

# The usefulness and costs of routine contrast studies after laparoscopic sleeve gastrectomy for detecting staple line leaks

Dimitry Terterov, MD  
 Philemon Ho-Yan Leung, MD  
 Laurie K. Twells, PhD  
 Deborah M. Gregory, BN, PhD  
 Chris Smith, MD  
 Darrell Boone, MD  
 David Pace, MD, MBA

This work was presented at the 2015 Canadian Surgery Forum in Québec, Que.

Accepted Apr. 7, 2017; Early-released  
 Aug. 1, 2017; subject to revision

## Correspondence to:

D. Pace  
 Faculty of Medicine, Memorial University  
 300 Prince Philip Dr  
 St. John's NL A1B 3V6  
 dpace@mun.ca

DOI: 10.1503/cjs.015216

**Background:** Although laparoscopic sleeve gastrectomy (LSG) has been shown to be a safe and effective treatment for severe obesity (body mass index  $\geq 35$ ), staple line leaks remain a major complication and account for a substantial portion of the procedure's morbidity and mortality. Many centres performing LSG routinely obtain contrast studies on postoperative day 1 for early detection of staple line leaks. We examined the usefulness of Gastrografin swallow as an early detection test for staple line leaks on postoperative day 1 after LSG as well as the associated costs.

**Methods:** We conducted a retrospective review of a prospectively collected database that included 200 patients who underwent LSG for severe obesity between 2011 and 2014. Primary outcome measures were the incidence of staple line leaks and the results of Gastrografin swallow tests. We obtained imaging costs from appropriate hospital departments.

**Results:** Gastrografin swallow was obtained on postoperative day 1 for all 200 patients who underwent LSG. Three patients (1.5%) were found to have staple line leaks. Gastrografin swallows yielded 1 true positive result and 2 false negatives. The false negatives were subsequently diagnosed on computed tomography (CT) scan. The sensitivity of Gastrografin swallow in this study was 33%. For 200 patients, the total direct cost of the Gastrografin swallows was \$35 000.

**Conclusion:** The use of routine upper gastrointestinal contrast studies for early detection of staple line leaks has low sensitivity and is costly. We recommend selective use of CT instead.

**Contexte :** Même si la gastrectomie longitudinale par laparoscopie (GLL) s'est révélée sûre et efficace pour le traitement de l'obésité sévère (indice de masse corporelle  $\geq 35$ ), les fuites survenant à la ligne d'agrafes demeurent une complication majeure et sont responsables d'une bonne partie des complications et des décès associés à cette chirurgie. Plusieurs des centres effectuant des GLL procèdent au dépistage systématique des fuites à la ligne d'agrafes en réalisant des tests avec des agents de contraste le jour suivant la chirurgie. Nous avons évalué l'utilité du test à la gastrografine comme méthode de dépistage précoce des fuites à la ligne d'agrafes au jour 1, ainsi que les coûts qui y sont associés.

**Méthodes :** Nous avons mené une étude rétrospective à partir d'une base de données créée de façon prospective qui portait sur 200 patients ayant subi une GLL entre 2011 et 2014 en raison d'une obésité sévère. Les principaux indicateurs de résultats étaient l'incidence de fuites à la ligne d'agrafes et les résultats obtenus aux tests à la gastrografine. Les renseignements sur le coût des tests d'imagerie nous ont été fournis par les départements appropriés des hôpitaux.

**Résultats :** Selon les résultats des tests à la gastrografine au jour 1 obtenus pour les 200 patients ayant subi une GLL, 3 patients (1,5 %) présentaient des fuites à la ligne d'agrafes. Il s'agissait en réalité d'un vrai positif et 2 faux négatifs. Le diagnostic des faux négatifs a ensuite été effectué par tomographie par ordinateur. La sensibilité du test à la gastrografine était donc de 33 % au cours de cette étude. Le coût total de ce test, pour les 200 patients, était de 35 000 \$.

**Conclusion :** Le recours à des examens systématiques du tractus gastro-intestinal supérieur au moyen d'agents de contraste pour le dépistage précoce des fuites à la ligne d'agrafes a une faible sensibilité et est associé à des coûts élevés. Nous recommandons plutôt l'utilisation sélective de la tomographie par ordinateur.

Obesity has been an increasing global health problem. In 2008, 1.4 billion people were overweight and 0.5 billion were obese worldwide.<sup>1</sup> The prevalence of adult obesity (BMI  $\geq$  30) in Canada has increased dramatically over the last 3 decades from 6.1% in 1985 to 20.2% in 2014.<sup>2,3</sup> In 2014, the proportion of obese adult residents in the Canadian province of Newfoundland and Labrador was 30.4%, which was much higher than the national average of 20.2%.<sup>3</sup>

Bariatric surgery has emerged as the most effective treatment for patients in whom conservative management has failed.<sup>4</sup> Globally, Roux-en-Y gastric bypass (RYGB) surgery and laparoscopic sleeve gastrectomy (LSG) are the most common bariatric procedures performed for the treatment of obesity.<sup>5</sup> Laparoscopic sleeve gastrectomy works by decreasing the volume of the stomach, thereby restricting food intake, as well as by means of neurohormonal effects (e.g., lowered ghrelin levels) resulting from the partial excision of the stomach.<sup>6,7</sup> Based on a 2013 meta-analysis conducted by Parikh and colleagues,<sup>8</sup> LSG has been shown to result in 57.6% excess weight loss (EWL) at 1 year and 70.1% EWL at 3 years. The procedure has grown in popularity, trending from 0% in 2003 to 5.3% in 2008 and 37% in 2013.<sup>5</sup> Canadian Institute for Health Information data indicate that 2362 of the 6525 (36.2%) bariatric surgeries carried out in Canadian hospitals in 2013–2014, were LSGs.<sup>9</sup>

Laparoscopic sleeve gastrectomy is considered a relatively safe procedure; however, it carries a risk of several serious and potentially fatal complications, including staple line leak, staple line bleed and stricture.<sup>6,7,10</sup> The procedure is associated with a leak rate of 2.2%, an overall mortality of 0.3% and a leak-related mortality of 0.1%.<sup>8</sup> In a 2012 systematic review of 29 studies involving 4888 patients, the authors reported leaks occurred in 0%–7% of LSG cases, with a higher leak rate observed in patients with a BMI above 50 than in those with a BMI below 50 (2.9% v. 2.2%).<sup>11</sup> Csendes and colleagues<sup>12–14</sup> reported that 3 types of leaks may develop after bariatric operations: 1) early leak, which appears 1–3 days after surgery and is usually secondary to technical surgical problems; 2) intermediate leaks, which appear 4–7 days after surgery; and 3) late leaks, which appear 8 or more days after surgery.

The rationale for obtaining an upper gastrointestinal (UGI) contrast study after LSG may be attributed to the risk of staple line leak or stricture. Unidentified staple line leak may lead to abdominal sepsis, which could lead to the development of a gastric fistula, multisystem organ failure, or death.<sup>15,16</sup> However, the necessity of routine UGI contrast studies has been questioned and remains a point of controversy. A recent meta-analysis by Quartararo and colleagues<sup>16</sup> evaluated the results of routine and selective postoperative UGI series after RYGB to assess its utility and cost-effectiveness. No differences in leakage detection or in clinical benefit between routine and selective approaches

were observed. The authors concluded that tachycardia and respiratory distress were the best criteria to perform UGI contrast studies for early diagnosis of leak after RYGB. It is important to note that the meta-analysis focused only on RYGB, the most popular procedure performed worldwide. As Rawlins and colleagues<sup>17</sup> pointed out, “LSG is inherently different in anatomy and in causes of leak and obstruction.” A limited number of studies have evaluated the usefulness of routine UGI contrast studies on postoperative day 1 (POD 1) after LSG. Studies conducted in the United States,<sup>18</sup> Europe,<sup>19</sup> Egypt<sup>20</sup> and the Middle East<sup>21</sup> have reported low sensitivity of the test. We have not identified any Canadian studies that investigated the utility and cost-effectiveness of routine UGI contrast after LSG.

A number of bariatric centres across Canada have adopted programs for early detection of staple line leaks,<sup>22,23</sup> whereas others have decided to discontinue the use of routine contrast studies and have chosen to order imaging only when clinically indicated.<sup>24</sup> These imaging studies usually involve a routine Gastrografin swallow study on POD1. This has also been the practice at our centre, where LSG accounts for 98% of the procedures performed.<sup>23</sup> Because of the low frequency of early staple line leak and the significant costs associated with early detection programs, we have questioned the usefulness of routine contrast studies. As a result, the aim of the present study was to determine the usefulness and costs of routine Gastrografin swallow studies on POD1 after LSG in detecting early complications.

## METHODS

### Study setting

The Provincial Bariatric Surgery Program was established in Newfoundland and Labrador in May 2011. The multidisciplinary team consists of 3 surgeons trained in bariatric surgery, a nurse practitioner and a dietician. The 3 surgeons (D.P., D.B., and C.S.), performed all procedures in this study and have advanced laparoscopic skills. Two surgeons (D.P. and C.S.) are fellowship-trained in minimally invasive (MIS) and bariatric surgery.

### Study design

The study is a retrospective review of prospectively collected data combined with a chart review of patients undergoing bariatric surgery in order to assess the usefulness of the routine Gastrografin swallow test in the detection of early complications (e.g., leak). The present study is part of a larger study, the Newfoundland and Labrador Bariatric Surgery Cohort Study, which has been described elsewhere.<sup>23,25</sup> For the present study, we examined data from 200 consecutive laparoscopic sleeve gastrectomies performed between May 11, 2011, and May 5, 2014. This

study was approved by the provincial Health Research Ethics Authority (#11.101). All participants provided written informed consent to take part in the study.

### *Participants*

Patients were referred, selected and worked-up according to previously published protocol.<sup>25</sup> Throughout this process, they were seen by a nurse practitioner, dietician, appropriate medical specialists, and 1 of the 3 bariatric surgeons. Patients were excluded if they were pregnant or planning a pregnancy within 2 years of surgical treatment; had a medical condition that would make surgery too risky, such as end-stage organ disease; or had a BMI greater than 60.

### *Operative procedure*

The operative technique has been described previously.<sup>23</sup> The gastrocolic omentum is divided close to the stomach with a vessel-sealing device, completely freeing up the greater curve of the stomach from the distal antrum to the angle of His. Multiple firings of the stapler are performed along a 42-Fr bougie starting at about 6 cm proximal to the pylorus. The staple line is leak tested using a gastro-scope. Staple line bleeds are clipped.

### *Gastrografin swallow procedure*

All patients underwent the Gastrografin swallow study on POD 1. Patients received no more than a single 120 mL bottle of Gastrografin. Occasionally it was diluted with 10–15 mL of water to make it more palatable. Fluoroscopy was used to acquire images. Standing position and antero-posterior orientation was used to obtain most images; however, supine position and oblique orientation were used as well to improve image quality. On average 1 image was taken per swallow of Gastrografin. The majority of patients found Gastrografin very unpleasant and difficult to consume. If the radiologist reported the study as normal (i.e., negative results), patients were started on a clear fluid diet and advanced as per protocol. Patients were seen by a dietician and the nurse practitioner before discharge and were instructed to return on an as-needed basis. Otherwise patients were seen in clinic at 4 weeks by the nurse practitioner and dietician for advice on dietary progression. Patients attended a follow-up consultation with the surgeon between 6 and 8 weeks after surgery. Follow-up visits with the multidisciplinary team were scheduled for 3, 6, 12, 18 and 24 months and annually thereafter.

### *Definition of a staple line leak*

A definition of staple line leak was proposed by the UK Surgical Infection Study Group; they define a leak as “the leak of luminal contents from a surgical join between two

hollow viscera.” A second definition proposed by the same group suggests that a leak may also be defined as “an out-flow of gastrointestinal content through a suture line around an organ. Thus luminal content can exit through the wall or drain, or can collect next to the anastomosis.”<sup>26</sup> In addition, these leaks have been classified in the literature by Csendes and colleagues<sup>12</sup> based on the time period in which they appear:

- early leaks appear between the first and third day after surgery,
- intermediate leaks appear between the fourth and seventh day after surgery, and
- late leaks appear more than 8 days after surgery.

In the present study, we define staple line leak based on the second definition proposed by the UK Surgical Infection Study group.

### *Data collection*

Presurgical data were collected from patients using standardized case report forms. Sociodemographic data and presurgical clinical data were collected by the nurse practitioner. Clinical data (e.g., leak, diagnostic testing) were obtained from chart review by the first author (D.T.). All staple line leaks were recorded, and the clinical course and management of these cases was reviewed by the bariatric clinical team. Costs of the Gastrografin swallow and of the abdomen and pelvis computed tomography (CT) scanning were obtained from the radiology department at the Health Sciences Department at Eastern Health.

### *Statistical analysis*

Descriptive analyses were performed for continuous variables, and data are presented as means and standard deviations or medians and interquartile ranges. For categorical variables data are presented as numbers and percentages. Leak incidence as well as overall test accuracy, sensitivity, specificity, and positive (PPV) and negative predictive values (NPV) of the Gastrografin swallow test were calculated.

## **RESULTS**

The data on 200 patients who underwent laparoscopic sleeve gastrectomy between May 20, 2011, and May 5, 2014, were collected. Mean age was 44 years, mean BMI was 49, and 82% of patients were women. Preoperative demographic characteristics and comorbidities are shown in Table 1. Staple line leak was diagnosed in 3 of 200 (1.5%) patients. One contrast study correctly confirmed a leak (a true positive), whereas 2 studies did not reveal a leak (false negatives). Details of the contrast studies, including leak information and treatment, are presented in Table 2 and Table 3. The Gastrografin swallow test had a sensitivity of 0.33, specificity of 1.00, PPV of 1.00 and NPV of 0.99 (Table 4).

A description of the clinical details of patients who experienced a leak in the present study follows. Three of 200 patients experienced staple line leaks near the gastroesophageal junction, which presented on PODs 1, 7 and 30, respectively. The results of postoperative Gastrografin swallow performed on POD 1 were negative in 2 of the 3 patients. In those patients, the clinical suspicion of staple line leak was confirmed by CT scan. One of the leaks required reoperation, whereas the other 2 were treated conservatively.

The first patient was a 45-year-old woman who was found to be tachycardic (i.e., up to 137 beats/min), with a white blood cell count of  $21 \times 10^9/L$  on POD 1. She was taken for a Gastrografin swallow, and a large leak was detected. She was then taken to the operating room for closure of the defect, irrigation of the abdominal cavity, drainage of the upper abdomen, and placement of a feeding jejunostomy tube. She recovered uneventfully.

The second patient was a 47-year-old woman who had an uneventful LSG and a negative Gastrografin swallow. On POD 7, she presented to the bariatric clinic with

shortness of breath, chest pain and a white blood cell count of  $23 \times 10^9/L$ . A CT pulmonary angiogram was done to rule out a presumed pulmonary embolism. It showed a small proximal staple line leak, which was confirmed by repeat Gastrografin swallow. The patient was managed conservatively with intravenous antibiotics and total parenteral nutrition. The leak was monitored with several repeat CT scans, endoscopies and contrast studies. The patient left against medical advice after a 2-month hospital admission.

The third patient was a 50-year-old woman who had an uneventful LSG and a negative Gastrografin swallow. She presented 1 month later with dysphagia, dehydration and a white blood cell count of  $18 \times 10^9/L$ . A subsequent CT scan confirmed a small proximal staple-line leak. She was treated successfully with conservative measures and was discharged home after a 1-month admission.

The cost of 1 Gastrografin swallow with a radiologist's interpretation at our centre was \$175 Canadian dollars. Therefore the total cost of conducting the swallow test on all 200 patients was \$35 000. On the other hand, based on patient symptomology, the cost of 1 contrast CT scan of the abdomen and pelvis with a radiologist's interpretation was estimated at \$1107. The total cost of the 2 CT scans performed in 2 patients for leak detection was \$2214.

DISCUSSION

Staple line leak is a complication dreaded by bariatric surgeons performing LSGs. Routine, early Gastrografin swallow studies have been used by some centres in an attempt to detect this complication before clinical symptoms appear. In this study, we assessed the usefulness of this test for patient management and its costs. Several conclusions and remarks can be made based on the results

Table 1. Demographic and clinical characteristics of the study sample (n = 200)

Characteristic	Mean ± SD or no. (%)
Age, yr	44 ± 10
Weight, kg	135.1 ± 23.7
BMI	48.8 ± 6.8
Duration of surgery, min	80.8 ± 29.6
Hospital stay, d	2.3 ± 1.6
Female sex	163 (81.5)
Leak	3 (1.5)
30-day mortality	0 (0)

BMI = body mass index; SD = standard deviation.

Table 2. Leak information and treatment (n = 3)

Patient	Classification as per POD <sup>12,37</sup>	POD at presentation	Presenting symptoms	Location	Severity* <sup>12,37</sup>	Treatment	CT abdomen/pelvis
45-yr F	POD 1–3 d (early)	1	Tachycardia (137 beats/min) BP 93/60 Abdominal tenderness WBC $21.2 \times 10^9/L$	Proximal stomach (below gastroesophageal junction)	Type II	Emergency laparotomy, primary closure of defect, drainage of the upper abdomen, placement of a feeding jejunostomy tube	No
47-yr F	POD 4–7 d (intermediate)	7	SOB Chest pain WBC $22.9 \times 10^9/L$	Proximal stomach (below gastroesophageal junction)	Type I	Intravenous antibiotics, total parenteral nutrition	Yes
50-yr F	POD > 7 d (late)	30	Dysphagia Not tolerating fluids Dehydration Weakness WBC $18.0 \times 10^9/L$	At gastroesophageal junction	Type I	Intravenous antibiotics, total parenteral nutrition; 4 clips placed across defect endoscopically	Yes

BP = blood pressure; CT = computed tomography; F = female; POD: postoperative day; WBC = white blood cell count.

\*Type I or subclinical leaks are those that appear as a localized leak, without spillage or dissemination, with few clinical manifestations; they are easy to treat medically. Type II leaks are those with dissemination or diffusion into the abdominal or pleural cavity by way of an irregular pathway, with the appearance of contrast medium (methylene blue, radiological contrast) or food through any of the abdominal drain, with severe clinical consequences.

presented here. First, the staple line leak rate in our study was similar to those previously published at 1.5%.<sup>7</sup> Second, although some centres in Canada use routine Gastrografin studies, we found that the test was not effective in early detection of leaks. The sensitivity, specificity, PPV and NPV were 0.33, 1.00, 1.00 and 0.99, respectively. Finally, the costs of such an early detection program are very high considering its ineffectiveness. In our sample of 200 patients, the total cost of Gastrografin swallows performed was \$35 000, whereas the cost of 2 CT scans used to diagnose leaks was \$2214.

The Gastrografin swallow proved to be an ineffective test for early leak detection. The sensitivity of the test was 33%, which is especially poor for an outcome with a low prevalence. One should not be misled by the high NPV of 0.99. In this study, it does not indicate the test's ability to rule out leaks, but simply reflects the relative rarity of the outcome. Although the PPV was also high at 1.00, this result simply reflects the fact that there were no false positive studies. A single positive study result would have decreased the PPV to 0.5.

Of the 3 leaks, only 1 was detected by Gastrografin swallow on POD 1. However, in this particular patient scenario, it could be argued that the swallow test was being used as a diagnostic rather than as an early detection test. Before the test was performed, the patient was tachycardic and reported abdominal pain. Her white blood cell count was elevated at  $21 \times 10^9/L$ . The other 2 leaks were missed by the Gastrografin swallow and detected on the CT scan of the abdomen when the patients presented with symptoms after hospital discharge. It must be noted that these 2 patients presented with symptoms at 7 days and 4 weeks after surgery, respectively. It is very likely that these patients experienced delayed leaks, which could be the reason for the negative test on POD 1. Thus, the

sensitivity of the Gastrografin swallows may have been limited by the timing of the test. Although most centres do the contrast study on POD 1, an editorial by Afthinos and Gibbs<sup>27</sup> expressed the view that most leaks are delayed and caused by ischemia rather than by technical error, and in 1 study have been observed to occur between 5 and 28 days after surgery.<sup>17</sup>

Comparing our study results to those of other published studies that evaluated the usefulness of routine contrast studies after LSGs, we find similar results in that most authors have not found routine contrast studies on POD 1 useful in detecting staple line leaks. The sensitivities quoted are consistent with the results of the present study and, as in our study, most leaks were detected on CT.<sup>18–21</sup> In contrast, there is 1 small study from Greece that looked at routine Gastrografin swallows after LSG on POD 3. That study found that all leaks (3 of 85) were detected by the contrast studies<sup>28</sup> and concluded that the routine contrast studies were indeed useful.

A larger number of similar studies have been conducted on patients who have undergone laparoscopic RYGB (LRYGB), and the findings are inconsistent. The majority conclude that routine Gastrografin swallow studies on POD 1 are not useful or cost-effective methods of early detection of anastomotic leaks.<sup>17,29–34</sup> However, 2 studies published on LRYGB have conducted sensitivity analyses comparing sensitivities of clinical signs versus routine Gastrografin swallows. These 2 studies found clinical signs to be less sensitive and therefore support the use of routine contrast studies.<sup>35,36</sup>

Some of the common reasons quoted in support of routine Gastrografin swallows on POD 1 are documentation (especially for young surgeons), ability to detect strictures, and the consideration that many CT scanners are not bariatric patient-rated.

When examining the costs of the imaging studies in the present analysis, it becomes evident that the total cost of the Gastrografin swallows, which proved to have low sensitivity, was more than 10 times greater than the cost of the 2 CTs used to diagnose the leaks in symptomatic patients. The early detection program was found to be very costly without providing any benefit to the patients. Studies on sleeve gastrectomies from Israel and

**Table 3. Swallow study 2 × 2 contingency table (n = 200)**

Gastrografin swallow	Complication, no.	Normal, no.
Positive	1	0
Negative	2	197

**Table 4. Gastrografin swallow test statistical probabilities**

Variable	Percentage	Definition
Prevalence	1.5	Overall complication rate
Sensitivity	33	Probability of a positive swallow test when leak or obstruction was present
Specificity	100	Probability of a normal swallow test when leak or obstruction was absent
PPV	100	Probability of a leak or obstruction when the swallow test was positive
NPV	99	Probability of no complication when the swallow test was negative
True positive	33	Probability that swallow test is positive when there is a complication
True negative	100	Probability of negative swallow test when there is no complication
False positive	0	Overall missed diagnosis rate
False negative	66	(FP + FN)

NPV = negative predictive value; PPV = positive predictive value.

the United States also looked at the costs of the early detection program and arrived at a similar conclusion.<sup>18,21</sup> In Canada, in a publicly funded health care system with limited resources and reduced budgets with a focus on cost-effectiveness, any test with low accuracy should be questioned in terms of money spent.

### Strengths and limitations

The strengths of this study include the use of prospectively collected data. In addition, all procedures were performed by surgeons at the same academic-affiliated health care institution using a 2 surgeons per case approach. The limitations of this study are as follows. First, we did not have access to data on patients who had a CT for symptoms, but in whom a leak was not subsequently diagnosed. This could potentially change the estimates for the cost analysis. Second, we did not examine strictures, for which some authors report the utility of routine contrast studies.<sup>18,28</sup> Moving forward, it would be interesting to analyze the data on sleeve strictures and to determine whether or not the absence of routine Gastrografin studies delays their diagnosis.

### CONCLUSION

At our newly established bariatric surgery centre, we found the Gastrografin swallow early detection program post-LSG to have inadequate sensitivity for correctly identifying staple line leaks. In addition, the costs of such a program and the cost to identify 1 correctly diagnosed leak is unjustifiably high. In our centre, based on this research and the results of other published studies, we have stopped the routine use of this test. Instead, we and others<sup>37</sup> recommend being mindful of patient clinical signs and symptoms suggestive of a leak and having a low threshold to investigate them either with a Gastrografin swallow, a CT scan, or early reoperation.

**Affiliations:** From the Eastern Health Sciences Centre, St. John's, NL (Terterov, Leung, Boone, Pace); the Faculty of Medicine, Memorial University of Newfoundland, St. John's, NL (Terterov, Leung, Twells, Gregory, Smith, Boone, Pace); and the School of Pharmacy, Memorial University of Newfoundland, St. John's, NL (Twells).

**Competing interests:** None declared.

**Contributors:** D. Terterov, C. Smith and D. Pace designed the study. All authors acquired and analyzed the data. D. Terterov, P. Leung, L. Twells, D. Gregory and D. Pace wrote the article, which all authors reviewed and approved for publication.

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