



AXIOS: A Case Report

WILLIAM J. SALYERS, JR., M.D. (Pictured) & MICHAEL S. GREEN, M.D.

Wesley Medical Center
University of Kansas School of Medicine
Wichita, Kansas, USA

Patient History

A 55-year-old male with a history of pancreatitis complicated by pancreatic pseudocyst formation was referred to the outpatient gastroenterology clinic for endoscopic cyst management. The pancreatic cyst was first identified two years prior to presentation and the patient reported that initially after cyst formation he underwent evaluation for surgical resection but the lesion was found to be un-resectable due to fusion of tissue planes. Cyst analysis at that time was consistent with a benign pseudocyst. Over the subsequent two years prior to presentation to the GI clinic, the cyst was monitored conservatively with interval follow up imaging.

At the time of presentation to GI clinic, the cyst was noted to be increasing in size up to 10 cm by 8 cm on interval follow up computed tomography (CT) imaging. The patient reported increasing nausea, vomiting, abdominal pain, and early satiety with recurrent hospitalizations due to the severity of his symptoms. Due to the increasing pseudocyst size with worsening symptoms, EUS-guided cystgastrostomy with AXIOS™ Stent placement was performed.

Procedure

The procedure was performed with general anesthesia to minimize the risk of aspiration due to the large fluid volume that would enter into the gastric lumen following cyst decompression with stent deployment. The patient received levofloxacin 500 mg intravenous prior to the procedure. CO₂ was used for insufflation throughout the procedure.

Upper endoscopy was performed with an adult endoscope to first screen for gastroesophageal varices and none were found. An extrinsic impression was noted along the posterior wall of the gastric body consistent with the known pseudocyst creating a mass effect on the gastric lumen. The upper endoscope was then exchanged for the linear echoendoscope. Echoendoscopic evaluation of the pancreatic pseudocyst revealed an anechoic lesion in the pancreatic body that was not in obvious communication with the main pancreatic duct. The cystic lesion measured up to 8.5 cm by 8.2 cm in maximal cross-sectional diameter within a single view (Figure 1). There was a small amount of internal debris present with the fluid-filled cavity. There was a single compartment with no septae present. The internal wall of the cyst cavity was confirmed to be less than 1 cm (measured at 5.4 mm) from the gastric lumen. Color Doppler imaging confirmed an absence of vascular structures within the needle path.

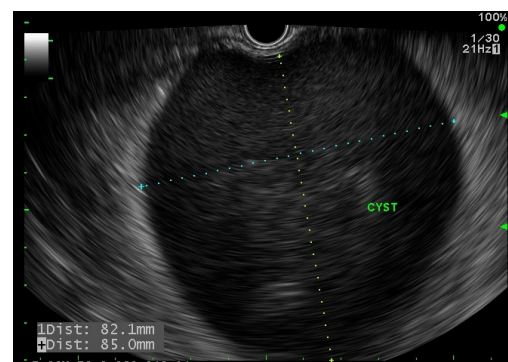


FIGURE 1

Pancreatic pseudocyst measuring 8.5 cm by 8.2 cm in maximal cross-sectional dimension.



FIGURE 2

EUS needle accessing the cyst cavity.

One pass was made into the cyst cavity with an EUS Needle (Figure 2) using the stylet with 5 mL of brown fluid collected and sent for analysis (CEA level, amylase, and cytology). A 450 cm by 0.035 inch Boston Scientific Dreamwire was then advanced through the needle into the cyst cavity (Figure 3) and allowed to coil several times under fluoroscopic guidance. The needle was then removed and a dilation balloon was then advanced over the wire. Dilation was performed with the inflated balloon held in place across the cystgastrostomy tract for 60 seconds (Figure 4). The balloon was removed and the 15 mm diameter metal AXIOS™ Stent was advanced over the wire and secured into place at the echoendoscope hub.

AXIOS Stent deployment was performed under echoendoscopic guidance using the 4 primary steps outlined below:

1. **Advance the deployment catheter.** Unlock the catheter lock and push down on the AXIOS catheter hub (labelled “down-arrow 1”) to advance the deployment catheter deep within the cyst cavity until it nears the cyst wall furthest from the EUS probe (Figure 5). Lock the catheter lock once the deployment catheter is in the optimal location within the cyst cavity.
2. **Deploy the first flange of the stent.** Remove the yellow safety clip that is located on the AXIOS Stent deployment hub. Unlock the stent lock and pull the stent deployment hub upward until it clicks into place at the white line just below the “up-arrow 2.” The first flange will be seen opening within the cyst cavity on the EUS image (Figure 6).
3. **Withdraw the first flange of the stent into position apposing the inner cyst wall.** Unlock the catheter lock and pull the catheter hub (labelled “up-arrow 3”) upward until the first flange is brought into position apposing the inner cyst wall under echoendoscopic guidance. EUS imaging of the first flange position is critical throughout this step and the catheter should be withdrawn until the first flange pulls up against the cyst wall forming a “football” shape (Figure 7). Lock the catheter lock once the first flange is in optimal location.
4. **Deploy the second flange.** Proceeding to Step # 4 on the AXIOS Deployment System handle, unlock the stent lock and pull the stent deployment hub upward to “up-arrow 4” to deploy the stent from the catheter system. Using the ‘EUS-guidance only’ method of AXIOS Stent placement, the stent will be deployed from the AXIOS Stent Delivery System within the working channel of the

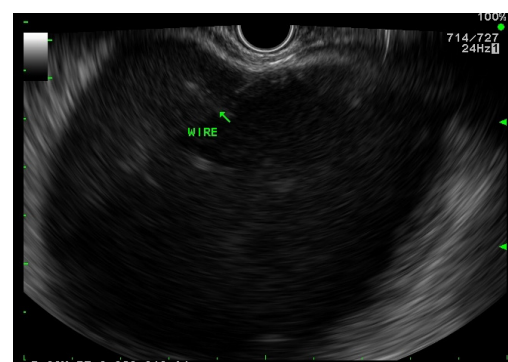


FIGURE 3
0.035 inch Dreamwire seen within the cyst cavity.

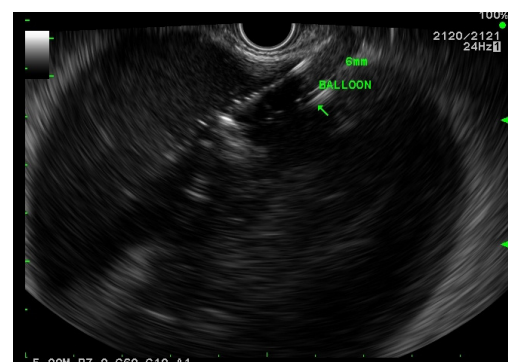


FIGURE 4
Dilation performed with a dilation balloon across the cystgastrostomy tract.

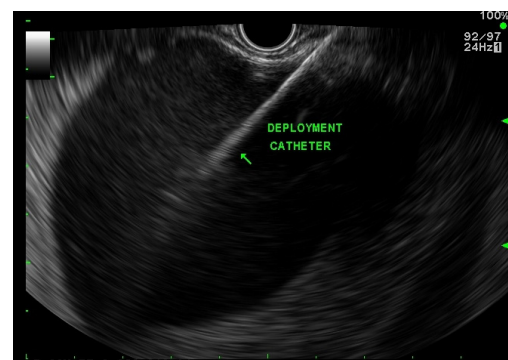


FIGURE 5
Step 1 - AXIOS deployment catheter advanced into cyst cavity.

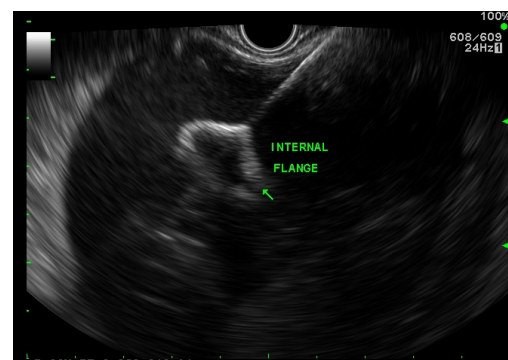


FIGURE 6
Step 2 – AXIOS stent first flange deployed within the cyst.

echoendoscope at this point. While keeping the internal flange positioned against the cyst wall, the echoendoscope is slowly withdrawn 1-2 cm with the elevator in the “open” position. The stent will come into the endoscopic view (Figure 8) as the deployed stent drops out of the working channel of the echoendoscope allowing the proximal gastric flange to open in proper position in the gastric lumen thus completing stent deployment (Figure 9). The AXIOS inner catheter along with the delivery system is then removed from the echoendoscope.

Outcome and Post Procedure

The patient was admitted for post-procedure observation and discharged 2 days after the procedure. He completed a 7 day course of levofloxacin 500 mg po once daily. On the first day post-procedure, he was started on clear liquids and advanced to a regular diet after 48 hours. Fluid analysis showed CEA and amylase levels that were consistent with the clinical diagnosis of a pseudocyst and cytology results were benign. He had no immediate or delayed post-procedure complications. Computed tomography performed 4 weeks after stent placement showed complete resolution of the cyst and he underwent upper endoscopy with stent removal 3 days later. The stent was removed using Raptor-grasping forceps without complications and the cystgastrostomy site was closed down to the size of only the internal flange at the time of stent removal. The patient has done well clinically without cyst recurrence and his pre-procedure symptoms resolved following stent placement with cyst decompression.

Conclusion

AXIOS™ Stent placement for cystgastrostomy creation is a safe and effective method for pancreatic pseudocyst management. It provides quick access to the pseudocyst cavity for necrosectomy and debridement and the large stent lumen diameter allows rapid resolution of the pancreatic cyst cavity. These features may allow patients with pancreatic pseudocysts to be managed with shorter lengths of stay in the hospital.

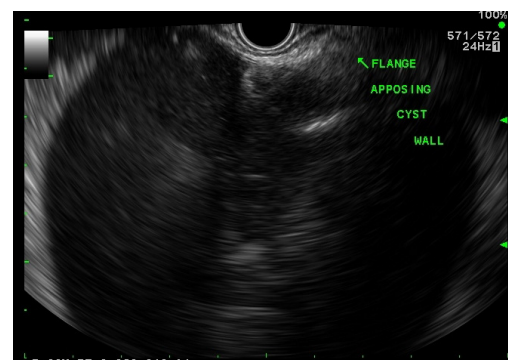


FIGURE 7

Step 3 – The first flange is withdrawn into position apposing the inner cyst wall until the flange creates a “football” shape.

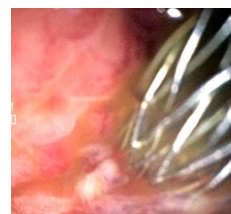


FIGURE 8

Step 4 – After the final stage of EUS-guided stent deployment, withdrawal of the echoendoscope brings the stent into the endoscopic view and further withdrawal of the scope allows full deployment of the second flange.



FIGURE 9

View of the second flange after withdrawal of the echoendoscope allows full deployment of the proximal flange. The deployment catheter has also been removed fully from the echoendoscope working channel and cyst contents are seen flowing into the gastric lumen.

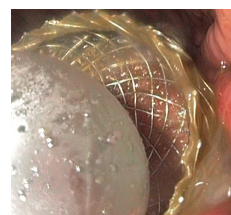


FIGURE 10

Dilation performed up to 13.5 mm using a balloon across the stent lumen.

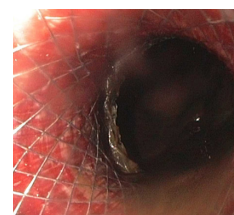


FIGURE 11

Endoscopic view across the cystgastrostomy tract with the cyst cavity seen through the stent lumen following balloon dilation.

Results from case studies are not predictive of results in other cases. Results in other cases may vary. Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

Caution: Federal (U.S) law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician.

Information for the use only in countries with applicable health authority product registrations.

WARNING: The safety and effectiveness of the WallFlex Biliary Stent for use in the vascular system has not been established. All trademarks are the property of their respective owners.

© 2015 Boston Scientific Corporation or its affiliates. All rights reserved.

**Boston
Scientific**

Advancing science for life™

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com/gastro

Ordering Information
1.888.272.1001

ENDO-338307-AA September 2015