EUS-guided transenteric gallbladder drainage with a new fistula-forming, lumen-apposing metal stent

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Laparoscopic cholecystectomy is the standard approach for patients with lithiasic acute cholecystitis.[1,2] However, some are patients unsuitable for cholecystectomy because of advanced age, underlying comorbidities, or malignances: in these cases, percutaneous transhepatic gallbladder drainage is the treatment of choice up to now,[3,4] with clinical success rates between 56% and 100%.[5,6] Nevertheless, the percutaneous approach has many drawbacks including pneumothorax, biliary peritonitis, or bleeding, reported in up to 12% of cases,[5] and potential complications secondary to premature tube removal or dislodgement in 0.3% to 12% of patients.[7-11] Furthermore, high rates of recurrence of cholecystitis (33%) have been reported after removal of the drainage catheter.[8] The procedure is also uncomfortable for the patient, and ongoing nurse maintenance is required. Endoscopic methods for gallbladder drainage include the transpapillary approach (with plastic stents[12,13] or naso-gallbladder drainage [NGBD][14,15]) or EUS-guided transmural gallbladder drainage. To date, there are scant data about safety and feasibility of EUS-guided transmural gallbladder drainage.[16-20] In contrast, EUS-guided transenteric drainage of peripancreatic collections by using tubular stents (plastic or self-expandable metal stents [SEMS]) has become a strengthened therapeutic procedure, replacing percutaneous or surgical drainages. However, tubular-shaped stents (plastic or metal) have disadvantages and risks, such as bile leakage or migration. Furthermore, the slow flow of bile and the small caliber of plastic stents can result in early malfunction and clogging. These inconveniences could be avoided with the recently developed self-expandable lumen-apposing metal stent AXIOS (Xlumena Inc, Mountain View, Calif), tested in preliminary reports[21,22] with encouraging results in both pseudocysts and gallbladder drainage. We report our experience with the AXIOS stent in gallbladder drainage of high-risk patients with acute cholecystitis unsuitable for cholecystectomy.

Abbreviation: NGBD, naso-gallbladder drainage; SEMS, self-expandable metal stent.

DISCLOSURE: *All authors disclosed no financial relationships relevant to this publication.*

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2012.09.021

Received August 1, 2012. Accepted September 17, 2012.

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PATIENTS AND METHODS

Patients

Between June 2011 and March 2012, thirteen patients with acute cholecystitis underwent EUS-guided transgastric/transduodenal drainage with AXIOS stents. The patients were not thought to be candidates for emergency cholecystectomy because of severe underlying comorbidities, poor surgical performance (scores III-IV on the American Society of Anesthesiologists Physical Status Classification System), and/or advanced malignancies. None of them had responded adequately after 24 hours of conservative therapy with bowel rest, fluid replacement, and intravenous wide-spectrum antibiotics and analgesics. Acute cholecystitis was diagnosed according to clinical standard criteria[23] and US or CT. ERCP was previously performed whenever signs of choledocholithiasis or dilation of the common bile duct were found. The study protocol was approved by the Institutional Review Board of our institution. All patients signed a specific written informed consent form.

Materials and methods

All of the procedures were performed by the same experienced interventional endoscopist (M. P-M.) at a single, tertiary-care institution. A linear array echoendoscope (GT-UCT 240-AL; Olympus Medical, Tokyo, Japan) was used. The AXIOS stent consists of a fully covered nitinol stent with bilateral anchor flanges. The silicone covering prevents potential bile leakages and tissue ingrowth, ensuring subsequent removability. The anchors maintain attachment to gastric/duodenal and gallbladder walls, allowing fistula forming and maturation. The stents were 10 and 15 mm in diameter of drainage lumen, with 6 and 10 mm of length between flanges. Punctures were performed with a 19-gauge needle (EUSN-19-T; Cook Endoscopy, Winston-Salem, NC) under direct EUS visualization from the distal gastric antrum or duodenal bulb to access the gallbladder body in the shorter way, avoiding interposition of vessels. After stylet removal, bile was aspirated and sent for culture, and cholecystography was performed by

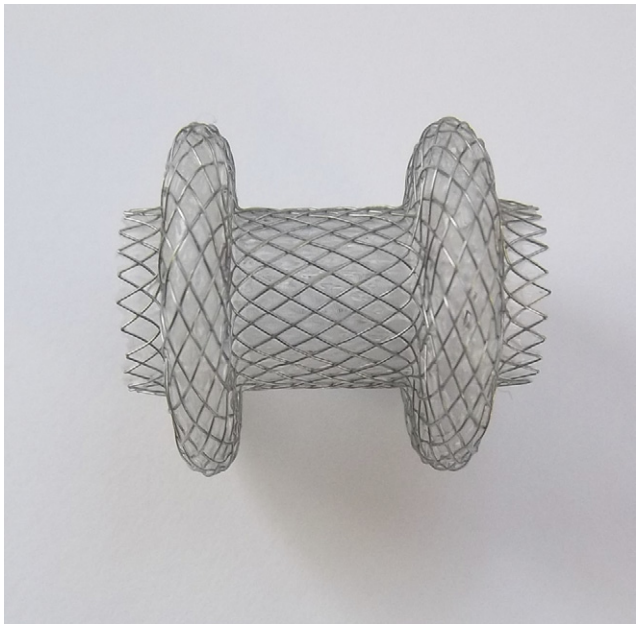

Figure 1. The lumen-apposing, fully covered AXIOS (Xlumena Inc, Mountain View, Calif) stent with bilateral anchor flanges.

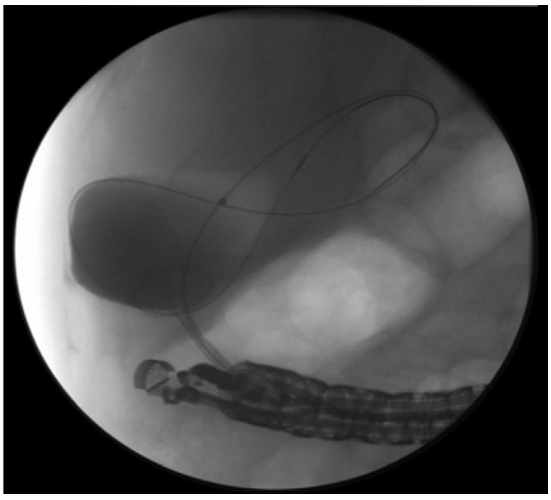

Figure 2. Gallbladder drainage by using the AXIOS (Xlumena Inc, Mountain View, Calif) stent: fluoroscopic image with the guidewire widely coiled in the gallbladder and AXIOS stent (intracholecystic end) partially deployed.

Figure 3. EUS-controlled releasing of the distal (intracholecystic) anchor flange.

injection of contrast medium. A 0.035-inch guidewire (Vysiglide; Olympus) was passed and the tract dilated by sequential use of an 8.5F cystotome (Cysto-Gastro-Set; Endoflex, GmbH, Voerde, Düsseldorf, Germany) and a 4-mm biliary balloon dilator (Hurricane; Boston Scientific, Natick, Mass). Finally, the AXIOS stent was inserted under direct fluoroscopic and EUS control. Sometimes, at the discretion of the endoscopist, a 10-mm balloon dilator (Controlled Radial Expansion balloon dilator; Boston Scientific) was inflated within the AXIOS lumen to achieve rapid deployment and prevent potential dislodgement secondary to therapeutic maneuvers through it (Figs. 1-4).

Standard or ultraslim endoscopes were introduced into the gallbladder to aspirate pus and sludge or for stone removal or lavage with 0.9% saline solution. A second tubular SEMS (Wallflex, Boston Scientific) was occasionally inserted coaxially through the AXIOS lumen to prevent dislodgement in the case of doubts about the proper anchoring of the distal flange, especially in patients with very thick gallbladder walls. Technical success criteria included the capability to access and drain the gallbladder. Clinical success was defined as complete resolution of symptoms with normalization of laboratory test data (Figs. 5-11).

RESULTS

Procedure details, patient data, and technical aspects are included in Table 1. Thirteen patients were included (5 women, 8 men; mean age 79.92 years; range 57-97 years). All patients had been diagnosed as having calculous cholecystitis and were considered unsuitable for cholecystectomy because of advanced malignances scores of III to IV of the American Society of Anesthesiologists Physical Status Classification System.

Insertion of the AXIOS stent was successful in 11 of 13 patients (technical success rate, 84.61%). Two cases failed: one because of a tight, cobblestoned gallbladder, which prevented deep insertion and progression of the guidewire; the other secondary to an uncontrolled stent release with accidental traction over the catheter shaft, which led to complete deployment into the gastric lumen. All patients (11/11) experienced immediate symptomatic relief, with progressive normalization of liver function test results and acute-phase reactant levels (clinical success rate, 100%). All but one (10/11, 90.90%) were transgastric-antral approaches. In 4 of 11 patients (36.36%), a second tubular coaxial SEMS was inserted to ensure permeability. There were complications in two cases, resolved with conservative management: one patient presented scant hematoche-