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Original article

The effect of residual gastric antrum size on the outcome of laparoscopic sleeve gastrectomy: a prospective randomized trial

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Abstract

Background: Laparoscopic sleeve gastrectomy (LSG) is gaining popularity worldwide as a definitive bariatric procedure. However, there are still some controversial issues associated with the technique, one of which is the size of the residual antrum. Objectives: The aim of this prospective randomized trial is to study the effect of the size of the residual gastric antrum on the outcome of LSG. Settings: University-affiliated hospital.

Methods: Between November 2009 and August 2013, 113 morbidly obese patients submitted for LSG were randomized into 2 groups, namely antral preserving-LSG (AP-LSG) and antral resecting-LSG (AR-LSG), depending on the distance from the pylorus at which gastric division begins. In the AP-LSG group, the distance was 6 cm from the pylorus and included 58 patients, whereas the distance was 2 cm in the AR-LSG group and included 55 patients. The follow-up period was at least 12 months. Baseline and 6 and 12 month outcomes were analyzed including assessments of the percent excess weight lost (%EWL), reduction in BMI, morbidity, mortality, reoperations, quality of life, and co-morbidities.

Results: Both groups were comparable regarding age, gender, body mass index (BMI), and co-morbidities. There was one 30-day mortality, and there was no significant difference in the complication rate or early reoperations between the 2 groups. Weight loss was significant in both groups at 6 and 12 months. At 12 months, weight loss was greater in the AR-LSG than in the AP-LSG group, but with was no significant difference between the 2 groups at 12 months (%EWL was 64.2% in the AP-LSG group and 67.6% in the AR-LSG group; $p > .05$). The resolution/improvement of co-morbidities, quality of life outcome and the overall prevalence of co-morbidities were similar.

Conclusions: LSG with or without antral preservation produces significant weight loss after surgery. The 2 procedures are equally effective regarding %EWL, morbidity, quality of life, and amelioration of co-morbidities. (Surg Obes Relat Dis 2015;▮:00–00.) © 2015 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords: Bariatric surgery; Morbid obesity; Residual antrum; Sleeve gastrectomy

The problem of obesity has reached epidemic proportions not only in Western countries but worldwide as well [1,2]. Bariatric surgery, meanwhile, has emerged as the only effective and durable treatment of morbid obesity. Bariatric surgery consistently induces durable weight loss and reliably causes the improvement or remission of co-morbid diseases such as diabetes mellitus and hypertension [3–10]. Laparoscopic sleeve gastrectomy (LSG), first described as the initial stage of a 2-stage biliopancreatic diversion-duodenal switch (BPD-DS), is emerging as a popular operation for the treatment of morbid obesity, with acceptable morbidity and long-term weight loss compared with the laparoscopic Roux-en-Y gastric bypass (LRYGB)

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and adjustable gastric band (AGB) [11–13]. The advantages of this procedure include the lack of an intestinal bypass, thus avoiding gastrointestinal anastomoses, metabolic derangements, and internal hernias, shorter operating times, and no implantation of a foreign body [14]. LSG has a favorable complication profile, making it an especially attractive procedure for higher-risk patients [14–16]. The technique has been adopted by a large number of surgeons, influenced heavily by the misconception that it is a simple and easy operation. In recent years, the number of procedures performed has risen exponentially, reaching 18,098 cases in 2008, which is a figure that has undoubtedly been exceeded in the years since [13].

However, the many points of controversy regarding the procedure create a range of possibilities without consensus: the size of the bougie used as a calibrator, the distance from the pylorus to the first line of section, the section shape at the gastroesophageal junction, the necessity and options available for reinforcing the staple line, and the routine use of intraoperative seal testing. All of these issues are constantly debated among the most experienced authors [17–21].

The aim of this prospective randomized trial is to address one of these controversial issues, which is the effect of the size of the residual gastric antrum on the outcome of LSG for morbidly obese patients regarding weight loss, complications and the resolution of co-morbidities.

Methods

Between November 2010 and August 2013, 113 morbidly obese patients who matched the inclusion criteria were submitted for LSG at the Gastroenterology Surgical Center at Mansoura University and enrolled in the trial. This prospective randomized study was carried out after the approval of the Institutional Research and Ethical Committee and was conducted according to the principles of the Declaration of Helsinki. The study was registered at the clinical trials registry of the National Institutes of Health (ClinicalTrials.gov ID. NCT01846637). Written informed consents were signed by all participating patients after explaining the advantages and complications of the surgical procedure. The change in lifestyle and the need for life-long follow-up of surgical procedures were emphasized.

In our weight management program, patients were accepted for surgery if they satisfied the guidelines of the Society of American Gastroenterological Surgeons [16] [body mass index (BMI) $\geq$40 kg/m^2 or BMI $\geq$35 kg/m^2 with at least one co-morbidity associated with obesity (type 2 diabetes, hypertension, dyslipidemia, obstructive sleep apnea), age between 18 and 60 years, and failure of conservative treatment over 2 years]. Exclusion criteria included (1) BMI $>$60 kg/m^2, (2) poorly controlled significant medical or psychiatric disorders, (3) active alcohol or substance abuse, (4) active duodenal/gastric ulcer disease, (5) difficult to treat gastroesophageal reflux disease (GERD) with a large hiatal hernia, (6) previous major gastrointestinal surgery, and (7) diagnosed or suspected malignancy.

Only the data of patients who had completed their 3-, 6-, and 12-month follow-up visits at the time of the study were further analyzed. Data collected included demographic characteristics, operative time, length of stay, postoperative complications, and weight loss.

Randomization

Patients were randomized into 2 groups depending on the distance from the pylorus at which the gastric division begins. In group A (antral preserving-LSG [AP-LSG]), the distance was 6 cm, and in group B (antral resecting LSG [AR-LSG]), the distance was 2 cm. Eligible patients were randomized into one of 2 groups using sealed opaque envelopes containing computer-generated random numbers. Envelopes were drawn and opened at the time of anesthesia induction in the operating room by a nurse not otherwise engaged in the study. Using this strategy, a total of 115 patients were eligible and randomized. Two patients were excluded because of a huge and heavy left liver lobe in one patient (he did not receive surgery), and one patient had a preoperative intragastric balloon 4 weeks before LSG. A total of 113 patients were ultimately included in the study.

All of the patients had a thorough preoperative evaluation by an internal disease specialist, a dietician, and a surgeon. Standard preoperative and metabolic blood investigations were carried out on all patients in addition to upper gastrointestinal endoscopy and abdominal ultrasound examination. A psychiatric evaluation was obtained if considered necessary. Peptic ulcer disease and *Helicobacter pylori* infection were treated before surgery if diagnosed during the initial assessment. Cholecystectomy was performed at the time of bariatric surgery only if gallstones were detected by abdominal ultrasound. All patients were given a low-calorie, high-protein diet for at least 2 weeks before surgery. An anesthetic review was arranged before surgery. Each patient was admitted the night before surgery, and subcutaneous low-molecular-weight heparin and elastic stockings were used for deep vein thrombosis prophylaxis. Chemoprophylaxis was administered with 1.5 g of cefuroxime upon induction of anesthesia.

Surgical technique

All patients were operated on using standardized operation techniques. In all patients, we used a 38-Fr bougie along the lesser curvature for calibration of the gastric tube. A Harmonic Scalpel™ (Ethicon Endo-Surgery, Cincinnati, OH) was used for freeing the greater gastric curvature, and all stapling was performed using an Echelon 60 Compact

Linear Cutter™ (60 mm), loaded with gold cartridges, which delivers 6 rows of stapling clips (Ethicon Endo-Surgery, Cincinnati, OH, USA). The longitudinal resection of the stomach began at 6 cm from the pylorus in the AP-LSG group and at 2 cm in the AR-LSG group. The distance was measured accurately (using a tape measure) from the pylorus, which was identified by the prepyloric vein of Mayo and by the thickness of the sphincter. The staple line was not reinforced in any patient, but a few stitches were made to control the bleeding of the staple line when necessary. Hiatal hernias were explored and were repaired if present, with posterior closure of the crura using non-absorbable stitches. Synchronous cholecystectomy was performed for patients with gallbladder stones discovered on preoperative abdominal ultrasound examination.

A contrast swallow test was performed the next day, and patients were allowed oral liquids if no leaks were found. The patients were usually discharged the same evening or the next day with a follow-up appointment 10 days later. Proton pump inhibitors (PPI) as well as long-term oral supplements (multivitamins, iron and calcium) were given to all patients. At the first outpatient review (at the 10th postoperative day), the patients were again seen by the surgeon and the dietician and were encouraged to start a soft diet for one week then a pureed diet for another week and subsequently, diet is changed to regular diet as tolerated. Subsequent appointments were at 1, 3, 6, and 12 months.

Assessment

Patients were followed 4 times during the first post-operative year and at yearly intervals thereafter. Anthropometric parameters, co-morbidities, clinical parameters including blood samples, and QOL using the Gastrointestinal Quality of Life Index (GIQLI) were routinely assessed [22]. Weight loss was assessed using BMI and the percent of excess weight loss (%EWL). Excess weight was calculated as the amount of initial weight in excess of the upper limit of the normal weight range estimated at the BMI of 25 kg/m^2 for a given patient height. Percent excess weight loss (%EWL) was defined as [(operative weight – follow-up weight) / (operative weight – ideal weight)] × 100, with ideal weight based on a body mass index (BMI) of 25 kg/m^2.

Co-morbidities were defined using international standard criteria. Remission or the improvement of co-morbidities was assessed according to the clinical, biochemical, hormonal and radiological documentation. The improvement of co-morbidities was defined as a reduction of medication taken and improvement of the symptoms or blood test specific to the co-morbidity.

Perioperative complications were defined using a standardized complication classification system, which has been shown to be very reliable [23]. In brief, the Clavien-Dindo classification system was used for grading the severity of complications [23].

Statistical analysis

The primary endpoint was weight loss expressed as the % of excess weight loss (%EWL). Considering a 15% mean failure rate for the antrum-preserving LSG treatment, an appropriate sample size was calculated based on the assumption of a difference of 10% in %EWL between the 2 groups to improve the success rate from 85% to 95%. The level of power for the study was set at 80% with a 5% significance level.

Categorical variables were described using absolute values and percentages. Comparisons of categorical variables between groups were conducted using the $\chi 2$ test, and lower incidences were compared using Fisher's exact test. Continuous variables were reported as the mean ± SD. Differences between groups in normally distributed continuous variables were tested using the independent samples t test, and the Mann-Whitney U test was used for non-normally distributed variables. Continuous variables were compared within groups with ANOVA with the post hoc Tukey HSD test for specific comparisons. In all of the tests used, P values less than .05 were considered significant. All calculations were performed with SPSS (version 17.0, SPSS Inc., Chicago, IL).

Results

A total of 126 morbidly obese patients were admitted to the hospital for LSG during the study period and were evaluated for eligibility for the study. Twelve patients were not enrolled in the study, including 7 patients who were not eligible for the study (2 patients had large hiatal hernias, 2 patients were older than 65 years, 2 patients had a previous major upper abdominal surgery, one was suspected of malignancy), 4 patients refused to participate in the study, and one patient had previously received treatment with an inserted intragastric balloon. A total of 114 patients were randomized; 59 patients were assigned to the AP-LSG group (beginning of gastric section 6 cm from pylorus) and 55 patients to the AR-LSG group B (2 cm from pylorus). One patient from the AP-LSG group was excluded because he had a huge heavy left liver lobe that was discovered upon exploration. The remaining 113 patients underwent the intended procedure. The follow-up rates for the 6-month visit were 100% and 94% for the AP-LSG group and AR-LSG group, respectively, and the rates for the 12-month visit were 97% and 94% for the AP-LSG group and AR-LSG group, respectively.

The 2 groups were similar in terms of sex distribution, age, weight, BMI, and QOL (Table 1). The rate of co-morbidities, such as diabetes, hypertension, hyperlipidemia, obstructive sleep apnea syndrome, and others, was almost

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Table 1
Preoperative demographic data, anthropometric measures, co-morbidities and quality of life in the 2 groups

	AP-LSG (n = 58)	AR-LSG (n = 55)
Age in years, mean ± SD	35 ± 3.9	37 ± 4.3
Female to male ratio	40/18	38/17
Weight in kg, mean ± SD	131.7 ± 17.7	128.3 ± 15.5
BMI in kg/m2, mean ± SD	44.6 ± 5.4	45.1 ± 5.9
Hypertension, n (%)	17 (29.3)	14 (25.4)
Diabetes, n (%)	8 (14.5)	5 (9.1)
Dyslipidemia, n (%)	18 (31)	17 (30.9)
OSAS, n (%)	6 (10.3)	7 (12.7)
GERD, n (%)	12 (20.9)	10 (18.2)
Back/joint pain, n (%)	15 (25.9)	10 (18.2)
GIQLI score, mean ± SD	97.3 ± 18.7	98.6 ± 19.3

AP-LSG = Antral preserving laparoscopic sleeve gastrectomy; AR-LSG = Antral resecting laparoscopic sleeve gastrectomy; BMI = Body mass index; OSAS = Obstructive sleep apnea syndrome; GERD = Gastroesophageal reflux disease; GIQLI = Gastrointestinal quality of life index.

P value was not significant in all items.

identical in the 2 groups (Table 1). All procedures were completed laparoscopically without the need for conversion in any patient. The mean operative time was similar in the 2 groups (83.5 ± 45.2 minutes in the AP-LSG group versus 91.2 ± 42.6 minutes in the AR-LSG group; $P = .153$). The median length of hospitalization after the operation was 3.0 ± 3.5 (1–9) days in the AP-LSG group versus 5 ± 12.6 (range 1–21) days in the AR-LSG group ($P > .05$). Additional operations were performed in 5 of 58 patients in the AP-LSG group and 3 of 55 patients in the AR-LSG group ($P = .32$). Among these additional surgeries, the main operations were cholecystectomies (3 in the AP-LSG group and 2 in the AR-LSG group), hiatal hernia repair with cruroplasty (1 in the AP-LSG group and 1 in the AR-LSG group), and umbilical hernia repair (1 in the AP-LSG group).

One mortality was recorded in the AR-LSG group on the 8th postoperative day, due to pulmonary embolism. Table 2 shows the perioperative complication rate (<30 days) and the complications stratified into minor/major complications according to the Clavien-Dindo classification method. Early (<30 days) morbidity was 13.8% (n = 8) in group A and 16.4% (n = 9) in the AR-LSG group ($P > .05$). There was no significant difference in the reoperation rate between the study groups ($P > .05$). There were no 30-day readmissions because all of the major complications were diagnosed during the initial hospitalization.

There was a significant weight loss at 6 months and at 12 months in both groups. In AP-LSG patients, the weight loss at 12 months was from 131.7 ± 17.7 to 90.9 ± 6.5 kg compared with the weight loss in AR-LSG LRYGB patients, which was from 128.3 ± 15.5 to 86.7 ± 4.9 kg. At 6 months, there was a statistically significant difference in weight loss, excess BMI loss, and % of EWL in favor of AR-LSG with a *P* value < .05 (Table 3). However, there was no difference regarding weight loss or %EWL between the 2 groups after 12 months (Table 3).

The rate of co-morbidities improved dramatically in both groups at 6 months and 1 year after the operation. Table 4 displays the percentage of patients who were cured or showed improvement in their co-morbidities. There was no statistically significant difference in remission or improvement of co-morbidities 6 and 12 months after surgery between the AP-LSG and AR-LSG groups except for a greater decrease in dyslipidemia after AR-LSG at 12 months (Table 4).

The QOL assessed at 6 and 12 months was equal between patients undergoing AP-LSG and AR-LSG, with 125 and 123 points, respectively, at 12 months (NS). We observed no significant difference between the 2 groups in nausea and vomiting scores at 12 months. Patients from both groups experienced a significant improvement in QOL compared with baseline ($P < .05$) and even exceeded that of healthy individuals who reach a score of 121 points ($P < .01$) [22].

Discussion

LSG is emerging as a popular operation for the treatment of morbid obesity, with acceptable morbidity and long-term weight loss compared with other procedures [24,25]. Recently, the number of procedures performed has risen exponentially all over the world and has been adopted by a large number of surgeons due to its simplicity [26,27]. However, the LSG technique is not fully standardized and there are still many controversial technical issues. One of these issues is the beginning of gastric resection. Some

Table 2
30-day postoperative complications.

Complication	AP-LSG (n = 58)	AR-LSG (n = 55)
Mortality	0	1
Major		
Leakage	0	1
Bleeding	2	1
Minor		
Dysphagia	1	0
Intraluminal bleeding	1	0
Bleeding staple line	1	0
Intraperitoneal infection	0	1
Wound infection	3	3
Wound hematoma	0	1
Pneumonia	0	1
Complication grade according to Clavien-Dindo classification		
I	2	2
II	2	3
III	2	1
IV	2	2
V	0	1
TOTAL; n (%)	8 (13.8)	9 (16.4)

Table 3
Weight loss at 6 and 12 months in the 2 groups

	Before surgery		Outcome at 6 months			Outcome at 12 months		
	AP-LSG (n = 58)	AR-LSG (n = 55)	AP-LSG (n = 57)	AR-LSG (n = 55)	*P*	AP-LSG (n = 54)	AR-LSG (n = 52)	*P*
BMI [kg/m^2]	44.6 ± 5.4	45.1 ± 5.9	39.0 ± 3.8	33.4 ± 5.1	.02	35.9 ± 4.5	32.3 ± 2.4	.143
Weight [kg]	131.7 ± 17.7	128.3 ± 15.5	109.0 ± 6.3	95.1 ± 5.6	.04	90.9 ± 6.5	86.7 ± 4.9	.381
%EWL [%]			50.6	57.1	.04	64.6	67.6	.705

AP-LSG = Antral preserving laparoscopic sleeve gastrectomy; AR-LSG = Antral resecting laparoscopic sleeve gastrectomy; BMI = Body mass index; % EWL = percentage of excess weight loss.

Weight loss was expressed as change in BMI and % Excess Weight Loss (%EWL), with the calculation of ideal weight as that equivalent to a BMI of 25 kg/m^2.

surgeons prefer antral resection and beginning stapling 2 cm from pylorus, [21,25,28] whereas others start 6 cm from the pylorus, thereby preserving the gastric antrum [21,29–34].

Supporters for antral resection claim that stapling within 2 cm of the pylorus adds more restriction and may contribute to better weight loss [25]. The mechanism of action of the sleeve gastrectomy is believed to involve a combination of gastric restriction, hormonal effects, and changes in gastric motility and eating habits [35]. Despite this clearly multifactorial mechanism, the size of the restriction performed is the most significant factor for weight reduction and maintenance. The resulting gastric remnant is reduced to < 50cc volume but functions normally; most foods can be consumed, albeit in small amounts, and gastric emptying is normal [28]. Moreover, the antrum tends to enlarge with time and the increased volume may contribute to weight regain [36].

On the other hand, advocates of antral preservation see that leaving the antrum may reduce distal gastric obstruction and subsequently reduce the risk of proximal leak at the gastroesophageal junction [19,20,37]. The main cause of fistulas in this area, as shown by Yehoshua, is high intraluminal pressure combined with low gastric tube compliance [38]. The antrum is thick relative to other gastric areas and seromuscular disruption with stapling may increase the incidence of staple line leaks. Stapling the antrum (the thickest part of the stomach) requires appropriate endo-stapler cartridge use (such as a 4.8 mm). Even so, occasionally, bleeding may be seen from suboptimal staple line integrity. Finally resecting the antrum may not reduce the total stomach capacity.

Michalsky et al. studied the effect of antral resection on gastric emptying using gastric emptying scintigraphy to determine the evacuation half-life and food retention in the 90th minute of the test both before the operation and 3 months afterward. They found that differences in the average values of weight, BMI, or %EWL between the 2 groups were not statistically significant. However, they concluded that even after a radical resection of the pyloric antrum, the physiologic stomach evacuation function can still be preserved [39].

Few studies tried to address the effect of antral resection on the clinical outcome of LSG. Recently a prospectively randomized trial studied this issue and found that antral resection is associated with better weight loss without increasing the morbidity [40].

In this work, we tried to address the lack of consensus between the 2 surgical techniques by implementing a randomized controlled trial comparing antral preservation and antral resection. According to our results, we found no difference between the 2 techniques in terms of weight loss, complications, resolution of co-morbidities, and quality of life. Weight loss was better in the antral resection group at 6 months, but at 12 months, this difference disappeared. We have no explanation for this difference in weight loss at 6 and 12 months but we observed a higher incidence of

Table 4
Resolution of co-morbidities after 6 and 12 months in the 2 groups

	Outcome at 6 months			Outcome at 12 months		
	AP-LSG (n = 57)	AR-LSG (n = 55)	*P*	AP-LSG (n = 54)	AR-LSG (n = 52)	*P*
Δ Hypertension, n (%)	4/17 (23.5%)	3/14 (21.4%)	NS	6/17 (35.3%)	3/13 (23.1%)	NS
Δ Type 2 diabetes, n (%)	5/8 (62.5%)	3/5 (60%)	NS	6/8 (75%)	3/5 (60%)	NS
Δ Dyslipidemia, n (%)	2/18 (11.1%)	2/17 (11.7%)	NS	4/17 (23.5%)	5/17 (29.4%)	NS
Δ OSAS, n (%)	4/6 (67%)	5/7 (71.4%)	NS	4/6 (67%)	4/5 (80%)	NS
Δ GERD, n (%)	2/12 (16.7%)	1/10 (10%)	NS	2/12 (16.7%)	1/10 (10%)	NS
Δ Back/joint pain, n (%)	3/15 (20%)	3/10 (30%)	NS	6/15 (40%)	7/10 (70%)	.029

AP-LSG = Antral preserving laparoscopic sleeve gastrectomy; AR-LSG = Antral resecting laparoscopic sleeve gastrectomy; OSAS = obstructive sleep apnea syndrome; GERD = Gastroesophageal reflux disease.

Δ denotes remission/improvement of patients with the diagnosis of co-morbidity in relation to the baseline prevalence.

nausea/vomiting among AR-LSG group in the early postoperative period, which may be a contributing factor to this difference.

LSG involves removing the majority of the stomach, leaving behind only a sleeve of stomach, thus restricting the amount of food that can be ingested and resulting in a significant weight loss. According to this mechanism of action of LSG, it was expected to have a greater weight loss after more restriction in patients having AR-LSG than those having AP-LSG. However, this was not the case in this study. We have no definite explanation for this but other contributing factors such as reduction of ghrelin hormone level and rapid gastric emptying may play a role. A contributing factor may be the reduction in serum levels of the hunger-stimulating hormone, ghrelin, and consequent increased satiety that result from removal of a great part of the fundus of the stomach, which is the predominant area of human ghrelin production [31,41].

Rapid gastric emptying was seen after LSG by Melissas et al. [42]. Contributing factors supporting rapid gastric emptying include alterations in the contractility of the proximal stomach, the absence of receptive relaxation after LSG, the resection of the fundus containing the largest amount of ghrelin cells, and possible antral distention, which leads to changes in the entero-hypothalamic axis.

In this study, leakage occurred in one patient in the antral resection group, but the difference in the incidence of leak was not statistically significant between the 2 groups. The 2 techniques are nearly equal, and the choice between the 2 techniques is left to the surgeon's preference. However, there are many limitations to this study: (1) the number of patients included is small, and the follow-up period was short; (2) the problem of weight regain was not studied in this trial; and (3) we did not compare the 2 techniques in super-obese patients with a BMI over 50 kg/m^2. We are currently investigating these points.

Conclusion

We were able to show that AP-LSG and AR-LSG are equally efficient regarding weight loss, reduction in comorbidities, and increasing QOL at 1 year after surgery. Therefore, we believe that both LSG techniques are valuable surgical alternatives for selected patients with morbid obesity. Long-term follow-up data and larger studies are needed to confirm these results, particularly in super-obese patients.

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