Published in final edited form as:

Surg Endosc. 2013 June ; 27(6): 2201–2208. doi:10.1007/s00464-012-2740-3.

Feasibility of NOTES Omental Plug Repair of Perforated Peptic Ulcers – Results from a Clinical Pilot Trial

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Abstract

Background—Ulcer perforation carries up to a 30% 1-year mortality rate. Intervention-related adverse events are among statistically significant predictors of 1-year mortality. A Natural Orifice Transluminal Endoscopic Surgical (NOTES) approach may be less invasive and may decrease procedure-related adverse events by diminishing the "second hit", thus leading to decreased morbidity and mortality.

Aim—To assess the feasibility of an endoscopic transluminal omental plug technique in patients with perforated gastroduodenal ulcers under laparoscopic guidance.

Methods—Patients with suspected acute gastroduodenal ulcer perforations were offered participation in this prospective pilot study. Closure of the perforation was attempted using NOTES omental plug technique. Demographic, clinical, endoscopic and radiographic data were abstracted, as well as morbidity, mortality and pilot data regarding quality of life (QOL).

Results—From February 2010 through Feb 2012, 17 patients presented to a tertiary care center with clinically suspected perforated ulcer. Of seven patients (mean age 79, range 64–89) who consented to the study, three underwent the study procedure. All patients had multiple comorbidities. Two patients presented with 4–6 mm perforated peptic ulcers and underwent successful laparoscopic-assisted NOTES omental and falciform ligament patch closure, respectively. Postoperative radiographic contrast studies showed no leak and patients were discharged home on postoperative days 3 and 4. The third patient had undergone enterocutaneous fistula repair with herniorrhaphy 6 weeks prior; a transluminal endoscopic approach was feasible; however, the omentum was under too much tension to be secured. This procedure was converted

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Study performed at: Mayo Clinic-Rochester, MN

Video Presented at: The American College of Surgeons (ACS), 97th Annual Clinical Congress, October 23–27, 2011, San Francisco, CA.

Disclosures

Juliane Bingener - no conflicts of interest or financial ties to disclose

Erica Loomis - no conflicts of interest or financial ties to disclose

Christopher Gostout - no conflicts of interest or financial ties to disclose

Martin Zielinski - no conflicts of interest or financial ties to disclose

Navtej Buttar - no conflicts of interest or financial ties to disclose

Louis Wong Kee Song - no conflicts of interest or financial ties to disclose

Todd Baron - no conflicts of interest or financial ties to disclose

Leili Shahgholi Ghahfarokhi - no conflicts of interest or financial ties to disclose

Elizabeth Rajan - no conflicts of interest or financial ties to disclose

to an open omental patch repair. For all but one consented patient, obtaining QOL data was feasible.

Conclusion—Initial results from a laparoscopic-assisted NOTES approach for closure of perforated peptic ulcers appear promising and enable swift recovery in selected patients. This is especially important in the elderly and/or immunocompromised patients. Technical details and patient selection criteria continue to evolve.

Keywords

NOTES; perforated ulcer; omental patch; laparoscopy; endoscopy; transluminal surgery

Introduction

Seventy percent of deaths associated with peptic ulcer disease are attributed to perforation. [1] In-hospital mortality rates range between 5% and 24%. [2, 3] One year mortality is up to 30 %. [4, 5] A recent study reported three parameters to be predictors of death after hospital stay: concomitant diseases ($p = 0.001$), post-interventional adverse events ($p = 0.002$), and age ($p = 0.049$). [4]

Age and comorbidities are not factors that can be altered. If the impact of post-interventional adverse events or "second hit" could be reduced, improvement in morbidity and mortality may be achieved.

Currently, an open operative approach is most frequently employed for treatment of perforated ulcers, [5] often using the repair described by Graham about 60 years ago. A well-vascularized omental pedicle is brought to the site of perforation and the hole is sealed with the omentum being tacked into place. [6, 7]

Laparoscopic omental patch repair for perforated ulcers has been shown to be a feasible and safe procedure in selected patients. [8–10] Laparoscopic repair offers advantages of a minimally invasive approach (smaller incisions requiring less postoperative opioid analgesics, fewer wound complications, and lower cardiopulmonary morbidity); however, laparoscopic repair requires technically advanced intracorporeal suturing skills which limits its availability in the general surgical population. [10, 11] In addition, some patients may not tolerate operative pneumoperitoneum in the acute setting.

A NOTES approach may reduce the physiologic impact of therapeutic intervention following peptic ulcer perforation and provide a technically less challenging procedure. Experimental data suggest that the NOTES repair may be possible with lower intra-abdominal pressures. [12]

Pre-clinical trials of endoscopic omental patch closures for upper gastrointestinal viscus perforations have been published. [13] Previous work from our group also demonstrated the technical feasibility of omental gastrotomy closure, including a randomized trial in a porcine model with excellent wound healing at 14 days. [12]

A retrospective review suggested that up to 50% of patients presenting with perforated ulcer might be candidates for a NOTES repair. [5]

Herein, we present a pilot clinical study evaluating the feasibility of endoscopic transluminal omental patch closure for perforated peptic ulcers, with the hypothesis that the technique will be successful at closing ulcer perforations as evidenced by intra-operative leak test and postoperative water-soluble contrast studies.

Methods

Overview

Patients with a clinical diagnosis of perforated viscus who were scheduled to undergo surgical exploration were recruited into this clinical pilot study (NCT 010803261) in collaboration with the Acute Care Surgery team (Figure 1). The NOTES on-call team attempted endoscopic transluminal omental patch closure if there were no contraindications. To ensure patient safety the procedure was performed in the operating room under general anesthesia with laparoscopic guidance. This setting allowed the surgical team to proceed with conversion to laparoscopic or open surgical therapy without delay if necessary. An administrative database review suggested that five patients/year might be candidates for the study.

The primary outcome was successful completion of the endoscopic procedure. Success and safety were determined by the endpoints described in Table 1. Inclusion and exclusion criteria are listed in Table 2.

To assess whether quality of life (QOL) assessments are feasible during an urgent/emergent perforation event, overall (SF 12), gastrointestinal (GIQLI) and surgically focused (ASIS) QOL instruments were administered before and after surgery.[14–16]

Patient Recruitment

Patients with the clinical working diagnosis of perforated duodenal or gastric viscus who were evaluated by an Acute Care Surgeon and deemed a surgical candidate for repair were approached for study recruitment. Consent for study participation was obtained after it was concluded that surgery was indicated and the patient was scheduled for an operation.

Personnel

A group of six interventional endoscopists (one surgeon, 5 gastroenterologists) underwent training in the NOTES ulcer procedure in the laboratory setting. A NOTES call team was established, consisting of an endoscopist and an endoscopy technician. This team was notified by the Acute Care Surgery team if the patient was a candidate for the study.

Preoperative Care

Fluid resuscitation, antibiotic therapy, and timing of the surgical intervention proceeded as per the treating physicians which was separate from the study team. After patient enrollment, American Society of Anesthesiologists (ASA) and Boey scores were determined. [17]

Procedure

Following induction of general anesthesia, pneumoperitoneum (12 – 14 cm H₂O) was established using a periumbilical trocar in Hasson technique. This served to confirm the diagnosis of ulcer perforation and for surveillance of the endoscopic procedure in this FDA-approved feasibility study.

If no findings necessitating other treatments were encountered, a standard 9.2 mm diameter single channel diagnostic upper endoscope (GIF-180; Olympus America, Center Valley, PA) with CO₂ insufflation was introduced through the oropharynx into the stomach and duodenum. The site of perforation was identified and measured using the width of an open biopsy forceps. The endoscope was carefully advanced through the perforation when

possible. A guidewire (Hydra Jagwire® Guidewire 0.035, Boston Scientific, Natick, MA) was available as needed to facilitate passage of the endoscope.

Once in the peritoneal cavity the endoscopist proceeded with inspection and irrigation. A viable mobile piece of omentum was identified, grasped using an endoclip (Resolution®, Boston Scientific, Natick, MA) and pulled intraluminally through the site of perforation. The omentum was then fixed to the mucosa of the luminal wall using several endoscopic clips. The falciform ligament was used if a suitable omental patch was not available. Following repair, the stomach or duodenum were insufflated to test for air leak. If the repair was sufficient, all operative equipment was removed. If the NOTES procedure was unsuccessful, either a laparoscopic or open omental patch repair was considered by the Acute Care Surgery team.

Postoperative Care

The patients' postoperative treatment and length of hospital stay were determined by the Acute Care Surgery team (not the study team). Subjects underwent water-soluble radiographic contrast studies on postoperative day two to document any subclinical leaks for research purposes.

Data Collection and Monitoring

Patient demographics, history of ulcer disease, use of ulcerogenic medications, and Boey and American Society of Anesthesiologists (ASA) scores were recorded. Procedural duration, conversions, and adverse events, as well as postoperative length of stay and results of radiographic contrast studies, were documented. The QOL questionnaires were administered by the study team while the patient was in the hospital; for follow-up, the questionnaires were mailed and the patients were called with reminders.

Study data were collected and managed using REDCap (Research Electronic Data Capture), a secure, web-based application designed to support data capture for research studies electronic data capture tools hosted at Mayo Clinic. [18]

A data safety monitoring board (DSMB) consisting of two surgeons and two gastroenterologists reviewed the data after consenting of the first three patients and at study conclusion.

Results

Between February 2010 and February 2012, 17 patients presented with perforated ulcer disease. (Figure 2) Of those, six patients were excluded for medical reasons including cirrhosis with coagulopathy, prior omentectomy, and hemodynamic instability. One patient was excluded because of inability to obtain written research consent from a family member, and three patients because of Acute Care Surgeon preference or study logistics (lack of on-call coverage). With the exception of the patient for whom research consent could not be obtained, these patients underwent open operative procedures.

Seven patients were consented for the study and proceeded to the operating room. En route to the operating room, one patient deteriorated hemodynamically and was approached with an open procedure. After initial access to the abdomen for trocar placement, one patient was found to have significant adhesive disease and laparoscopic access could not be obtained. Another patient exhibited gross contamination on laparoscopic access and was converted to an open procedure per emergency surgeon preference. An additional patient suffered from a giant ulcer perforation into the pancreas as found during endoscopy (6 cm diameter) and

underwent open antrectomy. The mean age of all patients consented for the study was 79 years (range 64–89), and the mean ASA score was 3.25 (range 3–4). The mean Boey score was 1.5 (range 1–2).

NOTES Cases

Case 1

An 80-year-old female on corticosteroids for Wegener's granulomatosis was found to have kissing ulcers at endoscopy, with a 4 mm anterior duodenal perforation. The perforation was too small to admit the entire endoscope. CO₂ insufflation from within the duodenum produced gas bubbles, thus the site could be easily appreciated from the laparoscopic view. Assistance from the laparoscopic approach with a small flexible catheter tip allowed the endoscopic clip applier to be advanced through the perforation. The Acute Care Surgeon found the falciform ligament to be better suitable for a patch and this was dissected, grasped with the clip applier and pulled into the duodenal lumen. It was clipped into place and an airtight seal was confirmed (Figure 3, Figure 4) The patient recovered uneventfully and underwent a water-soluble contrast study on postoperative day 2 which did not demonstrate any leak (Figure 5). She was discharged home on postoperative day 3. A repeat endoscopy was performed one month later which revealed complete healing of the perforated site and significant improvement of the posterior wall ulceration.

Case 2

A 64-year-old male presented with an NSAID (non-steroidal anti-inflammatory drug)-induced 4 mm gastric perforation in the anterior fundus after recent orthopedic surgery. Biopsies were obtained and the clip applier again brought through the perforation. A laparoscopic forceps advanced the omentum to the clip where it was grasped, pulled into the gastric lumen and clipped in place. An air tight seal was demonstrated. The patient recovered uneventfully. A water-soluble radiographic contrast study on postoperative day 2 is depicted in Figure 6. He was discharged home on postoperative day 4.

Case 3

An 81-year-old patient underwent enterocutaneous fistula repair with abdominal wall reconstruction 6 weeks prior. She developed an NSAID-related 1.2 cm anterior duodenal perforation, confirmed endoscopically. Repeat laparotomy was deemed difficult and NOTES repair was considered. The endoscope easily passed through the perforation site and into the peritoneal cavity where abundant adhesions and fibrinous exudate were seen, as a result of the prior (Figure 7 and Figure 8). Adhesion of the omentum to the mesh and surrounding structures was identified. After irrigation, a free omental pedicle was pulled successfully into the duodenum; however, it was under too much tension to be secured by the clip through the single channel endoscope. Securing involved opening the clip again after the omentum was pulled into the duodenum, at which time the omentum repeatedly slipped back into the abdomen. A mechanism to retract the omentum and secure it simultaneously was not available at the time. Laparoscopic closure was not feasible (limited suturing availability) and the procedure was converted to an open omental patch repair. As the NOTES procedure was not successful, she did not undergo a contrast study for research purposes. The patient was discharged to a nursing home on postoperative day 27.

Procedure Time

For the two patients who underwent successful laparoscopic assisted transluminal omental patch closure, the total procedure time was 91 minutes and 101 minutes, respectively, of which 64 minutes and 67 minutes were endoscopic procedure times. In comparison, the procedures, which were unsuccessful or primarily open (n=5), resulted in a total mean

procedure time of 199 minutes (range 153–244 minutes). For all procedures blood loss was minimal, with mean of 22 mL (range 5–50 mL).

Morbidity and Mortality

One patient who consented for the study and had a giant 6 cm perforation for which antrectomy was performed died in-hospital on post-operative day 20. The patient who underwent enterocutaneous fistula takedown 6 weeks prior to ulcer perforation was found to have a transverse colotomy when the surgical team converted to an open procedure with colostomy. It is unclear whether this was a complication due to endoscopic or laparoscopic manipulation; it is most certainly due to an iatrogenic injury.

QOL Data

The tools used were VAS pain scale, ASIS, GIQLI and SF 12. Of the seven enrolled patients, six completed preoperative VAS and ASIS questionnaires (including with assistance of family members); SF 12 and GIQLI tools were partially completed in five patients. In one patient there was insufficient time to fill out questionnaires before proceeding to the operating room.

In follow-up two patients returned questionnaires by mail for up to 3 months, no data were available at 6 months or 1-year follow up. Patients who did not undergo the NOTES procedure were not approached for follow-up QOL data. The average VAS pain scale for 4 patients before surgery was 7.25 (5–10). The two patients who successfully underwent transluminal omental patch noted VAS scores of 1 (0–2) in the post surgery days until postop day 4. The two patients with follow-up showed improvement in GIQLI in one month and 3 months time points from an average 108 to 132. The mean ASIS before surgery was 69.5, which improved to 126 at 1 week after surgery. Two patients completed SF-12 before surgery; their total scores were 18 and 33. The SF 12 total score was 40 and 43 at the 3 months time point for two patients, one of them with the preoperative score of 33, one of them without preoperative assessment. No follow-up scores were available for the patient with low preoperative score.

Discussion

The benefit of minimally invasive approaches to intra-abdominal pathology is now widely accepted, especially in patients with co-morbid conditions. Patients with perforated ulcer disease often cannot benefit from a laparoscopic approach, if the technical expertise of the acute care surgeon does not include advanced laparoscopic suturing.[5] Many acute care surgeons are quite familiar with endoscopic feeding tube placement and basic laparoscopic procedures and thus may be able to incorporate a NOTES or hybrid NOTES approach.

A NOTES approach to repair perforated peptic ulcers may reduce the physiologic impact of the therapeutic intervention following peptic ulcer perforation. Endoscopy has been used as an adjunct to laparoscopic omentoplasty in perforated ulcers in the past, especially in patients in whom laparoscopic repair for perforated peptic ulcers (PPU) was difficult due to gastric outlet obstruction or large perforations.[19–21] An endoscopic approach would also facilitate cancer diagnosis and allow for gastric outlet/duodenal lumen observation before and after patch placement. In addition, over time it may be possible to perform the procedure without general anesthesia, similar to drainage of pancreatic pseudocysts or for replacement of dislodged percutaneous endoscopic gastrostomy (PEG) feeding tubes as described by Marks et al.[22] The standard upper endoscope was guided through the gastrotomy created initially for the PEG. Peritoneal soilage was assessed and feeding tube replaced utilizing

both the initial gastrotomy and abdominal wall incision under moderate sedation thereby avoiding a surgical procedure under general anesthesia.

The initial findings from our study are promising. NOTES repair under laparoscopic guidance appears feasible in select patients. Copious peritoneal irrigation through the endoscope was possible using a pressure bag as supported by our laboratory data.[12] In the clinical environment, the flexible endoscope was able to reach some areas that the rigid laparoscope had difficulty accessing. Most of the contamination encountered was fibrinous and exudative. A plan was in place to treat large particles with an endoscopic retrieval net. This however was not necessary in our cases. NOTES omental patch closure required a mean total procedure time of 96 minutes, of which 66 minutes (range 64–67 minutes) were endoscopic procedure time. This is similar or shorter than open repairs. [5] Lam et al reported on 35 patients (mean age 47 years) undergoing laparoscopic Graham patch repair for perforated ulcers with a median operative time of 86 min (range, 55–163 min). and the median length of stay of 4 days. [10] Patients who underwent successful NOTES-assisted repair displayed a rapid recovery with hospital dismissal earlier than patients who required conversion to an open procedure, although all patients were of advanced age and had severe comorbidities. It is possible that the hybrid NOTES approach indeed avoided the “second hit” in a setting where laparoscopic suturing was not available. Avoiding the “second hit” is especially important in elderly and immunocompromised patients who may frequently suffer from a long recovery.

A long and difficult recovery may be expressed in QOL data. Obtaining preoperative QOL data in this elderly patient population in the emergent situation was surprisingly feasible. The postoperative QOL follow-up to three months was also feasible; thereafter, we were not successful in data collection. The changes in GIQLI and ASIS are similar to clinically important differences reported for elective surgical procedures. We report the data points we have obtained as pilot data, although no definite conclusions can be drawn.

Given the small overall number of patients in this study, overall generalization is not appropriate. Thirteen of the 17 patients were not candidates for any minimally invasive procedures in this setting, some of which due to surgeon preference for open procedures. It should be noted that the patient population at our institution is older and has more comorbidities than previously reported elsewhere. [5] Patient eligibility at our institution may therefore be more limited. While a retrospective review estimated a larger number of sizable ulcerations, by chance, the ulcers in two of our three patients were small and the more direct NOTES approach could not be studied. Smaller diameter imaging platforms as they are already in use for cholangioscopy, may in the future be useful for small perforated ulcers. Even if currently laparoscopic assistance may be needed, this approach can still provide a minimally invasive procedure for the patient.

During the case debriefings, the study team felt that an integrated grasping and clipping device without the need to re-open the grasping clip, would have been advantageous and would have facilitated omental closure in case 3. In retrospect, this patient with a very recent laparotomy and extensive intra-abdominal procedure is likely not a good candidate for initial NOTES approaches, although this is certainly a patient in which the surgeon would like to avoid a second laparotomy.

The conduct of this study entailed significant logistic barriers to evaluate more patients for this approach. The FDA guided research environment is not easily applicable in an emergency setting and contributed to the limited patient population (research consent, availability of study team members). The need for separate teams and call schedules, with the principal investigator not part of the acute care team, was not advantageous. Adoption of

this approach by acute care teams would increase the feasibility. Many of these teams perform percutaneous endoscopic gastrostomy (PEG) tube placement, which is similar to the endoscopic skills utilized here for the NOTES and hybrid NOTES approach. Our NOTES team is involved in future training courses for the technique to make it available to the community. Both approaches may bring patient benefit in an area where progress on morbidity and mortality has been stagnant. Even if only a small number of patients benefit initially, this technique may open a novel approach to a disease from which one of eight patients dies within 30 days and one in three patients does not live to one year postoperatively.

Many challenges remain for the NOTES approach; technical aspects and patient selection criteria continue to evolve. Laparoscopic guided or independent NOTES procedures may contribute to the future management of perforated ulcers.

Acknowledgments

This research was supported by a NOSCAR grant, and CTSA support (ULIR024150) IDE # G090219, CDRH; (NCT 010803261)

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Figure 1.

Overview of enrollment scheme for patients presenting to the Emergency Department with possible perforated viscus

Figure 2.
Flow of patient study participation

Figure 3.
Falciform ligament being clipped into place inside the duodenum

Figure 4.
Falciform ligament clipped into place, final intraluminal view

Figure 5.
Postoperative image taken from water-soluble radiographic contrast study (case #1)

Figure 6.
Image from postoperative water soluble radiographic study (case #2)

Figure 7.
Laparoscopic view of the endoscope exiting the ulcer perforation

Figure 8.
Endoscopic view of the peritoneal cavity with fibrinous exudate

Table 1

Study Endpoints

Feasibility	
1.	Completion of transluminal endoscopic omental patch repair of a perforated gastric or duodenal ulcer
2.	At the time of surgery, the repair was pressure tested using endoscopic insufflation
3.	Two days postoperatively, patients underwent water-soluble contrast radiologic studies to evaluate for subclinical leak
Safety	
1.	Procedural adverse events recorded during endoscopic transluminal omental patch repair
2.	Complications resulting from endoscopic transluminal omental patch recorded at the time of surgery

Table 2**Inclusion and Exclusion Criteria**

Inclusion Criteria	
1.	Patients presenting with clinical diagnosis of a perforated viscus who are scheduled to undergo surgical intervention
2.	Surgical candidate for endoscopic, laparoscopic, or open procedure
3.	Age ≥ 21
4.	Informed written consent
Exclusion Criteria	
1.	Prior gastric or duodenal surgery
2.	Prior total abdominal colectomy or transverse colectomy
3.	Prior omentectomy or omental flaps
4.	Known perforation site other than stomach or duodenum
5.	Patients with contraindications for laparoscopy
6.	Patients with contraindications for endoscopy
7.	Upper gastrointestinal anatomy that would preclude endoscopic therapy
8.	Coagulopathy or thrombocytopenia
9.	Pregnancy
10.	Age < 21 years
11.	Prisoners