The effect of bougie size on the short-term outcome of laparoscopic sleeve gastrectomy

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Background
Obesity is a worldwide epidemic. Laparoscopic sleeve (LS) gastrectomy has recently been identified as an innovative approach to the surgical management of obesity. One of the most debated issues is the size of the bougie used during the procedure. We conducted this study to elucidate a potential difference in the short-term outcome between 40 and 32 Fr bougies.
Objectives
To assess the effect of the size of bougie on the outcome of weight loss and quality of life (QOL).
Design
This was an interventional prospective randomized study.
Study duration
This study was carried out over a 27-month period (from January 2015 to March 2017).
Patients and methods
A total of 48 morbidly obese patients were candidates for LS gastrectomy with the aim to evaluate the effect of using 32 versus 40 Fr bougie on the outcome of laparoscopic sleeve gastrectomy. The patients were randomly divided into two equal groups: group 1 (24 patients), in which laparoscopic sleeve gastrectomy was carried out using 32 Fr bougie, and group 2 (24 patients), where LS gastrectomy was done using 40 Fr bougie. Body weight, BMI, bariatric QOL, lipid profile, and comorbidities were evaluated preoperatively and postoperatively for a duration of 12 months.
Results
There is no statistically significant difference between the two study groups according to the resolution of comorbidities throughout the postoperative follow-up ($P>0.05$). There was no statistically significant difference between the two study groups according to improvement of the QOL score during postoperative follow-up ($P>0.05$). There was no statistically significant difference between the two groups with regard to the incidence of complications (25% in group 1 vs. 25% in group 2; $P>0.05$).
Conclusion
Bougie size does not influence the short-term results of LS, that is, excess weight loss percentage, resolution of comorbidities, improvement of the QOL, and incidence of complications.

Keywords:
bougie, obesity, sleeve gastrectomy

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Introduction

Obesity is a worldwide epidemic. Recent data have shown an increased prevalence of obesity in the adult and pediatric populations. Globally, there are more than one billion overweight adults, with at least 300 million of them obese [1]. Using the WHO classification of obesity, it has been shown that individuals in each obesity class are at increased risk of obesity-related illness as compared with those with a normal BMI [1,2].

Remarkably, cancer is the leading cause of mortality in obese patients. Obesity accounted for as much as one in seven cancer deaths in men and one in five in women in the USA [3]. For patients with morbid obesity (obesity class II or III), surgical management remains the only evidence-based approach toward achieving clinically important and sustainable weight loss [4,5]. We are experiencing accelerated growth in the practice of bariatric surgery to address the global epidemic of morbid obesity. This bariatric explosion is owing to

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the poor results obtained with nonsurgical treatments, increasing evidence of significant and durable weight loss with surgery, as well as to a wide diffusion over the media and, consequently, an increased patient demand. This exponential growth is also related to the expansion of laparoscopy in the treatment of morbid obesity [5].

The physiologic and clinical benefits of the laparoscopic bariatric surgery over the open approach have encouraged more primary-care physicians to refer morbidly obese patients for surgical treatment and have motivated more patients to pursue this approach [6]. Laparoscopic sleeve (LS) gastrectomy has recently been identified as an innovative approach to the surgical management of obesity. In this procedure, the greater curvature of the stomach is resected producing narrow, tubular stomach with the size and shape of a banana [7]. This procedure has quickly attracted considerable surgical interest because it does not require a gastrointestinal anastomosis or intestinal bypass, and it is considered less technically challenging than laparoscopic Roux-en-Y gastric bypass [8]. LS gastrectomy also avoids the implantation of an artificial device around the stomach, in contrast to laparoscopic adjustable gastric banding [9].

The success of the sleeve surgery can be attributed to two main factors. First, a high-pressure system is conceived from a narrow lumen with the pylorus intact, which results in optimal restriction and improved satiety. Second, appetite suppression is achieved by removing the gastric fundus, the ghrelin-producing portion of the stomach. Numerous studies indicated that sharp declines in fasting and postprandial levels of this hormone following LS cause a long-term reduction of hunger feeling, which significantly reduces intake [10,11]. Ghrelin is a growth hormone-releasing peptide, an endogenous ligand for the growth hormone secretagogue receptor, mainly produced by the principal cells of the gastric fundus whose plasmatic concentration regulates meal-time hunger and food intake [12].

Initially, LS was used as a first-stage operation in severely morbidly obese patients to achieve some weight loss and lower the morbidity rate before more complex and definitive procedures. These patients showed marked weight loss and drastic improvement in comorbidities after undergoing LS alone. Today, LS is considered a stand-alone procedure [13].

The benefits of LS include low rate of complications, the avoidance of foreign bodies (no erosion, infection or revision of reservoir and no adjustments), the maintenance of normal gastrointestinal continuity (no anastomoses) with preservation of the pyloric antrum and a nerve supply permitting a faster than normal gastric emptying, the absence of a malabsorptive tool (intestinal bypass), a relatively short operative time, and the ability to convert this procedure into multiple other operations if the weight loss is inadequate [14]. Moreover, dumping syndrome does not develop because the pylorus is preserved, and the incidence of peptic ulcers is minimized as well. The absence of an intestinal bypass as seen in Roux-en-Y gastric bypass and biliopancreatic diversion with duodenal switch eliminates the risk of intestinal obstruction, vitamin deficiencies, anemia, and osteoporosis [15].

One of the most debated issues is the size of the bougie used during the procedure. Although larger-size (50–60 Fr.] bougies initially used in LS are generally avoided nowadays, it has been suggested that the optimal size may be well below 40 Fr. [16]. However, no consensus has yet been reached as to the optimum boogie size recommended for utilization in LS [17,18].

Patients and methods

Study design

The study was an interventional prospective randomized study.

Study setting

The study was conducted at the Department of Surgery, Suez Canal University and the Gastroenterology Surgical Center, Mansoura University, during the period from January 2015 to March 2017.

Study population

The study included morbidly obese patients admitted for LS gastrectomy.

Inclusion criteria were as follows (according to the NIH consensus conference in 1991) [10] :

(1) Obese patients class III obesity according to WHO classification (BMI $>40\,kg/m^2$).
(2) Obese patients with class II obesity according to WHO classification ($35–40\,kg/m^2$) with one or more comorbidities related to obesity, such as diabetes mellitus, hypertension (HTN), ischemic heart disease, obstructive sleep apnea syndrome (OSAS), osteoarthritis (OA), and hyperlipidemia.

Exclusion criteria

The following were the exclusion criteria:

(1) Patients aged below 18 years old or over 60 years old.
(2) Mental/cognitive impairment.
(3) Advanced neoplasia.
(4) Unstable coronary artery disease.
(5) Previous bariatric surgery.
(6) Previous intragastric balloon insertion.
(7) Previous upper abdominal surgery.
(8) Pregnancy.
(9) Severe gastroesophageal reflux (GERD) or large hiatus hernia.
(10) Contraindications for laparoscopy.

Sampling

The enrolled patients were randomized by simple block randomization. The selected patients were divided to two equal groups: the first group contained odd numbers (1, 3, 5, . . .) and the second group contained even numbers (2, 4, 6, . . .).

Data collection

The studied patients were randomly divided into two equal groups: group 1 (24 patients), where LS was carried out using bougie size 32 Fr, and group 2 (24 patients), with. LS conducted using 40 Fr bougie. Females constituted 66.7% (16 of 24 patients) of the first group and 58.3% (14 of 24 patients) of the second group, for a total of 62.5% (30 of 48 cases) of the total patient cohort. Body weight, BMI, bariatric quality of life (QOL), lipid profile, and comorbidities were evaluated preoperatively and postoperatively for a duration of 12 months.

Data management

Data entry and analysis were done using 'SPSS' for Windows program, version 19 (IBM Co., Armonk, New York, USA). Research results were presented in suitable tables and figures.

Ethical considerations

The study was approved by the local ethical committees at the Gastrointestinal Surgery Center, Mansoura University, and the Suez Canal Faculty of Medicine. Written informed consent was obtained from the patients before being involved in the study. The steps of the study, the goals, the benefits, and disadvantages were discussed with all the patients included in the study. The patient had the right to refuse participation. Confidentiality of all data and test results of the study population was preserved.

Results

During the period from January 2015 to March 2017, this study was carried out as an interventional prospective randomized study on 48 morbidly obese patients who were candidates for LS gastrectomy. Figure 1 demonstrates the stomach ready for firing the first stapling line.

The results are presented in the following tables.

Table 1 shows the changes in anthropometric data of the patients through follow-up period.

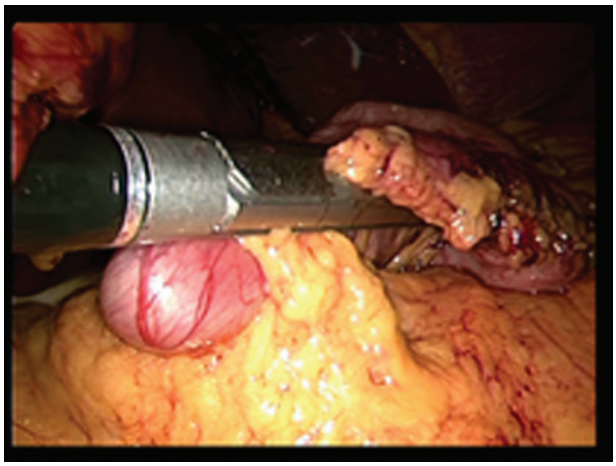
Table 2 shows resolution of comorbidities by 12 months postoperatively among the studied patients.

Table 3 shows that the bariatric QOL score has markedly improved postoperatively, compared with the preoperative score in both groups.

Table 4 shows the complications among studied patients.

Table 1 shows that mean weight was markedly decreased after 1, 3, and 6 months postoperatively, and the decline in body weight continued throughout the period of follow-up (12 months postoperatively). These findings were also demonstrated by significant decrease in BMI and also by the mean excess weight loss percentage (%EWL) which was significantly increased in group 1 from 17% of Excess Body Weight (EBW) at 1 month to 69% at 12 months postoperatively and in group 2 from 18% at 1 month to 70% at 12 months postoperatively.

Figure 1



LS: the stomach is ready for applying the first stapling line. LS, laparoscopic sleeve.

Table 1 Changes in anthropometric data of the patients throughout the follow-up period

Timing Parameter	Preoperative	Postoperative			
		1 month	3 month	6 month	1 year
Weight[a]					
32 Fr bougie	138.29±18.33	126.8±15.92	114.97±14.3	98.35±9.78	92.27±9.19
40 Fr bougie	137.42±17.72	125.05±14.8	111.3±13.42	96.05±10.22	89.5±9.2
P value	0.236 (NS)	0.7 (NS)	0.365 (NS)	0.428 (NS)	0.303 (NS)
BMI					
32 Fr bougie	47.91±4.77	43.93±4.05	39.82±3.36	34.1±2.01	31.97±1.52
40 Fr bougie	49.98±4.64	45.51±4.01	40.46±3.09	34.93±2.28	32.55±1.92
P value	0.761 (NS)	0.18 (NS)	0.493 (NS)	0.183 (NS)	0.247 (NS)
%EWL					
32 Fr bougie		17±3	35±5	60±6	69±6
40 Fr bougie		18±3	38±6	60±6	70±5
P value		0.53 (NS)	0.85 (NS)	0.89 (NS)	0.697 (NS)

[a]Body weight in kg. %EWL, excess weight loss percentage.

Table 2 Resolution of comorbidities by 12 months postoperatively among the studied patients

Operative data Comorbidity	32 Fr bougie (*N*=24)		40 Fr bougie (*N*=24)		*P* value
	Count	%	Count	%	
Diabetes					
Cured	12	80	11	78.5	0.37
Improved	3	20	3	21.5	
Hypertension					
Cured	6	75	5	71.4	0.51
Improved	2	25	2	28.6	
Hyperlipidemia					
Cured	15	71.4	13	65	0.43
Improved	6	28.6	7	35	
GERD					
Cured	6	75	6	66.67	0.28
Improved	1	12.5	2	22.22	
Unchanged	1	12.5	1	11.11	
OSAS					
Cured	1	50	2	66.67	0.94
Improved	1	50	1	33.33	
Depression					
Cured	11	100	13	100	0.96
OA					
Cured	8	50	7	50	0.81
Improved	6	37.5	5	35.72	
Unchanged	2	12.5	2	14.28	

GERD, gastroesophageal reflux disease; OA, osteoarthritis; OSAS, obstructive sleep apnea syndrome.

Table 3 Bariatric quality of life by postoperative time

Timing Parameter	Preoperative	1 month Po	3 months Po	6 month Po	1 year Po
QOL					
32 Fr bougie	26.96±4.37	37.38±6.06	51.21±6.93	53.33±7.82	55.25±8.34
40 Fr bougie	26.79±4.09	36.58±6.01	50.33±7.42	53.66±8.84	55.61±9.3
P value	0.89 (NS)	0.65 (NS)	0.71 (NS)	0.91 (NS)	0.63 (NS)

Po, postoperative; QOL, quality of life.

Table 2 shows that in group 1 diabetic patients (15 patients), 80% of them were completely cured [stopped the treatment Treatment ('TTT')] and the remaining 20% improved (reduced the dose of TTT); among hypertensive cases (eight patients), 75% of them were completely cured (stopped the TTT) and the

Table 4 Complications among studied patients

Bougie Complication	32 Fr bougie (*N*=24)		40 Fr bougie (*N*=24)		*P* value
	Count	%	Count	%	
Over all	6	25	6	25	0.72
Leakage	1	4.17	0	0	0.32
Bleeding	0	0	1	4.17	0.32
AITM	1	4.17	0	0	0.32
Splenic infraction	1	4.17	0	0	0.32
Intra-abdominal sepsis	0	0	1	4.17	0.32
Wound infection	3	12.50	4	16.67	0.69

AITM, acute paraesophageal intrathoracic migration of the sleeve.

remaining 25% improved (reduced the dose of TTT); among hyperlipidemic patients (21 patients), 71.4% of them were completely cured (laboratory values returned to normal) and the remaining 28.6% were improved (reduced cholesterol and low-density lipoprotein and elevated high-density lipoprotein in comparison with preoperatively but have not returned to normal); among patients with GERD (8 patients), 75% of them were completely cured (stopped the TTT) and 12.5% were improved (reduced the dose of TTT), and the remaining 12.5% were unchanged (continue to take medications to control their symptoms); among patients with OSAS (only 2 patients), one of (50%) them was cured (no episodes of apnea occurred) and the other one (50%) improved (reduced episodes of apnea and number of pillows he used to use in his sleeping); among depressed patients (11 pts.), all of them cured; and among patients with OA (16 pts.), 50% of them were completely cured (stopped the TTT) and 37.5% improved (reduced the dose of TTT), and the remaining 12.5% unchanged (continue to take medications to control their symptoms).

In group 2 diabetic patients (14 pts.), 78.5% of them were completely cured (stopped the TTT) and the remaining 21.5% improved (reduced the dose of TTT); among hypertensive patients (7 pts.), 71.4% of them were cured (stopped the TTT) and the remaining 28.6% improved (reduced the dose of TTT); among hyperlipidemic patients (20 pts.), 65% of them were completely cured (laboratory data returned to normal) and the remaining 35% improved (reduced serum cholesterol and low-density lipoprotein and elevated high-density lipoprotein levels compared with preoperatively but did not return to normal); among patients with GERD (nine patients), 66.67% of them were cured (stopped the TTT), 22.22% improved (reduced the dose of TTT), and the remaining 11.11% unchanged (continue to take medications to control their symptoms); among patients with OSAS (only three patients), two (66.6%) of them were cured (no episodes of apnea occurred), and the other patient (33.3%) improved (reduced episodes of apnea and number of pillows he used to use in his sleeping); among depressed patients (13 patients), all of them were cured; among patients with OA (14 patients), 50% of them were cured (stopped the TTT), 35.72% improved (reduced the dose of TTT), and the remaining 14.28% unchanged (continue to take medications to control their symptoms).

There is no statistically significant difference between the two study groups according to the resolution of comorbidities throughout the postoperative follow-up period. (independent t test) ($P>0.05$).

Table 3 shows that the bariatric QOL score has markedly improved postoperatively compared with the preoperative score, with no statistically significant difference between the two groups.

There is no statistically significant difference between the two study groups with regard to the improvement of the QOL score throughout the postoperative follow-up (c^2 test) ($P>0.05$).

Table 4 shows the complications among the studied patient population. Group 1 had a case of leakage, a case of gastroesophageal junction obstruction, a case of splenic infarction, and three cases of port site infection. Group 2 had a case of bleeding, a case of intra-abdominal sepsis, and four cases of port site infection as a minor complication.

There is no statistically significant difference between the two study groups according to the incidence of complications (independent t test) ($P>0.05$).

Discussion

The current study showed that the patients of group 1 have shown a mean initial weight of 138.29±18.33 kg, ranging from 99 to 180 kg, with a mean excess body

weight of 66.1±14.7 kg, ranging from 36.75 to 99 kg, and with a mean initial BMI of 47.91±4.77 kg/m^2, ranging from 37.72 to 58.77 kg/m^2. In group 2, the mean initial weight was 137.42±17.72 kg, ranging from 102 to 186 kg, with a mean postoperative excess body weight of 68.99±14.38, ranging from 39.44 to 103.51 kg, and with a mean initial BMI of 49.96 ±4.64 kg/m^2, ranging from 38.97 to 58.59 kg/m^2.

In a review of six studies reporting on a total of 328 SL cases, the mean initial BMI ranged from 37.2 to 65.4 kg/m^2, and one patient had an extreme BMI at 91 kg/m^2 with good short-term results [19]. Moreover, in a recent study including 124 cases, the baseline BMI extended from 35.9 to 72.0 kg/m^2 with a median of 51.6 kg/m^2 and reported comparably good long-term outcome [20]. These data suggest that very high and even extreme BMI do not represent a contraindication to LS. In fact, the two-staged approach is becoming the rule in the case of super-super obese patients (BMI>60 kg/m^2) in whom more complex procedures such as Roux-en-Y gastric bypass P or biliopancreatic diversion are very difficult to perform. The rationale for the staged approach to super and super-super obese patients is to achieve a substantial weight loss with consequent amelioration of obesity-related comorbidities with a simple procedure such as LS, thus allowing for the second surgery in patients with lower operative risks [19].

We have assessed our patients for the prevalence of comorbidities. In group 1, the most common diseases were hyperlipidemia (87.5%), OA (66.7%), diabetes (62.5%), depression (45.83%), gallstones (37.5%), HTN (33.3%), and GERD (33.3%) and in group 2 were hyperlipidemia (83.3%), OA (58.3%), diabetes (58.3%), depression (45.17%), gallstones (41.7%), GERD (37.5%), and HTN (29.2%). In a study on 102 sleeve gastrectomy cases, preoperative evaluation showed that 15 (14.7%) patients had HTN, 17 (16.6%) patients had type 2 diabetes mellitus (T2DM), eight (7.8%) patients had obstructive sleep apnea (OSA), and 20 (19.6%) patients had degenerative OA [21]. In the work of Spivak *et al.* [22], the prevalence of preoperative comorbid diseases was T2DM in 19 (29%) versus 23 (43%) patients, HTN in 22 (33%) versus 18 (33%) patients, and GERD in 28 (42%) versus 10 (19%) patients in groups 1 (42 Fr.) and group 2 (32 Fr.), respectively. In their series, Behrens *et al.* [23] found that the frequency rates of preoperative obesity-related comorbidity were 56% (n=19) for T2DM, 50% (n=17) for HTN, 32% (n=11) for dyslipidemia, 62% (n=21) for OSA, 62% (n=21) for knee and/or hip pain, and 44% (n=15) for depression and/or anxiety. These data affirm the association of obesity with a wide array of serious morbidities. Vivid examples exist in this regard, including derangement of lipid metabolism which is more prevalent among patients with central fat distribution and would result in hypercholesterolemia and higher levels of low-density and very low-density lipoproteins with their dire consequences. In addition, it was reported that a higher incidence of T2DM directly correlates with higher BMI [24].

The current work has shown that the mean operative time was similar in the two groups, as in group 1 it was 90.08±12.47 min and ranged from 70 to 120 ms, and in group 2, it was 87.75±8.96, ranging from 75 to 110 ms. In a study of 102 sleeve-gastrectomy cases, the mean operative time was 91±20.3 min (range, 64–240 min). In their systematic review, Iannelli *et al.* [19] reported that the mean operative time ranged from 70 min [21] to 143 ms [13]. Nienhuijs *et al.* [25] evaluated the effect of laparoscopic gastric sleeve on weight reduction and comorbidities, and the mean operative time was 82 ms, which is similar to that observed in the present study.

The mean postoperative hospital stay in our work was 2.54 ±1.38 days, ranging from 2 to 6 days in group 1 versus 2.67±1.2 days, ranging from 2 to 7 days, in group 2. None of our patients required conversion to open surgery. However, another study reported a mean hospital stay of 4 days, which is longer than our findings [25]. Similarly, a longer duration of hospital stay was described by Shi *et al.* [26], who pointed out that hospital stay varied from 1.9 to 8 days (average, 4.4 days). Hawasli *et al.* [27] suggested that the smaller bougie size of 32 Fr may result in a longer hospital stay, with a tendency toward increased nausea, more emergency department visits, and readmissions. Long-term weight loss was not affected. However, in another study on two groups of LS cases utilizing 32 versus 40 Fr bougies, the mean hospital stay was almost identical in the groups, that is, 2.3 and 2.2 days, respectively [21], which is consistent with the findings of our work.

Our study has shown that the mean weight has markedly decreased after 1, 3, and 6 months postoperatively and the decline in body weight continued throughout the follow-up period (12 months postoperatively). These findings were demonstrated by marked decrease in BMI and also by the percentage of loss of excess body weight, whose mean has notably increased in group 1 from 17% of excess body weight 1 month postoperatively to 69% of excess body weight after 12 months, and in group 2

from 18% of excess body weight 1 month postoperatively to 70% of excess body after weight 12 months. There was no statistically significant difference between the two groups pertinent to changes in weight, BMI, or percentage of weight loss all through the postoperative follow-up period ($P>0.05$).

The success of LS can be defined as percentage loss of excess body weight of more than 50% [28]. It was estimated that after 5 years postoperatively, an average LS patient loses about 60.5% of excess body weight with a standard deviation of 10.6% [29]. A recent study reported the %EWL was 82.0±18.8 at 1 year, 76.7 ±21.3 at 3 years, and 60.3±28.9 at 5 years[30]. In a multi-institutional work including 1395 LS cases, the percentage EWL was 53% at 1 year and 61% and 57% at 5 and 7 years, respectively [31]. An extended follow-up study including 1020 LS cases revealed that the mean percentage of EWL was 86% at 1-year, and was still maintained at 61% at 5 years, and 52% at 8-year follow-up [28]. Noel *et al*. [32] reported a mean EWL % of 76 and 67% at 5 and 8 years, respectively. Recently, a study of 100 LS cases with a median follow-up of 8 years, with a range of 7.1–10.7 years, described a percentage of EWL of 51.1% [20]. In another study, at 10 years after SL, the authors reported that 60.4% of LS cases achieved a mean percentage EWL of 53±25% [33]. These data are comparable to those documented in our study at 1 year postoperatively, with the EWL maintained for longer follow-up periods in these studies. Yehoshua *et al*. [34] reported that LS reduces the gastric volume by 70–80%, to be in the range of 90–220 ml, with a mean of 129 ml. It was observed that a 38 Fr bougie produces a gastric-sleeve volume of about 100 ml, which is satisfactory to effect good weight loss, and probably nullifies the possibility of excessive narrowing of the sleeve diameter [35]. On the contrary, the sleeve diameter created on a 32 Fr bougie may be narrower than that of the esophagus, which could increase the frequency of leakage and gradual gastric-cardia stenosis [16,36]. In a study that reviewed the data of one of the largest LS series, there were no significant differences among the 46, 40, and 36 Fr bougies regarding weight loss, BMI, or % EWL. In addition, the 7- and 4-cm antral pouches produced comparable results [37]. Similarly, another study revealed that utilizing a 42 or 32 Fr bougie in LS had no effect on weight loss or the resolution of comorbid conditions 1 year after surgery [22]. It was reported that most surgeons are in preference of a bougie size between 36 and 40 Fr [38].

In our work, there was no statistically significant difference between the two study groups relevant to the resolution of comorbidities throughout the postoperative follow-up period ($P>0.05$). In a study that compared the outcome of LS using bougie sizes 42 and 32 Fr at 1 year [22], the authors pointed out that the difference was not significant. The results in the 42 Fr group were the resolution of diabetes in 78.9%, improvement in 15.8%, and deterioration of 5.3% of diabetic patients; resolution of HTN in 81.8% and improvement of 18.2% of hypertensive cases; and resolution of GERD in 82.1%, improvement of 14.3%, and deterioration in 3.6% of patients with GERD. The results of the 32 Fr group were resolution of diabetes in 82.6%, improvement in 17.4%, deterioration in none of the diabetic patients; resolution of HTN in 61.1% and improvement of 38.9% of hypertensive pts.; and resolution of GERD in 60%, improvement in 30%, and deterioration in 10% of patients. These findings are also consistent with the findings reported in our work.

A review of 27 LS studies with a mean follow-up of 13.1 months and a range of 3–36 months revealed that T2DM was cured in 66.2%, improved in 29.6%, and remained stationary in 13.1% of cases [39]. Rosenthal *et al*. [40] indicated the regression of T2DM after LS in 27% of patients 2 months after the surgery and in 63% of patients after 6 months. Another study demonstrated resolution of diabetes at 1-year follow-up in 53.66% of patients who underwent LS and improvement regression in 43.34% of patients, which confirmed the effectiveness of LS in the treatment of diabetes in obese patients with metabolic syndrome [41]. Several authors have shown that the amelioration of comorbidities following LS continued for longer periods of follow-up compared with our study. Charalampakis *et al*. [42] have also described the effectiveness of LS for improving obesity-related comorbidities. At 24 months postoperatively, T2DM was improved in 18.8% and resolved in 81.2% of diabetic patients. The respective figures for arterial HTN were 45.5 and 54.5%; for sleep apnea, 25.0 and 75.0%; and for osteoarticular disease, 20.3 and 80.7%; however, dyslipidemia remained unchanged in 6.3%, improved in 40.6%, and resolved in 53.1% of the patients. Albanopoulos *et al.* [43] reported significant reduction in the percentages of patients with comorbidities including HTN (from 33.3 to 10.5%), hyperlipidemia (from 26.4 to 9.2%), diabetes mellitus (from 20.7 to 1.1%), OSA (from 20.2 to 1.1%), and GERD (from 27 to 9.2%) at 3 years postoperatively. Moreover, Wang *et al*. [44] described the resolution of obesity-associated comorbidities, such as T2DM (69.2%), OA (90.9%), and dyslipidemia (84.2%) at a

medium term of 3-year assessment. The proportions of patients with optimal glycemic control (fasting blood glucose < 5.6 mmol/l and glysated hemoglobin <6.5%) maintained well above 60%, even at 2 and 3 years postoperatively.

Regarding the health-related QOL, we have found that postoperatively, the bariatric QOL score has markedly improved compared with the preoperative score, and was nearly equal in both groups. We have employed the QOL score described by Elrefai *et al.* [45], with a minimum of 13 and a maximum of 65. The normal score starts from 50, and a score of more than 52 represents very good QOL. It has also been observed that the bariatric QOL improvement was higher at 12 months compared with 1, 3, and 6 months postoperatively, and there was no statistically significant difference between the two study groups pertinent to improvement of the QOL score all through the postoperative follow up-period ($P>0.05$). Bobowicz *et al.* [46] reported similar results, as the QOL was shown to be up-scaled to good or very good in 66% of LS patients at 12 months by employing the bariatric analysis and reporting outcome system (BAROS). Similarly, another study revealed that the QOL has significantly been improved postoperatively even for a longer duration of follow-up (24 months). They used the obesity-specific Moorehead-Ardelt II questionnaire. The Moorehead-Ardelt II score increased from −0.40 ±1.30 preoperatively to 1.75±.83, 2.18±0.80, and 1.95±0.71 at 6, 12, and 24 months postoperatively (trend $P<0.001$) [42]. Only a small number of studies longitudinally commented on the QOL after any bariatric intervention for a period of at least 2 years. Strain *et al.* [47] reported a decline in the Impact of Weight on Quality of Life score after the first postoperative year after LS. Similarly, D'Hondt *et al.* [48] observed a trend toward weight gain and drop in the QOL based on the BAROS score at 5 years postoperatively. Another study revealed a reduction in the mean %EBWL and QOL based on the BAROS scoring between the third and fifth years of follow-up [49]. On the contrary, other authors described stable QOL results after the first and up to the fifth year after surgery [50].

In this study, there were neither intraoperative complications nor postoperative mortalities. The overall complication rate was 25% (12 patients) in both groups combined; of those, major complications were encountered in only five (10.41%) patients. In group 1, there were three (12.5%) patients with major complications, that is, one (4.17%) patient developed postoperative leakage, one (4.17%) patient developed acute paraesophageal intrathoracic migration of the sleeve, and one (4.17%) patient developed splenic infarction, and three (12.5%) patients developed minor complications (port-site infection). In group 2, there were two (8.33) patients with major complications, that is, one (4.17%) of them developed postoperative acute bleeding and the other (4.17%) developed intra-abdominal sepsis, and there were four (16.67%) patients with minor complications (port-sites infection). There was no statistically significant difference between the two groups regarding the incidence of complications (25% in group 1 vs. 25% in group 2; $P>0.05$).Recently, the American Society for Metabolic and Bariatric Surgery reported that the mortality rate of LS varied from 0 to 1.2%, whereas the occurrence of morbidities ranged from 0 to 17.5% [51]. In a literature-review study, the mortality rate following LS was 0.6%, whereas the most common complications were reoperation (4.5%), gastric leakage (0.9%), stricture formation (0.7%), bleeding (0.3%), pulmonary embolism (0.3%), delayed gastric emptying (0.3%), intra-abdominal abscess (0.1%), wound infection (0.1%), splenic injury (0.1%), and trocar site hernia (0.1%) [36].

In a study of LS cases utilizing 32 bougies, there was no operative mortality, whereas the incidence of perioperative morbidity was 6.3%; leakage was encountered in 1.4% of cases and the reoperation rate of 2.8% [52]. In their recent work, Hoyuela [30] utilized 34 Fr bougies and reported a 0% death rate and a 30-day morbidity rate of 5.1% including staple-line leakage (1.2%), wound infection (1.2%), staple-line hemorrhage (0.6%), skin rash (0.6%), and urethral bleeding (0.6%). In another study of 529 LS cases employing 34 Fr bougies, the mortality rate was 0.19%, whereas morbidity occurred in 3.2% of patents, including vomiting (0.95%), mesenteric thrombosis (0.57%), deep venous thrombosis (0.38%), hemorrhage (0.38%), reflux esophagitis (0.38%), pulmonary embolism causing death (0.19%), infection (0.19%), and acute cholecystitis (0.19%) [53]. In a report of the complications associated with SL on 40 Fr bougies, there were no deaths, whereas the complication rate was 2.7% spanning staple-line bleeding (1.1%), splenic injury necessitating splenectomy (0.6%), trocar-site cellulitis (0.5%), and trocar-site hernia (0.5%) [54].

In a comparison between 27 and 39 Fr calibration bougies, the authors reported no significant effect on the complication rate, or weight loss at 1 year after LS

[55]. Likewise, the extracted data from a recent systematic-review work of 11 studies showed that bougie size was not significantly related to the incidence of complications; nevertheless, smaller bogie sizes effected more EWL% than larger ones [56]. However, in a review study, the 3-year follow-up of a large number of LS cases suggested that utilizing bougie sizes larger than 40 Fr may reduce the incidence of leakage without affecting %EWL compared with those of smaller sizes [57]. Similarly, Yuval *et al*. [58] believed that using larger bougies of 40 Fr caliber and higher may be associated with a relative leak-risk reduction of 66%, but the authors found no statistically significant difference in weight loss (measured in maximum %EBWL) between the study group using bougies of 40 Fr and higher and the group employing bougies smaller than 40 Fr. On the contrary, other authors observed that employing a 40 Fr bougie or larger could end up with gradual gastric sleeve dilatation within some years after surgery [1,36].

One of the limitations of the current study is the relatively short follow-up period. Moreover, the comparatively small number of patients included in our work may be considered as another limitation. We strongly encourage conducting other studies with extended follow-up for larger numbers of cases, preferably in a multi-institutional setting.

Conclusion

The current study concludes that LS is a feasible surgery for the management of morbid obesity and its associated complications with tangible short-term weight loss and improvement of weight-related QOL with reasonable postoperative morbidity.

Bougie size does not influence the short-term results of LS regarding %EWL, resolution of comorbidities, improvement of the QOL, and incidence of complications.

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Conflicts of interest

There are no conflicts of interest.

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