Use of a cardiac septal occluder in the treatment of a chronic GI fistula: What should we know before off-label use in the GI tract?

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A GI fistula is defined as an abnormal communication between 2 epithelialized surfaces, which can be characterized as internal (between 2 abdominal organs) or external (between an abdominal organ and the body surface). The most common causes of GI fistulas include postoperative adverse events, longstanding untreated leaks, chronic inflammatory conditions, malignancy, and radiation therapy.[1,2]

Chronic fistulas can be more challenging to close than acute GI leaks because of the development of an established epithelial tract near unhealthy tissue. De-epithelization of the tract with argon plasma coagulation, brushes, or other devices, is often required.[1,2] In many cases, endoscopic therapy can be used to interrupt or drain the flow of luminal contents through the defect. Various endoscopic techniques have been developed for the treatment of chronic fistulas, including through-the-scope clips, cap-mounted clips, covered self-expandable metal stents (CSEMSs), tissue sealants, endoscopic sutures, endoscopic internal drainage with double pigtails, and endoscopic vacuum therapy (EVT).[3-8] However, several characteristics of the defect must be considered to optimize the outcomes, including defect size, shape of margin, viability of the surrounding tissue, and location of the defect.[1,2]

Outcomes of the aforementioned closure techniques have previously been described. For example, closure devices such as hemostatic clips, cap-mounted clips, and suturing can be used with satisfactory immediate results, but late recurrence is frequent.[3,6] In acute leaks, CSEMSs show satisfactory results; however, in chronic leaks and fistulas, this is not an effective technique because of an established epithelial tract.[4] Internal drainage, either with plastic double-pigtail stents or EVT, has been shown to provide effective infection control and successful fistula closure. However, these techniques can require multiple endoscopic sessions.[7,8]

Given the variability in successful closure with these techniques, and the higher adverse event rates associated with surgical intervention, physicians continue to investigate other endoscopic options for fistula closure. An emerging technique is the off-label use of cardiac septal defect occluders (CSDOs).[1-3,9,10] Some case reports have demonstrated a high success rate in closure of chronic fistulas through the use of different sizes of CSDOs.[9,10] Therefore, although data are limited, CSDOs appear to be a new therapeutic option in the endoscopic treatment of chronic GI fistulas.

CASE REPORT

We present the case of a 62-year-old man with a longstanding history of GERD. He underwent a Nissen

Figure 1. External cutaneous fistula orifice.

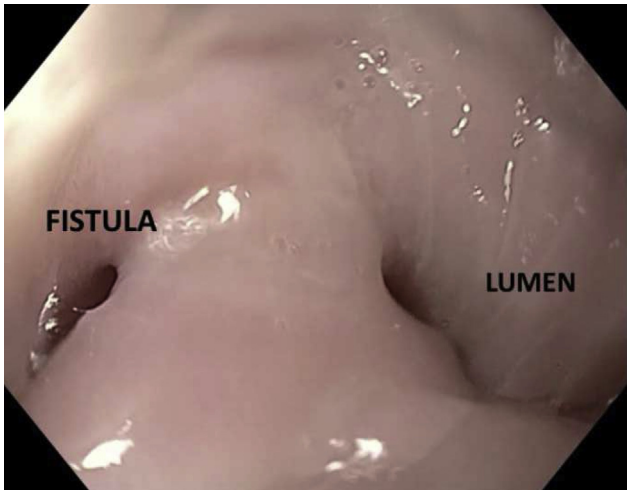

Figure 2. Endoscopic visualization of the esophageal fistula.

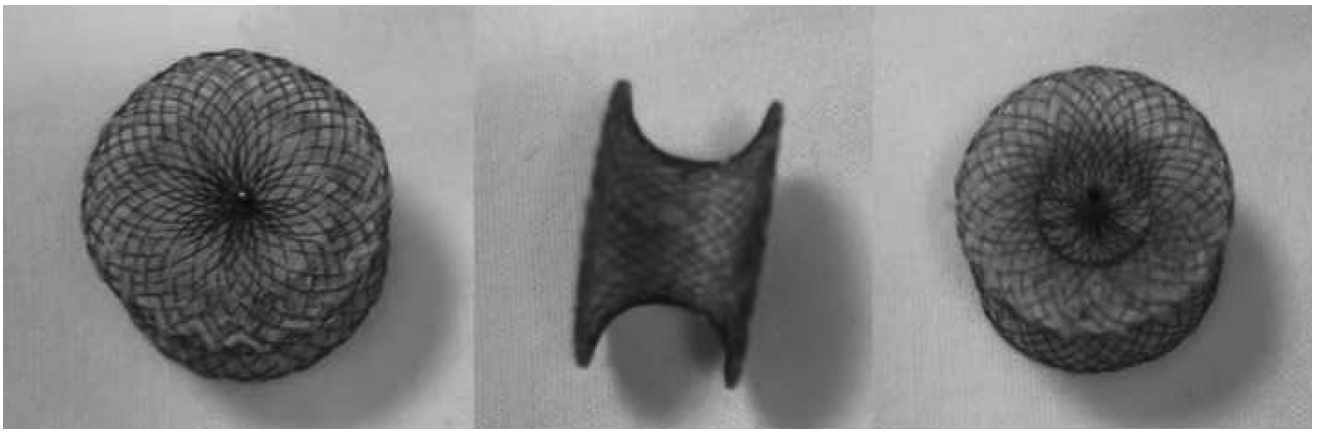

Figure 3. Ventricular septal defect occluder device.

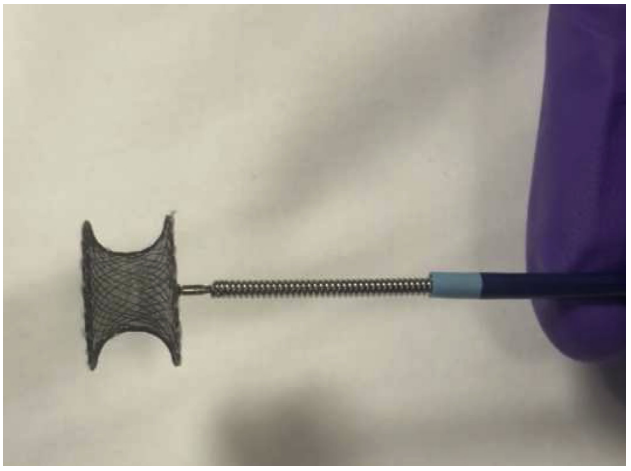

Figure 4. Ventricular septal defect occluder device attached to delivery system.

Figure 5. Introduction of the delivery system into the cutaneous orifice.

fundoplication, with a postoperative course complicated by an esophageal-cutaneous fistula (Fig. 1).

On EGD he was noted to have a persistent fistula, with a thin sinus tract approximately 2 to 3 mm in diameter (Fig. 2). To close the fistula, we started with de-epithelialization of the fistula tract using a cytology brush and several balloon sweeps. Next, a fistula closure plug was inserted, and fibrin sealant was injected, followed by placement of an esophageal fully covered SEMS, which was secured with endoscopic suturing. One month later, he returned for follow-up EGD. The esophageal stent was removed without adverse event. It was noted that the previous fistula site appeared to be healing well, and the remnant fistula closure plug was intact.

Unfortunately, approximately 45 days after his follow-up endoscopy, he experienced symptoms of fistula recurrence. Therefore, he underwent repeated therapeutic endoscopy, which again demonstrated a patent esophageal-cutaneous fistula. Given the failure with prior endoscopic techniques, the Amplatzer muscular ventricular septal defect occluder (AGA Medical Corporation, Plymouth, Minn, USA) (Fig. 3) was used (Video 1, available online at www.VideoGIE.org).

We performed this new endoscopic closure technique in 7 steps:

1. Identified the precise location of both the internal and external orifices of the fistula tract.
2. Endoscopically passed a guidewire from the esophagus through to the skin.
3. Performed tissue disruption of the fistula tract with balloon sweeping.
4. Externally introduced the delivery system (Fig. 4) with the CSDO through the skin (Fig. 5).

Figure 6. Endoscopic visualization of the cardiac septal defect occluder device closing the defect.

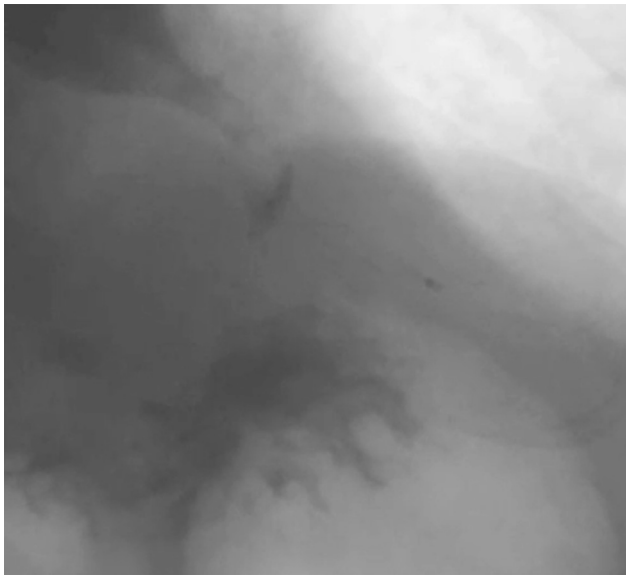

Figure 7. Fluoroscopic image of the cardiac septal defect occluder device after deployment.

5. Confirmed opening of the first flange in the esophageal lumen by endoscopic visualization (Fig. 6).
6. Confirmed opening of the second flange in the fistula tract by fluoroscopic guidance (Fig. 7).
7. Performed a leak test with water-soluble contrast material under fluoroscopic visualization (Fig. 8).

This procedure was technically successful and without adverse events. The patient had no symptoms after the procedure. The patient was seen in follow-up 2 months after deployment of the CSDO, and he was tolerating an oral diet well, without recurrence of symptoms. A barium swallow with oral contrast material showed no leakage (Fig. 9).

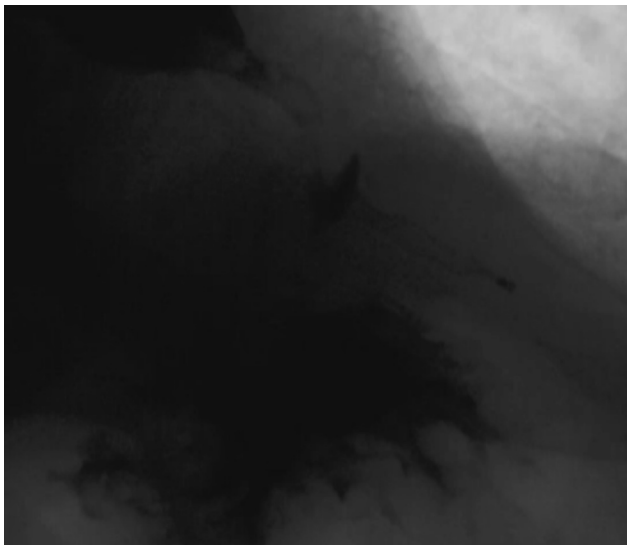

Figure 8. Fluoroscopic image demonstrating no extravasation of contrast material through the cardiac septal defect occluder device.

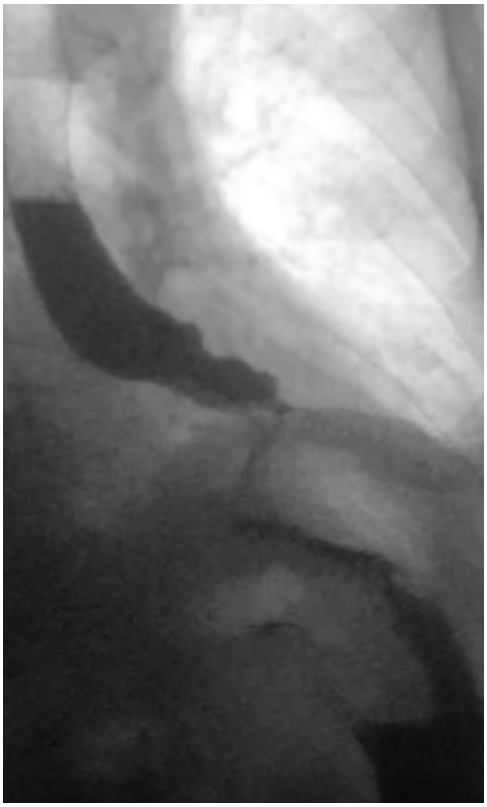

Figure 9. Follow-up barium swallow demonstrating no extravasation of contrast material after oral ingestion.

CONCLUSION

Use of the cardiac septal defect occluder appears technically feasible and safe in the treatment of chronic GI fistula. This technique may offer an alternative for patients in whom traditional endoscopic closure techniques have

been unsuccessful. Prospective studies may better clarify the long-term outcomes and optimal patient selection.

DISCLOSURE

Dr Thompson is a consultant for Boston Scientific. All other authors disclosed no financial relationships relevant to this publication.

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Abbreviations: CSDO, cardiac septal defect occluder; CSEMS, covered self-expandable metal stent; EVT, endoscopic vacuum therapy.

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