



Antimigration versus conventional fully covered metal stents in the endoscopic treatment of anastomotic biliary strictures after deceased-donor liver transplantation

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Abstract

Introduction Migration of fully covered metal stents (FCMS) remains a limitation of the endoscopic treatment of anastomotic biliary strictures (ABS) following orthotopic liver transplantation (OLT). The use of antimigration FCMS (A-FCMS) might enhance endoscopic treatment outcomes for ABS.

Methods Single center retrospective study. Consecutive patients with ABS following OLT who underwent ERCP with FCMS placement between January 2005 and December 2020 were eligible. Subjects were grouped into conventional-FCMS (C-FCMS) and A-FCMS. The primary outcome was stent migration rates. Secondary outcomes were stricture resolution, adverse event, and recurrence rates.

Results A total of 102 (40 C-FCMS; 62 A-FCMS) patients were included. Stent migration was identified at the first revision in 24 C-FCMS patients (63.2%) and in 21 A-FCMS patients (36.2%) ($p = 0.01$). The overall migration rate, including the first and subsequent endoscopic revisions, was 65.8% in C-FCMS and 37.3% in A-FCMS ($p = 0.006$). The stricture resolution rate at the first endoscopic revision was similar in both groups (60.0 vs 61.3%, $p = 0.87$). Final stricture resolution was achieved in 95 patients (93.1%), with no difference across groups (92.5 vs 93.5%; $p = 0.84$). Adverse events were identified in 13 patients (12.1%) with no difference across groups. At a median follow-up of 52 (IQR: 19–85.5) months after stricture resolution, 25 patients (24.5%) developed recurrences, with no difference across groups (C-FCMS 30% vs A-FCMS 21%; $p = 0.28$).

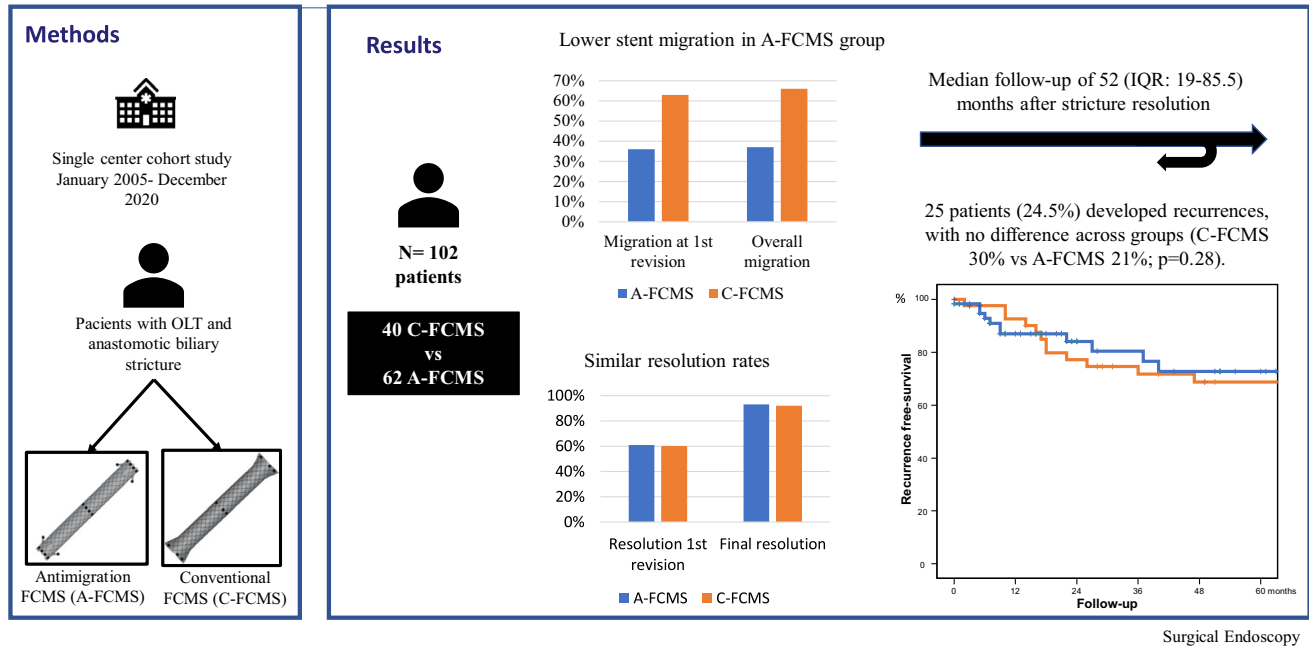
Conclusions The use of A-FCMS during ERCP for ABS following OLT results in significantly lower stent migration rates compared to C-FCMS. However, the clinical benefit of reduced stent migration is unclear. Larger studies focusing on stricture resolution and recurrence rates are needed

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Graphical Abstract



Keywords Liver transplantation · Anastomotic stricture · ERCP · Biliary stent

Orthotopic liver transplantation (OLT) is the current standard of care for end-stage liver disease and an accepted therapeutic option for acute liver failure and hepatocellular carcinoma. Survival following liver transplantation has improved over the past years, although, biliary complications remain a major problem, affecting up to 25% of OLT recipients.

Anastomotic biliary stricture (ABS) is the most common post-OLT biliary complication, accounting for 85% of biliary strictures [1]. ABS consist of an isolated postsurgical fibrosis localized within 1 cm from the original ductal anastomosis; ABS typically appear within one year of OLT. The occurrence of ABS is influenced by surgical technique, altered microcirculation in the bile duct, and the presence of bile leaks [1, 2].

Endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous drainage are available treatment options for ABS. ERCP minimizes patient discomfort and constitutes a safe and effective treatment approach with optimal long-term results. ERCP-based treatment includes balloon dilation followed by multiple plastic or a single fully covered metal stent (FCMS) placement. Both treatment options are comparable in terms of stricture resolution and recurrence. However, compared to plastic stents, FCMS are associated with lower adverse event rates [3], shorter treatment periods, fewer treatment sessions [4–6], and lower overall cost [5]. Technical success of FCMS for ABS after OLT is close to 100%, with stricture resolution rates ranging

between 86 and 100%, and recurrence rates between 15 and 30% [4].

Nevertheless, a common drawback of FCMS is the risk of migration, which in turn may compromise long-term treatment efficacy. Several studies on ABS have reported FCMS migration rates ranging from 15 to 62.7% [4, 7, 8]. Bordaça-har et al recently suggested that the use of antimigration FCMS (A-FCMS) with anchoring flaps in patients with ABS after OLT had a positive impact on stent migration rates resulting in higher stricture resolution and lower stricture recurrence rates [9].

The aim of our study was to further assess the efficacy of A-FCMS in post-OLT ABS in terms of migration, stricture resolution rate, and adverse events.

Methods

Design

The present retrospective cohort study was conducted at a tertiary referral center, using a prospectively maintained endoscopy database. Consecutive OLT patients who underwent ERCP between January 2005 and December 2020 with FCMS placement to treat ABS were identified and screened for inclusion. The local institutional review board approved

the study protocol (22-PI046) and all subjects gave written informed consent prior to the endoscopic procedure.

Participants

ABS was defined as an isolated fibrotic stricture localized within one centimeter of the surgical anastomosis on the endoscopic retrograde cholangiogram in patients with prior documented objective clinical, laboratory and imaging signs of biliary obstruction. OLT recipients with a proven diagnosis of ABS at the choledocho-choledocal duct-to-duct anastomosis were included. OLT recipients with any other type of biliary anastomosis, early (<30 days) ABS, presence of non-ABS, concomitant biliary leak, and previous FCMS placement were excluded. Similarly, ABS patients with FCMS who were subsequently shifted to plastic stent endotherapy were excluded from analysis. However, patients with a previous endoscopic or intraoperative plastic biliary stent who then underwent FCMS placement were included.

Endoscopic procedures

All endoscopic procedures for stent placement and removal were performed at a high-volume Endoscopy Unit (>1200 ERCPs/year) using standard duodenoscopes by experienced endoscopists. Antibiotic prophylaxis with 4/0.5 grams piperacillin/tazobactam (or ciprofloxacin/metronidazole in case of allergy) was routinely administered. The procedure was performed under endoscopist-directed sedation using propofol. Biliary cannulation was followed by cholangiography and sphincterotomy of native papillae. Balloon dilation was performed before FCMS placement using 8 or 10-mm biliary balloon-dilating catheters (Hurricane®, Boston Scientific, Natick, MA, USA) at endoscopist discretion. Finally, a FCMS was placed with the proximal end at least 2 cm above the ABS and the distal end across the papilla.

Stents

A-FCMS or conventional-FCMS (C-FCMS) were placed across the ABS at the index ERCP. The most common stent size was 80 × 10 mm. Less commonly, 60 × 10 mm or 100 × 10 stents were chosen to accommodate unusually short or long bile ducts, respectively. Similarly, stents of 8 mm in diameter were also used exceptionally.

C-FCMS were standard biliary stents, including the Wallflex® and Wallstent® models (both from Boston Scientific). A-FCMS had two to four anchoring flaps on either the internal (proximal) end (BCS Hanarostent®, M.I. Tech, Seoul, South Korea) or on both the internal and external ends (BCG Hanarostent®, M.I. Tech).

Patients were categorized as primary or secondary FCMS, depending on whether the FCMS was placed at the

time of initial ABS diagnosis or after previous plastic stent placement, respectively.

Follow-up

All OLT patients were followed up at the outpatient Liver Clinic using the same protocol. Patients were scheduled for 3 and 6-month follow-up clinic visits, with routine liver function tests (LFT) and transabdominal ultrasound. MRI was used selectively whenever LFT or ultrasound raised concerns for biliary complications.

FCMS removal was planned at 4–8 months from the index ERCP, depending on the time period when FCMS were placed. During the period 2005–2013, the first planned revision ERCP was scheduled at 4–6 months. During the period 2014–2020, the first planned revision ERCP was scheduled at 6–8 months. Our protocol evolved from a shorter time interval between the index ERCP and the first revision or between subsequent revisions to longer time intervals. C-FCMS were largely used during the first period, whereas A-FCMS were predominantly used during the second period, based on stent availability at the Unit. As stated above, all stent removal procedures were performed using a duodenoscope. A cholangiogram was obtained during the procedure upon stent removal to assess stricture response to stenting (see details for cholangiographic assessment of stricture resolution below). Unplanned ERCP was performed in case of cholangitis or suspected stent dysfunction based on LFT and/or imaging abnormalities.

During follow-up procedures, stent removal was performed with polypectomy snares and a detailed cholangiographic assessment of ABS resolution. In case of persistent ABS, a new FCMS was placed. In case of questionable ABS resolution and limited biliary contrast outflow, successful passage of an inflated 12-mm biliary balloon was used to define ABS resolution.

Study outcomes and definitions

Subjects were retrospectively grouped into C-FCMS and A-FCMS for analysis. The primary outcome was the stent migration rate. Secondary outcomes were the rates of stricture resolution, adverse events and recurrences. Stent migration was defined as any stent displacement from its original position across the ABS; migration was considered complete if the FCMS was no longer identified on fluoroscopy; migration was considered partial when the stent was still in the bile duct but no longer visible in the duodenum (proximal migration) or with its proximal end below the ABS (distal migration). The index migration rate was defined as the proportion of patients who experienced stent migration between the index ERCP and the first revision. The overall migration rate was defined as the proportion of patients

who experienced any instance of stent migration between the index ERCP and final FCMS removal after stricture resolution noted at any subsequent revision throughout their entire endoscopic treatment period.

Stricture resolution was determined at follow-up ERCP based on the cholangiogram and further confirmed clinically by the absence of any clinical or laboratory evidence of biliary obstruction within one month of FCMS removal. Recurrence of ABS was defined as new onset signs or symptoms of biliary obstruction which occurred a minimum of 1 month after FCMS removal, together with cholangiographic confirmation.

Adverse events were defined and graded according to the ASGE lexicon [10].

Patients shifting FCMS type from that used at the index ERCP at subsequent revisions before stricture resolution, were excluded from the calculation of final ABS resolution and overall migration rates.

Statistical analysis

Continuous variables are presented as mean and standard deviation and the median with interquartile range, as warranted. Categorical variables are presented as numbers and percentages. Chi-square is used to compare categorical variables. Student *t* test and Mann–Whitney *U* test are used for comparison of continuous variables with normal distribution and non-normal distribution, respectively.

Kaplan–Meier analysis with log-rank test is performed to evaluate the time until resolution and the time until recurrence between both groups.

The confidence interval of the differences between both groups is also estimated. Statistical analyses were performed using Stata (StataCorp. 2016. Stata Statistical Software: Release 13. College Station). A $p < 0.05$ was considered as statistically significant.

Results

Baseline characteristics

651 patients received OLT at our center between 2001 and 2020. A total of 102 patients from that cohort met inclusion criteria for the present study on ERCP treatment with FCMS for ABS. The median patient age was 58 years (IQR 50.5–63), and 82 were male (80.2%). The main indication for OLT was decompensated cirrhosis (Child B–C) and the most common etiology was alcoholic liver disease. A total of 57 patients received primary FCMS (55.9%), whereas 45 patients received secondary FCMS (44.1%). The median patient follow-up after FCMS removal was 57 months (IQR 24–98).

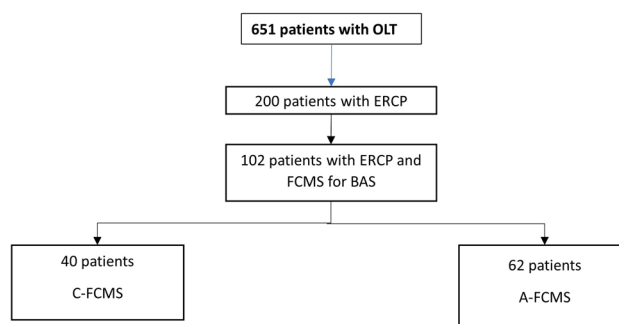


Fig. 1 Flow chart of included patients. OLT: orthotopic liver transplantation; ERCP: endoscopic retrograde cholangiopancreatography; C-FCMS: conventional fully covered metal stent; A-FCMS: anti-migration fully covered metal stent

Table 1 Baseline characteristics

	C-FCMS <i>N</i> = 40 patients	A-FCMS <i>N</i> = 62 patients	<i>p</i>
Age, median (IQR)	55 (50–61.5)	61 (53–65)	0.01
Male, <i>n</i> (%)	35 (77.8%)	51 (82.3%)	0.37
Indication for OLT			0.87
Child B–C	33 (73.3%)	43 (69.4%)	
HCC	9 (20%)	16 (25.8%)	
ALF	2 (4.4%)	2 (3.2%)	
Other	1 (2.2%)	1 (1.6%)	
Primary FCMS	20 (44.4%)	41 (66.1%)	0.02
Balloon dilatation	11 (25%)	14 (22.6%)	0.47

A total of 40 patients were grouped into C-FCMS and 62 patients into A-FCMS group (Fig. 1). Baseline characteristics were comparable, except that patients receiving C-FCMS presented more frequent use of previous plastic stent (24 [60%] vs 21 [33.9%], $p = 0.009$) and were slightly younger. Baseline characteristics of the study population are shown in Table 1.

Migration rate

Index stent migration was identified in 24 patients (63.2%) in the C-FCMS group and in 21 patients (36.2%) in the A-FCMS group ($p = 0.01$). Complete migration was identified in 20 patients (19.6%) during the first endoscopic revision, 6.5% in the A-FCMS group and 40% in the C-FCMS group ($p = 0.0001$). The incomplete index migration rate, however, was comparable in both groups (Table 2).

The overall migration rate (that is, including any migration at all subsequent endoscopic revisions), was 48.5%. Overall migration was significantly more common in patients with C-FCMS (65.8 vs 37.3%; $p = 0.006$). The overall complete migration rate was also higher in the A-FCMS

Table 2 Migration rates according to type of FCMS

	C-FCMS <i>N</i> = 40 patients	A-FCMS <i>N</i> = 62 patients	<i>p</i>
First revision			
Overall	24 (63.2%)	20 (34.5%)	0.01
Complete	16 (40.0%)	4 (6.5%)	0.001
Partial	8 (21.1%)	16 (27.6)	0.47
Final			
Overall	25 (65.8%)	22 (37.3%)	0.006
Complete	17 (44.7%)	6 (10.2%)	0.001
Partial	8 (21.1%)	16 (27.1%)	0.49

group. However, no differences were found between the C-FCMS group and the A-FCMS group in the overall partial migration rate (Table 2).

Resolution rate

The ABS resolution rate at the first endoscopic revision was similar in both groups (C-FCMS: 60.0% vs A-FCMS: 61.3%, $p = 0.87$). There were no differences between primary A-FCMS and primary C-FCMS. The median time until the first endoscopic revision was 5 months (IQR 2–7), with non-significant differences between groups (C-FCMS: 3 months, IQR 2–6 months vs A-FCMS: 5.5 months, IQR 2.75–7). Seven patients failed to reach the first endoscopic revision, 6 patients died, and another patient required retransplantation.

Final stricture resolution was achieved in 95 patients (93.1%), with no difference between both groups (92.5 vs 93.5%; $p = 0.84$). 80 % ABS were considered solved after 12 months since the first ERCP (Figure 2). The median time

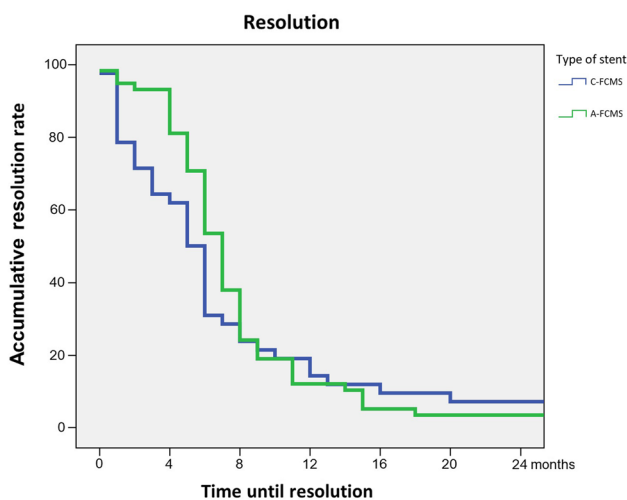


Fig. 2 Kaplan-Meier evaluating the time until resolution between both groups. No difference is observed when using log-Rank test ($p = 0.65$)

until ABS resolution was 6 months (IQR 4–8), 7 months in the A-FCMS (IQR 5–8.25) and 5 months in the C-FCMS (IQR 1.5–6; $p = 0.002$). Stent removal was successful in all patients, although 2 patients required stent-in-stent placement before definitive removal due to internal stent migration.

The mean number ERCP until resolution was 2.3 (SD ± 0.65), with similar results between the A-FCMS and C-FCMS (2.24; SD $\pm .54$ vs 2.25; SD ± 0.62 , $p = 0.28$).

At least one unplanned ERCP was required in 21 patients (20,6%) during their complete treatment period. No difference was observed across groups in the rate of unplanned ERCP when compared (A-FCMS:17.5% vs C-FCMS: 22.6%; $p = 0.54$).

Recurrence

After a median follow-up of 52 months after stricture resolution (IQR 19–85.5), recurrence was observed in 25 patients (24.5%), with no difference between both groups (C-FCMS, 30% vs A-FCMS, 21%; $p = 0.28$). Recurrence occurred in 10 patients during the first year, with a median of 17.5 months until recurrence (IQR 8.5–36.25) (Fig. 3).

Other adverse events

Stent obstruction was identified in 15 patients during the first endoscopic revision (14.7%), 20% in C-FCMS and 11.3% in A-FCMS ($p = 0.47$). Stent dysfunction occurred in 5 patients (4.9%), 2 patients with C-FCMS and 3 patients with A-FCMS.

Other adverse events were identified in 13 patients (12.1%). Post sphincterotomy bleeding was the most

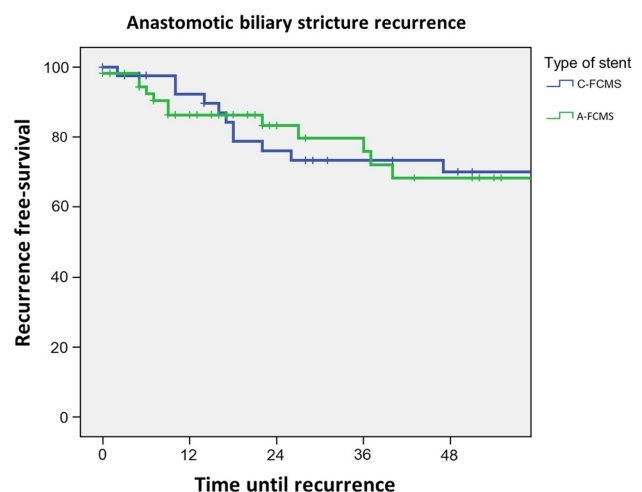


Fig. 3 Kaplan-Meier evaluating the time until recurrence. No difference was found between both group when using log-Rank test ($p = 0.73$)

common complication in 8 patients. Another 3 patients developed post-ERCP acute pancreatitis, of whom 1 patient developed severe acute pancreatitis. The remaining 2 patients were acute cholangitis. All except two episodes occurred during the index ERCP. Adverse events were similar in both groups.

Among 7 patients who did not achieve ABS resolution, 6 patients died before the first endoscopic revision, of whom only 1 were due to biliary sepsis while the rest were related to recurrence of hepatocellular carcinoma and autoimmune hepatitis. The remaining patient retransplantation was required due to autoimmune hepatitis recurrence.

Subanalysis

To reduce patient heterogeneity and to eliminate the confounding effect of prior plastic stenting on FCMS treatment outcomes, treatment naïve ABS patients were analyzed separately. After excluding patients with previous plastic stents, 16 patients with C-FCMS and 41 patients with A-FCMS were assessed. ABS resolution after the first endoscopic session was similar in both groups (C-FCMS 56.2% vs A-FCMS 58.5%, $p = 0.87$) while the migration rate at the first revision remained higher in the C-FCMS group (35 vs 19.5%; $p = 0.04$).

Final ABS resolution in this treatment naïve patient subgroup was achieved in 81.2% of patients with C-FCMS and in 95.1% of patients with A-FCMS ($p = 0.09$). The final overall migration rate was higher in patients with C-FCMS compared to patients with A-FCMS (40 vs 24.3%; $p = 0.04$).

ABS recurrence was similar in both groups (C-FCMS 12.5% vs A-FCMS 14.6%; $p = 0.83$).

Discussion

In this retrospective study we compared the outcomes of antimigration versus conventional-FCMS in terms of stent migration, stricture resolution, and recurrence rates. We observed a clear benefit when using an A-FCMS in consecutive OLT patients who underwent ERCP at a single-center, with significantly lower migration rates; however, we were unable to find any differences in terms of stricture resolution and recurrence rates. In our study, A-FCMS decreased the overall risk of migration from 65.8 to 37.3%, with comparable stricture resolution and recurrence rates.

Recently a pooled metaanalysis, including 8 randomized clinical trials with 524 patients comparing metal and plastic stent for benign biliary strictures, found no differences regarding stricture resolution or adverse event rates, although the mean number of ERCPs required to complete the treatment course was higher in the plastic stent group. Nevertheless, the migration rate was significantly higher in

patients receiving FCMS [11]. The risk of migration using FCMS for benign biliary strictures has been noted as a major problem in the setting of ABS following OLT [12, 13]. Poley et al., described a migration rate of 58.5% in a prospective study evaluating the use of C-FCMS for ABS following OLT [14]. Park et al first reported that FCMS with anchoring flaps (A-FCMS) were associated with significantly lower migration rates when compared to C-FCMS in the setting of benign biliary strictures [15]. More specifically, Bordaça-har et al. compared the use of A-FCMS in ABS following OLT in a study similar to our present study. These authors found that the risk of stent migration decreased from 28% for C-FCMS to 1.7% for A-FCMS ($p < 0.0001$) [9]. This strikingly decreased migration rate in patients with A-FCMS was associated with higher stricture resolution and lower recurrence rates compared to patients with C-FCMS. Our findings confirmed an overall higher risk of migration in patients with C-FCMS versus A-FCMS (67.4 vs 39.7%; $p = 0.009$); however migration was reduced to a lower degree than in the Bordaça-har et al study. This difference in the magnitude of reduced migration between both studies may help explain why our study failed to prove any difference beyond a non-significant trend to lower stricture recurrence. Interestingly, the effect of A-FCMS on stent migration rates was more marked in the subgroup of treatment naïve patients (24.3 vs 40%) than in the entire cohort as a whole (39.7 vs 67.4%). A trend towards increased ABS resolution was associated with A-FCMS in this patient subgroup (95.1 vs 81.2%). The relatively small number of treatment naïve patients likely prevented any statistical significance.

Another potentially useful antimigration option is the use of specifically designed intraductal stents. In a retrospective multicenter study, Aepili et al. reported that only 2.8% of OLT patients in whom this intraductal stent was placed across ABS experienced migration. However, in another prospective multicenter study migration of this intraductal stent was found to occur in 15.6% of ABS following living-donor liver transplantation [16]. Anchoring of C-FCMS with a 5F double-pigtail plastic stent has also showed to reduce the stent migration risk in a RCT on patients with mixed benign biliary strictures, from 41.2 to 6.3% ($p = 0.024$) [17]. Anchoring pig-tails involve a relatively more demanding biliary intervention; the use of two stents rather than just a single A-FCMS incurs additional costs.

There is an ongoing debate regarding the cost advantages of FCMS versus plastic stents in the endoscopic therapy of ABS. Treatment effectiveness is a key issue before any cost advantages can be properly assessed. Theoretically, FCMS choices that minimize the incidence of migration would potentially decrease treatment costs. Current data from studies reporting favorable results in terms of cost-efficacy for FCMS when compared to plastic stents [18], however, are challenged by other authors [19].

Beyond migration, FCMS represent a safe option with other less common adverse events are considered. In our study other adverse events were presented in 12.1%, including cholangitis, pancreatitis and bleeding in line with previous reports [20–22].

The overall stricture resolution rate in our patient cohort was high, at 93.5%. A sizable group of ABS patients required more than one session with a mean number of 2.3 ERCPs, without any significant difference between both FCMS types. When compared with our historical data, this number of ERCPs per ABS patient seems slightly lower [23]. Rather than improved treatment efficiency in the current study, this fact could be simply explained by the considerably larger study population.

Long-term outcomes of FCMS, remain a poorly defined area. ABS recurrence rates reported in the literature range from 8.3 to 47.4 [24–26], with differences in the length of follow-up as the most obvious explanation for these highly variable results. Tarantino et al reported a recurrence rate of 39% after four years of follow-up [22]. It is currently unclear what is the best strategy to manage recurrent ABS in OLT patients after a first successful treatment course with FCMS. A second treatment course with FCMS and bypass surgery are commonly used in practices. Studies specifically designed to address this open question would be instrumental to guide management choices.

To our knowledge, this is the largest study comparing two types of FCMS in ABS following liver transplantation. All patients included had their OLT performed at the same center were the follow-up and endoscopic procedures were performed avoiding heterogeneity of health care as a potential confounder. Also, only OLT from deceased brain-donors were included, avoiding the potential bias of mixing subtypes of donors.

There are some limitations to our study that should be mentioned. First, this is a retrospective, single-center study conducted over a relatively long period. Secondly, the endoscopic follow-up protocol was not entirely uniform during the study period. Third, the previous use of plastic stents was not evenly distributed across both treatment groups and this may have influenced treatment response; even if we did not find a statistically significant difference in ABS resolution across treatment naïve patients who underwent placement of either type of FCMS. Lastly, minor stent migration instances found in prospective studies may have gone unrecognized in our retrospective study.

In conclusion, A-FCMS significantly reduce the rate of stent migration in patients with anastomotic biliary strictures following OLT treated endoscopically. Longer stent revision intervals leading to a decreased treatment burden appear a viable strategy when using A-FCMS. The impact of reduced migration rates with A-FCMS versus C-FCMS on hard outcome measures, such as stricture resolution,

adverse events and stricture recurrence remains to be proven in future studies.

Declarations

Disclosures Manuel Perez-Miranda is a consultant for Boston Scientific, Olympus, Medtronic and M.I.Tech. Dr. Esteban Fuentes Valenzuela, Dr. Marina de Benito Sanz, Dr. Félix García-Pajares, Dr. José Estradas, Dr. Irene Peñas-Herrero, Dr. Miguel Durá Gil, Dr. Ana Yaiza Carbajo, Dr. Carlos de la Serna-Higuera, Dr. Ramon Sanchez-Ocana, Dr. Carmen Alonso-Martín, Dr. Carolina Almohalla, and Dr. Gloria Sánchez-Antolín have no conflicts of interest or financial ties to disclose.

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