Surg Endosc (2008) 22:1609–1613
DOI 10.1007/s00464-008-9750-1

Reliable gastric closure after natural orifice translumenal endoscopic surgery (NOTES) using a novel automated flexible stapling device

O. R. Meireles · S. V. Kantsevoy · L. R. Assumpcao · P. Magno · X. Dray · S. A. Giday · A. N. Kalloo · E. J. Hanly · M. R. Marohn

Received: 20 April 2007 / Accepted: 28 November 2007 / Published online: 10 April 2008

Abstract

Background Reliable closure of the translumenal incision is one of the main challenges facing natural orifice translumenal endoscopic surgery (NOTES). This study aimed to evaluate the use of an automated flexible stapling device (SurgASSIST) for closure of the gastrotomy incision in a porcine model.

Methods A double-channel gastroscope was advanced into the stomach. A gastric wall incision was made, and the endoscope was advanced into the peritoneal cavity. After peritoneoscopy, the endoscope was withdrawn into the stomach. The SurgASSIST stapler was advanced orally into the stomach. The gastrotomy edges were positioned between the opened stapler arms using two endoscopic grasping forceps. Stapler loads with and without a cutting blade were used for gastric closure. After firing of the stapler to close the gastric wall incision, x-ray with contrast was performed to assess for gastric leakage. At the end of the procedure, the animals were killed for a study of closure adequacy.

Results Four acute animal experiments were performed. The delivery and positioning of the stapler were achieved, with technical difficulties mostly due to a short working length (60 cm) of the device. Firing of the staple delivered four rows of staples. Postmortem examination of pig 1 (when a cutting blade was used) demonstrated full-thickness closure of the gastric wall incision, but the cutting blade caused a transmural hole right at the end of the staple line. For this reason, we stopped using stapler loads with a cutting blade. In the three remaining animals (pigs 2–4), we were able to achieve a full-thickness closure of the gastric wall incision without any complications.

Conclusions The flexible stapling device may provide a simple and reliable technique for lumenal closure after NOTES procedures. Further survival studies are currently under way to evaluate the long-term efficacy of gastric closure with the stapler after intraperitoneal interventions.

Keywords Flexible endoscopy · Gastric closure · NOTES · Transgastric · Translumenal procedures

Presented in part at the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Annual Meeting, Las Vegas, Nevada, April 2007.

O. R. Meireles · L. R. Assumpcao · E. J. Hanly · M. R. Marohn (✉)
Department of Surgery, Johns Hopkins University School of Medicine, 600 N. Wolfe Street, Halsted 608, Baltimore, MD 21287, USA
e-mail: mmarohn1@jhmi.edu

S. V. Kantsevoy · P. Magno · X. Dray · S. A. Giday · A. N. Kalloo
Division of Gastroenterology, Johns Hopkins University School of Medicine, 600 N. Wolfe Street, Halsted 608, Baltimore, MD 21287, USA

S. V. Kantsevoy
e-mail: svkan@jhmi.edu

Natural orifice translumenal endoscopic surgery (NOTES) embodies the traits of promising and disruptive technology with growing interest around the globe [1]. The NOTES procedure has the potential to eliminate abdominal wall incisions and to decrease postoperative pain. The peritoneal access-site closure continues to be one of the main challenges facing NOTES [2].

This study aimed to evaluate the use of an automated flexible stapling device (SurgASSIST; Power Medical Interventions, Langhorne, PA, USA) for closure of the gastrotomy incision in a porcine model.

Methods

This study was approved by the Johns Hopkins University School of Medicine Animal Care Institutional Review Board. We performed four acute experiments using 50-kg pigs (*Sus scrofus domesticus*). All procedures were performed with the animals under 1.5% to 2% isoflurane general anesthesia using 7-mm endotracheal intubation (Mallinckrodt Co, C. D. Juarez, Chih, Mexico). The preanesthesia medications were composed of an intramuscular injection of Telazol 100 mg/ml (tiletamine HCl C zolazepam HCl; Lederle Parenterals, Inc, Carolina, Puerto Rico) reconstituted with 100 mg/ml of ketamine HCl and 100 mg/ml of xylazine at a total dose approximating 0.05 ml/kg. The marginal ear vein was injected with 1 g of thiopental sodium at a dose of 6.6 to 8.8 mg/kg.

The procedure started with insertion of a 12-cm-long 14-gauge Veress needle infraumbilically through the abdominal wall. This was followed by insufflation of carbon dioxide (CO_2) using a standard autoregulated laparoscopic insufflator equipped with a built-in manometer (Electronic Endoflator 264305 20; Karl Storz, Tuttlingen, Germany) to accomplish pneumoperitoneum and ensure stable and well-controlled intraabdominal pressures, with a 12 mmHg setting point pressure and a 10 l/min of CO_2 flow rate [3].

A 60-cm-long automated flexible stapler was introduced per-orally and advanced into the stomach to determine the future gastrotomy site (between the stapler's arms). Once that area was visually identified and the distance from the front teeth recorded, the device was removed from the stomach.

A forward-viewing double-channel upper endoscope (GIF- 2T160; Olympus Optical Co. Ltd., Tokyo, Japan) was advanced into the stomach. The gastric wall was punctured with a triple-lumen needleknife (Wilson-Cook Medical Inc., Winston-Salem, NC, USA) using pure cautery at 20 J followed by pure cut at 30 J (Valleylab SSE2L; Tyco Healthcare Group LP, Boulder, CO, USA). The CRE dilating balloon (Boston Scientific Microvasive, Natick, MA, USA) was inserted into the gastric wall puncture site, then distended to 20 mm to gain access to the peritoneal cavity. The endoscope was advanced into the peritoneal cavity.

After peritoneoscopy, the endoscope was withdrawn into the stomach, and the stapler loaded with "Blue Load" staples (with a leg length of 3.3 mm and a median closed staple height of 1.2 mm) was reintroduced into the stomach. The arms of the stapler were opened. Two forceps were advanced through the working channels of the endoscope to grasp both edges of the gastric wall incision and to position them between the opened stapler arms. The arms of the stapler were closed, encompassing the gastrotomy site. Using the automated firing system, the stapler was fired, performing complete closure of the gastrotomy site.

In the first experiments, a load with the cutting blade was used, which made a transection between the lines of staples. Alternatively, in the subsequent experiments (pigs 2–4), a stapler's loads without the cutting blade were used.

After closure of the gastric wall incision, the stomach was fully distended, then filled with iohexol contrast (350 mgI/ml Ominipaque; GE Healthcare Inc, Princeton, NJ, USA) under fluoroscopic observation to assess the water tightness of the gastric incision closure. Then the animals were killed, and postmortem examination was performed to study adequacy of the closure and to check the intraperitoneal organs for possible transgastric access and closure-related complications.

Results

Four acute animal experiments were performed. In all the experiments, transgastric access to the peritoneal cavity and peritoneoscopy were accomplished without complications.

The delivery and positioning of the stapler required 14.5 ± 4.7 min and were achieved with technical difficulties mostly due to a short working length (60 cm) of the device. The distance between the incisors and gastroesophageal junction in 50-kg pigs was approximately 55 cm. With the current working length of the flexible stapler, we had to make the gastric wall incision in the cardiac region of the stomach within 5 cm from the gastroesophageal junction.

The use of the double-channel endoscope facilitated positioning of both edges of the gastric wall incision (with two endoscopic grasping forceps) between the opened arms of the stapler. Automated control allowed proper alignment of the stapler arms, their adequate approximation, and prevention of misfiring. The firing sequence of the staple lasted only 15 s and created four linear rows of staples, completely closing the gastric wall incision and creating 60-mm-long staple line.

The postmortem examination of pig 1 (when a cutting blade was used) demonstrated a full-thickness closure of the gastric wall incision. However, the cutting blade caused a transmural linear cut right at the end of the line of staples. For this reason, we stopped using the stapler loads with a cutting blade. In the three remaining animals (pigs 2–4), we were able to achieve a full-thickness closure of the gastric wall incision with good serosa-to-serosa approximation and without any complications. The x-ray with iohexol contrast did not show any leaks of the contrast through the line of staples.

Discussion

The concept of NOTES as a less invasive alternative to laparoscopic and open surgery is gaining popularity among gastroenterologists and surgeons [2]. Multiple NOTES procedures in animal models have been reported by researchers in the United States and abroad [4–17]. Nevertheless, many technical aspects of translumenal interventions remain unsolved including optimal access site, prevention of intraperitoneal infection, spatial orientation inside the peritoneal cavity, and development of new instruments [2, 18–21]. Among the unanswered questions, dependable closure of the peritoneal access site continues to be one of the main challenges facing NOTES [22].

Currently available methods that could potentially be used for closure of the transluminal access site include tissue anchors [23, 24], endoscopic clips [25–27], suction-based prototype suturing devices [28, 29], and other instruments [30–32]. Several studies have evaluated the use of different tissue anchors (T-bars) for closure of the transmural gastric wall incisions [23, 24]. Publications of these studies have demonstrated successful closure of small and large transmural defects of the gastric wall with tissue anchors. But deployment of the tissue anchors requires transmural puncture of the gastric wall with a hollow needle, which carries the T-bars [23] Although in published reports, the authors did not describe any complications related to the use of this delivery mechanism, there is a potential of damage to the adjacent organ or introduction of infection into the peritoneal cavity when the tissue anchors are deployed [33]. In addition, none of the published studies was designed to evaluate the use of tissue anchors specifically for closure of gastric wall incisions after NOTES procedures.

Currently, a variety of endoscopic clips are commercially available, easy to use, and gaining in popularity among gastroenterologists and surgeons for various

Fig. 1 Both edges of the gastric wall incision are grasped with endoscopic forceps

Fig. 2 The arms of the stapler are closed around the gastric wall incision, and the stapler is ready to fire (retroflex view)

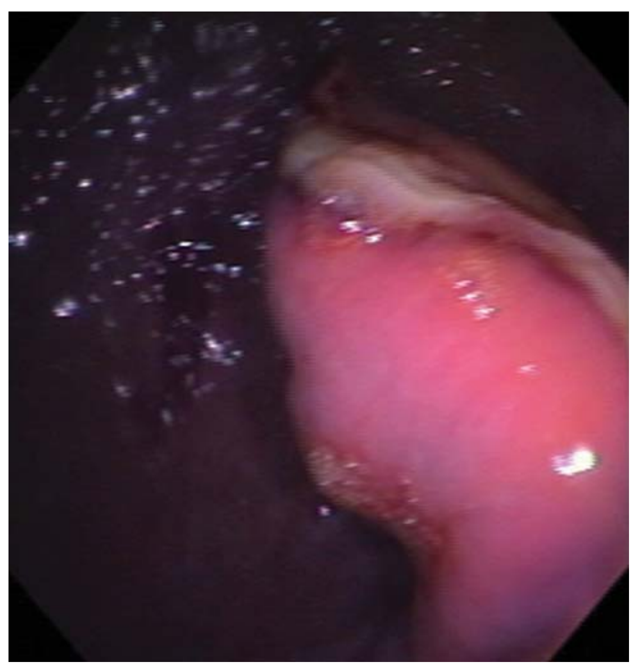

Fig. 3 Closure of the gastric wall incision with a linear line of staples is completed

endoluminal interventions [34, 35]. Several reports describe the clinical use of endoclips for mucosal closure of pathologic or iatrogenic gastrointestinal tract perforations [34–39], but dedicated use of endoscopic clips for NOTES access closure has yielded suboptimal results [28]. Thompson et al. [28] compared several methods of gastric closure including endoclips, surgical suturing, and a suction-based suturing device. Their study demonstrated that mucosal closure with endoclips results in significant air and fluid leakage via the line of endoclips.

Surprisingly, the full-thickness closure with a suction-based suturing device was more reliable than surgically made sutures [28]. The obvious weakness of this approach is the need to place the sutures before access to the peritoneal cavity, which may complicate subsequent translumenal intervention. In addition, with suction-based suturing devices, the depth of the sutures (too shallow or too deep) is difficult to control. This problem even has led to unintended capture of the small bowel loop adjacent to the stomach when another suction-based suturing device was used [29].

The current study aimed to evaluate the use of an automated stapler (SurgASSIST) for closure of the gastrotomy incision in a live porcine model. This flexible device has a built-in automated control, which allows proper alignment of the stapler arms, their adequate approximation, and prevention of misfiring. During these experiments we were able to make a full-thickness 60-mm-long line of staples, reliably closing the site of transgastric access into the peritoneal cavity.

In the first animal, we used the stapler load with a cutting blade, which led to a damage of the gastric wall right at the end of the staple line. To correct this problem, we started using stapler loads without a cutting blade and did not have any problems or complications with the three remaining animals. Postmortem examination demonstrated full-thickness closure of the gastric wall incision with good serosa-to-serosa approximation.

In our experiments, the location of the gastrotomy was restricted to the cardiac region within 5 cm from the gastroesophageal junction due to the short working length (60 cm) of the stapler. This limitation will be corrected in the next generation of the stapler (Natural Orifice Linear Cutter; Power Medical Interventions) currently under development. This new device will have a longer working shaft, a smaller diameter, and articulating abilities, which will allow closure of the gastrotomy made in any portion of the stomach.

In conclusion, the flexible stapling device may provide a simple and reliable technique for lumenal closure after NOTES procedures. Further survival studies currently are under way to evaluate the long-term efficacy of gastric closure with the stapler after intraperitoneal interventions.

References

1. Rattner D, Hawes RH (2006) NOTES: Gathering momentum. Surg Endosc 20:711–712
2. Rattner D, Kalloo A (2006) ASGE/SAGES Working Group on Natural Orifice Translumenal Endoscopic Surgery. October (2005). Surg Endosc 20:329–333
3. Meireles O, Kantsevoy SV, Kalloo AN et al (2007) Comparison of intraabdominal pressures using the gastroscope and laparoscope for transgastric surgery. Surg Endosc
4. Kalloo AN, Singh VK, Jagannath SB et al (2004) Flexible transgastric peritoneoscopy: a novel approach to diagnostic and therapeutic interventions in the peritoneal cavity. Gastrointest Endosc 60:114–117
5. Kantsevoy SV, Jagannath SB, Niiyama H et al (2005) Endoscopic gastrojejunostomy with survival in a porcine model. Gastrointest Endosc 62:287–292
6. Jagannath SB, Kantsevoy SV, Vaughn CA et al (2005) Peroral transgastric endoscopic ligation of fallopian tubes with long-term survival in a porcine model. Gastrointest Endosc 61:449–453
7. Park PO, Bergstrom M, Ikeda K, Fritscher-Ravens A, Swain P (2005) Experimental studies of transgastric gallbladder surgery: cholecystectomy and cholecystogastric anastomosis (videos). Gastrointest Endosc 61:601–606
8. Wagh MS, Merrifield BF, Thompson CC (2005) Endoscopic transgastric abdominal exploration and organ resection: initial experience in a porcine model. Clin Gastroenterol Hepatol 3:892–896
9. Pai RD, Fong DG, Bundga ME, Odze RD, Rattner DW, Thompson CC (2006) Transcolonic endoscopic cholecystectomy: a NOTES survival study in a porcine model (with video). Gastrointest Endosc 64:428–434
10. Kantsevoy SV, Hu B, Jagannath SB et al (2006) Transgastric endoscopic splenectomy Is it possible? Surg Endosc
11. Lima E, Rolanda C, Pego JM et al (2006) Transvesical endoscopic peritoneoscopy: a novel 5-mm port for intraabdominal scarless surgery. J Urol 176:802–805
12. Rolanda C, Lima E, Pego JM et al (2007) Third-generation cholecystectomy by natural orifices: transgastric and transvesical combined approach (with video). Gastrointest Endosc 65:111–117
13. Kantsevoy SV, Niiyama H, Jagannath SB et al (2006) The endoscopic transilluminator: an endoscopic device for identification of the proximal jejunum for transgastric endoscopic gastrojejunostomy. Gastrointest Endosc 63:1055–1058
14. Kantsevoy SV, Jagannath SB, Nijiyama H et al (2007) A novel safe approach to the peritoneal cavity for per-oral transgastric endoscopic procedures. Gastrointest Endosc 65:497–500
15. Swanstrom LL, Kozarek R, Pasricha PJ et al (2005) Development of a new access device for transgastric surgery. J Gastrointest Surg 9:1129–1136, discussion 1136–1137
16. Onders R, McGee MF, Marks J et al (2007) Diaphragm pacing with natural orifice transluminal endoscopic surgery: potential for difficult-to-wean intensive care unit patients. Surg Endosc 21:475–479
17. Onders RP, McGee MF, Marks J et al (2007) Natural orifice transluminal endoscopic surgery (NOTES) as a diagnostic tool in the intensive care unit. Surg Endosc 21:681–683
18. Ponsky JL (2005) Gastroenterologists as surgeons: what they need to know. Gastrointest Endosc 61:454
19. Hochberger J, Lamade W (2005) Transgastric surgery in the abdomen: the dawn of a new era? Gastrointest Endosc 62:293–296
20. Swain P (2007) A justification for NOTES—natural orifice translumenal endosurgery. Gastrointest Endosc 65:514–516
21. Reddy DN, Rao GV (2007) Transgastric approach to the peritoneal cavity: are we on the right track? Gastrointest Endosc 65:501–502

22. Lamade W, Hochberger J (2006) Transgastric surgery: avoiding pitfalls in the development of a new technique. Gastrointest Endosc 63:698–700
23. Ikeda K, Mosse A, Park PO et al (2006) Endoscopic full-thickness resection (EFTR): circumferential cutting method. Gastrointest Endosc
24. Sumiyama K, Gostout CJ, Rajan E, Bakken TA, Deters JL, Knipschield MA (2007) Endoscopic full-thickness closure of large gastric perforations by use of tissue anchors. Gastrointest Endosc 65:134–139
25. Raju GS, Ahmed I, Shibukawa G, Poussard A, Brining D (2007) Endoluminal clip closure of a circular full-thickness colon resection in a porcine model (with videos). Gastrointest Endosc 65:503–509
26. Raju GS, Ahmed I, Brining D, Xiao SY (2006) Endoluminal closure of large perforations of colon with clips in a porcine model (with video). Gastrointest Endosc 64:640–646
27. Raju GS, Pham B, Xiao SY, Brining D, Ahmed I (2005) A pilot study of endoscopic closure of colonic perforations with endoclips in a swine model. Gastrointest Endosc 62:791–795
28. Ryou M, Pai R, Sauer J, Rattner D, Thompson C (2007) Evaluating an optimal gastric closure method for transgastric surgery. Surg Endosc 21:677–680
29. Gelrud A, Thompson S, Mootoo ME, Gastrich J, Stokes M (2006) Novel transmural endoscopic suturing device. Gastrointest Endosc 63:AB81
30. Swain CP (1997) Endoscopic sewing and stapling machines. Endoscopy 29:205–210
31. Swain CP, Mills TN (1986) An endoscopic sewing machine. Gastrointest Endosc 32:36–38
32. Hu B, Chung SC, Sun LC et al (2005) Eagle Claw II: a novel endosuture device that uses a curved needle for major arterial bleeding: a bench study. Gastrointest Endosc 62:266–270
33. Kantsevoy SV (2006) Endoscopic full-thickness resection: new minimally invasive therapeutic alternative for GI-tract lesions. Gastrointest Endosc 64:90–91
34. Chuttani R, Barkun A, Carpenter S et al (2006) Endoscopic clip application devices. Gastrointest Endosc 63:746–750
35. Shin EJ, Ko CW, Magno P et al (2007) Comparative study of endoscopic clips: duration of attachment at the site of clip application. Gastrointest Endosc 66:757–761
36. Mana F, De Vogelaere K, Urban D (2001) Iatrogenic perforation of the colon during diagnostic colonoscopy: endoscopic treatment with clips. Gastrointest Endosc 54:258–259
37. Kim HS, Lee DK, Jeong YS et al (2000) Successful endoscopic management of a perforated gastric dysplastic lesion after endoscopic mucosal resection. Gastrointest Endosc 51:613–615
38. Cipolletta L, Bianco MA, Rotondano G, Marmo R, Piscopo R, Meucci C (2000) Endoscopic clipping of perforation following pneumatic dilation of esophagojejunal anastomotic strictures. Endoscopy 32:720–722
39. Binmoeller KF, Grimm H, Soehendra N (1993) Endoscopic closure of a perforation using metallic clips after snare excision of a gastric leiomyoma. Gastrointest Endosc 39:172–174