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Original article

Comparative use of different techniques for leak and bleeding prevention during laparoscopic sleeve gastrectomy: a multicenter study

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Abstract

Background: Laparoscopic sleeve gastrectomy (LSG) is an approved primary procedure for morbid obesity, but it is associated with serious complications, such as staple line leaks and bleeding. The objective of this study was to assess the effectiveness of staple line reinforcement (SLR) in reducing leaks and bleeding after LSG.

Methods: A total of 1162 patients underwent LSG (305 males, 857 females). The mean age was 43.7 years and the mean body mass index was 48 kg/m². The patients were divided into 6 groups based on the type of SLR, including a no-SLR control group, with evaluation of leaking and bleeding risk and correlation of patients' characteristics with complications.

Results: A total of 189 patients underwent LSG without reinforcement. The SLR method was oversewing in 476 patients, bovine pericardium in 312, synthetic polyester in 76, glycolide/tri-methylene copolymer in 63, and thrombin matrix in 46. The overall leak frequency was 2.8%; higher with synthetic polyester (7.8%), 4.8% with no reinforcement, and lower with bovine pericardium strips (.3%; $P < .01$). Postoperative hemorrhage occurred in 35 patients (3%), with a higher frequency being observed without SLR (13.7%; $P = .02$). Only diabetes was a risk-factor for a leak ($P < .01$).

Conclusion: SLR with bovine pericardium strips significantly reduced the leak risk. Postoperative bleeding was significantly lower with all SLR-methods, although there was no significant difference among the various techniques. Patients with type II diabetes had a higher risk of staple line leak after LSG. Further randomized, controlled studies are needed to improve our understanding of the efficacy of SLR during LSG. (Surg Obes Relat Dis 2013;■:00–00.) © 2013 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords:

Bariatric surgery; Sleeve gastrectomy; Staple line reinforcement; Leak; Bleeding

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Laparoscopic sleeve gastrectomy (LSG) was pioneered as the restrictive component of the biliopancreatic diversion and duodenal switch and was later proposed as a staged procedure in high-risk patients [1]. Since its first application in 2000, LSG has gained increasing interest in the bariatric community as a stand-alone procedure, because of the

excellent excess weight loss and improved obesity-related co-morbidities without the addition of a biliopancreatic diversion. In a recent systematic review of LSG as a stand-alone procedure, Gill et al. noted amelioration of type 2 diabetes mellitus (T2 DM) in >90% of patients with excess weight loss of 47% at the 13-month follow-up [2]. LSG effectiveness was comparable to other approved bariatric surgeries through an intermediate term [3,4]; the first long-term data are positive, although they need to be confirmed [5–7]. In 2009 LSG was recognized by the American Society for Metabolic and Bariatric Surgery as a primary procedure for the surgical management of morbid obesity [8]. This technique is also associated with several important benefits, including maintenance of gastrointestinal continuity without an anastomosis, avoidance of mal-absorption, absence of implantable nonabsorbable material, and potential convertibility to other operations [9].

Nevertheless LSG is not without complications. The least severe of these are gastroesophageal reflux disease, insufficient weight loss, and stricture or dilation of the gastric tube [10–12]. The most serious and feared complications are bleeding and leakage from the gastric staple line [13,14]. These events can lead to significant morbidity, ranging from a prolonged hospital stay for conservative treatment, stenting, the need for a total gastrectomy, or death [14,15].

The incidence of significant hemorrhage from the staple line, requiring blood transfusion or reoperation, is reported to be 1.1%–8.7% [8]. The most dangerous and life-threatening complication is the staple-line leak; the mean incidence from 24 studies with 1749 patients was 2.7% [16]. Leaks usually occur just below the gastroesophageal junction, perhaps because of the high internal pressure subsequently to the vertical tubularization of the stomach [17].

Staple-line reinforcement (SLR) has been proposed as a method to reduce the occurrence of both bleeding and leak after LSG. SLR can be obtained by several different methods: oversewing the staple-line, buttressing it with specific materials such as bovine pericardium strips (Peri-Strips Dry, Synovis, Deerfield, IL), synthetic polyester (Duet-TRS, Covidien, Dublin, Ireland) or glycolide and trimethylene carbonate copolymer (SeamGuard Bioabsorbable, W. L. Gore & Associates, Newark, DE), or by applying glue or hemostatic agents over the staple-line (Flo seal, Baxter, Deerfield, IL). Although a reduction of the

complications has been postulated, the published literature has failed to show a definite benefit of these techniques and, to date, no clear consensus exists regarding the efficacy of SLR.

The objective of this retrospective multicenter study was to assess the effectiveness of SLR in reducing staple-line leaks and bleeding in morbidly obese patients undergoing LSG at 4 high-volume bariatric centers. The patients were divided into 5 different groups according to the method of SLR, and the results were compared with those undergoing LSG without SLR. To the best of the authors' knowledge, this is the first multicenter study comparing 5 SLR techniques with each other and with a control group of LSG without SLR.

Materials and methods

Between October 2002 and January 2012, 1162 patients underwent LSG at the participating centers. All the procedures were performed by 4 leading bariatric surgeons, one for each hospital, with a recognized expertise in minimally invasive bariatric procedures.

There were 305 males and 857 females with a mean age of 43.7 ± 9.4 years (range: 17–67 yr) and a mean body mass index (BMI) of 48 ± 6.4 kg/m² (range: 35–84 kg/m²). The patients' demographic characteristics were equally distributed between the study groups (Table 1). The patients met the International Federation for the Surgery of Obesity, the European Association for the Study of Obesity (EASO), and the National Institute of Health indications for bariatric surgery. The Institutional Review Board approved the study.

Each patient had an extensive preoperative evaluation, including consultations with a nutritionist, psychiatrist, and medical internist. An esophagogastroduodenoscopy was performed to screen for *Helicobacter pylori* and incidental pathology. All the patients were extensively informed concerning the surgical procedure and provided written informed consent. Based on the management of the staple-line, the patients were divided into 6 groups: no reinforcement; oversewing; buttressing with Peri-strips Dry, Duet-TRS, or SeamGuard; and reinforcement with Flo seal. These procedures were at the choice of the operating surgeon; the patients were not randomized between no-SLR and the other techniques.

Table 1
The demographic data of patients included in the study

Demographics	No-SLR (189)	Oversewing (476)	Peri-Strips Dry (312)	Duet-TRS (76)	SeamGuard (63)	Flo seal (46)
Gender (n)						
Female	137	352	228	58	47	35
Male	52	124	84	18	16	11
Mean age (years)	46.3	44.6	43.1	39.8	47.1	41.4
Mean BMI	49	46	51	50	45	47
Type 2 diabetes (n)	53	135	84	23	20	10

BMI = body mass index; SLR = staple line reinforcement.

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