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Routine intraoperative leak testing for sleeve gastrectomy: is the leak test full of hot air?

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Abstract

BACKGROUND: Staple line leak after sleeve gastrectomy (SG) is a rare but dreaded complication with a reported incidence of 0% to 8%. Many surgeons routinely test the staple line with an intraoperative leak test (IOLT), but there is little evidence to validate this practice. In fact, there is a theoretical concern that the leak test may weaken the staple line and increase the risk of a postop leak.

METHODS: Retrospective review of all SGs performed over a 7-year period was conducted. Cases were grouped by whether an IOLT was performed, and compared for the incidence of postop staple line leaks. The ability of the IOLT for identifying a staple line defect and for predicting a postoperative leak was analyzed.

RESULTS: Five hundred forty-two SGs were performed between 2007 and 2014. Thirteen patients (2.4%) developed a postop staple line leak. The majority of patients (n = 494, 91%) received an IOLT, including all 13 patients (100%) who developed a subsequent clinical leak. There were no (0%) positive IOLTs and no additional interventions were performed based on the IOLT. The IOLT sensitivity and positive predictive value were both 0%. There was a trend, although not significant, to increase leak rates when a routine IOLT was performed vs no routine IOLT (2.6% vs 0%, $P = .6$).

CONCLUSIONS: The performance of routine IOLT after SG provided no actionable information, and was negative in all patients who developed a postoperative leak. The routine use of an IOLT did not reduce the incidence of postop leak, and in fact was associated with a higher leak rate after SG.
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The surgical treatment of obesity and obesity-related comorbidities has now become one of the most rapidly increasing areas in general and minimally invasive surgery. Although Roux-en-y gastric bypass (RNY) remains a very popular surgical option for obesity, the use of sleeve gastrectomy (SG) has significantly increased over the past decade. Owing to recent high quality, randomized data, the beneficial effects of SG over medical management alone in patients with diabetes mellitus and metabolic syndrome are now well accepted.[1] However, these clearly demonstrated benefits must be weighed against the potential risks associated with the procedure. Staple line leak following SG is a relatively uncommon but serious major complication that can result in significant morbidity and even death. The incidence of staple line leak following SG has been reported from 0% to 8%.[2]

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The authors declare no conflicts of interest.

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In an effort to detect and correct any staple line deficiencies at the time of surgery, many surgeons elect to test the newly constructed sleeve by means of an intraoperative leak test (IOLT), typically performed with injection of either air or a colored dye such as methylene blue. The use of an IOLT following RNY is supported in the literature, with a documented intraoperative leak detection rate between 5.9% and 15% and low postoperative leak rates (0% to 1%).[3–5] These findings are congruent with the evidence supporting intraoperative air leak testing following colorectal anastomosis.[6] However, there have been no such studies validating the routine use of IOLT with SG.

Importantly, IOLT is not without its own risk. There is theoretical concern that the sheer stress that the IOLT imposes on the newly formed staple line may actually result in perioperative staple line weakness, thereby contributing to the development of a postoperative staple line leak.[7] Moreover, IOLT requires instrumentation of the fresh staple like with a small but not negligible risk of iatrogenic injury. Nonetheless, insufflation leak testing has become commonplace during SG procedures despite a paucity of evidence supporting its use in this setting.[8,9]

The purpose of this study was to critically evaluate the clinical utility and efficacy of intraoperative leak testing during the performance of SG for morbid obesity. We hypothesized that the IOLT would have an extremely low yield, and would have little to no predictive ability for identifying patients at risk of a clinically significant postoperative sleeve leak.

Methods

After receiving human subjects approval, we retrospectively reviewed the records of all adult (age $>$ 17 years) patients who underwent SG between January 2007 and January 2014. All operations were performed as primary bariatric procedures by attending surgeons experienced in bariatric surgery and with a resident surgeon assistant. In general, patients had a body mass index (BMI $>$ 35) with at least one weight-related comorbidity, or a BMI greater than 40, and completed a protocolized multidisciplinary bariatric pathway preoperatively.

The exact operative technique was at the discretion of the operating surgeon. However, in general, the tubularized gastric "sleeve" was created through serial applications of linear cutting stapler devices. Sleeve formation was guided by either an orogastrically passed bougie (38 or 40 French) or an upper endoscope placed along the lesser curvature of the stomach. The majority of surgeons routinely used staple line buttressing with Seamguard (Gore Medical, Flagstaff, AZ), with one surgeon using no buttressing material but oversewing the staple line. In the majority of cases (91.1%), a routine IOLT was performed at the end of the procedure. The IOLT was performed by submerging the newly constructed sleeve under sterile saline while insufflating air with either an orogastric tube or an endoscope. A positive IOLT was defined as any visualization of air bubbles with insufflation, regardless of whether a visual staple line defect was identified. No surgeons in this series used any alternative method such as methylene blue instillation. A postoperative sleeve leak was defined as any evidence of contrast extravasation or staple line defect on radiologic examination or surgical re-exploration, or any patient with a postoperative abscess adjacent to the sleeve staple line (regardless of whether contrast extravasation was present or absent).

All surgeons included in this series performed routine IOLT on all cases, with the exception of one surgeon who stopped performing routine leak tests in the last 3 years of the study period. All operative reports and staff surgeon postoperative notes were reviewed, and cases were grouped by whether an IOLT was performed. In patients in whom an IOLT was performed, we evaluated the results and any intraoperative or postoperative action that was taken as a result of the test. The ability of the IOLT for identifying staple line deficiencies and its utility in predicting or ruling out a postoperative leak was evaluated. Additionally, we compared the incidence of postoperative staple line leaks between patients who received an IOLT vs those who did not. Detailed analysis was performed on any cases with either a positive IOLT or a postoperative staple line leak. For the study population, we collected data on age, sex, BMI, comorbidities, type of surgery, and any intraoperative or postoperative complication. Follow-up analysis examined the hospital courses of patients who experienced a postoperative leak with regard to patient characteristics and comorbidities, location of the staple line defect, timing of presentation, method of leak diagnosis, leak management strategy, and patient outcomes. Univariate analysis between groups who received an IOLT and those who did not was performed using Student *t* test for continuous variables and chi-square or Fisher's exact test for categorical data. Sensitivity and specificity analysis of the IOLT was also performed. All statistical analyses were performed with SPSS v 22 (IBM Corporation, Chicago, IL).

Results

There were 542 primary sleeve gastrectomies performed at our institution between January 2007 and January 2014. The majority of procedures were performed laparoscopically (92%), although open (2%) and robotic (6%) approaches were also utilized. A total of 13 patients (2.4%) developed a postoperative staple line leak. Of the patients who developed a postoperative leak, the mean BMI was 42 (range 27 to 52), the mean age was 41 (range 26 to 61), and 92% of the patients were female (Table 1). In total, 3 leaks (23%) developed after revisional surgery. Although 69% of leaks were diagnosed within the first 5 postoperative days, leaks were detected as late as 67 days postoperatively. The mean time to presentation of a leak was 12.2 days