Endoscopic removal of a weight-loss device with stoma closure using a tack-and-suture device

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BACKGROUND

The AspireAssist System (Aspire Bariatrics, King of Prussia, Penn, USA)[1,2] is an endoscopic weight loss modality approved by the U.S. Food and Drug Administration in 2016 for long-term use in individuals with a body mass index of 35 to 55 kg/m^2. The system facilitates partial drainage of postprandial stomach contents via a 26F percutaneous gastrostomy tube with a 15-cm fenestrated intragastric drainage catheter (A-tube). In April 2022, Aspire Bariatrics withdrew the AspireAssist device from the market, citing financial concerns. This withdrawal has necessitated the removal of all indwelling A-tubes. However, given the long-term retention of A-tubes and underlying obesity, patients are at heightened risk of developing a persistent gastrocutaneous fistula (GCF) if endoscopic closure is not complete.[3,4] The AspireAssist device is designed to remain in place for more than 1 year, increasing the likelihood of fistula tract epithelialization. Persistent GCF following A-tube explantation has been observed in approximately 1% to 2% of cases if removal occurs before 2 years and increases to approximately 30% to 40% of cases if removal occurs after 2 years, with nearly all cases of persistent GCF occurring in patients with A-tube implantation of 2 or more years' duration.[5,6]

Currently, there is no accepted standard for stoma closure at the time of tube removal. Conservative methods to promote GCF closure—including antibiotics, acid suppression, somatostatin analogues, prokinetics, temporary nasojejunal feeds, internal catheter drainage, and external silver nitrate—are prone to failure.[3,7] Endoscopic techniques include de-epithelialization of the fistula tract via argon plasma coagulation or agitation with a cytology brush,[6] hemostatic clips,[8] over-the-scope (OTS) clips,[4,9,10] OTS sutures,[11] banding,[7] and fibrin glue.[12] OTS clips have been reported to have a 40% to 50% success rate in treating chronic fistulae,[13] although fibrosis and induration of the fistula can result in difficulty adequately suctioning the tissue into the applicator cap. If these methods fail, surgical repair[4] or partial gastrectomy[3] can be pursued as salvage therapy. Removal of the tube with conversion to sleeve gastrectomy or Roux-en-Y bypass has also been reported.[14]

The X-Tack Endoscopic HeliX Tacking System (Apollo Endosurgery, Austin, Tex, USA) is a through-the-scope suturing device approved for the endoscopic closure of mucosal defects in the GI tract, including EMR defects, esophageal and gastric peroral myotomy mucostomy defects, and primary closure of iatrogenic gastrogastric fistula.[15] Closure of a chronic GCF using this device has not been reported.

This study was conducted following ethical principles outlined in the Declaration of Helsinki and was consistent with the Good Clinical Practices recommendation.

CASE PRESENTATION

A 49-year-old woman with hypertension, hyperlipidemia, GERD, and obesity (body mass index of 41 kg/m^2) presented 27 months after AspireAssist A-tube placement for elective removal. She lost 20.7% of total body weight (53.1% excess weight loss) during her 2-year treatment. Removal was prompted by the device's withdrawal from the U.S. market. The patient underwent outpatient upper endoscopy under general anesthesia. The A-tube was cut externally and removed endoscopically with the use of a snare (Fig. 1; Video 1, available online at www.videogie.org). Care was taken to snare the tube as proximally as possible to facilitate easier passage through the esophagus. The stoma was subsequently treated internally and circumferentially with argon plasma coagulation (40 W, 1.0 L/min). The X-Tack device was then advanced through the endoscope. Four tacks were placed in a figure-8 pattern around the stoma and cinched tight. The patient was discharged home and treated with 4 weeks of once-daily proton pump inhibitor therapy. Her stoma healed fully, without leakage or further adverse event, with complete closure confirmed at 3-, 6-, and 12-month follow-up visits.

To date, we have successfully removed and closed an additional 3 A-tube stoma tracts (average A-tube dwell time: 36 months; range, 24-59 months) with the X-Tack system.

Abbreviations: GCF, gastrocutaneous fistula; OTS, over-the-scope.

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True You Weight Loss, Cary, North Carolina, USA (1), Apollo Endoscopy, Duke University, Durham, North Carolina, USA (2).

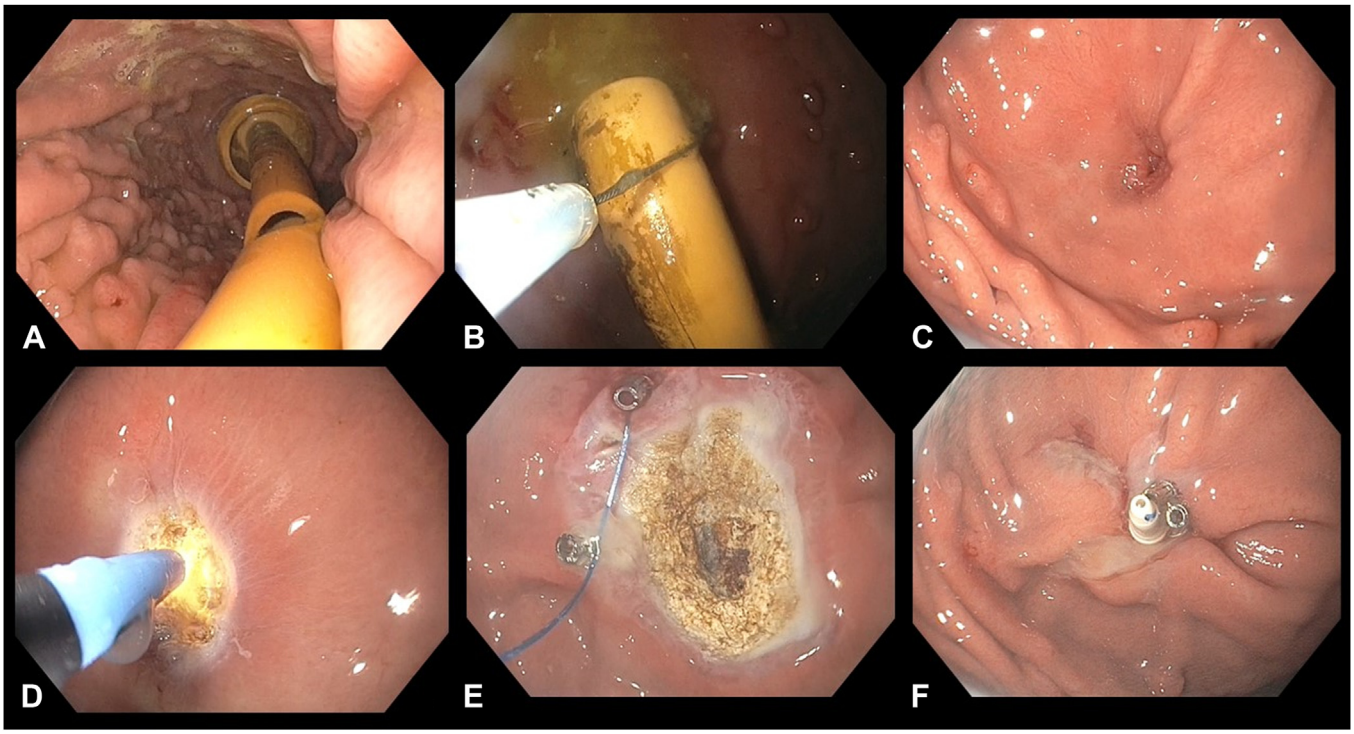

Figure 1. Endoscopic view of the AspireAssist tube removal and stoma closure. **A,** A-tube within anterior gastric wall. **B**, A-tube secured by endoscopic snare after device is cut externally. **C**, Stoma after A-tube extraction. **D**, Tissue ablation of stoma using argon plasma coagulation. **E**, X-Tack placement of tack 1 and tack 2. **F**, Stoma closure with X-Tack cinching.

CONCLUSION

Endoscopic mucosal ablation and tissue apposition with the X-Tack Endoscopic HeliX Tacking System resulted in successful closure of gastrostomy tube stoma after AspireAssist explantation. This approach should be considered for patients with indwelling AspireAssist devices in light of market withdrawal. Considering the high rate of persistent GCF, we recommend prophylactic endoscopic closure for patients with A-tubes of 2 or more years' duration.

DISCLOSURE

Dr Maselli is a consultant for Apollo Endosurgery. Dr McGowan is a consultant for Apollo Endosurgery. The other authors did not disclose any financial relationships.

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