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ORIGINAL CONTRIBUTION

Early Experience with Intraoperative Leak Test Using a Blend of Methylene Blue and Indocyanine Green During Robotic Gastric Bypass Surgery

Monika E. Hagen[1,2] · John Diaper[3] · Jonathan Douissard[1] · Minoa K. Jung[1] · Leo Buehler[1] · Florence Aldenkortt[3] · Gleicy Keli Barcelos[3] · Philippe Morel[1]

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Abstract

Introduction Leak tests using air or methylene blue (MB) for gastrojejunal anastomoses are often performed during gastric bypass surgeries to avoid leaks due to technical errors. Still, early leaks have been reported in the literature. Indocyanine green (ICG) fluorescence with laser excitement makes this dye easily visible even in small amounts, and, thus, may be an excellent agent for leak testing.

Methods During robotic gastric bypass surgery, a leak test of a gastrojejunal anastomosis was performed with air through a nasogastric tube under manual occlusion of the jejunum. Afterward, 50 ml of a mix of 100 ml sterile water, 2 mg of MB, and 5 mg ICG was injected through the same tube. The entire anastomosis was inspected for integrity under both fluorescent and normal light modes.

Results Leak tests with air and the blend of MB and ICG have been performed in 95 patients from January 2017 to April 2018. No intraoperative leak test-related adverse events occurred. Zero (0%) patients had a positive leak test with air, 0 patients showed MB excretion, and an ICG leak was observed in four (4.2%) patients. No anastomotic complications, including leaks and/or strictures, were found 30 days postoperatively.

Conclusions Leak tests using a blend of MB and ICG appear to be more sensitive for small defect detection of gastrojejunal anastomoses during robotic gastric bypass surgery. Larger datasets and research that is more stringent are needed to determine the exact clinical value of this new method.

Keywords Leak test · Gastric bypass · Anastomotic test · Indocyanine green · Methylene blue

Introduction

Intraoperative adverse events are described as the main cause of postoperative complications after laparoscopic Roux-en-Y gastric bypass (LRYGB) [1]. According to a position statement of the American Society for Bariatric and Metabolic Surgery (ASBMS), gastrojejunal leaks remain an important cause of morbidity and mortality after bariatric procedures and the identification of an intraoperative leak warrants repair and re-testing [2]. Various tests can be used, including endoscopic examination of the anastomosis, a pneumatic test by intraluminal injection of air, or dye test by intraluminal injection of MB.

Preoperative endoscopic examination of the anastomosis with air insufflation has been well described, and large case

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✉ Monika E. Hagen
monikahagen@aol.com

[1] Division of Digestive and Transplant Surgery, Department of Surgery, University Hospital Geneva, 4 Rue Gabrielle-Perret-Gentil, 1211 Geneva, Switzerland

[2] Division of Digestive and Transplant Surgery, Department of Surgery, University Hospital Geneva, 4 Rue Gabrielle-Perret-Gentil, 1205 Geneva, Switzerland

[3] Department of Anesthesiology, University Hospital Geneva, 4 Rue Gabrielle-Perret-Gentil, 1211 Geneva, Switzerland

series have reported no gastrojejunostomy postoperative leaks using this technique [3–6]. Unfortunately, in our country, as in others, surgeons do not have the credentials to perform endoscopies and qualified gastroenterologists are usually not routinely available.

As such, we have used alternative methods of testing using air and/or MB through a simple nasogastric tube during gastric bypass surgery. However, considering reports of early postoperative leaks despite the application of one or both of those leak tests, doubts regarding their sensitivity should be raised. Thus, for gastrojejunal anastomoses, there seems to be a need for a more sensitive but equally easy-to-use test that would be applied through a standard nasogastric tube with an alternative agent.

Indocyanine green (ICG) is a green dye that fluoresces in the near-infrared (NIR) domain. NIR fluorescence of ICG after laser stimulation is highly sensitive and allows very small amounts of dye to be detected [7]. Specific imaging devices that use NIR fluorescence of ICG are available in both laparoscopic and open surgery methods and is a standard element in the da Vinci Xi Surgical System (Firefly System, Intuitive Surgical Inc., Sunnyvale, CA, USA) [8]. This technique is mostly used for fluorescent micro-angiography and is gaining popularity among surgeons for a wide variety of applications due to its optical properties, cost-effectiveness, and minimal side effects [9].

We hypothesized that ICG-NIR fluorescence can be useful for the detection of the smallest gastrojejunal anastomotic defects with a sensitivity beyond that of standard pneumatic and blue dye techniques.

Materials and Methods

Surgery

Patients included in this study (from January 2017 to March 2018) underwent total robotic Roux-en-Y gastric bypass surgery (RYGB) using the da Vinci Xi Surgical System (Intuitive Surgical Inc., Sunnyvale, CA, USA). The surgery included the formation of a stapled gastric pouch of about 30 cc using the Echelon Endopath (Ethicon Endo-Surgery Inc., Cincinnati, OH, USA), an alimentary loop of about 150 cm, a biliary loop of about 75 cm, and gastrojejunal and jejuno-jejunal anastomoses. In addition, the closure of the intermesenteric window and the Space of Petersen was performed using non-absorbable sutures. Both anastomoses were robotically sutured using a needle driver in the right hand and long-tip forceps in the left hand while systematically applying a single layer 2-0 Vicryl suture (Ethicon Endo-Surgery, Cincinnati, OH, USA) for all patients until January 2018. Starting in January 2018, a gradual transition to a posterior double-layered gastrojejunal anastomosis with the same suture and instruments was conducted.

Novel Leak Agent Blend

For the novel leak agent, 2 mg of MB, 5 mg of ICG, and 100 ml of sterile water were mixed in a syringe.

Leak Test

At the end of the gastric bypass procedure, a nasogastric tube was pushed through the gastrojejunal anastomosis. The alimentary loop was bluntly occluded by pushing a robotic instrument through. First, sterile water was instilled to cover the anastomosis using a standard laparoscopic suction-irrigation device. Fifty milliliters of air was injected through the nasogastric tube in a single push. The air test was rated as positive when air bubbles were visible. In the next step, 50 ml of the previously described blend of sterile water, ICG, and MB was injected using a single push under laser activation (ICG mode). The anterior aspect and the left and right lateral in addition to the posterior aspects of the anastomosis were inspected with green and white light.

Data

Patients who underwent both air and the ICG plus MB leak test during robotic gastric bypass surgery from January 2017 to April 2018 were included in this analysis. Leak test data and clinical outcomes were collected prospectively as part of our institutional registry. Data for this analysis was abstracted and retrospectively analyzed.

Results

Ninety-five patients underwent both air and ICG plus MB leak tests from January 2017 to April 2018, operated by two surgeons. Twenty-three of these patients were male (24.2%) and 72 (75.8%) were female, with a mean body mass index of 43.5 (± 6.4) kg/m^2 and a mean age of 43.9 (± 11.1) years. No intraoperative adverse events caused by the leak test occurred. Zero (0%) patients had a positive air leak test. In zero (0%) patients, extra-luminal MB was detected. Four (4.2%) showed positive ICG detection. All of these ICG leakages were noted as a slight oozing at the anterior aspect of the gastrojejunal anastomosis (Video 1 and Video 2). The locations of ICG oozing were oversewn in all patients using a 2-0 Vicryl suture. Zero (0%) patients had postoperative leaks or other complications of their gastrojejunal anastomoses in the 30-day period. Table 1 shows detailed results.

Table 1 Results

Parameter	$n = 95$
Positive air test, *n* (%)	0 (0)
Positive test methylene blue, *n* (%)	0 (0)
Positive test indocyanine green, *n* (%)	4 (4.2)
Postoperative gastrojejunal leaks, *n* (%)	0 (0)

Discussion

Due to the high safety and easy-to-use profile of ICG, many studies have reported success with ICG-enhanced fluorescence-guided procedures. Kaibori et al. explained that ICG-enhanced fluorescent cholangiography could detect leaking bile duct stumps missed by traditional bile leak tests [10]. Mehraneh et al. described a reduced rate of anastomosis leak (AL), 6% in the NIR + ICG group versus 18% in the control group [11]. Masaki et al. demonstrated that ICG-enhanced imaging might decrease the incidence of AL following esophageal cancer (EC) surgery [12]. The variety of described applications lead us to hypothesize that ICG may also be a useful agent for the gastrojejunal leak test during gastric bypass surgery.

Gastrojejunal AL is associated with significant morbidity and mortality rates, and a longer in-hospital treatment period. Although the incidence of leaks after gastric bypass has decreased over time, it should be avoided whenever possible [2]. Our preliminary data show the safety and feasibility of using an MB and ICG blend for gastrojejunal leak tests during robotic gastric bypass surgery. During our still new experiences, no adverse events were observed. To our knowledge, no prior studies have examined the blend of the two agents before, neither has the blend been recommended by its vendors. As such, this is a first report of using a blend of MB and ICG. We decided to blend both agents instead of adding a third leak test in order to avoid increasing the stress on the gastrojejunal anastomosis and to avoid extending the total time for the procedures.

The higher rate of ICG test positivity when compared to traditional methods, including air and MB, suggests that the ICG test may be more sensitive than the other two methods. Based on our findings, we hypothesize that this could be the case particularly for the smallest gastrojejunal anastomoses leaks as they have occurred in our cases (Video 1 and Video 2).

The observed higher sensitivity of the ICG leak test may be explained by shortcomings of the other described methods. While we can only speculate about the exact reasons for their inferiority, we assume technical reasons. The most evident problem with our air test is that the leak indication fluctuates, unless when applying a continuous airflow under pressure control. When the anastomosis is set under a certain pressure, it causes air fill, which leads to the formation of bubbles until the pressure is released. This may occur for only a very short period, particularly for micro-defects. These challenges can be addressed by applying constant air flow into the tube during the leak test and taking adequate time to flush the anastomosis with water. While the MB test is more consistent than the air test in signaling (blue dye can be visualized when exuded in sufficient amounts until washed away), this new data shows that a certain threshold amount needs to be present beyond the defect in order to be detected with a surgical camera and the human eye without digital enhancement. During the two leak tests (Video 1 and Video 2), MB was not visible, despite a clear ICG signal. While the exact reason for the higher detection rate is not known, we hypothesize that the MB contrast during surgery may not be sufficient when present only in small amounts. In fact, the drastic contrast between the ICG and the dark surgical field in the ICG mode may be the reason why MB was visible with micro-defects.

Therefore, it seems reasonable to assume that the leak test with ICG delivers a higher sensitivity than the more common alternative leak tests with air and MB. However, the clinical relevance of this sensitive threshold needs to be evaluated. During earlier studies of our gastric bypass cohort, the leak rate was 0% versus 1% or lower in the literature [2, 13]. As a result, we cannot conclude that all four patients with positive ICG tests in this study would have suffered from a relevant postoperative leak. In theory, we could have studied the effect of the micro-leaks if we had left the small ICG extravasations untreated, but this would have been non-ethical and indefensible, given the lack of data and study design. Also, leaving visible leaks untreated is against the position statement of ASMBS [2]. Nevertheless, even if only a very small number of patients potentially benefit clinically from this test, the continuation of its application appears justified, particularly in the light of the low costs of ICG (a 25 mg vial of ICG costs 65 USD) [14]. Overall, it would be valuable to generate further systematic data concerning this novel leak test in order to clearly determine its clinical value.

Conclusion

This novel leak test using a blend of MB and ICG was feasible and appears to be more sensitive than air and MB alone. However, research that is more systematic should be conducted in order to determine the clinical value of this novel ICG application.

Compliance with Ethical Standards

Ethical Approval Our local ethics committee approved the review of our gastric bypass surgeries.

Informed Consent A statement regarding informed consent does not apply.

Conflict of Interest Dr. Hagen received personal fees and non-financial support by Intuitive Surgical Inc. and Ethicon Endosurgery Inc., outside this project. Dr. Jung received non-financial support by Intuitive Surgical Inc. and Ethicon Endosurgery Inc., outside this project. Prof. Morel received personal fees and by Intuitive Surgical Inc. All other authors have nothing to disclose.

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