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Original article

Technique or technology? Evaluating leaks after gastric bypass

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Abstract

Objective: To assess the relationship between technique and surgical devices on anastomotic and staple-line leaks after laparoscopic Roux-en-Y gastric bypass.

Background: Leaks after bariatric surgery remain a major source of morbidity and mortality. The association of surgical technique and devices with leaks after gastric bypass is poorly understood. **Setting:** Multi-centered study that included teaching and non-teaching hospitals that participate in a statewide consortium for quality improvement using a payer-funded outcome registry.

Methods: We analyzed data from the Michigan Bariatric Surgery Collaborative and performed a case-control study comparing patients who sustained a leak with those who did not after primary laparoscopic Roux-en-Y gastric bypass. A total of 71 (.44%) patients with leaks were identified between January 2007 and December 2011. The leak group was matched 1:2 to a control group (nonleak) based on procedure type, age, body mass index, sex, and the year in which the procedure was performed. Technique-specific case characteristics and device-specific factors were assessed by reviewing operative notes from all primary bariatric procedures in our study population.

Results: The rate of leak decreased during the study period, and there was a significant downward trend (slope estimate: -.19961%, P = .0372). After performing multivariate analysis, the type of anastomosis (circular stapler, hand-sewn, or linear stapler) and stapler manufacturer were not associated with leaks. The use of buttressing material was associated with a higher rate of leaks (odds ratio: 8.79 [95% confidence interval: 2.49–31.01], P = .0007), whereas the use of fibrin sealant was associated with a lower rate of leaks (odds ratio .11 [95% confidence interval: .03–.41], P = .0013). These findings could not be explained by differences in measures of surgeon performance.

Conclusion: Leak rates after laparoscopic gastric bypass have fallen in Michigan despite variations in technique and device utilization. Although the type of anastomosis and stapler manufacturer do not appear to be significantly associated with leaks, it appears that the use of buttressing material was more common in cases in which leaks occurred, whereas the use of fibrin sealant was not. Given the complex interplay of multiple variables that affect surgical outcomes, future studies justifying the benefits of operative devices should be evaluated prospectively in the context of

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Bariatric surgery; Outcomes; Complications; Fibrin sealant; Buttressing reinforcement

Anastomotic and staple-line leaks remain a feared complication after laparoscopic Roux-en-Y gastric bypass (LRYGB). Although the incidence of leaks has declined over time, recent studies still suggest rates as high as 1%– 3% [1–4]. Leaks are a major source of morbidity and mortality for patients and management is often complex, resulting in longer hospitalizations and increases in overall complication rates [2,5].

As a result, surgeons have employed numerous operative techniques and devices aimed at reducing the likelihood of leaks. Studies, including those published by the Michigan Bariatric Surgery Collaborative, have failed to find a significant relationship between the type of gastrojejunal anastomosis (i.e., linear stapled versus circular stapled versus hand-sewn anastomosis) and the rate of leak [1,6,7]. Other studies have evaluated the use of specific materials and devices used during LRYGB with the purpose of decreasing the likelihood of leaks. These include the use of buttressing material [8-13] and tissue sealants [14-16]. Thus far, the results from these studies are conflicting because they are often hampered by a low number of leaks within their study population and a failure to control for surgeon performance, patient characteristics, and variation in device use.

In this context, we conducted a case–control study using a prospective, statewide clinical registry. This study strove to understand the relationship between operative devices and postoperative leaks after LRYGB by evaluating the effect of stapler manufacturer and use of buttressing material and tissue sealants while evaluating technique and controlling for surgeon performance and patient characteristics.

Methods

Study population

Our study was based on analysis of data from the Michigan Bariatric Surgery Collaborative (MBSC), a payor-funded quality improvement consortium of hospitals and surgeons performing bariatric surgery in Michigan. The MBSC administers a prospective, externally audited clinical outcomes registry and includes >45,000 patients. Participating hospitals submit data on all patients who undergo primary and revisional bariatric procedures. Data include information on preoperative clinical characteristics and comorbid conditions, as well as perioperative clinical care and outcomes. Patient data are obtained by data abstractors from in-hospital records and recorded up to 30 days after surgery.

Centrally trained abstractors review medical records using a standardized and validated instrument, and each hospital within the MBSC is audited annually by nurses from the coordinating center to verify the accuracy and completeness of its registry data.

For this study, we identified all patients 18 years and older who underwent primary LRYGB between January 2007 and December 2011, resulting in 16,258 patients. Among these patients, we included those who were diagnosed with a gastrointestinal leak within 30 days of their operation and excluded patients who underwent revisional bariatric surgery or who had aborted procedures. Leaks were located at the gastrojejunostomy or at the staple line of the gastric pouch or remnant and were defined as events that required percutaneous drain placement or reoperation. Leaks secondary to missed injuries or perforations that occurred at other locations along the gastrointestinal tract were excluded.

Employing a case–control study design, we matched cases (leaks) in a 1:2 ratio to a control group (no leak) on the basis of procedure type (LRYGB), age (± 5 yr), body mass index (BMI) (± 7), sex, and year of procedure. Control patients all had their operations at different hospitals than their respective cases.

Data collected

Patient characteristics. Data on patient characteristics included demographic characteristics (age and gender), BMI, and presence of 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 characteristics and devices. Case-specific data obtained from MBSC data abstraction included date and location of procedure, operative time, stapler manufacturer (Covidien, Mansfield, MA, USA, and Ethicon Endo-Surgery, Cincinnati, OH, USA) and units of blood transfused in the perioperative setting. Operative techniques were assessed by collecting data from operative notes from all primary bariatric procedures in our study sample as well as from our matched control group. The operative reports reviewed independently by 2 reviewers (O. V., K. S.) who were blinded to operative outcome (leak versus no leak), surgeon, and location of procedure.

An instrument for data abstraction was created and used to allow for proper taxonomy and standardization. Incongruent data were resolved by a committee that included all Download English Version:

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