

Esophageal overtubes provide no benefit to safety or technical success in upper gastrointestinal tract endoscopic suturing



Authors

Andrew C. Storm, Eric J. Vargas, Reem Matar, Louis M. Wong Kee Song, Tarek Sawas, Fateh Bazerbachi, Navtej S. Buttar, Mark D. Topazian, Barham K. Abu Dayyeh

Institution

Division of Gastroenterology and Hepatology, Mayo Clinic School of Science and Medicine, Rochester, Minnesota, United States

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Corresponding author

Andrew C. Storm, MD, Division of Gastroenterology and Hepatology, Mayo Clinic College of Science and Medicine, 200 First St SW, Rochester, MN 55905
Fax: +1-507-255-7612
storm.andrew@mayo.edu

ABSTRACT

Background and study aim The role of esophageal overtubes in upper gastrointestinal endoscopic suturing is unknown. This study aimed to determine whether overtube use was associated with technical success or adverse events.

Patients and methods A retrospective review of consecutive patients who underwent endoscopic suturing for various indications was performed.

Results A total of 719 patients underwent endoscopic suturing for various indications, including endoscopic bariatric procedures in 262, stent fixation in 258, defect closure in 190, and hemostasis in nine. An overtube was used in 186 procedures (25.9%). Technical success was achieved in all cases. Minor mucosal trauma occurred in 15 cases (8.1%) with use of an overtube, and none without an overtube ($P < 0.0001$). No full-thickness esophageal perforation or hemorrhage related to overtube use or the suturing device occurred.

Conclusions Endoscopic suturing can be performed safely for a variety of indications, including endoscopic bariatric procedures, defect repair, and stent fixation without an esophageal overtube. Minor esophageal mucosal trauma and equipment cost are increased when an overtube is used.

Introduction

The OverStitch system (Apollo Endosurgery Inc., Austin, Texas, United States) is an endoscopic suturing device that is used clinically for placing full-thickness sutures within the gastrointestinal tract. Endoscopic suturing is performed for a variety of indications, including primary or revision endoscopic bariatric procedures, closure of partial or full-thickness defects, stent fixation, hemostasis, and other applications. When using the OverStitch device in the upper gastrointestinal tract, an esophageal overtube is generally recommended but sold separately [1].

Esophageal overtubes were originally developed to protect the esophagus during procedures requiring repeated intuba-

tions, or for peroral endoscopic removal of a sharp or potentially traumatic foreign object from the esophagus or stomach [2]. Use of an esophageal overtube with the OverStitch device theoretically prevents esophageal trauma during passage and removal of the device, but may not be required. Overtubes themselves are associated with risks, including mucosal tears, esophageal perforation and bleeding. Prospectively collected data demonstrate that at least minor, but sometimes serious, esophageal trauma may occur in more than 70% of cases employing an overtube [3–7]. Furthermore, placement of an esophageal overtube adds to the time, complexity and cost of the procedure.

With increasing experience using the OverStitch system, it has become our group's practice to perform OverStitch proce-

dures without an esophageal overtube, with rare exceptions including posterior oropharyngeal and esophageal stenosis. We hypothesize that upper gastrointestinal endoscopic suturing using the OverStitch system can be performed safely and more efficiently from a cost perspective, without the use of an overtube, thereby eliminating the risks and cost associated with it.

Patients and methods

We conducted a review of the electronic medical records of all patients who underwent endoscopic suturing for various indications between January 2013 and January 2018 at the Mayo Clinic, Rochester, Minnesota, United States. Data were abstracted for patient demographics, procedural indications and adverse events, and clinical outcomes. The Fisher exact test (SAS Institute, Cary, North Carolina, United States) was performed to assess for statistical differences in adverse event rates between patients who underwent endoscopic suturing with and those without an overtube. Transanal (lower gastrointestinal) or transabdominal suturing cases were excluded.

Upper endoscopic suturing procedures were all completed with endotracheal tube intubation. A diagnostic upper endoscopy was completed to determine the safety of proceeding with intended suturing. If the decision was made to use an overtube, the diagnostic upper endoscope shaft was loaded with an esophageal length 25-cm overtube (Guardus, US Endoscopy, Mentor, Ohio, United States). Given the retrospective nature of the study, the reasoning behind the decision to use or not use an overtube was not possible to determine in most cases. The OverStitch endoscopic suturing device was then attached to the therapeutic double channel endoscope (GIF-2TH180, Olympus, Center Valley, Pennsylvania, United States) and advanced through the mouth or overtube to complete the intended therapeutic intervention. Carbon dioxide insufflation was used for all procedures.

Data on adverse events (AEs) were collected and categorized. Esophageal mucosal injury was defined as any change in the endoscopic appearance of the mucosa seen on scope withdrawal at the end of the procedure as compared to initial intubation and examination. Luminal stenosis, for the purposes of this study, was defined as narrowing of the esophagus not permitting easy passage of the upper endoscope. Perforation was defined as a full-thickness tissue defect of the bowel wall caused by the endoscopic procedure.

The study protocol was approved by the Institutional Review Board of Mayo Clinic (IRB #18-007239).

Results

A total of 719 patients (57% men; mean age 57.2 years [range 18–88]) underwent upper gastrointestinal tract endoscopic suturing during the study period. Patient and procedural characteristics are shown in ► **Table 1**. Endoscopic suturing was performed for bariatric procedures in 262 (36.4%), stent fixation in 258 (35.9%), mural defect closure in 190 (26.4%), and hemostasis in 9 (1.3%) cases. An esophageal overtube was used in 186 procedures (25.9%) and more commonly during endo-

► **Table 1** Patient and procedural characteristics

Patient characteristics (n = 719)		
Gender (male)	408 (57%)	
Age (years)	58.3 ± 14.3	
Procedural characteristics		
Indication for endoscopic suturing	Total cases (%)	Overtube used (%)
Bariatric procedures	262 (36.4)	155 (59.2)
Stent fixation	258 (35.9)	15 (5.8)
Defect closure	190 (26.4)	14 (7.3)
Hemostasis	9 (1.3)	2 (22.2)

► **Table 2** Adverse events

Adverse event	Overtube used (n = 186)	Overtube not used (n = 533)	P value
Esophageal mucosal injury	15	0	<0.0001
Abdominal fluid collection	1	0	0.26
Luminal stenosis	1	0	0.26
Hemorrhage	0	1	1.0
Perforation	0	0	–

scopic bariatric cases. Technical success of placing the intended tissue plication(s) was achieved in all cases (100%). Minor esophageal mucosal trauma was reported in 15 cases (8.1%) with overtube placement as opposed to none in cases without an overtube ($P < 0.0001$). No esophageal perforation or bleeding related to overtube placement or endoscopic suturing occurred (► **Table 2**). Other non-esophageal AEs that occurred during suturing procedures using an overtube included one abdominal fluid collection after endoscopic sleeve gastropasty, which was drained endosonographically, and one symptomatic stenosis of a revised gastrojejunal anastomosis, which required endoscopic dilation. In the group without use of an overtube, one case of intraprocedural hemorrhage during gastrojejunal anastomotic reduction occurred that was managed with epinephrine injection and clip placement.

Discussion

In our large cohort of patients, use of an overtube to prevent esophageal trauma from the OverStitch device was associated with an increased incidence of clinically insignificant esophageal injury across a wide variety of indications for endoscopic suturing. There were no differences in rates of technical success and AEs between the groups of endoscopic suturing with and without an overtube. Furthermore, use of an esophageal

overtube increases equipment cost and procedural time for endoscopic suturing procedures.

While use of an overtube for upper endoscopic procedures that require multiple esophageal intubations or retrieval of sharp objects is warranted, we speculate that its utilization during gastrointestinal endoscopic suturing is associated with increased intraluminal pressure due to the sealing mechanism of the overtube around the endoscope, thus hampering the usual venting of gas. While our data suggest that risk of perforation or pneumoperitoneum is not significantly different whether or not an overtube is used, we believe an overtube, without judicious use of carbon dioxide insufflation, may lead to increased insufflation-related events, such as post-procedure abdominal pain and bloating, and in the worst case scenario, barotrauma injury, including pneumoperitoneum and perforation. Furthermore, use of an overtube can potentially hinder successful completion of endoscopic suturing for particular situations, such as repair of an acute perforation or stent fixation in the upper or mid-esophagus, which explains why an overtube was so rarely used for stent fixation.

Our experience should be interpreted with some caution because 75% of overtube placements occurred during the first 33% of endoscopic suturing cases, suggesting that with time and experience, providers may become more comfortable using the OverStitch device without concomitant use of an esophageal overtube. The increased rate of use of an overtube earlier in our experience of endoscopic suturing may also be a confounding factor for interpreting the increased rate of AEs with use of an overtube. However, as all OverStitch users were experienced advanced endoscopists, presumably adept at esophageal overtube placement, this should not explain the increased rate of esophageal mucosal injuries in cases using an overtube. It is conceivable that an overtube may protect from esophageal trauma early on in the utilization of the OverStitch device, but may no longer be needed with increased experience. While the exact number of cases required to feel comfortable using the OverStitch device is not known, a prior study has suggested that procedural time is reduced after performing seven procedures [8]. We would also caution that there are select situations in which overtube placement may be prudent independent of experience level, including expected difficult passage of the device through an esophageal stenosis or when repeated esophageal intubations are anticipated. Our study will ideally be followed by a randomized controlled trial of OverStitch with and without an esophageal overtube to confirm these findings.

Conclusion

In conclusion, endoscopic suturing using the OverStitch device may be performed safely for a variety of indications, including endoscopic bariatric procedures, defect repair, stent fixation and hemostasis, with or without use of an esophageal overtube. In the hands of experienced operators of the OverStitch device, use of an overtube can be forgone in most cases as it adds to procedural time and cost without a benefit in regards to AEs.

Competing interests

Dr. Abu Dayyeh is a consultant for Boston Scientific, Metamodix, BFKW, and USGI; receives research support from Aspire Bariatrics, GI Dynamics, Apollo Endosurgery, USGI, Medtronic, Spatz, and Cairns; and is a speaker for Johnson & Johnson and Olympus.

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