes	42	39.4 (13)	46.4 (17)	<0.05
Polycystic ovary syndrome†	14	36.3 (14)	46.1 (16)	<0.05
Gestational diabetes†	15	37.4 (11)	46.1 (15)	<0.05
Hypertension	152	44.7 (16)	46.3 (17)	NS
Mental illness‡	82	44.8 (18)	46.0 (17)	NS
Major mental illness‡	15	42.0 (16)	45.6 (17)	NS
Male sex	57	42.1 (14)	46.4 (17)	NS
Back pain	190	45 (16)	45.9 (17)	NS
Lower limb pain	151	45.1 (17)	45.7 (17)	NS
Previous bariatric surgery	29	39 (20)	46.2 (16)	NS

NS = not significant.

* *P*-values (2-sided) based on linear regression analysis after correction for group age and preoperative body mass index.

† As a group, those presenting with a diagnosis of polycystic ovary syndrome were significantly younger.

‡ Diagnosis of these conditions was reported during preoperative assessment.

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Table 2
Weight loss outcome and alcohol intake

Alcohol intake	%EWL1	*P*-value
Teetotalers (n = 145)	40 ± 15	NS
>20 g/wk (n = 224)	45.4 ± 15	<0.05
>100 g/wk (n = 71)	50.4 ± 15	<0.005

%EWL1 = percent excess weight loss in 1 year; NS = not significant.

larly had a greater weight loss than the remainder (Table 2). An alcohol intake of >10 standard drinks per week was seen to be beneficial. It should be noted that the study participants were drinking wine more than beer or spirits. A benefit from the latter beverages was not established by this study.

Not predictive of outcome

Importantly, we found that several possible criteria had no bearing on the outcome (Table 1). These include sex, presence of mental illness such as depression or bipolar disorder, most comorbidities except those linked to insulin resistance, a past history of bariatric surgery, and sweet-eating behavior. Some of these "nonpredictors" deserve added comment or data.

Sweet-eaters and weight loss

In 1987, Sugerman and colleagues [2] proposed that "sweet-eaters" did not do well with a restrictive operation, such as vertical banded gastroplasty (VBG), and should be offered a combined restrictive and malabsorptive operation, such as Roux-en-Y gastric bypass (RYGBP). They studied only 20 patients who had received VBG, classifying 12 of these as sweet-eaters. The sweet-eaters had a 36% EWL 3 years after surgery compared with a 57% EWL in the 6 patients who were not regarded as sweet-eaters. Two were lost to follow-up. The difference was said to be significant. On the basis of the outcome in this small number of patients, the concept of not doing restrictive procedures on sweet-eaters became broadly accepted across the United States (but not generally across the world).

As a part of the Swedish Obesity Study, in 1996, Lindroos and colleagues [3] tested this concept by comparing the outcomes of VBG or gastric banding in 375 severely obese patients with the outcomes of gastric bypass (GBP) in 34 patients 2 years after their surgery. They found an inverse relation between the outcome of the restrictive procedures and sweet-eating. Those in the quartile with the highest sweet-eating had significantly greater weight loss than those in the lowest quartile. The investigators questioned the widespread practice of selectively assigning sweet-eaters to GBP.

We have studied the association between sweet-eating

patterns preoperatively and the outcome after LAP-BAND placement in 200 patients studied at 1, 2, and 3 years after surgery. Regardless of how we analyzed the data, no differences could be seen. We recommend that sweet-eating behavior not be used in the decision to proceed with surgery, in the selection of the type of operation to be done, or in the advice given to the patient about reasonable expectations after surgery.

Revision of prior bariatric surgery to LAP-BAND

Revisional surgery of a failed gastric stapling operation by redoing the operation or converting to another type of stapling procedure has not generally been successful. In the Adelaide obesity study, a prospective randomized trial of gastric stapling techniques [4], 63 (20%) of the 310 patients who were randomized to 3 forms of gastric stapling required a revisional procedure during the first 4 years of follow-up. The outcome during a 2-year follow-up period was poor. Only 23% were judged to have achieved a successful result through the revision. Subsequent weight loss was inadequate in 32%, 11 additional revisional procedures were required, and reversal of the procedure was necessary in 3 patients.

Others have reported similar outcomes. Benotti and Forse [5] reported a complication rate of 16% and a modest but significant weight reduction—from BMI of 39 kg/m^2 to BMI of 34—in 63 patients who had had a range of previous weight reduction procedures. Behrns and colleagues [6] performed reoperative procedures on 61 patients, with 1 death, serious morbidity in 11%, and an overall weight loss of 16 $\pm$ 3 kg. Those patients converted to RYGBP showed better weight reduction than those converted to gastroplasty (54% EWL vs 24% EWL). This was also a feature of other studies [7,8]. There has thus developed a rather pessimistic view of the outcomes of revisional bariatric surgery.

This has not been our experience, however, with conversion of other bariatric procedures to the LAP-BAND. As a part of our LAP-BAND program, we have now treated 81 patients who have had an unsatisfactory outcome from previous gastric stapling or other bariatric surgical procedures and have sought this approach. In 2000, we reported on a prospective study of a consecutive group of 50 such patients and compared these outcomes with the 713 primary LAP-BAND patients we had treated to that date [9].

Significant perioperative complications occurred more frequently after revision than after primary placement (17% vs 1.1%). However, late complications were less frequent (2% vs 18%). In particular, there were no occurrences of gastric prolapse or erosion of the band into the stomach in this group. An EWL of 47% was found at the 3-year follow-up; this was not significantly different from the 53% EWL in the primary LAP-BAND group. All symptoms of obstruction due to the stapling were relieved by the revision and a number of comorbidities were markedly improved.

On the basis of these data, we do not believe that prior gastric stapling or other bariatric procedures should be a contraindication to LAP-BAND placement.

Value of psychologic evaluation

We do not use psychologic evaluation in our current assessment. In a previous study, we tried to identify which type of patient would do well and which type of patient would do poorly after bariatric procedures (unpublished data, collected as a part of the Adelaide obesity study [4]). Each patient was formally assessed by a psychiatrist and completed a panel of questionnaires and standard psychologic assessment instruments with the specific task of seeking to identify predictors of good or bad outcomes. At the completion of the 5-year study of 310 patients, no measures that predicted outcome, either positive or negative, could be discerned from the data. A recent Italian study [10] confirms the importance of physiologic and technical factors in the success of LAP-BAND placement, rather than psychologic and behavioral factors. The study found that patients with eating disorders before surgery (eg, binge-eaters, sweet-eaters, pickers, or grazers) had no adverse weight outcome.

Personality profiling and assessing psychosocial factors also have been found to be of limited value for predicting weight loss outcomes; there have been no consistent findings emerging from the literature [11–13]. Yet psychologic assessment is commonly used for patient evaluation in the United States, and approval by third-party payers sometimes requires the assessment. We are not aware of data to date demonstrating that this process enables better decision making. To reject a patient from a bariatric operation is a serious decision because it denies that person the considerable benefits of weight loss. Grounds for exclusion should therefore be defined clearly and their validity established by properly conducted clinical trials.

Contraindications

Absolute contraindications

Mentally defective patients are unable to understand the rules of eating and exercise, and therefore are unable to fulfill their part of the partnership. Malignant hyperphagia (Prader-Willi syndrome) combines mental retardation with an uncontrollable desire for food. Portal hypertension is seen as an excessive hazard to laparoscopic gastric surgery. This preclusion is based on the authors' clinical experience, and has not been demonstrated in the literature.

Relative contraindications

With increasing age, the weight loss is less effective and the risks of the procedure are greater. It is more likely that

cardiovascular or pulmonary disease is present, and the duration of benefit from the weight loss is shorter. We are generally reluctant to consider someone >65 years for these reasons. At the other end of the scale, we would not accept patients under the age of 16 years if we felt they lacked a good understanding of the significance of the decision.

In the presence of severe, irreversible disease, the benefit of weight loss is lessened and the risks of surgery increased. A judgment needs to be made in each case to determine the wisdom of proceeding. Reduced mental status is another contraindication. Obtaining a successful outcome after LAP-BAND placement requires a partnership between the surgeon and the patient, with both committed to fulfilling their role optimally. This is not possible if there is a lack of understanding on the part of the patient, and we would exclude those whose mental status precludes good understanding.

Selection criteria

On the basis of the data reported in this article and recognizing the contraindications described, we use the following 4 basic criteria for patient selection in LAP-BAND placement:

1. BMI >35. In the past, when performing RYGBP, we used BMI >40 as a cutoff because of the greater risk of the bypass. The safety of LAP-BAND surgery has been high; even the cutoff of BMI >35 is due for review. At least 1 randomized, controlled trial is under way, testing the appropriateness of this limit. In the United States, BMI limits are still linked to the 1991 National Institutes of Health Consensus Report [14], which required a BMI >40, or a BMI >35 with ≥2 serious comorbidities.
2. The presence of problems associated with the obesity. These may be medical, physical, psychosocial, or future health and life expectancy problems.
3. A history of prolonged attempts at weight reduction by multiple means. In general, there should be evidence of involvement in multiple significant programs for weight loss.
4. An understanding by patients of their role in ensuring a successful outcome, and the presence of realistic expectations of the possible outcomes, both good and bad. A successful outcome after LAP-BAND surgery requires a partnership in which both the surgeon and the patient have clear responsibilities. Both need to understand those responsibilities and have a commitment to do their best to fulfill them. The assessment of patients' understanding of their responsibilities can come only after all the information has been provided and full discussion has occurred.

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