Efficacy of the cardiac septal occluder in the treatment of post-bariatric surgery leaks and fistulas

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Background: Endoscopy has evolved to become first-line therapy for the treatment of post-bariatric leaks; however, many sessions are often required with variable success rates. Due to these limitations, the use of the cardiac septal defect occluder (CSDO) has recently been reported in this population.

Methods: The study population was a multicenter retrospective series of patients with post-bariatric surgical leaks who underwent treatment with CSDO placement. Data on the type of surgery, previous treatment details, fistula dimensions, success rate, and adverse events were collected. Leaks were grouped according to the International Sleeve Gastrectomy Expert Panel Consensus. Outcomes included technical and clinical success and safety of the CSDO. Regression analysis was performed to determine the predictors of response.

Results: Forty-three patients with leaks were included (31 sleeve gastrectomy and 12 Roux-en-Y gastric bypass). They were divided into acute (n = 3), early (n = 5), late (n = 23), and chronic (n = 12). Forty patients had failed previous endoscopic treatment and 3 patients had CSDO as the primary treatment. Median follow-up was 34 weeks. Technical success was achieved in all patients and clinical success in 39 patients (90.7%). All chronic, late, and early leaks were successfully closed, except one undrained late leak. The 5 patients with early leaks had an initial satisfactory response, but within 30 days, drainage recurred. The CSDOs were removed and replaced with larger-diameter devices leading to permanent defect closure. Acute leaks were not successfully closed in all 3 patients. Regression analysis showed that chronicity and previous treatment were associated with fistula closure; success rates for late/chronic leaks versus acute/early leaks were 97.1% and 62.5%, respectively ($P = .0023$).

Conclusion: This observational study found that the CSDO had a high efficacy rate in patients with non-acute leaks, with no adverse events. All early, late, and chronic leaks were successfully closed, except for one undrained late leak. However, early leaks required a second placement of a larger CSDO in all cases. These results suggest that the CSDO should be considered for non-acute fistula and that traditional closure methods are likely preferred in the acute and early settings. (Gastrointest Endosc 2019;89:671-9.)

Abbreviations: ASD, atrial septal defect; CSDO, cardiac septal defect occluder; EVT, endoscopic vacuum therapy; RYGB, Roux-en-Y gastric bypass; SEMS, self-expandable metal stent; SG, sleeve gastrectomy.

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INTRODUCTION

Obesity is a worldwide pandemic, and bariatric surgery is the most effective treatment modality. Despite satisfactory clinical results associated with surgery, the number of adverse events after bariatric surgery has increased due to broad adoption of the procedures.[1,2] Leaks are the most common serious adverse event associated with bariatric surgery, with rates varying from 0.4% to 5.6% after Roux-en-Y gastric bypass (RYGB) and 1.9% to 5.3% after laparoscopic sleeve gastrectomy (SG), with increasing rates after revision surgeries.[3-7] Leaks are often located at the suture and anastomosis line and are defined as a communication between intra- and extraluminal compartments due to a defect in the GI wall.[8,9] Fistulas usually occur due to an untreated long-term leak and can be divided into either internal (between an abdominal organ and another organ) or external (extending from an abdominal organ to the skin surface). Chronic fistulas involve an epithelialized tract that is typically surrounded by unhealthy tissue, making this one of the most challenging adverse events to treat endoscopically.[1,8,9]

Although reoperation is still frequently performed, high adverse event rates with increased morbidity and mortality have been reported.[7,10,11] The variety of endoscopic approaches and devices, including closing, covering, and drainage methods is transforming endoscopy into a first-line approach for the treatment of these conditions. Closing and covering endoscopic therapies include clips, cap-mounted clips, self-expandable metal stents (SEMSs), tissue sealants, and endoscopic suturing. Endoscopic drainage therapies include double pigtail stents, endoscopic vacuum therapy (EVT), and septotomy followed by achalasia balloon dilation. However, the literature shows that many sessions are often required with variable success rates.[12-19] Due to limitations of the current therapeutic approaches in the treatment of GI fistulas, off-label use of the cardiac septal defect occluder (CSDO), which is intended for percutaneous closure of atrial or ventricular septal defects, has been reported. However, the existing literature currently consists of only case reports.[20-24] This is the first observational study analyzing the results of the use of CSDO in post-bariatric leaks and fistulas.

MATERIALS AND METHODS

This is a retrospective multicenter analysis of prospectively collected data from 9 centers (Hospital das Clínicas Caracas, Hospital das Clínicas da Universidade de São Paulo, Brigham and Women's Hospital, Miami Cancer Institute, Rutgers Robert Wood Johnson, Hospital Reina Sofia, Policlínica Metropolitana, Centro Médico de Caracas, and Joe DiMaggio Children's Hospital), including 43 consecutive patients undergoing endoscopic treatment with the CSDO for post-bariatric surgery leaks and fistulas between November 2012 and July 2018. The inclusion criteria were patients with a leak or fistula diagnosed by clinical history and imaging examinations such as CT with contrast or upper GI studies including contrast swallow or upper GI endoscopy.

Ethical concerns

Institutional Review Board approval for retrospective analysis was obtained for each center before collecting data for this study. All patients were seen in the clinic before the procedure to discuss the risks, benefits, and alternatives to the off-label use of CSDO. The available literature and our limited experience with the procedure were discussed with patients at this visit. Written informed consent from each center was obtained from all patients before the procedures.

Outcomes

The outcomes of this study were to analyze the technical success, clinical success, and safety profile of the CSDO in post-bariatric surgery leak and fistula management. Clinical success was defined as complete and permanent resolution of abdominal or thoracic drainage with imaging documentation (contrast swallow) of closure after at least 2 months.

Cardiac septal occluder

The Amplatzer CSDO (St. Jude Medical, Plymouth, Minn) is a shape-memory, self-expanding double-disc ("double umbrella") closure device. It is made of nitinol and interwoven polyester, which promotes occlusion and tissue in-growth (Fig. 1). A thick waist allows the stent to adjust to variable fistula diameters, providing a tight seal. It can be easily recaptured and redeployed for optimal placement. There are 2 types of CSDO, the atrial septal defect (ASD) closure device and the ventricular septal defect closure device. Both devices are commercialized in different sizes, including disc diameter, waist length, and waist diameter. The characteristics of each are summarized in Table 1 and Figure 1.

The delivery system sheath size varies from 5F to 12F with a tip angle of 45° and 180°. The usable length varies from 60 cm to 80 cm.

Procedure

First, a diagnostic upper GI endoscopy was performed. The size of the Amplatzer CSDO was chosen according to the size of the leak or fistula orifice. This was estimated by the ability to advance an endoscope through the orifice using either a 5.8 mm or a 9.8 mm endoscope. The defects were divided into smaller than 5.8 mm, between 5.8 mm and 9.8 mm, and larger than 9.8 mm. The CSDO with a diameter at least 50% larger than the orifice was selected based on interventional cardiologist recommendations as used for cardiac septal defects. An exception was made for external fistula with short tracks where a smaller flange

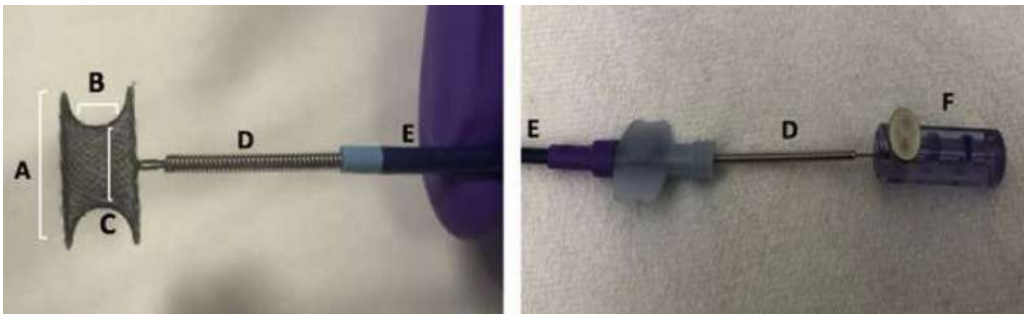

Figure 1. Description of the cardiac septal defect occluder and the delivery system. **A,** Disc diameter; **B**, waist length; **C**, device size (waist diameter); **D**, delivery cable; **E**, sheath; **F**, plastic vise.

diameter and narrower waist may be needed to prevent the stent from emerging from the skin. The procedure began with passage of a guidewire from the GI lumen through the fistula orifice or in some cases, when GI access was difficult, the wire was passed from a cutaneous orifice to the GI lumen. Then, the CSDO was introduced over the guidewire using a delivery sheath. The usable length of the longest delivery system is 80 cm and cannot be used through most available endoscopes. The stent comes separate from the delivery system, allowing the CSDO to be back loaded into an adapted endoscopic biliary catheter (10F or 8.5F or 7F) in order to provide enough length to be deployed through a 2.8 mm or 3.2 mm working channel endoscope. This was done in several cases by placing pediatric biopsy forceps down a large ERCP catheter and grabbing the stent to back load it into the distal portion of the catheter. This allowed the stent to be deployed and recaptured as needed though a standard large-channel endoscope (Fig. 2). During the procedure, the distal flange was released either into the GI lumen or the fistula tract depending on whether the catheter was being advanced from the skin or the endoscope. Then, after adequate position was confirmed, the proximal flange was deployed. The entire procedure was performed under endoscopic and fluoroscopic guidance. A post-procedure oral water-soluble contrast study was done immediately after the procedure. Most procedures were performed with the patient under general anesthesia; however, some procedures were performed with the patient under conscious sedation. Patients did not need hospitalization after the procedure and were discharged depending on their clinical condition. Restricted oral intake was required for 24 hours after the procedure, advancing to a full liquid diet at 3 days, followed by 3 days of a soft diet. Finally, after 1 week, patients were advanced to a regular diet. Proton pump inhibitors were prescribed for 30 days after the procedure. After 4 to 6 weeks, a contrast swallow and an upper GI endoscopy were performed.

Statistical analysis

For the qualitative analysis, technical success, clinical success, and adverse events were calculated. The averages and standard deviations were calculated using Microsoft Excel (Microsoft, Redmond, Wash). In this analysis, leaks were grouped according to the International Sleeve Gastrectomy Expert Panel Consensus[25] into acute (postoperative days 1-7), early (1-6 weeks), late (after 6 weeks), and chronic (>12 weeks).

For the quantitative analysis, a Student t test (for continuous variables) and a chi-squared test (for categorical variables) were used to find an association between successful fistula closure and several factors, including age, type of bariatric surgery, period of the fistula, size of the fistula orifice, and previous treatment. In this part of the study, leak duration was dichotomized into acute/early (<6 weeks) and late/chronic (>6 weeks). A multivariable logistic regression analysis was then performed to assess predictors of successful closure. Given the number of outcomes, 4 predictors were put into the model, and these were chosen a priori. These predictors included age, sex, duration of fistula, and fistula size. Given the collinearity between fistula duration and prior treatment, only the duration was put into the model. Statistical analysis was performed using SAS version 9.2 software (SAS Institute, Cary, NC).

TABLE 1. Description of cardiac septal defect occluders

Characteristics	ASD	VSD
Disc diameter (mm)		9-26
Right atrial disc	12-48	
Left atrial disc	16-54	
Waist length (mm)	3-4	7
Device size/waist diameter (mm)	4-38	4-18
Delivery system (Fr)	6-12	5-9

ASD, Atrial septal defect occluder; *VSD*, ventricular septal defect occluder.

RESULTS

Qualitative analysis

Forty-three patients treated with CSDO for post-bariatric surgery leaks were included in this analysis, including 15 men (34.9%) and 28 women (65.1%), with

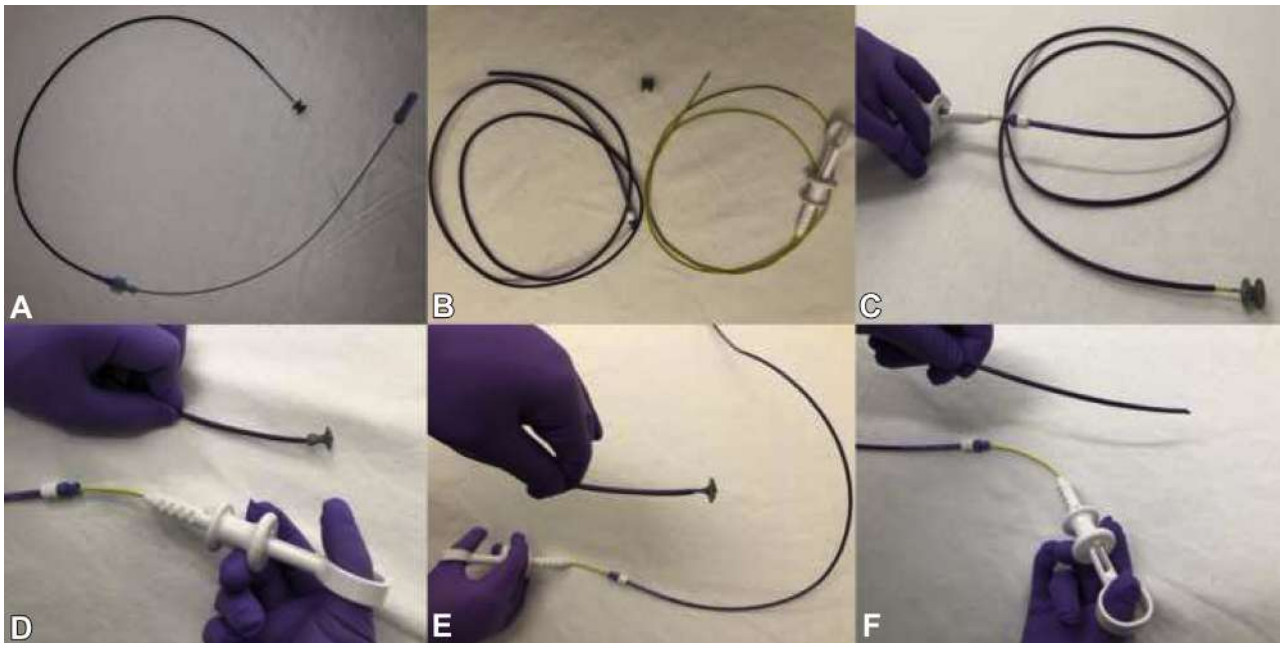

Figure 2. CSDO back loaded into a modified endoscopic biliary catheter. **A**, CSDO attached to the conventional 60-cm-length delivery system. **B**, Devices used in the modified delivery system (biliary catheter, pediatric forceps biopsy). **C**, CSDO attached to the modified delivery system. **D**, Biliary catheter back loading the proximal flange. **E**, Biliary catheter back loading the distal flange **F**, CSDO inside the modified delivery system. *CSDO*, Cardiac septal defect occluder.

an average age of 39 years (SD, 12 years). Most of the fistulas occurred after SG (72.1%) (Fig. 3), with 12 (27.9%) occurring after RYGB (Fig. 4). Thirty-eight fistulas were gastrocutaneous and 5 were gastrorespiratory (3 gastropleural and 2 gastrobronchial). The fistula size was divided into 3 groups: <5.8 mm (n = 14), 5.8 mm to 9.8 mm (n = 10), and >9.8 mm (n = 19). Conventional treatments had failed in most of the patients, including SEMSs, cap-mounted clips, enteral feeding tubes, jejunostomy, and gastrostomy in the excluded stomach. Just 3 patients (6.9%) had not undergone previous attempts at fistula closure.

Technical success confirmed by an oral water-soluble contrast study was achieved in all cases (100%). Of the 43 leaks, 39 were clinically successful with no residual drainage (90.7%) and 4 failed. The 5 patients with early leaks initially had a good response, but drainage recurred within 30 days. The CSDO were removed and replaced with a larger-diameter device, leading to permanent defect closure. Of the 4 failed cases, 3 were acute leaks (representing all the acute cases) and 1 was a late leak. This particular case was a gastropleural leak associated with an undrained cavity. A contrast agent was injected endoscopically to identify the fistula tract, and the pleural space could not be drained of residual contrast. The patient subsequently deteriorated with persistent fever and leucocytosis. After 12 days, the CSDO was removed endoscopically, and the referring surgeon decided to perform total gastrectomy. In the 3 acute leaks that failed CSDO treatment, an adequate initial response was observed. However, the cutaneous drainage reappeared at 72 hours. In these patients, upper endoscopy showed enlargement of the leak orifice. In all cases, the CSDOs were safely removed using forceps biopsy or a snare, and a SEMS was placed for a period of 6 weeks with complete resolution of the acute leaks.

The mean follow-up was 34.30 weeks (SD, 23.18 weeks). There were no adverse events and no deaths related to the use of CSDO. The clinical and demographic features are summarized in Table 2 and Supplementary Table 1, available online at www.giejournal.org.

Quantitative analysis

Univariable regression analysis showed that chronicity and previous treatment were associated with successful fistula closure ($P < .0001$) (Table 3). Specifically, the successful closure rates of acute/early versus late/chronic leaks were 62.5% versus 97.1%, respectively ($P = .0023$). The success rate of the CSDO in patients with previous treatment and patients without previous treatment were 97.5% versus 0%, respectively ($P < .0001$).

In the multivariable logistic regression analysis, late/chronic leaks remained a significant predictor of success with an odds ratio of 3.99 (compared with acute/early) with P value of .035 after controlling for age, sex, and fistula size. Age, sex, and fistula size were not significant predictors of success.

DISCUSSION

Endoscopic closure of post-bariatric surgery leaks represents a major advancement in the management of this

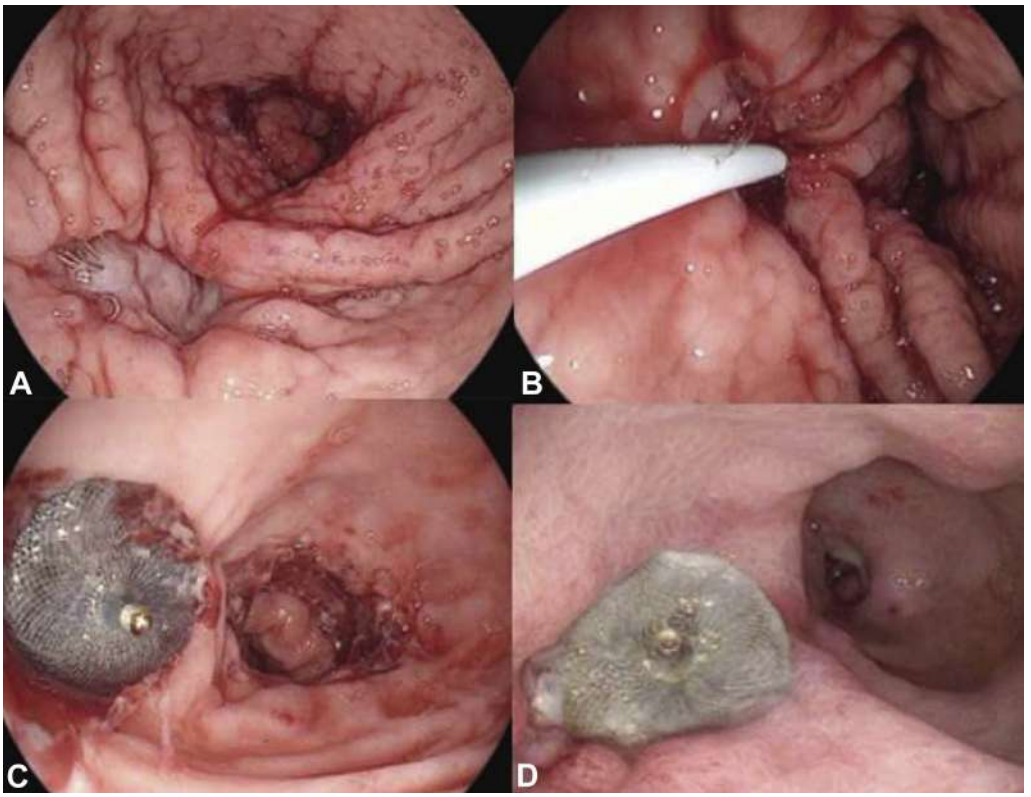

Figure 3. **A**, Endoscopic image of a fistula after sleeve gastrectomy; **B**, introduction of the adapted CSDO delivery system into the fistula tract; **C**, CSDO deployed occluding the fistula orifice; **D**, 2-month follow-up showing the CSDO with tissue in-growth. *CSDO*, Cardiac septal defect occluder.

challenge condition. SG leaks are becoming more common and typically occur along the superior staple line just below the gastroesophageal junction. RYGB are also of concern and may appear in several sites such as the gastric pouch, gastrojejunal anastomosis, the excluded stomach, and rarely in the blind portion of the Roux limb or the jejunojejunal anastomosis.[1,4,26] Precise diagnosis of the fistula site, leak duration, understanding the surgical anatomy, and an appropriate endoscopic approach to the fistula is essential in the effective management of this condition. Some basic yet important principles include drainage of undrained cavities and collections before attempted closure. It is also important to treat distal obstruction and to remove foreign material from the leak site such as staples, sutures, and external drains.[1,4,5,26] When using conventional endoscopic closure techniques, several features must be considered to optimize outcomes, including defect size, shape of the defect margin, viability of the surrounding tissue, and location of the fistula orifice.[27,28] However, even with this information and the correct choice of the device or technique, the literature shows variable success rates of fistula closure.

Different endoscopic treatments including covering, closing, plugging, and draining can be performed depending on the duration and location of the leak.[9] In cases of acute and early leaks, suturing, clips, and stents can be used. Among these devices, stents have been reported to have higher success rates. A recent meta-analysis showed success rates of 73% for SG leaks and 76.1% for gastric pouch and staple line leaks after RYGB.[18] In one multicenter retrospective study, endoscopic therapy achieved healing in 81 patients overall (73.6%), but the probability of successful endoscopic therapy decreased markedly with time, from 76.4 % at 1 month to 48.5 % at 6 months.[29] For late and chronic fistulas, endoscopic internal drainage leads to satisfactory results with pigtails, endoscopic vacuum therapy, or septotomy followed by achalasia balloon dilation. In addition, endoscopic internal drainage allows the introduction of the endoscope into the enclosed cavity to wash the contents.[9] Mahadev et al[30] showed symptom resolution in all patients who underwent septotomy after SG-associated collections. Intraprocedural bleeding and persistence of the cavity were noted in 33% of cases. Endoscopic internal drainage with pigtails has been used for treatment of fistulas, with satisfactory results in up to 84% of cases; however, more than 2 endoscopies are typically needed to complete the treatment.[19] EVT is another effective modality in the treatment of wall defects, with success rate up to 94.2%; however, this typically requires inpatient stays and multiple procedures, and deaths due to severe hemorrhage with this technique have been reported.[16,31,32]

Properties of the CSDO and early results reported in the literature suggest it may be useful in treating fistulas that

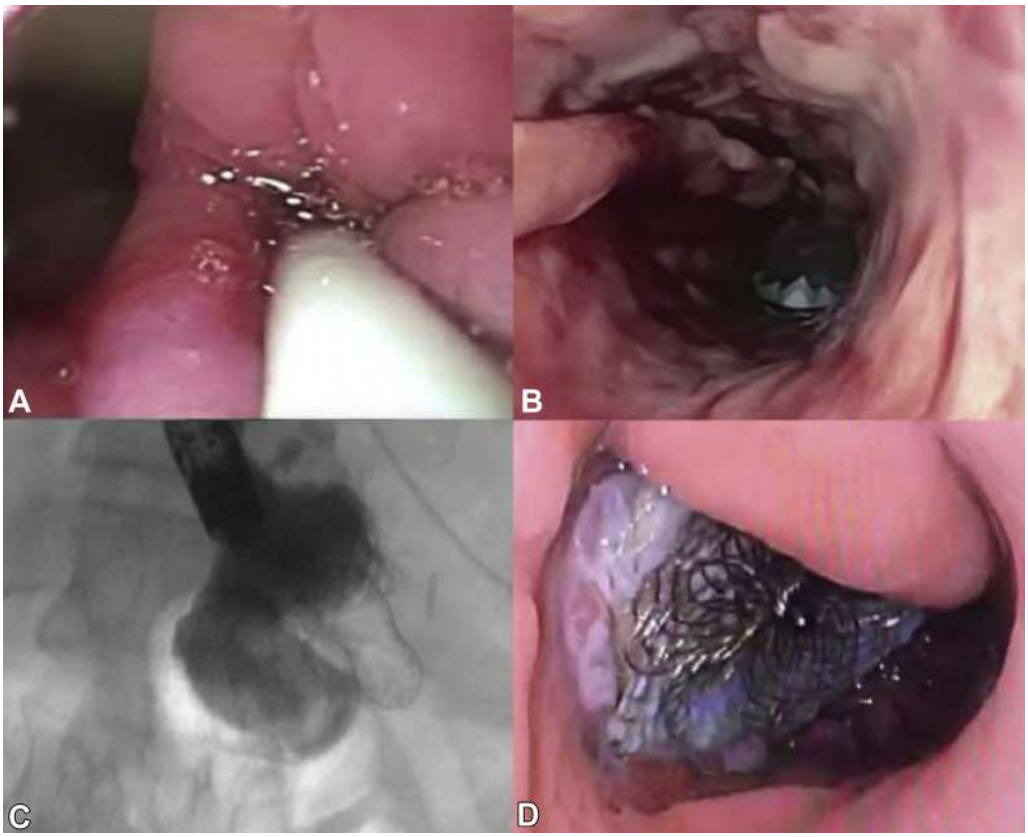

Figure 4. A, Gastric bypass with a gastrocutaneous fistula and an enteral feeding tube. **B**, Endoscope showing the epithelized tract of the fistula and an external drain. **C**, Fluoroscopy image of the CSDO with contrast injection showing occlusion of the fistula orifice and no leakage to the fistula tract. **D**, Image of the CSDO 1 month after placement into the gastrocutaneous fistula after RYGB. *CSDO*, Cardiac septal defect occluder; *RYGB*, Roux-en-Y gastric bypass.

are otherwise difficult to manage with available endoscopic techniques. The nitinol structure with interwoven polyester liner is available in multiple waist and disk sizes and is thought to promote tissue in-growth while sealing the fistula tract. These features may allow the device to better address fistulas with irregular margins, epithelialized tracts, and those in edematous or scarred tissue, which are less amenable to clipping, suturing, or stent placement.[20-24,33] Other technical advantages of the CSDO include the ability to reposition the device many times before final deployment. Furthermore, if deployment has been completed but the endoscopist is not satisfied with its position, the device can be removed endoscopically with standard endoscopic devices, reassembled, and placed again.

A total of 20 case reports (23 fistulas) have been published illustrating the use of the Amplatzer CSDO in benign fistulas, with a technical success rate of 100% similar to our results.[20-24,33-47] In some of these case reports, CSDOs were used in combination with other endoscopic approaches with similar results.[21,38,44] Of the 23 fistulas, including esophageal-respiratory, gastrocutaneous, gastrocolic, and other locations, 18 had successful closure, and no deaths were related to CSDO use. Three of these cases were performed for bariatric surgical leaks that did not respond to conventional endoscopic approaches, including 2 chronic leaks and 1 early leak, with 100% clinical success, similar to the results of our study.[20,22,24]

Other studies have used related devices, with similar results. Two studies[48,49] used a similar ASD closure device (Gore, Flagstaff, Ariz) in patients with tracheal-esophageal fistulas with successful closure. The Amplatzer vascular plug is made of an uncovered nitinol mesh and is indicated to embolize blood vessels; however, it has also been used in GI fistula closure.[50-53] Three case reports[50,51,53] demonstrated its efficacy in the closure of tracheal-respiratory fistulas with 100% success rate. However, in a separate report, the device was unable to close a rectovaginal fistula.[52]

In our study, we analyzed the use of CSDO in post-bariatric surgery leaks with 100% technical success, 90.7% clinical success, and no adverse events related to its off-label use. The CSDO achieved clinical success in all early, late, and chronic leaks, except for 1 undrained late fistula. However, the device failed in all acute leaks, with fistula enlargement in some of these cases. As the only non-acute failed fistula closure was associated with an adjacent undrained cavity, we strongly recommend adequate drainage of the leak cavity before placing CSDO.

All 5 early leaks responded well to CSDO placement initially; however, drainage recurred within 30 days. In all

TABLE 2. Clinical and demographic features

Age (years), mean (±SD)	**39 (±12)**
Sex, n (%)	
Male	15 (34.9)
Female	28 (65.1)
Type of bariatric surgery, n (%)	
Sleeve gastrectomy	31 (72.1)
Gastric bypass	12 (27.9)
Time from surgery to CSDO placement, n (%)	
Acute	3 (6.9)
Early	5 (11.6)
Late	23 (53.5)
Chronic	12 (27.9)
Tract path, n (%)	
Gastrocutaneous	38 (88.4)
Gastropleural	3 (6.9)
Gastrobronchial	2 (4.6)
Size, n (%)	
<5.8 mm	14 (32.5)
5.8-9.8 mm	10 (23.2)
>9.8 mm	19 (44.2)
Previous treatment, n (%)	
None	3 (6.9)
SEMS	7 (16.2)
SEMS + ETF	26 (60.4)
SEMS + gastrostomy	2 (4.6)
OTSC	3 (6.9)
Jejunostomy	1 (2.3)
Enteral feeding tube	1 (2.3)
Success closure, n (%)	
Yes	39 (90.7)
No	4 (9.3)
Follow-up (weeks), mean (±SD)	34.30 (± 23.18)

SD, Standard deviation; *CSDO*, cardiac septal defect occluder; *SEMS*, self-expandable metal stent; *ETF*, enteral tube feeding; *OTSC*, over-the-scope clip.

TABLE 3. Predictors of successful closure

Characteristic	*P* value
Age	.49
Sex	.51
Surgery type	.89
Chronicity (acute/early/late/chronic)	<.0001
Fistula size (small/medium/large)	.68
Previous treatment	<.0001

cases, the device was removed and replaced with a larger diameter CSDO, leading to permanent defect closure. In the statistical analysis, late and chronic fistulas as well as previous treatment were independent factors associated with successful closure. These results were confirmed in the multivariable logistic regression analysis, suggesting that it may be best to attempt traditional closure methods for leaks in the acute and early settings and reserve CSDO placement for late and chronic fistulas. In acute and early settings, SEMSs are traditionally recommended. These are thought to work by covering the orifice of the leak and also treating distal stenosis.[18,26,54] The stent migration rate is approximately 30%; thus, physicians should consider proximal stent fixation, either with endoscopic suturing or with the nasal bridle technique.[3,18,55-57] In the case of extraluminal collections, drainage is needed, and when feasible, endoscopic internal drainage either with the introduction of double pigtails or EVT is recommended.[9,12,16,19,54,58,59]

This study has some limitations that should be discussed. First, this is a retrospective analysis where patients were not randomly selected, and second, the type of CSDO and delivery system were selected based on endoscopist judgment not on prespecified criteria. In addition, many endoscopists did not have experience with the device and were on their learning curves during the study. This experience may improve with time with better technique and patient selection criteria. Also, the follow-up programs differed among the 9 centers.

As this is the first observational study regarding off-label use of the CSDO device, there are some questions that remain, including which CSDO device is ideal for specific size and length of fistula, if the device will lead to late adverse events, and if the device is equally effective in other conditions such as malignant fistulas. Li et al,[60] using a similar CSDO (ASD) (Lifetech Scientific Corporation, China) in 2 malignant fistulas, reported initial successful closure; however, the 2 malignant fistulas recanalized. Possibly, the pathophysiology of malignant defects is different than those with a mature epithelized fistula tract and adequate drainage.

In summary, the CSDO is thought to promote fistula closure by occluding the fistula tract and stimulating tissue in-growth. This analysis found the CSDO to have high efficacy rates in patients with non-acute leaks, with no adverse events. All cases of early, late, and chronic leaks were successful, except for 1 undrained late leak. However, early leaks required a second placement of a larger CSDO in all cases. These results suggest that the CSDO should be considered for non-acute fistulas and that traditional closure methods are likely preferred in the acute and early settings.

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SUPPLEMENTARY TABLE 1. Characteristics of 43 patients included in the study

Patient	Age (years)	Sex	Surgery type	Leak classification	Defect diameter	Tract path	Previous treatment	Defect closure	Follow-up
1	27	Female	SG	Chronic	<5.8 mm	GC	SEMS + ETF	Yes	72
2	49	Female	SG	Chronic	<5.8 mm	GP	Jejunostomy	Yes	59
3	42	Male	SG	Chronic	5.8-9.8 mm	GC	SEMS + ETF	Yes	56
4	46	Female	GBP	Chronic	<5.8 mm	GC	SEMS + gastrostomy	Yes	30
5	34	Male	SG	Chronic	<5.8 mm	GC	SEMS + ETF	Yes	48
6	51	Female	SG	Late	5.8-9.8 mm	GC	SEMS + ETF	Yes	49
7	36	Male	SG	Acute	>9.8 mm	GC	None	No	59
8	35	Male	SG	Late	5.8-9.8 mm	GC	SEMS + ETF	Yes	47
9	23	Female	SG	Acute	<5.8 mm	GC	None	No	6
10	44	Female	SG	Late	<5.8 mm	GC	SEMS + ETF	Yes	40
11	40	Male	SG	Late	>9.8 mm	GC	SEMS + ETF	Yes	45
12	21	Female	SG	Late	>9.8 mm	GB	SEMS + ETF	Yes	44
13	26	Female	SG	Late	5.8-9.8 mm	GP	SEMS + ETF	No	39
14	34	Female	SG	Late	>9.8 mm	GC	SEMS + ETF	Yes	58
15	31	Female	SG	Late	>9.8 mm	GC	SEMS + ETF	Yes	39
16	38	Male	GBP	Acute	<5.8 mm	GC	None	No	58
17	48	Female	SG	Late	>9.8 mm	GC	SEMS + ETF	Yes	30
18	25	Male	SG	Late	>9.8 mm	GC	SEMS + ETF	Yes	27
19	24	Male	GBP	Chronic	<5.8 mm	GP	SEMS + Gastrostomy	Yes	21
20	50	Male	GBP	Chronic	<5.8 mm	GC	SEMS	Yes	45
21	50	Male	GBP	Late	>9.8 mm	GC	SEMS	Yes	20
22	78	Female	GBP	Late	5.8-9.8 mm	GC	SEMS	Yes	8
23	35	Female	SG	Late	<5.8 mm	GC	SEMS + ETF	Yes	10
24	32	Female	SG	Chronic	>9.8 mm	GC	SEMS + ETF	Yes	8
25	48	Female	SG	Late	>9.8 mm	GB	SEMS + ETF	Yes	38
26	32	Male	SG	Late	>9.8 mm	GC	SEMS + ETF	Yes	4
27	40	Female	SG	Late	>9.8 mm	GC	SEMS + ETF	Yes	4
28	29	Female	SG	Late	>9.8 mm	GC	SEMS + ETF	Yes	5
29	23	Female	GBP	Late	<5.8 mm	GC	SEMS	Yes	54
30	38	Male	GBP	Early	<5.8 mm	GC	SEMS	Yes	54
31	38	Female	GBP	Early	<5.8 mm	GC	SEMS	Yes	59
32	58	Female	SG	Chronic	5.8-9.8 mm	GC	OTSC	Yes	72
33	47	Male	SG	Chronic	5.8-9.8 mm	GC	SEMS + ETF	Yes	109
34	38	Female	SG	Chronic	>9.8 mm	GC	OTSC	Yes	16
35	63	Female	SG	Early	5.8-9.8 mm	GC	SEMS + ETF	Yes	11
36	30	Female	GBP	Chronic	>9.8 mm	GC	SEMS + ETF	Yes	15
37	62	Female	SG	Late	<5.8 mm	GC	SEMS + ETF	Yes	23
38	30	Female	GBP	Early	5.8-9.8 mm	GC	SEMS + ETF	Yes	14
39	30	Female	SG	Late	>9.8 mm	GC	SEMS	Yes	18
40	38	Female	SG	Early	>9.8 mm	GC	SEMS + ETF	Yes	17
41	51	Female	SG	Late	5.8-9.8 mm	GC	OTSC	Yes	11
42	54	Male	SG	Late	>9.8 mm	GC	ETF	Yes	21
43	33	Male	GBP	Late	>9.8 mm	GC	SEMS + ETF	Yes	12

SG, Sleeve gastrectomy; *GC*, gastrocutaneous; *SEMS*, self-expandable metal stent; *ETF*, enteral tube feeding; *GP*, gastropleural; *GBP*, gastric bypass; *GB*, gastrobronchial; *OTSC*, over-the-scope clip.