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Sleeve gastrectomy as a rescue of failed gastric banding: comparison of one- and two-step approaches.

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Running Title: Gastric banding removal and sleeve gastrectomy.

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ABSTRACT

Background. Series comparing gastric banding (GB) removal and sleeve gastrectomy (SG) when procedures are performed as a one-step or a two-step approach are contradictory in their outcomes. No series comparing these approaches with mid-term weight loss are available.

5 **Objectives.** Compare the outcomes and weight loss of SG performed as one-step and two-step approaches as a revisional procedure for GB failure.

Setting. University Hospital, France, public practice.

Methods. Between February 2006 and January 2017, all patients undergoing SG with a previous history of implementation of GB (n=358) were included in this two-center,
10 retrospective, observational study. Revisional surgery was proposed in patients with insufficient excess weight loss ($EWL \leq 50\%$) or weight regain after GB. A one-step (1-step group, n=270) or two-step (2-step group, n=88) approach was decided depending on patient's choice and/or surgeon's preference. The primary efficacy endpoint was the comparison of weight loss in the 1-step group and 2-step group at the two-year follow-up. The secondary
15 efficacy endpoints were short-term outcomes (overall mortality and morbidity at POD 30, specific morbidity, reoperation, length of hospital stay, and readmission).

Results. In the 1-step group, the mean preoperative BMI before SG was 40.5 kg/m² (27.0 – 69.0), while in the 2-step group, the mean preoperative BMI was 43.5 kg/m² (31.5 – 61.7). Mean operating time was 109 minutes (50-240) in the 1-step group and 78.7 minutes (40-175)
20 in the 2-step group ($p=0.22$). In the 1-step group, 6 conversions to laparotomy occurred, while in the 2-step group, two conversions to laparotomy occurred ($p=0.75$). One death (0.2%, in the 2-step group) and 39 complications (30 in the 1-step group (11.1%) and 9 in the 2-step group (10.2%)) also occurred. The mean length of hospital stay was 6.2 days in the 1-step group and 4.1 days in the 2-step group.

25 At two-years follow-up, mean BMI was 32.4 kg/m² in the 1-step group and 33.2 kg/m² in the
2-step group ($p=0.15$), representing EWLs of 61.9 and 50.1 ($p=0.05$), respectively. The rates
of revisional surgery were 0.7% and 2.2%, respectively.

Conclusions. SG after previous GB is efficient with similar outcomes depending on the 1- or
two-step approach. The 1-step approach seems to have increased weight loss compared with
30 the 2-step approach.

Key words: sleeve gastrectomy; gastric banding; weight loss.

35 INTRODUCTION

Obesity is a real public health problem for developed countries. Bariatric surgery is currently the best treatment for morbid obesity. Many surgical procedures can be proposed, among which the most common are adjustable gastric banding (GB), sleeve gastrectomy (SG), and Roux-en-Y gastric bypass (RYGB). During recent decades, the implementation of GB has
40 decreased due to insufficient weight loss, weight regain, or complications related to GB [1]. For revisional surgery, RYGB and SG are the most frequently proposed.

In cases of weight regain or insufficient weight loss after failure of GB, the removal of GB alone without a further procedure is associated with physical deterioration and psychiatric comorbidities as well as low quality-of-life scores [2, 3]. For this reason, a further procedure is
45 proposed, and in cases of SG, two surgical strategies are described: removal of GB then SG as a two-step approach, or GB removal and SG during the same procedure (one-step approach).

The first series comparing SG with a previous history of GB showed that the 2-step approach was associated with a lower risk of morbidity, suggesting that SG should be performed some weeks after GB removal [4 - 7]. More recent series suggest contradictory results with a safe
50 approach for the 1-step approach [8 - 10]. For a comparison of these two approaches based on weight loss, no data concerning a large population study exists.

The objective of the present study was to retrospectively compare the outcomes and results in terms of weight loss of SG performed as a 1-step and a 2-step approach after failure of GB in two university hospitals.

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MATERIALS AND METHODS

Population

From February 2006 to January 2017, all patients undergoing SG with a previous history of implementation of gastric banding were included in this multi-center, retrospective, observational study. This study was a retrospective review of two prospective databases on a group of patients with a history of GB implementation (n=358) who underwent SG as a one-step approach (the 1-step group, n=270) or a two-step approach (the 2-step group, n=88).

Preoperative screening

The indication for bariatric surgery was validated in accordance with international guidelines [11] and a multidisciplinary obesity staff meeting [12]. Each patient's endocrine status was systematically assessed in order to detect thyroid and adrenal diseases requiring treatment prior to surgery. A psychiatric or psychological assessment was used to screen for personality disorders that would contraindicate (or that could be decompensated by) bariatric surgery. Preoperative nutritional support consisting of multiple consultations with a dietician and participation in obesity surgery-specific workshops was routinely provided. Hiatal hernia, Barrett's esophagus, GB migration, and *Helicobacter pylori* infections were evaluated by esophagogastroduodenoscopy. A preoperative barium swallow test was performed to check for absence of slippage and absence of esophageal dilatation. In case of SG with GB removal in the same procedure, esophagogastroduodenoscopy was performed to check for absence of band migration into the stomach. Severe esophagitis and/or Barrett's esophagus and/or dilatation of the esophagus [13] were considered as contraindications for SG. GERD before performing SG was not routinely assessed using a 24-h pH-meter and depended on clinical signs and endoscopy data.

Pulmonary function tests, including sleep polysomnography, were used to screen for obstructive sleep apnea (OSA) syndrome in all patients prior to surgery.

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Indications for one- or two-step approach

Revisional surgery was proposed in patients with insufficient excess weight loss ($EWL \leq 50\%$) or weight regain after GB. The 1- or 2-step approach was decided depending upon the patient's choice and/or surgeon's preference.

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Surgical procedures

The SG with GB removal as a one-step procedure was previously described ^[14]. Surgical technique was standardized using a four-trocar technique. The first step of the procedure consisted of disconnecting the tube of the GB. Next, during laparoscopy, any fibrosis between the stomach and the liver was removed. Then, the entire left side of the gastric tube was released starting 6 cm above the pylorus. The GB was removed at the end of the release of the gastric tube. This allowed the dissection to be guided, thus allowing an optimal release of the gastric fundus until the left crus of the diaphragm could be seen. After release of the gastric fundus, the GB was removed and placed under the right hepatic lobe. A 34-gauge French bougie was used for transection of the greater gastric curvature. Gastric resection was initiated 6 cm above the pylorus (in the antrum). Since 2014, stapling next to the gastric fundus was performed using black Tri-StapleTM reloads (COVIDEN France SAS) and using bovine pericardium such as Peri-Strips Dry with Veritas (Baxter France, Maurepas, France) or synthetic copolymer-polyglycol acid trimethylene carbonate (GORE SEAMGUARD) depending upon the surgeon's preference.

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In the 2-step approach, when removing the GB, the capsule surrounding the stomach was not removed. When performing the SG, the first step consisted of releasing all fibrosis around the

gastric fundus. The capsule surrounding the stomach was then extensively removed in order to reduce the thickness of the gastric wall. Then, gastric transection was performed similarly to SG with GB removal as the one-step approach.

A methylene blue test was always performed at the end of the surgical procedure. Abdominal drainage was not routinely performed for SG with a previous history of GB.

Post-operative management

Since 2014, no routine upper gastrointestinal study test has been performed. Oral feeding was started the same day or the day after surgery using mixed meal.

Inclusion and exclusion criteria

The inclusion criteria were a body mass index (BMI) between 35 and 60 kg/m², age between 18 and 68 years, previous history of GB. The exclusion criteria were absence of a previous history of GB, a previous history of GB for which gastric banding removal was performed in case of complications of the band (slippage, migration, etc.), SG with GB removal initially scheduled as one step for which intra-operative findings preferred to do it as two step, bariatric procedures other than SG.

Endpoints and parameters recorded

The primary efficacy endpoint was the comparison of weight loss in the 1-step and 2-step groups at the two-year follow-up. The secondary endpoints were short-term outcomes (overall mortality and morbidity at POD 30, specific morbidity, reoperation, length of hospital stay, and readmission).

The two groups were compared in terms of the following parameters:

- GB data: weight evaluation before GB implementation, maximum weight loss after GB (body mass index (BMI), excess weight loss (EWL)), time interval between GB implementation and GB removal, weight evaluation at time of SG.
- Demographic data before SG: age, gender, body mass index (BMI), comorbidities (hypertension, type 2 diabetes (T2D), dyslipidemia, metabolic syndrome, obstructive sleep apnea syndrome).
- SG operative data: operative time, conversion rate, abdominal drainage rate.
- Outcomes: mortality rate, complication rate according to the Clavien-Dindo classification ^[15], type of postoperative complications, reoperation rate, length of hospital stay.
- Follow-up data: weight loss at 6-, 12-, and 24-months follow-up; rate of revisional surgery after SG.

Statistics

Patient baseline characteristics are expressed as mean \pm standard deviation (SD), median (interquartile range) for continuous data, and number (frequency) for categorical data. Univariate analysis was based on Student's t-test for quantitative variables. The Mann–Whitney U-test was used for non-parametric variables. Univariate analysis was based on the chi-square test for qualitative variables. The limit for statistical significance was $p < 0.05$. All statistical tests were performed with SPSS software (version 15.0 for Windows, SPSS Inc., Chicago, IL, USA).

RESULTS

Population study

From February 2006 to January 2017, a total of 358 patients underwent SG after failure of GB. The 1-step group consisted of 270 patients (75.4%), of which 239 were women (88.5%) with a mean age of 44 years (22 - 71). Mean preoperative BMI at the time of GB implementation was 44.2 kg/m² (35.1 - 70.6). The maximum weight loss after GB implementation was obtained after a mean time interval of 0 months (0-0), representing a mean minimum BMI of 33.7 kg/m² (20.5 - 65.4) and a mean EWL of 51.9% (0 - 127.1).

The 2-step group consisted of 88 patients (24.6%), of which 61 were women (58%). Mean age recorded was 44.3 years (21 - 71). Mean preoperative BMI at the time of GB implementation was 46.7 kg/m² (35.0 - 64.0). After GB implementation, the maximum weight loss achieved was at a mean time interval of 5 months (3-12), representing a mean minimum BMI of 31.7 kg/m² (21 - 46.3) and a mean EWL of 54.1% (0 - 127).

Significant differences between the two groups regarding the primary SG's data were recorded, especially for time interval between GB removal and SG. Detailed data is presented in **Table 1**.

Pre-operative data

In the 1-step group, the mean preoperative BMI and EWL before SG were 40.5 kg/m² (27.0 - 69.0) and 16 (-88.2 - 85.2), respectively. A total of 243 comorbidities were recorded in 152 patients (56.3%), as follows: hypertension (25.9%; n=70), T2D (10%; n=27), obstructive sleep apnea syndrome (29.6%; n=80), and dyslipidemia (24.4%; n=66). The mean time interval between GB and SG was 100 months (15-238).

In the 2-step group, BMI improves between GB removal and performing of SG from 39.5 kg/m² to 43.5 kg/m² (p < 0.05) representing an EWL before SG relative to GB implementation of 2.6 (-122 - 59.2). Eighty-three comorbidities were recorded in 45 patients (51.1%): arterial hypertension (28.4%; n=25), T2D (15.9%; n=14), obstructive sleep apnea

syndrome (31.8%; n=28), and dyslipidemia (18.1%; n=16). The mean time interval between GB and SG was 110 months (17-212).

Intra-operative data

In the 1-step group, 6 conversions to laparotomy occurred (5 due to adhesions and one due to injury of the spleen), while in the 2-step group, two conversions to laparotomy occurred (one for adhesions and one for injury of the left gastro-epiploic vein). Mean operating time was 109 minutes (50-240) in the 1-step group and 78.7 minutes (40-175) in the 2-step group ($p=0.22$).

Outcomes (Table 2)

In the 1-step group, there was no postoperative death (0%). Thirty postoperative complications (11.1%) were observed, including 22 major complications (8.1%): 10 gastric leaks (3.7%), four cases of postoperative bleeding (1.5%), and two cases of post-operative stenosis (0.7%). Fifteen patients underwent early reoperation (5.5%). The mean length of hospital stay was 6.2 days (1-50).

In the 2-step group, there was one post-operative death (1.1%) relative to gastric leak. Nine complications were recorded (10.2%) including 7 major complications (8%). Six patients were reoperated (6.8%). The mean length of hospital stay was 4.1 days (1-35).

Weight loss

At one-year follow-up, mean BMI was 31.9 kg/m² (19.5 - 55.1) in the 1-step group and 32.4 kg/m² (23.2 - 44.4) in the 2-step group ($p=0.34$), representing EWLs of 62.9 (-10.9 - 130.1) and 59.5 (-13.1 - 105.5) ($p=0.24$), respectively. The difference between the two groups was even more important at the two-year follow-up (**Table 3 and Figure 1**). At 24 months follow-

up, two patients had revisional surgery in the 1-step group, such as RYGB for GERD, while two patients in the 2-step group had revisional surgery: one RYGB for GERD and one repeat SG for poor weight loss due to large remnant gastric fundus.

DISCUSSION

Bariatric surgery has been demonstrated to be the most effective therapy for achieving sustained weight loss and managing obesity-related complications. The implementation rate of GB has decreased over time and worldwide [26]. This decline is related to the adverse effects of GB, the complication rates in the mid- and long-term requiring GB removal, and especially the rates of insufficient weight loss and weight regain [17].

Faced with failure of restrictive surgery, a malabsorptive procedure is usually proposed, which is more frequently RYGB in the literature [18]. SG is an effective procedure in the long-term as demonstrated by many recent studies [19, 20], and it is associated with fewer events and complications occurring in the mid-long-term compared to RYGB [21]. Thus, some series that evaluated SG as a rescue of failing GB have been published. Most of these series described logically an increased rate in complications in cases of secondary SG [6, 14]. In their analysis of the American College of Surgeons National Surgical Quality Improvement Program database, Dietch et al. [6] showed that conversion of GB to SG compared to primary SG was associated with increased odds of serious 30-day morbidity (odd ratio of 1.44).

Series comparing SG and RYGB as rescues of failing GB in a large population study suggest that the rate of complications was increased in case of RYGB [22]. When analyzing the results on weight loss, few series have compared SG and RYGB. Ultimately, weight loss was similar between the two procedures [23, 24], suggesting that SG can be proposed as an alternative to RYGB, the main interests of such procedure being to limit the risk of mid/long term complications compared to a gastric bypass if GERD diseases are excluded.

The current series showed that conversion of GB to SG as a one- or two-step approach had similar outcomes concerning post-operative complications with overall complication rates of 11.1% in the 1-step group and 10.2% in the 2-step group ($p=0.82$). When considering gastric leak, no significant difference was found between the two groups (3.7% and 3.4%, respectively; $p=0.71$). Even if our length of stay was pretty high (6.2 days in the 1-step group vs. 4.1 days in the 2-step group) and probably due to the fact that the population study includes patients undergoing surgery on a long time period (starting from February 2006) with at this time used of many unnecessary post-operative assessment (such as routine abdominal drainage, routine upper gastrointestinal study test), our series showed no difference concerning length of stay between the two groups in favor of one type of approach.

The results of the current study agree with those in current publications. The first series to compare the two approaches found a decreased rate of complications in favor of the 2-step approach [4, 7]. Since then, other series have compared the two approaches, and no differences were found concerning complications between the one- and two-step approaches [9, 10]. Even more recently, the one-step approach has been considered as safer than the two-step approach [25].

The current study is interesting in that no series has compared two surgical approaches for the revision of failure of GB to SG from a weight loss point of view. In this series, weight loss was increased in the 1-step group with an EWL of 62.9% at the one-year follow-up compared to 59.5% in the 2-step group ($p=0.24$), and this difference was even more significant at the two-year follow-up (61.9% vs. 50.1%, respectively; $p=0.05$). This could be explained by the fact that in cases of previous GB, the gastric pouch was always located more posteriorly than in cases of primary SG [26]. If GB had been removed prior to the SG, some SG may have been performed leaving a larger part of the fundus. In the one-step approach, the GB was removed after the complete release of the stomach, just before beginning stapling. The GB serves as an

anatomical landmark for an optimal release of the gastric fundus and may aid in avoiding an incomplete resection of the fundus. Another interesting point of the current study was that despite an effective secondary procedure on weight loss, weight loss was less important in patients undergoing the two-step approach than with the GB (**Table 3**). Although this series presents several limitations, such as the retrospective design and the short follow-up (2 years), this study confirms that the one-step approach has similar early outcomes compared with the two-step approach. An important point highlighted in this study was that the one-step approach seems to achieve better results on weight loss compared to the two-step approach, probably due to the fact that surgery may be facilitated by the presence of the GB, allowing in some cases the facilitation of the intra-operative view of the anatomy. However, our result could have been impacted by the difference in pre-operative BMI and maybe that a case matched study would have been of interest if population study was more important to confirm our results. Among the other limitations of the study, the absence of learning curve is analyzed, because there were many surgeons performing surgery, and some preferred one approach over the other, not allowing for a comparison. Also, post-operative GERD evaluation and use of anti-acid medication before and after SG in our database was lacking, and could be a major problem in such revisional procedures in the future.

CONCLUSION

The current study shows that revision of GB to SG is effective in terms of weight loss. A comparison between the two approaches (1- and 2-step) showed similar complication rates and GL in particular. The 1-step approach would seem to have better weight loss than the 2-step approach at the two-year follow-up. The current results suggest that the one-step approach must be favored, if possible.

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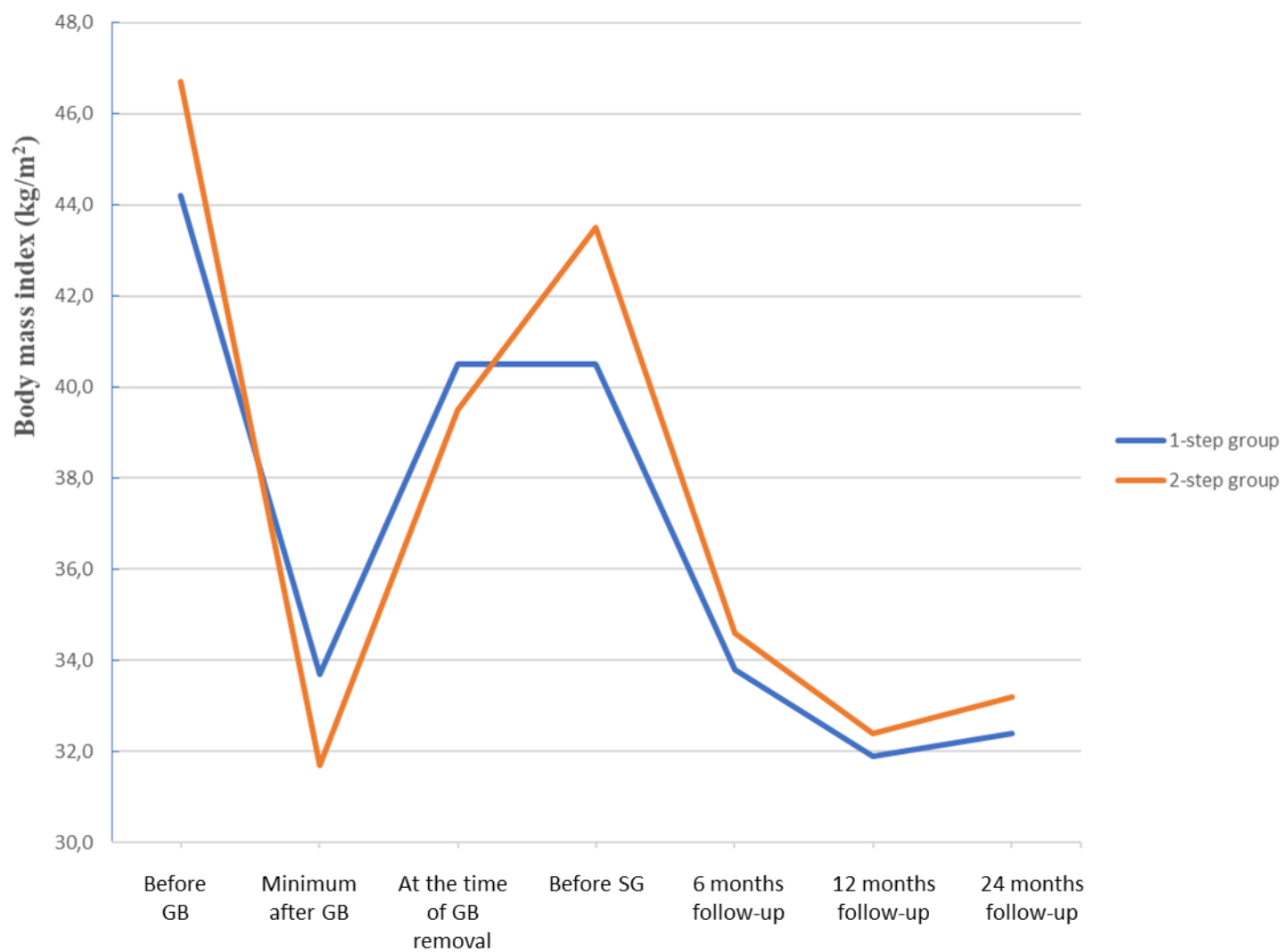
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FIGURE LEGENDS

Figure 1: Evolution of body mass index during time in 1 and 2-step group.

375 SG: sleeve gastrectomy

GB: gastric banding



1-step group	Number of patients	270	270	270	270	202	148	105
	BMI (kg/m ²)	44.2	33.7	40.5	40.5	33.8	31.9	32.4
2-step group	Number of patients	88	88	88	88	60	45	36
	BMI (kg/m ²)	46.7	31.7	39.5	43.5	34.6	32.4	33.2

Table 1: Pre-operative data of the two groups.

	1-Step group (n=270)	2-Step group (n=88)	<i>p</i>
Demographic data			
Mean age (years, range)	44.0 (22-71)	44.3 (21-71)	0.43
Male gender (n, %)	31 (11.4)	9 (10.2)	0.75
GB data			
BMI before GB (mean, range)	44.2 (35.0-70.6)	46.7 (35.0-64.0)	0.57
Minimum BMI after GB (mean, range)	33.7 (20.5-65.4)	31.7 (21.0-46.3)	0.99
Time interval between GB removal and SG (months, range)	0 (0-0)	5 (3-12)	0.001
SG data			
BMI before SG (mean, range)	40.5 (27.0-69.0)	43.5 (31.5-61.7)	0.001
Preoperative comorbidities before SG			
Hypertension (n, %)	70 (25.9)	25 (28.4)	0.33
T2D (n, %)	27 (10)	14 (15.9)	0.11
OSAS (n, %)	80 (29.6)	28 (31.8)	0.26
Dyslipidemia (n, %)	66 (24.4)	16 (18.1)	0.26

BMI: body mass index

GB: gastric banding

SG: sleeve gastrectomy

T2D: type 2 diabetes

OSAS: obstructive sleep apnea syndrome

Table 2: Intra and post-operative data depending different approaches.

	1-Step group (n=270)	2-Step group (n=88)	<i>p</i>
Intra-operative data			
Operative time (min, range)	109 (50-240)	78.7 (40-175)	0.22
Conversion rate (n, %)	6 (2.2)	2 (2.2)	0.75
Post-operative data			
Mortality (n, %)	0 (0)	1 (1.1)	0.55
Overall complications (n, %)	30 (11.1)	9 (10.2)	0.82
Major complications (n, %)	22 (8.1)	7 (8)	0.95
Leaks (n, %)	10 (3.7)	3 (3.4)	0.71
Bleeding (n, %)	4 (1.5)	2 (2.2)	0.12
Stenosis (n, %)	2 (0.7)	0 (0)	0.52
Other (n, %)	0 (0)	1 (1.1)	0.55
Reoperation rate (n, %)	15 (5.5)	6 (6.8)	0.66
Length of stay (n, range)	6.2 (1-50)	4.1 (1-35)	0.99
Readmission rate (n, %)	13 (4.8)	4 (4.5)	0.92

Table 3: Weight loss depending two types of approach as revision for GB.

	1-Step group (n=270)	2-Step group (n=88)	<i>p</i>
Before GB			
BMI (kg/m ² , range)	44.2 (35.1 - 70.6)	46.7 (35 - 64.0)	0.57
Minimum with GB			
BMI (kg/m ² , range)	33.7 (20.5 - 65.4)	31.7 (21 - 46.3)	0.99
EWL (%; range)	51.9 (0 - 127.1)	62.1 (0 - 127)	0.02
Before SG			
BMI (kg/m ² , range)	40.5 (27.0 - 69.0)	43.5 (31.5 - 61.7)	0.001
EWL (%; range)	16 (-88.2 - 85.2)	2.6 (-122 - 59.2)	0.001
6 months follow-up			
BMI (kg/m ² , range)	33.8 (20.8 - 58.4)	34.6 (23.5 - 54.5)	0.12
EWL (%; range)	52.3 (-6.5 - 123)	51.6 (-2.2 - 103.3)	0.39
12 months follow-up			
BMI (kg/m ² , range)	31.9 (19.5 - 55.1)	32.0 (23.2 - 44.4)	0.34
EWL (%; range)	62.9 (-10.9 - 130.1)	59.5 (-13.1 - 105.5)	0.24
24 months follow-up			
BMI (kg/m ² , range)	32.4 (17.7 - 46.4)	33.2 (21.5 - 49.4)	0.15
EWL (%; range)	61.9 (16.3 - 142)	50.1 (-28.6 - 116)	0.05
RS after SG (n, %)	2 (0.7)	2 (2.2)	0.24

BMI: body mass index

EWL: excess weight loss

RS: revisional surgery