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Mini Review

Management of Chronic Fistula Using the Cardiac Septal Defect Occluder

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Abstract

Therapeutic endoscopy plays a critical role in the management of gastrointestinal (GI) fistulas. Innovative endoscopic approaches have revolutionized the treatment of GI fistulas; however, current endoscopic treatment modalities require multiple sessions and are associated with highly variable success rates and safety profiles. Due to these currently limitations, the off-label use of cardiac septal defect occluders (CSDOs) has emerged as a promising device to treatment GI fistulas, with early studies suggesting it to be a technically feasible, effective, and safe treatment. Therefore, we believe CSDO devices may be a preferred option for the management of refractory GI fistulas.

Introduction

Gastrointestinal (GI) fistulas can occur via a variety of possible etiologies, including as a result of surgical complications, in the setting of chronic inflammation of tissue, and may be associated with malignancy or radiation therapy. Broadly speaking, fistulas may be divided into either internal or external. Currently, chronic gastrointestinal (GI) fistulas are one of the most challenging complications to treat [1, 2].

Given the complexity and challenging management of GI fistulas, it is no surprise there are a variety of endoscopic approaches and devices. Current treatment options include closure, covering, and drainage methods, and have essentially transformed the paradigm of management, making endoscopy the first-line approach for treating these conditions. Closure and covering endoscopic therapies include the use of clips, cap-mounted clips, self-expandable metal stents, tissue sealants, and endoscopic suturing and plication devices. Endoscopic draining therapies include internal endoscopic drainage using double pigtail plastic stents, endoscopic vacuum therapy (EVT), and septotomy. However, despite a wealth of tools at the endoscopists hands, literature has shown that many treatment sessions are often required, with variable success rates and an inconsistent safety profile. Owing to the limitations of the current therapeutic approaches, the off-label use of cardiac septal defect occluders (CSDOs) has been reported [3-5].

The CSDO device was first created by Dr. Kurt Amplatz, an interventional radiologist, to assist with closing atrial septal defects. Although CSDOs are intended for percutaneous closure of cardiac septal defects, they have been used to close extravascular defects, including bronchopleural and GI fistulas [6, 7]. In this review, we describe the off-label role of CSDOs in the management of GI fistulas.

CSDOs

CSDOs are a shape-memory alloy, self-expanding double-disc closure device. These devices have a thick waist to accommodate tissues and are composed of nitinol and inter-woven polyester, allowing for occlusion and tissue in-growth. The disc diameter varies from 9 mm to 54 mm, and the waist size varies from 4 mm to 38 mm. To select the correct or appropriate device, it is critical to understand the device characteristics and method of delivery. Notably, the CSDO delivery system has a maximal length of 80 cm. Therefore, the delivery system cannot be used through the channels of most available endoscopes. The CSDO is usually delivered over a guidewire under direct endoscopic visualization with fluoroscopic examination. Another technique is separate from the delivery system, allowing the stent to be backloaded into an adapted endoscopic biliary catheter to provide enough length to be deployed through a therapeutic endoscope. This can be performed by placing a pediatric biopsy forceps down a biliary catheter and then grasping the stent to be deployed and recaptured as needed through a therapeutic endoscope's working channel [8].

Discussion

The endoscopic treatment of GI fistulas represents a significant advancement in the field of gastroenterology and minimally invasive surgery. An appropriate endoscopic approach to GI fistula closure includes

several fundamental principles. In many cases, endoscopic therapy may be used to interrupt or drain the flow of luminal contents through a GI defect. Several features must be considered to optimize outcomes, including the size of the defect, shape of the margin, viability of the surrounding tissue, as well as defect location. Additionally, patient selection remains key to determining the best endoscopic therapy, including closure, covering, or draining techniques [9]. Given the variable success rates of these previously mentioned techniques, the adoption of CSDO devices to the endoscopists toolbox may significantly improve outcomes. The use of CSDO as an endoscopic method uses a closure principle and may be used when there is no collection, or in cases where a collection is present, as an adjunctive treatment along with external drainage.

The only systematic review and meta-analysis regarding CSDOs in the literature for management GI fistulas was previously published by our group [10]. In this review, we analyzed 19 case reports including 22 fistulas among 20 total patients. Technical success was achieved in 100% of the cases, proving that this is a feasible procedure. Of the 22 fistulas, 17 demonstrated successful closure, with a mean follow-up period of 32.02 weeks. When used in conjunction with adjunctive therapy, the study showed a CSDO success rate of 75%, with no advantage compared to independent treatment with the CSDO device. The mean fistula duration before attempted closure with CSDO was 64.54 weeks – compared to 16 of the 22 fistulas (72.72%) demonstrating failed fistula closure with alternative endoscopic techniques. Ultimately, this review highlighted that CSDOs were mostly used in chronic fistulas, with a well-epithelized tract allow for easy accommodation of the CSDO device. Adverse events occurred in five cases (22.72%), including three instances of migration (13.63%), one fistula enlargement (4.54%), and one migration owing to fistula enlargement (4.54%). No death was related to the use of CSDOs. There were no correlations of patient age, fistula size, fistula duration, prior treatment, and adjunctive therapy with successful fistula closure and adverse events on regression analysis.

After this systematic review and meta-analysis, our group contributed to a multicenter retrospective series of patients with post-bariatric surgical leaks who underwent treatment with CSDO devices [11]. Forty-three patients treated with CSDOs for post-bariatric surgery leaks were included in this analysis. Most of the fistulas occurred after sleeve gastrectomy (72.1%), with 12 (27.9%) occurring after Roux-en-Y gastric bypass (RYGB). The results showed that chronicity and previous treatment were associated with successful fistula closure (P<0.0001). Specifically, successful closure rates of acute/early versus late/chronic leaks were 62.5% versus 97.1%, respectively (P=0.0023). The success rate of the CSDOs among patients with previous treatment and patients without previous treatment were 97.5% versus 0%, respectively (P<0.0001). On multivariable logistic regression analyses, age, sex, and fistula size were not significant predictors of success; however, late/ chronic leaks remained a significant predictor of success with an odds ratio of 3.99 (compared with acute/early) with a P value of 0.035. Interestingly, when used in acute fistulas, CSDOs appeared to result in enlargement of the fistula with limited success.

Recently, our group has also illustrated the feasibility, efficacy, and safety of CSDO devices in the closure of gastrogastric (GG) fistulas after RYGB, which is challenging due to the epithelialization of the tract. For GG fistulas, standard endoscopic therapies are less efficacious than surgical revision, which is, unfortunately, fraught with high morbidity and mortality. In this case report [12], we described the successful placement of a CSDO in a female patient, resulting in a 10 kg weight loss with significant improvement in her reflux symptoms three months later. Repeat evaluation confirmed successful fistula closure, further highlighting that this new technique may be a new method of avoiding revisional surgery, especially in chronic fistulas.

In summary, our experience has shown that the CSDOs promote fistula closure by occluding the fistula tract and stimulating tissue in-growth. Despite the low quality of evidence available in the literature to date, the satisfactory efficacy and safety results suggest that CSDOs may be a great option in the management of chronic GI fistulas.

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Authors' Contributions

de Oliveira, GHP: acquisition of data, drafting the article; McCarty, TR: revising the article, final approval; Moura, DTH: analysis and interpretation of data, Moura, EGH: revising the article, final approval.

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