An Intestinal Occlusion Device for Prevention of Small Bowel Distention During Transgastric Natural Orifice Transluminal Endoscopic Surgery

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ABSTRACT

Background and Objectives: Bowel distention from luminal gas insufflation reduces the peritoneal operative domain during natural orifice transluminal endoscopic surgery (NOTES) procedures, increases the risk for iatrogenic injury, and leads to postoperative patient discomfort.

Methods: A prototype duodenal occlusion device was placed in the duodenum before NOTES in 28 female pigs. The occlusion balloon was inflated and left in place during the procedure, and small bowel distention was subjectively graded. One animal had no balloon occlusion, and 4 animals had a noncompliant balloon placed.

Results: The balloon maintained its position and duodenal occlusion in 22 animals (79%) in which the bowel distention was rated as none (15), minor (4), moderate (3), or severe (0). The intestinal occlusion catheter failed in 6 animals (21%) because of balloon leak (5) or back-migration into the stomach (1), with distention rated as severe in 5 of these 6 cases.

Conclusion: The intestinal occlusion catheter that maintains duodenal occlusion significantly improves the intra-abdominal working domain with enhanced visualization of the viscera during the NOTES procedure while requiring minimal time and expense.

Key Words: Natural orifice transluminal endoscopic surgery, Endoscopic surgery, Advanced endoscopy, New techniques in endoscopy

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INTRODUCTION

The development of natural orifice transluminal endoscopic surgery (NOTES) has led to renewed innovation in the field of minimally invasive surgery and interventional endoscopy, which has allowed limited transgastric human procedures.[1,2]

The work of Kalloo et al.[3] demonstrated the technique, and other researchers were able to expand the concept and bring it out of the laboratory and into the clinical realm.[4,5]

Once transluminal access has allowed entrance to the peritoneal cavity, success depends on proper visualization of all quadrants and the ability to approach a targeted site in the abdomen. Small bowel distention from luminal gas insufflation has the potential to reduce the peritoneal operative domain, increase the risk for iatrogenic injury, lead to postoperative patient discomfort, and make a potential rescue laparoscopy or laparotomy more difficult.[6–8] During endoscopic resection of esophageal or gastric cancers by use of carbon dioxide insufflation, the reported range of gas flow into the gastrointestinal tract was approximately 1.5 to 3 L/min.[13] Such distention has been identified as a potential barrier to the clinical practice of NOTES by the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR)[9,10]; however, no reliable technique to prevent distention has been described to prevent it during transgastric access as of yet.

In the study by Dubcenco et al.[11] studying transcolonic NOTES, it was noted that during endoscopic insufflation, the abdominal view was sufficiently obscured by the rising distention in the small bowel. This team found a significant improvement in both peritoneal visualization and colonic manipulation through the use of a balloon occlusion device, placed proximal to the site of colotomy. This balloon reduced insufflation to the colon and resultant small bowel and theoretically decreased peritoneal contamination by reducing the fecal stream. The study questioned whether a higher-pressure balloon would allow for a better seal and decreased contamination. Similar small bowel distention can be observed when a transgastric approach is performed because of the distention of the stomach and resultant distention of the small bowel.

This excess distension can cause patient discomfort a dilated abdomen and even bowel ischemia.[12]

We have previously described the use of a balloon occlusion catheter for a transgastric approach to NOTES.[14–17] Though mentioned in the "Methods" sections of these articles, the balloon occlusion catheter was never described in detail. The purpose of this study is to describe the design and testing of the device that we found suitable for prohibiting insufflated air from distending the small bowel during transgastric NOTES procedures. A comparison was made between no balloon; a commercially available endovascular balloon with relatively noncompliant walls capable of high pressure; and a novel, compliant balloon catheter made of several commercially available components.

MATERIALS AND METHODS

Subjects and Preoperative Care

This study used a total of 33 female domestic swine (*Sus scrofus domesticus*), with a mean weight of 32 kg. It was conducted in accordance with the US Department of Agriculture Animal Welfare Act, and the protocol was approved by the Animal Care and Use Committee at the Penn State College of Medicine. The animals were allowed standard chow until 48 hours before the procedure, at which time food was withdrawn, but free access to water was maintained. The animals were anesthetized and monitored by the veterinary staff at the Penn State Department of Comparative Medicine, as described previously.[14,15]

Equipment Preparation

The endoscope and all reusable endoscopic equipment underwent high-level disinfection with 2.4% glutaraldehyde (Cidex; Johnson & Johnson, New Brunswick, NJ, USA) before use. Laparoscopic or endoscopic equipment capable of autoclaving was sterilized in an autoclave before use. All surgical procedures were conducted with sterile technique.

Balloon Selection

The first arm of the study used a noncompliant Coda (NCC) endovascular balloon catheter (Cook Medical, Bloomington, IN, USA) that is readily available and expands to a consistent and predictable size (40 mm) that, when inflated, would sufficiently occlude the intestinal lumen. This device is relatively noncompliant when fully inflated and is used primarily in endovascular procedures to exert considerable pressure on surrounding structures, such as for dilation of a stricture or stenosis.

The second arm of the study was set up to create and test a more compliant device: a 190-cm-long, 5.5-French biliary stone extraction balloon catheter was modified into an intestinal occlusion catheter (IOC) (**Figure 1**). The catheter was modified by removing the existing balloon and attaching a largely compliant, low-pressure anorectal manometry balloon (Adult StimSENSE Balloon; Sandhill, Highlands Ranch, CO, USA). The balloon was attached with silk suture and inflated underwater to confirm absence of an air leak. The wire port was used for injection of air, and the other ports were blocked with stopcocks. Anorectal manometry balloons are designed to be high-volume balloons (up to 500 mL of air) with even pressure distribution throughout the inflated device. When inflated with only 35 to 40 mL of air, however, the balloon is 6 cm long and visibly occludes the porcine duodenum when placed endoscopically.

Procedure

Upper endoscopy was performed in all subjects preoperatively to identify anatomy. The placement techniques for the NCC balloon and IOC were similar: the catheter tip was grasped with an endoscopic grasping forceps, the catheter was introduced parallel to the endoscope into the esophagus, and the occlusion device was then maneuvered down into the gastric antrum (**Figure 2**). At the pylorus, the forceps grasping the balloon was first advanced into the duodenum and then the endoscope was introduced. The balloon was further advanced into the
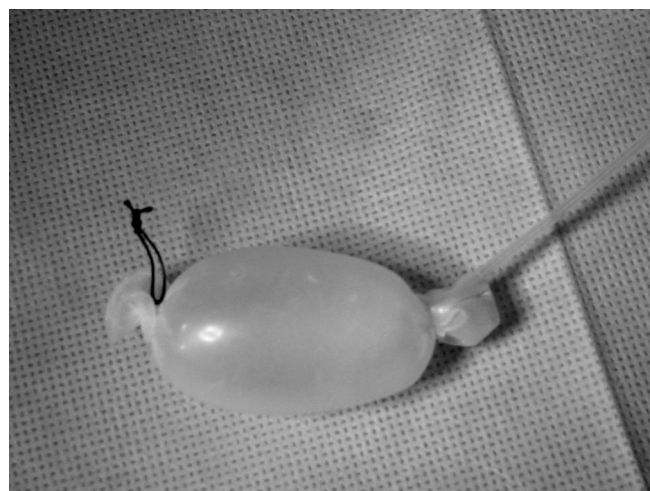
Figure 1. Example of inflated, fully assembled custom IOC.
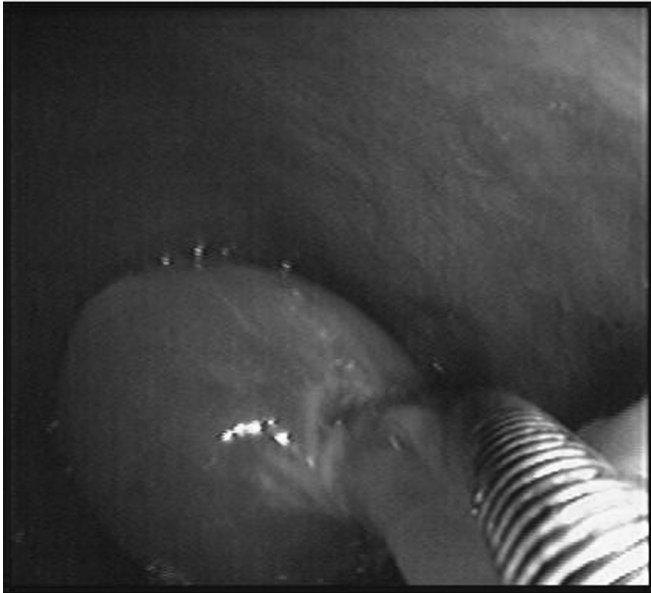
Figure 2. Endoscopically visualized placement of IOC into duodenum.

duodenum under direct visualization and partially inflated, whereupon the forceps was released and pulled back into the stomach. After this, the balloon was completely inflated and the catheter was reduced by pulling it back under direct visualization, confirming adequate placement in the first portion of the duodenum immediately distal to the pylorus. The balloon could be directly examined after deployment and the volume adjusted if needed. For the IOC, the ports of the catheter were kept closed to maintain balloon inflation throughout the procedure.

After upper endoscopy and balloon insertion, a self-approximating transluminal access technique (STAT) tunnel was created in all animals as previously outlined.[14] In brief, the stomach was irrigated with a povidone-iodine solution, and an endoscopic needle was used to elevate the mucosal layer from the underlying gastric muscle near the gastroesophageal junction. A 1- to 1.5-cm incision was then created by use of this mucosal pillow with a 4-mm needle knife (Huibregste; Cook Medical) and an electrocautery unit. A rat tooth grasping forceps (Olympus, Center Valley, PA, USA) was used to continue the dissection of the loose areolar tissue in the submucosal plane, separating the mucosa from the adjacent muscle layer.[15] After a sufficient-length tunnel was created to advance the endoscope to the desired position, the needle knife was again used to make a seromuscular incision that permitted endoscopic peritoneal access.

Two different protocols were used in this study to simultaneously assess the efficacy of the STAT tunnel. The first 14 animals underwent a targeted peritoneoscopy, in which STAT tunnels were created to aim the endoscope at particular quadrants. The 4 NCC balloon animals were part of this study group. These results have been published elsewhere.[15] The remaining 19 animals underwent organ resection after peritoneoscopy: either a uterine horn resection or a cholecystectomy.[16]

For assessment of function, bowel distension was assessed subjectively during the procedure with a 4-point Likert scale (1, no distention; 2, minimal distention with adequate operative domain; 3, moderate distention with reduced operative domain; and 4, severe distention with significant loss of operative domain). This criterion was based on the ease of visualization of structures, such as the gallbladder, spleen, and uterus; ease of movement within the peritoneum; and overall volume of small bowel in relation to insufflated abdomen. Failure of device function was determined to be a score of 3 or higher. Scores were analyzed with the Fisher exact test.
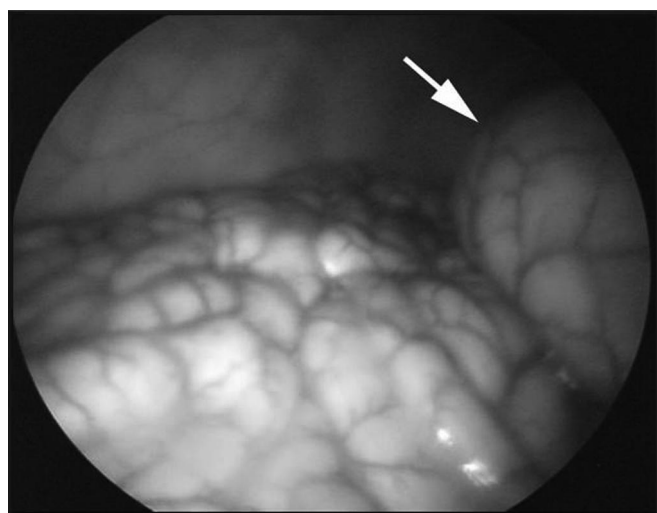
RESULTS

All animals underwent successful transgastric peritoneal access. The mean length of time for peritoneal access was 195 ± 72 minutes, and the mean length of time for tunnel creation time is 47 minutes.

Animal 1 was considered the control animal and had no occlusion balloon of any kind placed. Visibility was rated as severely impaired, and the working space was severely limited within the abdomen. The bowel was tense and difficult to manipulate or maneuver around, and after this, all animals subsequently had balloon occlusion.

NCC balloons were placed successfully in 4 animals. The first balloon was inflated to approximately 40 mm Hg. The next 2 animals had the balloon inflated with the full 40 mL of air as the packaging suggests for maximal balloon deployment. The final animal in the Coda group had the balloon deployed with 40 mL of saline solution. The mean balloon inflation time for these 4 animals was 121 minutes. Each method of deployment allowed for successful peritoneoscopy. However, at the end of the procedure, there was significant damage to the duodenum noted in all 4 animals, and significant ischemia was noted. Animal 1 had the least damage to the tissue noted; however, the small bowel distension was rated as 3, which was the highest in this group. The two balloons that were maximally inflated

with air caused a frank perforation of the duodenum. The one balloon filled with saline solution caused a serosal tear from the device. One animal (the second animal that had the balloon maximally inflated with air) was euthanized 24 hours after the procedure, and it was found to have significant duodenal ischemia and perforation at necropsy.
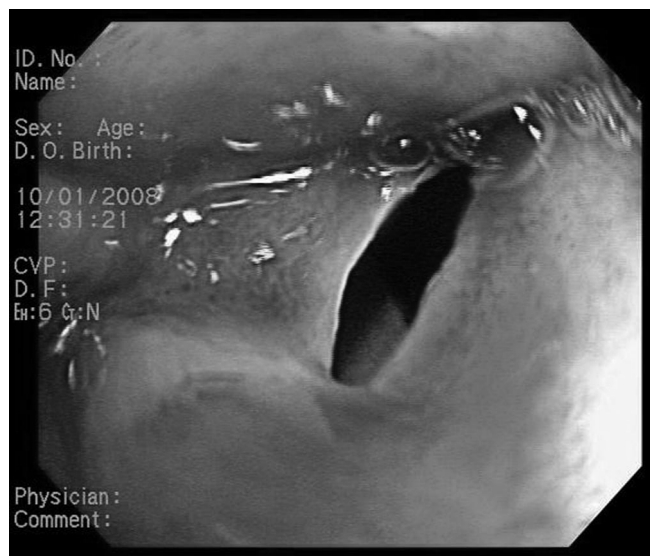
IOCs were successfully placed in 27 of 28 animals. The mean deployment time was 287 ± 66 seconds, and the mean balloon inflation time was 195 ± 72 minutes. The balloon maintained its position and duodenal occlusion in 22 animals (79%). In these animals bowel distention was rated as none[15] (**Figure 3**), minor (4), moderate (3), or severe (0). The IOC failed in 6 animals (21%) because of development of balloon leak (5) or back-migration into the stomach (1), with distention rated as severe (**Figure 4**) in 5 of these 6 cases. Considering moderate and severe small bowel distention as failures, we found that the distention was significantly decreased in those animals in which the duodenal occlusion balloon maintained occlusion compared with those in which it did not ($P = .003$, Fisher exact test). The mean balloon inflation volume was 36 ± 4 mL. Volumes were modified slightly in accordance with animal size but averaged approximately 1 mL/kg of weight. It was noted that two animals had mild discoloration at the occlusion site after the balloon was taken down. However, at necropsy after the specified survival period, no changes were noted. The animals also successfully gained weight. One significant complication occurred. The duodenal wall was perforated in one subject (**Figure 5**), likely by the stiff forceps as it

Figure 4. Severely distended small bowel after prolonged insufflation during intraluminal endoscopy.

Figure 5. Duodenal perforation from attempted blind placement of intestinal occlusion device.

Figure 3. Laparoscopic view of IOC within duodenum (arrow), with distal decompressed small bowel.

was pushed across the pylorus into the duodenum. This animal had difficult anatomy, and a relatively blind placement of the IOC was needed because endoscopic entry into the duodenum was prohibitively difficult. The inflated balloon was found free in the peritoneum with the

catheter traversing the perforation. The perforation site was easily identified and repaired by laparoscopy.

DISCUSSION

This study shows the need for intestinal occlusion when performing a prolonged upper endoscopy for the purpose of NOTES. Creation of the STAT tunnel has published lengths of time ranging from 13 to 51 minutes, which is a significant amount of time for gastric insufflation.[17] During this time, there is not constant insufflation; however, even periodic insufflation at 1.5 to 3 L/min can significantly distend the gastrointestinal tract over this length of time.[13]

The NCC balloon is a device that is used for endovascular, temporary occlusion of the aorta during endovascular repair or to expand endovascular devices. The pressures required for this function are generally much higher than what are required for occlusion of the small intestine during endoscopy. As such, the pressures exerted by the balloon were measured to be approximately 40 mm Hg. It is known that a pressure >20 mm Hg within the lumen of the bowel can cause changes in capillary blood flow and a pressure >40 mm Hg can cause a significant decrease in capillary blood flow at the site of increased pressure. Furthermore, these effects can be seen in the surrounding bowel.[12] This is likely the reason for ischemia and perforation with this device.

An important challenge when performing NOTES is maintenance of spatial orientation and visualization in the abdominal cavity. One of the factors that can have a dramatic effect on the intra-abdominal working domain is distended bowel loops, which are usually the result of gaseous insufflation to gain access.[9] Insufflation of the lumen will be necessary during the initial, luminal steps of a NOTES procedure, especially before peritoneal access and during closure of the incision sites. The chance of small bowel distention increases with the amount of time one spends in the stomach performing transgastric procedures. Such distention can cause significant patient discomfort.[11] In our experience, once inflated, the small bowel cannot be effectively deflated by standard suction technique. In addition to affecting peritoneal visualization, small bowel distention can be problematic if there is a need for conversion to urgent laparotomy.[6–8] The use of carbon dioxide instead of air allows for much faster absorption of the luminal gas but does not eliminate the problem of distention.[10] Thus placement of an intestinal occlusion device at the beginning of the procedure would be of benefit both for the intended procedure

and in the event of a complication requiring immediate laparotomy.

The IOC described in this report was fabricated from readily available endoscopic accessories. Further development of this device could lead to better performance and reliability over our device, which often leaked at the hand-tied suture, causing distension and partial occlusion or displacement of the balloon. A wire-guided balloon designed for intestinal occlusion can effectively overcome the issues listed. A low-pressure[12] (<20 mm Hg) large-volume balloon with high compliance appears to be suited for this purpose.

CONCLUSION

An IOC that maintains duodenal occlusion improves the intra-abdominal working domain with enhanced visualization of the viscera while requiring minimal time and expense. Improvement and standardization of the device and deployment technique would be required before clinical use. Limitations of this study include a lack of a formal control group, which would have allowed for a more rigorous protocol to be developed. In addition, to better appreciate the effects of insufflation on small bowel distension, a complete transection of the small bowel would have created a control in which no small bowel distension can occur. This would create an important base value to model future assessments of distension.

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