



Laparoscopic Adjustable Gastric Banding with the Adhesix® Bioring® for Weight Regain or Insufficient Weight Loss After a Roux-en-Y Gastric Bypass: Midterm Data from the *Pronto* Registry

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Abstract

Purpose Although Roux-en-Y gastric bypass (RYGB) is one of the most common bariatric procedures, insufficient weight loss is described to be as high as 20–35%. To treat weight regain/inadequate weight loss, laparoscopic adjustable gastric banding (LAGB) could be a feasible revisional strategy.

Materials and Methods We report on a prospective study which included 35 patients who presented inadequate weight loss or significant weight regain after primary RYGB (percentage excess weight loss [%EWL] at revision < 50%). All patients underwent revisional LAGB with the placement of an Adhesix® Bioring® adjustable gastric band (Cousin Biotech, Wervicq-Sud, France). Patients' weight loss, complications, frequency of revisions and quality of life were evaluated.

Results Follow-up data at 24 months are available for 80% of the included patients. The mean BMI before RYGB was 43.6 ± 5.4 kg/m² and before revisional LAGB was 38.8 ± 4.3 kg/m². The %EWL before revisional surgery was $23.3 \pm 24.8\%$. The average time between both procedures was 6.7 (mean) ± 3.6 (SD) years. Twenty-four months after revisional LAGB, the average BMI calculated from the weight at RYGB dropped to 32.0 ± 4.5 kg/m², with an additional %EWL of $49.9 \pm 30.3\%$ resulting in a total %EWL of $60.7 \pm 28\%$. The reoperation rate for complications related to LAGB was 21.2%. No band erosions occurred, but two bands needed to be removed during the study.

Conclusion Revisional LAGB may be considered a valid salvage procedure in patients with weight regain or inadequate weight loss after RYGB, though band- and port-related complications remain a notable concern.

Keywords Severe obesity · Bariatric surgery · Weight regain or ineffective weight loss after gastric bypass · Laparoscopic adjustable gastric banding · Revision surgery · Excess weight loss

Key Points

- An additional %EWL of 49.9% 24 months after LAGB placement is observed.
- Weight regain/inadequate weight loss after RYGB can be treated by revisional LAGB.
- An acceptable short-term complication rate of 21.2% is found.
- Quality of life increased significantly 24 months after LAGB.

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Introduction

Severe obesity is a chronic disease associated with major comorbidities, a reduced quality of life and a reduced life expectancy. The health benefits of bariatric surgery are well established, including long-term weight control [1, 2], resulting in the improvement of obesity-related co-morbidities, such as diabetes, hypertension, sleep apnoea and hyperlipidaemia, thereby ameliorating the patient's quality of life and long-term survival [3–5]. Bariatric surgery is increasingly performed worldwide due to the obesity pandemic and its proven effectiveness in terms of sustained weight loss and improvement on associated co-morbid diseases. Recently surpassed by the sleeve gastrectomy, the RYGB was for many years the gold standard and the most frequently performed procedure throughout all continents [6]. A percentage excess weight loss (%EWL) of 50–70% within 2 years is expected after RYGB surgery [7–9]. Unfortunately, 20 to 35% fail to achieve an adequate weight loss 10 years after the procedure [10–12]. This can be due to anatomic causes like dilatation of the gastric pouch, enlargement of the gastrojejunal anastomosis or, rarely, fistula formation between the gastric pouch and the bypassed stomach. Additionally, physiological changes and adaptation can cause a gradual decrease in the presumed malabsorptive and hormonal working mechanisms of the bypass. However, a major contributor to weight regain after RYGB, as for all bariatric procedures, is the patient's non-compliance resulting in the recurrence of an unhealthy lifestyle. Therefore, in the absence of any anatomical deformity such as a very large gastric pouch or a gastrogastroic fistula, all energy should be focused on improving the compliance of the patient by behaviour modification, dietary changes and exercise promotion. In adjunction to compliance enhancement, some promising results have recently been reported on a medical treatment with GLP-1 (glucagon-like peptide-1) receptor agonists in selected patients with unsuccessful weight loss after RYGB [13, 14]. Only if patients do comply, a surgical treatment, although challenging, can be offered. There is no standardised surgical strategy to cope with inadequate weight loss or weight regain after RYGB. The choice of operation is patient- and, in daily practice, mainly surgeon-dependent. Potential surgical treatment modalities are either malabsorption enhancing procedures, such as conversion to distal RYGB (DRYGB), duodenal switch (DS) or single anastomosis duodenal-ileal bypass with sleeve gastrectomy (SADI-S), or more restriction- or satiety-inducing procedures. Herein, a wide range of procedures are reported as a variety of endoluminal and laparoscopic techniques to downsize the gastric pouch and/or the gastroenterostomy, the construction of a new gastrojejunostomy and the placement of a non-adjustable or adjustable gastric band around the pouch [15–17]. The placement of a LAGB is a purely restrictive procedure that compartmentalises the gastric pouch by positioning an

inflatable prosthetic band proximal to the gastrojejunostomy. Although the popularity of primary band placement has dropped dramatically, as a revisional procedure, LAGB placement has some attractive potential. It is a reversible, adjustable and technically feasible option requiring minimal dissection and avoiding transection or anastomosis of gastro-intestinal structures. It reduces hunger and increases satiety: the main problems faced by many patients who are confronted with weight regain after RYGB [18].

We present the 24 months follow-up data of 35 patients that underwent revisional LAGB with the Adhesix® Bioring® adjustable gastric band (Cousin Biotech, Wervicq-Sud, France) after failed RYGB.

Materials and Methods

Study Design

The current Pronto registry was a monocenter, prospective, single-arm, investigational device registry of patients undergoing revisional LAGB after weight regain or inadequate weight loss following RYGB, defined by Christou et al. as a %EWL lower than 50% in patients post-RYGB surgery [10]. Enrolment started on July 2015 and the last follow-up was registered in December 2019. Patients with a life expectancy of less than 2 years and patients who were expected not to be compliant with the proposed follow-up visits were excluded from this registry. Only patients who were positively evaluated after a 3-month compliance enhancement period were considered eligible for a revisional procedure. This compliance improvement period is led and permanently evaluated by a nutritionist specialised in dietary modification for non-responders after primary bariatric procedures. A combined psychologist/nutritionist approach was opted for if deemed mandatory. The final decision to offer a revisional bariatric procedure and which type of procedure is made multidisciplinary, including the nutritionist, the psychologist, the endocrinologist and the team of bariatric surgeons. The choice of the revisional procedure is guided by a treatment algorithm we developed for unsuccessful weight loss after a RYGB and is thoroughly discussed with the patient. Patients who were scheduled to receive the Adhesix® Bioring® adjustable gastric band (Cousin Biotech, Wervicq-Sud, France) underwent standard follow-ups with the surgeon and the nutritionist 6 weeks, 3 months, 6 months, 1 year and 2 years after the operation. Additional visits were feasible or possible according to a problem and/or band (un)filling. The weight evaluation for this registry was performed at 6, 12 and 24 months after LAGB procedure. The trial protocol was approved by the Ethics Committee of AZ Sint-Jan Brugge-Oostende AV. All patients provided written informed consent. This trial was registered on clinicaltrials.gov (NCT02528565). The

primary objective was to investigate the efficacy of the revisional LAGB procedure. The patient's weight profile was described as BMI, percentage excess weight loss (%EWL) and percentage total weight loss (%TWL). The BMI was calculated as the weight divided by the square of the patient's height (in metres). The %EWL was defined as the baseline weight minus the follow-up weight, divided by the excess weight and multiplied by 100. The %TWL was defined as the baseline weight minus the follow-up weight, divided by the baseline weight and multiplied by 100. Secondary objectives of this trial included assessments of the safety profile (peri-operative, early and late complications), the mortality rate, quality of life (Moorehead-Ardelt Quality of Life Questionnaire II (MA II)) and the frequency of revisions after LAGB. The MA II questionnaire is an obesity-specific instrument to measure post-operative outcomes of self-perceived quality of life [19]. Six domains were scored: self-esteem, physical well-being, social relationships, work, sexuality and eating behaviour. Each domain was evaluated on a 10-point scale and scored from −0.5 to +0.5. The total score per patient was calculated, ranging from −3 to +3, and 5 outcome groups were defined: very poor (−3 to −2.1), poor (−2 to −1.1), fair (−1 to 1), good (1.1 to 2) and very good (2.1 to 3). Good and very good outcomes were considered satisfactory.

Surgical Procedure

The standard LAGB procedure was followed as much as possible. Adhesions of the omentum and/or the Roux limb are carefully dissected from the anterior abdominal wall and the caudal part of the left lobe of the liver. If a hiatal hernia was identified, it was repaired primarily. The pars flaccid technique is used as the primary dissection pathway (Figure 1A). In seven patients, an additional resection procedure was performed (pouch resizing in 5, gastrojejunal sleeve in 1 and a candy cane resection in another one). With a laparoscopic

clamp, the tip of the band is grasped and passed through the retro-gastric plane (Figure 1B), and the band is closed around the pouch. In all circumstances, the band could be placed in an appropriate position above the gastrojejunal anastomosis and under the gastroesophageal junction. The band is subsequently fixed by placement of non-absorbable sutures (Ethibond 2:0), both cranially and caudally, attaching the remnant stomach to the pouch (Figure 1C and D). Over the course of the study, we changed our surgical technique in exteriorising the gastric tube. Via the left lateral trocar opening, we create a tunnel behind the peritoneum (Figure 1E). Once at the level of the band, we perforate the peritoneum, catch the tip of the tube and guide it extra-peritoneal (Figure 1F). This technique was also described by Lecot et al. [20]. The tube is fixed to the port which is positioned in the left mid-axillary trocar site.

Statistics

Continuous variables are presented as mean \pm standard deviation (SD) and range. Categorical variables are presented as counts and percentages. MA II outcome groups (satisfactory vs non-satisfactory) were compared using the McNemar Chi-square test. The Bonferroni adjustment was used for multiple testing correction (p value $\leq \alpha/n = 0.025$). All analyses were performed in R version 3.6.0. (R Core Team, 2019).

Results

A total of 35 eligible patients (29 women and 6 men) underwent LAGB after RYGB with weight regain or inadequate weight loss. The patient's descriptive characteristics are listed in Table 1. Patients reported 50 co-morbidities at the time of revisional LAGB (hypertension in 4, diabetes mellitus in 2, hyperlipidaemia in 6, sleep apnoea in 3, gastroesophageal reflux disease in 5, osteoarthritis in 16 and depression in 14).

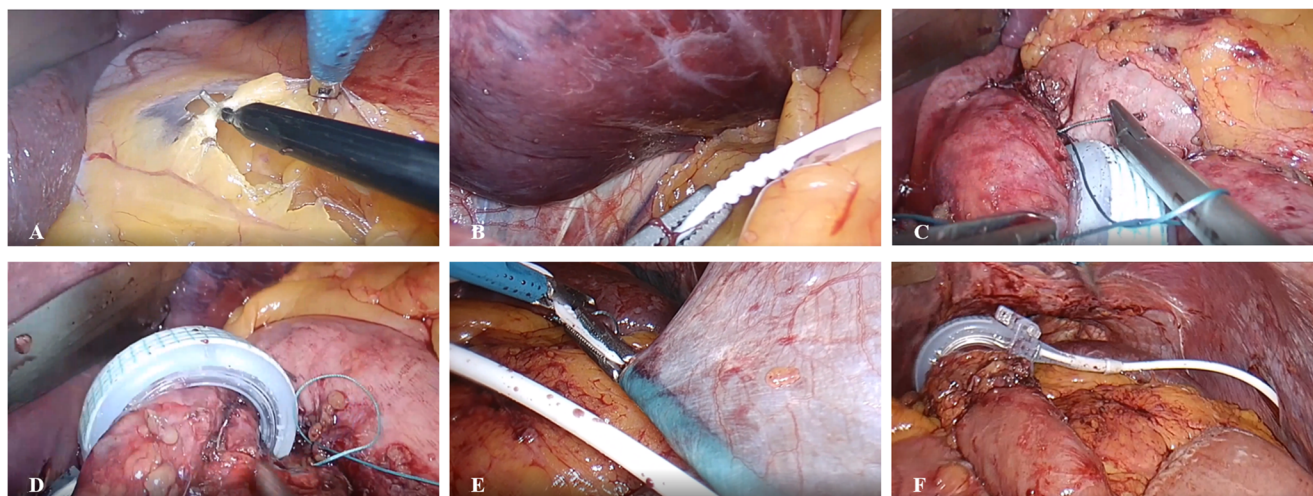


Figure 1 Surgical procedure

Table 1 Descriptive characteristics of all patients at the time of revisional LAGB

| Characteristics (n=35) | Value |
|--|---------------------------|
| Age (years) | 38 ± 9 (23–56) |
| Sex ratio (male:female) | 6:29 |
| Current smoker | 9/35 (25.7%) |
| Non-smoker | 23/35 (65.7%) |
| Ex-smoker (>6 months) | 3/35 (8.6%) |
| Co-morbidities | |
| Hypertension | 4/35 (11.4%) |
| Diabetes | 2/35 (5.7%) |
| Hyperlipidaemia | 6/35 (17.1%) |
| Sleep apnoea | 3/35 (8.6%) |
| Gastroesophageal reflux disease | 5/35 (14.3%) |
| Osteoarthritis | 16/35 (45.7%) |
| Depression | 14/35 (40.0%) |
| Weight profile | |
| Weight at primary surgery (kg) | 124.5 ± 20.8 (93.0–176.0) |
| BMI at primary surgery (kg/m ²) | 43.6 ± 5.4 (33.3–59.2) |
| Excess weight at primary surgery (kg) | 53.1 ± 17.1 (23.3–99.9) |
| Lowest weight since primary surgery (kg) | 82.5 ± 17.3 (52.0–126.0) |
| %EWL from primary surgery | 23.3 ± 24.8 (-35.2–49.0) |
| Inadequate weight loss (less than 50% EWL after primary surgery) | 7/35 (20%) |
| Weight regain after primary surgery | 28/35 (80%) |
| Weight at revisional surgery (kg) | 110.7 ± 16.9 (82.0–148.2) |
| BMI at revisional surgery (kg/m ²) | 38.8 ± 4.3 (29.4–48.1) |
| Excess weight at revisional surgery (kg) | 39.3 ± 13.1 (12.3–69.2) |
| Average time between RYGB and LAGB (years) | 6.7 ± 3.6 (1.8–18.1) |

n number of patients, *BMI* body mass index, *EWL* excess weight loss, *RYGB* Roux-en-Y gastric bypass, *LAGB* laparoscopic adjustable gastric banding

Patients waited an average 6.7 ± 3.6 years before LAGB revision with a mean age of 38 ± 9 years at the time of revisional surgery (Table 1). All LAGB procedures were performed laparoscopically without conversion to open surgery (Table 2). Revisional banding occurred in 24 patients (68.6%) with the medium-sized (2.8 cm diameter) Adhesix® Bioring® adjustable gastric band (Cousin Biotech, Wervicq-Sud, France). Nine patients (25.7 %) received a small size (2.3 cm diameter) and 2 patients (5.7%) an XL size (3.7 cm diameter). The band was peri-operatively filled in 9 patients (25.7%) with an average volume of 3.3 ± 0.9 cc. Additional procedures were performed in 9 patients (25.7%), including the aforementioned pouch resizing (5 patients), blind loop resection (1 patient) and complete gastrojejunal correction (1 patient), and 2 non-bariatric related procedures. The mean operating time was 80 min. Most patients (91.4%) had a length of stay of 1 day (Table 2). One intra-operative complication occurred (2.9%), namely a remnant stomach perforation during dissection, which was immediately sutured.

Of the 35 eligible patients recruited for revisional LAGB treatment, 2 patients were lost to follow-up immediately after the index procedure. At 6, 12 and 24 months, 8, 4 and 3

patients, respectively, had missing/invalid follow-up data. In the time leap between the 12- and 24- month follow-up, 2 bands had been removed. Those 2 patients were excluded

Table 2 Procedural characteristics of the revisional LAGB

| Characteristics (n=35) | Value |
|-----------------------------------|---------------------|
| Bioring | |
| Diameter 2.3 cm (S) | 9/35 (25.7%) |
| Diameter 2.8 cm (M) | 24/35 (68.6%) |
| Diameter 3.7 cm (XL) | 2/35 (5.7%) |
| Normal port location | 35/35 (100%) |
| Band filling performed | 9/35 (25.7%) |
| Average volume (cc) | 3.3 ± 0.9 (2.0–5.0) |
| Additional procedures | 9/35 (25.7%) |
| Pouch resizing | 5/9 (55.6%) |
| Blind loop resection | 1/9 (11.1%) |
| Complete gastrojejunal correction | 1/9 (11.1%) |
| Other | 2/9 (22.2%) |
| Conversion rate | 0/35 (0.0%) |
| Operating time (min) | 80 ± 29 (25–146) |
| Period of hospitalisation (days) | 1.1 ± 0.3 (1.0–2.0) |

LAGB laparoscopic adjustable gastric banding, *n* number of patients

from the weight analysis at the 24-month follow-up, leaving 25, 29 and 28 patients available for weight assessment at 6, 12 and 24 months, respectively.

At the time of RYGB, the patients had a mean weight of 124.5 ± 20.8 kg and a BMI of 43.6 ± 5.4 kg/m². Seven patients (20.0%) showed inadequate weight loss, unable to reach 50% EWL post-RYGB surgery (Table 1). The remaining patients experienced weight regain over time. At revisional LAGB, the patients had a mean weight of 110.7 ± 16.9 kg and a BMI of 38.8 ± 4.3 kg/m², and the remaining average %EWL was 23.3 ± 24.8 % (Tables 1 and 3). At the 24-month follow-up, the BMI decreased to 32.0 ± 4.5 kg/m², the additional %EWL was 49.9 ± 30.3 %, and a %TWL of 17.4 ± 11.3 % was achieved (Table 3, Figure 2A). Relative to the weight at primary RYGB surgery, the %TWL and %EWL were 26.0 ± 13.1 % and 60.7 ± 28.0 %, respectively, at 24 months (Table 3, Figure 2A). Although the group of patients was too small to draw adequate conclusions, results were seemingly better in the group of patients with weight regain after gastric bypass compared to the patients with inadequate weight loss after primary surgery (Figure 2B). Pouch resizing, gastrojejunum sleeve gastrectomy and blind loop resection were performed in, respectively, 5, 1 and 1 patients. Although a substantial additional weight loss could be attributed to that resizing, further analysis of this subgroup did not confirm this. No significant difference on changes in weight was found when both groups were compared using generalised linear mixed-effects model (LME) ($p=0.419$). Weight evolution of the individual patients is displayed in Figure 3. A potential bias that could not be ruled out is the weight loss resulting from individual compliance enhancement during the follow-up after LAGB placement.

Thirty-one (93.9%) patients came to the hospital on additional visits, outside of scheduled follow-ups (22/31 for band filling/unfilling, 5/31 for an additional regular appointment, 4/

31 because of medical or surgical complications). A mean number of 4.4 ± 3.4 additional visits per patient occurred. During the course of the study, the mean number of band fillings per patient was 2.2 ± 2.2 (ranging from 0 to 7) with a mean volume of 1.6 ± 0.5 cc (ranging from 1 to 3 cc). Band unfilling occurred at an average of 0.5 ± 1.2 times per patient (ranging from 0 to 6) with a mean volume of 1.3 ± 0.7 (ranging from 0.3 to 2.3).

A total of 7 complications occurred (21.2%). Two patients experienced band slippage resulting in surgery to reposition the band. Two port infections occurred, resulting in surgical removal of the port in both. In one of those, the tube was also shortened. Two patients experienced internal herniation through the window of a (too) long intra-abdominal route of the tubing. Both were surgically treated, necessitating band removal in one of them. Based on that experience, we changed our technique, as described above, and are favouring an extra-peritoneal route of the tubing. A second band was removed at the patient's request because of band intolerance (pain, vomiting, dysphagia). None of the patients deceased during the study.

Prior to revisional LAGB and at 12- and 24-month post-procedures, 35, 25 and 27 patients, respectively, were available for assessment of quality of life. The percentage of patients having a satisfying (good/very good) outcome increased from 28.6 to 56.0% after 12 months ($p=0.007$) and 51.9% at the 24-month ($p=0.011$) follow-up compared to pre-operation (Supplementary Table 1, Figure 4).

Discussion

With the increasing prevalence of severe obesity worldwide, bariatric surgery is performed more frequently, and, consequently, the number of patients requiring revisional surgery

Table 3 Weight change from primary RYGB to 24 months after revisional LAGB

| | n | Weight, kg | BMI, kg/m ² | %TWL from weight at LAGB | %TWL from weight at RYGB | %EWL from weight at LAGB | %EWL from weight at RYGB |
|--------------------|----|----------------------------------|-------------------------------|-------------------------------|---------------------------------|--------------------------------|---------------------------------|
| At primary RYGB | 35 | 124.5 ± 20.8 (93.0–176.0) | 43.6 ± 5.4 (33.3–59.2) | - | - | - | - |
| At revisional LAGB | 35 | 110.7 ± 16.9 (82.0–148.2) | 38.8 ± 4.3 (29.4–48.1) | - | 10.4 ± 10.4 (-14.3–27.1) | - | 23.3 ± 24.8 (-35.2–49.0) |
| At follow-up | | | | | | | |
| 6 months | 25 | 99.1 ± 19.0 (73.6–132.0) | 34.5 ± 4.4 (26.4–44.1) | 11.4 ± 6.9 (-2.3–30.7) | 20.6 ± 10.8 (-9.2–37.5) | 33.5 ± 20.9 (-7.6–80.8) | 48.0 ± 26.4 (-34.8–89.8) |
| 12 months | 29 | 93.0 ± 16.7 (71.0–126.0) | 32.8 ± 4.1 (25.8–42.7) | 15.5 ± 7.5 (1.6–33.3) | 23.7 ± 11.7 (1.6–45.1) | 45.1 ± 21.4 (5.0–94.4) | 55.7 ± 24.7 (3.9–96.0) |
| 24 months | 28 | 92.1 ± 16.3 (63.0–128.0) | 32.0 ± 4.5 (23.7–41.8) | 17.4 ± 11.3 (0.0–41.3) | 26.0 ± 13.1 (0.8–51.7) | 49.9 ± 30.3 (0.0–108.8) | 60.7 ± 28.0 (2.0–107.0) |

n number of patients, BMI body mass index, TWL total weight loss, LAGB laparoscopic adjustable gastric banding, EWL excess weight loss, RYGB Roux-en-Y gastric bypass

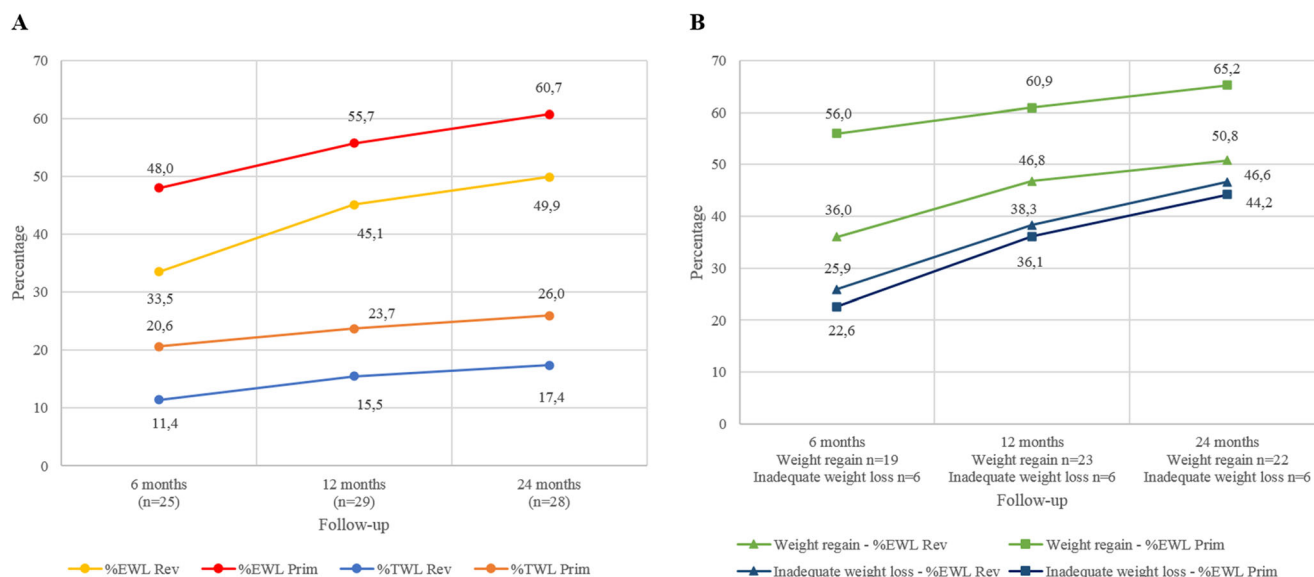


Figure 2 **A** %EWL and %TWL during the 24-month follow-up, relative to the weight at LAGB (Rev) and to the weight prior to RYGB (Prim). **B** %EWL during 24-month follow-up, relative to the weight at LAGB (Rev) and to the weight prior to RYGB (Prim) for patients with weight regain

increases. Weight recidivism after primary RYGB is a well-recognised problem and is estimated to occur in between 20 and 35 % [10–12].

Revisional surgery is technically complex and often associated with a high risk of complications including leaks and intra-operative injuries, longer operative times and an increased blood loss [15, 21, 22]. The optimal choice of a revisional procedure for a failed RYGB is equivocal. In order to fine-tune the optimal choice of a revisional procedure, we work by a treatment algorithm (Figure 5). Besides adequate radiologic, endoscopic and laboratory investigations, a thorough analysis of the patient's food diary and caloric intake takes part in our decision-making process. If no anatomical deformity of the RYGB is depicted, compliance enhancement (during 3 months) under guidance of a dedicated nutritionist and, if needed, of a psychologist is the cornerstone of our treatment policy. Only if the patient shows good compliance can a surgical revision be opted for. If the patient experiences loss of restriction (defined as a caloric intake > 1500 Kcal/d on the intake study) and an enlarged gastric pouch or gastrojejunostomy is confirmed peri-operatively, we prefer to perform a resizing of the pouch or the complete gastrojejunal complex, named a gastrojejunal sleeve. An adjustable band is the first choice of treatment for patients with insufficient restriction, but with an acceptable size of the gastric pouch and gastrojejunal anastomosis, evaluated during the revisional procedure. Only in those rare patients with no loss of restriction and a BMI > 40, we prefer to perform a Sugerma-type distalisation, leaving a minimum of 4 m of so-called total alimentary limb length (TALL), as described by Ghiassi et al. [23]. In this type of distalisation, the

biliopancreatic limb is substantially lengthened, assuring an enhanced malabsorptive effect of the RYGB construction. Of course, every algorithm has its flaws, but it can be a useful guiding tool to choose the optimal surgical treatment.

The positioning of an adjustable band around the gastric pouch is attractive from a surgical-technical point of view. There is no need to create an anastomosis or to perform a formal resection of the pouch or the gastrojejunal anastomosis, and, additionally, the pars flaccida technique guarantees a dissection in a relatively virgin territory. This approach is attributed to Marc Bessler, who first reported his early results in 2005 on 8 patients [24]. This concept has been valorised in a review paper by Gumbs et al. in 2007 [25]. In 2010, Bessler et al. published their long-term results on 22 patients. They showed a %EWL of 47.3% at a 2-year follow-up of the AGB revision (laparoscopic and open procedures) in 22 patients and 59.5% when combined with the primary RYGB surgery. Up to the 5-year follow-up, %EWL for the combined procedures remained stable at 59.3%. Only three major complications occurred (13.6%): 1 partial small bowel obstruction related to the band tubing, 1 band slip and 1 port infection. The band was removed in one patient [26]. Irani et al. presented data of a population that included 43 patients. The %EWL, using the weight at RYGB, at 28 months of follow-ups after salvage LAGB was 55%. The reoperation rate for complications related to the band was 10% and included 2 band erosions, 1 band slip and 1 port flip [27]. Shimizu et al. reported on revisional surgery and showed an even lower complication rate and no band-related complications within a population of 23 patients in a follow-up period of minimum 1 year [21]. Recently, a retrospective

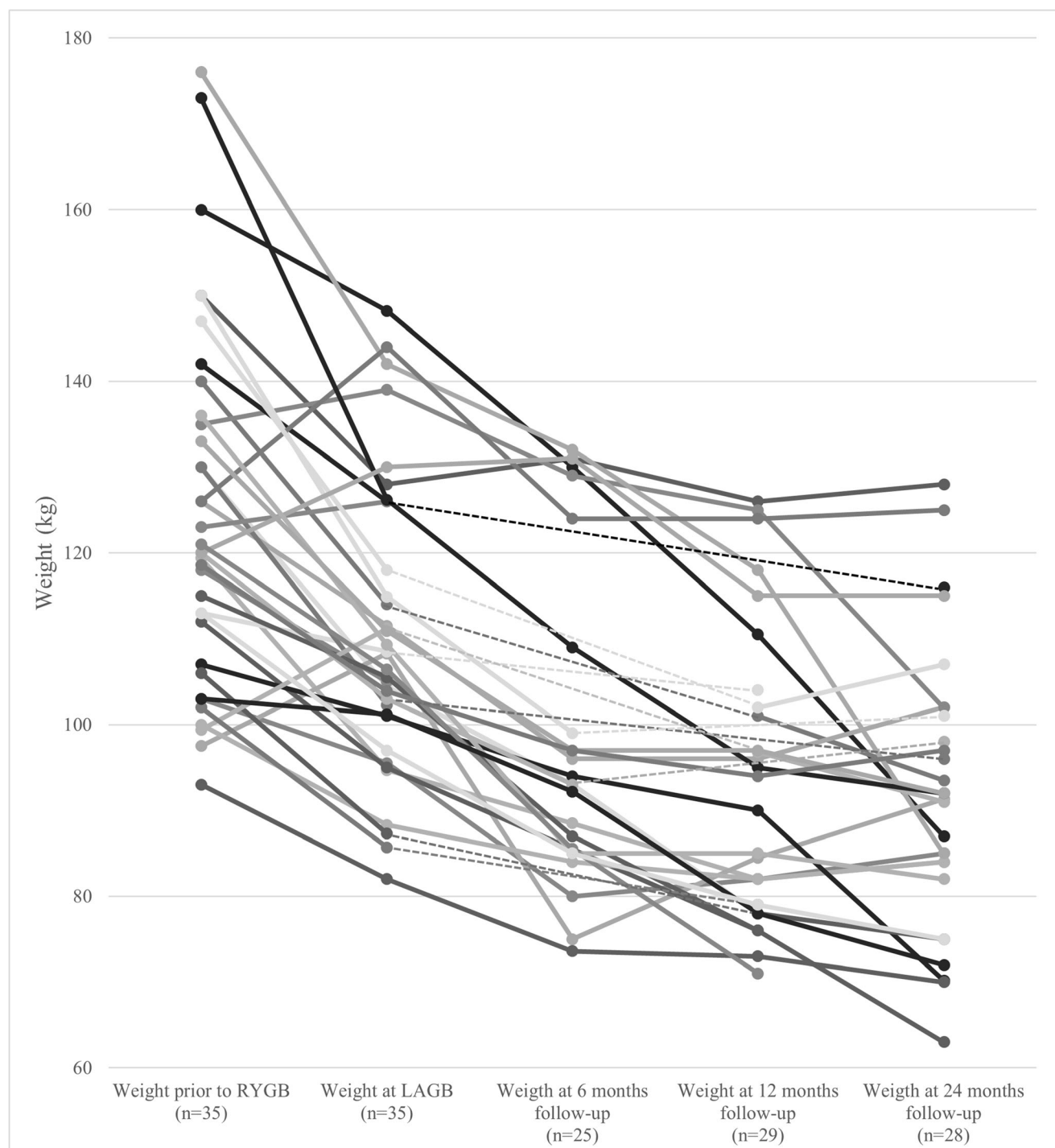
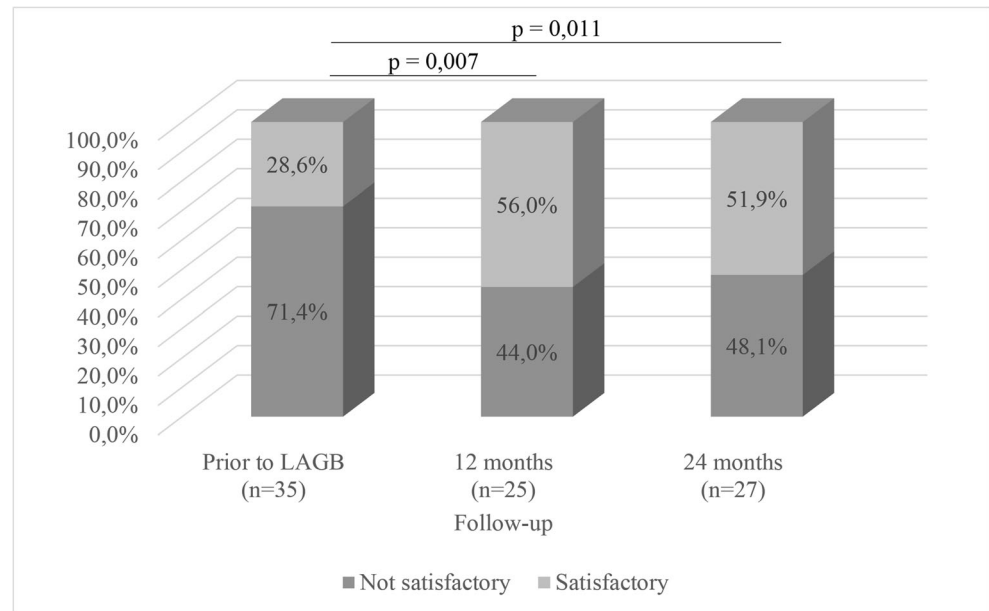


Figure 3 Scatterplot analysis of the weight evolution of individual patients. Abbreviations: *n* number of patients, *EWL* excess weight loss, *LAGB* laparoscopic adjustable gastric banding, *RYGB* Roux-en-Y gastric bypass

analysis from Liu et al. reported on a series of 86 patients. At the 2-year follow-up, patients had a mean BMI of 35.9 kg/m² with 27.2% TWL and 57.2% EWL, relative to the primary RYGB. Up to the 5-year follow-up, weight loss increased to a mean BMI of 33.6 kg/m² with 30.9% TWL and 65.9% EWL. The long-term reoperation rate for complications related to LAGB was 24.4% [28]. Schmidt et al. published in

2018 a retrospective multicentric analysis on data from 139 patients with revisional band over bypass placement. The median maximal weight loss after LAGB was 37.7%. At the last follow-up visit, the median excess weight loss was 27.5%. Median follow-up was 2.5 years (0.01–11.48). Eleven bands (8%) required removal, 4 for erosion, 4 for dysphagia and 3 for non-band-related issues [29].

Figure 4 MA II outcomes prior to LAGB and during follow-up. Abbreviations: *MA II* Moorehead-Ardelt II *LAGB* laparoscopic adjustable gastric banding, *n* number of patients. $P < 0.025$ is significant. The pairwise comparisons are as follows: McNemar Chi-square test used for comparing data prior to LAGB and at the 12-month follow-up and the 24-month follow-up



In conjunction to those good results in terms of weight loss reported in literature, this prospective registry reports an

additional excess weight loss of 49.9% and a total excess weight loss of 60.7% from the index RYGB procedure. The

Weight Regain/Ineffective Weight Loss after Gastric Bypass

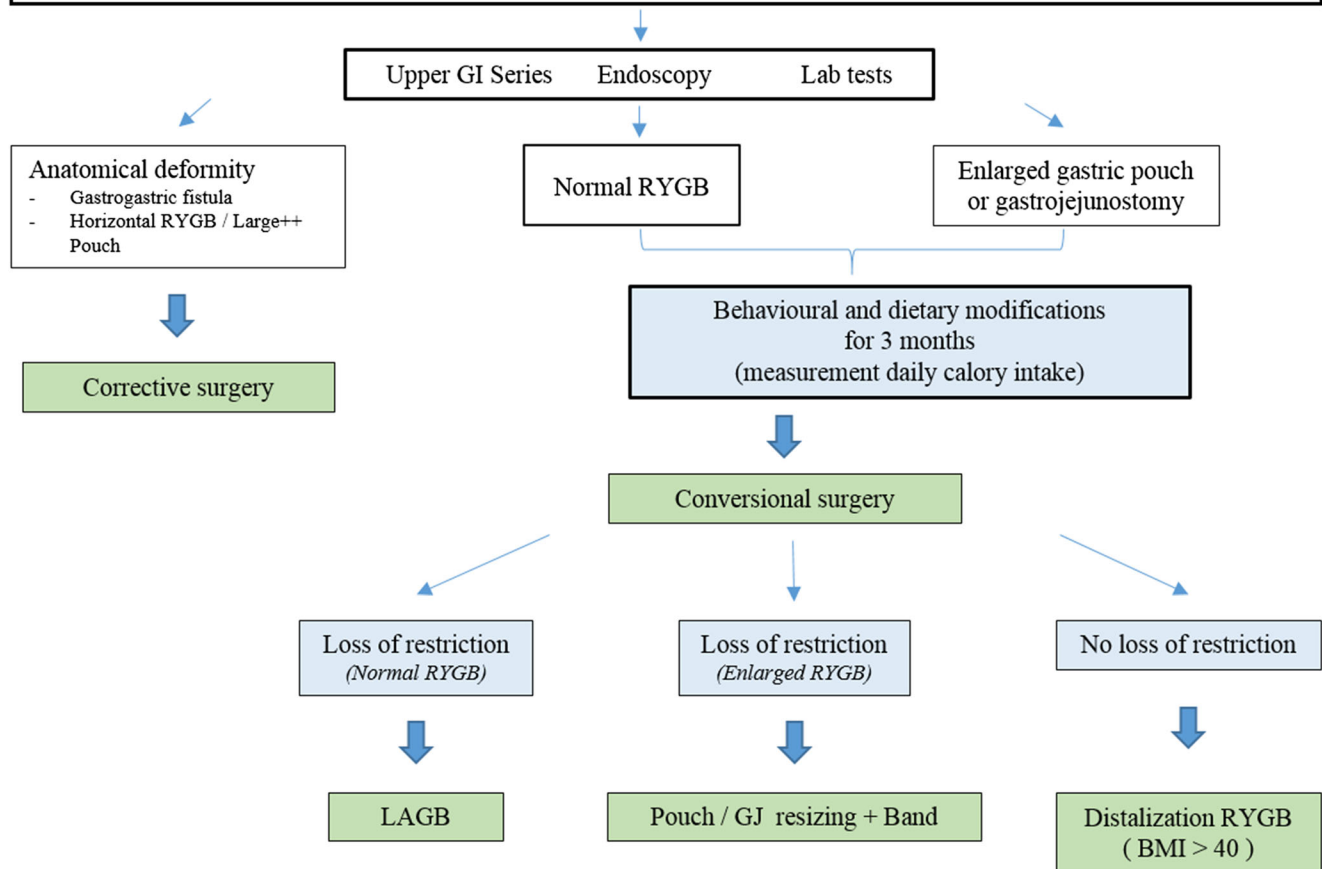


Figure 5 Treatment algorithm. Abbreviations: *GI* gastro-intestinal, *RYGB* Roux-en-Y gastric bypass, *LAGB* laparoscopic adjustable gastric banding, *GJ* gastrojejunal, *BMI* body mass index

reoperation rate for band-related complications was 21.2%. These findings are in support with aforementioned studies of Liu et al. and Schmidt et al. [28, 29]. In this study, we additionally evaluated the quality of life of a salvage banding on a bypass. In contrast to the relatively poor functional results of the primary band placement, we found fairly good results with a substantial increase in quality of life. The perception of patients having a satisfying outcome increased from 28.6% pre-operation to 51.9% 24 months after band placement.

This study has some shortcomings. Though prospective, the study encompasses a small group of patients, with a relatively short follow-up of 24 months, considering the risk of long-term failure and complications related to the band. And as mentioned before, individual compliance enhancement can have somewhat biased achieved weight loss results based solely on the LAGB placement.

Conclusion

The positioning of an adjustable band around the gastric pouch is a feasible surgical option for patients with insufficient weight loss after RYGB. The results of our prospective study are showing a satisfactory additional weight loss (49.9% EWL) after 24 months and an increased quality of life. The procedure is relatively easy to perform with acceptable short-term complications (21.2%). However, longer follow-up data are necessary to balance the gain in weight loss with the occurrence of adverse events, such as band-related complications.

Supplementary Information The online version contains supplementary material available at <https://doi.org/10.1007/s11695-021-05537-0>.

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Declarations

Ethics Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Consent to Participate Informed consent was obtained from all individual participants included in the study.

Conflict of Interest We report grants from Duomed NV Oeyvaersbosch 12 2630 Aartselaar Belgium, during the conduct of the study; consultancy fees from Medtronic and from Johnson and Johnson and speakers fees from Olympus, outside the submitted work.

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