A non-randomized study in consecutive patients with postcholecystectomy refractory biliary leaks who were managed endoscopically with the use of multiple plastic stents or fully covered self-expandable metal stents (with videos)

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Background: Endoscopic management of postcholecystectomy biliary leaks is widely accepted as the treatment of choice. However, refractory biliary leaks after a combination of biliary sphincterotomy and the placement of a large-bore (10F) plastic stent can occur, and the optimal rescue endotherapy for this situation is unclear.

Objective: To compare the clinical effectiveness of the use of a fully covered self-expandable metal stent (FCSEMS) with the placement of multiple plastic stents (MPS) for the treatment of postcholecystectomy refractory biliary leaks.

Design: Prospective study.

Setting: Two tertiary-care referral academic centers and one general district hospital.

Patients: Forty consecutive patients with refractory biliary leaks who underwent endoscopic management.

Interventions: Temporary placement of MPS (n = 20) or FCSEMSs (n = 20).

Main Outcome Measurements: Clinical outcomes of endotherapy as well as the technical success, adverse events, need for reinterventions, and prognostic factors for clinical success.

Results: Endotherapy was possible in all patients. After endotherapy, closure of the leak was accomplished in 13 patients (65%) who received MPS and in 20 patients (100%) who received FCSEMSs ($P = .004$). The Kaplan-Meier (log-rank) leak-free survival analysis showed a statistically significant difference between the 2 patient populations (χ^2 [1] = 8.30; $P < .01$) in favor of the FCSEMS group. Use of <3 plastic stents ($P = .024$), a plastic stent diameter <20F ($P = .006$), and a high-grade biliary leak ($P = .015$) were shown to be significant predictors of treatment failure with MPS. The 7 patients in whom placement of MPS failed were retreated with FCSEMSs, resulting in closure of the leaks in all cases.

Limitations: Non-randomized design.

Conclusion: In our series, the results of the temporary placement of FCSEMSs for postcholecystectomy refractory biliary leaks were superior to those from the use of MPS. A randomized study is needed to confirm our results before further recommendations. (Gastrointest Endosc 2015;82:70-8.)

(footnotes appear on last page of article)

This video can be viewed directly from the GIE website or by using the QR code and your mobile device. Download a free QR code scanner by searching "QR Scanner" in your mobile device's app store.

Biliary leaks can occur after laparoscopic cholecystectomy in 0.3% to 2.7% of patients.[1] ERCP has emerged as a minimally invasive method for the primary treatment for bile leaks.[2-11] The outcome of sealing the leak can be accomplished by a variety of endoscopic techniques. These methods include biliary sphincterotomy alone, biliary stenting with or without sphincterotomy, and nasobiliary drainage.[2-10] All of these methods of endotherapy seem to be equally effective in allowing the leak to heal in

most cases, but the approach of choice remains controversial.[2,8-10] Although there is no consensus regarding the optimal endoscopic intervention, recent data suggest that a combination of biliary sphincterotomy and the placement of a transpapillary biliary stent has a better outcome for the treatment of high-grade and more complex biliary leaks.[3] However, despite the high success rate and safety of endotherapy for bile leaks, there are reports of difficult-to-treat refractory bile leaks that require multiple endoscopic interventions and sometimes require surgery.[3,4,9,10,12] In recent years, the temporary placement of a fully covered self-expandable metal stent (FCSEMS) has emerged as an effective rescue therapy for refractory biliary leaks.[12-20] However, in patients with persistent biliary leaks, instead of using FCSEMSs, the endoscopist could place >1 plastic stent at a lower cost to further decrease the transpapillary pressure gradient and to seal the leak. However, costs also should be considered as far as rescue therapy is concerned. In our country, the cost of an ERCP with placement of multiple plastic stents (MPS) is U.S. $2200, and the cost of an ERCP in which a FCSEMS is used is U.S. $3200. The price of the ERCP is the same for both treatments, but the placement of an FCSEMS increases the price by $1000, and this issue can be included in the treatment decision. Further, in the United States the problem is similar, being that the price of the ERCP is the same, but the cost of the stents is different, increasing the price by >$1000. Until now, there have been no comparative studies between these 2 types of endoscopic treatment, and the decisions regarding treatment of a refractory biliary leak must be made on an individual basis.[12,16-18] Therefore, it is not known whether the MPS used for the closure of a refractory biliary leak are as successful as the use of an FCSEMS. We conducted a non-randomized study aiming to compare the clinical effectiveness of the use of an FCSEMS with the placement of MPS for the treatment of postcholecystectomy refractory biliary leaks. Additionally, we compared the technical success, adverse events, need for reinterventions, and prognostic factors for clinical success.

METHODS

Patients and setting

This work was a prospective clinical study. Between May 2010 and September 2013, 2 consecutive cohorts of patients with refractory biliary leaks were enrolled in the study and followed prospectively. The patients were referred for ERCP if they had a postcholecystectomy biliary leaks that failed to close after endotherapy, specifically a combination of biliary sphincterotomy and the placement of a 10F transpapillary biliary stent. Patients were submitted to endotherapy in 2 consecutive cohorts of 20 patients each. The first 20 patients were treated with MPS, and the next cohort of 20 patients was treated with the temporary placement of FCSEMSs. In each group of consecutive patients, the treatment was done at the discretion of the endoscopist, meaning that the endoscopist was allowed to choose the number, type, and size of the plastic stents in the MPS group or the size and type of the metal stent in the FCSEMS cohort. Further, this decision was done accordingly with the diameter of the duct and the location of the leak. Patients with refractory bile leaks with an etiology other than postcholecystectomy were excluded from the study. This study was conducted at 3 institutions (2 tertiary-care referral academic centers and 1 general district hospital). All of the patients provided informed written consent before their procedures. Each institutional review board involved approved this study.

Outcomes and definitions

The primary outcome was the clinical success of each type of endotherapy, defined as closure of the leak. The secondary outcomes included the determination of prognostic factors associated with closure of the leak, technical success, safe removal of the stents, duration of treatment, adverse events, and the need for reinterventions. Refractory biliary leaks were defined as leaks that failed to close after endoscopic intervention with a combination of biliary sphincterotomy and the placement of a 10F transpapillary biliary stent, regardless of the biliary leak location (cystic stump, common bile duct and/or common hepatic duct, Luschka).[17] All of the plastic stents used were at least 7 cm long. High-grade biliary leaks were defined as leaks observed fluoroscopically before intrahepatic opacification.[3] Closure of the leak was considered after the cessation of bile output, which was defined as biliary drainage of <5 mL/day in the percutaneous drains[17] and confirmed at follow-up ERCP. Failure of endotherapy was defined as the persistence of biliary drainage through the percutaneous drain or the persistence of a bile leak at follow-up ERCP. Reintervention was defined as the need for further intervention to control the leak after the initial endotherapy for the refractory leak, including repeat ERCP for additional stenting or surgery. Adverse events were defined as any adverse event related to the ERCP or stent placement, and adverse events were carefully monitored by using previously determined definitions.[13,14,17,21]

Intervention, stents, and follow-up

The ERCP procedures were performed with the patient in the prone position under sedation with propofol administered by an anesthesiologist. All procedures were performed by 2 experienced pancreatobiliary endoscopists (J.C., M.L.). During the study, J.C. performed the endoscopic procedures at the 3 participating centers, and M.L. performed most of the endoscopic examinations in center 1 (Cuf). Patients were considered eligible to enter the study if, after the first treatment for the biliary leak, the output of the drain was ≥600 mL/day at the sixth day, >500 mL/day after the 10th day, or ≥400 mL/day at