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Prospective Study of a Two-Stage Operative Concept in the Treatment of Morbid Obesity: Primary Lap-Band® Followed if Needed by Sleeve Gastrectomy with Duodenal Switch

Ralph Peterli, MD[1]; Bettina K. Wölnerhanssen, MD[1]; Thomas Peters, MD[2]; Beatrice Kern, MD[1]; Christoph Ackermann, MD[1]; Markus von Flüe, MD[1]

[1]Department of Surgery and [2]Interdisciplinary Center of Nutritional and Metabolic Diseases St. Claraspital, Basel, Switzerland

Background: We investigated the success rate of a two-stage operative concept for treatment of morbid obesity: primary laparoscopic adjustable gastric banding (LAGB, Lap-Band®) for all morbidly obese patients, followed by sleeve gastrectomy with biliopancreatic diversion (duodenal switch or DS) in case of failure.

Methods: From Dec 1996 to May 2004, 366 consecutive patients (female 78%, mean age 41 (17-66) years, BMI 44.3 (35-75) kg/m² were prospectively evaluated, using the two-stage operative concept. The follow-up rate after a mean of 4.1 (1-8.4) years was 98%. Primary outcome measure was BAROS score, defined according to weight loss, quality of life, reduction in co-morbidities, complications and re-operations.

Results: A *very good-to-excellent* result was found in 118 patients (32%), 141 (39%) had a *good* results, 76 (21%) a *fair* result, and 31 (8%) were *failures*. 39 patients needed re-banding due to slippage, 68 a DS, and 11 patients had band removal. Early morbidity of the Lap-Band® was 3.8%, that of DS 13%, and mortality was zero. The excess weight loss at last follow-up of all the patients was 44% (40% after Lap-Band®/rebanding, and 82% 2 years after DS).

Conclusion: The two-stage concept with primary LAGB, followed by DS in case of failure, leads to a good result in 71% of morbidly obese patients. LAGB alone does not appear to be an adequate procedure for every morbidly obese patient.

Key words: Morbid obesity, obesity surgery, laparoscopic gastric banding, biliopancreatic diversion, duodenal switch, staged operations

Correspondence to: Ralph Peterli, MD, Department of Surgery, St. Claraspital, Kleinriehenstrasse 30, CH-4016 Basel, Switzerland. Fax: +41 (0) 685 84 81;
e-mail to: Ralph.peterli@claraspital.ch

Introduction

Obesity is reaching epidemic proportions in the developed world.[1] In morbidly obese patients, conservative treatment (i.e. diet, lifestyle changes, and drugs) leads to sufficient weight loss with reduction of co-morbidities in <4%.[2] Only bariatric surgery leads to sustained weight loss and cure of co-morbidities in the majority of patients[2-7] and possibly to a reduction of mortality.[8,9] Bariatric surgery is a rapidly growing discipline, with an increasing number of interventions performed every year, in spite of lacking consensus on which operation is the best for which patient.[10]

The ideal therapy concept for all morbidly obese patients has not yet been found. The advantages of the less invasive, reversible gastric restrictive operations are contrasted by less weight loss and lower effect on co-morbidities when compared to malabsorptive procedures. On the other hand, more aggressive operations have more complications and severe side-effects. A sequential, staged-therapy concept, might be ideal: to begin with an effective less aggressive operation, and continue to a more invasive one if necessary. One might argue that a patient should obtain the most effective therapy at the beginning. However, there are patients who are satisfactorily treated with a less aggressive option alone, so that, otherwise, they would be overtreated.

At our institution, we have followed a two-stage-therapy concept for all morbidly obese patients:

first, laparoscopic adjustable gastric banding (LAGB, Lap-Band System®, Inamed/Allergan, Santa Barbara, CA), followed by the duodenal switch (DS) operation (sleeve gastrectomy with biliopancreatic diversion) in cases of failure. With this concept, we first offered an easy, laparoscopic, fully reversible, adjustable procedure with low morbidity to all morbidly obese patients. This step revealed patients who do not need more than this simple restriction; for patients who needed a second surgical intervention (DS), it reduced the perioperative risk by getting patients into a lower American Society of Anesthesiologists (ASA) class by initial weight loss with somewhat improved co-morbidities by the primary intervention.

The primary outcome measure of this study was success-rate as defined by BAROS score (bariatric analysis and reporting outcome system).[11] Additionally, early and late morbidity of all operations was analyzed.

Patients and Methods

Between December 1996 and May 2004, morbidly obese patients with BMI >40 kg/m^2 or >35 kg/m^2 with severe obesity-related co-morbidities, were treated following the two-stage-therapy concept with LAGB as the primary bariatric procedure, followed by DS in cases of failure. In this prospective study, 366 consecutive morbidly obese patients with a mean BMI of 44.3 (35-75) kg/m^2 were operated. Mean age was 41 (17-66) years, and 78% were females.

An interdisciplinary team evaluated surgical candidates with a nutritional and endocrinological investigation. Preoperative assessment included abdominal ultrasound, upper GI series and gastroscopy. The Lap-Band® was applied by the perigastric technique in 168 patients until June 2000, when we changed to the pars flaccida technique to decrease the number of slippages, first using the 9.75-cm Lap-Band® in 15 patients and thereafter using the 11-cm band for the rest of the patients.[12] In 25 patients with extensive adipose tissue around the stomach, the pars flaccida-to-perigastric technique was applied.[13] If preoperative abdominal ultrasound showed gallstones, a laparoscopic cholecystectomy was performed additionally. For thrombo-embolic prophylaxis, all patients received low molecular weight heparin in weight-adjusted dosage preoperatively and for 4 weeks postoperatively. An abdominal wall suspension hook helped maintain a pneumoperitoneum at 10 mmHg in an attempt to further reduce the risk of thrombosis, and since 2004 sequential lower-limb compression devices were additionally used. All patients received 36-hour perioperative antibiotic prophylaxis with a second-generation cephalosporin and, for 4 weeks, a proton pump inhibitor. Oral vitamin and mineral supplementation was instituted.

All patients were followed-up by the surgeon or the endocrinologist four times in the first year, twice yearly in the following 4 years, and once per year thereafter. If needed, the follow-up was intensified. Additionally, the patients were counseled by a dietician on a regular basis. The first band adjustment was done under radiological control 6 weeks after the operation, depending on weight loss and symptoms, by blind puncture of the reservoir or under radiological control thereafter.[14] Changes in body weight and gastro-esophageal function were controlled clinically, co-morbidities were also followed carefully, and medication, such as anti-diabetic and antihypertensive medication, was adjusted to meet need. Blood samples were taken regularly to detect any malnutrition early, such as hypoalbuminemia or vitamin deficiency. The primary outcome was repeatedly assessed by means of the BAROS score, including quality of life, amount of weight loss, reduction of co-morbidities, complications and re-operations.[11] We counted re-operations for port and tube revisions as minor complications (minus 0.2 points) and deducted 1 point for all obesity-associated re-operations, including all patients requiring DS, despite the fact that DS was part of the staged concept. Outcome groups were defined as follows: *failure* (1 point or less), *fair* (>1 to 3 points), *good* (>3 to 5 points), *very good* (>5 to 7 points) and *excellent* (>7 to 9 points).

According to our protocol, whenever a patient developed symptoms after primary intervention, such as food intolerance, reflux, or insufficient satiety, the correct position of the band was checked by contrast swallow. If a slippage was diagnosed, laparoscopic re-banding was attempted if the course had otherwise been uneventful and weight loss suf-

ficient. The old band was always removed and a new band applied in a higher position.

If the LAGB procedure was found to be insufficient with regard to weight loss (excess weight loss <40%) and/or patients suffered from band intolerance or esophageal motility disorder, the DS was recommended as a secondary intervention. DS was performed through an upper midline laparotomy, according to Marceau et al.[15] The Lap-Band® was removed. The duodenum was transected distal to the pylorus, and the duodenum distally was closed as a stump. An alimentary limb of 250 cm of ileum (in patients >50 years, 350 cm) was brought up in a retrocolic fashion and hand-sewn to the proximal duodenum. The bypassed, proximal small bowel (biliopancreatic limb) was anastomosed by hand end-to-side into the alimentary limb, creating a common channel of 100 cm. Additionally, prophylactic cholecystectomy and appendectomy were performed. Of all interventions, 94% were performed by the first author (RP) and the remainder by the fourth author (BK).

All data were prospectively collected using a standardized protocol and were continually updated in a computer database. The minimal follow-up time was 1 year, with a mean of 4.1 and maximum of 8.4 years. The follow-up rate was 100% in the first year and 98% at the time of publication (2 deaths not related to obesity, 5 lost to follow-up). Comparisons between nominal variables were made using chi-square tests. To compare groups within continuous variables, *t*-tests were performed. For all statistical tests, a *P*-value <0.05 was considered significant.

Results

Characteristics and Early Complications of Primary Lap-Band®

The prevalence of preoperative co-morbidities is shown in Figure 1. Laparoscopic cholecystectomy was performed in 59 patients (16%) at the time of the primary operation; 35 patients had had a cholecystectomy previously. The early complications in the 366 LAGB procedures was low (3.8%) (Table 1). There has been no mortality.

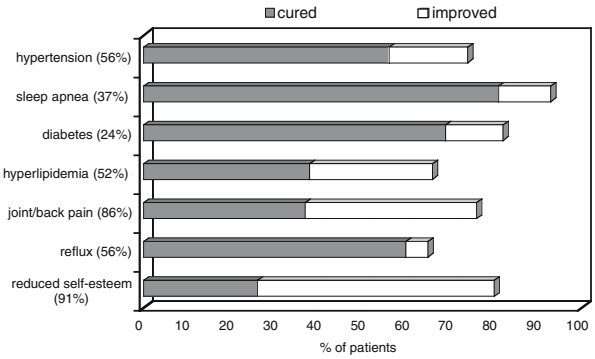

Figure 1. Reduction in co-morbidities of all patients (N = 366). Numbers in parenthesis = prevalence of each co-morbidity preoperatively.

Characteristics and Early Complications of Re-Operations

Thirty-nine patients needed laparoscopic re-banding due to slippage after a mean of 23 (3-67) months following the primary operation (Figure 2). One patient required revision of an abdominal wall hematoma 3 hours after the intervention. Thirty-one patients (8.4%) underwent uneventful revisions for port and/or tube-related problems (Table 2). Eleven patients desired laparoscopic band-removal without accepting another bariatric operation to be per-

Table 1. Early complications of the interventions

Complication	Primary Lap-Band® (n=366)	Lap re-banding (n=39)	DS (n=68)
Surgical			
conversion	1		
leak			2
wound problem (without infection)	2		1
dysphagia	5	1	1
hematoma		1*	
Non-surgical			
pulmonary embolism	4		3
pneumonia			2
psychological	3		
Total (%)	3.8	5	13.2

DS = sleeve gastrectomy with BPD (duodenal switch).
*requiring re-operation the same day.

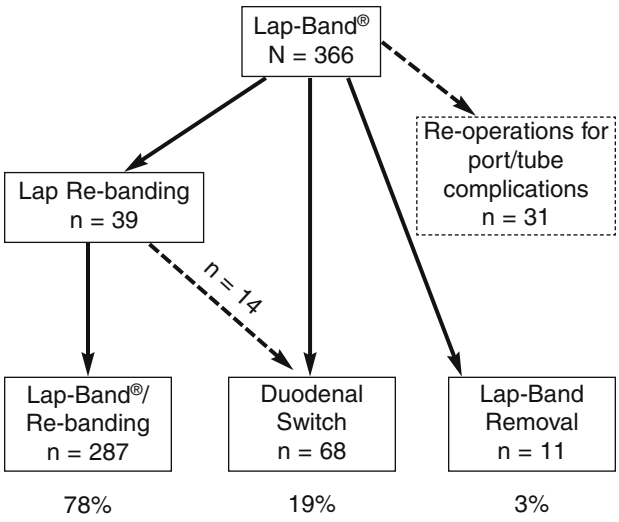

Figure 2. Diagram showing all operations performed.

Table 2. Long-term complications after laparoscopic gastric banding*

Complication	Primary Lap-Band® N=366	
	n	%
Band associated #		
slippage	45	12
concentric pouch	14	4
esophageal motility disorder	24	6.5
migration	1	0.2
Port/tube associated		
port dislocation	15	4.4
tube disconnection, leak	15	4
Hernia	0	
Gallstones	10	4†
Deficiencies (incidence per year):		
Vit. B_{12}		5
Vit. D		9
Folate		1.5
Fe		7
Zinc		21
Deaths	2	
reasons	car accident alcoholic liver cirrhosis	

* after a mean follow-up time of 4.1 (1-8.4) years.
# more than one possible per patient.
† of the 272 patients without history of cholecystectomy

formed, two after having lost sufficient weight, and the others due to slippage (n=1), band intolerance (n=5), psychological reasons (n=1), unclear abdominal pain (n=1) and, insufficient weight loss (n=1) after a mean of 20 (3-42) months. There was no early morbidity observed in these patients. DS was performed in 68 patients, on average 46 (14-92) months after primary LAGB. The indication for DS was one or more of the following: slippage (15%), band intolerance (60%), esophageal motility disorder (34%), and insufficient weight loss (20%). Fourteen patients had had previous re-banding 32 (5-82) months before DS. Early morbidity of open DS was 13%. There has been no mortality.

Outcome of all Patients (Intent to Treat)

At the last follow-up visit 4.1 (1- 8.4) years after primary LAGB, excess weight loss (EWL)[16] of all patients, including those with band removal and re-operations, was 44% (-25-115). The mean BAROS score was 4.14 (-2.5-8.75). An excellent result (BAROS >7 points) was found in 9 patients (2%), 109 (30%) had a very good result (BAROS >5 to 7 points), 141 (39%) a good result (BAROS >3 to 5 points), 76 (21%) a fair result (BAROS >1 to 3 points), and 31 (8%) were failures. Reduction in co-morbidities was observed in the majority of cases (Figure 1).

Outcome of Patients with Lap-Band® and Re-banding

At last follow-up, 287 of the original 366 treated patients (78%) still had their band, 25 of them after re-banding. Their mean EWL was 40% (-25-111) (Figure 3). The mean BAROS score was 4.1 (-2.5-8.75). An excellent result (BAROS >7 points) was found in 4 patients (1%), 87 (30%) had a very good result (BAROS >5 to 7 points), 117 (41%) a good result (BAROS >3 to 5 points), 59 (21%) a fair result (BAROS >1 to 3 points), and 20 (7%) were failures, not accepting another bariatric operation. Long-term complications are listed in Table 2. The deficiencies observed could be treated by intensified oral supplementation; parenteral therapy was seldom necessary. In a subgroup of 109 patients who had fulfilled a follow-up of 5 years, mean EWL after 5 years was 38% (-2-110), 31% of these patients had EWL >50%.

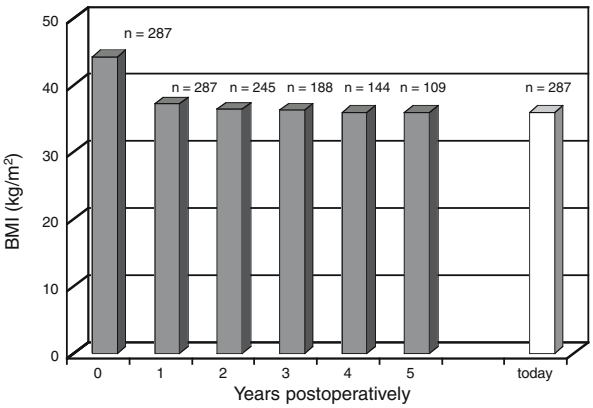

Figure 3. Weight loss of banded patients (Lap-Band® and re-bandings).

Outcome of Patients with DS

In the period between Lap-Band® and DS, most patients had already lost weight, on average 25% EWL (-35-105). In patients with a minimal follow-up of 6 months after DS (n=53), EWL was 82% (48-115) since the primary operation (Figure 4), and 87% of these patients had >50% EWL. The mean BAROS score was 4.7 (0-8.75). An excellent result (BAROS >7 points) was seen in 5 patients (9%), 18 (34%) had a very good result (BAROS >5 to 7 points), 20 (38%) a good result (BAROS >3 to 5 points), 7 (13%) a fair result (BAROS >1 to 3 points), and 3 (6%) were failures. The most frequent long-term surgical complication after DS was incisional hernia, with a prevalence of 16% (Table 3). To date, no restoration has been necessary, despite two patients needing hospitalization for severe protein malnutrition with re-education to correct eating habits. Oral substitution was successful in most of the patients with deficiencies, except for 30% of iron deficiency, 25% of vitamin B_{12}, and 30% of vitamin D, who required parenteral therapy. Patients who needed DS were younger than the others (38.8 ± 8.5 vs 41.7 ± 10.4 years, $P<0.047$), but no differences were found with regard to gender, initial BMI or eating disorder. Co-morbidities were more often cured after DS than after LAGB alone, i.e. hypertension (76% vs 52%, $P<0.0005$) or diabetes (75% vs 66%, n.s.).

Table 3. Long-term* complications after DS

Complication	DS n	N=68 %
incisional hernia	11	16
bowel obstruction	1	1.5
peptic ulcer	0	
arthralgia	2	3
kidney stones	2	3
deficiencies (incidence per year):		
Vit. B12		11
Vit. D		20
Folate		4
Fe		16
Zinc		30
Protein		
minor		8
severe†		1
deaths	0	

* after a mean follow-up of 4.1 (1-8.4) years.
† requiring hospitalization.

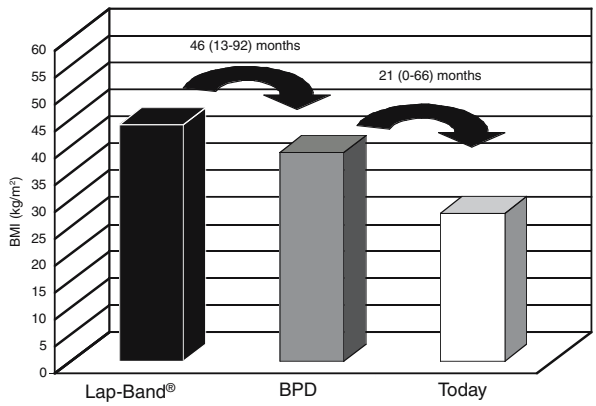

Figure 4. Weight loss prior to and after DS (n=68).

Discussion

In countering the increasing health threat of morbid obesity,[1] only bariatric surgery leads to a sustained weight loss and cure of co-morbidities in the majority of patients.[2-9] More bariatric operations have to be performed, more surgeons must be trained, and, therefore, the operations should be effective but not too difficult to perform. An ideal therapy concept has not been found thus far. LAGB appeared to be the ideal operation to perform first in all morbidly obese patients, because it is the least invasive bariatric procedure, with little morbidity, full reversibility, and adjustability at any time. In contrast to laparoscopic

proximal Roux-en-Y gastric bypass (RYGBP), LAGB seemed to have less morbidity and mortality and yet comparable results in terms of EWL.[7,17-20] For this reason, in 1996 we chose the Lap-Band® as the primary intervention in all morbidly obese patients, with DS as the second-stage operation in case of failure of the LAGB (Figure 2).

In our cohort of 366 consecutive patients treated according to this two-stage concept until May 2004, we observed low early morbidity after LAGB (3.8%). At 4.1 years after LAGB, EWL was 40%. In patients who completed 5-year follow-up (n=109), the mean EWL did not exceed 38%, unlike other series with EWL 5 years after LAGB of 50% and more.[7,17-19] Our selection criteria, perioperative management, and long-term follow-up did not differ from the Melbourne group,[7,17] but their success rate and EWL were not matched in our series.

More stringently selecting patients for LAGB could possibly improve our results. Other series described patients with binge-eating disorder or extensive intake of sweets, and higher age, to be predictors of poor outcome after LAGB.[21-24] Patients with an initial BMI >50 kg/m^2 cannot reach a BMI <30 kg/m^2 by 40% EWL, and patients with diabetes are probably better treated with a gastric bypass because, in addition to the weight loss itself, the changes in GI hormones may have a direct effect on glucose metabolism.[25] In our cohort, we found a non-significant increase in the cure of diabetes in patients after DS compared to Lap-Band® (75% vs 66%).

More than 4 years after primary gastric banding, 78% of the patients still had their bands and 71% of them had a good-to-excellent result according to BAROS. Twenty-two percent were not successfully treated with a band alone, 11 patients (3%) did not agree to another operation, and 68 patients (19%) received the malabsorptive procedure (DS). The morbidity of this open procedure was higher than that of LAGB but was not impaired by the fact that it was a re-operation,[26] where complications are usually substantially higher than that of a primary operation.[27] Patients already had 25% EWL at the time of DS with very few adhesions following Lap-Band®, possibly making the second operation safer. The EWL of 82% at 2 years after DS was very good, most of the patients attaining a BMI <30 kg/m^2. BAROS score (including quality of life) and successful cure of co-morbidity were better in DS patients than in the rest of the cohort.[28]

Where there was failure of LAGB and/or rebanding, patients underwent DS. Other authors have suggested RYGBP as the operation of choice after complications of gastric banding. If band intolerance, rather than insufficient weight loss, is the reason for failure, RYGBP seems to be the better choice because adding malabsorption could be an overtreatment in these cases.[19,29-31] In our series, patients after DS had comparably little long-term morbidity, except for a high rate of incisional hernias (16%), but no patient has had to undergo revision due to severe diarrhea or hypoalbuminemia to date.[15,32,33]

A two-stage concept – selecting patients for a malabsorptive operation on the basis of the fact that they had failed a restrictive operation – could be the approach of choice. The first operation, however, should be more successful than the Lap-Band® in patients in whom a poor result may be anticipated (binge-eating disorder, sweets-eater, very high BMI). In these patients, a laparoscopic sleeve gastrectomy may be the logical first-stage operation because it can be transformed into a DS or RYGBP where appropriate.[34-38]

At our institution, we subsequently have abandoned the two-stage concept with primary LAGB in all morbidly obese patients despite the fact that we observed many excellent results after the Lap-Band®, even in patients with risk factors for failure. The failure rate of LAGB as primary intervention in unselected patients was too high. Today, we perform laparoscopic RYGBP in patients with binge-eating disorder or long-duration diabetes, also considering other factors (BMI, sweets-eater, gender, age, and patient wish) in making the choice of primary operation. In patients in whom we expect a malabsorptive procedure to be necessary, we consider performing a laparoscopic sleeve gastrectomy as a first-stage procedure.

In cases of band complications (slippage, migration, band intolerance) and a successful course of the restriction, we perform laparoscopic RYGBP instead of rebanding. If the restriction has failed, we change to the DS.

In conclusion, we abandoned the two-stage concept with primary LAGB in all morbidly obese patients, followed by DS in case of failure. To increase the success rate of the primary intervention, either a tailored approach (to offer all bariatric procedures individually to the patients) or a better two-stage concept (with a more potent first stage operation, such as laparoscopic sleeve gastrectomy) seems necessary.

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