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▶ To cite this version:

A. Denneval, C. Chalumeau, S. Iceta, E. Pelascini, E. Disse, et al.. Revision of Mason's procedure (vertical banded gastroplasty) to Roux-en-Y gastric bypass: role of an associated fundectomy in weight loss outcomes. Surgery for Obesity and Related Diseases, 2021, 17 (5), pp.870-877. 10.1016/j.soard.2020.12.014. inserm-03274423

HAL Id: inserm-03274423 https://inserm.hal.science/inserm-03274423

Submitted on 9 May 2023

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Revision of Mason's procedure (Vertical Banded Gastroplasty) to Roux-en-Y Gastric

Bypass: role of an associated fundectomy in weight loss outcomes.

Axel Denneval ^{1,2}, Claire Chalumeau³, Sylvain Iceta ^{2,4,6}, Elise Pelascini ^{1,2}, Emmanuel Disse

^{2,4,5,7} Maud Robert ^{1,2,4,5,7}

¹ Department of Digestive Surgery, Center of Bariatric Surgery, Hôpital Edouard Herriot, Hospices

Civils de Lyon, Lyon, France,

² Centre Intégré et Spécialisé de l'Obésité de Lyon, Groupement Hospitalier Lyon Sud, Hospices Civils

de Lyon, Pierre Bénite, France

³ Fédération de chirurgie viscérale, Centre Hospitalier William Morey, 4 rue Capitaine Drillien 71100

Chalon-sur-Saône

⁴ Université Claude Bernard Lyon 1, Lyon, France

⁵Department of Endocrinology, Diabetology and Nutrition, Groupement Hospitalier Lyon Sud,

Hospices Civils de Lyon, Pierre Bénite, France

⁶ Quebec Heart and Lung Institute (IUCPQ), Québec, QC G1V 4G5, Canada. School of Nutrition, Laval

University, Québec, QC, G1V 0A6, Canada.

⁷Carmen lab, INSERM Unit 1060

<u>Corresponding author</u>: Axel DENNEVAL

Adress: 1 rue Michel SERVET, 42000 SAINT ETIENNE, France

Email: axel. denneval@gmail.com

Phone: +336 58 011 800

VBG conversion to RYGB: factors of success

Abstract

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Introduction: Vertical Banded Gastroplasty (VBG) presents a significant rate of long-term complications and revisions are often necessary. Conversion to RYGB seems to be preferred, but literature data remain limited.

5 Objectives: to analyze the indications, safety, results of conversions of VBG to RYGB, and to identify predictive factors of success or failure.

Methods: this bicentric retrospective study included all the patients who benefited from a conversion of VBG to RYGB between 2008 and January 2020. Demographic characteristics, indications, preoperative work-up, intraoperative data, complications and weight loss results were analyzed.

Results: 85 patients underwent a conversion to RYGB during the study period. The mean BMI before conversion was 40.6kg/m². 82.3% of the patients were converted because of weight loss failure and 17,6% because of a complication of their VBG. The global rate of complications was 25%. After an average follow-up of 35 months and a rate of lost to follow-up of 33%, the mean BMI was 33.5kg/m. Weight loss success rate according to Reinhold's criteria was 64.7% and the resolution of complications was obtained in 89.1%. The association of a fundectomy was a predictive factor of weight loss (OR = 0.27; p = 0.04) whereas primary failure of the VBG was a predictive factor of failure.

Discussion: the conversion of VBG to RYGB remains the procedure of choice to achieve satisfying weight loss and resolution of functional complications. The addition of a fundectomy appeared to have a significant positive impact on weight loss outcomes.

Introduction

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For the last number of decades, morbid obesity has been a public health issue in constant evolution ⁽¹⁾. Since the beginning of the 21st century, bariatric surgery has demonstrated superiority over medical treatment of obesity and remains the gold standard management of obesity and its comorbidities ^(2,3). The surgical techniques have evolved greatly since the advent of bariatric surgery in the United States in the 1960's. The vertical banded gastroplasty (VBG) was one of the first restrictive techniques described by Mason, a pioneer of bariatric surgery, in 1982 ⁽⁴⁾. This procedure, widely performed by laparotomy in the 2000s ^(2,5), was gradually replaced by the adjustable gastric band, also favored by the advent of laparoscopy. Mid to long term results of the VBG appeared to be less satisfactory and more heterogeneous, with complications reaching 45% in the literature ^(6,7): gastro-esophageal reflux disease (GERD), dysphagia, weight regain due to the repermeabilization of the staple line and/or dilatation of the gastric pouch were reported to lead to a reoperation rate of 21.4% up to 56% ^(8,9)

As a result, revisional surgery for weight loss failure, weight regain or for complications of the VBG is often necessary. The conversion of VBG to RYGB remains the procedure of choice for many bariatric teams (10–16) despite its technical difficulty and the significant risk of morbidity (17).

Nevertheless, literature data is lacking regarding the outcomes of conversion of VBG to RYGB and its benefit to risk ratio.

We conducted a bicentric retrospective study of all the patients who underwent a conversion of VBG to RYGB over a period of 12 years. Our main objective was to analyze the indications, the weight loss and functional results of conversions of VBG to RYGB. The

second objectives were to assess the safety and to identify the predictive factors of success or failure of the conversion.

Methods

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Pre-Operative work-up

From February 2008 to January 2020, all the patients who underwent a conversion of VBG to RYGB in two specialized centers of bariatric surgery were included. This was a retrospective study of prospectively collected data. Demographic data (age, gender, weight, height, Body Mass Index-BMI), past medical history and especially weight loss history (initial weight at VBG, nadir weight and weight regain after VBG) were recorded. The indication for conversion was analyzed, whether for weight loss failure or for complications of the VBG (gastro-esophageal reflux, malnutrition, dysphagia, gastroparesis). A distinction was made between patients presenting a primary failure (having never satisfied the Reinhold's criteria (BMI \leq 35 and/or EWL% \geq 50%⁽¹⁸⁾)) and those presenting a secondary failure (initially satisfying the Reinhold's criteria but secondarily regaining weight, therefore not satisfying those criteria anymore). The pre-operative use of an upper gastro intestinal endoscopy (upper GI endoscopy), a gastrografin swallow and/or a gastric computed tomography with gas (gastric CT) was detailed: the presence of esophagitis, gastric pouch dilatation, staple line dehiscence and/or gastric stenosis at the calibration banding. Gastric pouch dilatation was considered significant when the volume exceeded 100cc on gastric CT and/or mentioned on the patient file through other exams (upper GI endoscopy, gastrografin swallow). All patients benefitted from a multidisciplinary re-evaluation (psychologic, dietitian and nutritional assessment) prior to validation of the indication to convert the VGB to RYGB by an accredited multi-disciplinary bariatric team.

Peri- and Post-Operative Data

Peri-operative data including operative time, surgical approach (laparoscopic or laparotomy), associated procedures (fundectomy, cholecystectomy), peroperative and early complications (< 30 days) were collected. The surgical technique of conversion of the VBG to RYGB consisted of performing a new gastric pouch by stapling the pre-existing pouch using a linear stapler transversely above the calibration band and then vertically inside of the pre-existing staple line; the gastric pouch was calibrated by a 37French bougie. A fundectomy was performed if technically feasible without increasing the surgical risk from 2012: the aim was to resect the pre-existing staple lines and the calibration band to avoid possible leakage or other complications. The gastric bypass was then performed according to the Lonroth technique (19), with a biliary limb of 50cm and an alimentary limb of 150cm. The alimentary limb was either antecolic in one center or retrocolic in the other. Early and late complications (> 30 days) were recorded according to the Clavien Dindo classification (20). Postoperative visits were scheduled at 2, 6, 12, 18, 24 months and then annually. Weight loss was expressed in delta BMI (Initial BMI minus current BMI), in excess weight loss percentage (EWL% = ((initial weight - current weight) / (initial weight - ideal weight)) x 100) and in total weight loss percentage (TWL% = ((initial weight - current weight) / (initial weight)) x 100) at each time of the follow up. Ideal weight was calculated for a BMI of 25. The conversion of VBG to RYGB was considered a weight loss success if Reinhold's criteria were achieved at last follow up. Duration of the follow-up was recorded; patients were considered lost to follow up if no medical visit or news were found for more than one year.

Statistical analysis

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Data were analyzed using medCalc® software v19.3 (MedCalc Software, Ostend, Belgium). Categorical variables were expressed as frequencies and proportions and were compared with X² or Fisher's test for the bivariate analysis. Continuous data were expressed as a mean or median with standard deviation (SD). A Student's t-test was performed for data with a normal

distribution or a Mann-Whitney U test when appropriate. Data extraction was performed using Orange Datamining Software® v3.27.1 (University of Ljubljana, Slovenia) and its native ReliefF algorithm to determine predictive factors of weight loss success or failure according to Reinhold's criteria. A comparison of the two groups (weight loss success or failure at the end the follow-up) was performed using univariate analysis. A logistic regression analysis was then performed in order to define the independent factors involved in the weight loss success of the conversion of VBG to RYGB. A p-value <0.05 was considered statistically significant.

Results

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Studied population and indications of the conversion of VBG to RYGB

Between 2008 and 2020, 85 patients were included: 51 in one center group and 34 in the other. There was 81.1% of women (n= 69) and 18.9% of men (n = 16). The mean age at conversion was 50±10.6 years (22 – 73) and mean BMI prior to conversion was 40.6±8.9 kg/m² (21.5 - 68.8). All VBG procedures were performed between 1990 and 2014, with a mean BMI of 46.64±7.04 kg/m² (33.98 - 63.59) at the time of the VBG, reaching a mean BMI of 29.5±5.78 kg/m² (19.05 - 47.46) at the nadir point, corresponding to a mean EWL of 82 ± 25.9% (26.6 - 137.8). The indication of conversion to RYGB was mainly for weight loss failure of the VBG in 70 cases which were analyzed to find predictive factors of weight loss success or failure of the conversion: 27 of them (38.5%) also presented functional complications of the VBG (dysphagia +/- GERD +/- malnutrition +/- gastroparesis). The other 15 patients (17.6%) were converted for complications of the VBG but did not fail to lose weight (figure 1). The functional complications of the VBG were represented by dysphagia (n= 27/85, 31.7%), gastro-esophageal reflux (n = 22/85, 25.9%), malnutrition (n = 2/85, 2,3%), and in one case by a gastroparesis worsened by diabetes. Among the patients with

weight loss failure of the VBG (n = 70), 9 were considered as a primary failure (12.8%) and 61 (87.2%) as a secondary failure (initial weight loss and weight regain). Five patients were excluded due to the technical failure of the conversion to RYGB (5/85= 5.9%): the presence of scar tissues and severe adhesions did not make the dissection possible. In these 5 cases, the original indication for conversion was a weight loss failure of the VBG. Four patients underwent conversion to sleeve gastrectomy, and no intervention was finally performed for the fifth patient.

The pre-operative work-up included a gastroscopy for almost all cases (97.6%, n=83/85), a gastric CT with gas in 47.1% of the cases (n=40/85) and a barium swallow in 32 patients (36.7%): most common findings were a repermeabilization of the staple line (32.9%) and a dilation of the gastric pouch (35.3%; Table 1).

Peri operative data and complications

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The average operative time of the conversion was 214 ± 62 minutes (130 - 460). Laparoscopy was possible in 84.7% of the cases. The most common associated operative procedure was the association of a fundectomy (58/85, 68,2%). A repair of incisional hernia was performed in seven cases, two of them being according to Goni-Moreno, a cholecystectomy in five cases, a sigmoidectomy and a right hemicolectomy in one case each. The median post-operative length of stay was 5 days (2 - 124).

A per protocol analysis was conducted, with an exclusion of patients for whom the procedure was abandoned due to technical failure (n = 5): early post-operative complications were reported in 20 cases (25%), of which 13 (65%) required re operative procedures (Table 2).

Late complications of conversion of VBG to RYGB appeared in 23 patients (28.75%) of which 11 (Clavien III; 47.8%) benefitted from re-operative procedures. Medical late complications (Clavien I – II; n=12, 15%) are presented in table 2.

145 There was no post-operative mortality.

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Weight loss and functional results after the conversion of VBG to RYGB

The mean post-operative follow-up was 35.5 ± 27.8 months. Twenty-eight patients (n = 28/85, 32.9%) were lost to follow-up. Regarding patients who had a conversion in the context of a weight loss failure (n = 65), weight loss evolution is represented in figure 2. The mean BMI at the end of the follow up was 33.6 ± 6.6 kg/m² (15.8 - 49.7) with a mean reduction of 9.5 ± 4.8 BMI points, a %TWL% of $21.6\pm10.1\%$ and an average % EWL of $55.8\pm30.4\%$ (1.6-192.8). The weight loss success rate according to Reinhold's criteria was 63.1%; 49 patients out of 65 had a fundectomy (75.4%) (n=49/65).. For the patients who had a conversion of VBG for functional complications alone (n=15) and/or associated with weight loss failure (n=22), the global resolution rate of symptoms was 89.1% (table 3). Dysphagia and GERD which were the most common symptoms improved in 96.3% and 86.4% respectively. Weight loss changes over time function of the indication for conversion to RYGB are represented in figure 3.

Predictive factors of weight loss success or failure of the conversion of VBG to RYGB

Using datamining analysis, we found that the main factors associated with failure of the conversion to RYGB were the absence of associated fundectomy, as well as a high BMI at each stage of patient management. Univariate analysis showed that mean BMI pre VBG, nadir BMI achieved after VBG, and at conversion to RYGB were significantly higher in the weight loss failure group compared to the success group (50.4, 34.2 and 47.1 kg/m² versus 45.3, 28.0 and 40.9 kg/m² respectively; p<.05). Primary failure of the VBG was also significantly linked to weight loss failure after the conversion to RYGB (30.0% versus 4.8% in the success group; p=.02). A fundectomy was performed in 82.9% of successfully converted cases and in only

62.5% of unsuccessfully converted cases, close to statistical significance (p=.06). Post-operative complications did not seem to differ between the two groups.

Using logistic regression analysis, we found that the addition of a fundectomy to the conversion to RYGB significantly reduced the risk of weight loss failure (OR=.27; 95%CI[.07 – .98]; p= .04), independently of BMI at conversion (OR=1.16, 95%CI[1.05-1.27]; p=.003), of age (OR=1.01, 95%CI[.95-1.08]; p=.58) and gender (OR=0.67, 95%CI[.17-2.6]; p=.56). No difference was found on the VBG pouch dilatation rate. Gastric pouch dilatation did not impact success or failure of the conversion to RYGB (OR=1.69, 95%CI[.46-6.14]; p=.42).

Discussion

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Our bicentric and historic series of conversion of VBG to RYGB including 85 patients is one of the largest published in the current literature. Other studies already published on the topic are mostly retrospective and monocentric, including from 45 to 153 patients (10,12,16,21). The study of Suter al (11) is the only multicentric one, with 203 patients across four centers. Other studies on revisional surgery were also published but include several kind of revisional procedures, were nonspecific of revision of VBG to RYGB and with small sample sizes (22). In the literature, the laparoscopic conversion of VBG to RYGB seems to be the gold standard treatment at the current time, as much for weight loss failure as for the management of functional complications of the VBG. In our study, the conversion to RYGB has demonstrated to be effective on complications of the VBG with a resolution of dysphagia and GERD in 96.3% and 86.4% of the cases, respectively. Our results are similar to those published in the literature: Vasas, Athanasiadis and Gagné found a 100% resolution rate of dysphagia (10,12,23) whereas Gys (14) and Schouten (21) reported 94% and 90% of improvement. GERD was improved in about 95% of the cases in most of the series (10,12).

When analyzing the results of the other available surgical options to manage failure of VBG, conversion to sleeve seems responsible for a high rate of complications: a 14% rate of leaks was reported due to the fragility of the new gastric stapling performed on a previously stapled zone at the time of VBG (24). Redo VBG by re-stapling or re-calibrating the gastric pouch resulted in the same levels of operative failure (25). It seems to us that in the case of failure of restrictive surgery such as VBG, the addition of a malabsorptive component is a supplementary argument to optimize weight loss. The risk of worsening GERD symptoms already quite common after VBG, goes against the conversion to sleeve gastrectomy. The improvement of GERD following a RYGB is another argument in favor of this technique which stands as the procedure of choice when converting a VBG.

Revisional bariatric surgery is often technically demanding, due to severe adhesions secondary to previous surgeries. In our series, we reported 5 operative failures out of 85 (5.9%). This could also be explained by the fact that VBG were mostly performed by laparotomy prior the years 2000 increasing the risk of adhesions. Several authors reported longer operative times, higher rates of complications, and lower weight loss after revisional bariatric surgery compared to first-line bariatric procedures (26). Our 25% rate of short term complications is concordant with other findings in the literature (11,12,21). Nevertheless, we observed a 3.75% rate of abdominal wall complications that are explained by the association of incisional hernia repair in 7 cases including 2 giant incisional hernia: this complex abdominal wall surgery represents a bias in our analysis of surgical complications. Early and late severe complications (\geq Clavien III) occurred in 16.2% and 13.7% of the cases respectively and are concordant with published data, despite the heterogenous follow up and classification: complications ranged from 6.2% up to 50% in the literature (13-15,23). The long operative time reported in our study (mean of 214 minutes) can partly be explained by associated procedures (repair of giant incisional hernias requiring laparotomy and right

colectomy in super obese patients ⁽²⁷⁾) and illustrates the complexity of patients being reoperated for failed VBG. The mean % EWL obtained in our series was 55.8%, with an average follow up of 35.5 months, corresponding to a success rate of 64,7% according to Reinhold's criteria. These results are satisfactory when considering that 82.4% of our population (70/85) had weight loss failure after the VBG, and reflect those of the literature ^(11,12,14,23). It is worth noting that the mean initial BMI of 44 kg/m2 in our study is higher than in most other series and can explain the moderate weight loss observed.

One strong point of our study is the demonstration that patient's weight loss history was significantly linked to conversion results. Indeed, we found that primary failure of the VBG was significantly linked to weight loss failure after conversion to RYGB, with 30.0% of primary failure versus 4.8% in the weight loss success group (p=.02). Thus, patients with a good initial weight loss after VBG but who regained weight later (secondary failure) had greater chance of weight loss success after the conversion to RYGB: conversion was more effective after a regain of weight than after an insufficient initial weight loss. Thus, after primary failure of a restrictive procedure, and a probably severe 'obesity illness', the addition of a malabsorptive component by conversion to RYGB makes perfect sense. Beside the fact that the greater the initial BMI, the greater the objective (BMI \leq 35 and/or EWL > 50%) is difficult to achieve, our study confirmed that the weight loss trajectory of the patient is marked by his bariatric history; it also confirmed the difficulties of the most obese to maintain their results over time whatever the surgical technique (28).

Another interesting finding is the positive impact of a concomitant fundectomy on weight loss outcomes of the conversion of VBG to RYGB. While initially not systematic, the fundectomy became more frequent in order to avoid the risks of gastric staple line leaks or fundus dilatation if left in situ. This procedure has not shown an increased morbidity and seems to have a major role in weight loss: the addition of a fundectomy reduced the risk of failure by 4

in our series (OR= 0.27) and was already found as an effective procedure in the literature (29,30). This could also have a positive impact on Type 2 Diabetes by reducing ghrelin secretion, responsible for increased appetite and hyperglycemia, as demonstrated in previous studies (31). Indeed, the physiology of this hormone is characterized by an increased secretion during fasting periods and a rapid postprandial decrease. In obese patients, the level of ghrelin is elevated during fasting periods but suffers from diminished post prandial inhibition (32): the reduction of ghrelin secretion as well as a reduction in serum plasma levels has already been demonstrated after RYGB with fundectomy (32). Even if the population size and its bi-centric nature are strengths of our study, it would be interesting to perform a randomized control trial to confirm the real impact of fundectomy on weight loss results: this could lead to add this procedure to standard surgical practice. The measure of serum ghrelin level would be of major interest to verify the impact of this hormone on weight loss and Type 2 Diabetes evolution.

The main limits of our study are its retrospective nature and its heterogenicity due to the inclusion of patients who have had a VBG by different surgeons, in different centers, in a variable period of time.

Conclusion

This historic, bi-centric study confirms that the conversion of VBG to RYGB remains the procedure of choice to achieve satisfying weight loss and resolution of functional complications. The addition of a fundectomy appeared to have a significant positive impact on weight loss outcomes. Our study showed that the weight loss trajectory of the patient is marked by his bariatric history with a significant negative impact of primary failure of the VBG on weight loss results.

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Conflict of interest. The authors declare that they have no conflict of interest.

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Figure 1. Flowchart

Figure 2: Evolution of % EWL after conversion of the VBG to RYGB for weight loss failure

350 BMI= Body Mass Index, VBG= Vertical Banded Gastroplasty, %EWL = Percentage of excess weight loss

Figure 3: Weight changes according to the surgical indication over time (weight loss failure or complication of the VBG)

BMI= Body Mass Index, VBG= Vertical Banded Gastroplasty

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Table 1: Pre-operative workup and results

Table 2. Post operative complications according to Clavien-Dindo classification in the per protocol population (n=80)

Table 3: Functional results of patients operated for complications of VBG (GERD: Gastro

860 Esophageal Reflux Disease)

Table 4. Factors involved in weight loss success or failure of the conversion of Vertical

Banding Gastroplasty (VBG) to Roux-en-Y Gastric Bypass (RYGB) according to Reinhold's

criteria (BMI = Body Mass Index)

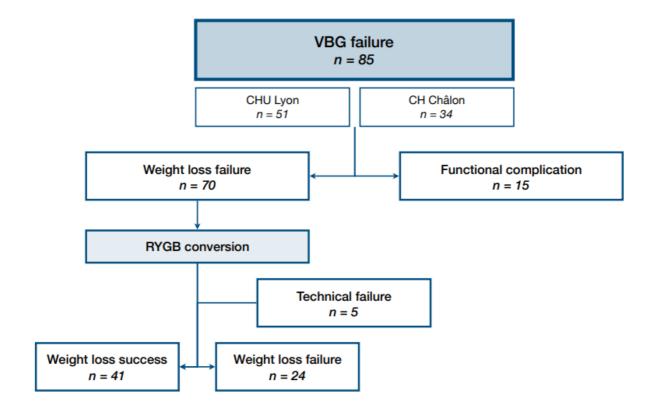


Figure 1. Flowchart

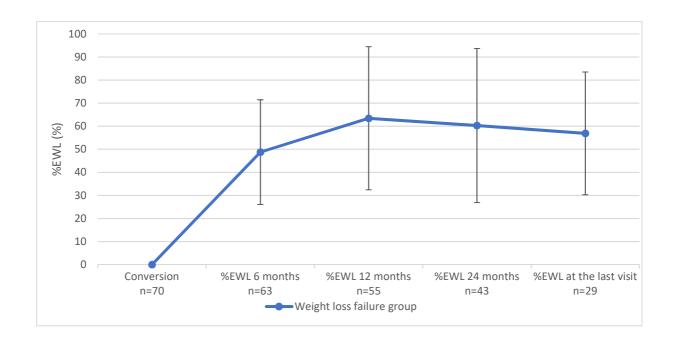
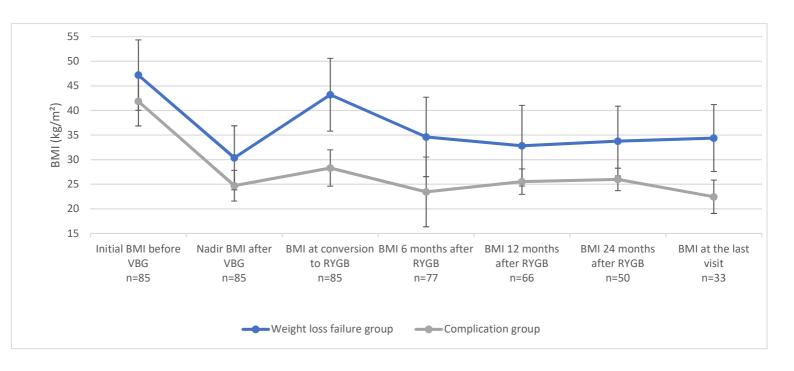


Figure 2: Evolution of % EWL after conversion of the VBG to RYGB for weight loss failure

BMI= Body Mass Index, VBG= Vertical Banded Gastroplasty, %EWL = Percentage of excess

weight loss



<u>Figure 3 : Weight changes according to the surgical indication over time (weight loss failure or complication of the VBG)</u>

BMI= Body Mass Index, VBG= Vertical Banded Gastroplasty

	Patients, n=85 (%)
Iodality	
Upper GI endoscopy	83 (97.6)
Gastric CT Scan	40 (47)
Gastrografin Swallow	32 (37.6)
Results	
Esophagitis	20 (23,5)
Gastric pouch dilatation	30 (35.3)
Gastro-gastric fistula	7 (8.2)
Stenosis at the calibration banding	21 (24.7)
Repermealization of the staple line	28 (32.9)

Table 1: Pre-operative workup and results

Early Complications			
Complication	Chalon-sur-Saône, n=30 (%)	Lyon, n=50 (%)	Total, n=80 (%)
Clavien I	0	1 (1,9)	1 (1.25)
Dysphagia	0	1 (1,9)	1 (1.25)
Clavien II	3 (10)	3 (6)	6 (7.5)
Sepsis	1 (3.3)	2 (3,9)	3 (3.75)
Urinary tract infection	0	1 (1,9)	1 (1.25)
Anastomotic ulcer	2 (6.6)	0	2 (2.5)
Clavien III	5 (16.7)	8 (15,6)	13 (16.25)
Stenosis of the biliary limb	1 (3.3)	2 (3,9)	3 (3.75)
Biliary limb leak	1 (3.3)	0	1 (1.25)
Gastro-jejunal stenosis	0	1 (1,9)	1 (1.25)
Gastro-jejunal leak	1 (3.3)	1 (1,9)	2 (2.5)
Staple line bleeding	0	1 (1,9)	1 (1.25)
Parietal thickness dehiscence	0	2 (3,9)	2 (2.5)
Strangulated incisional hernia	0	1 (1,9)	1 (1.25)
Small bowel kinking	2 (6.6)	0	2 (2.5)
Total	8 (26.6)	12 (22,6)	20 (25)
Late Complications			
Complications	Chalon-sur-Saône, n=30 (%)	Lyon, n=50 (%)	Total, n=80 (%)
Clavien I	2 (6.6)	8 (15,6)	10 (12.5)
Dumping syndrome	2 (6.6)	5 (9,8)	7 (8.75)
Incisional Hernia	0	2 (3,9)	2 (2.5)
Gastro-gastric fistula	0	1 (1,9)	1 (1.25)
Clavien II	1 (3.3)	1 (1,9)	2 (2.5)
Posterior cord syndrome	0	1 (1,9)	1 (1.25)
Entero-cutaneous fistula	1 (3.3)	0	1 (1.25)
Clavien III	5 (16.7)	6 (11,7)	11 (13.75)
Recurrence of incisional hernia	0	2 (3,9)	2 (2.5)
Incisional hernia	0	1 (1,9)	1 (1.25)
Gastro-jejunal fistula	0	1 (1,9)	1 (1.25)
	1 (2.2)	0	1 (1.25
Long alimentary stump limb	1 (3.3)	U	- (
Long alimentary stump limb Internal Hernia	0	2 (1,9)	2 (2.5)
Internal Hernia	0	2 (1,9)	2 (2.5)

Table 2. Post operative complications according to Clavien-Dindo classification in the per protocol population (n=80)

	Pre-conversion n, (%)	Post conversion, n (%)	Rate of remission (%)
Functional Complications	37	4	89,1
Dysphagia	27 (72,9)	1 (2,7)	96,3
GERD	22 (59,4)	3 (8,1)	86
Malnutrition	2 (0,5)	0 (0)	100
Diabetic Gastroparesis	1 (0,25)	0 (0)	100

Table 3: Functional results of patients operated for complications of VBG (GERD: Gastro

Esophageal Reflux Disease)

ariables	Weight loss success	Weight loss failure	p-value
	(n=41)	(n=24)	
ntients characteristics			
Age	50.02	49.3	.78
Gender M/F	8/33	7/17	.37
BMI at conversion to RYGB	40.9	47.09	.0009*
re Operative Workup			
Gastric Pouch Dilatation (%)	37.8	50	.39
Staple line dehiscence (%)	43.9	29.1	.24
Stenosis at the calibration banding (%)	37.9	13.3	.09
er Operative Data			
Fundectomy (n, (%))	34 (82.9)	15 (62.5)	.06
Operative time (min)	207	227	.21
All Complications (%)	17	20.8	.70
Complications ≥ grade III (%)	4.8	16.6	.11
Veight Changes			
BMI pre VBG	45.3	50.4	.05*
Nadir BMI after VBG	28	34.2	.0001*
Primary Failure of the VBG (n (%))	2 (5)	7 (30)	.02*
Secondary Failure of the VBG (n (%))	39 (95)	17 (70)	.13

Table 4. Factors involved in weight loss success or failure of the conversion of Vertical Banding

Gastroplasty (VBG) to Roux-en-Y Gastric Bypass (RYGB) according to Reinhold's criteria

(BMI = Body Mass Index)