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Research Article

Eight-Year Results of Laparoscopic Sleeve Gastrectomy

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Abstract

Background: Our objective was to evaluate the efficacy and safety of laparoscopic Sleeve Gastrectomy (SG) at 8 years follow-up.

Methods: From May 2004 to November 2006, 64 patients underwent a SG. Percentage of excess weight loss (%EWL), % of excess BMI loss (%EBL), co-morbidities, Gastroesophageal Reflux Disease (GERD), and complications were evaluated at 2 years post-SG according to our database. Results at 8 years were evaluated according to a patient survey.

Result: A complete record was obtained for 55 patients (85.9%) including 45 patients who only had a SG and 10 who had a second bariatric procedure (7 gastric bypasses, 3 revisional SG). The mean %EWL of 55 patients was 58.4±18.1% at 2 years and 52.1±19.2% at 8 years; mean %EBL was 65.1±20.6% at 2 years, 57.2±22.7% at 8 years. Three patients (5.5%) had postoperative complications: 2 leaks (3.7%), 1 haemorrhage (1.9%). The long-term complications reported were trocar site hernias: 3 patients (5.5%). The sub-group analysis of 45 patients who only had a SG presented a mean %EWL of 59.1±16.6% at 2 years and 50.3±19.6% at 8 years; the mean %EBL was 66.1 ±18.7% at 2 years and 54.2±22.2% at 8 years. For these 45 patients we found a favorable evolution of comorbidities at 8 years follow-up: type 2 diabetes mellitus decreased of 46.2%; hypertension decreased of 47.1%; dyslipidemia decreased of 50%; sleep apnea syndrome decreased of 68%. But the frequency of GERD treated by PPI tripled.

Conclusion: Weight loss was satisfying, improvement of co-morbidities was noticed. Few surgical complications were reported, but the frequency of GERD increased.

Keywords: Morbid obesity; Sleeve gastrectomy; Long-term results; Re-sleeve gastrectomy; Gastric bypass

Introduction

Usual weight loss cures - as diets, physical activity, behavior therapy and pharmacotherapy - have been continuously implemented but still have relatively poor long-term success and mainly scarce adherence. Bariatric surgery is to date the most effective long term treatment for morbid obesity and it has been proven to reduce obesity-related co-morbidities, among them nonalcoholic fatty liver disease, and mortality [1]. Surgical treatment of morbid obesity has significantly changed since the advent of laparoscopy. Many surgical procedures with multiple variants have been proposed and presented as the treatment of choice for morbid obesity. Laparoscopic Sleeve Gastrectomy (SG) was initially proposed as a first step in superobese patients while waiting for a definitive bariatric procedure [2]. More recently, due to promising short and medium-term results, SG has been proposed as the only and definitive treatment for morbid obesity by several authors [3-6]. SG is gaining wide spread popularity as a definitive bariatric operation that provides satisfactory and durable weight loss as well as comorbidity resolution. Weight loss and the beneficial effects on comorbidities are equivalent among elderly and younger patients. SG should be offered to elderly patients who are deemed to be appropriate candidates [7]. Few authors have reported long-term results of the SG as definitive treatment of morbid obesity [8,9]. However, since 2011, SG has become the most performed bariatric procedure in France [10]. With experienced surgeons, appropriate protocols, and a consistent operative team, SG can be performed safely in a free-standing ambulatory surgical centers on select “high acuity” patients [11]. SG is gaining popularity and has become the procedure of choice for many bariatric surgeons. Long-term weight loss failure is not uncommon. The preferred revisional procedure for these patients is still under debate [12]. Our goal was to evaluate the long-term efficacy and safety of SG at 8 years after surgery.

Patients and Methods

Patients and study design

From May 2004 to November 2006, 64 consecutive obese patients not wishing to have gastric banding or Gastric Bypass (GBP), while these techniques were performed in our unit, wished and had a SG as a definitive treatment for morbid obesity. At this time, SG was a relatively new procedure in France. All procedures were performed by the same surgeon (JMC), with large experience in bariatric surgery. In all cases, the surgical decision was made in collaboration with a multidisciplinary group as later recommended by the « Haute Autorité de Santé » (HAS) [13].

Preoperative evaluation and results at 2 years after SG were evaluated according to a retrospective study using our prospectively

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Table 1: Patient characteristics.

	Mean ± SD	Range
44 females (80%) / 11 males (20%)		
Age (years)	41.5±11.1	19-60
Weight (kg)	134.8±29	90-220
BMI (kg /m²)	49.7±9.2	35.5-71.8
Excess weight (kg)	66.3±26.5	30.4-143.6

SD: Standard Deviation; BMI: Body Mass Index.

collected database. The evaluation at 8 years after SG was carried out according to a patient survey from April 2013 to December 2014. Patients were asked to complete a questionnaire and to state their weight during an office and/or telephone consultation.

Surgical technique

SG was performed according to the previously described laparoscopic technique [14], systematically using a 36 French calibration tube. The left crus of the diaphragm were consistently visualized during the freeing of the greater curvature of the stomach. Gastric division was started at the gastric antrum at 6cm from the pylorus, and was continued parallel to the calibrating boogie positioned along the lesser curvature of the stomach, until reaching the angle of Hiss.

Evaluation and evolution of weight loss, co-morbidities, and gastroesophageal reflux disease (GERD)

For each patient, the weight used was that recorded after 2 full years post-SG (weight during the third year after SG), and that recorded after 8 completed years post-SG (weight during the 9th year after SG). The evaluation of weight loss was conducted based on changes in BMI, changes in the percentage of excess weight loss (%EWL), and the percentage of excess BMI loss (%EBL). A calculated method was used for the determination of the ideal body weight [11]. % EBL uses BMI 25 as the limit of normal, and it is not quite the same as % EWL based on the Metropolitan Tables which uses the mid-point of the medium fram as their ideal weight [15].

Table 2: Results at 2 and 8 years after SG: Progressive change of BMI, %EWL, and % EBL.

	Preoperative	2years	8years
«SG alone» (n=45)			
. Mean BMI (kg/m²) (±SD)	48.9±8.4	33.4±5.7	35.9±6.6
Range (kg/m²)	35.7-66.7	23.9-49.6	23.2-53.4
. Mean % EWL (±SD)		59.1±16.6	50.3±19.6
Range (%)		26.3-96.2	14.1±91.4
. Mean % EBL (±SD)		66.1 ± 18.7	54.2±22.2
Range (%)		31.4-106.2	15.4-110.7
«SG and SG+Re-SG and SG+GBP» (n=55)			
. Mean BMI (kg/m²) (±SD)	49.7±9.2	33.8 ± 6.4	35.4±7.3
Range (kg/m²)	35.5-71.8	23.2-53.2	23.3-55.4
. Mean % EWL (±SD)		58.4±18.1	52.1±19.2
Range (%)		16.6-96.2	14.1-91.4
. Mean % EBL (±SD)		65.1±20.6	57.2±22.7
Range (%)		18.3-106.3	15.9-110.6

SG: Sleeve Gastrectomy; Re-SG: Revisional Sleeve Gastrectomy; GBP: Gastric Bypass; BMI: Body Mass Index; EWL: Excess Weight Loss; EBL: Excess BMI Loss; SD: Standard Deviation.

The presence or absence of co-morbidities preoperatively, and their persistence or resolution at 2 years and at 8 years, were defined by the need for medication to treat Type 2 Diabetes Mellitus (T2DM), hypertension, and dyslipidemia. The absence of T2DM was confirmed, or not, by a glycated hemoglobin inferior to 6.5% without any treatment. All patients had one general practitioner referent that watched the evolution of co-morbidities and prescribed or not the long-term medical treatment. The preoperative presence of Sleep Apnea Syndrome (SAS) was diagnosed by polysomnography for all patients. Long-term resolution of SAS was affirmed by discontinuation of C-PAP or, for patients not using C-PAP, by the bed partner's observation that apnea did not occur during sleep, and/or by good quality restorative sleep combined with absence of daytime somnolence. Persistence, development or resolution of GERD was confirmed by the need for PPI medication, diagnostic confirmation by endoscopy, and/or GERD-associated symptoms (heartburn, retrosternal burning and nocturnal cough).

Data were analyzed with SPSS 13.0 software (SPSS Inc., Chicago, IL, USA). The results were expressed as mean ± Standard Deviation (SD).The comparison of means of continuous variables was performed using the Student t test for paired data. A p value <0.05 was considered statistically significant. The evolution of co-morbidities and GERD were evaluated by Chi^2 test for trends.

Results

Patient characteristics

From May 2004 to November 2006, 64 patients underwent SG. A complete collected data with a follow-up at 8 years was obtained for 55 patients (85.9%). Patient characteristics are summarized in Table 1.

Three patients refused to cooperate. Six patients were lost to follow-up. These 9 patients could not be assessed, but were not excluded from the study in order to perform calculations based on intention to treat of the 55 patients, 10 (18.2%) had a second step, another bariatric surgery, due to insufficient weight loss: 7 Gastric Bypass (GBP), 3 Revisional Sleeve Gastrectomy (Re-SG). A second step procedure was proposed if the %EWL was below 50%, mostly with the persistence of comorbidities. Re-SG was proposed to patients with gastric tube dilation on upper GI series. The second operation was carried out from 17months and up to 46months after the initial SG. These 10 patients were included in the study according to the methodology used with the intention to treat. Data were analyzed for the group of 55 patients, including those who have had a SG alone (n=45), a SG followed by a GBP (n=7) and a SG followed by a Re-SG (n=3). This composite group will be called "SG and SG + Re-SG and SG + GBP" group. The data were also analyzed for the group of 45 patients who only had SG, which will be called "SG alone" group.

Effectiveness of weight loss

For the "SG alone" group (Table 2), the average BMI was 48.9±8.4 kg/m² preoperatively, 33.4±5.7 kg/m² at 2 years, and 35.9±6.6 kg/m² at 8 years. The mean %EWL was 59.1±16.6% at 2 years and the mean %EBL was 66.1±18.7% at 2 years. At 8years, the average %EWL was 50.3±19.6% and the average %EBL 54.2±22.2%. Comparisons

Table 3: Objective Success at 2 years after SG (calculation based on intention to treat).

	Success	Failure
Evaluated Patients: n=55	n=37	n=18
	SG alone with %EWL ≥50%: n=37	SG alone with %EWL <50%: n=8
		SG + Re-SG: n= 3
		SG + GBP: n=7
Impossible Evaluation: n=9		n=9
		Lost to follow-up: n=6
		Refuse to cooperate: n=3
Total = 64	37/64 = 57.8%	27/64 = 42.2%

SG: Sleeve Gastrectomy; Re-SG: Revisional Sleeve Gastrectomy; GBP:Gastric Bypass; EWL: Excess Weight Loss.

at baseline, 2 and 8 years after SG for mean BMI (p=0.035), mean %EWL (p=0.015), and mean %EBL (p=0.015), showed a statistically significant weight regain between 2 and 8 years after SG.

For the "SG and SG + Re-SG and SG + GBP" group (Table 2), the mean BMI was 49.7±9.2 kg/m² preoperatively, 33.8±6.4 kg/m² at 2 years, and 35.4±7.3 kg/m² at 8 years. At 2 years, the average %EWL was 58.4±18.1% and the average %EBL was 65.1±20.6%.At 8 years, the average %EWL was 52.1±19.2% and the average %EBL was 57.2±22.7%. % Comparisons at baseline, 2 years and 8 years after SG for mean BMI (p=0.164), mean %EWL (p=0.181), and mean %EBL (p=0.171), did not show a statistically significant weight regain between 2 and 8 years after SG.

Six patients (9.4%) were lost to follow up, 3 patients (4.6%) refused to cooperate, and 10 patients (15.4%) required additional bariatric surgery. These 19 patients should be considered as failures of SG and grouped with the group of patients who achieved a %EWL less than 50% according to Reinhold's criteria [16]. At 2 years, the objective failure rate was 42.2%. It was 54.7% at 8 years. Therefore, 45.3% of SG followed for 8 years was an objective success (Table 3&4).

Evolutions of co-morbidities and Gastroesophageal Reflux Disease (GERD)

The evolution of co-morbidities in "SG alone" group and "SG and SG + Re-SG and SG + GBP" group are reported in Table 5. We found a decrease in the frequency of hypertension, SAS, T2DM, and dyslipidemia in both groups at 8 years. Eight full years after the initial SG, and for the group "SG alone", T2DM decreased by 46.2%, hypertension decreased by 47.1%, dyslipidemia decreased by 50% and SAS decreased by 68%. In addition, for the "SG alone" group, the frequency of GERD medically treated by PPI tripled (Table 5). No revisional surgery was performed for GERD dependant to PPI treatment. All patients with GERD were alleviated with PPI.

Table 4: Objective Success at 8 years from SG (calculation based on intention to treat).

	Success	Failure
Evaluated Patients: n=55	n=29	n=26
	SG alone with %EWL ≥50%: n=29	SG alone with %EWL <50%: n=16
		SG + Re-SG: n=3
		SG + GBP: n=7
Impossible Evaluation: n=9		n=9
		Lost to follow-up: n=6
		Refuse to cooperate: n=3
Total=64	29/64 = 45.3%	35/64 = 54.7%

SG: Sleeve Gastrectomy; Re-SG: Revisional Sleeve Gastrectomy; GBP: Gastric Bypass; EWL: Excess Weight Loss.

Postoperative and late complications

No death was reported at 8 years after SG. Three major postoperative complications (5.5%) required urgent re-operation: 2 leaks from the gastric staple line (3.7%), 1 staple line hemorrhage (1.9%). The only complication reported on the long term was the trocar site hernia. Three patients (5.5%) presented a trocar site hernia at the site of extraction of the resected stomach on a 15mm trocar. Patients were operated between 10 and 34 months after the initial SG.

Discussion

The present study, which includes patients with a high BMI (mean BMI of 49.7kg/m²), shows weight loss profile at 8 years after SG evoking some results obtained after GBP [17-21]. Indeed, for patients who had SG as the only bariatric treatment, we found at 8 years an average reduction in BMI of 13kg/m², an average %EWL of 50.3% and an average %EBL of 54.2%. Both postoperative and late complications frequency reached 5.5%. Obesity related co-morbidities were decreased: 46.2% decrease for T2DM, 47.1% for hypertension, 50% for dyslipidemia, and 68% for SAS. But the frequency of GERD in our patients has tripled.

We report that 45.3% of patients who had SG and followed up to 8 years were objectively considered as a success. The possible selection bias that can be linked to the 3 patients who refused to cooperate and the other 6 patients lost to follow-up was corrected by the intention to treat. However, considering all patients lost to follow-up as failures is probably a bit incorrect. In our experience, the whole lifestyle change after SG explains that some operated patients reorganize their lives away from their surgical area. This reflects the reality of this chronic disease, as patients even with good results tend to change their work, home address and city. So our reported success rate is probably underestimated. As reported by Langer et al. [22], our study underlines the benefit of proposing a second operation in case of poor weight loss after SG, thus improving the efficiency of weight loss. GBP, or biliopancreatic diversion with duodenal switch [2], may be proposed in the absence of an expansion of the gastric tube, and Re-SG may be an option if dilatation of the gastric tube is evidenced. Note that patients in a situation of failure are not always motivated to undergo a second bariatric surgery. That is why, in our study, the timing of the second bariatric intervention ranged from 17 to 46 months after the initial SG. For the composite group "SG and SG + Re-SG and SG + GBP" (n=55), we found at 8 years, an average reduction in BMI of 14.3 kg/m² *vs*. 13kg/m² for the group "SG alone" (n=45). This is in favour of the efficiency of the second step in case of insufficient weight lost after SG alone. We also noted a post-SG weight regain, after a nadir at 2 years, while Himpens et al. reported this starting at 3 years [8]. This suggests that we have to strengthen monitoring patients' compliance with lifestyle changes and regular physical activity at 2 years after the SG. Our current strategy is to focus on patient education with our dietary experts six months before surgery, allowing an easier dietary control following surgery.

Table 5: Evolution of co-morbidities and development of GERD after SG (calculations with the Chi² test for trend).

	Preoperative	2 years	8 years	*p
«SG alone» (n=45)				
Hypertension	17/45 (37.8%)	7/45 (15.6%)	9/45 (20%)	0.02
SAS	25/45 (55.6%)	7/45 (15.6%)	8/45 (17.8%)	<0.001
T2DM	13/45 (28.9%)	4/45 (8.9%)	7/45 (15.6%)	0.03
Dyslipidemia	12/45 (26.7%)	4/45 (8.9%)	6/45 (13.3%)	0.042
GERD	5/45 (11.1%)	6/45 (13.3%)	15/45 (33.3%)	0.008
«SG and SG + Re-SG and SG + GBP» (n=55)				
Hypertension	19/55 (34.5%)	8/55 (14.5%)	10/55 (18.8%)	0.006
SAS	27/55 (52.8%)	8/55 (14.5%)	9/55 (16.4%)	<0.001
T2DM	14/55 (25.5%)	5/55 (9.1%)	8/55 (14.5%)	0.009
Dyslipidemia	12/55 (21.8%)	4/55 (7.3%)	7/55 (10.9%)	0.049
GERD	6/55 (10.9%)	7/55 (12.7%)	15/55 (27.3%)	0.013

*Chi² test; SG: Sleeve Gastrectomy; Re-SG: Revisional Sleeve Gastrectomy; GBP: Gastric Bypass; GERD: Gastro-Oesophageal Reflux Disease; SAS: Sleep Apnea Syndrome; T2DM: Type 2 Diabetes Mellitus.

The long-term efficacy of SG on weight loss and reduction of co-morbidities [23,24], the technical ease of the surgical procedure and the absence of malabsorption explain the major interest shown by French bariatric surgeons for this technique. This should hypothetically lead to a decrease in obesity related mortality for patients who had SG, as it has been demonstrated after GBP [18]. The mechanisms of the effectiveness of SG are still incompletely understood. The efficiency of SG is related to gastric volume reduction, as was shown by the effectiveness of a Re-SG when SG failure was due to an expansion of the gastric tube [25,26]. The SG also has a hormonal effect, because it is responsible for a decrease in the secretion of the orexigenic hormone "ghrelin" [27]. If the resolution of hypertension is directly related to weight loss after SG, the disappearance of T2DM is not only related to weight loss but also has a hormonal origin [23,24]. It may be that rapid gastric emptying may allow ingested material to proceed to the ileumun digested and there stimulate endocrine cells ecretion of GLP-1. Different reviews underlined metabolic changes and diabetes remission after GBP which stimulate endocrine cells ecretion of GLP-1 [28-31].

The risk of complications after SG is low [32,33]. In particular, we had 5.5% postoperative complication rate, 5.5% late complication rate, and these results underlying the fact that we have achieved this intervention in patients with high BMI. Three patients (5.5%) presented a trocar site hernia. It occurred at the site of extraction of the resected stomach, on a 15mm trocar. Nevertheless, at the trocar site, aponevrosis was systematically closed by non-absorbable sutures. Weight loss coupled with nutritional changes and large trocar site contributed to the development of these incisional hernias. The complication rate after SG in our series is consistent with those observed in the literature [19,33,34] ranging from 3.2% to 14.3%, with a mortality rate ranging from 0% to 3.3% and zero in our study. The most common complication is the occurrence of proximal gastric fistulas with varying frequency, according to a review by Braghetto et al. [19], ranging from 0% to 8% (mean: 1.5%±2.1%). While the distal leaks are less frequent and ranging from 0% to 6.6% of cases (mean: 0.5%±1.2%) [19,23,35-40]. A leak rate of 2/55 patients may seem high, but this shows data at the beginning of our experience. Our leak rate for the past four years is less than 1%. Stroh et al. [41] Reported recently that leaks after SG decrease with the learning curve. For some authors, the use of a larger calibration boogie size can reduce the incidence of fistula [42-45].

In our study, 8 years after SG, the frequency of GERD has tripled. This increase may seem high, but it is well controlled by PPI. No case of GERD has required the conversion of a SG to GBP because of the ineffectiveness of medical treatment with PPI. The physiopathological mechanism involved in GERD after SG is certainly related to anatomical changes at the esophago-gastric junction that alter the anti-reflux mechanism of the cardia [46]. The fibers of the lower esophageal sphincter can be transected during SG, with consequent hypotension of the lower esophageal sphincter [46]. In addition, the new gastric tube has a volume of less than 200ml [23], and an intact pylorus, results in increase of intra gastric pressure causing GERD and dilatation of the cardia. Thus Lazoura et al. [46] suggested that the anatomical changes caused by the SG led to this complication. Finally, our outcomes considering SAS have limitations because patients were not assessed using polysomnography leading to over evaluate rate of remission of SAS.

Our study has some limits: it is retrospective and non-randomized. Changes in quality of life, vitamin and iron deficiencies have not been evaluated. The small size of our series is due to the recent nature of the SG [14,23,24,32, 33,36,39,47]. Our results are comparable to other published studies [9,48]. Prospective randomized studies with long follow-up comparing the SG to GBP are needed in order to better assess the risk-benefit ratio.

Conclusion

At 8-year post-SG, weight loss was efficient according to Reinhold's criteria [16], and few surgical complications were reported in the short and long term. In case of insufficient weight loss after SG, patients may benefit from a second surgery: GBP may be proposed in the absence of an expansion of the gastric tube, and Re-SG may be an option if dilatation of the gastric tube is evidenced. Weight regain between 2 and 8 years after SG also suggests strengthening patients' compliance with lifestyle changes and regular physical activity in the

long term. This can improve and sustain the effectiveness of the SG.

Ethical 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 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent

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

Contributors

JMC performed the research, contributed to the design of the study, draft the article, revised the article content. NS and RD interpreted the data and draft the article. YB interpreted the data. RR and CB contributed to the design of the study. RC contributed to the design of the study, revised the article content. Finally all authors approved the version to be published.

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