Three-year outcomes of laparoscopic sleeve gastrectomy using a 36 Fr bougie

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Context
Laparoscopic sleeve gastrectomy (LSG) is a bariatric procedure that causes weight loss by reducing gastric capacity. The evaluation of the effectiveness of this procedure is in constant research.
Aim
The aim of this study was to evaluate the 3-year outcomes of LSG and its effect on preoperative diabetes mellitus (DM) and hypertension (HTN) and to develop the de-novo gastroesophageal reflux disease (GERD) using a 36 Fr bougie size.
Settings and design
This is a prospective case series.
Patients and methods
Seventy-seven patients were included in the study that underwent LSG using a 36 Fr bougie. The preoperative BMI was recorded. The postoperative BMI and percentage excess weight loss were recorded at 3, 6, 12, 24, 36 months. Furthermore, the postoperative status for DM and HTN were noticed with the development of de-novo GERD symptoms.
Statistical analysis
Continuous variables were expressed as mean±SD. Categorical variables were expressed as frequency and percentage.
Results
The mean±SD BMI preoperatively was 43.13±3.77 kg/m^2. The mean±SD BMI after 3, 6, 12, 24, and 36 months was 37.19±3.28, 32.9±2.91, 29.23±2.75, 27.86±2, and 26.6±1.5 kg/m^2, respectively. The mean percentage excess weight loss after 3, 6, 12, 24, and 36 months was 34.62±1.36, 55.94±5.88, 68.53±5.87, 72.08±4.92, and 74.99±4.99%, respectively. Of patients having type II DM, 70.3% showed dramatic improvement. In addition, with respect to HTN, 64.5% of the patients having HTN showed improvement. After the procedure, 17 (22.1%) patients suffered from GERD after 1 year, eight (10.4%) after 2 years, and four (5.2%) after 3 years.
Conclusion
LSG is an effective operation in weight loss and in the management of type II DM and HTN. However, long-term studies (>6 years) should be conducted to justify the maintenance of weight loss and the alleviation of the symptoms of GERD.

Keywords:
gastroesophageal reflux, laparoscopic sleeve gastrectomy, medium-term outcome, morbid obesity, sleeve gastrectomy

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Introduction

Obesity has gradually become a public health problem worldwide under the prevailing sedentary lifestyle. According to the estimate of the WHO, there were ~700 million obese people in 2015 [1].

Laparoscopic sleeve gastrectomy (LSG) is a bariatric procedure that induces weight loss, mainly by reducing the gastric capacity and changing hormone secretion to limit food intake and appetite. It was initially performed as the first part of a two-step approach in morbidly obese patients (BMI>50 kg/m^2) [2].

Due to its effectiveness in weight loss and improvement of comorbidities, LSG has become one of the most-common surgical procedures aimed at treating morbid obesity and its associated comorbidities. LSG was verified in the International Consensus Summit of Sleeve Gastrectomy in 2007, 2009, and 2011 as a safe and feasible primary bariatric procedure [3]. However, the number of studies reporting medium-term and long-term results are still not enough.

The objective of this study was to evaluate the outcomes of a 3-year follow-up for LSG in the management of obese patients regarding weight loss, associated comorbidities, and safety.

Patients and methods

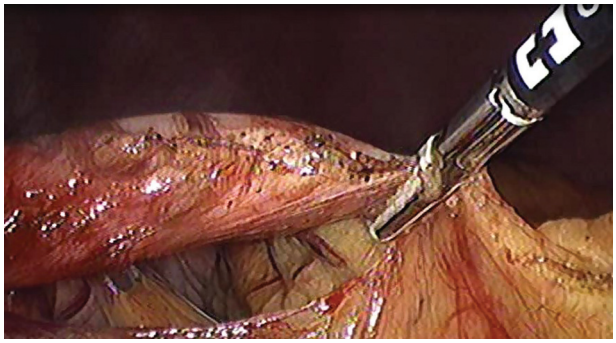
The study included 77 patients that presented in the outpatient clinic for bariatric surgery to achieve weight loss. The study took place between December 2011 and November 2016 with a minimum follow-up of 36 months for each patient. All patients were bulk eaters and were scheduled for LSG. The inclusion criteria for laparoscopic bariatric surgery were based on those approved by the Society of American Gastrointestinal and Endoscopic Surgeons Guidelines for Clinical Application of Laparoscopic Bariatric Surgery (medically uncontrolled, age between 18 and 65 years, and BMI $>30\,kg/m^2$ with obesity-related comorbidities) [4] and were approved by the Ethical Committee of the Faculty of Medicine, Ain Shams University. Each patient was evaluated by a multidisciplinary team who discussed the procedure, the risks and benefits with the patient, and the possible postoperative complications before acquiring the patient's consent.

All patients were followed up in the outpatient clinic for their BMI, excess weight loss (EWL), level of HbA1c and insulin need (for diabetic patients), blood pressure, and symptoms of gastroesophageal reflux disease (GERD).

Surgical technique

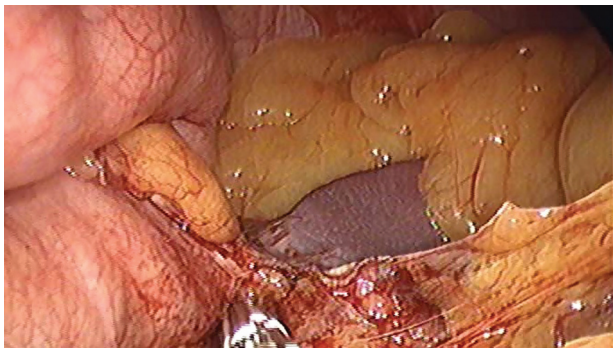
All procedures were successfully completed laparoscopically. All patients had established IV access, nasogastric and urinary catheter tube insertion, and application of compression stockings. After establishment of pneumoperitoneum, five trocars were inserted: a 10-mm port for the camera, a 12-mm port for the left working port, a 5-mm port at the left midclavicular line as the right working port, another 5-mm port at the left lateral abdominal wall for retraction by the assistant, and a 5-mm port for the liver retractor that was inserted through a subxiphoid skin puncture for exposure of the angle of His. The greater omentum (Fig. 1) and short gastric arteries (Fig. 2) were ligated and dissected by using 5-mm laparoscopic Ligasure (Covidien, Norwalk, Connecticut, USA) system, starting at 6 cm from the pylorus (the second branch of the right gastroepiploic artery) till the angle of His away from the sling fibers at the cardioesophageal junction and the gastroepiploic vessels. The posterior wall of the stomach was dissected from the pancreatic adhesions if any were present (Fig. 3). After the stomach was completely mobilized, a bougie of size 36 Fr was placed along the lesser curvature of the stomach, directed toward the pylorus as a calibrator before starting the gastric resection. A vertical transection of the stomach was carried out (Fig. 4) with 5–6 firings of a 60-mm linear stapler (Endo GIA, Covidien). The height of the firing stapler was determined according to the thickness of the gastric tissues, using a green (4.1 mm) or black (4.4 mm) stapler near the antrum and a blue (3.5 mm) stapler for the rest of the gastric resection. The trocar was removed during the introduction of the green cartridge and reinserted to complete the rest of the firings. During the gastric transection, a minimal of 1-cm margin of gastric fundus from the angle of His must be left to avoid

Figure 1



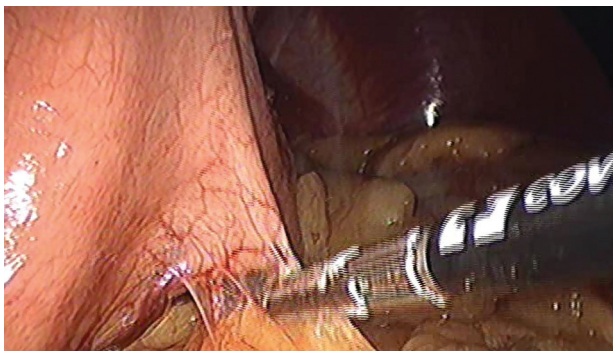
Starting dissection 6 cm from the pylorus separating the greater omentum.

Figure 2



Short gastric vessels' sealing and cutting.

Figure 3



Dissection of the posterior gastric adhesions.

a critical vascular area in the cardioesophageal junction. An intraoperative leak test was carried out by methylene blue to test for staple line integrity. The resected stomach was extracted and subhepatic drain applied (Fig. 5). The fascial defect was closed with a vicryl suture.

All patients underwent gastrografin swallow on the first postoperative period before sips of clear liquids were allowed. The patients were usually discharged on the second postoperative day. Patients were started postoperatively on soft diet within 2 weeks, progressing to a normal diet by 4 weeks. Standard follow-up included visits to the outpatient clinic at 1, 3, 6 months, 1, 2, and 3 years. The patients' data were recorded including their BMI and %EWL.

Results

The collected data were revised, coded, tabulated, and fed into a PC using the statistical package for the social science (SPSS 20; SPSS Inc., Chicago, Illinois, USA). Data were presented and suitable analyses were carried out according to the type of data obtained for each parameter.

Descriptive statistics:

(1) Mean±SD for numerical data.
(2) Frequency and percentage of non-numerical data.

Analytical statistics:

(1) The analysis of variance (ANOVA) test was used to assess the statistical significance of the difference between the means of more than two study groups.
(2) The post-hoc test was used for comparisons of the means of all possible pairs of groups.
(3) The McNemar test was used to assess the statistical significance of the difference between qualitative variables measured twice for the same study group.

Patients' demographics

The study included 77 patients who underwent LSG and were followed up for up to 3 years between December 2011 and November 2016.

The mean±SD age was 39.88±6.94 years. Out of the 77 patients, 13 (16.9%) patients were men and 64 (83.1%) were women. The mean±SD preoperative weight was 128.09±12.61 kg with a mean±SD BMI of 43.13±3.77 kg/m^2.

Patients' comorbidities

Out of the 77 patients included in the study, 27 (35.1%) patients suffered from type II diabetes mellitus (DM) and 31 (40.3%) patients suffered from hypertension (HTN).

Operative time and hospital stay

The mean±SD operative time was 108.05±11.15 min and the mean±SD period for inpatient hospital admission was 2.64±2.49 days.

Postoperative complications

Only five (6.5%) patients had postoperative complications. Two patients had postoperative leak: one of them was reoperated by the open approach with repair of the disrupted staple line, and the other was managed conservatively. Three patients had postoperative bleeding: one of them required exploration to control bleeding from short gastric vessels and the other two were managed conservatively.

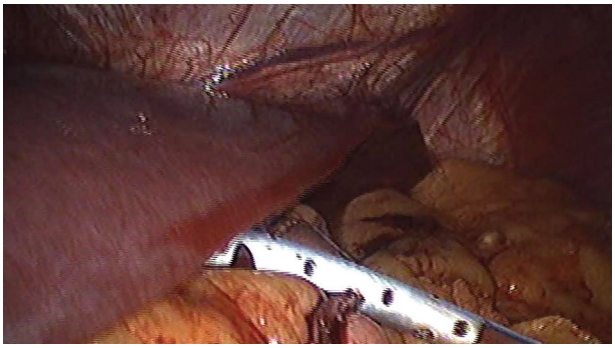
BMI and %EWL follow-up

After 3 months following the LSG, the mean±SD BMI was 37.19±3.28 kg/m^2 and the mean %EWL was 34.62±1.36%. At the 6 months' follow-up, the mean±SD BMI was 32.9±2.91 kg/m^2 and the mean±SD %EWL was 55.94±5.88%. At 1 year's follow-up the mean±SD BMI declined to 29.23±2.75 kg/m^2 and the mean±SD %EWL was 68.53±5.87%. After

Figure 4

Gastric sleeve completed on a 36 Fr bougie.

Figure 5



Subhepatic suction drain inserted.

2 years' follow-up the mean±SD BMI declined to 27.86 ±2 kg/m^2 and the mean %EWL was 72.08±4.92%. After 3 years' follow-up the mean±SD BMI declined to 26.6± 1.5 kg/m^2 and the mean±SD %EWL was 74.99±4.99%. The *P*-value by the ANOVA test for multiple variables was less than 0.001, which was statistically significant, indicating significant weight loss throughout the 3 years following the operation. The post-hoc test was statistically significant between each two variables for both BMI and %EWL throughout the 3 years, indicating significant weight loss till the end of the study. The BMI and %EWL are represented in Figs 6 and 7.

Improvement in DM and HTN

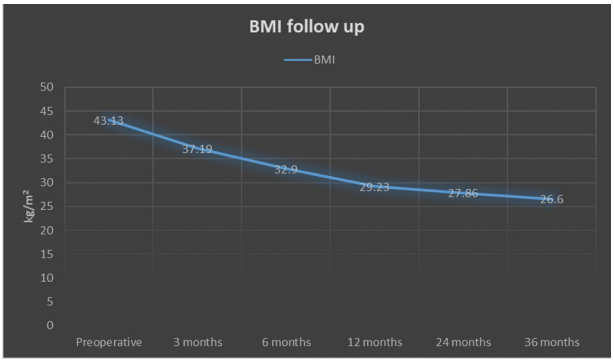
Out of the 27 patients having type II DM, 19 (70.3%) patients showed dramatic improvement in their condition with regression of the disease, as evidenced by the maintenance of the level of HbA1c below 6.5 g% without the use of medications till the end of the study. The percent of patients with DM dropped from 35.1% preoperatively to 10.4% postoperatively, which is found to be statistically significant ($P<0.001$ by using the McNemar test). The difference in the preoperative and postoperative states concerning DM and HTN was shown in (Fig. 8).

Furthermore, with respect to the HTN, 20 patients out of 31 (64.5%) patients having HTN showed improvement in their blood pressure levels, dropping below 140/90 on more than three separate occasions without the use of drugs as compared with the preoperative state. The percent of patients with HTN dropped from 40.3% preoperatively to 14.3% postoperatively, which was statistically significant ($P<0.001$ by using the McNemar test).

Newly developed gastroesophageal reflux disease

All patients included in the study did not suffer from GERD preoperatively. After the procedure, 17 (22.1%) patients suffered from newly developed symptoms of acid reflux after 1 year. During the follow-up period the number of patients with GERD declined to eight (10.4%) after 2 years, and then to four (5.2%) after 3 years. This was considered by the relief of GERD symptoms clinically without the use of proton pump inhibitors for at least 3 months.

Figure 6

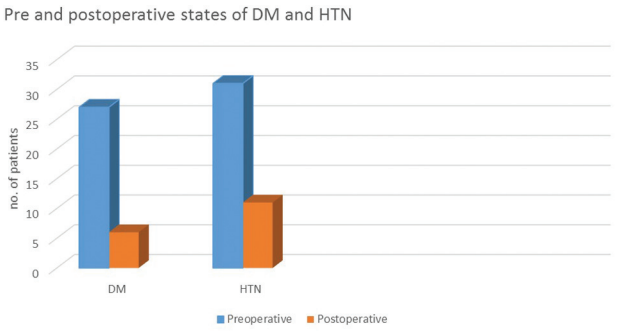


The mean BMI follow-up during the study.

Discussion

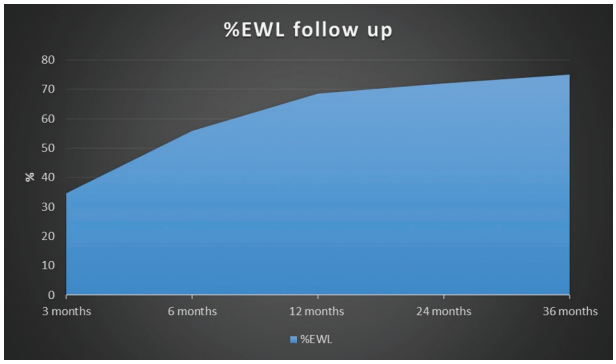
LSG has been gaining popularity as a stand-alone bariatric surgery worldwide since it was introduced in 1988 [3]. The less operative time and lower morbidity and mortality have increased its popularity as a definitive surgery [4]. There have been differences in the procedure from one center to another, including the size of the bougie used in the operation. In addition, few studies have been published concerning the medium-term outcomes after LSG using a standard bougie size throughout the study. In the current study we evaluated the effect of LSG using a 36 Fr bougie on BMI and %EWL, the effect on preoperative type II DM and HTN, and the incidence of newly postoperative

Figure 7



The mean %EWL follow-up during the study. EWL, excess weight loss.

Figure 8



Preoperative and postoperative states of DM and HTN. DM, diabetes mellitus; HTN, hypertension.

GERD after the procedure for a follow-up period of 36 months after the procedure.

The current study included 77 patients who underwent LSG using a 36 Fr bougie with fixation of the surgical team and the surgical procedure.

The mean±SD BMI after 3, 6, 12, 24, and 36 months was 37.19±3.28, 32.9±2.91, 29.23±2.75, 27.86±2, and 26.6±1.5 kg/m^2, respectively. The mean±SD %EWL after 3, 6, 12, 24, and 36 months was 34.62±1.36, 55.94±5.88, 68.53±5.87, 72.08±4.92, and 74.99 ±4.99%, respectively. Some researchers have reported a %EWL after 1 and 2 years of ±62 and ±72%, respectively [5–8]. In a study conducted by Ramos *et al.* [9] for LSG outcomes using a 32 Fr-caliber bougie showed that the mean BMI preoperatively was 40.2 kg/m^2 and after 3, 12, 18, and 24 months it was 32.2, 29.5, 28.2, and 26.9 kg/m^2, respectively. Moreover, in the study done by Pok *et al.* [3], using a 36 Fr bougie, where the BMI preoperatively was 37.3 kg/m^2 (which was relatively low in comparison with the current study), the weight loss outcome at 1, 2, and 3 years showed a mean BMI of 26.3, 25.2, and 25.3, respectively, with mean EWL of 76.0, 79.6, and 77.3%, respectively. This was in agreement with this study indicating comparable results between 32 and 36 Fr bougie size on the effect on weight loss, although the study conducted by Pok and colleagues had a lower preoperative BMI. The *P*-value by using the ANOVA test for multiple variables was less than 0.001, which was statistically significant, indicating significant weight loss throughout the 3 years after the operation. The post-hoc test was statistically significant between any two variables for both BMI and %EWL throughout the 3 years, indicating significant weight loss till the end of the study. This effect could be attributed to the fact that the loss of ghrelin-producing fundus maintain the weight-loss mechanism. However, other studies showed that silent ghrelin-producing cells scattered throughout the GIT can lead to loss of this mechanism in the long run. Thus, this justifies that long-term studies should be carried out (>6 years) to evaluate the efficacy of LSG to maintain the weight loss [10].

Out of the 27 patients having type II DM, 19 (70.3%) patients showed dramatic improvement in their condition with regression of the disease. In the study by Ramos *et al.* [9] all patients (eight patients representing 6.6% of the study patients) with type II DM had remission. This is due to the fact that increased gastric emptying is associated with higher levels of glucagon-like-peptide-1, a glucose-regulating insulin-enhancing agent that has been linked to weight loss and resolution of type II DM [11–15]. In addition, with respect to the HTN, 20 out of 31 (64.5%) patients having HTN showed improvement in their blood pressure levels as compared with the preoperative state. In the study carried by Ramos *et al.* [9], 23 patients had HTN. Of them, 64.3% of patients had normalized their blood pressure (<140/90 mmHg) without medication.

All patients included in the study did not suffer from GERD preoperatively. After the procedure, 17 (22.1%) patients suffered from newly developed symptoms of acid reflux after 1 year. During the follow-up period the number of the patients with GERD declined to eight (10.4%) after 2 years and then to four (5.2%) after 3 years. This was in agreement with the study done by Himpens *et al.* [8] they had 22% incidence of post-LSG GERD after 1 year, which came down to 3% after 3 years; furthermore, in the study conducted by Ramos *et al.* [9] GERD was identified in 22 (18.3%) patients who had received proton pump inhibitors, and in the study done by Pok *et al.* [3] 17% of the patients developed de-novo symptoms of GERD. During sleeve gastrectomy, the critical point is at the angle of His, where the surgeon (for safety reasons) usually staples away from the left crus, which might result in proximal dilatation with 'neofundus' formation. This neofundus causes both weight regain and GERD. In addition, patients with neofundus can experience the effects of relative midstomach stenosis, which causes stasis of food, whereas the growing surface of acid producing mucosa increases acid production. Both conditions are known to cause GERD [16]. Another study by Himpens *et al.* [16] showed that GERD had a biphasic pattern following LSG. The first peak was at the first postoperative year and disappears before the third postoperative year, most likely because of an increased gastric compliance and gastric emptying, and the second peak showed up later on and might be linked with the appearance of a neofundus [10,16].

Conclusion

LSG is an effective operation in weight loss and in the management of type II DM and HTN. The development of de-novo GERD after 1 year was associated by decreased symptoms after 3 years with medical treatment. However, long-term studies (>6 years) should be conducted to justify the maintenance of weight loss and the alleviation of the symptoms of GERD as these two parameters are liable to increase in the long run.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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