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CASE REPORT

Natural Orifice Surgery (NOS) Using StomaphyX™ for Repair of Gastric Leaks after Bariatric Revisions

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Abstract Gastric leaks represent serious complications of bariatric surgery. With the increasing popularity and performance of bariatric procedures, the incidence of leaks and associated complications are expected to increase. Minimally invasive natural orifice surgery represents a novel and promising approach to gastric leak management, especially for morbidly obese patients who are at much higher risk from open or laparoscopic surgical procedures. The present article reports two cases of the safe and successful use of the EndoGastric Solutions StomaphyX™ device to alter the flow of gastric contents and repair gastric leaks resulting from bariatric revision surgery. Both patients were at a high risk and could not undergo another open or laparoscopic surgery to correct the leaks that were not healing. The StomaphyX procedures lasted approximately 30 min, were performed without any complications, and resulted in the resolution of the gastric leaks in both patients.

Keywords RYGB · Revision · Complications · Bariatric · Volume reduction

Introduction

The Roux-en-Y gastric bypass (RYGB) is the most commonly performed bariatric procedure in the USA to treat morbid obesity [1]. Numerous studies have documented the effectiveness of RYGB in promoting excess body weight loss typically in the 65–80% range after 1.5 to 2 years [1]. Despite the favorable short-term outcomes of this bariatric surgical procedure, approximately 10–40% of patients do not achieve successful long-term weight loss [2]. The weight regain occurs typically within 2 to 7 years after RYGB surgery and is associated with dilation of the pouch or stoma [3, 4]. Several open and laparoscopic bariatric revision procedures have been used in an attempt to correct these dilations, but they all have been associated with serious complications, such as perforations, obstruction, staple-line disruption, blind loop syndrome, stomal ulcer, and incisional hernias [2, 5, 6]. The most feared complication of gastric surgery for morbid obesity, however, is a postoperative gastric leak with the development of peritonitis [2, 5]. After RYGB, leaks have been reported at the gastrojejunostomy, the distal stomach, or the jejunojenuostomy in up to 5% of all revision procedures with a significant morbidity and mortality rate that may exceed 50% [7, 8].

StomaphyX™ (EndoGastric Solutions, Inc., Redmond, WA, USA) is an incisionless transoral fastening device that creates plications using polypropylene SerosaFuse™ fasteners (Fig. 1). StomaphyX has been cleared by the US Food and Drug Administration for tissue approximation and ligation in the gastrointestinal (GI) tract. The device has been successfully used for pouch and anastomosis volume reduction [9, 10]. The present study reports the results of two patients who were treated with StomaphyX for management of gastric leaks that developed after revisions of RYGB.

Case 1

A 58-year-old woman underwent a RYGB procedure at another institution in 2003. The procedure was successful and resulted in the creation of a 40-cc gastric pouch. The patient completed counseling for eating disorders before and after her original surgery. Unexpected events in her life,

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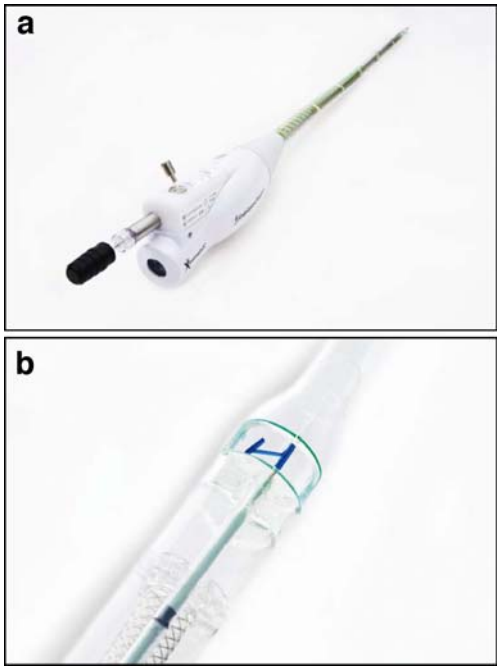

Fig. 1 A general view (**a**) and the shaft part (**b**) of the StomaphyX device

however, brought on depression, and she subsequently returned to overeating, which resulted in dilation of the gastric pouch to 600 cc and commensurate weight regain.

Once the patient regained control of her personal life and her eating habits, she complained of a lack of satiety. An open pouch reduction surgery was undertaken after extensive discussions with the patient, counselors, and her family members. The patient initially did well after the surgery, but by day 12, she complained of increasing abdominal pain and experienced fever of 38.9°C. Computer tomography revealed a leak from the gastric pouch. The patient was taken to the operating room and underwent debridement of the staple line from the area of the initial surgery, dehiscence on the gastric pouch (approximately 2 cm in length), primary closure with drainage, and placement of a feeding jejunostomy in the biliopancreatic limb. Despite an initially successful procedure, a leak had redeveloped on day 5 and required another sump drain to be placed. The jejunostomy feeding tube was utilized, but there was ongoing minute reflux of tube feeds, bile, and gastric contents from the pouch recovered by the drains. The output of the drains was more than 50 cc per hour when the patient was on tube feeds and 20 cc per hour when total parenteral nutrition (TPN) was used; therefore, TPN was used to maintain the patient's nutritional status. A positive nitrogen balance was attained by an adequate caloric intake and confirmed by a pre-albumin level greater than 14. The drains were slowly backed out but resulted in no improvement in the patient's gastric leak. The patient remained medically stable and afebrile.

An upper endoscopy was performed, and the leak was found to be in a dependent position relative to the gastrojejunostomy (Fig. 2), assuring that gastric contents flowed preferentially through and placed pressure on the leak. Removal of residual sutures was performed endoscopically, and the leak was estimated to be approximately 24F bougie in size (7.6 mm). The patient received conservative therapy with maximal nutritional support, but there was no progression in the healing of the leak for 4 months. Because of the patient's condition, another open revision surgery was considered to be of high risk.

As an alternative to an open or laparoscopic procedure, the patient elected to undergo natural orifice surgery (NOS) using the StomaphyX device. The patient was taken to the operating room and placed under general anesthesia. An upper endoscopy was performed to identify the anatomical landmarks of the pouch and to locate the leak. The endoscope was then inserted through the shaft of the StomaphyX device (Fig. 1), and the device was introduced through the patient's mouth into the pouch under continuous visualization. Once inside the pouch, vacuum was employed to draw a large fold of tissue proximal to the leak into the shaft of the device. The stylet of the device, which is maintained entirely within the shaft at all times, was advanced, and the first polypropylene fastener was deployed across the base of the tissue fold creating a stable full-thickness plication. Without removing the device from the patient, another five plications were created circumferentially at 1 cm from the leak. The plications on opposing sides of the leak were then pulled together and fastened to each other using the StomaphyX device in the same manner that was used to create the first plications. Additional three fasteners were deployed to create a bridge of tissue to shield the leak. The device was removed, and a second upper

Fig. 2 Upper GI radiography showing leak inferior to the jejunum in patient 1

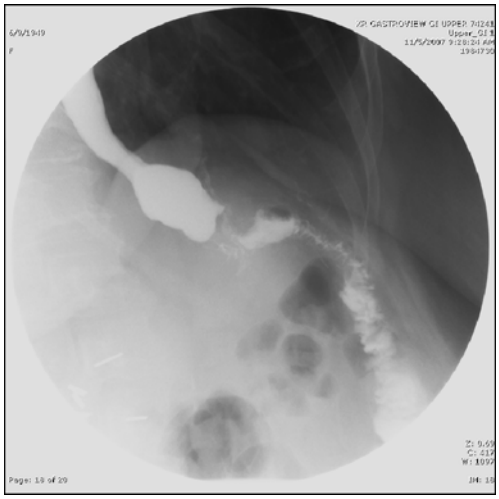

Fig. 3 Upper GI radiography after the StomaphyX procedure showing flow into the jejunum in patient 1

Fig. 4 Upper GI radiography showing a horizontal leak from duodenal switch near gastro-esophageal junction on the greater curvature side of the stomach in patient 2

gastrointestinal endoscopy was performed to evaluate the results (Fig. 3). The duration of the procedure from insertion of the devices to its withdrawal was 30 min. There were no perioperative or postoperative complications. The endoscopy revealed that the leak was reduced by at least 70%. The side of the pouch was also shortened to eliminate the dependency of the leak relative to the gastrojejunostomy. By pleating the pouch and including the leak, the revised anatomy of the pouch formed a ridge of tissue that changed the flow of gastric contents. This was documented by a change in irrigation flow before and after the StomaphyX procedure. At this time, the outflow from the drains essentially stopped. The leak rapidly closed within a few days, and all drains were removed. The patient was released 4 days after the procedure and was instructed to remain on a liquid diet, avoid strenuous physical activities for the first 1 to 2 weeks, and advance progressively to a regular diet and normal lifestyle activities over the following 5 to 6 weeks. An endoscopy examination at 6 months revealed the absence of a leak or fistula.

Case 2

A 42-year-old man desired a revision for weight regain after an RYGB performed in 1997. Five years after the original RYGB, a perforated stomach ulcer was diagnosed and treated at another institution by closing the ulcer and reconfiguring the small bowel. Ten years after the original RYGB, the patient underwent additional revisional surgery. A vertical sleeve and duodenal switch was performed. A leak of about 1 cm in diameter developed immediately along the staple line of the vertical sleeve within 5 cm from the gastroesophageal junction (Fig. 4) and was accompanied by symptomatology typical for a leak. The leak did not close despite NPO and conservative therapy with maximal nutritional support by tube feeds. The nutritional support provided an adequate caloric intake and a positive nitrogen balance, which was confirmed by a pre-albumin level greater than 14. The patient remained stable, but there was no improvement in the leak after 6 weeks despite the drains being slowly backed out.

The patient underwent the NOS StomaphyX procedure under general anesthesia following the protocol used for patient 1. The procedure lasted 30 min and resulted in the creation of six plications and a tissue shield over the leak. A computer tomography scan performed the next day confirmed that the leak had been completely eliminated (Fig. 5). No perioperative complications or postoperative symptoms were reported. The patient was released 4 days after the procedure and followed the same dietary and

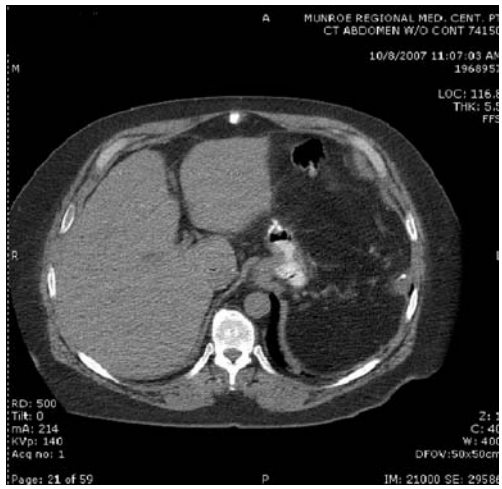

Fig. 5 Computer tomography scan on the day after the StomaphyX procedure showing no evidence of leak in patient 2

physical activity regimens as described for patient 1. Normal nutrition and lifestyle were resumed within 60 days. An endoscopy examination at 3 months revealed the absence of a leak or fistula.

Discussion

The two cases presented in this article demonstrated a successful repair of gastric pouch leaks using the StomaphyX device. In the first case, the StomaphyX procedure resulted in reducing the leak by 70% and promoted its healing by diverting the gastric content flow in such a way that the leak was no longer dependent to the gastrojejunostomy. In the second case, the leak was not dependent upon the gastrojejunostomy, and the StomaphyX device was used to close the leak and create a shield of tissue that allowed the leak to heal. The StomaphyX procedures were fast and safe, as they lasted only 30 min and did not result in any complications. Both patients were released in 4 days after the procedure and were able to return to their normal diet and lifestyle within 60 days.

The StomaphyX device made possible the repair of gastric leaks in two patients who were not candidates for the standard higher risk open or laparoscopic procedures. The transoral StomaphyX device proved invaluable to these patients. Transoral incisionless surgery using StomaphyX eliminates the risk of incisional infection and incisional herniation and reduces the risk of nosocomial infections. It is expected that, with future modifications, StomaphyX will allow handling of post-gastric bypass leaks, fistulas, perforated ulcers, and, possibly, other post-bariatric complications, which are expected to increase with the increasing popularity and performance of bariatric procedures.

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