ELSEVIER

Surgery for Obesity and Related Diseases ▮ (2016) 00–00

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Evaluating the effect of operative technique on leaks after laparoscopic sleeve gastrectomy: a case-control study

Michigan Bariatric Surgery Collaborative, Oliver A. Varban, M.D., F.A.C.S.[a,*], Kyle H. Sheetz, M.D.[a], Ruth B. Cassidy, M.A.[b], Amanda Stricklen, R.N., M.S.[b], Arthur M. Carlin, M.D., F.A.C.S., F.A.S.M.B.S.[c,d], Justin B. Dimick, M.D., F.A.C.S.[a,b], Jonathan F. Finks, M.D., F.A.C.S.[a]

[a]*Department of Surgery, University of Michigan Health Systems, Ann Arbor, Michigan*
[b]*Center for Healthcare Outcomes and Policy, University of Michigan, Ann Arbor, Michigan*
[c]*Wayne State University, Detroit, Michigan*
[d]*Department of Surgery, Henry Ford Health System, Dearborn, Michigan*

Received July 8, 2016; revised September 10, 2016; accepted November 29, 2016

Abstract

Objective: To assess the effect of operative technique on staple line leaks after laparoscopic sleeve gastrectomy (LSG).

Background: Staple-line leaks after LSG are a major source of morbidity and mortality. Variations in operative technique exist; however, their effect on leaks is poorly understood.

Methods: We analyzed data from the Michigan Bariatric Surgery Collaborative (MBSC) to perform a case-control study comparing patients who had a clinically significant leak after undergoing a primary LSG to those who did not. A total of 45 patients with leaks were identified between January 2007 and December 2013. The leak group was matched 1:2 to a control group based on procedure type, age, body mass index, sex, and year the procedure was performed. Technique-specific factors were assessed by reviewing operative notes from all primary bariatric procedures in our study population. Conditional logistic regression was used to identify techniques associated with leaks. To increase the power of our analysis, we used a significance level of .10.

Results: Leak rates with LSG have decreased over the past 5 years (1.18% to .36%) as annual case volume has increased (846 cases/yr to 4435 cases/yr). Surgeons who performed 43 or more cases per year had a leak rate $<1\%$. Leaks were more common among cases requiring a blood transfusion (26.2% versus 1.08%, $P = .0031$) and when cases were converted to open surgery (7.14% versus 0%, $P = .0741$). However, there was no significant difference in operative time between cases involving a leak and their matched controls (95.4 min versus 87.1 min, $P = .1197$). Oversewing of the staple line was the only technique associated with less leaks after controlling for confounding factors (OR .397 CI .174, .909, $P = .0665$). Notably, surgeons who oversewed routinely were also found to have higher case volume (307 versus 140, $P = .0216$) and less overall complication rates (4.81% versus 7.95%, $P = .0027$). Furthermore, oversewing technique varied widely as only 22.6% of cases involved oversewing of the entire staple line.

Conclusion: Despite considerable variation in operative technique, leak rates with laparoscopic sleeve gastrectomy have decreased over time as operative volume has increased. Oversewing of the staple line was associated with fewer leaks, but specific suturing technique was not uniform and

This paper received funding from Blue Cross Blue Shield of Michigan/ Blue Care Network. The funding source had no involvement in collection, analysis, and interpretation of data; writing of the report; or in the decision to submit the article for publication.

*Correspondence: Oliver A. Varban, M.D., University of Michigan Health System, 2210 Taubman Center, 1500 E Medical Center Drive, SPC 5343, Ann Arbor, MI 48109-5343.

E-mail: ovarban@med.umich.edu

http://dx.doi.org/10.1016/j.soard.2016.11.027

oversewing was performed routinely by more experienced surgeons with higher case volumes and less complication rates overall. Before standardizing surgical technique one must take into account variations in surgeon skill and experience. (Surg Obes Relat Dis 2016;▮:00–00.) © 2016 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords: Bariatric surgery; Sleeve gastrectomy; Outcomes; Complications; Buttressing reinforcement; Technique; Skill

Staple-line leaks after laparoscopic sleeve gastrectomy (LSG) are a potentially disastrous complication resulting in significant patient morbidity and mortality. Management of leaks after LSG is complex and often results in longer hospitalizations as well as higher rates of overall complications. Although the incidence of leaks has declined over time, recent series still suggest rates as high as 2% to 3%. [1–7]

To reduce the likelihood of leaks after LSG, surgeons have employed a variety of strategies including oversewing of staple lines, use of buttressing material, tissue sealants, as well as varying the distance from the pylorus and bougie sizes. [3,6–12] Thus far, data from these studies are conflicting and often fail to control for patient demographic characteristics, surgeon skill, and variations in technique.

In this context, we conducted a case-control study using a prospective, statewide clinical registry. The goal of this study is to understand the relationship between operative technique and leaks after laparoscopic sleeve gastrectomy while controlling for patient characteristics.

Methods

Study population

This study analyzes data from the Michigan Bariatric Surgery Collaborative (MBSC), a payor-funded quality improvement program of 40 bariatric surgery programs and 70 surgeons across the state of Michigan. The program administers a prospective, externally audited clinical outcomes registry. Participating hospitals submit data on all patients who undergo primary and revisional bariatric procedures. Data include information on co-morbid conditions, as well as perioperative complications and weight loss outcomes. Patient data are obtained by data abstractors from in-hospital records 30 days after surgery as well as from patient surveys obtained at 1, 2, and 3 years after surgery. Centrally trained abstractors review medical records using a standardized and validated instrument; each hospital within the MBSC is audited annually by nurses from the coordinating center to verify that the data is complete and accurate.

For this study, we identified all patients 18 years and older who underwent primary laparoscopic sleeve gastrectomy (LSG) between January 2007 and December 2013, which included 11,855 patients. Among these patients, we included those who were diagnosed with a staple line leak within 30 days of their operation and excluded patients who underwent revisional bariatric surgery or had aborted procedures. Leaks were defined as those requiring percutaneous drain placement or reoperation after LSG.

Study design

We designed a case-control study to compare variations in operative technique and device utilization among patients who sustained a staple-line leak after LSG surgery to those who did not. Patients identified with a leak who met our inclusion criteria were matched 1:2 to a control group (no leak) based on age (±5 years), body mass index (BMI) (±7), sex, and year of procedure. Cases involving a leak were also matched to patients from different institutions. Operative reports of all primary bariatric procedures were obtained and reviewed independently by 2 reviewers (OV, KS) who were blinded to operative outcome (leak versus no leak).

Data collected

Data on patient characteristics included demographic characteristics (age, gender), BMI, and co-morbidities including diabetes, chronic pulmonary disease, liver disease, psychological disease, congestive heart disease, chronic renal failure, peripheral vascular disease, and peptic ulcer disease. Case-specific data from the MBSC included date and location of procedure as well as stapler vendor (Covidien, Mansfield, MA, USA, and Ethicon Endo-Surgery., Cincinnati, OH, USA), operative time, blood transfusions, conversion to open surgery, and incidence of leak within 30 days of the procedure.

Operative technique was assessed by collecting data from operative notes from all primary bariatric procedures in our study population as well as from the matched control group. An instrument for data abstraction was created and utilized to allow for proper taxonomy and standardization. Incongruent data was resolved by a committee that included all authors. Device-specific data included use of buttressing material, fibrin sealant, and drains. Device failures were captured, if noted, in the operative note. Technique-specific data included size of bougie, oversewing of the staple line, staple line distance from the pylorus, type of leak test, result of the leak test, and use of intraoperative endoscopy. Finally, additional procedures such as hiatal hernia repair, ventral hernia repair, cholecystectomy, and extensive