—Original Article—

Endoscopic ultrasound-guided pancreatic pseudocyst cystogastrostomy using a novel self-expandable metal stent with antimigration system: A case series

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ABSTRACT

Background and Objectives: Development of symptomatic pseudocysts after acute pancreatitis is a common occurrence. Endoscopic ultrasound (EUS)-guided transmural drainage has become the treatment of choice for symptomatic pseudocysts. Following this procedure, stent migration can occur. A recently developed fully covered biliary metal stent with antimigration system has shown promise as an alternative endoprosthetic option for cystogastrostomy. The aim of this study is to describe the success and complications of using covered metal stents with antimigration system to drain pseudocysts at a single tertiary care center. **Materials and Methods:** The patients undergoing cystogastrostomy using the biliary metal stent with antimigration system over the course of a 10-month period (January-November, 2014) were retrospectively reviewed and all the pertinent information including length of the follow-up, age and sex of the patient, pseudocyst size, pseudocyst size at follow-up, and symptom improvement were recorded. **Results:** Five patients underwent endoscopic cystogastrostomy using a biliary metal stent with antimigration system. The average age of the patients was 57 years, with all the patients being males. The average size of the largest dimension of pseudocyst was 9 cm. The average follow-up time to repeat imaging was 30 days. All the patients had a significant improvement in their pseudocyst size, with two patients having complete resolution, one patient with a residual 2 cm cyst, and another with a residual 5 cm pseudocyst at follow-up. The average size at follow-up was 2 cm. No complications occurred during the follow-up period. No episodes of stent migration occurred. All the patients had symptom improvement at follow-up. **Conclusion:** Using a novel biliary covered self-expandable metal stent with antimigration system with EUS guidance to drain pseudocysts appears to be a safe and effective procedure in certain settings. Our experience shows rapid cyst resolution with no complications and no stent migration. This stent gives the providers another option when performing cystogastrostomy.

Key words: Antimigration, cystogastrostomy, endoscopic ultrasound (EUS), metal stent, pancreatic pseudocyst

INTRODUCTION

Pseudocysts are a common occurrence in the setting of acute and chronic pancreatitis, developing in 10-20% of acute pancreatitis and up to 40% of chronic pancreatitis. Endoscopic management of pseudocyst has become the standard of care in tertiary care centers. Endoscopic management of pseudocysts was shown to be as successful as surgical management, with the advantage of shorter hospital stays and lower costs.[1,2]

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EUS-guided drainage is the preferred method of endoscopic drainage in terms of technical success and occurrence of procedure-related adverse events.[3-5] The type and the number of stents for pseudocyst drainage have been well studied. In one study on 122 patients, the total success rate was 94%; however, they

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found no difference in the outcomes for the size or the number of stents used.[6] A novel exchange-free device developed for transluminal therapy has been shown to be successful and quicker for endoscopic drainage.[7,8] Fully covered stents have been shown to be as successful as plastic stents for pseudocyst drainage, with the advantage of a need for fewer stents.[9] A new, fully covered self-expandable metal stent (FCSEMS) customized for cystogastrostomy with an antimigration system has also been shown to be successful and has a low complication rate.[10,11] More recently, this new stent (AXIOS Stent, Xlumena, Mountain View, CA, USA) with lumen-apposing flaps was shown to be successful in 30 of 33 patients and recently gained U.S. Food and Drug Administration (FDA) approval for cystogastrostomy.[12] Large trials examining the new FCSEMS with antimigration for pseudocyst drainage are yet to be performed.

We examined the use of a novel biliary endoprosthesis and FCSEMS with antimigration system in the first five cases of cystogastrostomy at our institute, looking specifically at procedural success and complication rate.

MATERIALS AND METHODS

The patients undergoing cystogastrostomy using a FCSEMS with antimigration system over the course of a 10-month period (January-November, 2014) were retrospectively reviewed and all the pertinent data including length of the follow-up, age and sex of the patient, pseudocyst size, pseudocyst size at follow-up, and symptom improvement were recorded. The records were reviewed specifically for procedural-related complications. All the patients developed pseudocysts as a consequence of an episode of acute or chronic pancreatitis. All the stents were placed by a single advanced endoscopist trained in EUS (DVG) with the assistance of two different advanced fourth-year fellows (EAJ and AJW). The study was approved by our Institutional Review Board. In addition to obtaining the standard preprocedure informed consent, the patients were also notified of the potential use of the FCSEMS with antimigration flaps to drain their pseudocysts and that this was an off-label use of the device.

The indications for this procedure were the following: Gastric outlet obstruction in three patients, duodenal compression, and severe abdominal pain. Figure 1 shows a pseudocyst causing gastric wall compression. A GORE® VIABIL® (CONMED, Utica, NY, USA) Biliary Endoprosthesis FCSEMS with antimigration device was used in all the cases [Figure 2]. All the procedures were performed under general anesthesia. Antibiotics were given prior to all the procedures.

Procedure description

Endoscopic Ultrasound GF-UC140-AL5 (Olympus of America, Center Valley, PA, USA) scopes were used in all the cases. The pseudocysts were studied utilizing the color Doppler imaging technique to identify the interposed vessels. Endoscopic ultrasound (EUS) imaging was used to ensure proper placement of the needle and to demonstrate the lack of vasculature [Figure 3]. Each cyst was then punctured under the EUS guidance with the 19-gauge Cook needle (Cook, Bloomington, IN, USA). The cyst was then injected with full-strength ionic contrast, and a cystogram was obtained under fluoroscopy. A straight VisiGlide (Olympus of America, Center Valley, PA, USA) wire was inserted into the pseudocyst under fluoroscopic

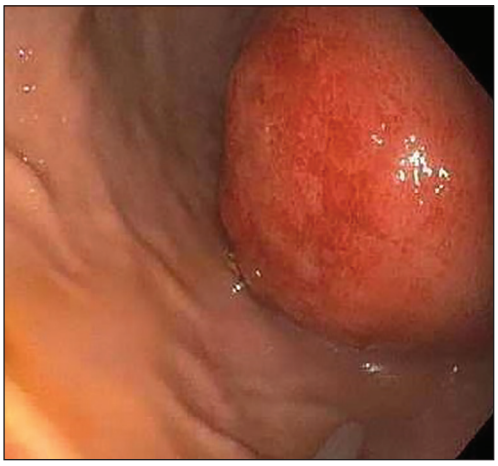

Figure 1. Endoscopic view of pseudocyst causing compression gastric lumen

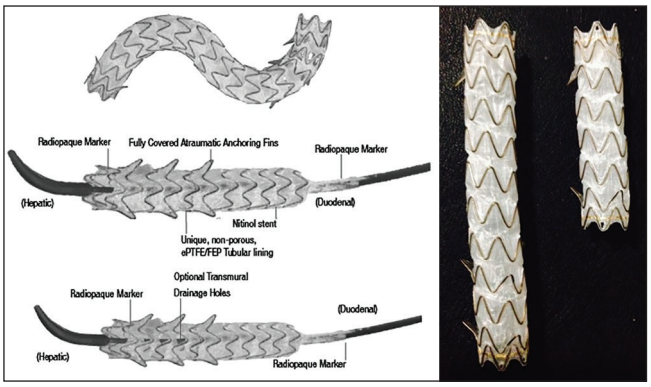

Figure 2. GORE® VIABIL® Biliary Endoprosthesis-covered metal stent with antimigration device. Examples of 4-cm and 6-cm stents shown (right). (Courtesy of CONMED, USA)

guidance and allowed to coil twice [Figure 3]. The cystotomy was dilated with 4-5-7-Fr catheter, 5-7-8.5-Fr catheter, and 10-Fr catheter dilators (Cook, Bloomington, IN, USA), and then dilated with a Quantum® 8 mm × 3 cm balloon [Figure 4]. A GORE® VIABIL® Biliary Endoprosthesis-covered metal stent with antimigration device [Figure 5] was then deployed with fluoroscopic and endoscopic guidance. All the stents were 10 mm in diameter.

All the patients underwent computerized tomography (CT) imaging prior to stent placement and at follow-up to assess pseudocyst resolution. All patients were attended to in the gastroenterology clinic for the assessment of symptomatic approval while the stent was still in place. All patients had follow-up endoscopies with stent removal.

RESULTS

Five patients underwent EUS-guided cystogastrostomy using the FCSEMS stent with an antimigration system. All the five stents were successfully placed. Table 1 details the clinical course of each patient. The average age of the patients was 57 years (age range was 48-64 years), with all patients being males. The average size of the largest dimension of the pseudocyst was 9 cm. The average time to repeat CT imaging was 30 days [Figure 6]. All the patients had significant improvement in pseudocyst size, with two patients having complete resolution, one patient with a residual 2-cm cyst, and another with a residual 5-cm pseudocyst at follow-up, but with complete resolution of the symptoms. One patient (patient 2), who had an initial improvement in symptoms with significant drainage, was noted to have necrosis and subsequently required combined multimodality with interventional radiology-placed drain and irrigation. This, along with the internal FCSEMS, improved the cyst and necrosis.

Average pseudocyst size at follow-up was 2 cm. All the patients had continued to be asymptomatic at clinical follow-up, with an average interval of follow-up of 52 days. No complications occurred during the follow-up period. One patient had a prolonged hospital course; however, it was unrelated to stent deployment. Additionally, one patient required external drainage of

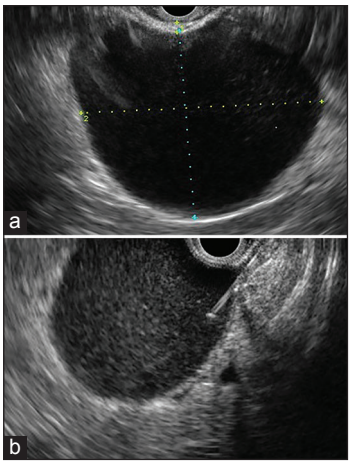

Figure 3. (a) EUS images demonstrating a large pseudocyst (6.35 cm × 4.94 cm) in close proximity to gastric wall. (b) Represents fine-needle aspiration (FNA) needle puncturing pseudocyst

Figure 5. Successful deployment of the FCSEMS with antimigration system (VIABIL® stent)

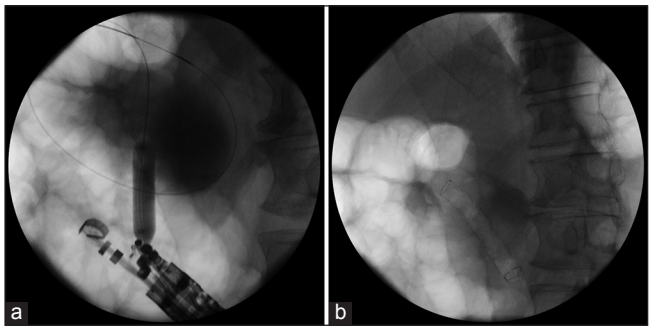

Figure 4. Fluoroscopic images of stent placement. (a) Demonstrates dilation of drainage tract with a Quantum 8 mm × 3 cm balloon and a 0.025 VisiGlide wire in place. (b) Shows final image with VIABIL® stent in place

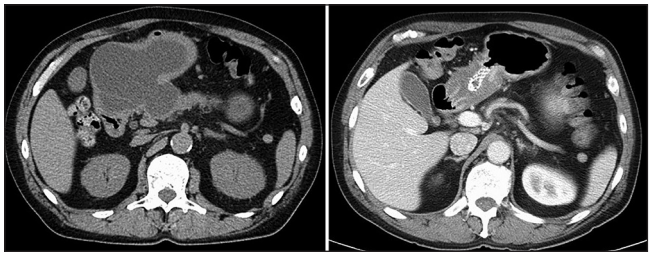

Figure 6. CT imaging of pseudocyst (left) before measuring 6.8 cm and after (right) placement of VIABIL® stent with complete resolution of pseudocyst

cyst collection. No episodes of stent migration occurred and all stents were removed without complication.

DISCUSSION

In this single-center experience examining EUS-guided cystogastrostomy with a new FCSEMS with antimigration system, there was successful drainage in all cases with no stent-related complications. This study demonstrates the importance of EUS guidance as a means of successful cystogastrostomy.

EUS-guided pseudocyst drainage was first described in 1992.[13] Since 2003, when Giovannini *et al.* reviewed the safety of EUS-guided cystogastrostomy, its acceptance has grown and it is now the preferred method of endoscopic drainage based on documented safety and efficacy.[5] Multiple authors have demonstrated its success. Most studies quote a success rate of 88-100% for EUS-guided cystogastrostomy.[2,14,15] In a study over a 5-year period with a 45-week average follow-up, the authors reported a treatment success of only 75%; this lower success rate was thought to be a product of longer follow-up time and labeling any complication as unsuccessful deployment. The complications in this study included stent clogging, stent migration, infection, and recurrence. Based on these results, the authors concluded that EUS-guided cystogastrostomy should be done only at tertiary care centers.[16] Recently, another series with long term follow-up again showed high treatment success, with success in 19 of 22 patients.[17] Most studies used multiple plastic stents, but recently, institutes have begun to use specialized FCSEMS designed specifically for cystogastrostomy. The advantage of the newer stents is the decreased risk of stent migration and shorter procedure length.

In our series, EUS-guided placement of the novel FCSEMS with antimigration (GORE® VIABIL® Biliary Endoprosthesis) was found to be easy to deploy and alleviated the need for multiple stent placement. Use of other FCSEMS without antimigration flaps (biliary or esophagus stents) has the risk of stent migration.[18] With the assistance of EUS, it is a safe and reliable procedure. There were no complications related to the stent, and it was easily removed irrespective of the length of the interval the stent was in place.

Although this is a small case series, others have had similar success with FCSEMS with antimigration designed specifically for cystogastrostomy; one series showed

Table 1: Patient's treatment data

Patient	Age (years), sex	Cyst largest diameter (cm)	Cause of cyst	Reason for stent placement	Duration of placement (days)	Complications	Cyst size at follow-up (cm)	Symptoms at follow-up	VIABIL stent length (cm)
1	52, M	6.8	Chronic pancreatitis	Gastric outlet obstruction	44	None	0	Mild abdominal pain due to chronic pancreatitis	6
2	64, M	13	Acute pancreatitis	Gastric outlet obstruction	60	Necrosis, successfully drained with combined approach	2	None	6
3	64, M	6.7	Acute on chronic pancreatitis	Gastric outlet obstruction	27	None	0	None	4
4	48, M	11.5	Acute pancreatitis	Worsening abdominal pain	86	Prolonged hospital stay due to pain	6	None	6
5	58, M	7	Acute pancreatitis	Duodenal obstruction	37	None	2	None	6

success in the drainage of both pseudocyst and walled-off pancreatic necrosis (WOPN) drainage. In the series done by Yamamoto *et al*., the authors used a stent (Nagi stent, Taewoong medical,Gyeonggi-do, Soulth Korea) designed specifically for cystogastrostomy; all the five pseudocysts were successfully drained and there was only one episode of migration (into the stomach), thought to be from complete drainage of the cyst. Their series had also not recorded any stent-related complications.[10] Additionally, the use of the recently FDA-approved AXIOS stent (Taewoong Medical, Gyeonggi-do, South Korea) was shown to be successful in 30 of 33 patients with pancreatic fluid collections (both WOPN and pseudocysts).[19] Other case reports and series have also demonstrated similar success and ease of use of FCSEMS with luminal-apposing flaps.[11,12,19,20]

Our series is limited, as it is a small retrospective study based predominantly on patients with large and symptomatic pseudocysts. Although the VIABIL stent is not specifically designed for cystogastrostomy, its success in this series further questions the true necessity of the new stents designed specifically for cystogastrostomy. There are other studies that have used the VIABIL FCSEMS, but those have utilized a pigtail plastic stent within or alongside the FCSEMS to prevent stent migration. The antimigration flaps, which we used, theoretically reduce the risk of migration. As they are biliary, the stents are also designed to be 10 mm in maximum diameter, and although their use in symptomatic but uncomplicated pseudocyst drainage may be reasonable, the role of treating cysts with WOPN remains unclear. It is unlikely that this type of stent by itself would allow improvement of WOPN. These stents are also unlikely to provide direct endoscopic access into the cyst, compared to larger FCSEMS on the market. The double FCSEMS placed side by side in the instance of WOPN may be a reasonable option in these cases. Alternatively, a combined technique with interventional radiology, as in patient 2, or multiple transluminal gateway technique may be an option, but their effectiveness in resolving WOPN remains uncertain.[21,22] A comparative cost analysis was also not performed, and this may also be a factor for providers considering the use of novel FCSEM stents. The VIABIL stent gives providers another option for pseudocyst drainage and may be more cost-effective than those stents designed specifically for pseudocyst drainage. Additionally, another potential added benefit for the use of this type of stent is in those centers where the likelihood of using FCSEMS for biliary indications is higher than pseudocysts. Stocking a single type of stent that can be used for dual purpose may be more cost-effective than stocking additional dedicated "pseudocyst stents."

Presently, however, metal stents have not been shown to be superior to plastic stents in most outcomes; they appear to have an advantage in ease of use and possibly shorter duration of the procedure, compared to the plastic stents. Some authors argue that currently there are not enough data to support routine use of metal stents over plastic stents for routine pseudocyst drainage;[9] however, with the development of new stents specifically designed for cystogastrostomy, the landscape may change. It is also uncertain whether use of these stents reduces the postprocedure complication rates, including superinfection. Although the VIABIL stent is not designed specifically for cystogastrostomy, its luminal-apposing metal flaps to prevent migration give it a distinct advantage over other biliary FCSEMS in cystogastrostomy.

In this small single-center series, early results support the use of this new biliary FCSEMS with antimigration system for cystogastrostomy. As more investigations are done, these newly designed stents with antimigration metal flaps may be a reasonable alternative option for the drainage of symptomatic and uncomplicated pseudocyst; its role in the treatment of cysts with WOPN is less clear. Presently there is not enough evidence for its routine use; however, given the success of this stent, further prospective investigations to assess its cost-effectiveness and complication rates including migration, stent occlusion, and superinfection would be beneficial.

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