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Percutaneous placement of a retrievable fully covered metal stent with anchoring flaps for the treatment of biliary anastomotic stricture following LDLT

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Abstract

To investigate the outcomes following percutaneous placement of a retrievable fully covered self-expanding metal stent (fcSEMS) with anchoring flaps at proximal and distal ends for the treatment of biliary anastomotic strictures following living-donor liver transplantation (LDLT). We retrospectively reviewed the medical records of nine patients who underwent this procedure at our centre between April 2020 and March 2021. Percutaneous stent placement was technically successful in 100% patients, and all stents were successfully retrieved. No proximal or distal stent migration or occlusion was observed during the mean (±SD) stent indwelling period of 191 (± 77) days. Clinical success was 89%. There was one major bleeding complication related to the biliary approach and one minor stent-related complication of calculus/sludge. During the mean (±SD) follow-up period of 595 ± 207 days after stent retrieval, only one patient developed recurrent clinical biliary stricture and symptoms. Percutaneous placement of a retrievable fcSEMS with anchoring flaps is safe and feasible for the treatment of biliary anastomotic strictures following LDLT.

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Introduction

Orthotopic liver transplantation is the primary treatment for end-stage liver diseases of various aetiologies, including primary liver cancer and acute liver failure.[1] The demand for liver transplantation is increasing, and living-donor liver transplantation (LDLT) is rapidly increasing worldwide owing to the limited availability of deceased-donor liver transplantation.[1–3] Advancements in surgical techniques, organ preservation, and immunosuppressants have contributed to an overall increase in the success rate of liver transplantation. However, biliary complications remain a challenging issue in 6–40% of patients and affect graft survival, mortality, and morbidity rates.[2,4,5]

Biliary stricture is a common biliary complication after orthotopic liver transplantation, with an overall incidence of approximately 13%.[6] It arises more frequently after LDLT because of local tissue ischaemia during hilar dissection of the graft and the small size of the bile ducts.[6,7] Moreover, duct-to-duct anastomosis in LDLT has become the preferred technique in recent decades owing to its physiological advantages. However, anastomotic strictures are the most common type of biliary stricture, occurring in approximately 6–12% of cases because of the fibrotic healing process of the biliary epithelium.[2,4] Early detection and proper management of biliary strictures are essential to improve graft survival and patients' quality of life.

In the past, surgical management was the standard treatment for biliary strictures. However, non-surgical treatments, such as endoscopic or percutaneous management, have emerged as first-line treatments, and surgical management is now reserved for refractory or complicated cases.[4,5] Endoscopic placement of multiple plastic stents (MPS) is commonly performed but it is associated with complications, such as stent occlusion, and may require many repetitive procedures.[8] Covered self-expanding metal stents (cSEMS) have been reported to overcome these problems and are non-inferior to MPS but complications, such as stent migration, persist.[9,10] Several cSEMS with antimigration mechanisms have been developed to address these shortcomings and are available for treating biliary strictures.[11] The purpose of this present study was to investigate outcomes following placement of a retrievable fully covered self-expanding metal stent (fcSEMS) with anchoring flaps at proximal and distal ends for the treatment of biliary anastomotic strictures following LDLT.

Methods

Patients

For this retrospective study, medical records of 17 consecutive, adult (i.e., >18 years of age) patients who had been referred by a liver surgeon for the management of biliary strictures after LDLT at our centre between April 2020 and March 2021 were reviewed by two investigators [J.H., S.L.C.]. Patients with malignant stricture, concurrent biliary leakage, hepaticojejunostomy state, and those where retrievable-stent insertion was not possible because of multiple ductal strictures, were excluded from the study.

The reporting of this study conforms to CARE guidelines.[12] The study obtained formal approval from our Institutional Review Board (IRB No. 2203-017-19410). Written informed consent was not required due to the retrospective design of the study and patient data were anonymized prior to analysis.

Procedures

In brief, all procedures were performed under local anaesthesia. A branch of the bile duct was punctured using a 21 G Chiba needle (Cook, Bloomington, IN, USA) under ultrasound and fluoroscopic guidance, followed by insertion of a 9-Fr sheath (Super Arrow-Flex; Arrow International, Reading, PA, USA). Anastomotic strictures were negotiated using 0.035-inch hydrophilic guidewires (Radiofocus; Terumo, Tokyo, Japan) or 0.018-inch microwires (Meister; ASAHI INTECC Co., Nagoya, Japan). Before wire negotiation, the diameter of the dilated biliary duct was measured on cholangiography. To prevent wall erosion or biliary epithelial overgrowth, a stent diameter similar to that of the dilated duct before stricture formation was selected, and a stent with an appropriate length forming smooth angle was selected. The stent delivery system was advanced over the 0.035-inch guidewire and positioned within the anastomotic stricture. A retrievable fully covered self-expanding metal stent (fcSEMS) with anchoring flaps 1cm from proximal and distal ends (to prevent proximal or distal migration) and a lasso at the proximal end for retrieval (Hanaro; M.I. Tech, Seoul, South Korea) was used (Figure 1).

For most patients, stent placement was performed immediately after the biliary approach but in a few patients, it was delayed up to one week, depending on the management of obstructive cholangitis.

Figure 1. Fully covered self-expanding metal stent with anchoring flaps (arrows) and a lasso (arrowhead).

Additional balloon dilatation was performed if stent expansion was insufficient on cholangiography performed immediately after deployment. Following stent placement, an 8.5-F drainage tube with a pigtail loop (Cook, Bloomington, IN, USA) was placed to prevent bile leakage; it was removed two weeks after the biliary approach.

Scheduled stent retrieval was performed after an indwelling time of approximately six months because data from a randomized clinical trial had shown a potentially low stricture recurrence rate when cSEMS were left in place longer than six months.[13] We considered stent exchange for early stent occlusion or migration less than three months. The biliary duct was accessed in the same manner, and a 9-Fr sheath (Super Arrow-Flex; Arrow International, Reading, PA, USA) was inserted. However, in cases of difficult access because of non-dilated bile ducts, the proximal end of the stent was targeted and punctured first, the needle was left in place, and contrast medium was injected to opacify the peripheral ducts which were then punctured using a second needle. Finally, the proximal radiopaque lasso was captured using forceps (Taewoong Medical, Seoul, Korea) or a snare (ev3, Irvine, CA, USA), and the stent was contracted and retrieved. If the cholangiogram after stent retrieval showed calculi or sludge, saline lavage was performed.

Outcomes and follow-up

Technical success was defined as successful stent deployment without migration within 48 h and successful stent retrieval.

Clinical success was defined as the absence of elevated laboratory parameters, such as bilirubin levels, or clinical symptoms (including pruritus or fever), during the stent indwelling period.

During the follow-up period after stent retrieval, laboratory and imaging studies, including liver computed tomography (CT) and magnetic resonance imaging (MRI), were performed to assess recurrent anastomotic strictures. Clinical follow-up, including laboratory examinations, were performed at 1, 3, 6, and 12 months after stent retrieval and imaging studies were performed at 3, 6, and 12 months. Irrespective of scheduled follow-up dates, imaging studies were also performed to assess recurrent anastomotic stricture if there was an increase in laboratory parameters or clinical symptoms. All complications were categorised as major or minor according to the guidelines of the Society of Interventional Radiology Standards of Practice Committee.[14]

Statistical analysis

Categorical variables were presented as numbers and percentages. Continuous variables were described as median (interquartile range) or mean ± standard deviation.

Results

Of the 17 patients initially identified, nine patients (eight men, one woman) were eligible for the study. The median (range) age of the group was 62 (39–78) years (Table 1). Of the nine patients, two (22%) had a history of drainage-tube placement following balloon dilatation, and one (11%) had undergone MPS placement. This man was in his mid-60's with underlying alcoholic liver cirrhosis and a history of MPS insertions following LDLT. He developed recurrent biliary anastomotic stricture 119 days after multiple plastic stent removal. CT scans and fluoroscopic images of the procedures he underwent are shown in Figure 2.

Table 1. Demographic characteristics of the study patients.

Characteristic	Results n = 9
Age, years	62 (39–78)
Sex, M:F	8:1
Aetiology of underlying liver disease	
Alcohol	4 (44)
Hepatitis B virus	3 (33)
Hepatitis B virus	1 (11)
Non B or C	1 (11)
Treatment history	
None	6 (67)
Drainage tube + balloon dilatation	2 (22)
Multiple Plastic Stents	1 (11)
Interval from LDLT, days	362 (51–1568)

LDLT, living-donor liver transplantation.
Data are expressed as, n, or n (%), or median (range).

The median interval from LDLT to stent insertion was 362 days (range 51 to 1568 days) and the interval varied according to treatment history. Two patients underwent stent placement distant from the biliary approach for the management of cholangitis. The stent diameters used were 6 mm (4 patients), 8 mm (4 patients), and 10 mm (one patient). Only one patient underwent dilatation using a 7 mm diameter balloon after deployment because of insufficient expansion of an 8mm diameter stent.

Percutaneous stent placement was technically successful in 100% patients, and all stents were successfully retrieved (Table 2). No proximal or distal stent migration or occlusion was observed during the mean stent indwelling period of 191 (±77) days (range, 121–375). Among all stent deployment and retrieval procedures, a procedure-related complication of bleeding occurred only once and was managed using peripheral-branch arterial embolization. One minor stent-related complication of

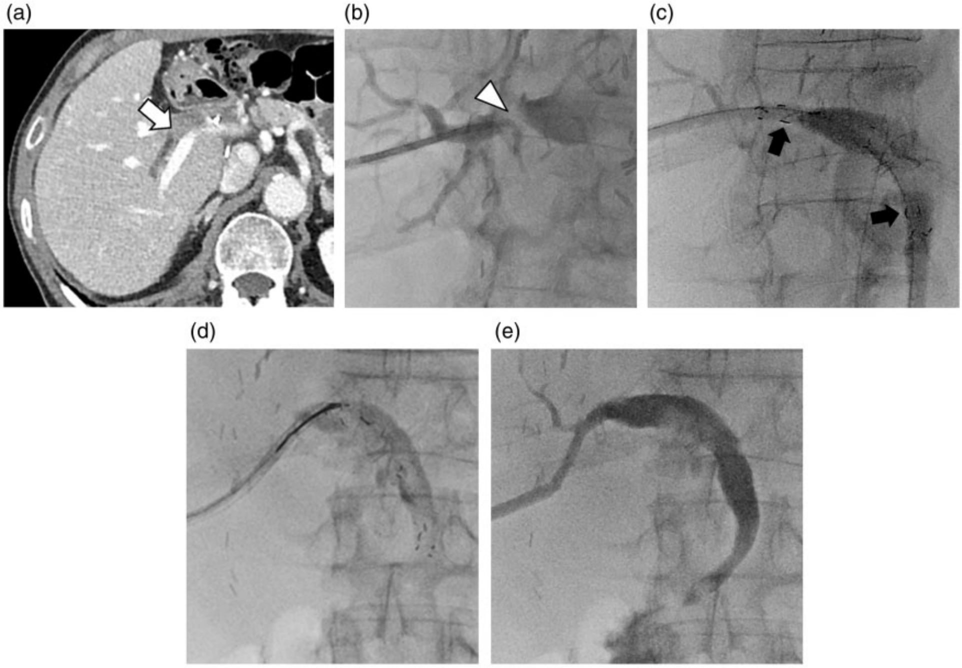

Figure 2. Computed tomography (CT) scan and fluoroscopic images from a man in his mid-60's with underlying alcoholic liver cirrhosis and a history of multiple plastic stent insertions following living-donor liver transplantation (LDLT). He developed recurrent biliary anastomotic stricture 119 days after multiple plastic stent removal. (a) CT scan of the liver showing a dilated biliary duct with an anastomotic stricture (white arrow). (b) The anastomotic strictures (arrowhead) were negotiated. (c) A fully covered self-expanding metal stent with anchoring flaps (black arrow) was placed. (d) After a stent indwelling period of 179 days, stent retrieval was performed by capturing the lasso using a snare catheter and (e) Cholangiogram immediately after stent retrieval showing resolution of the biliary stricture. No stricture recurrence occurred during the 818-day follow-up period.

calculus/sludge was detected on cholangiography immediately after stent retrieval and was resolved with saline lavage alone.

In eight patients, laboratory parameters (e.g., bilirubin levels) did not increase and so clinical success was 89% (Table 2). In addition, no imaging evidence of recurrent anastomotic stricture was observed during a mean follow-up of 595 ± 207 days (range, 311–852). However, one patient, with no treatment history, developed hyperbilirubinemia with general weakness 852 days after stent retrieval. Therefore, this patient underwent placement of an 18-F drainage tube across the stricture segment for approximately six months and is currently being followed up.

Discussion

The relatively high success rate and feasibility of re-treatment have increased the use of non-surgical procedures for biliary strictures following liver transplantation.[4,10] In spite of including patients with a history of previous treatment, the overall stricture-resolution rate in our study was 89%. We believe that this result is similar to, or slightly superior to, those previously reported, but direct comparisons are

Table 2. Outcomes and complications.

Outcomes and complications	Results n = 9
Technical success	9 (100)
Stent indwelling time, days	191 ± 77 (range, 121–375)
Procedure-related complication	
Major	1 (11)
Minor	0 (0)
Stent-related complication	
Major	0 (0)
Minor	1 (11)
Follow-up after stent retrieval, days	595 ± 207 (range, 311–852)
Clinical success	8 (89)

Data are expressed as, n (%) or mean ± standard deviation.

difficult because of different study designs and indwelling periods.[15–18] Maintaining maximal dilatation over a long period is important for achieving a better stricture-resolution rate.[13] In this regard, a fcSEMS with anchoring flaps may be advantageous because it can expand to a larger diameter than MPS can achieve and can remain unchanged over a long indwelling period.[5] In addition, it allows for fewer treatment sessions compared to that for MPS, which generally requires repeated treatment sessions especially for long indwelling periods. Compared with the percutaneous long-term placement of a large-bore drainage catheter, fcSEMS with an anchoring flap does not cause severe pain related to irritation of the diaphragm or skin problems.

Stent migration rates of cSEMS in benign biliary strictures vary widely from 4–100%; data related to LDLT are limited.[4,15,19] Although a meta-analysis found no statistically significant difference in the migration rates between fcSEMS and MPS, stricture recurrence rates tended to be higher when fcSEMSs were removed early.[18] Likewise, one study found the stricture-recurrence rate in patients with a stent indwelling period of less than three months was 15%, compared with 8% in those with more than three months.[20] With regard to stent migration, one study reported rates of 18% and 75% at three and six months, respectively. [15] This result suggests that the longer the stent indwelling period, the higher the migration rate.[15] Therefore, for a long stent indwelling period, such as six months, an antimigration mechanism is essential to maintain the cSEMS. Among the cSEMS with various antimigration mechanisms, retrieval failure owing to tissue ingrowth has been reported in partially uncovered SEMS and flaps tend to show better results than flared ends or a waist.[19–21] In our study, no stent migrated during the mean 191 day indwelling period, and no retrieval failure was observed, suggesting that anchoring flaps are an effective and safe antimigration mechanism. To the best of our knowledge, this is the third study assessing the migration rate of fcSEMSs with anchoring flaps, and, the first study to evaluate their usefulness in patients who have undergone LDLT.[19,21]

Regarding stent occlusion, MPS have been associated with occlusion requiring early endoscopic intervention in approximately 6% of cases.[22] In our study, no stent occlusion occurred during the indwelling period, although in one case, the duration from deployment to retrieval was 375 days. Therefore, in patients requiring long stent indwelling duration, fcSEMSs may be advantageous compared with MPS, which requires the exchange or addition of stents over multiple treatment sessions.

Our study had several limitations. For example, it was a single-centre, retrospective study with a small sample size. In addition, the sample included patients with varying time intervals between LDLT and stenting and different treatment history. Moreover, the average follow-up duration of approximately 600 days may not be sufficient given the tendency for stricture recurrence over time. Therefore, a prospective, multicentre study with a large sample size and a long follow-up period is required to validate our results.

In conclusion, data from this small study showed that percutaneous placement of a fcSEMS with anchoring flaps for the treatment of biliary anastomotic strictures following LDLT was associated with a low risk of stent migration and retrieval failure, and had a good clinical success rate.

Declaration of conflicting interests

The authors declare that there are no conflicts of interest.

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References

1. Halliday N and Westbrook RH. Liver transplantation: need, indications, patient selection and pre-transplant care. *Br J Hosp Med (Lond)* 2017; 78: 252–259.
2. Kyoden Y, Tamura S, Sugawara Y, et al. Incidence and management of biliary complications after adult-to-adult living donor liver transplantation. *Clin Transplant* 2010; 24: 535–542.
3. Yoon SB, Kim J, Paik CN, et al. Endoscopic and Percutaneous Biliary Interventions after Liver Transplantation: Nationwide Data in Korea. *Gut Liver* 2022; 16: 300–307.
4. Larghi A, Tringali A, Rimbaş M, et al. Endoscopic Management of Benign Biliary Strictures After Liver Transplantation. *Liver Transpl* 2019; 25: 323–335.
5. Koksal AS, Eminler AT, Parlak E, et al. Management of biliary anastomotic strictures after liver transplantation. *Transplant Rev (Orlando)* 2017; 31: 207–217.
6. Akamatsu N, Sugawara Y and Hashimoto D. Biliary reconstruction, its complications and management of biliary complications after adult liver transplantation: a systematic review of the incidence, risk factors and outcome. *Transpl Int* 2011; 24: 379–392.
7. Wan P, Yu X and Xia Q. Operative outcomes of adult living donor liver transplantation and deceased donor liver transplantation: a systematic review and meta-analysis. *Liver Transpl* 2014; 20: 425–436.
8. Tringali A, Tarantino I, Barresi L, et al. Multiple plastic versus fully covered metal stents for managing post-liver transplantation anastomotic biliary strictures: a meta-analysis of randomized controlled trials. *Ann Gastroenterol* 2019; 32: 407–415.
9. Morelli J, Mulcahy HE, Willner IR, et al. Long-term outcomes for patients with post-liver transplant anastomotic biliary strictures treated by endoscopic stent placement. *Gastrointest Endosc* 2003; 58: 374–379.
10. Tal AO, Finkelmeier F, Filmann N, et al. Multiple plastic stents versus covered metal stent for treatment of anastomotic biliary strictures after liver transplantation: a prospective, randomized, multicenter trial. *Gastrointest Endosc* 2017; 86: 1038–1045.
11. Lam R, Muniraj T. Fully covered metal biliary stents: A review of the literature. *World J Gastroenterol* 2021; 27: 6357–6373.
12. Gagnier JJ, Kienle G, Altman DG, CARE Group, et al. The CARE guidelines: consensus-based clinical case reporting guideline development. *Headache* 2013; 53: 1541–1547.
13. Coté GA, Slivka A, Tarnasky P, et al. Effect of Covered Metallic Stents Compared With Plastic Stents on Benign Biliary Stricture Resolution: A Randomized Clinical Trial. *Jama* 2016; 315: 1250–1257.
14. Sacks D, McClenny TE, Cardella JF, et al. Society of Interventional Radiology clinical practice guidelines. *J Vasc Interv Radiol* 2003; 14: S199–202.
15. Devière J, Nageshwar Reddy D, Püspök A, Benign Biliary Stenoses Working Group, et al. Successful management of benign biliary strictures with fully covered self-expanding metal stents. *Gastroenterology* 2014; 147: 385–395.

16. Gwon DI, Ko GY, Ko HK, et al. Percutaneous transhepatic treatment using retrievable covered stents in patients with benign biliary strictures: mid-term outcomes in 68 patients. *Dig Dis Sci* 2013; 58: 3270–3279.
17. Im BS, Gwon DI, Chu HH, et al. Percutaneous Transhepatic Treatment of Benign Bile Duct Strictures Using Retrievable Covered Stents: Long-Term Outcomes in 148 Patients. *Korean J Radiol* 2022; 23: 889–900.
18. Tringali A, Tarantino I, Barresi L, et al. Multiple plastic versus fully covered metal stents for managing post-liver transplantation anastomotic biliary strictures: a meta-analysis of randomized controlled trials. *Ann Gastroenterol* 2019; 32: 407–415.
19. Park DH, Lee SS, Lee TH, et al. Anchoring flap versus flared end, fully covered self-expandable metal stents to prevent migration in patients with benign biliary strictures: a multicenter, prospective, comparative pilot study (with videos). *Gastrointest Endosc* 2011; 73: 64–70.
20. Kao D, Zepeda-Gomez S, Tandon P, et al. Managing the post-liver transplantation anastomotic biliary stricture: multiple plastic versus metal stents: a systematic review. *Gastrointest Endosc* 2013; 77: 679–691.
21. Mangiavillano B, Manes G, Baron TH, et al. The use of double lasso, fully covered self-expandable metal stents with new "anchoring flap" system in the treatment of benign biliary diseases. *Dig Dis Sci* 2014; 59: 2308–2313.
22. Hsieh TH, Mekeel KL, Crowell MD, et al. Endoscopic treatment of anastomotic biliary strictures after living donor liver transplantation: outcomes after maximal stent therapy. *Gastrointest Endosc* 2013; 77: 47–54.