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Successful use of a novel biological plug in the percutaneous treatment of a refractory gastro-cutaneous fistula following omental patch repair of perforated peptic ulcer

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ABSTRACT

Background: Gastro-cutaneous fistula following re-leak of omental patch repair of perforated peptic ulcer is a very rare but challenging surgical complication. We describe the use of a novel biological plug as a viable repair for gastro-cutaneous fistula that failed medical, endoscopic, and operative management. Additionally, we present a thorough literature review of reported cases of gastro-cutaneous fistulae following omental patching of peptic perforations to further highlight their treatment challenges. **Summary:** A 69-year-old man underwent repair of a perforated pyloric ulcer with a pedicled omental patch. After one week, patient developed a re-leak from the omental patch, and underwent a second laparotomy with repeat omental patching of the gastric perforation. Ten weeks after the second operation, the patient developed a gastro-cutaneous fistula that failed conservative management with nil per os and enteral nutrition delivered distal to the fistula site; multiple image-guided percutaneous attempts at fistula closure by interventional radiology via fibrin sealant injection and collagen-based vascular closure device; and endoscopic clipping by gastroenterology. Ultimately, this refractory gastro-cutaneous fistula was closed with a novel biological plug (Biodesign® Enterocutaneous Fistula Plug, Cook Biotech).

Conclusion: Gastro-cutaneous fistulae following omental patching of perforated peptic ulcer represent a significant complication requiring a multidisciplinary management approach. The Biodesign® Enterocutaneous Fistula Plug offers a promising new tool for the non-operative treatment of refractory gastro-cutaneous fistulae.

Keywords: perforated peptic ulcer, omental patch, gastro-cutaneous fistula, fistula plug.

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Introduction:

Iatrogenic gastro-cutaneous fistula is a challenging surgical complication usually caused by injury to the stomach following upper abdominal surgeries, leak from a gastro-duodenal or gastro-jejunal anastomosis, or following removal of long-standing gastrostomy tubes. Gastro-cutaneous fistula formation following omental patching of a peptic perforation is very rare, and only a few cases have been described in the literature ^{1,2}.

In this article, we report on a patient who underwent surgery for peptic perforation repair with an omental flap, and subsequently developed a gastro-cutaneous fistula that failed medical, endoscopic, and operative management and resolved after percutaneous

placement of a novel fistula plug. The reported treatment options of post-operative gastro-cutaneous fistulae are also presented.

Case Description

A 68-year-old man with multiple comorbidities was admitted at another institution with perforated peptic pyloric ulcer for which he underwent an exploratory laparotomy with repair of the gastric perforation using a pedicled omental patch. One week post-operatively, patient developed sepsis and was found to have a persistent leak from the repair site of the gastric perforation. He underwent a second laparotomy with washout of the abdomen and repeat omental patching of the gastric perforation.

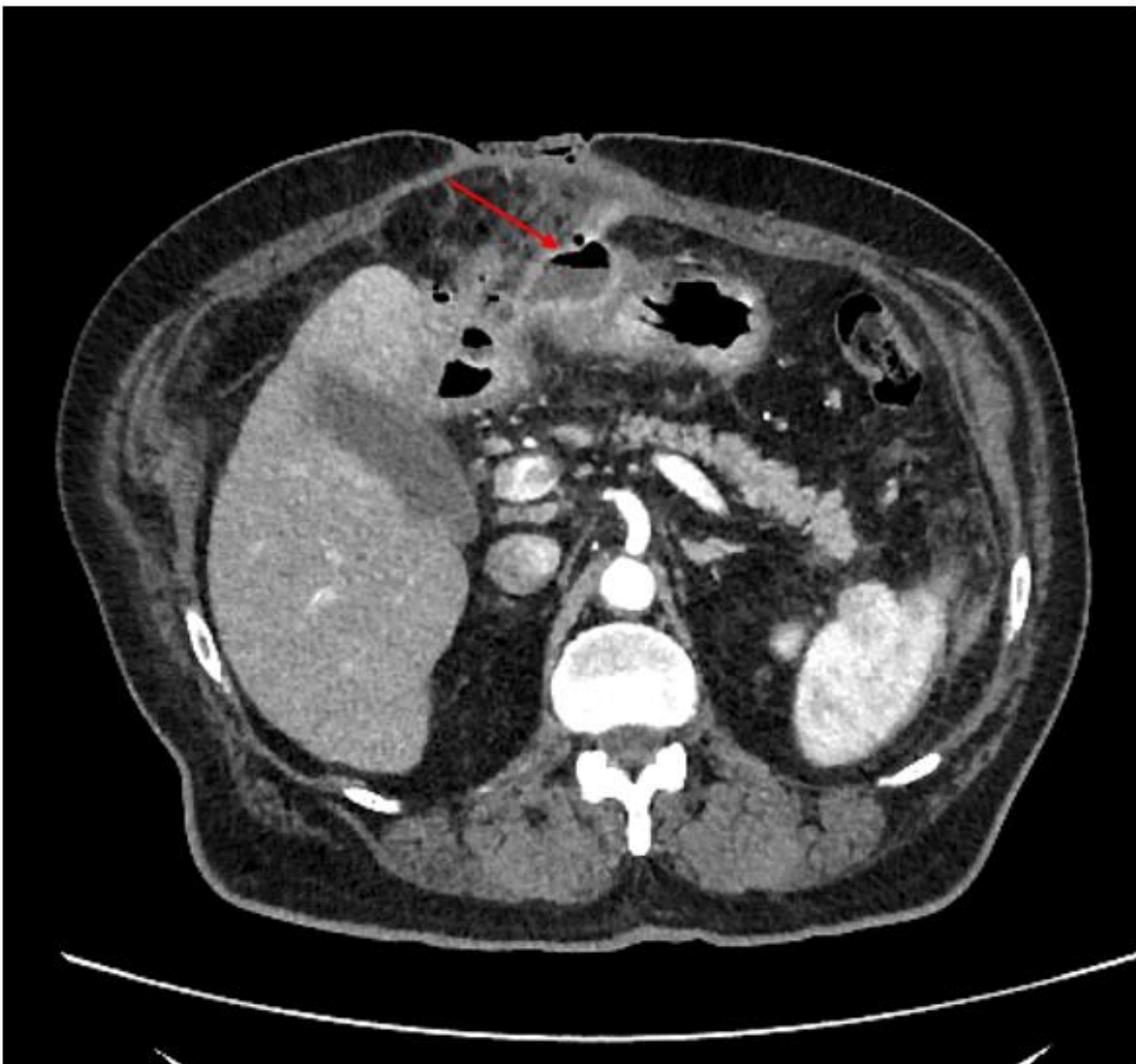


Figure 1. Axial CT scan showing a peri-gastric abscess contiguous with the superficial wound, suggesting a gastro-cutaneous fistula (arrow).

Ten weeks after the surgery, the patient presented to our institution with fever, leukocytosis, and gastric fluid emanating from a small wound in the epigastrium, consistent with a gastro-cutaneous fistula. CT imaging confirmed the diagnosis and revealed a peri-gastric abscess contiguous with the superficial wound, consistent with a gastro-cutaneous fistula (Figure 1). Subsequently, the patient was started on broad-spectrum antibiotics, and underwent image-guided, percutaneous drainage of the intra-abdominal abscess. The daily fistula output was trended and peaked as high as 250 ml of drainage per day. Oral feeding was withheld, and enteral nutrition was initiated via a percutaneously-placed feeding tube positioned distal to the fistula site. A wound collection pouch was placed around the fistula site to effectively collect the gastric effluent and to prevent irritation of the surrounding skin. An upper endoscopy could not identify a clear fistula

opening. Biopsies collected adjacent to the repaired perforation site were consistent for chronic gastritis without malignant changes.

After 12 weeks of conservative medical management, the patient's gastro-cutaneous fistula persisted with unchanged daily output. The patient underwent two failed image-guided, percutaneous attempts at fistula closure by the interventional radiology team using an injection of fibrin sealant in the fistula tract as well as the use of a collagen-based vascular closure device (Angio-Seal™). After failed management by interventional radiology, a 12 F catheter was percutaneously placed through the fistula tract, terminating in the stomach, in an attempt to create a controlled fistula eventually amenable to resolution through tract maturation. However, after 8 weeks of percutaneous tube management the fistula output persisted.

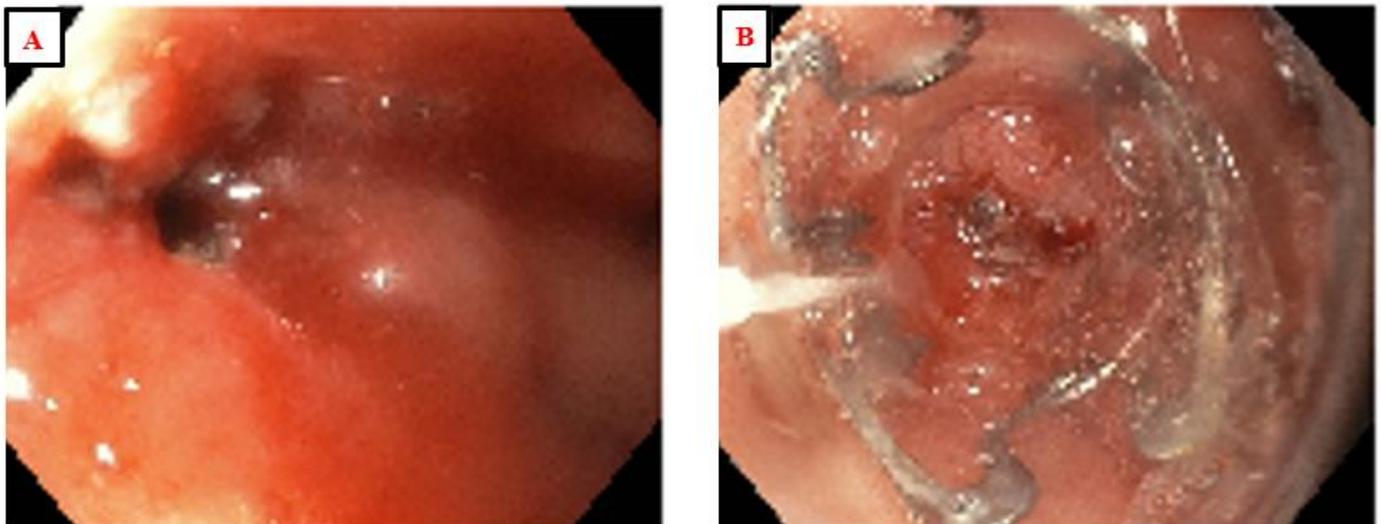


Figure 2. A) Fistula site in the pre-pyloric region. B) Clip over the fistula site.

Given the failure of the percutaneous interventions, the case was ultimately reviewed by gastroenterology who planned for endoscopic closure of the gastro-cutaneous fistula. The percutaneously-placed intra-luminal drain facilitated identification of the fistula site during endoscopy. A 2-3 mm fistula site was visualized in the pre-pyloric region (Figure 2A). Wire

brushing of the fistula site was followed by argon-plasma coagulation to denude the lining of the fistulous tract. An 11 mm Over-The-Scope Clip (OTSC®, Ovesco Endoscopy GmbH, Tübingen, Germany) was applied over the fistula site (Figure 2B), thereby mechanically closing the fistula.

While endoscopic management was initially successful with no fistula output for approximately 2 weeks, the gastro-cutaneous fistula eventually re-opened.

Given the importance of avoiding a third high-risk surgery in a patient with multiple comorbidities, a multidisciplinary decision was made to consider the percutaneous placement of a novel enterocutaneous fistula plug, the Biodesign® Enterocutaneous Fistula Plug (Cook Biotech) (Figure 3). The Biodesign plug is a non-cross-linked, non-dermis-based biologic graft that remodels into strong, well-vascularized tissue, and has been used successfully to close entero-cutaneous fistulae.

Under fluoroscopy guidance, a guidewire was placed in the fistula tract followed by brushing of the tract. After serial dilations of the fistula tract, a 16 F sheath was inserted, and its intra-gastric position was confirmed. The plug was then introduced with the pusher and its flange was deployed into the stomach and pulled back to occlude the internal fistula opening. After the excess plug was trimmed at the level of the skin, it was secured at the skin with a Molnar disc.

Fistula drainage stopped immediately, and the patient was discharged 5 days later with oral nutrition. At a three-month outpatient follow-up visit patient had no evidence of fistula recurrence.

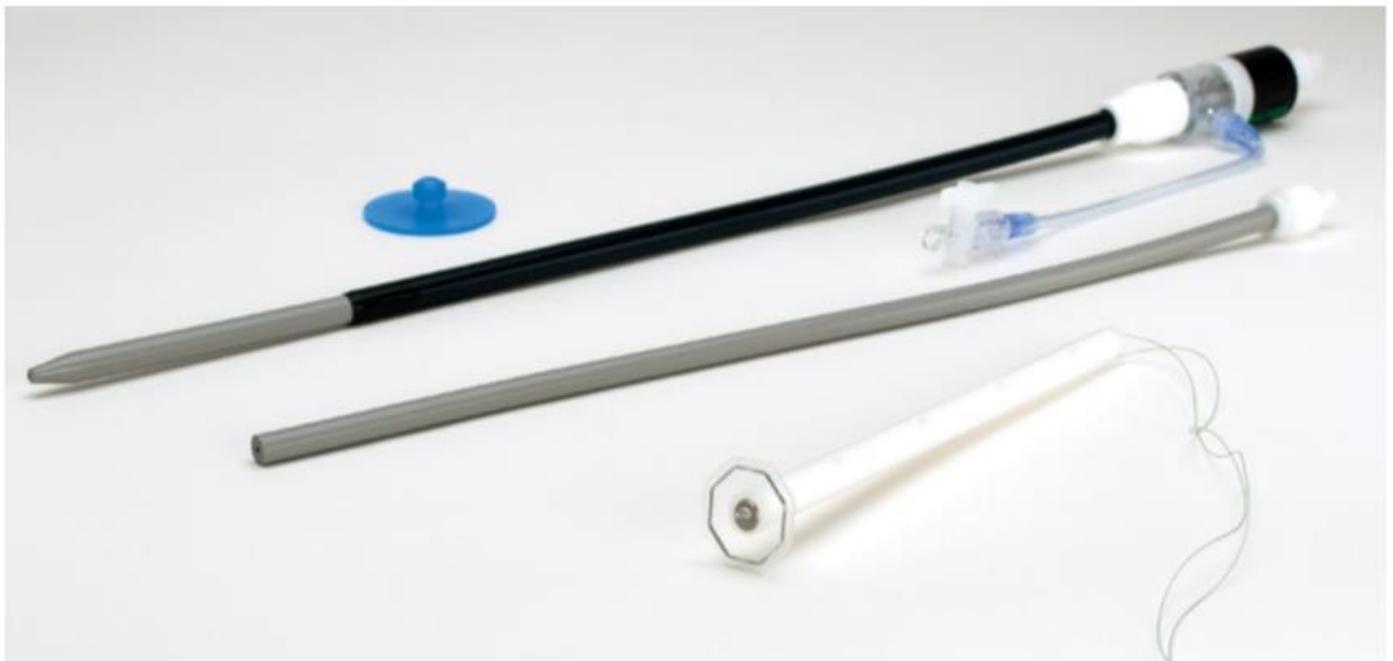


Figure 3. Biodesign® plug kit (Cook Biotech) containing (from top to bottom) the Molnar disk, the delivery sheath with the dilator, the pusher, and the plug.

Discussion

Persistent leak following omental patch repair of perforated peptic ulcer is a challenging surgical complication, with an incidence ranging from 4-16%^{3, 4-6}. There is evidence suggesting that leakage after omental patch results in prolonged hospital stay, increased morbidity, and considerable mortality (29-56%)^{3,5}.

Various factors that contribute to re-leak after omental patching of perforated peptic ulcers

include age over 65, presence of pre-operative septic shock, hypoalbuminemia (less than 2.5 grams/dl), or anemia (hemoglobin level less than 10 g/dl); more than 12 hrs delay of surgery; size of perforation more than 1-3 cm; and intra-operative technical errors such as performing a primary closure of an indurated perforation prior to placing the omental patch and tight suturing of the omentum (leading to necrosis and partial or complete separation of the omental patch)^{3,5,7}.

Traditionally, re-operation has been considered necessary in all cases of re-leak following omental patching of perforated peptic ulcer^{6,7}. The nature of the surgical intervention is based on the intra-operative findings and the clinical stability of the patient. Reported surgical interventions performed include jejunal serosal patch^{3,8}; gallbladder patch⁸; T-tube placement through the perforation⁸; reinsertion of omental patch³; wedge resections⁵; distal gastrectomy⁵; and drain placement adjacent to the perforation to create a controlled fistula in unstable patients⁶. Gastro-cutaneous formation is an extremely rare late complication of re-leak after omental patching of perforated peptic ulcer, and consequently there is no data to support a consensus on the optimal treatment modality.

Mithilesh et al.¹, reported a case of gastro-cutaneous fistula 6 months after a 30-year-old patient underwent omental patching of the gastric perforation. After failing non-interventional management, a repeat omental patch repair was performed to successfully close the fistula. Kouklakis et al.², published a case report of a gastro-cutaneous fistula following omental patching of perforation located in the greater curvature of the stomach in a 44-year-old patient. After failing 6 weeks of medical therapy (with external drainage, gastric decompression with nasogastric tube, parenteral nutrition, and antisecretory drugs), the fistula was closed with over-the-scope endoscopic clip placement.

As outlined above, our patient failed multiple therapies shown to be successful in the management of gastro-cutaneous (and other) fistulae, such as expectant therapy (with post-pyloric enteral feeding)⁹, external drainage with tubes placed both adjacent to the perforation and through it^{6,8}, injection of fibrin sealant in the fistula tract¹⁰, use of vascular closure devices¹¹, and over-the-scope endoscopic clip placement². Ultimately, we were able to close this refractory gastro-cutaneous fistula by using the Biodesign, a novel biologic plug, that has been previously

used successfully to close fistulas originating in the small bowel¹² and the duodenum¹³.

To the best of our knowledge, this report describes the first experience with the use of the Biodesign enterocutaneous fistula plug in the management of a refractory gastro-cutaneous fistula following omental patching of perforated peptic ulcer. Based on our experience with the present case, as well as review of previously reported cases of gastro-cutaneous fistulae after omental patching of peptic perforations, we propose a multidisciplinary algorithm in their management in order to optimize outcomes. We propose that clinically stable patients should first undergo a trial of non-operative management consisting of nutritional support via a feeding tube positioned distal to the fistula site, attempts at over-the-scope endoscopic closure of the perforation, and image-guided placement of entero-cutaneous fistula plugs. Surgery should be reserved only for cases of failed non-operative management.

Conclusion

Gastro-cutaneous fistulae following omental patching of perforated peptic ulcer represent a significant challenge. A multidisciplinary approach is very important in their management, with surgery being reserved for failed non-operative treatment. The Biodesign enterocutaneous fistula plug offers a promising new approach for the non-operative treatment of refractory gastro-cutaneous fistulae.

Disclosure Statement: The authors have no conflicts of interest or financial disclosures to declare.

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