Feasibility and safety of EUS-guided transgastric/transduodenal gallbladder drainage with single-step placement of a modified covered self-expandable metal stent in patients unsuitable for cholecystectomy

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Background: Although early laparoscopic cholecystectomy is the treatment of choice for patients with acute cholecystitis, percutaneous cholecystostomy has been performed in patients unsuitable for cholecystectomy. EUS-guided transgastric/transduodenal gallbladder drainage by using a plastic stent and/or nasobiliary drainage may be an alternative effective treatment for these patients, but bile leakage into the peritoneal space causing bile peritonitis is not uncommon during placement of a plastic stent.

Objective: To evaluate the technical feasibility and safety of EUS-guided transgastric/transduodenal gallbladder drainage with single-step placement of a modified covered self-expandable metal stent (CSEMS) in patients with acute cholecystitis who are unsuitable for cholecystectomy.

Design: Prospective feasibility study.

Setting: Tertiary-care referral center.

Patients: This study involved 15 patients with acute cholecystitis who did not respond to initial medical treatment and were unsuitable for cholecystectomy.

Intervention: EUS-guided transgastric/transduodenal gallbladder drainage with single-step placement of a modified CSEMS.

Main Outcome Measurements: Technical success, functional success, complications associated with the placement of a metal stent, and recurrence of acute cholecystitis.

Results: Modified CSEMSs were successfully placed in all patients through the stomach (n = 10) or duodenum (n = 5). All patients achieved functional success within 3 days of metal stent placement. Pneumoperitoneum occurred in two patients during or after the procedure, but both patients improved with conservative management. During follow-up (median 145 days, range 60-297 days), no patient experienced recurrent cholecystitis.

Limitations: Small patient population without long-term follow-up.

Conclusion: Placement of a modified CSEMS after EUS-guided transgastric/transduodenal gallbladder drainage may be a feasible and safe alternative to treatments such as percutaneous cholecystostomy in patients with acute cholecystitis who are unsuitable for cholecystectomy.

Although early laparoscopic cholecystectomy is the treatment of choice for patients with acute cholecystitis, this procedure is unsuitable for patients with advanced malignancy who have limited life expectancy or for patients with underlying comorbidities that place them at high risk if given general anesthesia and if treated by surgery.[1] Percutaneous cholecystostomy is therefore the definitive treatment in such patients,[2] but this procedure has several drawbacks, including the risks of bleeding, pneumoperitoneum, bile leakage, and catheter dislodgement.[3] In addition, continuous percutaneous drainage causes patient discomfort, associated with both the catheter per se and management of a catheter and bag.[3,4] This may espe-

Abbreviation: CSEMS, covered self-expandable metal stent.

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cially affect the quality of life of patients with advanced malignancy who have limited life expectancy.

In contrast, EUS-guided transgastric/transduodenal gallbladder drainage by using a plastic stent and/or nasobiliary drainage, which does not require an external drainage catheter, has recently been accepted as an effective method of managing acute cholecystitis in patients unsuitable for cholecystectomy.[4-6] However, the main disadvantage of plastic stent placement is bile leakage into the peritoneal space, which may cause bile peritonitis. Insertion of a plastic stent requires a fistula tract of diameter larger than, or at least equal to, the diameter of the inserted stent. However, if the diameter of the fistula tract is larger than that of the inserted stent, bile leakage through the gap between the fistula and stent may occur.

Because of expandability, a metal stent can seal the gap between the stent and the fistula of the gallbladder wall, thus preventing bile leakage. We have evaluated the safety and feasibility of a modified covered self-expandable metal stent (CSEMS) in patients with acute cholecystitis who were unsuitable for cholecystectomy.

Take-home Message

- EUS-guided transgastric/transduodenal gallbladder drainage with single-step placement of a modified covered self-expandable metal stent can be a feasible and safe alternative treatment in patients with acute cholecystitis who are unsuitable for cholecystectomy. Large-scale and long-term follow-up data are required.

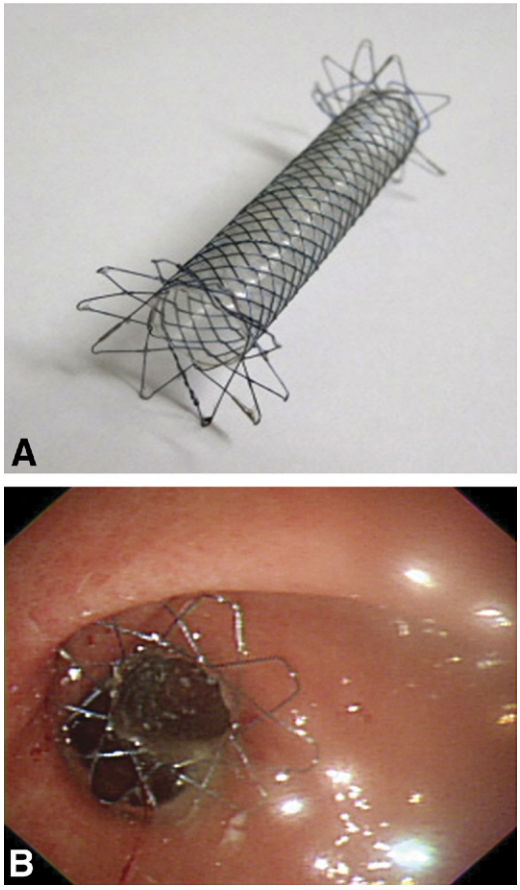

Figure 1. A, A modified covered self-expandable metal stent (CSEMS). **B,** Endoscopic image of the flared end of a modified CSEMS of which the distal end is in the antrum.

PATIENTS AND METHODS

Patients

Between January 2010 and October 2010, 15 patients in our institution underwent EUS-guided transgastric/transduodenal gallbladder drainage with single-step placement of a modified CSEMS. Patients were included if they had acute cholecystitis with advanced malignancy or poor surgical performance (American Society of Anesthesiologists Physical Status Classification System score of IV or V).[7] Acute cholecystitis was diagnosed according to the Tokyo guidelines, including a combination of typical clinical symptoms (right upper quadrant pain, fever, positive Murphy's sign, and elevated leukocyte count or serum C-reactive protein level) and radiological findings consistent with acute cholecystitis.[8] All patients were initially managed by bowel rest, intravenous antibiotics, and fluids, but they did not improve. All patients had previously undergone ERCP with a transpapillary cystic approach, but this procedure was unsuccessful. Cholecystectomy was considered inappropriate for these patients because of the overall risk of complications. All EUS procedures were performed by one endosonographer (S.S.L.), who had previously performed more than 3000 EUS procedures. All patients provided written informed consent for EUS-guided transgastric/transduodenal gallbladder drainage with single-step placement of a modified CSEMS. The study protocol was approved by the institutional review board of our center.

Modification of the CSEMS to prevent bile leakage and migration

All CSEMSs were partially covered metal stents (BONA-AL Stent, Standard Sci Tech Inc, Seoul, Korea) containing a nitinol wire and with a silicone cover membrane. The stents were 10 mm in diameter and 4 to 7 cm in length (Fig. 1A). We designed a modified BONA-AL stent by enlarging the flares (22-mm external diameter), and the ends of the stent had 90° angulation that prevented migration after placement (Fig. 1B).

Techniques

All patients were sedated by intravenous administration of midazolam, meperidine, and (occasionally) propofol. EUS-guided transgastric/transduodenal gallbladder drain-