Sheppard et al., Surgery Curr Res 2013, 3:4
DOI: 10.4172/2161-1076.1000144

Surgery: Current Research

Research Article Open Access

Laparoscopic Sleeve Gastrectomy with *Tri-Staple*™ Reinforcement for Severe Obesity

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Abstract

Background: Obesity is a chronic disease that affects over 500 million adults globally. Bariatric surgery is the only evidence-based treatment to achieve sustainable weight loss. Laparoscopic Sleeve Gastrectomy (LSG) is a restrictive procedure with important physiologic changes. Staple line dehiscence and hemorrhage represent two of the major complications associated with this procedure. Respectively, surgeons have attempted numerous modalities to avert these issues by using various stapling products, buttresses and hemostatic adjuncts. The purpose of this study is to analyze the utility of a Tri-staple non-buttressed stapler on the incidence of postoperative leakage and hemorrhage post LSG.

Methods: A retrospective review of medical records was performed for 97 consecutive patients that underwent LSG with the Tri-Staple™ between July 2011 and October 2012.

Results: The mean age of patients was 44.4 ± 9.2 years, with mean preoperative BMI of 48.5±10.6kg/m^2. Preoperative comorbidities included Type 2 diabetes (34%), hypertension (42%), dyslipidemia (28%), and obstructive sleep apnea (43%). The mean operative time was 80.0 ± 22.0min. There were no intraoperative leaks identified. There were no documented postoperative leaks or bleeds after a median follow up of 12 months. At 12 months following surgery, BMI had significantly decreased to 33.9 ± 6.6 kg/m^2 ($p<0.05$), corresponding to a EWL% of 54.8% ± 24.2%. HbA1c was significantly reduced after 1 year (6.7 ± 1.2 vs 5.6 ± 0.7, $P<0.05$).

Conclusion: The Tri-Staple™ configuration used in LSG seems to mitigate staple line failures. Furthermore, weight loss and co morbidity reduction was determined to be acceptable and equivalent to LSG using other staplers.

Keywords: Sleeve gastrectomy; Obesity; Complications; Tri-Staple; Staple line leaks

Introduction

According to WHO, obesity is a chronic disease that has a global impact. As of 2008, over 500 million adults globally are obese. The impact of obesity spans all demographic types, and has been increasing in prevalence among youth. Obesity significantly affects the entire body, and is associated with millions of premature deaths [1]. Comorbidities of obesity include cardiovascular, adrenal, orthopedic, gastrointestinal, and an increased risk of cancer [2].

Laparoscopic Sleeve Gastrectomy (LSG) is a bariatric surgical procedure. It involves resection of approximately 80% of the stomach, including the fundus and the majority of the body; thus, restricting stomach volume, and decreasing consumption. Furthermore, circulating ghrelin levels, involved in satiation, are decreased. The combination of reduced ghrelin levels and decreased food consumption are thought to contribute to the effectiveness of this procedure [3].

LSG has been shown to significantly increase quality of life. It has been found to have equivalent results to other restrictive and malabsorptive procedures in weight loss and resolution of comorbidities. In the literature, postoperative excess weight loss % (EWL%) has been found to be between 18-30% at 1 month, 37-41% at 3 months, 54-61% at 6 months, and 50-78% after 1-3 years [4-7].

LSG has been shown to be a safe procedure. The most common postoperative complication is a staple line failure causing a leak, fistula, or bleed. These arise in 1-3% of patients after LSG. Whether these complications arise from issues with the stapling device used, the surgeon's skills, or the gastric tissue condition is unknown [8-10].

Since the introduction of LSG there has been concern with stapler misfiring and resulting staple line leak. As a result some surgeons have decided to reinforce the staple line by using buttressing material or over sewing of the staple line. Examples of buttressing materials include polytetrafluoroethylene, bioabsorbable polyglycolide acid, trimethylene carbonate, fibrin glue, or bovine pericardium strips. However, bovine pericardium strips have been known to migrate after surgery. Others do not reinforce the staple line, and believe that over sewing may lead to strictures in the sleeve causing more harm to the patient [11-13]. Previous research has shown promising results for the Duet TRS™ reinforcement system in LSG [14]. However, this practice has been abandoned due to fatal complications [15]. New techniques have been adapted for reinforcing devices, such as the Tri-Staple™ stapler.

The Tri-Staple™ stapler design involves three rows of staples to decrease the likelihood of staple line leaks, while avoiding the use of additional reinforcement materials [16]. There is limited evidence to support the effectiveness of preventing complications in the LSG procedure. Therefore, the objective of this study was to identify the complication rates after LSG performed using the Tri-Staple™ stapler for severe obesity.

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Received August 10, 2013; **Accepted** August 27, 2013; **Published** September 05, 2013

Citation: Sheppard CE, Whitlock KA, Birch DW, Karmali S (2013) Laparoscopic Sleeve Gastrectomy with *Tri-Staple*™ Reinforcement for Severe Obesity. Surgery Curr Res 3: 144. doi:10.4172/2161-1076.1000144

Materials and Methods

Study design

We performed a retrospective review of prospectively collected data for all LSG patients with Covidien Tri-Staple™ reinforcement of the gastric staple line performed by two surgeons at our institution from July 2011 to October 2012. The Covidien Tri-Staple™ technology has been used exclusively at our institution since May 2011 for staple line reinforcement of LSG. Our institution's ethics board granted approval for this study.

Data recorded

Initial weight and BMI values were collected upon entry of the patient into our adult weight management clinic (Weight Wise). Preoperative characteristics included patient sex, age, height, weight, BMI, and presence of comorbidities (Type 2 diabetes mellitus (T2DM), hypertension, hyperlipidemia, and obstructive sleep apnea). Operative data included OR time, intraoperative complications, leak testing, and conversion rates. Postoperative data includes length of hospital stay, postoperative complications, weight/BMI, comorbidities, and reoperation rates. Postoperative follow-up occurred at 1, 3, 6, and 12 months at the Weight Wise clinic.

Outcomes

The primary outcome of this study was the postoperative 30-day complication rate. Postoperative bleeding was suspected in patients presenting with symptoms of hypotension and pain. A complete blood count was done in all suspected cases of postop bleeds. We considered the bleed significant if the patient required a transfusion or reoperation and if it was diagnostically confirmed through imaging studies. Conservative treatment was employed in cases that did not require blood transfusion. Secondary outcomes included weight/BMI change, co morbidity resolution, length of stay, operative time, and intraoperative complication rate. Co morbidity resolution was defined as discontinuation of medications being used to treat the co morbidity. Additionally, hemoglobin A1c values were recorded to assess resolution of T2DM.

Treatment details

Selection for surgery was based on the 1991 National Institutes of Health criteria for bariatric surgery. Patients had to be greater than 18 years of age with a BMI >40 kg/m^2 or a BMI ≥ 35kg/m^2 with comorbidities. All patients attended an adult weight management clinic called "Weight Wise" prior to being selected for surgery. The clinic is a publically funded, multidisciplinary program that provides treatment options for adults with obesity.

In order to be selected for surgery each patient must attend the Weight Wise clinic, and work with the multidisciplinary staff on modifying their nutrition, exercise, eating behavior, and medical obesity management. Eligible patients are then counseled on the different surgical options available, and make an informed decision based on a consultation with a bariatric surgeon. The extensive preoperative management is designed to ensure patients are motivated, and will pursue follow-up care after surgery.

Surgery was performed at a Canadian, publically funded hospital with a level 2 trauma center and 750 inpatient beds. The center is located in the inner city, and has university based teaching services for medical/surgical trainees.

All laparoscopic sleeve gastrectomies were performed by one of two surgeons in this study. All cases had a fellow or resident present for teaching. The sleeve gastrectomy was constructed over a 50-French (F) sizing bougie inserted orally. The antral staple line was created with a 2 black Covidien Endo GIA™ 60mm staples with Tri-Staple™ Technology. The staple line was started approximately 6cm proximal to the pylorus. Stapling was continued with 4 to 5 purple Covidien Endo GIA 60 mm staples up to the angle of HIS. The final staple fire was deviated away from the esophago-gastric junction at a distance of 1cm from the junction towards the Angle of HIS. All cases concluded with a methylene blue and air leak test. Patients remained in hospital until they tolerated a liquid diet. Advancement to a solid diet generally occurred at 2 weeks postoperative. Patients were given specific postoperative and follow-up instructions.

Statistical analysis

Continuous data was presented as mean ± SD. Categorical data was presented as a percentage. A paired t test was used to test continuous variables. Significance was defined as $P<0.05$.

Results

There were 97 consecutive patients that underwent LSG with the Tri-Staple™ technology. The mean BMI upon entry into the Weight Wise program was 48.5 ± 10.6 kg/m^2. Patients attended a median of 9 preoperative visits over a median of 12 months prior to being selected for surgery. The preoperative patient characteristics are detailed in Table 1. The mean age was 44.4 ± 9.2 years, and the mean preoperative BMI was 44.9 ± 9.3 kg/m^2.

In-hospital outcomes

The median length of stay was 2 days, and the mean operating time was 80.0 ± 22.0 min. There were no intraoperative leaks identified by methylene blue or air testing. There were no intraoperative complications for any of the 97 patients.

Outcomes

The median postoperative follow up time was 6 months. Missing data was due to patients not attending the Weight Wise clinic for follow-up appointments. Seven patients (7.2%) were unable to attend follow-up due to living out of province. Figure 1 illustrates the postoperative BMI change. At 12 months follow-up the mean BMI was significantly decreased to 33.9 ± 6.6 kg/m^2 ($P<0.05$). Excess weight loss percent (EWL%) after 12 months was 54.8% ± 24.2%. Complications are summarized in Table 2.

Table 3 shows the resolution rates for comorbidities after LSG. In 33 patients with T2DM, HbA1c levels improved from 6.7% ± 1.2% to 6.0% ± 0.6% 6 months after LSG. Twelve months after LSG the mean HbA1c level was significantly decreased to 5.6% ± 0.7% ($P<0.05$). Seventeen patients with T2DM (51.5%) had complete resolution of their T2DM within 6 months after LSG.

Discussion

The objective of this study was to identify complication rates and weight loss for 97 patients who underwent LSG using a Tri-Staple™ design. There were no leaks reported after surgery for any patient. These complication rates are comparable to a study previously completed by Gill et al. on the Duet TRS™ at our institution. They observed no gastric leaks, and one bleed from the gastric staple line (0.9%) [14]. Complication rates were low with only one wound infection (1%) and one hematoma (1%). Some patients developed symptoms of gastro esophageal reflux (7%) and dysphasia (1%).

A recent prospective cohort study by Yazbek et al. included 90 patients who underwent LSG with the Tri-staple™ stapler. They reported five gastric leaks (5.5%), four hemorrhages or gastric hematomas (4.4%) and two parietal hematomas (2.4%) after LSG. However, this study was converting failed AGB to LSG; thus, scar tissue or other obstacles with the procedure conversion could contribute to higher rates of complications [17]. To our knowledge no other literature exists using the Tri-Staple™ for LSG. This may be due to the product's recent introduction to the market in 2010. In other gastric procedures such as laparoscopic Roux-en-Y gastric bypass, the triple staple technique has been found to be associated with a low rate of postoperative complications [18].

We compared our results to findings from other studies, which used other staple designs and configurations for LSG. Burgos et al. and Frezza et al. had higher postoperative complication incidences, using the Covidien Endo GIA with green and blue cartridges and either a 32F or 38F bougie, with seven gastric leaks (3.3%), and two leaks (3.7%) and one bleed (1.8%), respectively [19,20]. Triantafyllidis et al. also had a higher total postoperative complication rate of 12.5%, using a 36F bougie, with a leak prevalence of 3.5% and hemorrhage incidence of 3.5% [21]. Lalor et al. [12] had similar results to ours using a 52F or 44F bougie and an Ethicon stapler, with a total postoperative complication rate of 2.9% including one leak (0.7%), and one hemorrhage (0.7%).

An argument could be made for the size of the bougie affecting the complication incidence. We use a more conservative bougie size, which could contribute to a lower complication rate. It has been shown that using a smaller bougie size is correlated with increased leak rates [22]. However, in the study by Yazbek et al. [17] there was no significant difference between prevalence of gastric leaks between procedures using a 36Fr or 40Fr bougie.

In order to decrease the rate of staple line failure, the Tri-Staple™ stapler has three rows of staples of differing heights. The manufacturers of the Tri-staple™ state that by providing varied staple heights within the same firing, there is less stress on the tissue in the outer staple line of the triplet, and provides better hemostasis than the regular Covidien Endo GIA green or blue cartridges [16]. In the literature, variation in staple height has been found to be important for preventing leaks. Areas such as the pylorus and antrum require longer and stronger staples due to the thickness of the tissue, while the thinner esophagogastric junction requires smaller staples for adequate hemostasis [23]. A staple that is too long may not allow for the tissue to join properly, increasing the risk of a staple line leak. In addition, staples that are too short may not be able to fully close and force the tissue together leading to damage and ischemia [24].

The adaptation of varying staple heights should be adequate to prevent leaks without staple line reinforcement. The use of reinforcement for LSG has been an ongoing discussion in the bariatric field. Some surgeons have concerns about the stapler misfiring, and potentially introducing a staple line leak for the patient. Therefore, they decide to reinforce the staple line to decrease complications for the patient. There are generally two approaches to staple line reinforcement: buttressing material over the staple line or over sewing of the staple line. Others do not reinforce the staple line believing that over sewing is not necessary and may lead to strictures in the sleeve causing more harm to the patient [11-13]. Infact, while the Duet TRS™ used during LSG demonstrated favorably low complication rates; it has since been removed from the market due to patient morbidity and fatality [15].

Mery et al. [24] created a study to specifically look at the leak pressures of different stapling techniques of the bowel. They found that the leak pressure greatly varied, possibly caused by varying thickness of the tissue or variable compression from the stapler. Buttressing decreased leak pressure and bleeding. However, Stamou et al. [10] found no significant difference with reinforcement on the rate of leaks ($p>0.316$), but a significant difference in favor of reinforcement for overall complications ($p<0.007$). Mery et al. [24] believed by combining green or blue staples with reinforcement, the reinforcement may be compensating for the lack of variable staple height necessary for

Characteristic	LSG with Tri-Staple™ Technology (N=97)
Age at Surgery (yrs)	44.4 ± 9.2
Male (n, %)	17 (18%)
Female (n, %)	80 (82)
Height (m)	1.68 ± 0.09
Initial BMI (kg/m²)	48.5 ± 10.6
Preop Visits (n)	9*
Length of Preop (mo)	12*

*Median Value

Table 1: Laparoscopic sleeve gastrectomy patient characteristics represented as mean and standard deviation (n=97).

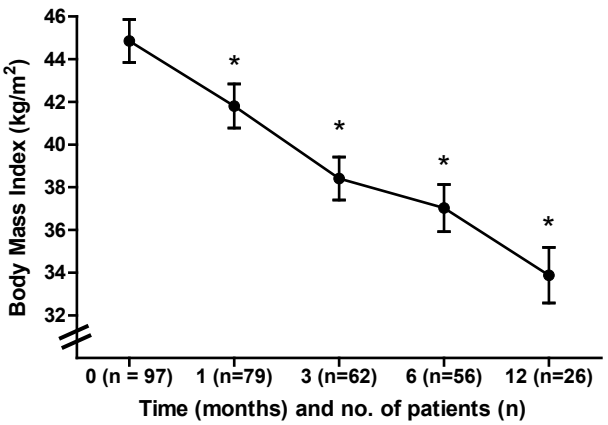

Figure 1: Patient body mass index (kg/m²) following laparoscopic sleeve gastrectomy (*P<0.05 vs. preoperative BMI).

Postop Complication	1 month (n)	3 months (n)	6 months (n)	12 months (n)	Total (n, %)
Gastroesophageal Reflux	2	3	1	1	7 (7%)
Dysphagia	0	1	0	0	1 (1%)
Wound infection	1	0	0	0	1 (1%)
Hematoma	1	0	0	0	1 (1%)
Gastric Leak	0	0	0	0	0 (0%)
Upper GI Bleed	0	0	0	0	0 (0%)
Cardiopulmonary	0	0	0	0	0 (0%)

Table 2: List of common postoperative (postop) complications following laparoscopic sleeve gastrectomy, and the total incidence of each in this study (n,%).

Co morbidity	Preop (n, %)	Resolved (n, %)
T2DM	33 (34%)	17 (52%)
Hypertension	41 (42%)	16 (39%)
Dyslipidemia	27 (28%)	7 (26%)
OSA	42 (43%)	3 (7%)

Table 3: Incidence of patient preoperative co morbidity (n, %), and its resolution following laparoscopic sleeve gastrectomy. T2DM: Type 2 diabetes mellitus. OSA: Obstructive sleep apnea.

different tissue thicknesses and reduces the risk of staple line leaks [24]. The Tri-Staple™ eliminates the reinforcement step by altering staple height throughout the three staple rows.

LSG using the Tri-Staple™ lead to appropriate weight loss in this study. The LSG procedure had comparable weight loss results to other LSG procedures without Tri-Staple use. Excess weight loss percent (EWL%) was 17.6% ± 9.1% at 1 month, 33.0% ± 15.8% at 3 months, 42.7% ± 22.0% at 6 months, and 54.8% ± 24.2% at 12 months. These results are comparable to the current literature [4-7]. The results at 12 months were comparable to Parikh et al. [25] (EWL% of 52.5%) [20]. They also found similar results using a 40Fr bougie with a EWL% of 38.8% after 6 months, and EWL% of 51.9% after 12 months. Therefore, the Tri-Staple™ technology provides comparable weight loss results for bariatric patients.

The improvement in HbA1c was comparable to other LSG studies in the literature. A recent retrospective review by Abbatini et al. [26] reported a reduction in HbA1c to 5.9 ± 0.4% at 3 months postoperative. This value was comparable to our HbA1c of 5.9% ± 0.8% at 3 months.

Conclusion

LSG performed using the Tri-Staple™ Covidien stapler was found to control the risk of staple line failures. Furthermore, weight loss and comorbidity reduction was determined to be acceptable using this stapler.

Financial Disclosures

Caroline Sheppard, Kevin Whitlock have no conflicts of interest or financial ties to disclose Daniel Birch and Shahzeer Karmali have no conflict of interests or financial ties in relation to the preparation, data collection, or review of this manuscript. Daniel Birch and Shahzeer Karmali provide consultancy and have received honoraria for speaker's bureau for Covidien, Ethicon Endosurgery and BARD.

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