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Invited Review Article

Specially designed stents for translumenal drainage

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A B S T R A C T

Endoscopic ultrasonography (EUS)-guided translumenal drainage of pancreatic fluid collections and obstructed bile and pancreatic ducts has been widely practiced for over a decade now, using conventional tubular plastic and metal stents. Their application for transmural drainage has been "off label" and limited by the lack of lumen-to-lumen anchorage that can lead to leakage, perforation, and stent migration. In addition, the length of a tubular stent exceeding the anatomical requirement of a translumenal anastomosis can lead to tissue trauma at the stent ends. Novel stent designs dedicated to applications of translumenal drainage have recently emerged and promise to make transmural drainage quicker, safer, and more effective. Importantly, passage of an endoscope through a translumenal stent will enable the endoscopist to expand the frontier of endoscopic intervention to structures outside of the gastrointestinal tract.

Keywords: cholecystenterostomy, choledochoenterostomy, cystenterostomy, endosonography, translumenal

Introduction

A new era in therapeutic endoscopy began with the first endoscopic biliary stent placement by Soehendra and Reynders-Frederix in 1979,[1] 5 years after the first sphincterotomy. Subsequently, an array of plastic stents with various configurations was commercialized. Plastic stents have been limited by clogging, which typically occurs 3–4 months postinsertion, and migration. The observation that an increase in stent diameter produces increased patency rates led to the development of self-expandable metal stents (SEMS). Randomized controlled trials comparing expandable metallic stents with plastic stents have demonstrated significantly lower rates of stent obstruction and cholangitis.[2,3] Nonetheless, SEMS also occlude over time, mainly due to tumor ingrowth and/or overgrowth and mucosal hyperplasia induced by a chronic inflammatory reaction to the stent mesh.[3] The covering of SEMS has made these removable for the treatment of benign disease, however, these have a higher propensity to migration.

With the emergence of interventional endoscopic ultrasonography (EUS), translumenal drainage of the bile and pancreatic ducts, and associated fluid collections such as bilomas[4] and pancreatic fluid collections, has become part of the realm of the interventional endoscopist. The linear array echoendoscope, which enables real-time ultrasound visualization of a tool pushed out of the accessory channel, extends the reach of endoscopic intervention to targets outside of the gut wall. The development of EUS-guided translumenal interventions has required the rapid evolution of new endoscopic tools and stent designs. This review will cover the development of specialized stents for translumenal access and therapy.

General considerations

Specific stent designs for translumenal intervention are influenced by several considerations. First is the location of the target to be drained. This may be directly adjacent to the bowel wall or further removed within an organ such as the liver or pancreas. Second is the adherence of the target to the bowel wall. Third is the therapeutic intent, which may include specific extralumenal interventions such as necrosectomy for walled-off pancreatic necrosis and removal of stones in the gallbladder, bile, or pancreatic ducts.

Lumenal versus translumenal stents

Conventional lumenal stents used in endoscopy are tubular in form, conceived for coaxial placement within a lumen. The most common indication for stenting is lumen recanalization to relieve an obstruction due to a malignant or benign stricture.[3] Stents have also been placed to treat fistulas and leaks.

Whether plastic or metal, tubular stents have several limitations when applied to translumenal drainage. Firstly, they do not impart lumen-to-lumen anchorage. This may result in leakage of contents if there is physical separation of the lumens. Secondly, stent

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migration may occur, due to the absence of a stricture to hold it in place. Thirdly, the length of tubular stents exceeds the anatomical requirement of a shorter translumenal anastomosis. The exposed stent ends may cause tissue trauma, resulting in bleeding or perforation. Finally, the longer the stent length, the more prone the stent is to clogging.

A translumenal stent of sufficient diameter should enable the passage of an endoscope into the target lumen for endoscopic interventions. The stent thereby serves as both a conduit for drainage as well as an access port. This extends the array of potential interventions to those routinely performed in the bowel lumen, such as tumor resection and ablation. In the gallbladder and bile duct, biliary interventions for stone disease, such as mechanical and electrohydraulic lithotripsy under direct endoscopic guidance, should be possible.

Lumen-apposing stents

AXIOS

The development of a lumen-apposing stent designed for translumenal drainage was first reported by Binmoeller and Shah in 2011.[5] The AXIOS stent (Xlumena Inc., Mountain View, CA, USA) consists of double-walled flanges that are perpendicular to the lumen and hold the tissue walls in apposition (Fig. 1). Fully expanded, the flange diameter is approximately twice that of the stent lumen. Lumen diameters are 10 mm, 15 mm, and 20 mm. The stent flanges are designed to distribute pressure evenly on the lumenal wall. The stent is made of braided nitinol wire and fully covered to prevent tissue ingrowth and tract leakage, as well as enable removability.

The AXIOS stent is delivered through a 10.8F catheter. Preliminary tract dilation by bougienage, balloon dilation, or cautery is needed to enable advancement of the catheter across tissue planes into the target lumen. A tapered “nosecone” at the catheter tip facilitates passage across the wall after this dilation has occurred. Two radiopaque markers on the catheter indicate each end of the preloaded stent to enable fluoroscopic control of stent position, if needed. An endoscopically visible marker identifies the point at which the proximal stent anchor should be released from the delivery catheter.

The handle of the AXIOS delivery system is Luer-locked onto the echoendoscope instrumentation channel inlet port, analogous to a standard fine needle aspiration needle (Fig. 2). This gives the operator full control of stent deployment with the right hand alone. The handle consists of a distal portion for catheter control and a proximal portion for stent control. Advancement of the “catheter control hub” along the distal portion advances the catheter into the target lumen. The desired intraluminal catheter position is then secured in place by activating the “catheter lock”. Retraction of the “stent deployment hub” to the halfway mark retracts the catheter sheath to deploy the distal stent anchor in the target lumen. The “catheter lock” is then released to retract the “catheter control hub” until the distal anchor engages the wall of the target lumen. Complete retraction of the “stent deployment hub” deploys the proximal anchor in the bowel lumen. A unique feature of the delivery system is the ability to deploy the distal and proximal stent anchors independent of one another in two sequential steps, with a full “stop” after the release of the distal anchor to prevent unintended deployment of the proximal anchor.

An evolutionary modification of the AXIOS delivery system is the integration of cautery into the nosecone at the catheter tip (Hot

Fig. 2. The handle of the AXIOS delivery system is Luer-locked onto the echoendoscope instrumentation channel inlet port, analogous to a standard fine needle aspiration needle. The handle consists of a distal portion for catheter control and a proximal portion for stent control.

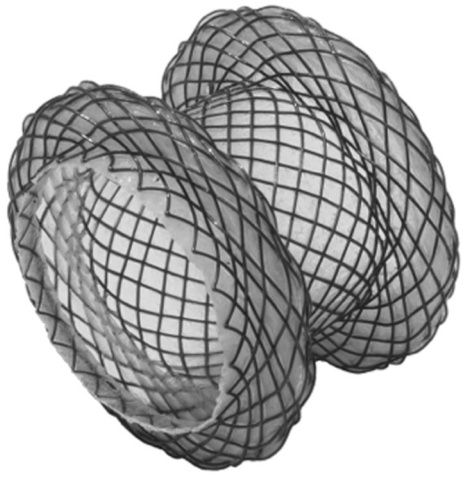

Fig. 1. The AXIOS stent (Xlumena Inc., Mountain View, CA, USA) consists of double-walled flanges that are perpendicular to the lumen and hold the tissue walls in apposition.

Fig. 3. Tip of the 10.8Fr Hot AXIOS catheter. Two radially distributed diathermic wires converge around the guide wire lumen. The catheter houses the AXIOS stent for immediate deployment after entry into the target lumen.