

A Chinese prospective multicenter cohort study evaluating EUS-guided drainage of pancreatic fluid collections using the Hot AXIOS system

Peng Li^{1,*}, Zheng Zhang^{1,*}, Sheng Wang², Zhendong Jin³, Yiqi Du³, Aiming Yang⁴, Yunlu Feng⁴, Xiaoping Zou⁵, Lei Wang⁵, Xiaoyan Wang⁶, Li Tian⁶, Pinghong Zhou⁷, Yiqun Zhang⁷, Jun Liu⁸, Zhen Ding⁸, Junwen Zhang⁹, Jian Yang⁹, Siyu Sun², Shutian Zhang¹

¹Department of Gastroenterology, Beijing Friendship Hospital, Capital Medical University, Beijing, China; ²Department of Gastroenterology, Shengjing Hospital of China Medical University, Shenyang, Liaoning Province, China; ³Department of Gastroenterology, Changhai Hospital, Second Military Medical University/Naval Medical University, Shanghai, China; ⁴Department of Gastroenterology, Peking Union Medical College Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; ⁵Department of Gastroenterology, The Affiliated Drum Tower Hospital of Nanjing University Medical School, Nanjing, Jiangsu Province, China; ⁶Department of Gastroenterology, Third Xiangya Hospital, Central South University, Changsha, Hunan Province, China; ⁷Endoscopy Center, Zhongshan Hospital, Fudan University, Shanghai, China; ⁸Department of Gastroenterology, Wuhan Union Hospital, Tongji Medical College of Huazhong University of Science and Technology, Wuhan, Hubei Province, China; ⁹Department of Gastroenterology, The First Affiliated Hospital of Chongqing Medical University, Chongqing, China

ABSTRACT

Background and Objectives: The Hot AXIOS system, which features a cautery-enhanced lumen-apposing metal stent, facilitates EUS-guided transmural drainage of pancreatic fluid collection (PFC). We aimed to evaluate the safety and efficacy of stents in a multicenter Chinese cohort. **Patients and Methods:** Thirty patients from nine centers with a single pancreatic pseudocyst (PP) or walled-off necrosis (WON) who underwent EUS-guided transgastric or transduodenal drainage with the novel stent were prospectively enrolled. **Results:** We included 15 (50%) patients with PPs and 15 (50%) with WONs. The mean diameter of the PFCs was 11.06 ± 3.56 cm. Stent placement was technically successful in all patients (100%), whereas clinical success was achieved in 93.3% of patients (28/30). Clinical success was defined as the alleviation of clinical symptoms combined with at least a 50% reduction in PFC diameter within 60 days after surgery. 73.3% (22/30) of AXIOS stents were removed after reaching clinical success in the 1st month of follow-up. A total of 14 (46.7%) PFC-associated

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*These authors contribute equally to this work.

Address for correspondence

Prof. Siyu Sun, Department of Gastroenterology, Shengjing Hospital of China Medical University, Shenyang 110004, Liaoning Province, China. E-mail: sun-siyu@163.com

Prof. Shutian Zhang, Department of Gastroenterology, Beijing Friendship Hospital, Capital Medical University, National Clinical Research Center for Digestive Disease, Beijing Digestive Disease Center, Beijing Key Laboratory for Precancerous Lesion of Digestive Disease, Beijing 100050, China. E-mail: zhangshutian@ccmu.edu.cn

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infections occurred (4 pre- and 10 postoperation), which recovered within 1 week after treatment. Other complications included three (10%) partially or fully blocked stents and two (6.7%) stent migrations. Regarding the fully opened stent without blocking, complete remission of PFCs within 1 month was independently predicted by a previous pancreatitis attack > 6 months prior (adjusted odds ratio: 11.143; 95% confidence interval: 1.108–112.012; $P = 0.041$). **Conclusion:** EUS-guided drainage of PFCs using the Hot AXIOS system is safe and efficient. Regarding completely patent stents, a previous pancreatitis attack > 6 months prior predicts a greater chance of achieving 100% remission of PFCs within 1 month of AXIOS treatment.

Key words: EUS, evaluation, Hot AXIOS system, pancreatic fluid collection drainage

INTRODUCTION

EUS-guided transmural drainage with the placement of a “cold” lumen-apposing metal stent (LAMS) has been recommended for the treatment of symptomatic pancreatic fluid collection (PFC).^[1–3] A recent study showed that both technical and clinical successes in patients with PFC treated with LAMS were achieved 97.6% and 90.1%, respectively.^[4] In addition, LAMS for drainage has a lower complication rate than double-pigtail plastic stents (16.0% *vs.* 20.2%).^[5] However, deployment of LAMSs requires a prior needle, guidewire, and dilation, which greatly extends the operating time. Currently, the novel “hot” LAMS (Hot AXIOS, Boston Scientific) with a cautery-tipped stent delivery system was introduced to achieve single-step EUS-guided PFC stenting from puncture to deployment of the stent for a streamlined, exchange-free procedure.^[6]

Recently, the Hot AXIOS system has been used for several off-label indications, such as gastrojejunostomy and drainage of PFCs, gallbladder, and bile duct.^[7–9] Several retrospective studies reported that the use of this new AXIOS stent for the above indications had high rates of technical (93.1%–97.7%) and clinical success (86.4%–95.6%).^[10–12] Owing to the lack of sufficient materials and patients, few prospective multicenter cohort studies have been conducted to verify the safety and efficacy of the Hot AXIOS system in PFC drainage. Moreover, literature regarding the release timing of PFCs and the timing of device removal remains scarce, with a lack of international consensus.^[13]

Herein, we report our experience using the AXIOS system for the drainage of PFCs from a Chinese multicenter, prospective, and premarket approval study. We also conducted a logistic analysis of the risk factors that influenced the remission of PFCs.

PATIENTS AND METHODS

Study design and patient selection

This was a prospective, multicenter, signal-arm, nonrandom study involving nine tertiary care centers from April 2019 to September 2020. The study protocol was approved by various medical ethics committees, and all patients provided informed consent before AXIOS stent placement.

The inclusion criteria were as follows: (1) males or females aged 18–75 years who were diagnosed with pancreatic pseudocyst (PP) or walled-off necrosis (WON) according to the revised 2012 Atlanta classification; (2) the maximum diameter of the PFC under computed tomography (CT) was ≥ 6 cm; (3) the proportion of liquid volume in the PFC was > 70% (according to the instruction manual for AXIOS stent, <https://www.bostonscientific.com>); and (4) the target was adherent to the gastric or bowel wall (no more than 1.5 cm). Patients with cystic neoplasms, immature pseudocysts or WON, repetitive cystic structures, more than one PFC, abnormal blood coagulation (INR > 1.5, unresolved bleeding disorder), anatomic abnormalities, varicose veins or blood vessels within a 1 cm radius of the puncture site, allergies, and pregnant women were excluded from the study.

Procedure

All procedures were performed by experienced physicians who were experts in endoscopic drainage of PFCs. The baseline CT diameter, main symptoms, history of pancreatitis, previous intervention, and general medical history were routinely recorded during screening. Drainage was performed within 30 days. About one-third of patients (9/30) get periprocedural antibiotics as a prophylactic treatment.

Drainage was performed under either monitored anesthesia care (MAC) or general anesthesia. If a patient was considered to be at a risk of aspiration

pneumonia by an anesthesiologist, MAC would be conducted. Linear EUS was used to locate the PFCs, assess fluid content, and confirm the puncture pathway. Subsequently, the electrocautery-enhanced delivery system directly broke into PFCs under EUS guidance, which built a connection between the cyst wall and gastric wall without the help of a prior needle or guidewire. Single-step EUS-guided puncture was assisted by cautery. Immediately after entry into the PFCs, the lumen-apposing stent was deployed under EUS and endoscopic guidance. Two main types of AXIOS stents (10 mm × 10 mm and 15 mm × 10 mm) with a common 10.8 Fr conveying system were used for drainage. Necrosectomy sessions were performed in PFCs containing solids or necrotic material, at the discretion of the endoscopist. Necrosectomy procedures involved PFC lavage, blunt dissection, and removal of necrotic tissue using different devices. Finally, intraoperatively, the target gastrointestinal (GI) site and properties of the drainage fluid were described.

Antibiotics would be routinely used after the surgery. Body temperature and white blood cell (WBC) number would be monitored before and after surgery. Moreover, PFC resolution would be assessed by abdominal CT scan at 7 ± 2 , 28 ± 7 , or 60 days after stent placement until 50% reduction in PFC diameter being detected. Endoscopic assessment would be performed when the patient had a fever for more than 3 days, poor relief in the diameter of the cyst, or debridement being needed for WON. If the PFCs achieved clinical success, the AXIOS stent was then removed. Otherwise, the stent would also be removed after 60 days. A follow-up office visit occurred 7 days after stent removal. Complications, such as infection, stent migration, bleeding, and proliferation, were recorded throughout the procedure.

Definition of endpoints

Technical success was defined as satisfactory patency of the LAMS and drainage of the PFCs during endoscopy after stent placement. Clinical success was defined as the alleviation of clinical symptoms in combination with at least a 50% reduction in PFC diameter within 60 days after surgery. Complications included bleeding, perforation, PFC infection, stent migration, and blocking. Procedure-related major complications were defined as those that required endoscopic or surgical intervention. Postoperative infection was defined as infection after initial endoscopic drainage, as shown

by fever and/or positive blood cultures, regardless of preoperative symptoms of infection.

Statistical analyses

IBM SPSS Statistics version 20.0 (IBM Corp., Armonk, N.Y., USA) was used for data analysis. Continuous variables are reported as mean (standard deviation) and median (range), as appropriate. Categorical variables are reported in terms of frequency counts and proportions. Logistic regression analysis was performed to calculate the odds ratios and their corresponding 95% confidence intervals for predictors of clinical success.

RESULTS

Clinical demographics

Thirty patients were enrolled from nine Chinese centers, with a median of three patients per center (range: 2–7). There were 16 women and 14 men, aged 47 ± 14 years, and body mass index ranged from 15.43 to 33.46. The etiologies were acute (76.7%) and chronic pancreatitis (23.3%). According to the history of pancreatitis, patients were divided into a recent attack group (< 6 months, 53.3%) and a previous attack group (> 6 months, 46.7%). The types of PFCs included PPs (93.3%) and WON (6.7%), which were diagnosed using CT scans. However, the ratio was 1:1 (15 PPs and 15 WONs) under EUS assessment. Common PFC symptoms included PFC infection (WBC > $1.0 \times 10^9/L$, 13.3%), abdominal pain (40%), gastric outlet obstruction symptoms (nausea/vomits/early satiety, 30%), and weight loss (40%). The first three symptoms resolved within 1 month after stent placement. Six patients had previous percutaneous drainage, and two underwent previous pancreatic duct stent drainage. However, they all experienced poor effects of drainage or cyst recurrence. Diabetes (30%), hyperlipidemia (23.3%), and hypertension (23.3%) constituted the top three general medical histories; the details are summarized in Table 1.

Clinical outcomes

AXIOS stents were successfully placed in 100% of patients, including that two patients underwent stent placement twice due to improper stent release procedure, resulting in incomplete stent deployment. Moreover, 38.5% (10/26), 73.3% (22/30), and 93.3% (28/30) of the patients achieved clinical success at the 1-week, 1-month, and 2-month visits, respectively. The mean PFC size was 11.06 ± 3.56 cm, which decreased by 47.7% at the 1-week visit (5.78 ± 3.48 ,

Table 1. Demographics of patients

Characteristic	Ratio, n (%)
Sex	
Female	16/30 (53.3)
Male	14/30 (46.7)
Age (years)	
Mean \pm SD	47 \pm 14
Range	22-73
BMI	
Mean \pm SD	22.41 \pm 3.79
Range	15.43-33.46
Type of pancreatitis	
Acute	23/30 (76.7)
Chronic	7/30 (23.3)
History of pancreatitis (months)	
Recent attack (< 6)	16/30 (53.3)
Previous attack (> 6)	14/30 (46.7)
Type of PFCs (under EUS)	
PP	15/30 (50)
WON	15/30 (50)
PFC symptoms	
Infection	4/30 (13.3)
Pain	12/30 (40.0)
Gastric outlet obstruction (nausea/vomit/early satiety)	9/30 (30.0)
Losing weight	12/30 (40.0)
Previous intervention	
Percutaneous drainage	6/30 (20.0)
Pancreatic duct stent	2/30 (6.7)
General medical history	
Diabetes	9/30 (30.0)
Hyperlipidemia	7/30 (23.3)
Hypertension	7/30 (23.3)
Others	4/30 (13.3)

PP: Pancreatic pseudocyst; WON: Walled-off necrosis; PFCs: Pancreatic fluid collections; SD: Standard deviation; BMI: Body mass index

$P < 0.01$) and 67.7% at the 1-month visit (3.57 ± 2.67 , $P < 0.01$). The target GI sites were mainly divided into the stomach body group (86.7%, 26/30) and the duodenal bulb group (13.3%, 4/30). Drainage properties were described as turbid (53%), clear (26.7%), pus (16.7%), or necrotic (3.3%).

Endoscopic examination revealed that 90% of the stents remained completely patent, and two (6.7%) were partially filled with necrotic tissue. Only one AXIOS stent (3.3%) was completely blocked. Approximately half of the patients had postoperative PFC infections (46.7%) which included four patients with a fever before surgery. However, all of the patients recovered after treatment with antibiotics and/or endoscopic necrosectomy within 1 week. 53.3% of patients underwent necrosectomy due to intractable cyst infection or necrosis blocking in the stent. However, not all the patients with WON (4/30, 13.3%) needed

endoscopic debridement, and 13.3% of patients (4/30) with PP under EUS still need endoscopic debridement to relieve the fever. Chyme stuck in the stent (3/4) and misjudgment of the necrotic material due to an unclear EUS image (1/4) may be the possible reasons. Finally, two stent migrations (6.7%) were observed during endoscopic examination. There were no severe complications affecting the hospital stay or life expectancy of the patients, such as GI bleeding, proliferation, or cardiovascular accidents. The clinical outcomes are summarized in Table 2.

Risk factor analysis

Multivariate analysis of the risk factors (history of pancreatitis attack, necrosectomy, previous percutaneous intervention, and initial CT diameter) for 100% remission of PFCs at 1 month demonstrated that a pancreatitis attack >6 months prior was an independent predictive factor for the 100% drainage effect of the AXIOS stent if the stent was fully opened without any blocking. The results of the univariate analysis are summarized in Table 3.

DISCUSSION

Endoscopic drainage of PFC is a novel treatment and can only be performed in a few tertiary hospitals.^[14,15] We tried to conduct the large prospective multicenter clinical trial to assess the success and complication rates associated with the Hot AXIOS system in PFCs in China.

The Hot AXIOS system simplified the procedure to connect the PFCs and gastric wall without the needle and cystectomy^[16,17] and, herein, achieved approximately 93.3% clinical efficacy. In the two cases that did not reach clinical remission, one had to remove the sent at the 1-month follow-up due to a postoperative allergic reaction (pruritus), when the maximum CT diameter decreased by 49%. Although the allergic reaction occurred on the day 24 after the stent placement and was relieved by treatment with anti-allergic drugs, we had to remove the stent as the patient's request. The other failed case also had the stent removed at the 34-day follow-up without repeat CT. In spite of these two cases having the possibility to achieve clinical remission, we have to count them as failed cases.

The system had low complication rates and no extended hospital stays. Overall, 14 patients showed a

Table 2. Clinical impressions of patients

Characteristic	Ratio, n (%)
Technical success	30/30 (100)
Clinical success	
1-week visit	10/26 (38.5)
1-month visit	22/30 (73.3)
2-month visit	28/30 (93.3)
Maximum CT diameter of PFCs (cm)	
Mean \pm SD	11.06 \pm 3.56
Range	7.2-21
Target GI site	
Stomach body	26/30 (86.7)
Duodenal bulb	4/30 (13.3)
Drainage properties	
Turbid	16/30 (53.3)
Clear	8/30 (26.7)
Pus	5/30 (16.7)
Necrotic	1/30 (3.3)
Stent size	
10 mm \times 10 mm, 10.8 Fr	11/30 (36.7)
15 mm \times 10 mm, 10.8 Fr	19/30 (63.3)
1-week CT diameter (cm)	
Mean \pm SD	5.78 \pm 3.48
Range	0-11.7
1-month CT diameter (cm)	
Mean \pm SD	3.57 \pm 2.67
Range	0-8.1
100% remission on 1 month	7/30 (23.3)
Stent patency on 1-month visit	
Patent	27/30 (90)
Partial occlusion	2/30 (6.7)
Blockage	1/30 (3.3)
Necrosectomy	16/30 (53.3)
Complications	
Postoperative infection	14/30 (46.7)
Stent migration	2/30 (6.7)

SD: Standard deviation; CT: Computed tomography; PFCs: Pancreatic fluid collections; GI: Gastrointestinal; Fr: French

Table 3. Multivariate analysis of the risk factors for 100% remission of pancreatic fluid collections on 1 month

Characteristic	OR (95% CI)	P
Previous pancreatitis attack > 6 months	11.143 (1.108-112.012)	0.041
Necrosectomy	0.161 (0.147-3.232)	0.125
Previous intervention	0.237 (0.019-2.976)	0.265
Maximum CT diameter > 11 cm	2.25 (0.369-13.707)	0.382

OR: Odds ratio; CI: Confidence interval; CT: Computed tomography

fever ($> 37.3^{\circ}\text{C}$) or increased WBC numbers, including 4 preoperation and 10 postoperation. Moreover, all of the infections recovered within 1 week after treatment with antibiotics and/or endoscopic necrosectomy (53.3%). More than half of the cases underwent necrosectomy; however, 93.3% of cases were diagnosed as PPs by CT scan, suggesting that CT

evaluation of WON was significantly underestimated. The results of EUS assessment (15 PPs and 15 WONs) also verified the underestimation. Moreover, not all the patients with WON needed debridement and several PPs still needed debridement, indicating that a comprehensive postoperative monitoring of the infection status should be a routine. The above results also suggest that a routine antibiotic may be necessary for the drainage of PFC. Timely debridement was often chosen to treat with the stent blockage of necrotic tissues and help eliminate fever.^[18,19]

With regard to the influence of PFC size on symptoms and disease outcome, we focus on the remission of the size of this cystic disease. Exploring the pattern of pseudocyst contraction after AXIOS stent placement may aid in developing a more appropriate follow-up plan and provide evidence on the timing of stent removal. Currently, international guidelines recommend that the timing of stent removal for acute necrotizing pancreatitis should be controlled within 4 weeks,^[20] but high-level evidence for different types of PFCs is lacking. Therefore, we focused on the assessment of postoperative clinical remission rate within 1 month according to international guidelines and previous literature.^[21,22] Our data showed that the mean diameter of the 30 PFCs was significantly decreased by 47.7% at the 1-week CT follow-up and by approximately 67.7% at the 1-month follow-up. Therefore, we hypothesized that the timing of stent removal could be advanced according to the definition of clinical success (reduction $> 50\%$). Further studies are needed to verify this hypothesis.

In addition, the results showed that 23% of cases achieved complete remission, while other cases achieved only 20% to 30% remission at the 1-month follow-up. To explain the contrasting results, we tried to conduct a multivariate regression analysis of the risk factors for achieving 100% remission after AXIOS placement. Vitas and Sarr conducted a study to follow 114 patients with the diagnosis of PP for more than 5 years. The results showed that in patients managed by a nonoperative approach, resolution of the pseudocyst occurred in 57% of patients, with 38% resolving more than 6 months after diagnosis.^[23] Moreover, Lankisch *et al.* demonstrated that the spontaneous complete resolution of the PPs occurred in 11 (31%) of the 36 patients on 6-month

follow-up.^[24] Therefore, PFC may resolve spontaneously without interventional treatment, and this may take more than 6 months. To analyze the effect of time on PFC drainage, we designed two groups by whether the history of pancreatitis attack was more than 6 months. And then, considering that the three stent blockage cases may be a risk factor for the reduction in PFC,^[25,26] we excluded these three patients from this analysis. We found that the most complete remission was achieved when the attack time of pancreatitis was > 6 months, which may be related to the maturity of PFC formation. Therefore, we also speculate that the longer the PFC formation, the better the drainage effect. By comparing the average reduction rate after AXIOS stent placement, we found a decrease in the previous attack group than in the recent attack group (77.92% *vs.* 62.64%, respectively). However, the *P* value is greater than 0.05, which may be caused by the small amount of data and large variance. Larger cohort studies should be conducted to further explore the remission pattern of PFCs after AXIOS stent placement to guide clinical stent removal.

CONCLUSION

EUS-guided drainage of PFCs using the Hot AXIOS system is highly efficient and safe. With regard to fully opened drainage without blockage, a previous pancreatitis attack > 6 months prior predicted a greater chance of achieving 100% remission of PFCs after AXIOS stent treatment.

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Conflicts of interest

Siyu Sun is the Editor-in-Chief of the journal; Zhendong Jin is an Associate Editor; Aiming Yang and Xiaoping Zou are Editorial Board Members. This article was subject to the journal's standard procedures, with peer review handled independently of the editors and their research groups.

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