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Standardised Sleeve Gastrectomy Without Reinforcement

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ABSTRACT

Background and Objectives: Laparoscopic sleeve gastrectomy (LSG) has some unique complications, the most concerning of which is sleeve leak. Staple line reinforcement (SLR) has been suggested as a means of decreasing the risk of sleeve leak, but it increases the cost. However, there is little in the literature regarding the effect of standardized operative technique in reducing the complications and improving the outcomes in LSG. We sought to demonstrate that standardization of the operative procedure and perioperative care is the key to an excellent 30-day outcome and that SLR is not necessary to ensure a negligible staple line leak and bleeding rate.

Methods: A prospectively maintained database was analyzed to identify 303 consecutive patients undergoing LSG between July 2010 and November 2017. Data on patient demographics, length of hospital stay, conversion to open surgery, perioperative complications, and mortality were analyzed. Standardized operative technique and postoperative protocol were followed in all cases. SLR was not used in any case.

Results: Among 303 cases, there were 15 complications (5%), 5 (1.7%) of which were severe (Clavien-Dindo grade ≥3a). There were no conversions to open procedure, no staple line leaks, and no inpatient deaths in the cohort. No patient was readmitted with an early stricture.

Conclusions: The use of a standardized operative and postoperative protocol led to an excellent early outcome in our LSG cases. Standardization may act to obviate the need for routine SLR techniques which are associated with a significant financial cost to both patient and hospital.

Key Words: Sleeve gastrectomy, Sleeve leak, Standardization, Staple line reinforcement.

INTRODUCTION

The prevalence of obesity is continuing to increase worldwide,[1] and the effectiveness of bariatric surgery in treating these patients is widely accepted.[2] The improvement seen in diabetes control, blood pressure, and cardiovascular risk profile is also well documented.[3] Laparoscopic sleeve gastrectomy (LSG) has gained popularity as a stand-alone procedure because of its effectiveness and perceived ease of performing surgery.[4,5] LSG, although a safe procedure, has some unique complications, the most concerning of which is sleeve leak. Staple line reinforcement (SLR) has been suggested to be a method of decreasing the risk of sleeve leak and of staple line bleeding,[6–8] although there is controversy about its effectiveness.[9–11]

Standardization of operative technique is another important determinant in optimizing outcomes and it is demonstrated to be effective in laparoscopic Roux-en-Y gastric bypass (LRYGB).[12] However, there are few publications in the literature regarding the effect of standardization in reducing the complications and improving the outcomes in LSG.[13]

Our study, therefore, details our experience in performing LSG without SLR and using rigorous standardization of operative technique and postoperative protocol. We performed a retrospective case series analysis of 303 consecutive LSGs, using a prospectively collected database. LSGs were performed by a single surgeon who was beyond the learning curve.[14] We wanted to demonstrate that standardization of operative procedure and perioperative care is the key to excellent 30-day outcomes and that SLR is not necessary to ensure a negligible staple line leak and bleeding rate.

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Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: For this type of study formal consent is not required.

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All procedures performed in studies involving human participants were in accordance with the ethics standards of the institutional and the National Research Committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. For this type of study, formal consent of patients is not required.

METHODS

A prospectively maintained database was analyzed to identify 303 consecutive patients who underwent LSG from July 2010 through November 2017. Patient confidentiality was maintained. Patient demographics, length of hospital stay, conversion to open surgery, perioperative complications, and mortality were analyzed. A perioperative complication was considered to have occurred if documented within 30 days of surgery. Patient selection was as per national guidelines at the time of surgery.[15]

Operative Technique

LSG was performed with a 4-abdominal-trocar technique and Nathanson liver retractor. In 301 cases the greater omentum was dissected from the greater curve of stomach with a harmonic scalpel (Harmonic ACE; Johnson & Johnson, Wokingham, UK), whereas in 2 cases, a bipolar/ultrasonic energy device was used (Thunderbeat; Olympus UK, Cardiff, Wales, UK) on a trial basis introduced by the hospital. The greater omentum was further treated with harmonic scalpel to produce a beaded appearance with the purpose of interrupting the epiploic arcade of vessels at multiple levels to reduce the risk of postoperative bleeding (**Figure 1**). A full fundus mobilization was performed until the left crus was identified.

An antrum-sparing sleeve commencing 2–4 cm from the pylorus was then created over a 30-French bougie, with sequential firings of a laparoscopic stapling device to form a sleeve with a capacity of 60 mL. The cartridge choice in all cases was standardized with an initial one 60-mm (4.4-mm staple height) black cartridge, followed by two 60 mm purple (4.0-mm staple height) (Medtronic Limited, Watford UK)/green (4.1-mm staple height) (Johnson & Johnson) cartridges (**Figure 2**). If the stomach was noted to be thick, a further 60-mm purple/green cartridge was used. LSG was then completed with 60-mm tan (3.0-mm staple height) (Medtronic Limited) or gold (3.8-mm staple height) (Johnson & Johnson) cartridges up to the gastroesophageal junction. To avoid angulation and potential stricture formation at the incisura, no angulation of stapling device was undertaken for the first 2 firings (**Figure 3**). This method ensured sufficient distance from the incisura. At the apex of the LSG, a distance of at least 1 cm from the gastroesophageal junction was ensured (**Figure 4**).

SLR was not used in any case in this series. A methylene blue test was used to assess any staple line leaks during surgery. Next, a hemostatic test was performed by artificially raising the patient's blood pressure to a supranormal level (>140 mmHg systolic). The isolated bleeding areas were then clipped with a laparoscopic clip applicator (Ligaclip 10 mm; Johnson & Johnson) to create a characteristic hedgehog appearance of the sleeve in situ (**Figure 5**). A 20- or 24-French Robinson drain was placed alongside the staple line in all cases.

Enhanced-recovery principles were followed in all cases. All patients were encouraged to drink clear fluids with a straw from the recovery room and mobilized on the day of surgery, and a standardized medication plan was followed (**Table 1**). Incentive breathing exercises were undertaken at the bedside. Patients were permitted free fluids via straw on the first postoperative day. Contrast studies were not obtained after surgery on a routine basis. Discharge was planned at postoperative day 2, if the criteria in **Table 1** were fulfilled. All patients were followed up by the bariatric specialist nurse at 2 weeks after surgery and subsequently reviewed by the senior author.

Data were analyzed with SPSS, version 21.0 (IBM, Armonk NY, USA). Complications were recorded and stratified according to the Clavien-Dindo classification.[16]

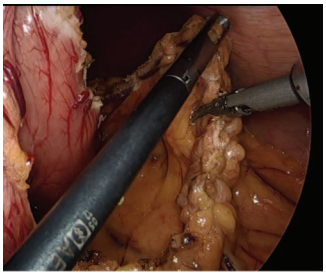

Figure 1. Beading of the greater omentum.

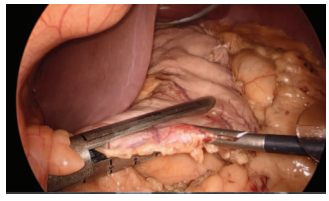

Figure 2. First stapler firing with black cartridge without angulation.

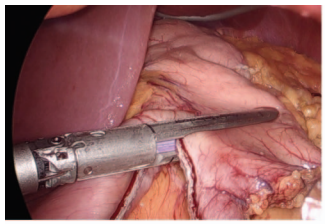

Figure 3. Second stapler firing without angulation.

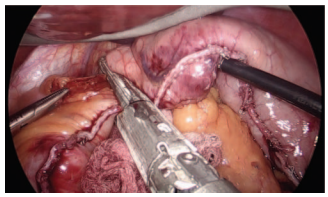

Figure 4. Final stapler firing > 1 cm from the GOJ.

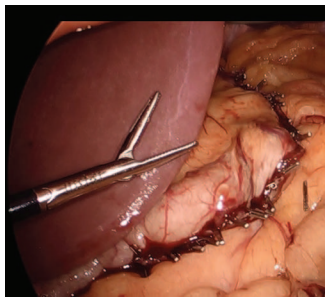

Figure 5. Hedgehog appearance of the final gastric sleeve.

RESULTS

A total of 303 LSGs were performed during the study period. The demographic characteristics are shown in **Table 2**. The mean age was 43.6 (SD 10.8) years, and body mass index was 47.8 (SD 7.41) kg/m^2. Most patients were female (77.88%). The median American Society of Anesthesiologists grade was 2 (interquartile range [IQR] 2–3) and the median obesity surgery mortality risk score (OSMRS) was A (IQR A-B). The mean length of stay was 2.5 (SD 2.5) days.

The 30-day or perioperative outcomes are shown in **Table 3**. Among 303 cases, there were 15 (5%) perioperative complications, of which 5 (1.7%) were defined as severe (Clavien-Dindo grade ≥3a). The rate of chest infection was 1.3%. Four patients were readmitted with dysphagia within 30 days. All investigations were normal, and no abnormality with regard to the sleeve was detected. There were no conversions to open procedure, no staple line leaks, and no inpatient deaths in the cohort. No patient was readmitted with an early stricture. Complications classified according to the Clavien-Dindo scale are shown in **Table 4**. One patient died within 30 days in a different institution.

Of 15 patients, 5 underwent reoperation, all procedures were performed laparoscopically. Two patients had a negative laparoscopy for abdominal pain. Two cases had a second laparoscopy with findings of intra-abdominal hematoma, but no active bleeding point was identified, therefore, the rate of bleeding in this series was 0.66%. In one case, a thermal injury to the sleeve from a bipolar ultrasonic energy device (Thunderbeat; Olympus UK) was identified.

DISCUSSION

In this study, we demonstrated that excellent results in terms of minimal complications and no sleeve leaks can be achieved, in our series of 303 consecutive LSGs. We believe that by applying a standardized operative technique and rigorous postoperative protocol, complications can be minimized.

Standardization of Technique

Attempts have been made to form a consensus as to a standard technique for LSG,[17] but there is still considerable variation between surgeons regarding elements of the operation, and a lack of data concerning standardization. Initial reports by Kueper et al[18] with their own standardized operative technique for LSG in a short case series (16 patients) demonstrated complication rates similar to those in their experience with laparoscopic adjustable gastric banding. Daes et al[19] reported that a standardized protocol resulted in a very low incidence of gastroesophageal reflux disease (1.5%) 6–12 months after LSG, when focusing on technical details, including routine repair of hiatal hernia. A retrospective case series of 927 patients revealed that adopting a standardized operation to avoid excessive narrowing of the incisura in the final 489 cases resulted in no further episodes of gastric stenosis, compared with their initial experience.[20] Our own standardized technique has produced excellent outcomes in occurrence of early complications with an overall complication rate of 5%. Severe complications (Clavien-Dindo >3a) were seen in 1.7% of patients only.

Staple Line Reinforcement

The use of SLR is popular, with up to 80% of bariatric surgeons using it routinely[21]; however, it remains an issue for debate. The potential benefit of lower leak and hemorrhage rates must be counterbalanced with the increased

Table 1.
Standardized Postoperative Protocol for LSG

Day of Surgery	Day 1	Day 2	Discharge
In Recovery	**On Ward**	**On Ward**	**TTA**
• Sips of water with straw **On ward** • Clear fluids with straw • Out of bed to a chair • Mobilize to toilet • Deep breathing exercises • Regular saline nebulizers • Analgesia: Paracetamol IV+diclofenac PR (if not contraindicated) +/− morphine sulphate liquid PO PRN • Antiemetics: Ondansetron IV+metaclopramide IV+cyclizine PRN IV • Antibiotics: 2× postop doses • PPI: Omeprazole IV • Fluids IV 8 hourly	• Free fluids with straw 100ml/h • Chest physiotherapy • Saline nebulizers • Mobilize on ward • Analgesia: Paracetamol IV+diclofenac PR or codeine phosphate liquid if diclofenac contraindicated • Stop morphine sulphate liquid • Antiemetics: Ondansetron IV+metaclopramide IV+cyclizine PRN IV • PPI: Omeprazole IV • Fluids IV 12-hourly • Peppermint water • Routine blood tests • Drain: fluid color and volume review • Bariatric Specialist Nurse review	• Free fluids with straw 200ml/h • Chest physiotherapy • Saline nebulizers • Mobilize on ward • Medications as per postop day 1 • Remove drain if hemoserous only • Routine blood tests **Discharge** Discharge if **5P** criterion met: **1. P**ain controlled **2. P**ulse <90 **3. P**ipe (drain) hemoserous and removed **4.** CR**P** declining trend **5. P**assed wind (flatus)	• Enoxaparin 40 mg OD SC for 7–14 days • TED stockings for 30 days • PPI: Lansoprazole orodispersible; 30 mg OD for 6 months • Chewable multivitamins and minerals lifelong • Analgesia: liquid paracetamol 5 days and codeine phosphate 3 days) • Laxatives: lactulose 14 days and PRN thereafter **Dietary advice** • Free fluids with straw, slowly 200 mL/h (2 weeks LRYGB, 3 weeks LSG) • Puree diet 2 weeks subsequently for both • Semisolid 2 weeks subsequently for both • Solids 2 weeks subsequently for both
Throughout hospital stay			
• VTE prophylaxis with pneumatic calf compression devices while immobile, TED stockings, and LMWH (enoxaparin 40 mg SC commencing 6 hours after surgery every 24 hours thereafter).			

IV, intravenous; PR, per rectum; PO, per ora; PRN, pro re nata; PPI, proton pump inhibitor; CRP, C-reactive protein; LMWH, low-molecular-weight heparin; OD, once daily; SC, subcutaneous; TED, thromboembolic deterrent; TTA, take-away medications; VTE, venous thromboembolism.

cost associated with the use of SLR. Reinforcement may be with sutures, glue, or bioabsorbable buttressing. Different buttressing materials are available (bioabsorbable polyglycolic acid and trimethylene carbonate (SeamGuard; W L Gore & Associates, Flagstaff, Arizona, USA), bovine pericardium (Peri-Strips Dry; Baxter, Deerfield, Illinois, USA), and small intestine submucosa (Surgisis; Cook Surgical, Bloomington, Indiana, USA).

Staple Line Leak

In our series, there were no staple line leaks and SLR was not used. Several meta-analyses have been performed to assess whether there is any difference in outcome with the use of SLR. The largest meta-analysis of patients was performed by Shikora and Mahoney[6] including 56,309 patients showed a benefit of SLR. Gagner and Buchwald[7] reported statistically

Table 2.
Patient Demographic Details

Age, y (mean/SD)	43.6 (SD 10.8)
Gender (M:F)	67:236
BMI (kg/m^2) (mean/SD)	47.8 (SD 7.41)
ASA Grade (median/IQR)	ASA 2 (IQR 2–3)
OS-MRS (median/IQR)	A (IQR A-B)

BMI, body mass index.

Table 3.
LSG Complications

LSG	n (%)
Total complications	15 (5.0)
Severe complications*	5 (1.7)
Chest infection	4 (1.3)
Abdominal pain: normal investigations	3 (0.99)
Dysphagia: normal investigations	4 (1.3)
Staple line bleeding	2 (0.66)
Chest pain: normal investigations	1 (0.33)
Thermal gastric injury	1 (0.33)
Staple line leak	0
Conversion to open	0
In-patient mortality	0
Early stricture	0

N = 303. LOS, length of stay. *Clavien-Dindo grade 3a.

Table 4.
Complications According to Clavien-Dindo Classification

LSG	n (%)
Grade 1	6 (1.9)
Grade 2	4 (1.3)
Grade 3a	0
Grade 3b	4 (1.3)
Grade 4a	1 (0.33)
Grade 4b	0
Grade 5	0

N = 303.

significant reduction in leak rate with the use of bioabsorbable materials. Parikh et al[9] analyzed 9991 patients and found no benefit to SLR in preventing leaks. Similarly, Knapps et al[10] analyzed 4881 patients and found no benefit to SLR in reducing the leak rate. A much smaller analysis by Choi et al[8] showed reduced rate of postoperative leaks with routine use of SLR. A further small analysis by Wang et al[11] of 8 randomized trials showed no benefit in reduction of leak rate.

Several randomized trials have been conducted to define the role of SLR in LSG. Albanopoulos et al[22] randomized 90 patients to either suture-based or SeamGuard reinforcement, with no difference in complication rates. In a 3-armed randomized trial, Dapri et al[23] found no difference between no reinforcement and sutured or SeamGuard reinforcement; however, SeamGuard added nearly 1000 euros to the cost of each case. Gentileschi et al[24] randomized 120 patients to suturing, Floseal (Baxter Medical), or SeamGuard with no difference between the groups in leak rate. Berger et al[25] analyzed the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database of 189,477 LSGs and showed that the use of SLR is associated with an increased risk of staple line leak.

Several cohort studies have reported the effect of reinforcement on leak rate.[25,26] Noel et al[26] analyzed 2012 LSG cases and reported a significant decrease in leak rate with SLR. Ser et al[27] also reported a positive effect of reinforcement on leak rate, but Stamou et al[28] showed no such positive effect of reinforcement.

The size of tube used to calibrate the LSG against the lesser curve has been debated. We used a 30-French tube in all cases. Berger et al[25] suggested that bougie size <38 French is associated with an increased leak rate. Parikh et al[9] reported that bougie size >40 French may decrease the leak rate without affecting weight loss. Yuval et al[29] also reported a leak rate of 0.92% with bougie size >40 French, compared with 2.67% for smaller bougies. Aurora et al[30] reported similar results with a leak rate of 0.6% with the use of a >40 French bougie compared with 2.8% with a <40 French bougie. Despite the use of a narrow tube, there were no leaks in our cohort, which, given the rates reported above, might have been expected.

Our technique involved firing the first stapler at 2–4 cm from the pylorus. Commencing the firing at <2 cm from the pylorus can increase the leak rate.[31] The initial firing and the second firing of the stapler were always performed without angulation. The importance of avoiding narrowing of the incisura has been emphasized by Gibson et al.[31] Chang et al.[13] reported the positive effects of a technique change in stricture rates at the incisura. We believe that the rate of narrowing of the incisura is increased with angulation of the initial 2 firings of the stapler. In our series, the firings were always performed

without angulation and therefore may have prevented early strictures in all 303 cases. Also, s a 30-French tube was used in our series, and the propensity for narrowing the incisura with this tube size could have increased if the method of no angulation had not always been followed.

Hemorrhage

The hemorrhage rate in our series is 0.66%. We did not use SLR, but routinely performed a hemostatic test by raising the patients' blood pressure to supranormal levels. Metallic clips were used to control any areas of the staple line that bled after the hemostatic test, which creates a characteristic hedgehog appearance of the sleeve. We also treated the greater omentum with an ultrasonic device at multiple levels to create a beaded effect. We believe that the combination of these 3 factors acted to reduce the rate of bleeding seen in our series to levels equal to or lower than those in cases with SLR. Hemorrhage rates after LSG have been reported between 0.7%,[33] 3.4%,[34] and 5.6%.[35] SLR seems to decrease the rate of both intraoperative and significant postoperative hemorrhage; Consten et al[36] reported an estimated decreased intraoperative blood loss of 90 mL with SeamGuard. Shikora and Mahoney[6] analyzed 41,864 patients and found a hemorrhage rate of 3.45% in patients without SLR compared to 1.23% with SLR. However, Simon et al[37] failed to show an advantage with SeamGuard. Saleh et al[38] reported 204 SLR cases with an overall complication rate of 6.9% and a risk of bleeding of 0.9%. This result is similar to our series, but we did not use SLR. Use of glue to reinforce the staple line has not been shown to reduce postoperative hemorrhage.[39] The use of tranexamic acid as a routine intraoperative method of reducing hemorrhage has been proposed.[40]

CONCLUSION

The use of a standardized operative and postoperative protocols leads to excellent early outcomes in LSG. Standardization may act to obviate the need for routine SLR techniques,, which are associated with a significant financial cost to both patient and hospital.

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