

ADVANCES IN ENDOSCOPY

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Endoscopic Closure Techniques for Gastrotomies

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G&H What were the goals of your recent animal study of endoscopic closure techniques for gastrotomies?

RR With an increase in utilization of advanced intraluminal endoscopy such as endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD), along with the development of natural orifice transluminal endoscopic surgery (NOTES), reliable, effective, and safe methods of closure are mandatory. The aim of our study, which was recently published in *Endoscopy*, was to compare the safety and efficacy outcomes of a standard, current-use endoscopic tissue clip with a newly designed over-the-scope clip (OTSC) in a live porcine model of gastrotomy closure.

G&H Could you discuss the experimental design and principal findings of this study?

RR We performed this study at the animal facility at Dartmouth-Hitchcock Medical Center after approval from our Institutional Animal Care and Use Committee. Following gastrotomy creation, a 2T160 double-channel upper endoscope (Olympus, Center Valley, Pennsylvania) was passed through the gastric wall into the peritoneal cavity and a brief peritoneoscopy was performed to exclude access-related injuries. The pigs were randomly assigned to either endoclip repair (n=10) or OTSC closure (n=10). The mean time to close the gastrotomy was defined as the time from insertion of the initial closure devices into the endoscope to final withdrawal of the instrument after satisfactory deployment of the last clip. The twin grasper used with both closure methods has 2 jaws that move

independently in order to approximate the edges of the gastrotomy before applying the clips. In both groups, the number of clips was unlimited and clips were applied until a sufficient closure was obtained, as judged by the operating endoscopist.

Following closure, a direct observational leak test was performed with a 12-mm trocar placed at the umbilicus for a 30-degree laparoscope, and one 5-mm trocar placed laterally for a suction irrigator. The stomach was maximally insufflated while being submerged in saline. Bubbling from the serosal surface was considered to be a leak. The absence of bubbling was considered to exclude a significant leak. The pigs with significant leak had additional clips placed until there was essentially no leaking. The animals were survived for 10–14 days.

The primary study objective was to determine infection-free survival of the animals. Therefore, the peritoneal cavity was examined at necropsy to identify signs of infectious complications such as peritonitis, abscesses, or adhesions. Secondary outcomes were defined as weight gain, time to perform the procedures, procedure-related complications, and leak test results. Microscopic examination of the gastrotomies was performed to determine the layers incorporated within the closure and to assess ischemia, necrosis, inflammation, ulceration, or persistent defects.

The results showed a mean (\pm SD) time for gastrotomy closure using endoclips of 31.5 ± 24.2 minutes (range, 8–88 minutes) compared to 8.5 ± 9.1 minutes (range, 2–31 minutes) using OTSC ($P = .002$). No intraoperative complications occurred. Laparoscopic leak tests with insufflation and saline immersion demonstrated 3 minor leaks and 1 major leak in the endoclip closures. No leaks were observed in the OTSC group. At necropsy, complete sealing of the gastrotomy sites was found in all OTSC closures. Small, localized perigastric abscesses were observed in 2 animals in the OTSC group and in 3 animals in the endoclip group. One animal in the endoclip group was sacrificed prematurely due to signs of sepsis and was found to have gross peritonitis secondary to a leak. At necropsy, evidence of peritonitis was identified in 2 other animals in the endoclip group. We concluded that NOTES gastrotomy closure using standard endoclips, even with the assistance of an effective tissue approximation grasper, is associated with an increased risk of leakage and intra-abdominal infection compared to OTSC closure. The occurrence of perigastric abscesses, which were seen in both groups, was concerning and warrants further investigation.

G&H What are the implications of this study for NOTES procedures in humans?

RR For human NOTES procedures to be successful, closure of the visceral entry site needs to be effective and reliable. Currently available closure methods have typically used devices that were designed for other purposes and may not be optimized for uses in NOTES. Currently available tissue clips were designed to engage mucosal depth and not the deeper layers of the visceral wall. These clips are effective for hemostasis and superficial closure of mucosa, but, as we have shown, are not designed for gastrotomy closure. A cardiac septal defect closure device is not practical even if capable to assist in gastrotomy closure. T-tag suturing is effective and comparable to open surgical closure, as evidenced in a recent randomized controlled study, but the technique is time-consuming and, like most new technology, has an initial learning curve. The OTSC shortens the time for closure, is relatively easy to deploy with a short learning curve, and appears reasonably reliable and effective. It may be a solution for closure in NOTES using a transgastric approach.

G&H What are the limitations of clip closure techniques?

RR The limitations for clip closure include issues related to effective engagement of the tissue edges, depth of tissue apposed, flexibility in positioning and deployment, and reversibility after placement. The various clips available for this purpose have individual characteristics and limitations. The tissue grasper used in our study allowed very precise positioning of the gastrotomy edges for apposition. This was a benefit for both clips when placed. The bigger “bite” of the OTSC engaged more tissue and deeper layers, and was able to overcome leaking seen with the current standard tissue clips. Another limitation of clips is that they are not easily removed. The OTSC, once placed, is not removable. If misaligned, another clip can be placed next to it to effect a bulking and closure.

G&H Is infection risk from NOTES a concern?

RR It is commonly thought that the infection risk from NOTES would be significant and inadequate closure would be part of the cause. In animal and human experience to date, reliable closure is possible, and while the risk of infection remains a real concern, it may be minimized by improvements in closure devices and techniques.

G&H Are further studies in animal models or human subjects planned?

RR The OTSC has been successfully studied in animal models of other visceral closures such as the esophagus,

small bowel, and colon. Now that OTSC is commercially available, we will see the real-world experience of human clinical use in closures of iatrogenic perforations, fistulae, staple line breakdown, and many other purposes.

G&H Do you envision endoscopic gastrotomy for access to the peritoneum and abdominal organs becoming commonplace?

RR Just as a minority of clinical gastroenterologists perform endoscopic retrograde cholangiopancreatography and endoscopic ultrasound and an even smaller number perform advanced procedures such as EMR and ESD, it is likely that, at least initially, only a very small percentage will be interested in performing transluminal diagnostic and therapeutic procedures. I do believe that appropriately trained gastrointestinal endoscopists can perform diagnostic and staging peritoneoscopy and procedures such as targeted liver or lymph node biopsy. More advanced procedures will require adequate surgical training, but an era may be arising for hybrid training of gastroenterologists and surgeons in advanced flexible endoscopic surgery including NOTES. The engagement of complementary skills allows for collegial activities and advancement of the field. Laparoscopic surgeons are now learning single port techniques, and as these incorporate more flexible instruments, the port can move from umbilicus to natural orifice. Superb flexible endoscopic skills are needed and that is the current purview of the gastrointestinal endoscopist.

It is clear that NOTES is an evolution of traditional surgical concepts hybridized with techniques and devices designed for use with flexible endoscopes and insertion instruments. Participation in NOTES will take the training necessary to acquire superb endoscopic skills and basic surgical knowledge. It is not yet ready for prime time with the currently available instruments, but the field is ripe for entrepreneurship and innovation. Looking at the fundamental need for closure, as we did in our study, shows that devices and methods for visceral closure that are easy to use, reliable, safe, and effective will add to the armamentarium of all endoscopy practices, whether focused on routine or advanced procedures.

Suggested Reading

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