Evelauation of the use of Gastrisail[tm] Gastric Positioning Device during Laparoscopic Sleeve Gastrectomy, Early Experince

Ahmed M.S.M Marzouk, Haitham S. Omar
Department of General Surgery, Faculty of Medicine, Cairo University

ABSTRACT

Aim: *Laparoscopic sleeve gastrectomy (LSG) has markedly evolved for the management of morbid obesity; The dissection complications is the main concern. Gastrisail™ is a recently released gastric positioning system technology aiming to facilitate better control of potential surgical complications. In this work, we evaluate the Gastrisail™ positioning system use, with its impact on the early surgical outcome.* ***Methods:*** *Retrospective comparative study of Gastrisail™ Gastric positioning system comparing its use in 20 patients against 20 patients had sleeve gastrectomy without its use with assessment of the effectiveness and impact on the operative and early postoperative outcomes.* ***Results:*** *Patients' characteristics in (Group A) 16 (80%) were females and 4 (20%) were males, age was (Mean 33.75/ SD 6.48), BMI (Mean 43/ SD 3.97), while in (Group B) 13 (65%) were females, and 7 (35%) were males, age (Mean 37.35/ SD 4.36), BMI (Mean 44.19/ SD 4.06), Mean operative time was 140 Min. and 162.6 Min. Mean gastric dissection in both groups was 24.9 and 37.3Min., mean gastric stapling time was 32.2 and 37.4 Min respectively. Number of ports used was 4 ports in 14 patients (70%) and 5 ports in 6 patients (30%) for (group A), 5 in 18 patients (90%) and 6 in 2 patients (10%) in (Group B), number of needed stapling reloads (60 mm) was 5 in 11patients (55%), 6 in 8 patients (40%), 7 in one patient (5%) (group A), and 5 in 4 patients (20%), 6 r in 13 patients (65%) and 7 in 3 patient (15%) in (group B). Intraoperative bleeding from solid organ injury in 2 cases in (Group A) and 5 cases in (Group B) (P value < 0.01).* ***Conclusion:*** *Despite the added cost of the use of Gastrisail™ Gastric positioning system, the early outcomes push the use of such device to ensure safer surgery. However, larger randomized studies are required.*

INTRODUCTION

Morbid obesity worldwide is currently considered as a pandemic disease. Together with the related co-morbidities involving a wide variety of chronic diseases which in turn affect quality of life with reduction of life expectancy [(1)] weight loss surgery has become the mainstay of severe obesity management and is associated with long-term weight reduction and decreased overall morbidity and mortality.

Per the American Society for Metabolic and Bariatric Surgery (ASMBS) estimate of bariatric surgery numbers, sleeve gastrectomy accounted for the most bariatric procedures (53.8% of the 196,000 surgeries), followed by gastric bypass (23.1%)in 2015. [(2)]

Even though Laparoscopic sleeve (vertical) gastrectomy (SG) was first introduced in 1999 as a primary step of the biliopancreatic diversion duodenal switch (BPD-DS) procedure [(3)], It is currently considered as the main preferred primary bariatric worldwide surgical option. However, its technical steps are still debatable.

One of these debates is the of gastric calibration tube type and size used during the procedure. Although the initial tubes used were (50-Fr to 60-Fr) in size, however they are avoided nowadays with current suggested tube size below 40-Fr. [(4-9)] Another aspect is the manufacturing properties of the tube material regarding the tip bluntness and firmness of the tube which on one hand may cause oesophageal injuries if markedly rigid with rough manipulations during insertion, on the other hand the use of softer tubes not completely innocent as they may be falsely included in the staple line if not recognized especially with unexperienced hands, for this reason some authors start to relay on visual estimation for gastric sleeve pouch sizing.[(10)]

A review regarding the technical errors and difficulties which may be encountered during laparoscopic sleeve gastrectomy and may mandate extra actions to handle such errors found that most them were during the dissection of the greater curvature, opening of the lesser sac and gastric stapling with significant correlation with postoperative adverse effects. [(11)]

Such technical difficulties push the development of aided materials in order to overcome these difficulties. Gastrisail™ is a recently released gastric positioning system technology which was approved by the U.S. Food and Drug Administration 2015 with the intention to facilitate better control of potential surgical complications during laparoscopic sleeve gastrectomy.

In this work, we evaluate the Gastrisail™ positioning system use during laparoscopic sleeve gastrectomy with its impact on the early surgical outcome.

PATIENTS AND METHODS

A retrospective review of 20 patients underwent laparoscopic sleeve gastrectomy as weight loss procedure with the use of Gastrisail™ positioning system as a gastric calibration device (Group A) were evaluated against another 20 patients had the same procedure without the use of the Gastrisail™ positioning system (Group B) during the period from January 2016 to January 2017. Both groups were done by the same surgical teams.

All patients were included in the applicable bariatric surgery guidelines which include Body Mass index (BMI) above 40 Kg/m^2 or 35-39.9 Kg/m^2 with associated obesity related comorbidity, all patients had a throughout preoperative clinical assessment by a dedicated multidisciplinary team regarding the dietary life style to be indicated for sleeve gastrectomy as a restrictive procedure, previous weight loss attempts, associated co-morbidities, presence of gastric reflux symptoms and sleep disorders. Moreover, a Psychological and Cardiological assessment were routinely done for every patient.

In addition, a full laboratory assessment including laboratory investigations in the form of blood picture, liver and kidney functions, random blood glucose with assessment of glycated haemoglobin (HbA1c), coagulation profiles, lipid profiles, thyroid function assessment, serum calcium, vitamin B1, B12 and D screening. Besides, ultrasound screening for associated gall stones and chest X- ray were done. Electrocardiogram and Trans-Thoracic Cardiac Echocardiography were done on individual basis as required by the cardiologists involved in the patients screening preoperatively.

An informed consent was discussed with all the patients including the weight loss surgery Pros and Cons, Possible intra and post-operative early and late complications, the need for nutritional supplementations post-operative together with a detailed preoperative low carbohydrates and post-operative diet plans.

Patients were admitted to the hospital in the same day of the surgery fasting 8 hours for solid food and 6 hours for fluids, preoperative subcutaneous anticoagulation in the form of low molecular weight heparin together with a single dose of prophylactic antibiotics were given and compression lower limbs stockings, in our practice we do not insert urinary catheter.

Operative steps: In both groups after establish pneumoperitoneum using veress needle at the left hypochondrium just below the costal margin at the midclavicular line, ports are inserted: Camera midline (11 mm) port around 15 Cm below the costal angle, assistant (5 mm) port at the left anterior axillary, working (12mm) port a hand breadth from the camera port and slightly upward in the left hypochondrial area, working (15mm) port at the right hypochondrium, in case that liver retractor is needed extra (5mm) port is inserted just below the subcostal angle. (Fig.1)

Fig. 1: Port sites

In (Group A) the Gastrisail™ positioning system is a 36 Fr flexible non-sterile, single patient use device gastric tube designed to be inserted into the oesophagus by an anaesthesiologist and it consists of a multi-lumen flexible tube with multiple perforations and an adjacent sail connected at the distal end. The distal end is a closed rounded tip. The semi-rigid

sail is deployed, expanding the stomach radially, thus positioning the bougie along the lesser curvature where it is desired. The sail includes battery-powered LED lights. The batteries are housed in the handle at the proximal end of the device. (Fig.2) [12].

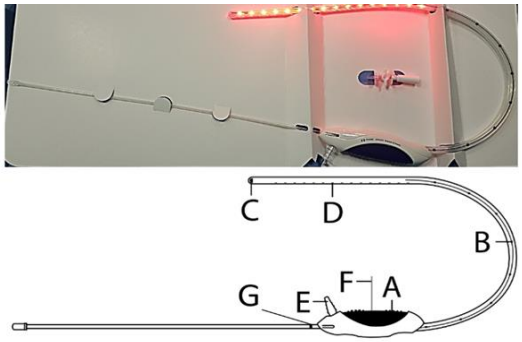

Fig. 2: Gastrisail™ Gastric Positioning System A) Axial handle houses batteries and aids in insertion and placement. B) External markings direct orientation and insertion depth of device. Markings also indicate location of sail depolyment and retraction . C) LED lights at the distal tip illuminate providing visalization of both the sail when deployed and the main tube when the sail is fully retracted. D) Perforations in the distal protein of the main tube provide suction and leak testing. E) Universal tapered inflation and suction conncection is regulated up to 150 mmHg. F) sheipping wedge. G) Inner tube safety point.

Prior to the device introduction, the anaesthesiologist activates the LED light system through removal of the shipping wedge from the handle and introduce it with lubricant under vision through the oesophagus, in same time we observe the introduction though the gastroesophageal junction guided with the LED lights (Fig.3)

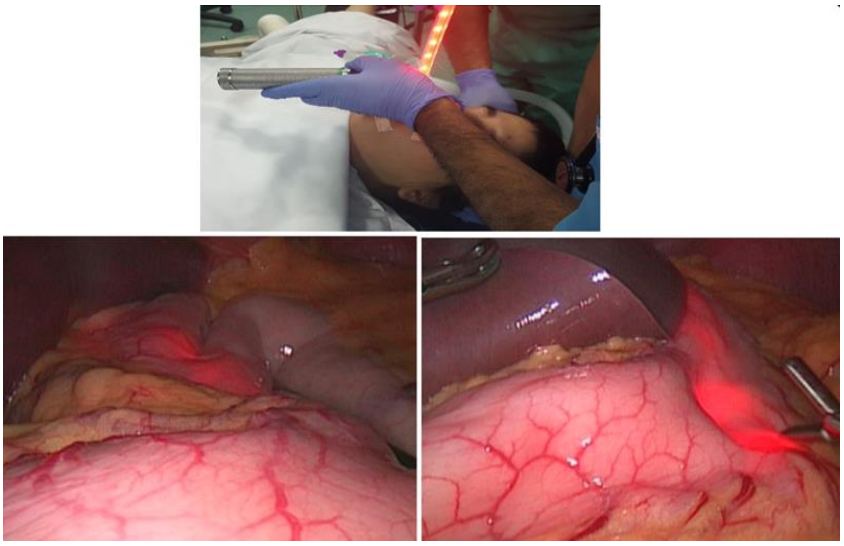

Fig. 3: Device introduction under vision and though the gastroesophageal junction guided with the LED lights

Once positioned in the stomach, the anaesthesiologist push the inner tube to expand the stomach's greater curvature radially while the outer tube will be deployed be easily elevated by the left surgeon's working hand stretching the greater curvature vascular structures with dissection of the greater curvature starting by opening of the lesser sac. (Fig.4)

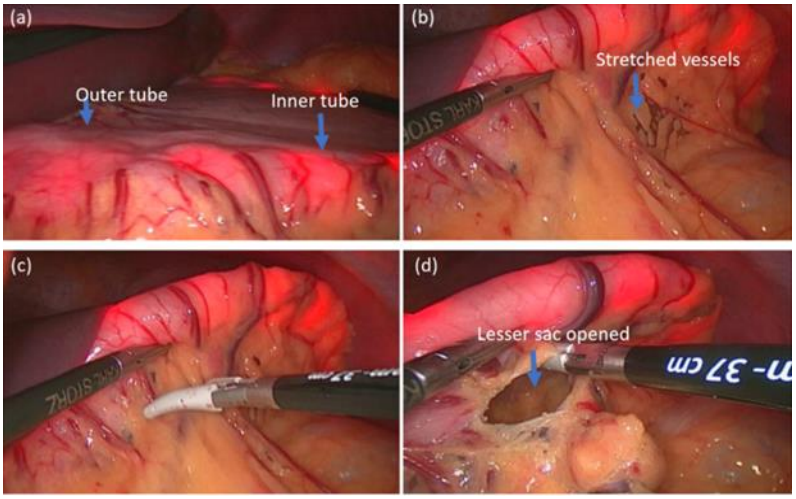

Fig. 4: Gastrisial deployment innertube at the greater curvature and outer tube at the lesses curvatuve (a) gastric elevation exposing vasculature (b) Dissection start point mid part of greater curvature (c) lesser sac opdning (d)

Upon opening the lesser sac, a continuous dissection of the gastroepiploic vessels, short gastric and posterior gastric vessels releasing posterior gastric adhesions to ensure complete gastric fundus mobilization and exposure of the left crus and dissection of the gastroesophageal ligament with identification of the oesophagus aided by the device light (Fig.5)

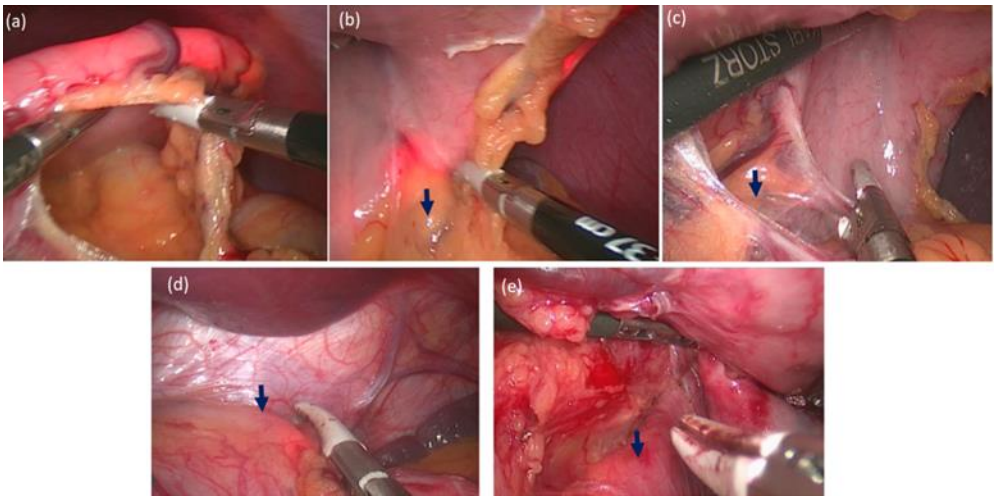

Fig. 5: Dissection of (a) gastroepiplic vessels, (b) short gastric vessels, (c) posterior gastric adhesions, (d) Gastroesophageal ligmanet exposing (e) the left crus.

After complete gastric greater curvature, and posterior gastric wall dissection with fundus mobilization we routinely start stapling about 4 Cm from the pyloric ring. Before starting we ask the anaesthesiologist to withdraw the inner tube till the black safety point (Fig.2-G) appears to avoid inclusion of the inner tube in the staple line. Guided by the LED light stapling is continued till completion of the sleeve gastrectomy (Fig.6)

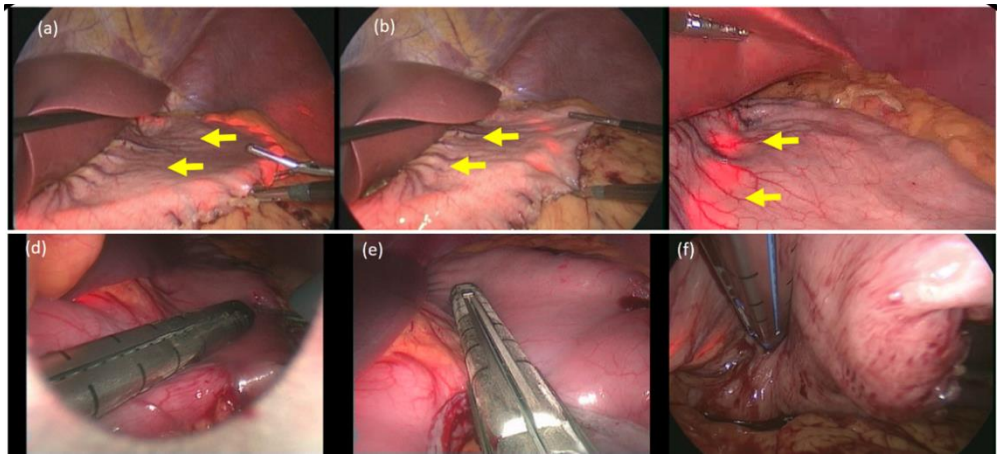

Fig. 6: Withdrawal of the inner tube (a,b,c), gastric stapling guided by the illuminating tube (d,e,f)

In (Group B) we start the surgery with gastric dissection 4 Cm from the pyloric ring to the hiatal opening without introduction of any gastric tubes unless decompression is needed to minimize the introduction and withdrawal of the gastric tubes and in turn to avoid the possible gastro-oesophageal injuries, during dissection an interaction between the surgeon and assistant is desired to create a traction and counter traction between the stomach and the attached omentum in order to dissect the right plane, after completion of the gastric dissection the anaesthesiologist introduce the calibration bogie and surgeon should place it in order to be deployed over the lesser curvature and extending to the pylorus, followed by gastric stapling starting 4 Cm from the pyloric ring.

We routinely use Tri-Staple™ black Covidien Endo GIA™ 60mm staples at the antral area and then continue stapling with purple Covidien Endo GIA 60 mm staples up to the angle of HIS. The final staple fire is deviated 1cm away from the oesophago-gastric junction.

After completion of gastric sleeve, Methylene Blue injection and air leak test are done routinely while the tube in place (Group A) (Fig.7), while they are done after retraction of the bogie to the gastro-oesophageal orifice (Group B) to check the integrity of the staple line, followed by staple line reinforcement (Fig.8) using absorbable polyglactin 3/0 suture material and insertion of para gastric drain with extraction of the resected gastric part through the Right hypochondrial port site.

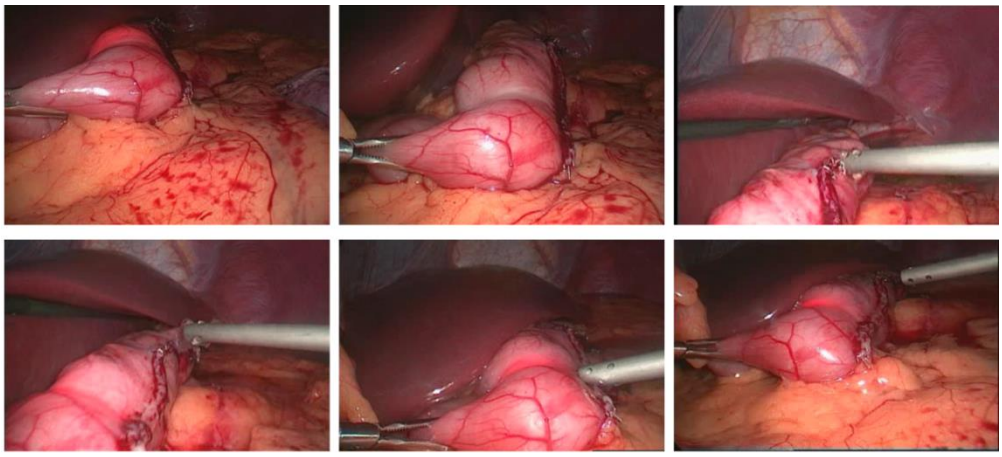

Fig. 7: Methylene Blue leak test (a,b,c), Air leak test (d,e,f)

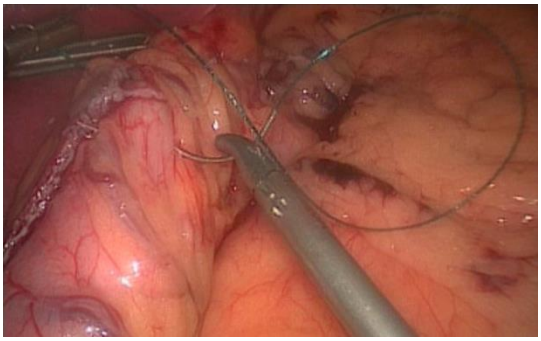

Fig. 8: Staple line re-enforcement guided by LED light.

Postoperative continuing anticoagulation prophylaxis, proper hydration, early ambulation and regular use of spirometer as respiratory exercises were followed. 1st post-operative day a contrast study is routinely done before starting oral fluids and usually we discharge the patients on the 1st or 2nd post-operative day on a structured diet program with instructions for proper hydration, multivitamin replacements and proton pump inhibitors.

In this study, we have reviewed the operative steps in both groups (Fig.9) and time needed for each step was calculated. Evaluation of laparoscopic sleeve gastrectomy With (Group A) and Without (Group B) the use of Gastrisail™ positioning system regarding total operative time, gastric dissection time, gastric stapling time, number of staple reloads used, Intra-operative complications, post-operative early outcomes, resume of oral fluids, total hospital stay duration. Statistical analysis of the outcomes was done with the aid of (IBM SPSS Statistics V20) software. Data was summarized using Mean and SD for quantitative variables and number and percent for qualitative variable. Comparison between quantitative variable done using paired-samples T test for variables which where normally distributed and nonparametric Wilcoxon for quantitative variables, which were not normally distributed. Comparison between qualitative variables done using chi square. P value less than 0.05 was consider of statistically significant.

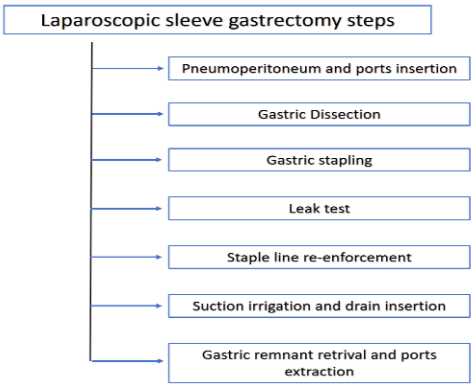

Fig. 9: Operative steps

RESULTS

Patients characteristics:

Among the 20 patients underwent laparoscopic sleeve gastrectomy with the aid of Gastrisail™ positioning system (Group A) 16 patients (80%) were females and 4 patients (20%) were males, age of the patients was (21-50 years, Mean 33.75/ SD 6.48), BMI (38-51.3 Kg/m^2, Mean 43/ SD 3.97), while in (Group B) 13 (65%) were females, and 7 (35%) were males, age (29-46 years, Mean 37.35/ SD 4.36), BMI (39-54.6 Kg/m^2, Mean 44.19/ SD 4.06) (Table.1) (Fig. 10)

Table 1: Patient characteristics [^ Mean/SD, * Correlation is significant at the 0.01 level (2-tailed)]

	Group A	**Group B**	***P Value***
M/F	4/16	7/13	0.001*
Age ^	33.75/ 6.48	37.35/ 4.36	0.121
BMI^	43/ 3.97	44.19/ 4.06	0.152

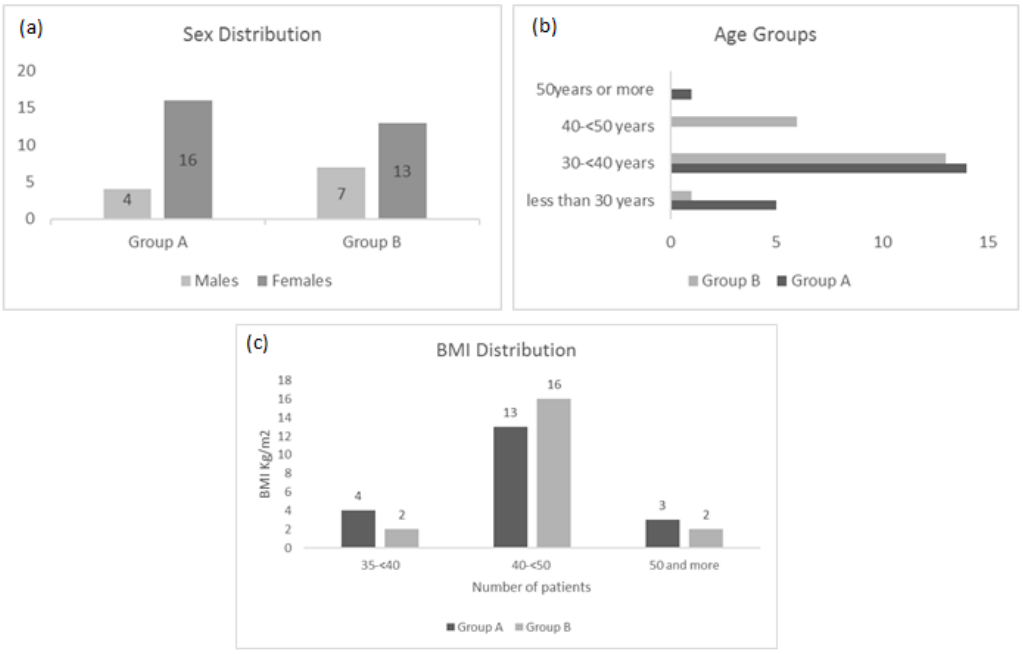

Fig. 10: Patients characteristics (a) Groups sex distribution, (b) Age groups, and (c) BMI distribution

Operative variables: (Tab.2) (Fig.11, 12)

Operative time was (110-198 min, mean 140, SD 22.9) in (Group A) and (143- 180 min, mean 162.6 , SD 9.89) in (Group B), calculation of the gastric dissection in both groups was (19-35 minutes, mean 24.9, SD 3.68) in (Group A), and (31-45 minutes, mean 37.3, SD 3.68) in (Group B) while gastric stapling time was (23-60 minutes, mean 32.2, SD 7.08) for (Group A) and (29-45 minutes, mean 37.4, SD 3.87) in (Group B).

2 patients (10%) in (Group A) and 3 patients (15%) in (Group B) had associated laparoscopic cholecystectomy simultaneous in same setting which was significantly increase the total operative time (P value <0.05). Regarding the number of ports used we found that no liver retractor was needed in 14 patients (70%) reducing the number of ports to 4, however in 6 patients (30%) extra port for liver retraction was needed either in (group A), however in (Group B) number of ports needed were 5 in 18 patients (90%) and 6 in 2 patients (10%). Moreover, we have noticed that number of needed stapling reloads (60 mm) was 5 reloads in 11patients (55%), 6 reloads in 8 patients (40%) and 7 reloads in one patient (5%) in (group A), and 5 reloads in 4 patients (20%), 6 reloads in 13 patients (65%) and 7 reloads in 3 patients (15%) in (group B).

Table 2: Operative parameters [^ Mean/SD, $ Percentage, * Correlation is significant at the 0.05 level (2-tailed)]

	Group A	**Group B**	***P Value***
Operative duration^	140/22.9 Min	162.6/9.89 Min	0.032*
Gastric dissection time^	24.9/3.68	39.9/ 3.11	0.118
Gastric stapling time^	32.2/ 3.97	37.4/ 3.87	0.626
Number of staples used	5 (55%) 6 (40%) 7 (5%)	5 (20%) 6 (65%) 7(15%)	0.363
Number of ports$	4 (70%) 5 (30%)	5 (90%) 6 (10%)	0.541
Intraoperative bleeding$	2 (10%)	5 (25%)	0.008*

Intraoperative reported complications were bleeding from solid organ injury (left hepatic lobe and spleen) in 2 cases in (Group A) and 5 cases in (Group B) (P value < 0.01), we reported that all liver injuries encountered during the introduction of the epigastric port specially in patients with marked hepatomegaly, while the splenic injuries encountered during the mobilization of the gastric fundus, all those injuries were self-limited and was controlled by applying direct compression and haemostatic patches with no reported post-operative sequalae however they added more operative time was needed in such patients. No reported cases of bowel injury or other possible intraoperative complications in both groups.

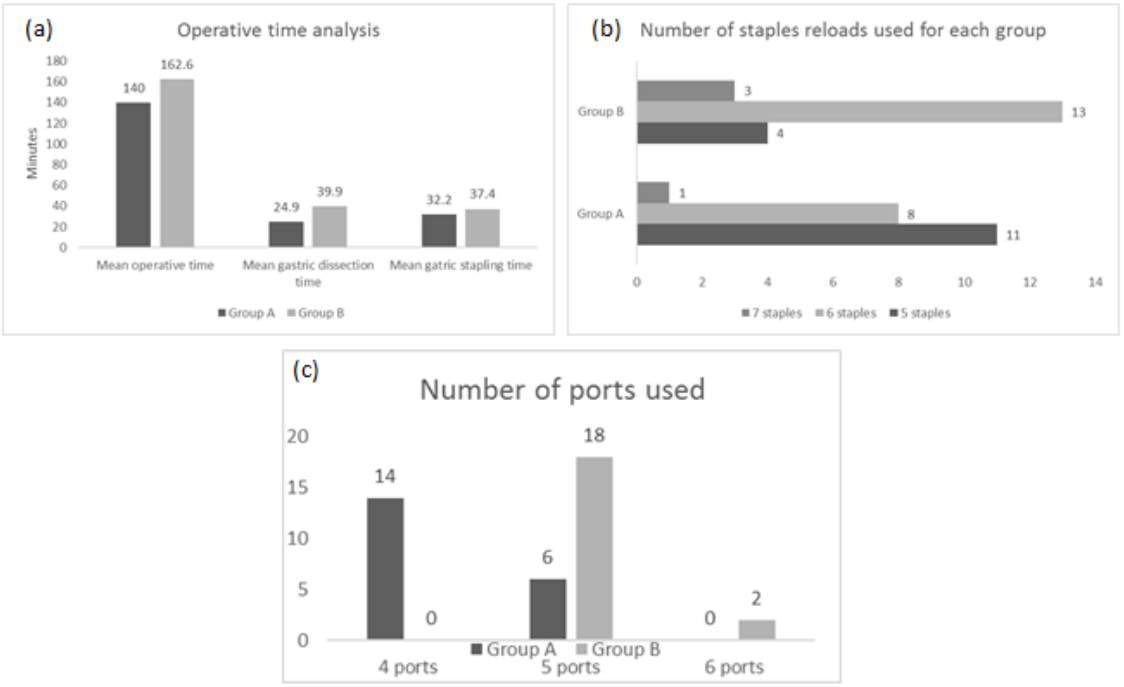

Fig. 11: (a) Operative time analysis, (b) Staples reloads used in each group, and (c) Number of ports used.

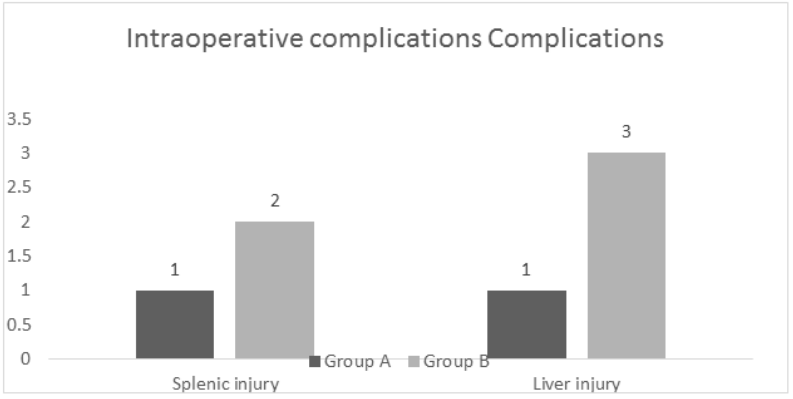

Fig. 12: Intraoperative bleeding rate in both groups

In all patients, oral resumption was in 1st post-operative day after contrast study scan which showed no cases of staple line leakage or gastric stenosis, hospital stay was 2 days in 10 patients (50%) and 3 days in the other 10 patients (50%) in (group A) and 2 days in 12 patients (60%) and 3 days in the other 8 patients (40%) in (group B) with no statistical correlated significance. The extended hospital stay was due to feeling of nausea and vomiting which was medically controlled.

No reported cases of repeated vomiting, fever, thromboembolism necessitate prolonged hospital stay and on 1st 40 days of follow up there were no reported cases of re-admission or major complications in both groups.

DISCUSSION

As a weight loss restrictive procedure sleeve gastrectomy has become the most reputable surgical option for weight loss to the extent that it exceeded gastric bypass procedure as shown in latest publications [(2)] However, it is not as simple as surgeons consider as it requires accurate tissue dissection and a step wise meticulous surgical steps. [(13)]

With the rapid developments and technologies in minimally invasive surgery field, the key terms of safety and effectiveness of the surgical procedures are considered the main priorities for the bariatric surgery providers owing to the fact that bariatric surgery nowadays is done mainly laparoscopically. Sleeve gastrectomy related post-operative complications including leakage and bleeding may rise through the potential hazardous steps of the greater curvature and hiatal dissection and the stapling of the stomach to form the sleeved part. [(11)]

In this study, early experience of the use of Gastrisail™ gastric positioning device in laparoscopic sleeve gastrectomy with evaluation of the surgical steps related to the use of such device with comparison to surgery without it have shown that the Gastrisail™ gastric positioning device has helped in the accessibility and easiness of the gastric dissection with less related difficulties specially in patients with marked intrabdominal fat, the device LED light helps in identification of the gastroesophageal sphincter during the device introduction as well as better identification of the greater curvature for better dissection. Moreover, the idea of creating gastric flab by the application of negative pressure with adherence of the anterior and posterior gastric walls helped in dissection through reduction of assistant interaction to create counter traction on the omental vessels therefore reduction of unnecessary incidence of bleeding or visceral injuries specially at the gastro-splenic and gastric fundus mobilization.

In addition to the above-mentioned dissection advantages gastric stapling was done efficiently with the guide of the LED light as well with better identification of the gastric pouch with no reported cases of post-operative stenosis or persistent vomiting owing to the fact that most of post sleeve related complications including leakage bleeding may rise through the potential hazardous steps of the greater curvature and hiatal dissection and the mispositioning of the staplers to form the sleeved part. [(11)] In all our patients, oral intake was tolerated in first post-operative day with no reported radiological or manifested gastric pouch stenosis specially at the level of incisura angularis which is the most amenable part of post-operative stenosis and in turn risk of leakage from staple line. [(3,14)]

Gastrisail being 36 Fr follows the sleeve gastrectomy practice guidelines, which recommended gastric calibration size not to be larger than 32-36 Fr with care to avoid stapling very close to it. [(8)] The presence of LED light directs the surgeon's attention to do stapling with better visual assessment to the fashioned gastric sleeve. Moreover, we have noticed that the number of needed stapler reloads were reduced to 5 in 55% of the cases which in turn may reduce the operative costs without affecting the outcomes.

Besides, we found that using such device the need for liver retraction was reduced specially in patients followed strict preoperative diet preparation, therefore reduction of the number of needed ports for the surgery which in turn reduce the post-operative pain, port site related complications as well as reduce the operative costs without affecting the outcomes.

In our study the apparent reduction in staples reloads and ports numbers used in Gastrisail use group were helpful to reduce the operative time through the reduction of gastric dissection time and time needed for stapling in comparison to the non-use group of patients, however it was not

statistically significant possibly owing to the small sample size.

On the other hand, the use of gastrisail was helpful in reduction of intraoperative possible complications in form of bleeding and organ injuries which was statistically significant when compared to non-use group. The advantage of better traction counter traction aided by the gastrisail device together with minimal tissue manipulations and reduction for the need of liver retraction all are contributing factors to reduce such complications and in turn reduction of possible post-operative morbidities.

Despite the apparent advantages of the Gastrisail™ device, its added cost being single use to the operative cost which is already expensive may limit its use, however the apparent potential reduction the used ports and staplers reloads may weigh such expense.

Finally, the study sample size with being a non-randomised study with lack of published research articles related to such new device may represent the weak aspect of the study, however the early promising outcomes push towards the implementation of larger series of studies with longer follow up duration and comparison with other available calibration devices.

CONCLUSION:

Despite the added cost of the use of Gastrisail™ Gastric positioning system, the early outcomes in the operative ease through apparent favourable safe dissection, with efficient gastric suction and leak tests assessments push the use of such device to ensure safer surgery. However, a larger size studies with proper controlled randomization and assessment with the other available calibration devices are still required.

Disclosure and conflict of interest:

Ahmed M.S.M. Marzouk has no conflicts of interests to declare in relation to this article. Haitham S.E. Omar has no conflicts of interests to declare in relation to this article by any means of funding, employment or personal financial interest.

Statement OF INFORMED CONSENT:

Informed consent was obtained from all individual participants included in the study including an informed consent for video and photos recording for research and learning objectives.

REFERENCES

1. Yanovski SZ, Yanovski JA. Obesity. N Engl J Med. 2002; 346:591–602.
2. https://asmbs.org/resources/estimate-of-bariatric-surgery-numbers , 2016.
3. Gumbs A, Gagner M, Dakin G, et al. Sleeve gastrectomy for morbid obesity. Obes Surg. 2007; 17:962–9.
4. Rosenthal RJ et al. International Sleeve Gastrectomy. Expert Panel Consensus Statement: best practice guidelines based on experience of >12,000 cases. Surg Obes Relat Dis. 2012; 8(1):8–19.
5. Atkins ER, Preen DB, Jarman C, et al. Improved obesity reduction and co-morbidity resolution in patients treated with 40-French bougie versus 50-French bougie four years after laparoscopic sleeve gastrectomy.Analysis of 294 patients. Obes Surg. 2012; 22(1):97–104.
6. Yuval JB, Mintz Y, Cohen MJ, et al. The effects of bougie caliber on leaks and excess weight loss following laparoscopic sleeve gastrectomy. Is there an ideal bougie size? Obes Surg. 2013; 23(10):1685–91.
7. Lazzati A, Guy-Lachuer R, Delaunay V, et al. Bariatric surgery trends in France: 2005-2011. Surg Obes Relat Dis. 2013; S1550–7289(13): 00253–0. doi:10.1016/j.soard.2013.07.015.
8. Parikh M, Issa R, McCrillis A, et al. Surgical strategies that may decrease leak after laparoscopic sleeve gastrectomy: a systematic review and meta-analysis of 9991 cases. Ann Surg. 2013; 257(2): 231–7.
9. Spivak, H., Rubin, M., Sadot, E. et al. Laparoscopic Sleeve Gastrectomy Using 42-French Versus 32-French Bougie: The First-Year Outcome. OBES SURG. 2014, 24: 1090. doi:10.1007/s11695-014-1199-9.
10. Mahawar, K.K. Bougie-Related Oesophageal Injury with Bariatric Surgery: An Unrecognised Problem. OBES SURG. 2016,26: 1935. doi:10.1007/s11695-016-2213-1
11. Van Rutte, P., Nienhuijs, S., Jakimowicz, J. et al. Identification of technical errors and hazard zones in sleeve gastrectomy using OCHRA. Surg Endosc. 2017, 31: 561. doi:10.1007/s00464-016-4997-4.

12. Gastrisail gastric positioning system product information kit (2017) http://www.medtronic.com/content/dam/covidien/library/us/en/product/surgical-stapling/gastrisail-gastric-positioning-system-product-information-kit.pdf
13. Kassir R, Breton C, Lointier P, et al. Laparoscopic Roux-en-Y gastric bypass with hand-sewn gastrojejunostomy using an absorbable bidirectional monofilament barbed suture: review of the literature and illustrative case video. Surg Obes Relat Dis. 2014; 10:560–1.
14. Nguyen N.T., Xuan-Mai N. T., dholakia C. The use of Endoscopic Stent in Management of Leaks After Sleeve Gastrectomy. Obes Surg. 2010, 20:1289-1292.