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High secondary failure rate of rebanding after failed gastric banding

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Abstract

Background Over the last decade, more than 130,000 laparoscopic adjustable gastric bandings (LAGB) have been performed for the treatment of morbid obesity. Nowadays, longer follow-up data are available in the literature and increasing numbers of late complications and treatment failures of gastric banding have been reported. The aim of the present study was the long-term evaluation of two different rescue operations after failed LAGB: conversion to laparoscopic Roux-en-Y bypass (LRYGB) versus laparoscopic gastric rebanding.

Methods Between January 1997 and November 2002, 74 consecutive patients underwent either laparoscopic gastric rebanding ($n = 44$) or LRYGB ($n = 30$) after failed LAGB. There were 14 men and 60 women, with a median age of 42 (23–60) years. The indication for reoperation was an increasing body mass index (BMI) and band-related complications such as pouch dilatation, band slippage, and penetration after LAGB. Rebandings were done by preference during the initial period of the study and LRYGB was the treatment of choice during the latter period. The success of the rescue operation was assessed by postoperative changes in the BMI, improvements of co-morbidities, and the need for further reoperations (secondary failure).

The median follow-up was 36 months (range, 24–60 months).

Results Patients who underwent LRYGB had a significantly better weight loss than patients with a rebanding operation (mean -6.1 versus $+1.5$ BMI points). In addition, the LRYGB patients showed a significantly better control of serum cholesterol during the long term follow-up (-0.6 versus $+0.1$ mmol/l). Almost half of the patients (45%) in the rebanding group needed a further operative revision, whereas only 20% underwent reoperation after rescue LRYGB. Thus, the secondary failure rate in the rebanding group was significantly higher compared to the bypass group ($p = 0.028$).

Conclusions The present long-term study confirms our previous finding that LRYGB is a better treatment than rebanding after failed laparoscopic gastric banding regarding weight loss and treatment of co-morbidities. During the long-term follow-up the reoperation rate due to secondary failure became significantly higher in the rebanding group. We therefore recommend that LRYGB should be preferred as rescue procedure after failed laparoscopic adjustable gastric banding.

Keywords Laparoscopic gastric bypass · Laparoscopic rebanding · Secondary failure · Bariatric surgery · Obesity · Clinical trial

M. K. Müller and N. Attigah contributed equally to this work
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Surgical therapy for morbid obesity is becoming more and more frequent in the United States and Europe. In the U.S., the number of bariatric operations between 1998 and 2002 increased by 450% (from 12,775 to 70,256 procedures per year), and for 2004, the American Society for Bariatric Surgery (ASBS) anticipated an annual number of approximately 140,000 bariatric procedures in the U.S. [14]. For

2006 more than 200,000 procedures were estimated [17]. One procedure often performed in Europe is laparoscopic adjustable gastric banding (LAGB). After the first such procedure in 1993, performed by Belachew et al. [1], and the modifications of the operative technique by Belachew and Zimmermann [2], more than 130,000 LAGB procedures have been performed worldwide.

Because of its minimal invasiveness, reversibility, and adjustability, LAGB was considered a breakthrough in bariatric surgery [2]. Many series have shown excellent weight loss with low long-term morbidity [6, 16, 24]. Nevertheless, reports of long-term failures and complications of LAGB have increased, since this procedure came to be used on a routine basis in the treatment of morbid obesity [8]. In some series complications like band erosion, band slippage, and esophageal dilatation are present in 15%–58% of all patients, requiring a reoperation [15, 20, 21].

The possibilities for treatment at reoperation are (1) removal of the banding with no further bariatric procedure, (2) rebanding or (3) conversion to another bariatric procedure, like the gastric bypass. Which of these procedures is best to treat the failure of LAGB remains controversial. Disappointing results with 6 of 9 patients regaining weight after rebanding were published in 2001 [22]. In a study published in 2003, we were able to demonstrate that LRYGB is superior to LAGB as rescue procedure in patients with a failed gastric banding [23]. The limitation of that report, however, was the relatively short follow-up of only 1 year. Therefore, we again analyzed the results after 3 years of follow-up with respect to weight loss and effect on co-morbidities. In this new analysis, we have placed particular emphasis on the secondary failure rate, which became evident after 3 years. To date no other study has presented data on secondary failure rates after laparoscopic rebanding.

Methods

Patient characteristics and Follow-up

Between January 1997 and November 2002, 74 consecutive patients underwent a rescue operation after failed LAGB and were included in this study. Of these, 30 patients underwent laparoscopic Roux-en-Y gastric bypass and 44 had laparoscopic rebanding. In the first period of the study (from January 1997 until June 2000), we preferentially performed laparoscopic rebanding procedures as rescue operations after failed gastric banding, when the band was initially successful. With continuing experience with laparoscopic gastric bypass, we progressively switched to this procedure after June 2000 as a rescue procedure after failed gastric banding. The rebanding procedure

was then performed only in cases when the patient refused to undergo a Roux-en-Y gastric bypass, most often because of its irreversibility. A motility disorder of the esophagus represented a contraindication for rebanding in the latter part of the study. For all patients, the median age at the initial gastric banding was 42 years (range, 23–60 years). The overall mean preoperative BMI was 46.1 kg/m² before primary bariatric surgery. There was a predominance of women, with a female to male ratio of almost 5 to 1 (60 women versus 14 men). The preoperative weight before primary gastric banding was comparable in the two groups (127.9 kg in the bypass group versus 124.7 kg in the rebanding group), as was the BMI (47.1 in the bypass group versus 45.4 kg/m² in the rebanding group; $p = 0.346$). The BMI before the rescue procedure, however, was significantly higher in the bypass group than in the rebanding group ($p = 0.001$; 41.9 kg/m² versus 35.9 kg/m²).

Outpatient clinic exams were performed on a regular 6 to 12 monthly basis, and data were prospectively collected in our bariatric database. The follow-up included a physical examination, laboratory tests, and assessment of nutritional status. The data collection was cross-validated by copies of all medical records, including the initial admission, radiological reports, the relevant x-rays, operative reports, and all outpatient follow-up and hospitalization documents. The median follow-up after the rescue procedure was 36 months (range, 24–60 months).

Indication for primary and rescue surgery

The indication for primary surgery in both groups was according to the federal regulations in Switzerland. Those criteria follow basically the recommendations of the American Society for Bariatric Surgery consensus conference held in 2005 [3]. These include minimum weight criteria for uncomplicated obesity (body mass index [BMI] ≥ 40 kg/m²) and complicated obesity (BMI ≥ 35 kg/m² with co-morbidities). The initial laparoscopic gastric banding was done by a perigastric technique.

Reoperations were performed in cases of band-related complications such as slippage, pouch dilatation, band penetration, and band leakage [12]. Another indication for reoperation was insufficient weight loss or regain of weight.

Operative technique

In the performance of a rescue operation, 5 trocars were placed and the stomach wall was entirely released from the band to restore the original anatomy. Next, the band was cut open and removed. If rebanding was performed, a calibration balloon was inserted. The balloon was filled with 25 ml of saline to guide the ideal position of the new

band and to create a proximal gastric pouch of optimal size. After dissection at the lesser curve and retrogastric tunneling, a new band (Bioenterics®) was placed around the proximal stomach in a perigastric technique. In case of dilated pouch the dissecting was done proximally to the previous band position. If only the anterior wall had slipped through, the band was repositioned and fixed with 4 to 6 gastro-gastric sutures to avoid gastric herniation through the band. The band reservoir was not filled until the fourth to sixth postoperative week [10].

The laparoscopic gastric bypass was performed as described by Wittgrove and Clark [25]. The stomach was transected, creating a pouch of 25 ml size. The jejunum was transected 50 cm distal of the duodenojejunal flexure. A stapled side-to-side jejunojejunostomy was created with a Roux limb length of 150 cm. The Roux limb was positioned in an antecolic direction, and the gastrojejunostomy was performed using a circular stapler (CEEA 25 mm, Tyco®, Mansfield, MA). All conversions to a gastric bypass could be done laparoscopically with no conversion to open surgery in this series. In the postoperative course all patients underwent a contrast study of the esophagus and stomach 1 day after rebanding and 3 days following a gastric bypass procedure. Resumption of oral diet was started in the absence of a leakage and if a prompt passage was documented by a gastrografen-swallow. Postoperatively, deep venous thrombosis prophylaxis with low molecular weight heparin was administered for 3 weeks, and prophylactic intake of proton inhibitors (omeprazole) was given for 6 weeks in both groups.

All procedures were performed by the same three surgeons. All of them are experienced bariatric surgeons performing between 100 and 150 bariatric operations a year.

End points

The focus of this study was on the outcome of the rescue procedure; therefore the weight parameters were compared first to the baseline set at the time of the rescue surgery. Because the BMI was different in both groups prior to the rescue procedure, the change of BMI was assessed at 12, 24, and 36 months. Additionally the course of the entire therapeutic concept, either laparoscopic banding followed by rebanding or laparoscopic banding followed by laparoscopic bypass was analyzed with regard to BMI and impact on co-morbidities. Total cholesterol, triglycerides, and HbA1c prior to the first bariatric surgery and 1 year after reoperation were assessed to monitor metabolic parameters.

Secondary failure was diagnosed when another operation was necessary because of failure of the rescue operation. The reasons for secondary failure were similar to the

indications for the rescue procedure and predominantly were weight regain and esophageal dysmotility, as well as slippage, pouch dilatation, band penetration, and band leakage (see Table 2).

Statistical analysis

All patient data were collected in a prospective database (Excel, Microsoft Corporation, Redmond, WA, USA), and data consistency checks were performed. In case of missing values or obvious entry mistakes, original patient files were again consulted to minimize incomplete data sets. The descriptive statistical analysis included the calculation of the mean and standard deviation (SD) unless otherwise stated. The means of continuous variables were compared by Student's *t*-test. Proportions were compared by Pearson's chi square or Fisher's exact test as appropriate. Statistical significance was assumed at $p < 0.05$. Data analysis was performed with SPSS 12.0.1 (SPSS Inc., Chicago IL, USA).

Results

Weight control

The mean changes in BMI were significantly different in the Roux-en-Y gastric bypass group and in the rebanding group at 12, 24, and 36 months after the rescue procedure ($p < 0.001$). Patients with a bypass procedure lost a mean of 6.1 BMI points after 3 years. In contrast, the patients receiving a rebanding increased their weight in mean by 1.5 BMI points in the observation period (Fig. 1).

For the entire therapeutic concept this resulted in a mean BMI of 35.2 kg/m² 3 years after rescue procedure in patients with banding followed by gastric bypass. In contrast, the mean BMI was 38.9 kg/m² in patients who had a banding followed by rebanding ($p = 0.035$).

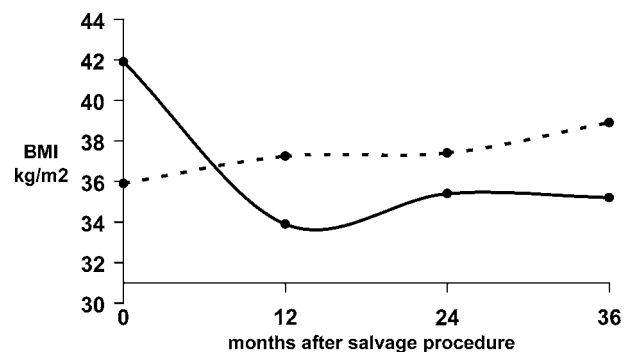


Fig. 1 Course of body mass index (BMI; kg/m²) after gastric rebanding (dotted line) and gastric bypass procedure (plain line) for failed gastric banding. After 36 months the BMI in the gastric bypass group was significantly lower than in the rebanding group ($p = 0.035$)

Table 1 Mean change in metabolic parameters

	Rebanding	Gastric bypass	<i>p</i> Value
Total cholesterol	+0.11 (0.90)	-0.60 (1.07)	0.015
Triglycerides	-1.11 (2.94)	-0.42 (1.02)	0.430
HbA1c	-0.37 (0.76)	-1.03 (1.25)	0.261

Change of total cholesterol, triglycerides, and HbA1c from first laparoscopic banding to 1 year after definitive bariatric treatment. Values for cholesterol and triglycerides are given in mmol/l and for HbA1c in percent (%). Results are expressed as means and standard deviation (SD).

Metabolic parameters

Both strategies were effective in managing triglyceride and HbA1c levels, which decreased significantly in both groups. In the bypass group triglycerides dropped from 2.1 to 1.65 mmol/l ($p < 0.001$), and HbA1c decreased from 6.4% to 5.4 % ($p < 0.001$). In the rebanding group triglycerides decreased from 1.8 to 1.23 mmol/l ($p < 0.001$) and HbA1c from 5.8% to 5.5 % ($p < 0.001$). Total cholesterol in the rebanding group was slightly increased (from 5.2 to 5.3 mmol; $p = 0.001$), whereas total cholesterol was significantly decreased in the bypass group (from 5.6 to 4.9 mmol; $p < 0.001$).

The mean changes in metabolic parameters are given in Table 1. There was a trend toward improvement in HbA1c levels and a significant improvement in cholesterol levels in the bypass group compared to the rebanding group.

Secondary failure

In those patients who underwent rebanding as rescue therapy for failed primary laparoscopic banding ($n = 44$), 20 patients (45%) experienced a secondary failure with need for revisional surgery (Table 2).

The secondary failure rate among patients who received a laparoscopic Roux-en-Y gastric bypass was significantly lower ($p = 0.028$), with only 6 patients (20%) undergoing a revision of their bypass procedure (Fig. 2).

In almost a quarter of the rebanding patients ($n = 9$), the banding failed because of slippage, penetration, infection, or leakage. Ten patients (25%) had insufficient weight loss after rebanding, and 6 of those patients developed esophageal dysmotility and a subsequent weight gain.

One patient decided to have the band removed because of persistent discomfort; she refused further bariatric interventions. One patient showed an acceptable weight loss with her second banding, but leakage of the port system developed, leading to a third laparoscopic gastric banding and continuous successful weight control. Of the 20 patients with secondary failure in the rebanding group, 18 received a laparoscopic Roux-en-Y gastric bypass as a third definitive treatment.

Table 2 Reason for secondary failure

	Rebanding ($n = 44$)	Gastric bypass ($n = 30$)
Slippage	4	–
Penetration	2	–
Infection	1	–
Leakage	2	–
Dissatisfaction	1	–
Insufficient weight loss	4	4
Esophageal dysmotility with consecutive weight regain	6	–
Small bowel obstruction	–	1
Pouch diverticula/blind loop syndrome	–	1
Total	$n = 20$	$n = 6$
<i>p</i> value	0.028	

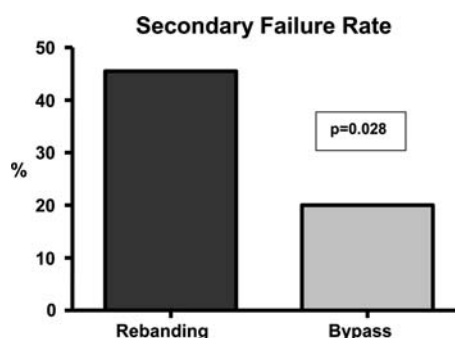


Fig. 2 Secondary failure rate after gastric rebanding (black column) and gastric bypass as a rescue procedure after failed gastric banding

The reasons for secondary failure in the bypass group are shown in Table 2. One out of 4 patients with insufficient weight loss was diagnosed with a pouch-gastric fistula, which was divided laparoscopically. The other three were treated with a conversion from a proximal to a distal bypass, and in two of those cases, this was done in combination with a resizing of the pouch [13]. One patient had a laparoscopic resection of the blind end of the jejunum at the end-to-side gastro-jejunostomy. This blind end had been left too long at the initial operation, causing discomfort, with halitosis and recurrent vomiting. After the resection these complaints disappeared. One patient underwent a laparotomy because of a small bowel obstruction due to an internal hernia. All other reoperations were done laparoscopically.

Discussion

The purpose of this single-center, nonrandomized follow-up study was the outcome evaluation of two rescue strat-

egies in patients with failed LAGB after a 3-year follow-up period. The two strategies consisted of laparoscopic rebanding or conversion to a laparoscopic Roux-en-Y gastric bypass (LRYGB), respectively.

In a previous study we demonstrated that both laparoscopic conversion to a Roux-en-Y gastric bypass and laparoscopic rebanding are feasible and safe procedures for a failed gastric banding. However, the gastric bypass showed considerably better results regarding weight loss 1 year after the rescue surgery [23]. Because a single year of follow-up is relatively short in bariatric surgery, we now present the results after 3 years of follow-up. They confirm that the mean change in BMI after 3 years remains significantly better in patients undergoing LRYGB as rescue operation compared to those who received rebanding after failed LAGB. Interestingly, after rebanding, patients on average increased their BMI. This is because some of them have been reoperated for band slippage, which had caused severe dysphagia leading to malnourishment and even dehydration. These patients often regained their weight to the level they had with a non-slipped band.

Most surprisingly, 20 of 44 patients (45%) in the rebanding group experienced a second failure when rebanding was performed as a rescue operation. As a consequence, 18 of these 20 patients later underwent a LRYGB as their third operation. The reasons for secondary failure in the rebanding group in almost 50% of the cases were device-related problems like slippage, penetration, and leakage. These results are consistent with recent data from other centers, which also report high rates of device-related problems in patients with a primary LAGB leading to a reoperation rate as high as 10%–58% [8, 9, 12].

In the gastric bypass group, the secondary failure rate was significantly lower. Six patients (20%) in the bypass group required reoperation, two as a result of late complications, i.e., a small bowel obstruction and a long blind end at the gastro-jejunostomy, even though weight loss was satisfactory. Only four patients underwent revision of the gastric bypass because of insufficient weight loss. In those patients, restriction was increased by a pouch downsizing and enhancement of the malabsorptive component by shortening the common channel.

Today, costs are an important issue when discussing surgical treatment strategies. It has been demonstrated that bariatric surgery is cost effective when compared to no treatment [7]. In our opinion, one important factor to reduce the costs of bariatric surgery is the correct selection of the initial procedure. It seems obvious that every rescue procedure adds to the cost of treating morbid obesity. This is also true for rescue bariatric surgery. Rescue gastric rebanding has a high secondary failure rate that requires reoperations and consequently increases costs.

The beneficial effect of bariatric surgery, as compared to conservative treatment of morbid obesity, on hyperlipidemia, diabetes, and blood pressure is well documented in the SOS study, which provides data over a period of 10 years [18]. There are studies investigating the effect of LRYGB on lipid metabolism, showing a beneficial effect on dyslipidemia. However, they only provide 1 or 2 years of follow-up [5, 26]. Even though we analyzed patients with failure of their first bariatric procedure, which might include a more difficult study population, those beneficial effects were largely reproducible in our study. Thus, we found significant improvement with regard to triglycerides, HbA1c, and total cholesterol 1 year after the rescue procedure. Interestingly, the decrease in metabolic changes comparing LRYGB and LAGB patients was only of statistical significance with regard to total cholesterol, favoring the LRYGB group. The levels of HbA1c showed a trend of improvement favoring the LRYGB group without reaching statistical significance. It seems obvious that a persistent control of metabolic risk factors like hyperlipidemia and HbA1c can only be achieved with a surgical strategy that provides the best long-term results in terms of weight loss.

Nonetheless there are still patients who profit from gastric rebanding. In our experience these are patients who had a technical failure involving leakage of the band system and who successfully lost weight with the banding. Patients with pre-existing eating behavior like sweet-eating are not good candidates for purely restrictive procedures [19]. Likewise, patients with binge eating disorder tend to have a worse outcome after primary banding [11] or need intensive additional psychological support to be successful [4]. We hypothesize that this is also true for the rebanding. Patients who developed esophageal dysmotility because of the banding [8] should also not have a rebanding. Thus we believe that patient selection is crucial for a successful rebanding procedure and that the course after the primary banding before failure is the main indicator for future success.

This study shows that LRYGB remains superior in terms of weight loss and reduction of metabolic risk factors in a 3-year follow-up compared to rebanding as a rescue procedure after failed LAGB. In addition, the secondary failure rate of 45% was significantly higher in patients receiving rebanding compared to those undergoing LRYGB. Based on our results, we recommend conversion to Roux en-Y gastric bypass after failed gastric banding.

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