Role of GastriSail device in laparoscopic sleeve gastrectomy

Mostafa R. Elkeleny

Department of General Surgery, Gastrointestinal Surgery Unit, Alexandria University Hospital, Alexandria, Egypt

Correspondence to Mostafa R. Elkeleny, MD, MRCS, Department of General Surgery, Gastrointestinal Surgery Unit, Alexandria University Hospital, Alexandria, Egypt.
e-mail: mostafa.refaie910@gmail.com

Received: 25 July 2019
Accepted: 15 September 2019
Published: 14 February 2020

The Egyptian Journal of Surgery 2020, 39:86–93

Background
The aim of this study is to evaluate the possible merits of GastriSail device in laparoscopic sleeve gastrectomy (LSG) over the standard LSG.
Patients and methods
A prospective study was conducted on 40 patients who were randomly divided into two groups: group A included 20 patients who underwent LSG using GastriSail, and group B included 20 patients who underwent LSG with the standard bougie. The groups were compared regarding operative time, consistent sleeve formation, delineation and visualization, intraoperative and postoperative complication rates, hospital stay, gastric pouch design, and percentage of excess weight loss percentage.
Results
Regarding intraoperative time, the mean time was 72.0±13.58 and 79.0±11.74 for groups A and B, respectively. Although no patients in group B had consistent sleeve formation, 12 (60%) patients had consistent sleeve formation. Delineation and visualization was accomplished in 100% of group A patients but was not accomplished at all in group B patients. Alignment of the stomach was reached in 12 patients in group A but no patients at all in group B. There was no significant difference between both groups regarding hospital stay. The smaller tube design shown by gastrografin radiography at third postoperative day was accomplished in eight (80%) patients and two (20%) patients in groups A and B, respectively. Postoperative computed tomographic volumetric study illustrated smaller gastric volume in group A but without significant difference.
Conclusion
The use of GastriSail device is superior to the standard LSG in consistent sleeve formation, visualization and delineation, good alignment, and accomplishment of a small tube design, with no significant difference in excess weight loss. Operative time is less with the use of GastriSail but with no statistical significance.

Keywords:
bariatric surgery, GastriSail device, laparoscopic sleeve gastrectomy

Egyptian J Surgery 39:86–93

1110-1121

Introduction

Over the time, the laparoscopic sleeve gastrectomy (LSG) has become the most popular bariatric procedure worldwide. Many studies have demonstrated that the LSG is effective for weight loss and in improvement or even resolution of comorbidities like type 2 diabetes as in Roux-en-Y gastric bypass but with less morbidity and mortality [1,2].

A critical step in the LSG is ensuring sleeve-size consistency. According to the International Sleeve Gastrectomy Expert Panel Consensus Statement, 100% of the surgeons perform sleeve with an orogastric tube. There are many types of orogastric sleeve tubes used during LSG such as standard French bougie with different sizes ranging from 30 to 50 Fr, MIDSLEEVE gastric calibration tube, ViSiGi 3D suction calibration tube, endoscopic calibration, and GastriSail gastric positioning system [3].

GastriSail device gastric positioning system

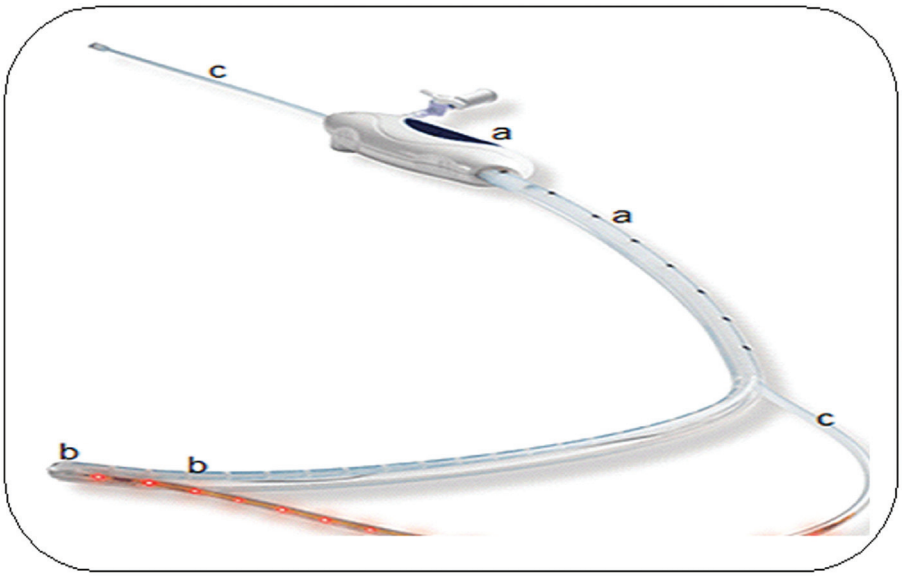
GastriSail device (gastric positioning system) is a three-in-one surgical device replacing the standard bougie used in LSG for the application of suction and decompression and to serve as a sizing guide for gastric sleeve creation [3,4] (Fig. 1).

GastriSail is a 36 Fr tube that could promotes more consistent sleeve creation and greater procedural efficiency when compared with a standard bougie [4,5].

GastriSail has dual lumen in one transoral insertion for sizing, suction, and irrigation system. This may reduce the potential for esophageal trauma with only one

 DOI: 10.4103/ejs.ejs_140_19

Figure 1



GastriSail system. (a) Axial handle and external markings aid in guided insertion, placement, and orientation. (b) Perforations at the distal tip allow for decompression of the stomach and leak testing capabilities. (c) Sail tube radially expands stomach into natural noncontracted orientation. (d) LED lights illuminate and identify the main tube from the pylorus up to the gastroesophageal junction. LED, light-emitting diode.

transoral insertion needed versus the up to three insertions for sizing, decompression, and leak testing needed for other devices [4,5].

Moreover, the multiple openings at the distal end of GastriSail serve for regulated suction, provide desired apposition of the anterior and posterior stomach walls, and ensure correct calibration, which allows for leak testing capabilities and allows for better alignment of anterior and posterior walls, which may lead to decreased incidence of spiraled sleeve [4,5].

GastriSail has a flexible deployable sail that extends the stomach radially, which helps in positioning into a natural, noncontracted orientation and automatic placement of the main tube along the lesser curve, and deflection of the tip toward the pylorus increases efficiency of placement and positioning of the bougie, with a reduced total procedural time [4,5].

Light-emitting diode (LED) lights of GastriSail serve better visualization of GastriSail system as it passes from the esophagus into the stomach, the sail during dissection and the main tube during staple line placement; this may decrease the clinical risk associated with resecting the bougie owing to its ability to provide enhanced delineation and visualization [4,5].

Patients and methods

During a 12-month period from April 2017 to March 2018, 40 patients with morbid obesity were included in this prospective study. After approval of the local ethics committee, all patients included in the study were informed well about the procedure and an informed written consent was obtained. They were randomly divided into two groups:

Group A included 20 patients who underwent LSG using GastriSail.

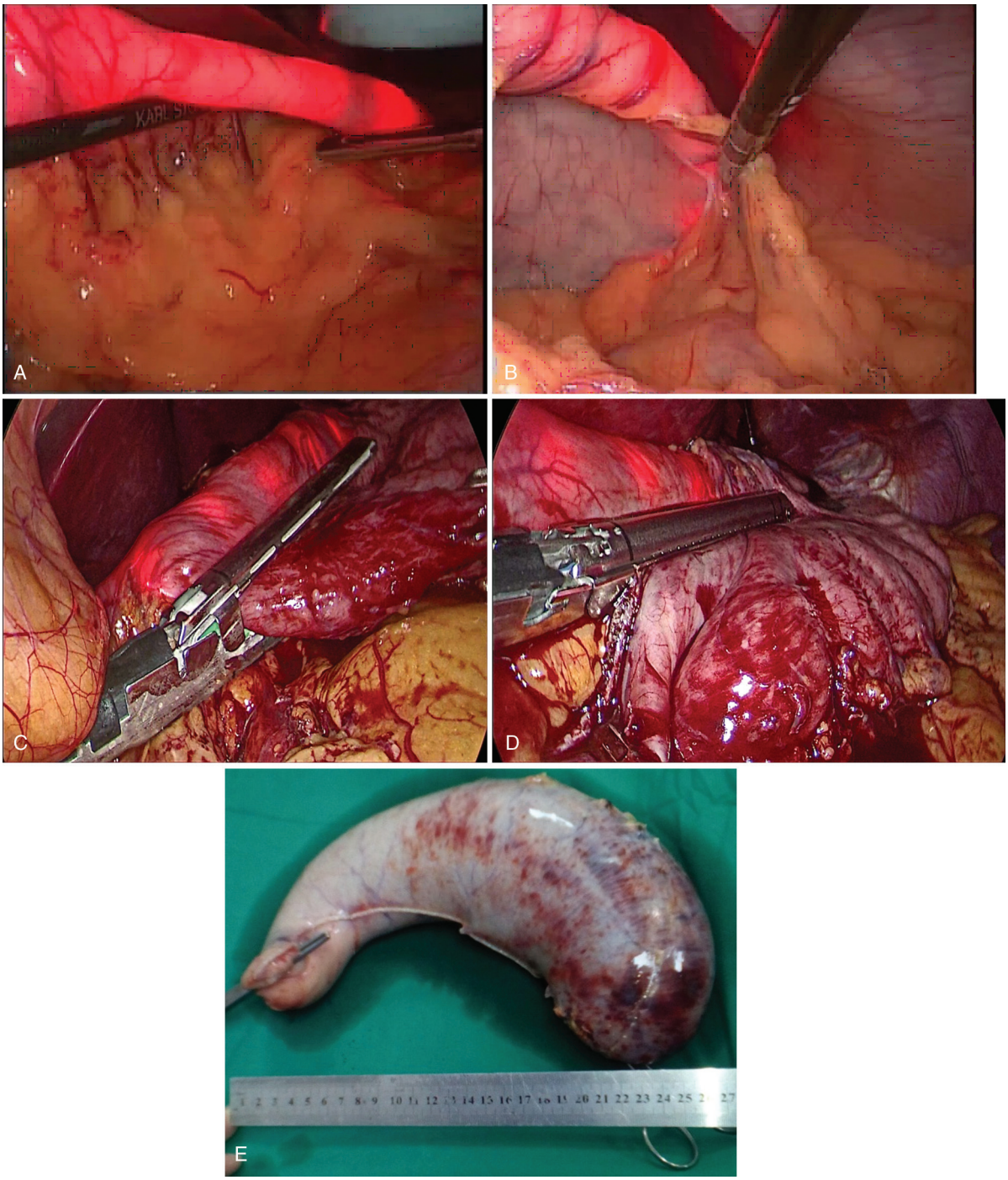
Group B included 20 patients who underwent LSG using standard bougie without the use of GastriSail.

Group A included 10 males and 10 females, whereas group B included 14 males and six females. The mean ages for groups A and B were 37.10±2.85 and 34.60 ±4.48, respectively.

Surgical technique

In all patients, standard LSG was performed (Fig. 2) [6]. The technique of sleeve gastrectomy in the both groups will be the same, except in group A, where GastriSail was used instead of the standard bougie. GastriSail was slowly advanced transorally, like a standard bougie and following similar precautions, through the esophagus until the LED lights become visible at the gastroesophageal junction. When the GastriSail was inserted into the stomach, stomach decompression was done by suction if needed. Under direct visualization, the sail was deployed by advancing the inner tube at the proximal end of the device and to maintain anterior and posterior alignment; active suction tubing was connected to the small-bore

Figure 2



Technique of laparoscopic sleeve gastrectomy (LSG) in group A. (a) Maintaining anterior and posterior alignment of the stomach LED lights at greater curvature. (b). Devascularization of greater curvature of stomach using GastriSail as guide. (c, d). GastriSail positioned along the lesser curve of the stomach, and the LED lights can serve as a guide during gastric resection. (e) Specimen extraction. LED, light-emitting diode.

connector located at the proximal end of the GastriSail. The sail was retracted by pulling the inner tube located at the proximal end of the device until the inner tube is fully retracted within the main tube of the bougie. Confirmation that the main tube was positioned along the lesser curve of the stomach was done, and the LED lights served as a guide during gastric resection. If repositioning is needed, disconnection of the suction and insufflation by inserting a small amount of air to break the seal were done. The sleeve gastrectomy was created along GastriSail tube using linear staplers. Sleeve gastrectomy was proceeded as the standard to the end. For leak testing, the stomach was insufflated or injected with methylene blue through the port of the handle of the GastriSail poststapling, and after removing the suction tubing. At the end of the operation, the device was removed through the mouth with gentle traction [4,5].

In group B, standard LSG was performed using the standard bougie [5].

Intraoperative parameters were recorded in both groups, including the operative time, consistent sleeve formation, procedural efficiency, delineation and visualization, alignment of anterior and posterior walls, and any intraoperative difficulties. Intraoperative complications in both groups were recorded. Gastrografin meal radiography at third postoperative day to show the gastric pouch designed in both groups was done for all patients. Hospital stay in both groups also was recorded. Postoperative complication such as hemorrhage, hematoma formation, leakage, abscess formation, collection formation, and fever more than 38°C. Weight loss parameter were recorded for each patient at 3 and 6 months postoperatively.

Patients were referred for abdominal multislice computed tomography with dedicated volumetric assessment of gastric pouch at 1 month after surgery in both groups.

Results

Regarding intraoperative time, the mean time was 72.0 ±13.58 and 79.0±11.74 for groups A and B, respectively. No patients in group B had consistent sleeve formation, and 12 (60%) patients had consistent sleeve formation in group A. Delineation and visualization was accomplished in 100% of group A patients, whereas it was not accomplished at all in group B patients. Alignment of the stomach was achieved in 12 patients in group A but not achieved in group B patients. The mean number of days of admission was 2.20±0.42 and 2.40±0.84 for groups A and B, respectively, whereas the median was two in both groups. The smaller tube design shown by gastrografin radiography at third postoperative day was accomplished in 16 (80%) patients and four (20%) patients in groups A and B, respectively (Tables 1 and 2). Postoperative computed tomography volumetric study illustrated smaller gastric volume in group A but without significant difference (Table 3). For group A, the mean patient weight was 153.5±23.10,130.99±23.17, and 108.03 ±16.38, preoperatively, 3 months postoperatively, and 6 months postoperative, respectively, whereas for group B, it was 136.50±22.49, 115.57±24.54, and 106.65±17.31, respectively (Table 4). There were no significant differences in both groups regarding perioperative complications (Figs 3 and 4).

Discussion

To the best of our knowledge, we are the first study that compared between the use of GastriSail device and standard Bougie during LSG in the Middle East. As

Table 1 Comparison between the two studied groups according to intraoperative parameters

Intraoperative parameters	Group A (*N*=20) [*n* (%)]	Group B (*N*=20) [*n* (%)]	Test of significance	*P*
Consistent sleeve formation	12 (60.0)	0	χ^2=8.571*	^{FE}P=0.011*
Procedural efficiency	16 (80.0)	8 (40.0)	χ^2=3.333	^{FE}P=0.170
Delineation and visualization	20 (100.0)	0	χ^2=20.0*	<0.001*
The operative time (min)				
Minimum–maximum	55.0–90.0	60.0–90.0	*t*=1.233	0.233
Mean±SD	72.0±13.58	79.0±11.74		
Median	75.0	80.0		

FE, Fisher exact test; χ^2, value for Chi square test; Sig. bet. stages were done using Chi square test. *Statistically significant at $P \leq 0.05$.

Table 2 Comparison between the two studied groups according to hospital stay

Hospital stay (days)	Group A (*N*=20)	Group B (*N*=20)	*U*	*P*
Minimum–maximum	2.0–3.0	2.0–4.0	48.0	0.912
Mean±SD	2.20±0.42	2.40±0.84		
Median	2.0	2.0		

Table 3 Comparison between the two studied groups according to gastric volume using computed tomography volumetry of the studied patients after 1 month

Gastric volume using CT volumetry of the studied patients after 1 month	Group A (*N*=20)	Group B (*N*=20)	*t*	*P*
Minimum–maximum	91.5–160.40	105.0–196.2	1.936	0.069
Mean±SD	125.3±23.58	146.42±25.2		
Median	121.25	142.30		

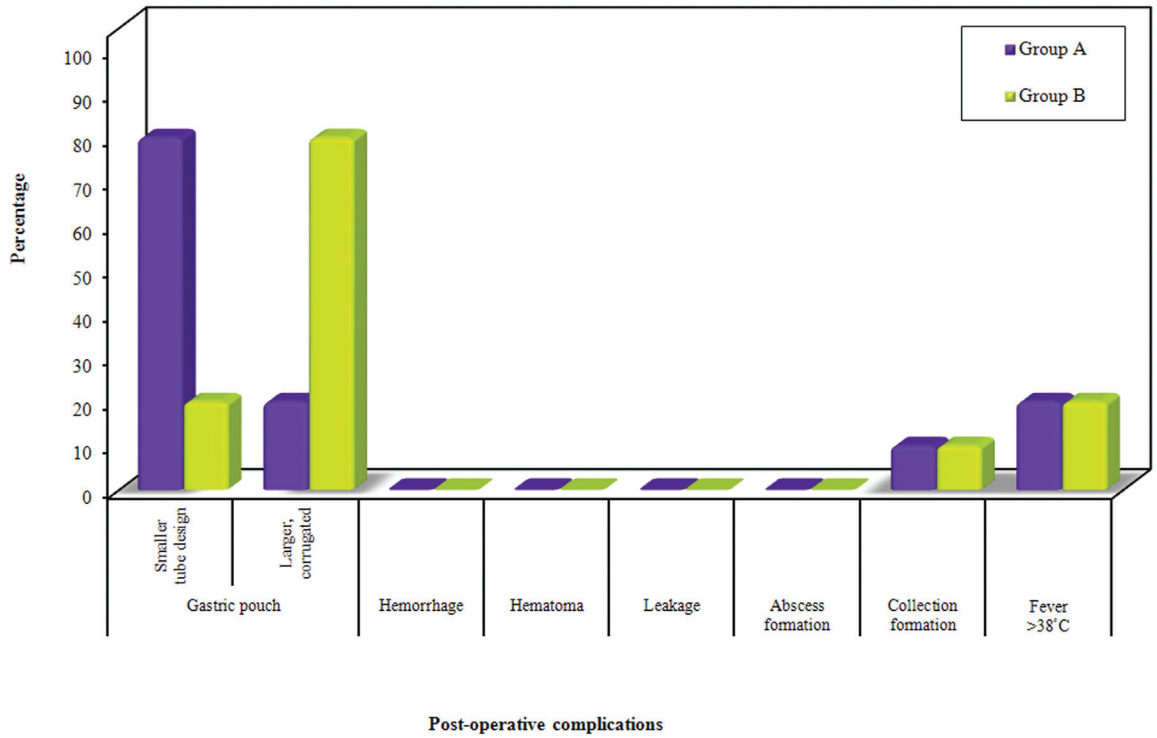
CT, computed tomography.

Table 4 Comparison between the two studied groups according to expected weight loss

Weight (kg)	Preoperative	3 months postoperatively	6 months postoperatively
Group A			
Minimum–maximum	110.0–175.0	96.20–152.70	82.50–126.80
Mean±SD	153.5±23.10	130.99±23.17	108.03±16.38
Median	160.0	140.0	105.0
Group B			
Minimum–maximum	115–170	95–150.7	80.5–126.0
Mean±SD	136.50±22.49	115.57±24.54	106.65±17.31
Median	130.0	105.0	104.50
t	1.667	17.941	17.945
P	0.113	0.166	0.857

Group A: patients will undergo with the use of GastriSail. Group B: patients will undergo without the use of GastriSail.

Figure 3

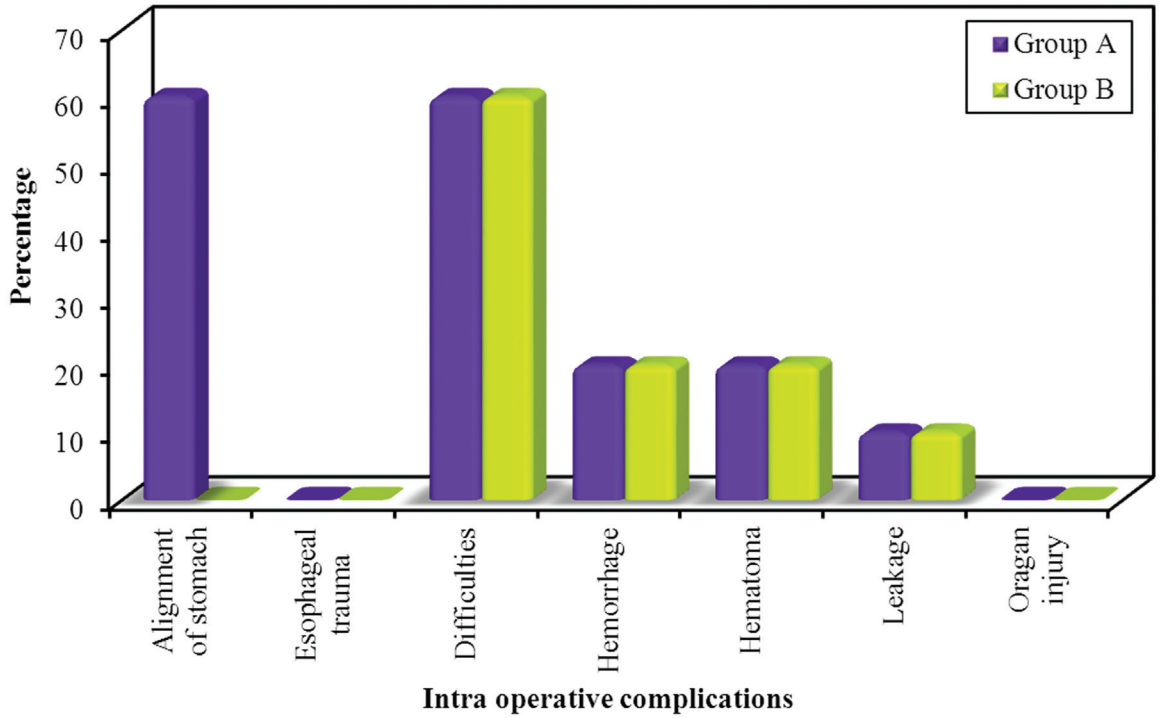


Postoperative complications.

GastriSail was not Food and Drug Administration approved till 2015, the postmarketing studies on the device are still rare. Our results showed that using GastriSail had benefits in consistent sleeve formation and delineation and visualization, whereas it had no significant benefits in procedural efficiency and operative time.

Trivedi *et al.* [7] agreed with us in that using GastriSail is superior to standard bougie during LSG in delineation and visualization, in addition to consistent sleeve formation, but they found, in contrast to our study, that GastriSail may have benefits in decreasing operative time. Musella *et al.* [8] also agreed with our results in that GastriSail helped in better visualization and delineation, besides consistent sleeve formation, but they did not study the effect of the device on the operative time. Internal benchtop test study [5] has compared GastriSail system to standard bougie and ViSiGi 3D system and found that the longer length of perforations on the GastriSail system resulted in a maximum height difference throughout the length of the lesser curvature, whereas both the standard bougie and ViSiGi 3D maintain a maximum height difference only in the top portion of the stomach. The perforations along the main tubes of both the GastriSail system and ViSiGi 3D devices allow for stomach decompression and fixation along the tissue. This suction pulls the surrounding tissue closer to the

Figure 4



Intraoperative complications.

tube, allowing for more patent delineation. The same study found that GastriSail system had statistically significant diameter consistency, independent of subject, surgeon, and location on the sleeve. Although, Gagne and Huang [9] did not use GastriSail, they had proved the superiority of using a bougie in general against the ordinary LSG.

Regarding operative time, in contrast to our results, they proved that using bougie in general significantly reduced the operating time needed to complete each step of a sleeve gastrectomy and therefore the total operating time. Agreeing to our results, they suggested that the bougie provides controlled and uniform suction, which may enable symmetrical lateral traction, thus preventing corkscrewing and hence better delineation. They also matched our results in that using bougie is associated with better consistent sleeve formation.

Regarding intraoperative complications, we found that the use of GastriSail and the standard LSG both have the same risks of hemorrhage, hematoma, esophageal injury, leakage, and intraoperative difficulty. We found GastriSail was much better in stomach alignment only. One study disagreed with us regarding the benefit of the use of GastriSail in decreasing the risk of esophageal trauma [10]. They found that GastriSail has a much lesser risk of esophageal injury than the standard LSG. However, they did not study the risk of other organ injury or other intraoperative complications we have studied. Trivedi *et al.* [7] agreed with us regarding the superiority of GastriSail in stomach alignment versus the standard LSG. However, they found GastriSail to be superior in other risks of complications like hemorrhage, hematoma, esophageal injury, and leakage. Musella *et al.* [8] found the use of GastriSail to have great benefits over standard LSG in contrast to our results. They explained that these results may be owing to the ability of the device to visualize the gastroesophageal junction, as angle of His is the major site o leakage [11] owing to ischemic causes, because of the particular vascular supply present in the area of the gastroesophageal junction [12]. Several factors have been indicated to be responsible for a leakage onset. The higher intraluminal pressure resulting at the end of the procedure [13], the use of a tighter bougie [14] as well as technical pitfalls during surgery are well known causes of leakage. Nevertheless, the potential ischemia induced on the sleeved stomach by both aggressive dissection or by the staplers, coupled with the irregular vascularization present in the area of the gastroesophageal junction, remains the main reason to explain this complication. So, the ability of GastriSail to visualize this area may be the reason they found it superior in that risk of complication. Another study [5] agreed with us in the significant

benefits of GastriSail in the alignment of stomach, but despite this, disagreed with our results in intraoperative risk of complications. They found that GastriSail has significant benefits in decreasing the risk of hematoma, hemorrhage, leakage, and organ injury including esophagus.

Nandra and Ing [15] performed a review of the Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database for complications associated with the traditional bougie, Boehringer Labs ViSiGi 3D and the Medtronic GastriSail since 2011. In addition, they looked for reported cases in the literatures of complications with these devices. They found that GastriSail has 35 reported complications since introduction in 2015. This includes 17 perforations of either the stomach or esophagus and 11 device malfunctions. GastriSail-related complications required foreign body retrieval for seven cases with all 17 perforations reportedly leading to organ repair or esophageal stent placement. In total, 24 (68%) of GastriSail complications needed subsequent intervention. Regarding literature, they found no published cases or reviews of complication rates from either the ViSiGi 3D or GastriSail. It should be noted that MAUDE reports cannot accurately determine the incidence of complications owing to underreporting and lack of verification of reports. It is difficult, then, to make conclusions based off a MAUDE analysis alone. Nevertheless, a review of these reports shows a clear disparity in the safety of different orogastric tube devices, with the GastriSail having a higher reported incidence of complications.

We have also found that the use of GastriSail was associated with smaller tube design in contrary to standard LSG, which was associated with larger corrugated design. Almost all the reviewed articles agreed with us in this result, which may be owing to the high probability of GastriSail helping to promote more consistent sleeve creation and greater procedural efficiency within the sleeve gastrectomy procedure. During the LSG procedure, there is the potential for spiraling of the stomach. Spiraling occurs when there is uneven traction placed on either the anterior or posterior stomach wall during stapling. More severe spiraling may lead to obstructive symptoms, prolonged nausea, and delayed ability to tolerate liquids [7]. The current technique of using a GastriSail device as a guide to creating the sleeve gastrectomy can lead to variability depending on how the surgeon placed the bougie against the lesser curvature. It combines the benefits of three devices into one, allowing surgeons to consistently size and decompress the stomach pouch and test for leaks without removing and reinserting another device [4]. With fewer device insertions, there is potentially less risk of irritating or injuring the esophagus during the procedure [8]. It appears that the GastriSail system can be used to help guide the surgeon's staple lines to ensure consistent shape of the stomach pouch from procedure to procedure. Once the surgeon positions the GastriSail system in the stomach, the system's unique LED lights illuminate through the stomach tissue allowing the surgeon to see a clear line delineating where the stomach should be dissected, stapled, and divided [5]. Regarding postoperative excess weight loss and 1-month postoperative gastric pouch volume, we found that there were no significant statistical differences between the use of GastriSail and the standard LSG. Despite the smaller size of the gastric pouch shown by computed tomography volumetry in group A using GastriSail, it has no statistical significance, and more cohorts will be needed to validate this point. To the best of our knowledge, we were the first in the world to study these two parameters with GastriSail system use.

Conclusion

The use of GastriSail device is superior to the standard LSG in consistent sleeve formation, visualization, delineation and good alignment, and accomplishment of a small tube design, with no significant difference in excess weight loss and operative time. However, gastric pouch size 1 month postoperatively is less with the use of GastriSail, but with no statistical significance. Further studies with larger cohort size are recommended.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1 Schauer PR, Bhatt DL, Kirwan JP, Wolski K, Brethauer SA, Navaneethan SD, *et al.* Bariatric surgery versus intensive medical therapy for diabetes-3-year outcomes. N Engl J Med 2014; 370:2002–2013.

2 Hutter MM, Schirmer BD, Jones DB, Ko CY, Cohen ME, Merkow RP, *et al.* First report from the American College of Surgeons Bariatric Surgery Center Network: laparoscopic sleevegastrectomy has morbidity and effectiveness positioned between the band and the bypass. Ann Surg 2011; 254:410–420.

3 Rosenthal RJ, Diaz AA, Arvidsson D, Baker RS, Basso N, *et al.* International Sleeve Gastrectomy Expert Panel. International Sleeve Gastrectomy Expert panel consensus statement: best practice guidelines based on experience of [12, 000 cases. Surg Obes Relat Dis 2012; 8:8–19.

4 Medtronic. Bench top testing, cadaver lab with 4 surgeons, Comparison of GastriSail™ versus Standard Bougie in Sleeve Gastrectomy in a Cadaver Model Report #PCG-025_rev 1 1/13/15. Available at: www.medtronic.com/covidien/clinical-solutions/bariatric-health. [Access on February 2018].

5 Bench top 2015 testing, porcine model, Esophageal trauma in-vivo anlaysis: GastriSail™ Report #R2274-007-0 10/3/14. Available at: http://www.medtronic.com/covidien/clinical-solutions/bariatric-health

6 Srinivasa S, Hill LS, Sammour T, Hill AG, Babor R, Rahman H. Early and mid-term outcomes of single-stage laparoscopic sleeve gastrectomy. Obes Surg 2010; 20:1484–1490.

7 Trivedi A, Miesse A, Shah R. Novel approach for creation of a non-spiraled and consistent sleeve gastrectomy. Surg Obes Relat Dis 2015; 11:S120.

8 Musella M, Milone M, Bianco P, Milone F. The visualization of gastro-esophageal junction vascular supply during a laparoscopic sleeve gastrectomy. Role of a new device. Updates Surg 2017; 69:541–544.

9 Gagner M, Huang RY. Comparison between orogastric tube/bougie and a suction calibration system. Surg Endosc 2016; 30:1684-165.

10 Gagner M, Huang RY. Comparison between orogastric tube/bougie and a suction calibration system for effects on operative duration, staple-line corkscrewing, and esophageal perforation during laparoscopic sleeve gastrectomy. Surg Endosc 2016; 30:1648.

11 Aurora AL, Khaitan L, Saber AA. Sleeve gastrectomy and the risk of leak: a systematic analysis of 4, 888 patients. Surg Endosc 2012; 26:1509–1515.

12 Ferrer-Marquez M, Belda-Lozano R, Ferrer-Ayza M. Technical controversies in laparoscopic sleeve gastrectomy. Obes Surg 2012; 22:182–187.

13 Del Genio G, Tolone S, Limongelli P, Brusciano L, D'Alessandro A, Docimo G, *et al.* Sleeve gastrectomy anddevelopment of 'de novo' gastroesophageal reflux. Obes Surg 2014; 24:71–77.

14 Parikh M, Issa R, McCrillis A, Saunders JK, Ude-Welcome A, Gagner M. Surgical strategies that may decrease leak after laparoscopic sleeve gastrectomy. A systematic review and metaanalysis of 9991 cases. Ann Surg 2013; 257:231–237.

15 Nandra K, Ing R. Safety of orogastric tubes in foregut and bariatric surgery Surg Endosc 2018; 32:68–70.