Annals of Medicine and Surgery 10 (2016) 83–87

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.annalsjournal.com

Laparoscopic sleeve gastrectomy using a synthetic bioabsorbable staple line reinforcement material: Post-operative complications and 6 year outcomes

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HIGHLIGHTS

- Laparoscopic sleeve gastrectomy shows sustainable long-term weight loss.
- Laparoscopic sleeve gastrectomy shows excellent resolution of comorbidities.
- The use of a bioabsorbable staple line reinforcement material is safe.

ARTICLE INFO

Article history:
Received 7 July 2016
Received in revised form
7 August 2016
Accepted 8 August 2016

Keywords:
Sleeve gastrectomy
Weight loss
Comorbidities
Long-term
Outcomes

ABSTRACT

Background: Gastric leak after laparoscopic sleeve gastrectomy (LSG) is a serious complication. Currently, the literature lacks long-term outcomes in LSG and leak rates after reinforcement of the staple line. The aims are two-fold: to present leak rates from using staple line reinforcement and six year outcomes of LSG in relation to resolution of obesity-related comorbidities and long-term weight loss.

Materials and methods: This is a single-institution, retrospectively reviewed study of 204 patient case files. Data from all patients undergoing LSG between December 2007 and May 2013 was collected.

Results: The total complication rate was 6.9% (14/204), with no recorded staple line leaks. The mean postoperative Body Mass Index (BMI) at 1 year, 2 years, 3 years, 4 years, 5 years, and 6 years was 39.3 ± 8, 38.7 ± 8, 40.4 ± 9, 40.5 ± 10, 43.0 ± 10, and 42.4 ± 7, respectively. The mean % excess weight loss at 1 year, 3 years, and 6 years was 48.4 ± 19, 51.7 ± 28, and 41.0 ± 21, respectively. There were no significant differences between follow-ups at year 1 and 3 ($p > 0.05$), and between year 3 and 6 ($p > 0.05$) for the mean % excess weight loss. The resolution rates for all patients were 74%, 61%, 79%, and 90% for hypertension, hypercholesterolemia, diabetes mellitus type 2 and obstructive sleep apnea, respectively.

Conclusion: The synthetic bioabsorbable reinforcement material shows no staple line leaks making it safe to use. LSG as a procedure had a high resolution of obesity-related comorbidities as well as sustainable long-term weight loss.

1. Introduction

Since 2003, laparoscopic sleeve gastrectomy (LSG) has been rising in popularity in Europe, increasing to 127 officially documented operations in 2007 [1,2]. In the United States (US), the number of bariatric surgeries amounted to 179,000 in 2013 with 42.1% of procedures being LSGs while Roux-en-Y gastric bypasses comprised 34.2% of procedures. This now makes LSG the most commonly performed bariatric procedure in the US [3].

Controversy exists regarding the role of staple line reinforcement in preventing gastric leaks [4–6]. Knapps et al. [7] concluded that more studies were needed to assess the safety profile of synthetic bioabsorbable reinforcement materials in LSG. However, Choi et al. [8] and Gagner [15] showed a decreased incidence of leaks when using these materials intraoperatively.

Additionally, long-term outcomes of LSG in general in terms of weight loss are lacking in the literature. Diamantis et al. [9] showed

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http://dx.doi.org/10.1016/j.amsu.2016.08.005

that only three studies consisted of patients at the six year follow-up period and only nine studies contained long-term data of patients at the five year follow-up period postoperatively. Several authors have realized this gap in the literature and there are now more papers in the literature with outcomes of LSG spanning 5 years or more [10,11].

The aims of this study are (1): to present our leak rates from using staple line reinforcement and (2) to display six year outcomes of LSG as a procedure in itself in relation to resolution of obesity-related comorbidities and long-term weight loss.

2. Materials and methods

2.1. Study design and data collection

This is a single-institution, retrospectively reviewed study of 204 consecutive patient case files who underwent LSG with reinforcement between December 2007 and May 2013. The data was collected from clinic letters, electronic records and telephone consultations representing a six year series.

Resolution of obesity-related comorbidities (obstructive sleep apnea, diabetes, hypertension, hypercholesterolemia) was noted. Percent excess weight loss (% EWL) and percent excess BMI loss (% EBL) was calculated at each year postoperatively using the ideal body weight estimate with a Body Mass Index (BMI) of 25 as the reference point for normal weight.

Hypertension was defined by a blood pressure greater than 140/90 mmHg and its resolution by a normalized blood pressure and cessation of all blood pressure medications taken preoperatively. Obstructive sleep apnea was diagnosed by a sleep study (polysomnography) and resolution by cessation of the continuous positive airway pressure machine. Diabetes mellitus type II was diagnosed by a fasting blood glucose >7.0 mmol/l (126 mg/dL) or HbA1c > 42 mmol/mol (6 g/dL). Resolution was defined by normalization of one of these laboratory values and cessation of any diabetic medications postoperatively. Lastly, hypercholesterolemia was diagnosed by total blood cholesterol levels >5.2 mmol/l (200 mg/dL) and resolution by stopping medication.

Major complications such as severe vomiting and sleeve stenosis related to LSG in general within the first 30 days postoperatively were recorded. Leaks from the staple line were also recorded using the intraoperative leak test.

Patients who had a primary stand-alone LSG without previous or subsequent weight-loss surgery within the specified time period were included in the study. All patients consented to the collection of data. The study was submitted as an official audit to the institutional review board for ethical approval and registration.

2.2. Materials

The GORE® SEAMGUARD® bioabsorbable staple line reinforcement material (W. L. Gore & Associates, Arizona, USA) has been used at our institution throughout all LSG cases since 2007. The material adds a reinforcement strip to the staple line, which is preloaded onto the stapler, and is eventually absorbed within six months [12].

2.3. Surgical technique

The patient is placed on the operating table in the supine position. The abdominal cavity is entered through a small, transverse left subcostal incision with the bladeless 12 mm trocar, loaded with the 10-mm O-degree laparoscope, and under laparoscopic observation.

The blunt tip retractor is placed below the xiphoid process to retract the left lobe of the liver exposing the gastro-esophageal junction. The lesser sac is entered through the gastrosplenic ligament and the greater curvature of the stomach is freed up to the angle of His. Next, a bougie is passed into the distal stomach and the endostapler loaded with the reinforcement strips is introduced first from the right upper quadrant port to carry out the sleeve gastrectomy. The bougie size used for all operations was 32F. The mean proximal distance from the pylorus used for all operations was 5 cm (standard deviation of 0.69 cm). A mean total of 5 staple firings (standard deviation of 1.04 firings) preloaded with the bioabsorbable material were used for all procedures.

2.4. Statistical analysis

The data were analysed with GraphPad Prism 5.0 (GraphPad Software, La Jolla, CA, USA). Continuous data points are presented as mean ± standard deviation, mean (range), and analysed using the two-tailed paired *t*-test. Statistical significance was defined at a p-value of <0.05.

3. Results

3.1. Patient characteristics

Of a total of 257 patients who had undergone an LSG operation with reinforcement between December 2007 and May 2013, 204 patients (80%) met the inclusion and exclusion criteria. There were 61 males and 143 females. Of the 21/53 patients who were excluded: 16 patients had previously attempted bariatric procedures and 5 patients had subsequent bariatric surgery due to unsatisfactory weight loss. 32/53 patients have also been excluded since they were performed using a different type of staple line reinforcement (Duet TRS by Covidien). These products have been terminated due to major complications associated with their use [13].

3.2. Complication rates, morbidity and mortality

The complications experienced in this study were grouped according to the Clavien-Dindo classification [14]. There were nine Grade I complications (vomiting resolved by antiemetics and sleeve stenoses), three Grade II complications (wound infection requiring antibiotics) and two Grade III complications (major bleeding requiring surgical intervention) (complications displayed in Table 1). The intraoperative leak test was used to determine any potential gastric leaks from the staple line.

In terms of bleeding, there were 2 in the series. The first was taken back to theatre 8 h postoperatively due to tachycardia and a low blood pressure. In theatre, 1.8 litres of clot was seen in left upper quadrant which was removed. No obvious bleeding source was found and the staple lines were dry. The patent was discharged 3 days after the operation.

The second patient had an uneventful postoperative course and was discharged 2 days after the operation. However, this patient

Table 1
Major complication rates related to sleeve gastrectomy within the first 30 days post-operatively.

Complication	Patients (%)
Staple line leak	0/204 (0%)
Severe vomiting	7/204 (3.4%)
Sleeve stenosis	2/204 (0.9%)
Major bleeding	2/204 (0.9%)
Wound infection	3/204 (1.5%)
Death	0/204 (0%)
Total	**14/204 (6.9%)**