REVIEW ARTICLE

Entanglement of an over-the-scope full-thickness endoscopic suturing device during stent fixation: a case series of adverse events and rescue strategies

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Background and Aims: Esophageal fully covered self-expandable metal stents (FCSEMSs) and lumen-apposing metal stents are used for the management of strictures and luminal defects. Stent fixation can minimize stent migration risk, and endoscopic suturing is an effective option. Here, we describe an adverse event of over-the-scope endoscopic suturing device entanglement during stent fixation and discuss rescue maneuvers.

Methods: Three experienced advanced endoscopists performed 5 cases of stent fixation with an over-the-scope endoscopic suturing device.

Results: Esophageal through-the-scope FCSEMSs were placed in 3 patients; all had previous radiation. During stent fixation, the needle driver was caught on the stent, out of the field of view. An argon plasma coagulator with a second endoscope inserted adjacently was used to free the stent in 2 cases; in the third case, forceful handle separation with the device outside the patient facilitated stent release. In 2 gastric cases, stents (FCSEMSs and lumen-apposing metal stents) in the stomach were disentangled using rat-tooth forceps.

Conclusions: Over-the-scope suturing device entanglement with FCSEMSs is possible and can occur outside the field of view. Reduced esophageal wall compliance caused by radiation and the use of more-flexible through-the-scope stents may have contributed to this adverse event. Rescue maneuvers for entanglement include argon plasma coagulation of the stent wire, rat-tooth forceps, and forceful handle separation. (VideoGIE 2026;11:31-4.)

INTRODUCTION

Esophageal full covered self-expandable metal stents (FCSEMSs) and lumen-apposing metal stents (LAMSs) are used to treat malignant and benign strictures as well as luminal defects. Because of a low rate of tissue ingrowth, there is a high migration risk, and stent fixation with tools, including over-the-scope full-thickness endoscopic suturing systems, can minimize this risk.[1,2] Over-the-scope suturing device entanglement with FCSEMSs has been previously described,[3,4] although the frequency and risk factors for this issue are unknown. In this case series (Video 1, available online at www.videogie.org), we demonstrate entanglement of the over-the-scope suturing device with the stent's proximal end during suturing (Fig. 1A) and show rescue options.

Abbreviations: APC, argon plasma coagulation; FCSEMS, fully covered self-expandable metal stent; LAMS, lumen-apposing metal stent; MAUDE, Manufacturer and User Facility Device Experience; TTS, through-the-scope.

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ESOPHAGEAL FCSEMS CASES

Case 1

An 85-year-old woman with esophageal squamous cell carcinoma on chemoradiation underwent EGD for ongoing dysphagia after completing neoadjuvant therapy. During the procedure, an obstructing mass was seen in the distal esophagus, causing a luminal obstruction. Wire-guided balloon dilation was performed to 11 mm, and an 18-mm × 120-mm

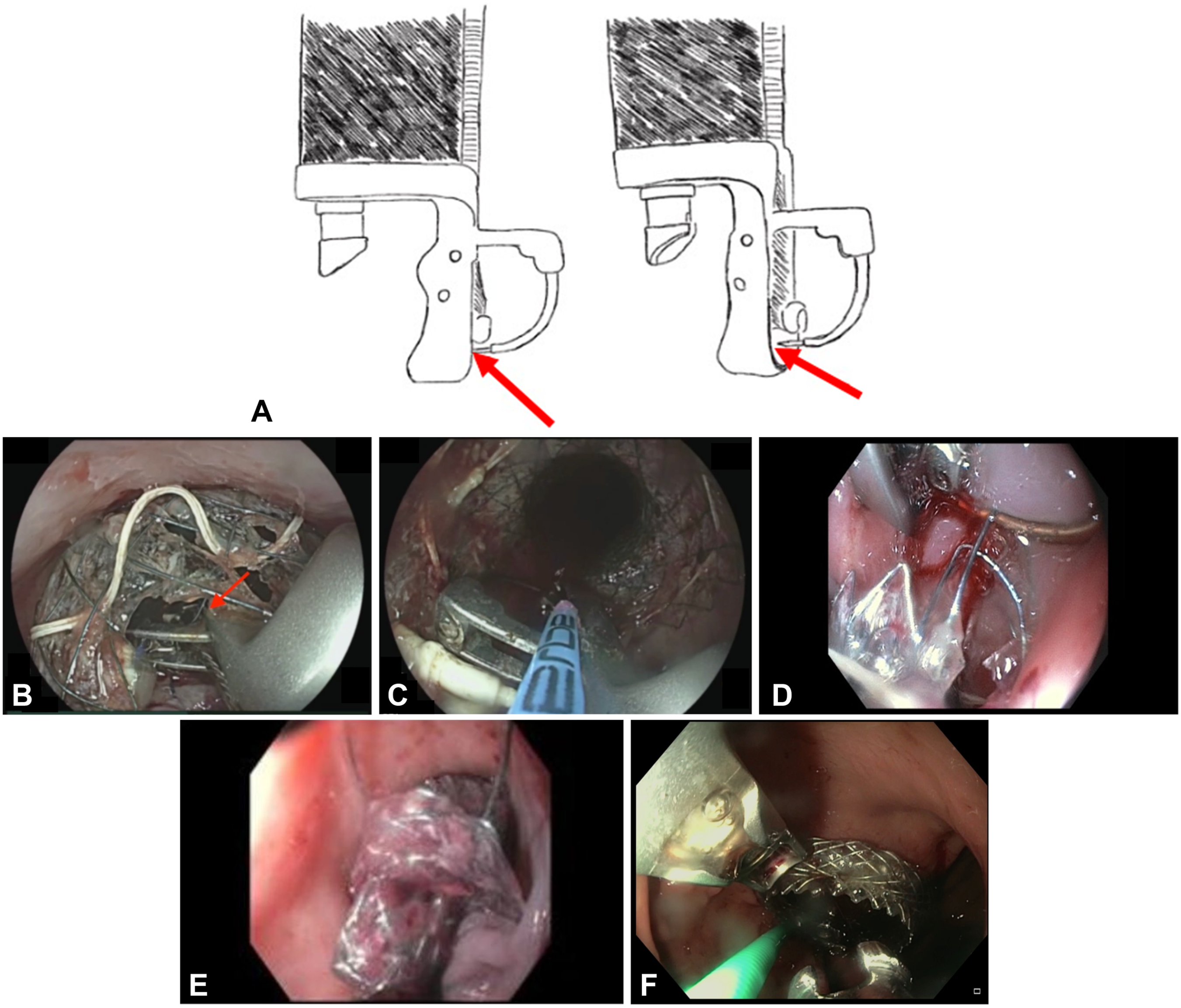

Figure 1. A, Diagram demonstrating the area of stent entrapment (*red arrows*). **B,** Case 1: the stent interstices (*red arrow*) caught in the needle driver, as seen from an upper endoscope inserted adjacent to the double-channel therapeutic scope with the attached, entangled over-the-scope endoscopic suturing device. **C,** Case 1: retraction of the stent to the appropriate position after successful argon plasma coagulation of the caught stent wire. **D,** Case 2: one of the stent interstices was caught in the needle driver between the metal loop and the scope mount, as seen from an upper endoscope inserted adjacent to the double-channel therapeutic scope. **E,** Case 3: an upper endoscope was used to visualize the needle driver (out of the frame) caught on a stent interstices—the tangled proximal end of the stent along with the entrapped interstices is stretched toward the top of the frame. **F,** Case 5: use of rat-tooth forceps to manipulate the stent away from the area of entanglement (behind scope) in the large gastric lumen.

through-the-scope (TTS) FCSEMS (Taewoong, Gimpo, South Korea) was placed over a guidewire. An over-the-scope suturing device (Boston Scientific, Marlborough Mass, USA) was used for stent fixation mounted on a double-channel therapeutic (2T) upper endoscope. After completion of the first suture, the device was stuck on the stent out of the field of view, behind the scope mount (Fig. 1B). Rat-tooth forceps were used unsuccessfully to try to free the stent. An upper endoscope placed adjacent to the therapeutic scope visually confirmed the stent was caught in the needle driver between the metal loop and the mount. Argon plasma coagulation (APC) was applied to the stent at 0.8 L/min at 60 W for a few seconds, which fractured the interstices, and freed it from the device (Fig. 1C). The final positioning of the stent was excellent, and a second suture was placed successfully to complete the procedure.

Case 2

A 69-year-old man with esophageal adenocarcinoma treated with chemoradiation and esophageal stent placement underwent an endoscopy for stent migration. During the procedure, the stent was removed uneventfully. An

TABLE 1. Summary of cases and outcomes

Stent type	Location of entanglement	Rescue maneuver
Esophageal TTS FCSEMS (Taewoong, Gimpo, South Korea)	Esophageal lumen	APC through adjacent upper endoscope
Esophageal TTS FCSEMS (Taewoong)	Esophageal lumen	Device removal, forceful handle hyperextension
Esophageal TTS FCSEMS (Taewoong)	Esophageal lumen	APC through adjacent upper endoscope
Esophageal TTS FCSEMS (Taewoong)	Gastrojejunal anastomosis	Rat-tooth forceps through 2T therapeutic channel
Lumen-apposing metal stent (Boston Scientific, Marlborough Mass, USA)	Gastric body (EDGE procedure)	Rat-tooth forceps through 2T therapeutic channel

2T, Double-channel therapeutic; *APC*, argon plasma coagulation; *EDGE*, EUS-directed transgastric ERCP; *FCSEMS*, fully covered self-expandable metal stents; *TTS*, through-the-scope.

18-mm FCSEMS (Taewoong) was deployed in the narrowed esophageal lumen. During stent fixation with the over-the-scope endoscopic suturing device (Boston Scientific), the needle driver was caught on the stent beyond the field of view. Confirmation was obtained with a second endoscope inserted adjacent to the 2T scope (Fig. 1D). Using moderate force, we removed the entangled scope with the partially attached stent. Outside the patient, forceful handle separation facilitated stent release. A second stent was then placed and sutured uneventfully.

Case 3

A 52-year-old woman with oral squamous cell carcinoma treated with surgery, chemoradiation, and feeding gastrostomy tube (PEG) was seen for closure of a gastrocutaneous fistula after PEG removal. An over-the-scope clip was attached to the scope for fistula closure. During passage of the endoscope with the over-the-scope-clip in place, a 7-cm linear mucosal laceration of the esophageal wall was noted, and an 18-mm FCSEMS (Taewoong) was placed. An over-the-scope endoscopic suturing device (Boston Scientific) was then attached to the T2 scope for stent fixation. During stent fixation, entanglement of the device was noted, and a second endoscope was used to visualize the needle driver caught on the stent (Fig. 1E). APC was applied to the stent 0.8 L/min at 60 W, which fractured the interstices, and the stent retracted to its original place.

Gastric FCSEMS/LAMS cases

In case 4, the device mounted on a 2T scope (Olympus, Center Valley, Pa, USA) was caught in the proximal end of a LAMS (Boston Scientific) during an EDGE procedure (Fig. 1F). This occurred after safely deploying the LAMS and during the stent fixation process. In case 5, the over-the-scope endoscopic suturing device (Boston Scientific) mounted on a 2T scope (Olympus) became entangled in an 18-mm esophageal FCSEMS (Taewoong) during fixation of the stent across a narrowed gastrojejunal anastomosis. In both cases, there was adequate room for manipulation in the larger gastric lumen. Small scope movements including gentle rotation, in combination with the insertion of rat-tooth forceps through the second channel of the 2T endoscope, and pushing the stent away from the suturing device helped free the stents in both cases.

DISCUSSION

There are several known adverse events that can occur with the use of over-the-scope endoscopic suturing systems. Analyses of the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) indicate that some of the most common device-related adverse events include suture cinch failure (22.5%) and difficulty removing the device (15.6%).[5,6] Entrapment of the device is also described, although the most reported mechanism of entrapment or entanglement has been failure of tissue helix release (32.5%).[6] Here, we highlight a specific mechanism of entrapment related to how the device performs when interacting with another endoscopic tool—entanglement of the device needle with a fully covered stent (esophageal and LAMS). These cases highlight an intraprocedural adverse event not previously well reported, and it is important to recognize as a possibility.

In the needle driver open position, there is usually not enough space between the needle and the needle guard to allow the stent wire to get caught. In our described cases, this small space is the area of entrapment. We suspect the cause is multifactorial. In all 3 of our cases of entanglement in the esophageal lumen, the patients had radiation changes to the esophagus that likely reduced esophageal wall compliance and limited mobility. Device factors such as the use of a particularly flexible stent (TTS esophageal stent or LAMS) may also explain an increased likelihood for the stent to find the otherwise inaccessible area of entanglement.

When entrapment with the stent is recognized, several rescue maneuvers exist (Table 1). The partially fixed stent can be removed from the patient with the entrapped device attached, although moderate force is likely required, and there is potential for esophageal trauma including perforation. Once outside the patient, the handles were able to be fully opened and, when combined with forceful handle hyperextension, facilitated release of the stent. Although this was successful in one of our cases, with the knowledge that entanglement is possible and with the ability to recognize the signs (sudden limitation to maneuverability, inability to completely close the needle driver, stent movement with the closure of the needle driver, and inability to separate the needle driver from the stent), use of additional tools through the working channel of a second endoscope inserted side by side may optimize patient safety. The insertion of the second endoscope serves several roles including confirmation of the entanglement, identification of the area of entanglement, and facilitation of use of APC, which has become our preferred method of rescue. When more manipulation is possible, such as in a gastric lumen, this second endoscope may not be required. In our gastric cases, there was adequate room for maneuvering of the entangled device, and rat-tooth forceps inserted through the second channel were used to free the caught stent wire.

Given the known possibility of this adverse event, we recommend several procedural considerations to optimize patient safety and procedure efficacy. For all of our cases in which a stent is planned and stent fixation with over-the-scope suturing devices (especially for TTS stents) is a possibility, we recommend considering discussing general anesthesia with the anesthesia team. This was true for all 5 of the cases in this review, and we believe it optimized patient safety. As the suturing process is done under direct visualization, we did not need fluoroscopic guidance to identify nor rescue the entrapped device. However, at our institution, all cases of stent placement are done in fluoroscopy-capable rooms should fluoroscopy be necessary.

Despite adequate preparation, entanglement may continue to occur unless changes to the device design are considered. The area of entrapment is between the needle body and the needle guard. A more narrow or compact needle guard or a design that limits open space on the back of the needle guard may limit this adverse event. Alternatively, a design that allows for easier hyperextension of the needle driver and needle body temporarily beyond the needle guard may serve as a type of "emergency release" that could be a viable rescue option. In addition, modification of existing TTS stents, either in their proximal end design or the thickness of the stent wires, to prevent them from getting trapped in the over-the-scope suturing device would be another option.

In conclusion, entanglement of over-the-scope endoscopic suturing systems in endoscopic stents is a possible adverse event that may be due to a combination of patient and device factors. Patient safety can be optimized when planning to use these endoscopic devices together by advocating for general anesthesia and fluoroscopy back-up. Changes in device design to close the small entrapment area and changes in stent design that would not allow entrapment should be considered by device manufacturers. Meanwhile, endoscopists should be prepared to recognize this event and utilize rescue maneuvers including insertion of a second endoscope, use of APC, and rat-tooth forceps.

PATIENT CONSENT

The patients in this article have given written informed consent to publication of their case details.

DISCLOSURE

The following authors disclosed financial relationships: D. Loren: Consultant for Olympus and Boston Scientific. A. Kumar: Consultant for Olympus and Boston Scientific; paid speaker for Penta. All other authors disclosed no financial relationships.

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