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Migration of fully covered self-expandable metallic stents used to treat anastomotic strictures after orthotopic liver transplantation

A single-center, retrospective analysis

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Abstract

Insertion of a fully covered self-expandable metallic stent (FCEM) through endoscopic retrograde cholangiopancreatography is an effective solution for biliary anastomotic stricture following orthotopic liver transplantation (OLT). However, FCEM migration continues to plague patients. This study aimed to evaluate the FCEM migration rate in our center, and to investigate the factors increasing the migration risk for FCEM.

The study enrolled 43 post-OLT patients with confirmed duct-to-duct AS. The effects of age, gender, albumin, alanine aminotransferase, aspartate aminotransferase (AST), γ-glutamyl transpeptidase, alkaline phosphatase, total bilirubin, direct bilirubin, ABO (blood group system consists of four antigens) incompatibility, stricture length, FCEM brand, FCEM length, donor liver and recipient bile duct diameters, size mismatches between the donor and recipient bile ducts >2 mm, diabetes and/or hypertension status, endoscopic sphincterotomy status, the use of plastic stents or nasobiliary drainage prior to FCEM implantation, duration from OLT to FCEM placement, and OLT etiology on FCEM migration were retrospectively analyzed.

The FCEM migration rate was 48.8% (21/43) at 6 months. The serum AST level was significantly higher in the migration group than that in the nonmigration group (52.48 vs 29.50 U/L, $P < .05$). A lower serum AST level was associated with a decreased risk of FCEM migration in post-OLT patients with duct-to-duct anastomotic stricture (hazard ratio = 0.968, 95% confidence interval: 0.940–0.996, $P = .028$).

In this single-center, retrospective cohort study, we showed that an elevated serum AST level was a potential risk factor for FCEM migration.

Abbreviations: AKP = alkaline phosphatase, ALT = alanine aminotransferase, AS = anastomotic stricture, AST = aspartate aminotransferase, DB = direct bilirubin, ERCP = endoscopic retrograde cholangiopancreatography, EST = endoscopic sphincterotomy, FCEM = fully covered self-expandable metallic stent, GGT = γ-glutamyl transpeptidase, OLT = orthotopic liver transplantation, PBS = plastic biliary stent, TB = total bilirubin.

Keywords: anastomotic stricture, aspartate aminotransferase, endoscopic retrograde cholangiopancreatography, fully covered self-expandable metallic stent, orthotopic liver transplantation

1. Introduction

The first orthotopic liver transplantation (OLT) was performed in 1963 by Dr. Thomas E Starzl[1] from the Denver Veterans Administration Hospital in the United States. At that time, the rate of mortality after OLT was high. Half a century later, OLT has become the principal treatment for end-stage liver diseases, including liver cancer, due to continuous improvements in surgical techniques and the availability of new antirejection drugs. However, biliary complications post-OLT persist, and are a major cause of death in adult recipients (11.5%–34%).[2–4] Biliary complications include anastomotic strictures (AS), bile leakage, biloma, stones, sludge, biliary cast syndrome, sphincter of Oddi dysfunction, cholangitis, and hemobilia. AS is the most common problem, which develops in 4% to 9% of OLT patients.[5] Endoscopic retrograde cholangiopancreatography (ERCP) is the first-line post-OLT treatment for duct-to-duct AS.[6] Repeat placement of plastic biliary stents (PBSs) every 3 months for 1 year was the classic precaution against AS post-OLT. Currently, AS dilation via fully covered self-expandable metallic stent (FCEM) insertion is an established alternative.[7–9] Compared to repeat PBS placement, FCEM insertion is associated with higher resolution rates (over 80%).[10] In addition, in a previous study, the number of ERCPs performed,

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treatment duration, and costs were lower in the FCEM group than the PBS group.[6] However, stent migration may occur in 0% to 41% of cases treated via FCEM placement.[10]

To better treat post-OLT AS, there is an urgent need to define risk factors for FCEM migration. In this study, we aimed to determine these related factors.

2. Materials and methods

2.1. Patients

The present study was approved by our institutional ethics review board (approval no.: 2020017). The inclusion criteria were FCEM insertion in our hospital and OLT recipients aged ≥18 years without graft rejection. Patients were excluded if follow-up care was <6 months after FCEM insertion (n = 2), AS was combined with ischemic cholangiopathy (n = 4), OLT was performed not in our hospital (n = 4), patients with post-transplant lymphoproliferative disorders (n = 1), or active removal of FCEMs (n = 8) due to ERCP-related pancreatitis or cholangitis. Finally, we enrolled 43 post-OLT (cadaveric liver transplant) patients with confirmed duct-to-duct AS who underwent endotherapy between January 2017 and April 2019.

2.2. Protocol for FCEM placement and follow-up

At our center, magnetic resonance cholangiopancreatography revealing a biliary stricture at the anastomotic site, combined with abnormal liver blood test results (such as elevated serum levels of bilirubin, γ-glutamyl transpeptidase [GGT], alanine aminotransferase [ALT], aspartate aminotransferase [AST], and/or alkaline phosphatase [AKP]), often trigger a diagnosis of post-OLT AS. The preferred length of the FCEM above the AS was about 1 to 1.5 cm (case presentations are shown in Fig. 1). No patients underwent balloon dilation or percutaneous intervention. There was no case of insertion of a PBS inside a FCEM. Patients underwent surveillance with abdominal color Doppler ultrasound at 1 month after FCEM insertion. At 3 months and 6 months, patients underwent surveillance with abdominal color Doppler ultrasound combined with abdominal computed tomography or magnetic resonance cholangiopancreatography. The definition of stent migration was that the FCEM had partially slipped out below the AS but was still indwelling in the bile duct, or that the FCEM had slid completely out of the bile duct and was discharged from the intestine. The stent migration rate at 6 months after FCEM insertion served as the endpoint.

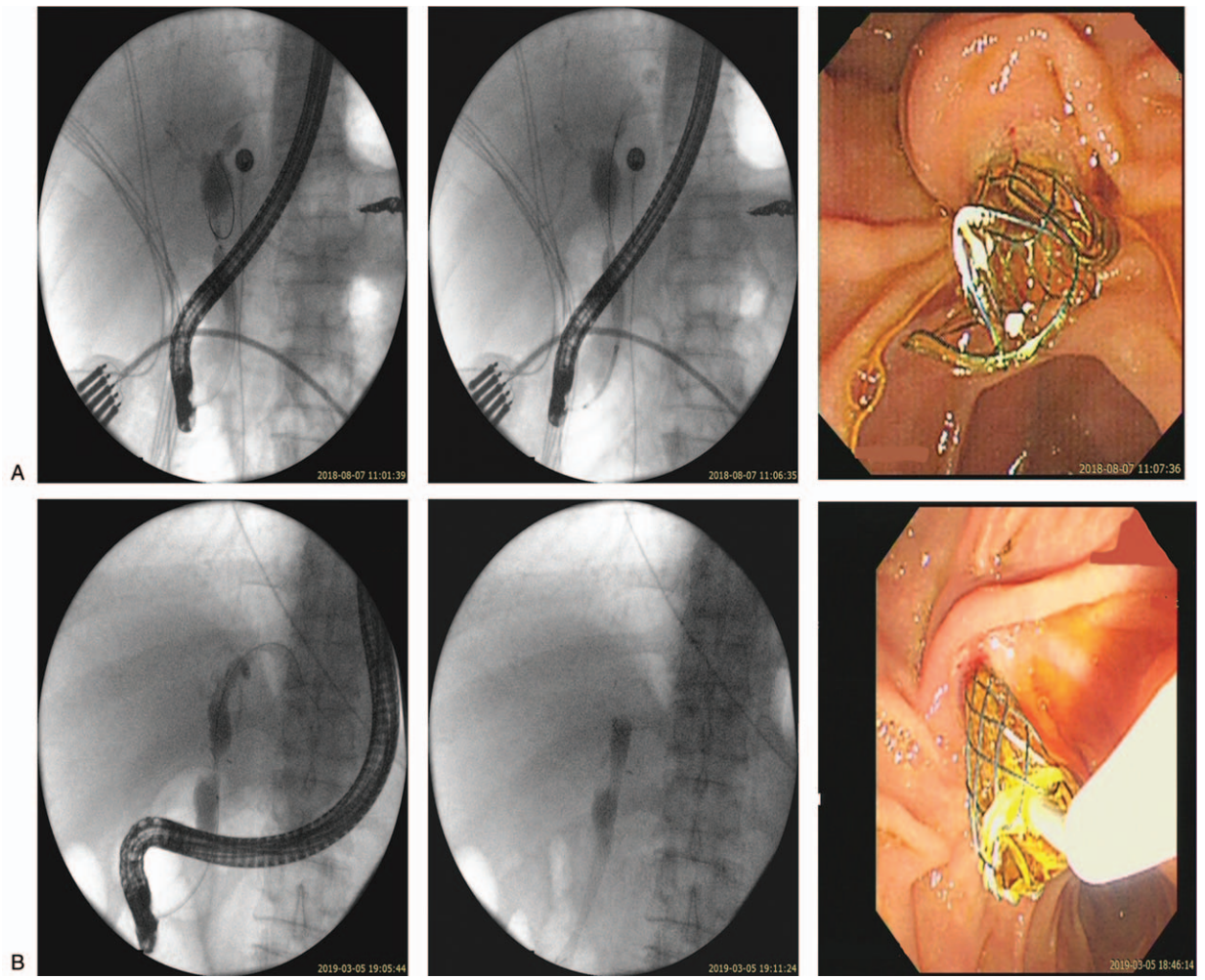

Figure 1. Case presentations. A) Stent migration case. B) Stent nonmigration case.

2.3. Explored factors

We analyzed the effects of age, gender, ABO incompatibility, diabetes and/or hypertension status, endoscopic sphincterotomy (EST) status, PBS placement or nasobiliary drainage prior to metallic stent implantation, the FCEM brand (Boston M00570530/M00570540, Niti-S BS1006F/BS1008F, or ENDO-FLEX BIL-1-10-80-RP), FCEM length, a size mismatch between the donor and recipient bile ducts >2 mm, the OLT etiology, duration from the day of OLT to the day of FCEM placement, stricture length (measured by comparing it to the transverse diameter evident on duodenoscopy after contrast agent was injected into the bile duct), donor liver and recipient bile duct diameters (also measured via comparison to the transverse duodenal diameter after injection of contrast medium into the bile duct), the levels of serum albumin, ALT, AST, GGT, AKP, total bilirubin (TB), and direct bilirubin (DB) (liver biochemical tests 1 day before ERCP) on FCEM migration.

2.4. Statistical analysis

Statistical analyses were performed using the Statistical Package for Social Sciences for Windows version 19 (IBM, Armonk, NY). The chi-square test was used to compare categorical variables and Student *t* tests or a nonparametric test was employed to compare numerical variables. Binary logistic regression testing was used to derive risk factors. A *P*-value <.05 was taken to reflect significance.

3. Results

3.1. Comparison of categorical variables between the migration and nonmigration groups

In the present study, FCEM migration was evident in 21 (48.8%) cases, which were all found during a routine review. There were no significant differences in gender, ABO incompatibility, FCEM length, size mismatches between the donor and recipient bile ducts >2 mm, diabetes and/or hypertension status, using of plastic stents or nasobiliary drainage prior to metallic stent implantation, or OLT etiology between the migration group and the nonmigration group (Table 1). However, Niti-S FCEM did not seem to slip easily. Of the 23 patients given Niti-S FCEMs, 7 became displaced; of 18 patients who received Boston FCEMs, 12 became displaced; of the 2 patients who received ENDO-FLEX FCEMs, both became displaced (Table 1). Somewhat more unexpectedly, the proportion of patients who underwent EST was significantly lower in the migration group than that in the nonmigration group (6/21 vs 13/22) (Table 1, $P < .05$).

3.2. Comparison of numerical variables between the migration and nonmigration groups

The serum AST level was significantly higher in the migration group than in the nonmigration group (52.48 vs 29.50 U/L) (Table 2, $P < .05$). In addition, ALT was significantly higher in the migration group than in the nonmigration group (66.52 vs 34.59 U/L) (Table 2, $P < .05$). However, there were no significant differences in the patients' age, AS length, diameters of the donor

Table 1

Summarized categorical variables of the migration group and the nonmigration group.

	Total, n = 43	Migration group, n = 21	Nonmigration group, n = 22
Gender (male)	32	15	17
ABO incompatibility (yes)	3	1	2
Diabetes and/or hypertension (yes)	12	6	6
Nasobiliary drainage or PBS before FCEMs placement (yes)	32	18	14
Sphincterotomy (yes)	19	6	13
Length of FCEMs			
6 cm	17	7	10
8 cm	26	14	12
FCEMs brand			
Boston biliary uncovered stent	18	12	6
Niti-S biliary uncovered stent	23	7	16
ENDO-FLEX Biliary uncovered stent	2	2	0
Size mismatch between donor and recipient bile duct >2 mm (yes)	14	8	6
Etiology of OLT			
Nonmalignancy	20	7	13
Hepatitis B virus	9	1	8
Alcohol	3	1	2
Alcohol with hepatitis B virus	1	0	1
Wilson	1	1	0
Cholestasis	1	1	0
Caroli disease	1	1	0
Intrahepatic bile duct stones	1	0	1
Hepatic veno-occlusive syndrome	1	1	0
Severe drug-induced hepatitis	1	1	0
Schistosomiasis	1	0	1
Malignancy	23	14	9
Hepatocellular carcinoma	20	13	7
Cholangiocarcinoma	3	1	2

FCEM = fully-covered self-expandable metallic stent, OLT = orthotopic liver transplantation, PBS = plastic biliary stent.

Table 2

Summarized numerical variables of the migration group and the nonmigration group.

	Total, n = 43	Migration group, n = 21	Nonmigration group, n = 22
Age (yr, mean)	52.0	51.2	52.7
AS length (cm, mean ± SD)	0.70 ± 0.55	0.59 ± 0.34	0.81 ± 0.68
Diameter of the donor bile duct (cm, mean ± SD)	0.99 ± 0.27	1.00 ± 0.25	0.98 ± 0.29
Diameter of the recipient bile duct (cm, mean ± SD)	0.85 ± 0.20	0.85 ± 0.18	0.85 ± 0.21
Time from the day of OLT to the day of FCEM placement (mo)	3.86 ± 3.93	4.19 ± 4.25	3.54 ± 3.68
Albumin (35–55 g/L)	39.06 ± 4.03	38.58 ± 3.65	39.52 ± 4.40
ALT (5–40 U/L)	50.19 ± 53.40	66.52 ± 68.19	34.59 ± 27.46
AST (8–40 U/L)	40.72 ± 30.90	52.48 ± 35.66	29.50 ± 20.71
GGT (11–50 U/L)	153.70 ± 174.01	167.38 ± 189.32	140.64 ± 161.42
AKP (11–150 U/L)	156.35 ± 99.28	149.76 ± 88.71	162.24 ± 110.14
TB (0–21 μmol/L)	18.84 ± 20.07	21.48 ± 25.61	16.32 ± 12.94
DB (0–5 μmol/L)	13.49 ± 19.43	16.48 ± 25.28	10.63 ± 11.34

AKP = alkaline phosphatase, ALT = alanine aminotransferase, AS = anastomotic stricture, AST = aspartate aminotransferase, DB = direct bilirubin, FCEM = fully-covered self-expandable metallic stent, GGT = γ-glutamyl transpeptidase, OLT = orthotopic liver transplantation, TB = total bilirubin.

and recipient bile ducts, the duration from the day of OLT to the day of FCEM placement, and the serum levels of albumin, GGT, AKP, TB, and DB between the migration group and the nonmigration group (Table 2, $P > .05$).

3.3. Identification of risk factors related to FCEM migration

In the univariate analysis, factors that were related to an increased rate of FCEM migration in patients with biliary AS following OLT included a higher serum AST level and EST nonperformance ($P < .05$). However, the binary logistic regression analyses indicated that only a lower serum AST level was associated with a decrease in the risk of FCEM migration (hazard ratio = 0.968, 95% confidence interval: 0.940–0.996, $P = .028$) (Table 3).

4. Discussion

A biliary stricture is the most common biliary complication after OLT.[11] AS occurs in 4% to 9% of OLT recipients, both early (within 12 weeks) and later,[12–15] and endotherapy used to be the first-line treatment.[16] In a previous study, the AS resolution rate was >60% for balloon dilation with subsequent PBS insertion.[17] However, this must be repeated at 3-month intervals for at least 1 year. Therefore, FCEM placement has attracted increasing attention; only 2 procedures are required: stent placement and removal. A systematic review published in 2013 found that metal stents show promise[17]; since then, FCEMs have increasingly been used to treat AS.[18–20] Today, an FCEM is an established alternative to PBS. Temporary FCEM placement (usually for 6 months) in patients with post-OLT AS affords initial resolution rates of 87.5% to 100% and recurrence rates of

Table 3

Potential risk factors for the FCEM migration.

	Univariate	Multivariate		
Variables	***P* value**	***P* value**	**HR**	**95% CI**
AST	<.05	.028	0.968	0.940–0.996
ALT	>.05	.807	/	/
Sphincterotomy status	<.05	.187	/	/
FCEM brand	>.05	.074	/	/
Age	>.05	.302	/	/
Gender	>.05	.831	/	/
ABO incompatibility	>.05	.658	/	/
Diabetes and/or hypertension status	>.05	.857	/	/
AS length	>.05	.257	/	/
Diameter of the donor bile duct	>.05	.856	/	/
Diameter of the recipient bile duct	>.05	.875	/	/
Size mismatch between donor and recipient bile duct > 2 mm	>.05	.621	/	/
Nasobiliary drainage or PBS before FCEM placement	>.05	.161	/	/
Time from the day of OLT to the day of FCEM placement	>.05	.362	/	/
Length of FCEM	>.05	.624	/	/
Etiology of OLT	>.05	.124	/	/
Albumin	>.05	.753	/	/
GGT	>.05	.398	/	/
AKP	>.05	.139	/	/
TB	>.05	.975	/	/
DB	>.05	.942	/	/

95% CI = 95% confidence interval, AKP = alkaline phosphatase, ALT = alanine aminotransferase, AS = anastomotic stricture, AST = aspartate aminotransferase, DB = direct bilirubin, FCEM = fully-covered self-expandable metallic stent, GGT = γ-glutamyl transpeptidase, HR = hazard ratio, OLT = orthotopic liver transplantation, PBS = plastic biliary stent, TB = total bilirubin.

4.5% to 7.4%.[12] However, stent migration remains a major concern. Zeair et al[10] reported migration in 0% to 41% of cases, whereas Devière et al[21] reported migration rates of up to 75% at 6 months.

At our center, the proximal ends of the FCEMs all passed over the narrow segments of the anastomotic stoma (above the AS by 1–1.5 cm) and were placed by professional endoscopists. The auto-migration rate was still relatively high, attaining 48.8% at 6 months. It could not be simply attributed to the changes in anatomical structure or the destruction of nerve fibers controlling biliary tract contraction. For a potential explanation, this retrospective study was performed to determine the risk factors.

AST and ALT have been regarded as classical markers of liver injury, including a wide range of etiologies from viral hepatitis to novel coronavirus disease 2019.[22,23] Meanwhile, cholangitis secondary to biliary stricture can also cause serum elevation of AST and ALT. Furthermore, liver transplant specialists have disclosed that AST and ALT are very sensitive tests in post-OLT patients with biliary stricture and graft rejection[24,25]; serum levels of AST and ALT are at least 2-fold higher in the graft rejection group than in the biliary stricture group (222 vs 101.6 U/L, 337.4 vs 158.6 U/L, respectively).[26] In 2009, Traina et al[8] reported that the average value of ALT in 16 patients with AS after liver transplantation was 149 U/L. In 2020, Warner et al[27] reported that the average value of AST before ERCP was 101 U/L in 54 patients with AS after liver transplantation. In the present study, the serum levels of AST and ALT seemed relatively lower at 40.72, 52.48, and 29.50 U/L, 50.19, 66.52, and 34.59 U/L, respectively, in total patients, in the migration group, and in the nonmigration group. This may be partly related to different regions, countries, and races. Interestingly, we found that serum levels of AST and ALT were significantly higher in the migration group than that in the nonmigration group, and that an elevated serum AST level was a potential risk factor for FCEM migration. So far, this is the first time to disclaim the relationship between AST and FCEM displacement, and the internal mechanism is not yet clear. It is also unclear why ALT, the other indicator of hepatocyte injury, is not a risk factor for FCEM displacement, which is worthy of further study.

A high preoperative serum level of bilirubin is an independent risk factor for biliary complications (including AS and bile leakage) post-OLT,[28] and AKP and GGT has been considered as an early, noninvasive, and inexpensive markers for diagnosing AS.[29] We postulated that FCEM migration was related to the serum levels of GGT, TB, DB, and AKP; however, there were no significant differences in the serum levels of GGT, TB, DB, or AKP between the migration group and the nonmigration group, and binary logistic regression analyses indicated that they were not potential risk factors. There were no significant differences in the age, AS length, diameter of the donor bile duct, diameter of the recipient bile duct, or the serum value of albumin between the migration group and the nonmigration group, either. Similarly, retrospective analysis did not suggest that these factors were related to FCEM displacement.

We suspected that the higher FCEM migration rate was related to EST, the use of plastic stents or nasobiliary drainage prior to FCEM implantation, and the duration from the day of OLT to the day of FCEM placement. Adversely, sphincterotomy seemed to be beneficial for FCEM indwelling in the bile duct. In the migration group, 6 patients underwent EST and 15 did not. In the nonmigration group, 13 patients underwent papillary sphincterotomy and 9 did not. Meanwhile, there were no significant differences in the duration from the day of OLT to the day of FCEM placement or the proportion of patients using plastic stents or nasobiliary drainage prior to FCEM implantation between the migration and the nonmigration groups. There was no significant difference in male proportion of patients between the migration group and the nonmigration group, either. Similarly, retrospective analysis did not suggest that the gender was related to FCEM displacement.

It is noteworthy that there were no complications such as intestinal obstruction or perforation caused by the migration of FCEMs to the small bowel. Inadvertently, they were all discharged from the intestine. In the nonmigration group, no serious adverse events occurred when extracting the FCEMs, such as massive bleeding or perforation. Difficulty in pulling out the deformed FCEMs due to "improper grab" using grasping forceps occurred in 2 patients and after 1 week "rest", the 2 metal stents were successfully removed using biopsy forceps.

The limitations of the study are that the sample size was small and that it was a retrospective study. In addition, we used only FCEMs with a diameter of 10 mm. Although the diameter of the bile duct of the donor liver in this study was about 1 cm, we should carry out a head-to-head study on whether the migration rate of FCEM with a diameter of 8 mm is lower than that with a diameter of 10 mm.

In conclusion, stent migration remains the major drawback of FCEM use. Given that the number of OLT patients is increasing, and the incidence of AS is not decreasing, risk factors for FCEM migration must be urgently identified.

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