



Banding the Pouch with a Non-adjustable Ring as Revisional Procedure in Patients with Insufficient Results After Roux-en-Y Gastric Bypass: Short-term Outcomes of a Multicenter Cohort Study

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Abstract

Background After laparoscopic Roux-en-Y gastric bypass (RYGB), approximately 10–35% of patients with morbid obesity regain weight after an initial good result or fail to achieve a sufficient amount of weight loss. Patients in which conservative measures are not successful may potentially benefit from revisional surgery.

Objective To evaluate the effect of a non-adjustable ring placed around the gastric pouch in patients with insufficient weight loss or weight regain after RYGB.

Setting Four specialized bariatric hospitals in The Netherlands, Germany, and Switzerland.

Methods From 2011 to 2017, 79 patients underwent revisional surgery using a non-adjustable silicone ring because of insufficient results after RYGB. Data on weight loss and complications up to 2 years after revisional surgery was collected and analyzed retrospectively.

Results A follow-up percentage of 86% after 1 year and 61% after 2 years was achieved. In 75% of patients, further weight regain was prevented. Percentage total body weight loss improved by 7 to 26% 1 year after revisional surgery and remained stable during 2 years of follow-up. The additional weight loss effect of placing a non-adjustable ring was more pronounced in patients with an initial good result after primary RYGB. Eighteen (23%) rings were removed, most often due to dysphagia.

Conclusion Especially for patients who experience weight regain after initial good weight loss, placing a non-adjustable silicone ring around the gastric pouch results in modest improvements in weight loss. To prevent the risk of ring removal due to dysphagia, surgeons should take notice not to place the ring too tight around the gastric pouch during revisional surgery.

Keywords Morbid obesity · Bariatric surgery · Roux-en-Y gastric bypass · Insufficient weight loss · Weight regain · Revisional surgery · Non-adjustable ring · Weight loss

Introduction

Since the introduction in 1966, the Roux-en-Y gastric bypass (RYGB) has proven itself in terms of weight loss and

remission of comorbidities in patients with morbid obesity [1, 2]. Unfortunately, 10–35% of patients regain weight after an initial good result or fail to achieve a sufficient amount of weight loss [3–5]. To get these patients back on track, additional counseling by a dietitian or a lifestyle coach is always the first line of treatment. The goals that patients with weight regain set themselves are often different from that of their healthcare providers and this often leads to disappointment on both sides. In patients in which conservative interventions do not improve results, revisional surgery can be taken into consideration after multidisciplinary evaluation. With the increasing number of revisional bariatric procedures performed, it is important to look further into the technical options and their outcomes.

Some revisional procedures, such as distalization of the gastric bypass, aim to induce hypoabsorption, whereas others

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aim at increasing restriction by adding an adjustable gastric band or resizing the pouch [6, 7]. Unfortunately, there is a paucity of high-quality studies on revisional surgery and results are often inconsistent in terms of weight loss and complication rates. Due to the lack of a standardized treatment protocol, revisional surgery after failed gastric bypass is mainly based on local experience. Therefore, there is a need for good clinical studies on this subject.

Another revisional option after insufficient weight loss or weight regain is banding of the gastric bypass [8]. This banded gastric bypass, using a non-adjustable ring (Fig. 1), is already performed as a primary procedure with promising results [9]. It is hypothesized that additional placement of a ring prevents long-term weight regain due to dilatation of the gastric pouch. Therefore, it can be postulated that placement of a ring as a revisional procedure could counteract weight regain and improve weight loss results in patients with a Roux-en-Y gastric bypass [10, 11]. In addition, the ring may delay food passage through the pouch, resulting in decreased food intake. As this revisional procedure is not frequently performed, a multicenter approach is necessary to collect reliable data. The aim of this study is to investigate the effect of a non-adjustable ring placed around the gastric pouch on weight loss in patients with insufficient weight loss or weight regain after RYGB 2 years after revisional surgery.

Methods

Patient Selection and Data Collection

All patients that underwent revisional surgery for either weight regain or insufficient weight loss after RYGB by means of a non-adjustable ring from 2011 to 2017 were included in this study. Patients that received a non-adjustable ring for dumping were not included in this study and are



Fig. 1 Non-adjustable silicone ring

analyzed in a different retrospective study. The participating hospitals were Rijnstate Hospital in Arnhem, the Netherlands (31 patients); St. Claraspital in Basel, Switzerland (33 patients); Helios Klinikum in Berlin, Germany (4 patients); and St. Franziskus-Hospital in Köln, Germany (11 patients). Patients were divided into two subgroups based on the maximum weight loss result after the initial RYGB. Poor responders (insufficient weight loss) were defined as patients that achieved a total body weight loss (TBWL) <25% and good responders (weight regain) as patients that achieved TBWL >25%. The protocol of this retrospective study was approved by the local research committees of all four participating centers and this study was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments. All patients' data were collected retrospectively from medical records or from a prospective database by an investigator in the participating center after informed consent was obtained.

Surgical Procedure and Postoperative Management

All included patients had a previous laparoscopic gastric bypass. All revisional procedures were performed laparoscopically. After introduction of the trocars and identification of the anatomic structures, adhesiolysis was performed. Approximately 2 cm proximal to the gastroenterostomy, a perigastric tunnel was created through the omental bursa, dorsal of the gastric pouch from medial to lateral. The non-adjustable silicone ring (Minimizer™, Bariatric Solutions, Stein am Rhein, Switzerland) was introduced into the abdomen, passed through this tunnel from the lateral side, and locked at one of the four closing positions enabling to close the ring at 6.5, 7.0, 7.5, or 8.0 cm circumference. Before locking, a 36-French or 40-French gastric bougie was inserted into the pouch. The soft needle at the tip of the ring was cut and removed. The ring was fixed using one or two non-absorbable sutures. Postoperatively, thrombosis prophylaxis was prescribed according to local protocols. All patients were advised to take optimized multivitamins designed for bariatric patients.

Outcomes and Statistical Analysis

The primary endpoint of this study was the percentage total body weight loss (%TBWL) 2 years after revisional surgery. The %TBWL was defined as weight loss in kilograms divided by total body weight measured before revisional surgery. To give an overview of the total body weight lost after bariatric surgery, the %TBWL was also calculated using the weight before initial RYGB. To enable comparison with other studies, percentage excess weight loss (%EWL) are also shown. Secondary endpoints included postoperative complications (general and ring-related) and band removal. Patients in whom

the ring was removed were excluded from the complete analysis to avoid potential skewness. Statistical analysis was performed with IBM® SPSS® (version 21.0 Windows). All values are presented as mean \pm standard deviation (SD), unless specified otherwise. Differences between the groups were analyzed by using Fisher's exact test for categorical data and Student's *t* tests for continuous variable. To adjust for baseline covariates, i.e., age, sex, preoperative body mass index (BMI), adjustable gastric band (AGB) in history, and preoperative type 2 diabetes (T2D), a linear regression analysis was performed to calculate the difference in weight loss between the two groups. Tests were two-tailed and a *p* value < 0.05 was considered statistically significant.

Results

Seventy-nine patients, divided in 24 (30%) poor responders and 55 (70%) good responders after RYGB, underwent revisional surgery through surgical placement of a non-adjustable ring. The mean time between the primary RYGB and the placement of the ring was 56 months. The good responder group had a significantly higher body mass index (BMI) before RYGB and, as expected, the poor responder group had a significantly higher BMI before revisional surgery. In the poor responder group, there were more patients who had an adjustable gastric band in their history. All baseline characteristics are presented in Table 1.

During follow-up, ten rings were removed during the first year of follow-up and an additional eight during the second year. In total, 24 patients were lost to follow-up despite persistent efforts. A follow-up percentage of 86% (59 patients) after 1 year and 61% (37 patients) after 2 years was achieved.

Weight Regain

The lowest weight and BMI obtained after the initial RYGB of the total group was 89.6 ± 18.8 kg and 31 ± 5 kg/m². Before revisional surgery, patients regained on average 14.6 kg resulting in a BMI of 36 ± 7 kg/m². After revisional surgery, further weight regain was prevented in 75% of patients during the 2-year of follow-up resulting in a BMI of 33 ± 6 kg/m². A limited mean regain of 2.3 kg was seen in patients in whom revisional surgery did not prevent further weight regain.

Weight Loss

An overview of the %TBWL over time, calculated with the weight prior to RYGB, is presented in Fig. 2. Approximately, one-third of patients reached a higher %TBWL 1 year after revisional surgery compared with the maximal %TBWL obtained after RYGB. One year after revisional surgery, %TBWL improved by 6% in the poor responder group and

8% in the good responder group resulting in a %TBWL of $14 \pm 12\%$ (weight 102 ± 21 kg, BMI 36 ± 6 kg/m²) and $34 \pm 11\%$ (weight 87 ± 17 kg, BMI 30 ± 4 kg/m²) respectively 1 year after revisional surgery. These results remained stable up until 2 years after placing the non-adjustable ring. Two years after revisional surgery, 13% of the patients in the poor responder group achieved a %TBWL $> 25\%$, compared with 91% in the good responder group.

One year after revisional surgery, a significant difference in %TBWL, calculated with the weight prior to revisional surgery, between the groups was found. After adjustment for age, sex, preoperative BMI, AGB in history, and preoperative T2D, the difference in %TBWL between the poor responder group and the good responder group was 6% ($p = 0.031$, $n = 52$) after 12 months and 5% ($p = 0.204$, $n = 37$) after 24 months in favor of the good responder group. In a subset analysis in which all the patients who had an AGB in the surgical history were removed from the analysis, the difference in %TBWL between the good responder group and the poor responder group reduced to 4.4% after 12 months ($p = 0.128$).

Complications

In total, 27 (34%) patients suffered from complaints or a complication in the first 2 years following revisional surgery (Table 2). The most common reason for readmission to the hospital was persistent dysphagia. Twenty-six (33%) patients underwent a reoperation. A total number of eighteen (23%) rings were removed after a mean follow-up of 9 months and five (6%) were adjusted to a larger circumference. The main reason for band removal or adjustment was dysphagia ($n = 22$). One ring was removed 1-day postoperative because of a perforation located just proximal to the ring. In one patient, treatment of a gastric ulcer at the gastroesophageal junction necessitated removal of the silicone ring. Two patients were reoperated because of complications unrelated to the ring. Of the first 10 non-adjustable rings placed in each center, 26% was removed. This percentage decreased to 17% when experience increased (> 20 procedures) (Fig. 3).

Discussion

Although gastric bypass surgery has been shown to induce long-term weight loss, a subset of patients fails to achieve a sufficient amount of weight or regains weight after an initial good result [3–5]. Many factors such as lifestyle, metabolic imbalance, and technical aspects following surgery may contribute to insufficient weight loss after RYGB [12]. Additional counseling by a dietitian and/or a lifestyle coach for weight loss treatment is preferred; however, a substantial number of patients may require revisional surgery to improve results. Patients with failed weight loss surgery pose a challenge for

Table 1 Baseline patients characteristics

	Total (n = 79)	Poor responders (n = 24)	Good responders (n = 55)	p value
Age, years	45 ± 11	46 ± 9	44 ± 12	0.580
Female (%)	68 (86)	21 (88)	47 (86)	1.000
AGB in history (%)	15 (19)	11 (46)	4 (7)	< 0.001
BMI, kg/m ²				
•Pre-RYGB	45 ± 7	43 ± 6	46 ± 8	0.032
•Minimal post RYGB	31 ± 6	35 ± 5	29 ± 5	< 0.001
•Pre-revisional surgery	36 ± 7	39 ± 6	34 ± 6	0.003
Months after RYGB	56 ± 36	49 ± 34	59 ± 36	0.267
Length alimentary limb, cm	142 ± 21	142 ± 23	143 ± 21	0.910
Length biliopancreatic limb, cm	60 ± 23	61 ± 25	60 ± 22	0.877
Circumference ring (%)				
•6.5 cm	20 (25)	6 (25)	14 (26)	
•7.0 cm	27 (34)	7 (29)	20 (36)	
•7.5 cm	18 (23)	4 (17)	14 (26)	0.409
•8.0 cm	5 (6)	3 (13)	2 (4)	
•Unknown	9 (11)	4 (17)	5 (9)	

± standard deviation, AGB adjustable gastric band, BMI body mass index, RYGB Roux-en-Y gastric bypass
Italic values indicate statistical significant outcomes ($p < 0.05$)

healthcare providers, especially when obesity-related comorbidities recur. Despite the growing number of patients, there is no consensus in the literature and a standardized treatment protocol is not available. The present study investigated the effect of placing a non-adjustable silicone ring around the pouch as a revisional procedure in patients with insufficient results after RYGB.

In the literature, only Dapri et al. described their results after placing a non-adjustable silicone ring after failed RYGB surgery in six patients [8]. An average percentage excess weight loss of 70% was achieved 1 year after revisional surgery. However, it must be mentioned that these six patients had an average preoperative BMI of 29.5 kg/m².

In our study reporting on 79 patients, it is demonstrated that placing a non-adjustable ring prevented further weight regain in 75% of patients and limited weight regain in the remaining patients. In addition, the %TBWL based on the weight before primary surgery improved by 7% to a total of 26 ± 15% 1 year after revisional surgery and remained stable until 2 years after the procedure. It can be debated if an overall 7% increase in TBWL corresponding with roughly 12 kg has enough clinical relevance [13]. However, more weight loss is associated with better clinical outcomes. Furthermore, it must be stressed that without revisional surgery, it is very likely that the trend of weight regain would have led to even worse results of the earlier RYGB, which now could be prevented. From a

Fig. 2 Total body weight loss after Roux-en-Y gastric bypass and revisional surgery. %TBWL percentage total body weight loss, RYGB Roux-en-Y gastric bypass

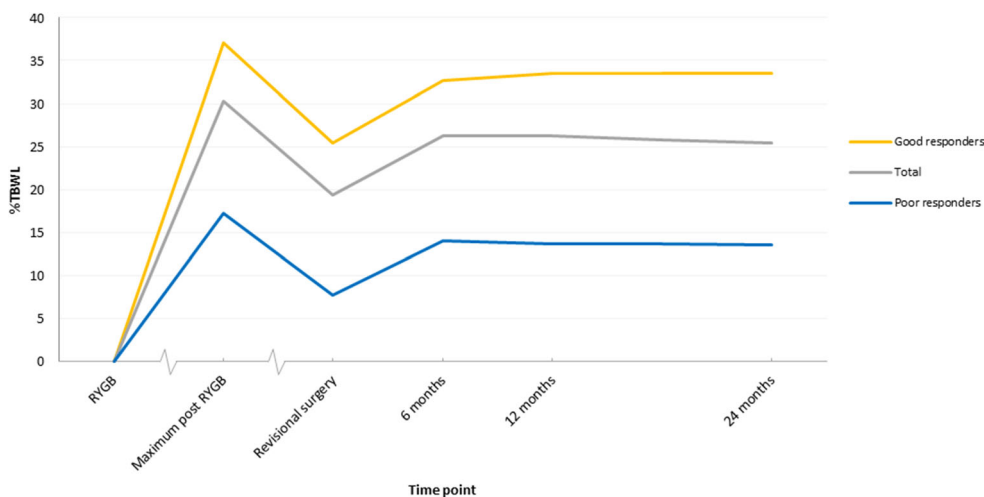


Table 2 Complications

	Total	Poor responders	Good responders	<i>p</i> value
Total number of patients (%)	27 (34)	6 (25)	21 (38)	0.309
Reoperation	26	5	21	
Ring removal	18	3	15	
Ring adjustment	5	-	5	
Internal herniation	1	1	-	
Hiatal hernia	1	-	1	
Cicatricial hernia	1	1	-	
Conservatively treated bleeding	1	1	-	
Stomach ulcer	1	-	1	

patient's perspective, weight regain is a significant physical and psychological burden that weighs heavily on self-image and quality of life. Any intervention that can help to turn around the progressive debilitating process of involuntary weight regain should be welcomed.

The additional weight loss effect of placing the non-adjustable ring was more pronounced in patients that had an initial good result after the RYGB compared with patients with insufficient weight loss after this procedure. This difference in %TBWL decreased when all the patients who had an AGB in the surgical history were removed from the analysis, probably because of a type II error due to a smaller study group. The additional weight loss effect of the ring in the poor responder group did not contribute to an amount of weight loss that is defined as clinically successful (%TBWL > 25%). Only 13% of the patients in the poor responder group achieved this amount of weight loss. However, when preventing weight regain is the goal, placement of the ring could also be considered in this specific group of patients. To obtain a %TBWL > 25% in patients with insufficient

weight loss after a RYGB, other surgical interventions (e.g., distalization) may be necessary. However, these procedures often require adjustments of bowel configuration to induce malabsorption hence posing these patients at a higher risk of postoperative complications [6].

Weight regain due to enlargement of the gastric pouch and dilatation of the gastric pouch outlet has often been described [9, 14]. Unfortunately, information about the aspect of the pouch during the revisional procedures in this study was not documented in detail in operative charts and therefore could not be taken into account. Results of this study do suggest that placement of a ring around the pouch counteracts these pouch-related problems causing weight regain. Although hard evidence is lacking, the non-adjustable ring could potentially prevent further weight regain by preventing further dilatation of the gastric pouch. Alternatively, restriction may play a role. But unlike the adjustable gastric band, the ring is not to be placed tightly around the pouch and therefore should not induce a primary restrictive effect. However, it could hamper the passage of a food bolus when eating large portions. Additional studies are needed to investigate these theories and are currently being performed at our institute.

Revisional surgery after RYGB is often associated with high perioperative morbidity [7]. Numerous studies on additional banding placement using adjustable and non-adjustable bands and rings are available, but it proves hard to draw definite conclusions from them [7, 15, 16]. It is suggested that a silicone non-adjustable ring leads to less adhesions and a lower complication rate [9]. This is confirmed in a study using a non-adjustable ring in 178 primarily operated patients in whom only 2.8% of the rings were removed and 3.4% were replaced due to a broken band during 5 years of follow-up [9]. The percentage of rings removed in our study (23%) is much higher and therefore of concern. This may suggest that placement of a non-adjustable ring is technically more demanding when performed as a secondary procedure. Compared with an adjustable band that is usually placed through the pars flaccida route, the perigastric placement of the non-adjustable ring is technically more challenging. Adhesion formation in the bursal sac induced by pouch formation during the gastric bypass

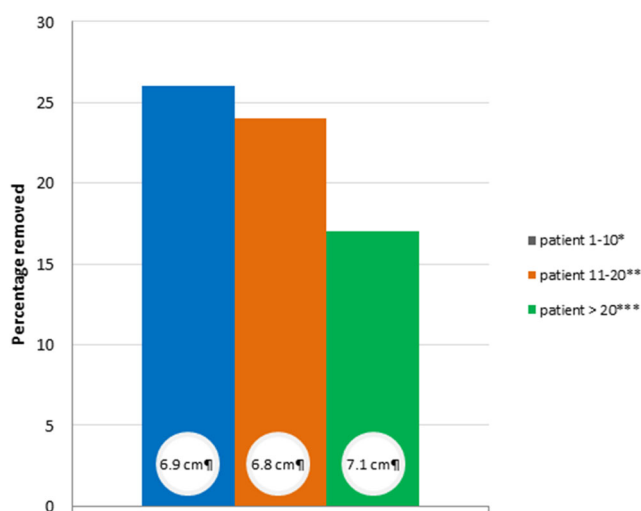


Fig. 3 Percentage non-adjustable rings removed during 2-year follow-up. A single asterisk indicates 4 centers, double asterisks indicate 3 centers, triple asterisks indicate 2 centers, and a pilcrow sign indicates mean circumference of removed rings

can make tunneling behind the pouch more difficult at the time of revision. After analyzing the results in this study, it was shown that most of the rings in this study that had to be removed were placed in the start-up phase. Furthermore, most removed rings were constructed with a relatively small diameter. This suggests a significant learning curve effect in the first procedures per center. With increased experience and use of a larger circumference, the number of removed rings decreased. Therefore, surgeons considering the use of a non-adjustable ring during gastric bypass surgery should keep in mind not to close the ring too tight. As advised by the manufacturer, a 40-French tube inside the pouch and an additional 5-mm instrument should easily pass between the pouch and the ring when closed. In addition, the ring should be placed perpendicularly in regard to the axis of the pouch to prevent tilting and sliding over the gastrojejunostomy.

Postoperative dysphagia associated with placement of a ring around the pouch is a matter of concern. Although the non-adjustable ring should not be placed tightly around the pouch, some patients have complaints of dysphagia which resulted in removal or adjustment in 22 patients in this study. In theory, the number of patients experiencing some degree of dysphagia may be even higher, but many patients consider this a desired consequence of the procedure and therefore will not report these complaints. These patients adapt their eating pattern which results in less complaints and often a good result in terms of weight loss [9]. However, when considering dietary intake and risk of nutritional deficiencies, these eating patterns may be insufficient and therefore should be monitored carefully. In future studies, dysphagia and eating behavior and the effect on quality of life should be taken into account.

We acknowledge that this study has several limitations due to its retrospective design and important factors such as reduction of comorbidities and quality of life were not taken into account. Ring removal and loss to follow-up resulted in a reduced number of patients available for analysis. It is unclear how patients who dropped out performed at 24 months, but from our historical experience with adjustable banding, it must be feared that results in that group could be disappointing. Furthermore, by creating two groups based on the %TBWL achieved after the primary RYGB, it is possible that baseline differences may have affected overall outcome. Despite these limitations, this study is to our knowledge, the first multicenter study reporting on non-adjustable ring placement as a revisional procedure in a relatively high number of patients. Since there is no clear treatment algorithm for the management of patients with insufficient weight loss or weight regain after RYGB, this study could be the first step in creating an evidence-based treatment protocol for this specific group.

Conclusion

Patients who fail to counteract weight regain or insufficient weight loss following gastric bypass surgery with conservative measures could be considered candidates for revisional surgery. Placement of a non-adjustable ring around the gastric pouch is a technically feasible revisional bariatric procedure. Especially in patients who suffer from weight regain after initial good weight loss, modest improvements in weight loss were shown at midterm follow-up. Placement of the ring around the gastric pouch should not be too tight in order to prevent the high number of patients with postoperative dysphagia in whom ring removal was necessary.

Compliance with ethical standards

The protocol of this retrospective study was approved by the local research committees of all four participating centers and this study was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments. All patients' data were collected retrospectively from medical records or from a prospective database by an investigator in the participating center after informed consent was obtained.

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