Fully covered self-expanding metal stents for benign biliary stricture after orthotopic liver transplant: 5-year outcomes CME

Jan-Werner Poley, MD,[1] Thierry Ponchon, MD, PhD,[2] Andreas Puespoek, MD,[3] Marco Bruno, MD, PhD,[1] André Roy, MD, LMCC, CSPQ, FRCSC,[4] Joyce Peetermans, PhD,[5] Matthew Rousseau, MS,[5] Vincent Lépilliez, MD,[2] Werner Dolak, MD,[6] Andrea Tringali, MD, PhD,[7] Daniel Blero, MD, PhD,[8] David Carr-Locke, MD,[9] Guido Costamagna, MD,[7] Jacques Devière, MD, PhD,[8] for the Benign Biliary Stenoses Working Group

Rotterdam, The Netherlands; Lyon, France; Vienna, Austria; Montréal, Québec, Canada; Marlboro, Massachusetts; New York, New York, USA; Rome, Italy; Brussels, Belgium

Background and Aims: Minimally invasive treatments of anastomotic benign biliary stricture (BBS) after orthotopic liver transplantation (OLT) include endoscopic placement of multiple plastic stents or fully covered self-expandable metal stents (FCSEMSs). No multiyear efficacy data are available on FCSEMS treatment after OLT.

Methods: We prospectively studied long-term efficacy and safety of FCSEMS treatment in adults aged ≥18 years with past OLT, cholangiographically confirmed BBS, and an indication for ERCP with stent placement. Stent removal was planned after 4 to 6 months, with subsequent follow-up until 5 years or stricture recurrence. Long-term outcomes were freedom from stricture recurrence, freedom from recurrent stent placement, and stent-related serious adverse events (SAEs).

Results: In 41 patients, long-term follow-up began after FCSEMS removal (n = 33) or observation of complete distal migration (CDM) (n = 8). On an intention-to-treat basis, the 5-year probability of remaining stent-free after FCSEMS removal or observation of CDM was 48.9% (95% confidence interval [CI], 33.2%-64.7%) among all patients and 60.9% (95% CI, 43.6%-78.2%) among 31 patients with over 4 months of FCSEMS indwell time. In 28 patients with stricture resolution at FCSEMS removal or observed CDM (median, 5.0 months indwell time), the 5-year probability of no stricture recurrence was 72.6% (95% CI, 55.3%-90%). Sixteen patients (39%) had at least 1 related SAE, most commonly cholangitis (n = 10).

Conclusions: By 5 years after temporary FCSEMS treatment of post-OLT BBS, approximately half of all patients remained stent-free on an intention-to-treat basis. Stent-related SAEs (especially cholangitis) were common. FCSEMS placement is a viable long-term treatment option for patients with post-OLT BBS. (Clinical trial registration number: NCT01014390.) (Gastrointest Endosc 2020;92:1216-24.)

Abbreviations: BBS, benign biliary stricture; CDM, complete distal migration; CI, confidence interval; FCSEMS, fully covered self-expandable metal stent; HR, hazard ratio; MPS, multiple plastic stent; OLT, orthotopic liver transplantation; RCT, randomized controlled trial; SAE, serious adverse event.

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Current affiliations: Department of Gastroenterology and Hepatology, Erasmus MC University Medical Center, Rotterdam, The Netherlands (1), Service d'Hépato-Gastroentérologie, Hôpital Edouard Herriot, Lyon, France (2), Department of Medicine, Division of Gastroenterology and Hepatology, Medical University of Vienna, Vienna, Austria (3), Département de Chirurgie, Hôpital Saint-Luc, Centre Hospitalier de l'Université de Montréal, Montréal, Québec, Canada (4), Boston Scientific Corporation, Marlboro, Massachusetts, USA (5), Universitätsklinik für Innere Medizin III, Medizinische Universität Wien, Vienna, Austria (6),

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Approximately 6% to 12% of patients who undergo liver transplantation subsequently develop an anastomotic biliary stricture.[1] Anastomotic strictures in the early post-transplant period may be attributed to, among other factors, scarring, donor–recipient bile duct mismatch, edema of the healing anastomosis, peritransplant infection, anastomotic leaks, and possibly surgical technique.[2] Late anastomotic stricture tends to result from fibrotic healing because of ischemia at the end of the donor or recipient bile duct.[2] Even though most clinicians assume early strictures are associated with a better prognosis and generally do not need intensive treatment, the literature on this subject is conflicting.[2-4]

Symptomatic anastomotic strictures warrant clinical intervention because biliary obstruction can lead to jaundice, cholangitis, common bile duct stones, and potentially biliary cirrhosis in chronic cases.[5] Endoscopic management is the first-line treatment for anastomotic strictures after orthotopic liver transplantation (OLT).[4] Multiple plastic stents (MPSs) or fully covered self-expandable metal stents (FCSEMSs) as endoscopic treatment options have been studied in randomized controlled trials (RCTs).[6,7] Progressive plastic stent placement of anastomotic strictures after OLT is highly efficacious and saves 80% of patients from undergoing complicated surgical repair or even retransplantation; however, the protocol is demanding and burdensome, necessitating 4 or more ERCP procedures with adverse events occurring in 1 of 5 procedures.[8] Although FCSEMSs have the advantage of fewer anticipated stent exchanges, a 2013 systematic review[9] and two 2017 meta-analyses[10,11] of observational data did not suggest a clear overall advantage of SEMS use over MPSs for biliary anastomotic stricture after OLT. A 2019 meta-analysis[12] including 4 RCTs concluded that FCSEMSs and MPSs had equal anastomotic biliary stricture resolution and recurrence and similar overall rates of adverse events or stent migration. A trend toward a higher stricture recurrence rate in FCSEMSs disappeared when trials with shorter stent indwell time were excluded.[12] Anastomotic stricture resolution rates are higher for liver transplant patients treated with more than 12 months of stent indwell and a higher total number of stents.[4] Accordingly, a 2018 meta-analysis of 4 RCTs of metallic versus plastic stents to treat biliary stricture after OLT mentioned the importance of long-term follow-up to support evidence-based conclusions regarding stricture recurrence in these patients, stating that "a follow-up of 12 months is probably not enough to make firm assumptions on long-term efficacy (especially in the FCSEMS group because more is known about the chance of recurrence in the MPS group[p E920])."[13]

To estimate long-term efficacy and safety of FCSEMSs in this patient population, we studied 41 patients with a history of OLT who participated in a prospective cohort study of FCSEMSs to treat anastomotic biliary stricture.[14] Participants were followed up to 5 years after FCSEMS removal or after observation of complete distal migration (CDM) of the stent to assess maintenance of stricture resolution, rates of freedom from stent placement, and long-term safety.

METHODS

Study design

This analysis is part of a multicenter, prospective, non-randomized observational study (ClincialTrials.gov NCT01014390 and CTRI/2012/12/003166) of an FCSEMS to treat benign biliary stricture (BBS) including 187 total participants in 3 patient subgroups: patients with chronic pancreatitis, with a history of cholecystectomy, or with a history of OLT. Methods of the main study were documented previously.[14] Patients from 8 of the 13 original study sites were represented in the current analysis. The Independent Ethics Committee at each study site approved the study protocol, and all study participants provided written informed consent. An Independent Medical Reviewer reviewed all stent- or stent removal–related serious adverse events (SAEs), all reinterventions, and all deaths. The medical reviewer was a gastroenterologist experienced in treating biliary obstructions and performing interventional endoscopic procedures and not employed by the study sponsor or by a clinical study site. The study was sponsored and funded by Boston Scientific Corporation.

The FCSEMS studied was the fully covered WallFlex Biliary RX Stent (Boston Scientific, Marlborough, Mass, USA), which is U.S. Food and Drug Administration–approved for palliative and preoperative use in malignant biliary strictures and for indwell up to 12 months to treat BBSs secondary to chronic pancreatitis. The FCSEMS was placed at the baseline visit (Fig. 1), after which patients had telephone or in-person assessments for symptoms of biliary obstruction (right upper quadrant pain, fever/chills, jaundice, itching, dark urine, pale stools, nausea/vomiting), adverse events, and/or device malfunction at 1 week, 3 months, or ad lib in response to concerning symptoms or adverse events. FCSEMS removal was planned at 4 to 6 months with the expectation that a shorter indwell time (compared with standard 12-month indwell for plastic stents and FCSEMSs for other indications) would prevent late adverse events in immunosuppressed post-OLT patients.[14] After stent removal, assessments were performed at 1, 3, 6, 12, 18, and 24 months and then annually up to 5 years. Patients were followed until 5 years after FCSEMS removal or until stricture recurrence (managed with new stent placement), whichever occurred earlier.

Patient population

Eligible patients were 18 years and older with cholangiographic confirmation of a bile duct stricture and an

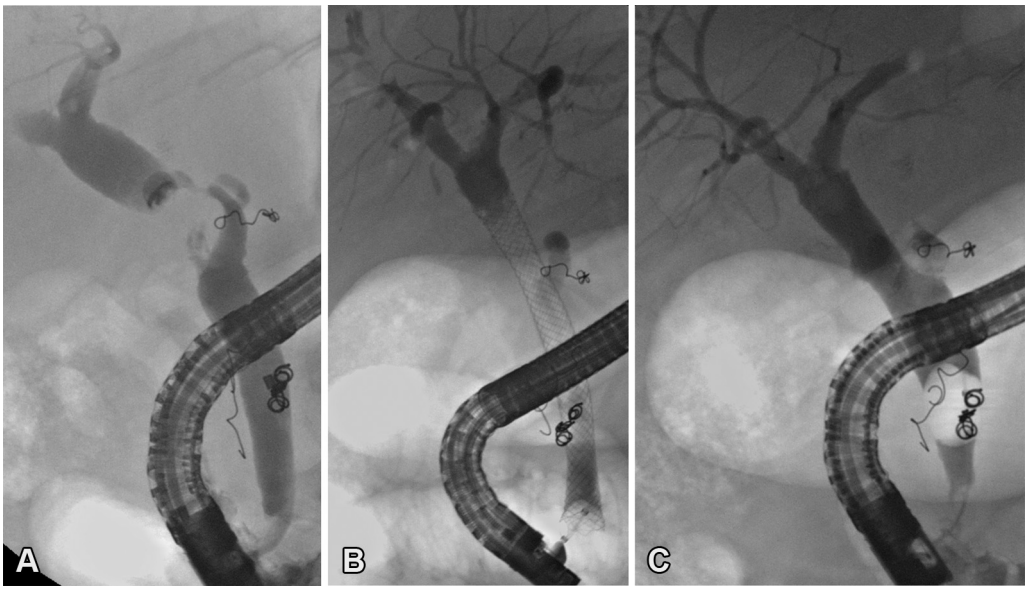

Figure 1. A, Cholangiogram showing an anastomotic stricture after orthotopic liver transplant treated by (**B**) placement of fully covered self-expanding metal stent. **C,** The stricture is resolved after stent removal. Visible coils were placed during radioembolization before transplantation.

indication (eg, clinical symptoms, abnormal laboratory values with known bile duct stricture, planned exchange of plastic stents) for ERCP with stent placement to treat BBSs of the common bile duct. Patients with or without documented history of previous treatment with any number of plastic stents were eligible. Exclusion criteria included history of live liver donor transplantation, malignant biliary stricture, stricture location within 2 cm of bile duct bifurcation, prior biliary SEMSs, suspected stricture ischemia based on imaging of hepatic artery occlusion, or endoscopic evidence of biliary cast syndrome, bile duct perforation, known fistula, or symptomatic duodenal stenosis with gastric stasis.

Stricture resolution and long-term endpoints

Stricture resolution was established at the time of endoscopic FCSEMS removal or observation of CDM and was defined by the lack of a need for recurrent stent placement at that time. The long-term efficacy endpoint was freedom from stricture recurrence defined by absence of recurrent stent placement during the 5-year follow-up after stent removal or observation of CDM. This was assessed on an intention-to-treat basis during 5 years of follow-up after FCSEMS removal or observation of CDM for all patients and in the subset of patients observed to have stricture resolution at the time of FCSEMS removal or observation of CDM.

The safety endpoints were SAEs related to the stent or to stent removal or any SAEs occurring within 30 days before stricture recurrence. An SAE was defined as an event that led to death, serious deterioration in health (life-threatening illness or injury, permanent impairment of bodily structure or function or medical/surgical intervention required to prevent such an impairment, or new or prolonged hospitalization), or fetal death, distress, or abnormality.

Statistical analysis

Baseline characteristics of patients and their endoscopic procedures were calculated, including mean, median, standard deviation, interquartile range, and range for continuous variables (age, time from transplant, serum total bilirubin, and alkaline phosphatase) and were stratified by incidence for categorical variables (sex, primary reason for transplant, stricture location, history of plastic stent placement, stricture location, and size of the FCSEMS placed). Freedom from stricture recurrence and freedom from recurrent stent placement were analyzed using Kaplan-Meier techniques, and the differences between those with and without migration were tested using the log-rank test. Univariate and multivariate analyses were used to determine whether baseline characteristics predicted outcomes. Specifically, logistic regression using a Firth bias adjustment was used for stricture resolution, and Cox proportional hazards models were performed for SAEs and freedom from stricture recurrence. Both were performed using the model-building technique of stepwise regression, with $P < .10$ for covariates to stay in the model and $P > .10$ to exit the model. The significance level for all analyses was set at .05. All analyses were performed using SAS, version 9.4 (SAS Institute, Cary, NC, USA).

RESULTS

Baseline characteristics and endoscopic stent placement

Of 42 patients enrolled, 1 could not be evaluated because of death from an infection that was unrelated to the study. This patient had not experienced any FCSEMS- or FCSEMS placement–related adverse event and had no

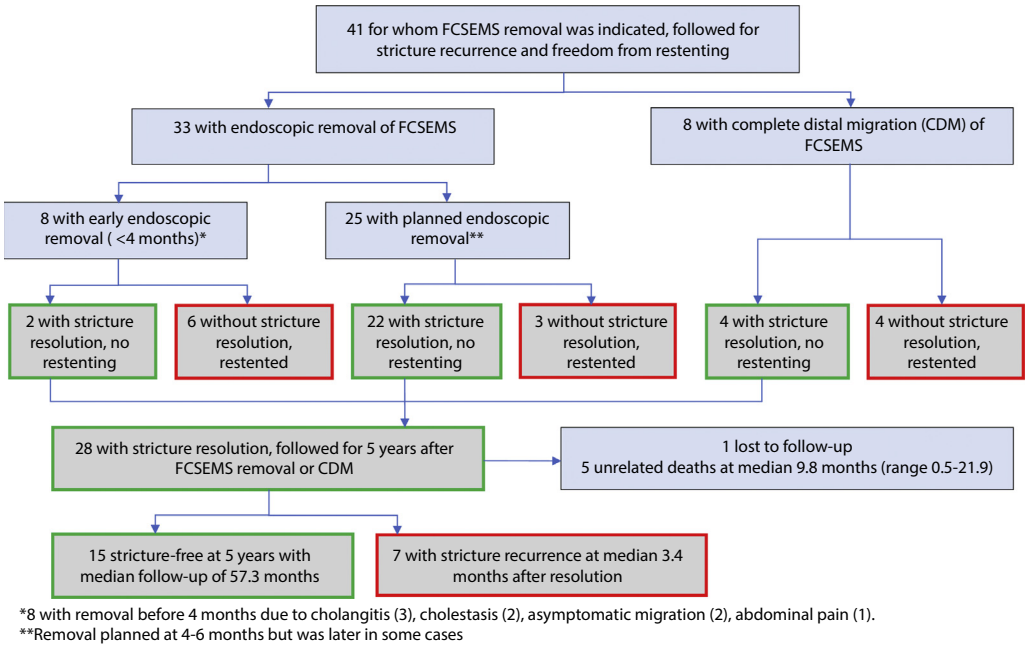

Figure 2. Flowchart of patients with a history of orthotopic liver transplant and benign biliary strictures treated with fully covered self-expanding metal stents (FCSEMSs).

signs of FCSEMS dysfunction at the time of death. Forty-one patients with a history of OLT were included in the current analysis of 5-year outcomes after FCSEMS removal or after observation of CDM (Fig. 2). The OLT cohort had a mean age of 56.7 11.5 years and was predominantly male (82.9%, 34/41) (Table 1). All patients had received transplants from cadaveric donors, with a mean time since transplant of 32.9 months (range, .1-234.5). Alcoholic cirrhosis (39.0%, 16/41) and hepatitis B or C (26.8%, 11/41) were the most common primary reasons for liver transplant; other documented reasons included cryptogenic cirrhosis (9.8%, 4/41), hepatocellular cancer (7.3%, 3/41), primary biliary cirrhosis (4.9%, 2/41), primary sclerosing cholangitis (2.4%, 1/41), autoimmune hepatitis (2.4%, 1/41), acute liver failure (2.4%, 1/41), and other (4.9%, 2/41). Most patients (95.1%, 39/41) had a history of sphincterotomy, and almost half (48.8%, 20/41) had undergone prior plastic stent placement.

At the baseline endoscopic examination, patients were found to have strictures located in the proximal (39.0%, 16/41) and mid (61.0%, 25/41) common bile duct. Plastic stents were removed from 14 patients (34.1%), ranging from 1 stent (26.8%, 11/41) to 3 to 5 stents (2.4%, 1/41) before FCSEMS placement. FCSEMS placement was technically successful with satisfactory positioning in all patients. The most common size of study FCSEMS placed at the baseline visit was 10 mm × 80 mm in 32 patients (78.0%) (Table 1).

Migration and stricture resolution assessed at time of stent removal

Twenty-five patients (61.0%) underwent FCSEMS removal during the planned period of 4 to 6 months (median indwell, 153 days), 8 (19.5%) underwent removal before 4 months (median indwell, 22 days), and 8 (19.5%) were observed to have spontaneous CDM after an estimated median indwell of 167.5 days (Fig. 1). Six patients had over 6 months of indwell time, 5 with stent removal within 198 days (6.6 months) and 1 with removal at 355 days (11.8 months). Successful endoscopic removal of all 33 FCSEMSs (100%) that had not completely migrated was achieved using forceps/graspers/snares (n = 31) or a stent-in-stent technique (n = 2). The FCSEMS covering was observed to not be compromised for any stent at the time of removal.

Twenty-four patients (58.5%) were noted to have stent migration at the time of FCSEMS removal. Of these, 8 were spontaneous CDM, 8 were partial distal migrations, and 8 were proximal migrations; within these groups, 4, 3, and 2 patients, respectively, were symptomatic at the time of FCSEMS removal and were restented with a plastic stent(s) immediately. A multivariate model suggested that "over 1 year since transplant" was associated with significantly lower risk (hazard ratio [HR], .4; 95% confidence interval [CI], .2-.8; $P = .018$) and "alcoholism as reason for transplant" with higher risk (HR, 2.8; 95% CI, 1.2-6.4; $P = .013$) of any stent migration. "Alcoholism as reason for transplant" was also associated with higher risk (HR, 5.7; 95% CI, 1.2-26.8; $P = .029$) of proximal migration.

Twenty-eight patients (68.3%; 95% CI, 51.9%-81.9%) had either stricture resolution or observation of CDM and did not require recurrent stent placement. Univariate/multivariate analyses did not reveal independent predictors for stricture resolution observed at the time of stent removal.

TABLE 1. Baseline characteristics of patients and their procedures (n = 41)

Characteristic	Value
Patients	
Age, y	56.7 ± 11.5 (28.0-77.0)
Male	82.9 (34/41)
Primary reason for liver transplant	
Alcoholic cirrhosis	39.0 (16/41)
Hepatitis B or C	26.8 (11/41)
Other	34.1 (14/41)
Time from transplant, mo	32.9 ± 53.2 (.1-234.5)
Total bilirubin level, mg/dL	4.5 ± 8.1 (.3-35.4)
Alkaline phosphatase level, IU/L	332.6 ± 429.4 (39.0-2282.0)
Baseline procedure	
Stricture location	
Mid	61.0 (25/41)
Proximal	39.0 (16/41)
Gallbladder in situ	0.0 (0/41)
Sphincterotomized	95.1 (39/41)
Prior plastic stent placement only	22.0 (9/41)
Prior balloon dilation only	9.8 (4/41)
Prior plastic stent placement and balloon dilation	17.1 (7/41)
Plastic stents removed	
0	65.9 (27/41)
1	26.8 (11/41)
2	4.9 (2/41)
3-5	2.4 (1/41)
Study stent size	
8 × 80 mm	2.4 (1/41)
10 × 60 mm	19.5 (8/41)
10 × 80 mm	78.0 (32/41)
Technical success	100 (41/41)

Values are mean ± standard deviation (range) or % (n/N).

Freedom from recurrent stent placement after stent removal

Among all 41 patients, the probability of remaining free from recurrent stent placement by 5 years after FCSEMS removal was 48.9% (95% CI, 33.2%-64.7%) (Fig. 3A). Post hoc analyses showed that among 31 patients with an implanted stent for more than 4 months, the probability of remaining stent-free by 5 years after FCSEMS removal was 60.9%. In addition, 75.5% of patients (95% CI, 54.5%-96.5%) without migrations compared with 27.9% of patients (95% CI, 9.1%-46.8%) with migrations remained stent-free by 5 years after FCSEMS removal ($P = .004$) (Fig. 3B).

Freedom from stricture recurrence in patients with stricture resolution at time of stent removal

Among the 28 patients who had stricture resolution or observation of CDM at the time of FCSEMS removal (after a median of 151 days indwell time [5.0 months]), the probability of being without stricture recurrence by 5 years after stent removal was 72.6% (95% CI, 55.3%-90%) (Fig. 4). Seven patients had stricture recurrence during follow-up, with a median time to recurrence of 3.4 months (interquartile range, 1.8-6.6). All recurrent strictures were at the original location and occurred by 15 months (range, 1.7-14.7) after stent removal. All recurrent strictures were successfully managed with recurrent stent placement; no patients required reintervention with bypass surgery. Univariate/multivariate analyses did not reveal independent risk factors for stricture recurrence.

SAEs related to stent or stent removal

Among all 41 participants, 16 (39%) had at least 1 FCSEMS- or FCSEMS removal–related SAE, with cholangitis (n = 10) and abdominal pain (n = 4) the most common (Table 2). Univariate and multivariate analyses showed that compared with those with transplantation less than 1 year before enrollment, patients with transplantation at least 1 year before enrollment had a significantly lower risk of adverse events (HR, .3; 95% CI, .1-.8) and cholangitis specifically (HR, .2; 95% CI, .1-.7). Among the 7 patients who had stricture resolution after FCSEMS treatment and then experienced stricture recurrence during follow-up, 5 had cholangitis/fever and/or elevated liver function tests within 30 days before recurrence.

DISCUSSION

We studied the efficacy and safety of FCSEMSs to treat anastomotic stricture in patients with OLT followed for up to 5 years after FCSEMS removal. On an intention-to-treat basis, the probability of remaining stent-free was 49% for all patients and 61% for those with a stent indwelling for the full intended 4 to 6 months. Among patients with stricture resolution at the time of FCSEMS removal, the 5-year probability of being without stricture recurrence was 73%. All recurrent strictures were at the original location and occurred no later than 15 months after stent removal. Spontaneous CDMs occurred in 20% of participants, and SAEs related to the stent or stent removal occurred in 39% of participants.

Since Costamagna et al[15] described the technique in 2001, progressive dilation by insertion of increasing numbers of MPSs has been the most widely used endoscopic treatment for BBS. An average of 3 to 4 ERCP procedures are required to dilate, deploy stents, up-size, and ultimately remove all stents once the stricture has

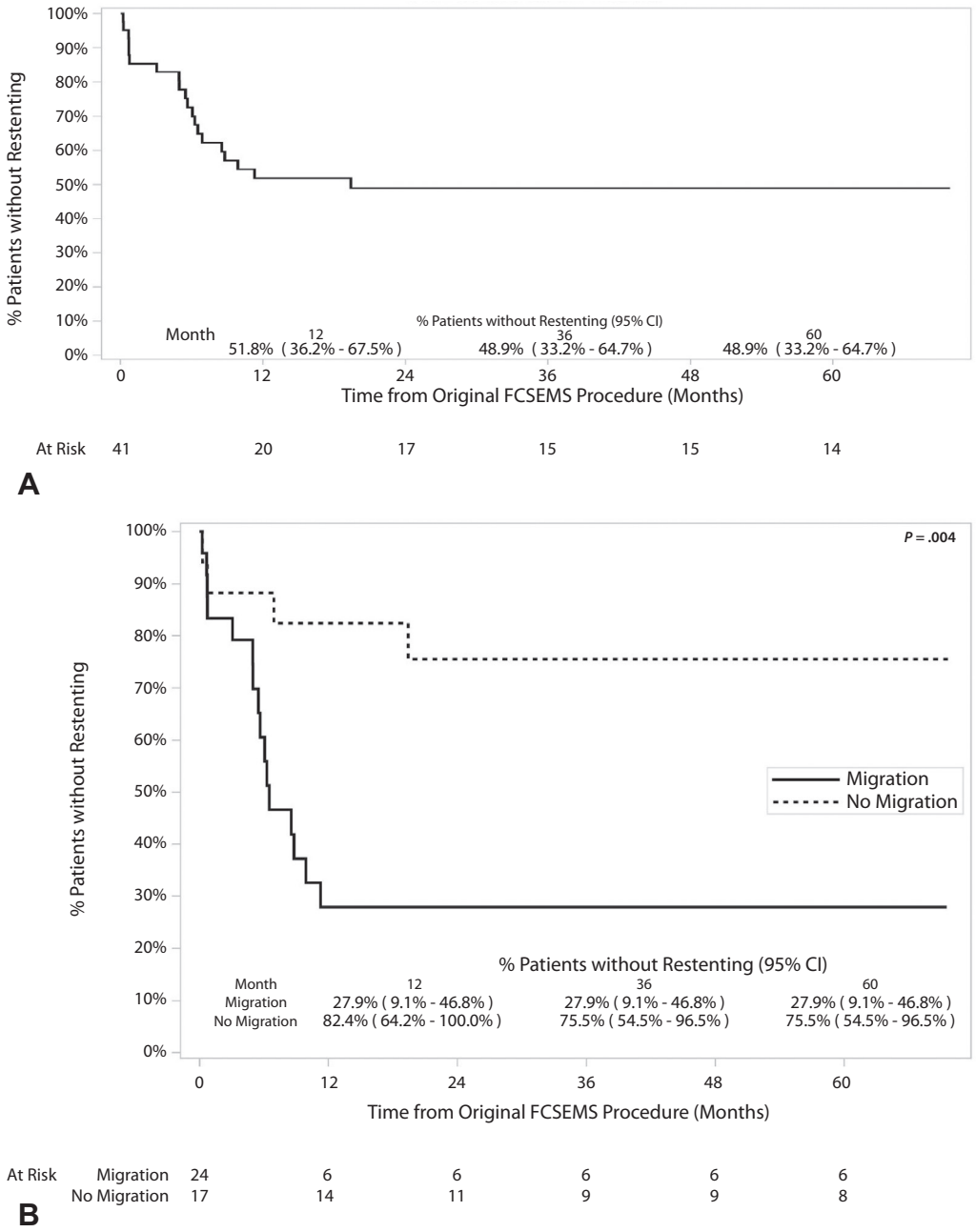

Figure 3. A, Kaplan-Meier analysis of patients who remained free from recurrent stent placement (n = 41). The cumulative probability of remaining free from recurrent stent placement after removal of fully covered self-expanding metal stent (FCSEMS) placement until 5 years after FCSEMS removal was estimated among all patients. Patients who died, were treatment failures or those lost to follow-up between FCSEMS removal to 5 years of follow-up were censored. Median follow-up time was 62.2 months after FCSEMS placement. Median time to recurrent stent placement was 5.6 months after FCSEMS placement (range, .2-19.4; interquartile range, .7-7.7). **B,** Kaplan-Meier analysis of patients who remained free from recurrent stent placement by stent migration (n = 41). The cumulative probability of remaining free from recurrent stent placement from removal of a FCSEMS until 5 years later was significantly longer in patients with no stent migration compared with those with migration (75.5% vs 27.9%, respectively; $P = .004$). *CI*, Confidence interval.

resolved,[16] and the repeated endoscopic interventions may extend up to 24 months to achieve sustained clinical success.[10] FCSEMS treatment of BBS has been studied since 2009,[17] and 4 randomized trials comparing FCSEMS with MPSs to treat BBS in cohorts including post-OLT patients have been conducted since 2014.[6,7,18,19] Prospective and retrospective cohort studies and randomized trials focused on post-OLT patients have consistently reported FCSEMSs to be noninferior to MPSs with respect to stricture resolution, stricture recurrence, and overall adverse events,[10-13] with 1 RCT reporting a higher stricture recurrence rate in the FCSEMS groups

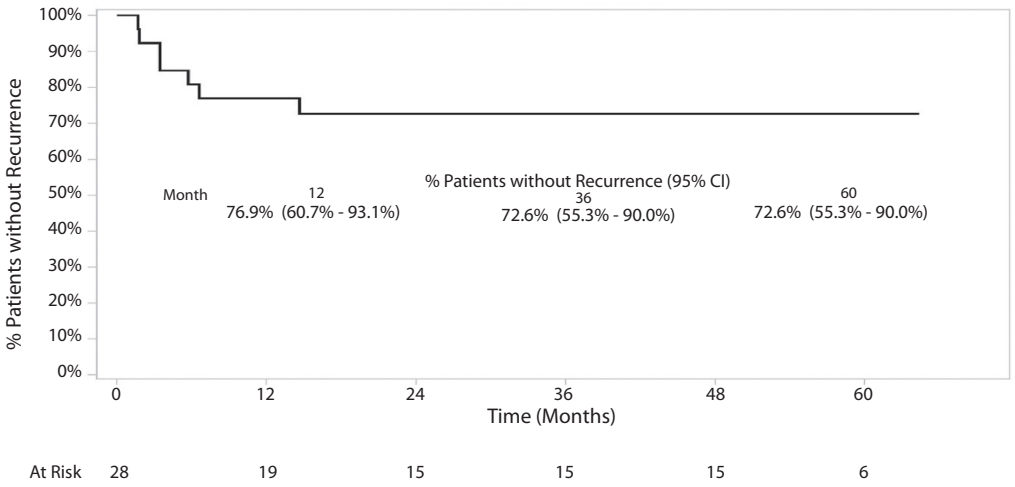

Figure 4. Kaplan-Meier analysis of freedom from stricture recurrence in patients with stricture resolution at the time of endoscopic fully covered self-expanding metal stent (FCSEMS) removal or observation of complete distal migration (n = 28). The cumulative probability of being free from recurrent stent placement from the time of FCSEMS removal until 5 years later in patients who had stricture resolution at removal (n = 28) is presented. Patients who died or were lost to follow-up from the time of FCSEMS removal to 5-year follow-up were censored. The median follow-up time after FCSEMS removal was 57.3 months (interquartile range, 21.9-60.2) for 28 patients. The median time to stricture recurrence after FCSEMS removal was 3.4 months (interquartile range, 1.8-6.6) in 7 patients. *CI*, Confidence interval.

TABLE 2. Stent- or stent removal–related serious adverse events among all patients (n = 41)

Serious adverse events	Percent of patients (n/N)
Cholangitis/fever	24.4 (10/41)
Abdominal pain	9.8 (4/41)
Cholestasis	2.4 (1/41)
Self-limited bleeding in bile duct	2.4 (1/41)
Elevated serum bilirubin	2.4 (1/41)
Total patients with ≥1 serious adverse events*	39.0 (16/41)

*One patient had both abdominal pain and cholangitis.

when the stents were removed early.[7] A 2019 meta-analysis of data from 4 RCTs concluded that FCSEMSs were associated with a reduced number of procedures and were a cost-sparing intervention overall.[12] However, because only 205 patients were represented in the RCTs and follow-up was as short as 1 year, experts have emphasized the need for further RCTs with larger sample sizes and longer follow-up times (eg, at least 2 years[13]) for more definitive findings. In our study, strictures recurred as late as 15 months after FCSEMS removal, which supports that follow-up of at least 2 years is important for a thorough evaluation of FCSEMS efficacy and safety.

The overall 5-year stricture recurrence rate was 31.7% in our OLT cohort, which was similar to[7,18] or higher than[6,19] stricture recurrence rates in the FCSEMS arm of RCTs in OLT cohorts followed for 1 to 3 years on average. This rate was higher than the estimated 5-year rates of stricture recurrence reported for patients postcholecystectomy (15.4%)[20] or with chronic pancreatitis (22.6%)[21] in the original cohort.[14] The higher rate was understandable considering multiple etiologies for biliary stricture in OLT patients including ischemia of the biliary tree from chronic rejection or technical biliary adverse events such as kinking or anastomotic leaks.[22] Multivariate analyses in our study did not identify independent predictors of 5-year stricture recurrence, but findings were limited by the small number of participants who could be followed for this endpoint. For example, prior studies have reported that liver transplant patients with more than 12 months of plastic stent placement for BBS are less likely to have stricture recurrence compared with those without prior stent placement.[23] Of the 28 participants who were followed for 5-year stricture recurrence, 7 had stricture recurrence, of whom 4 (51.7%) had prior plastic stent placement. A larger study population and details regarding the time period of prior stent placement would have allowed further investigation of this predictor.

Stent- and stent removal–related SAEs occurred in 39% of these patients, primarily because of cholangitis (24.4%). This compares with overall SAE rates ranging from 10% (1/10) to 40.4% (23/57) in 3 RCTs of covered metallic stents versus plastic stents for BBS that included OLT patients.[6,7,18] Biliary adverse events as a whole are common in the OLT patient population, occurring in 10% to 30% after whole-organ OLT and resulting in mortality rates of up to 10% of cases.[22] Age over 60 (seen in 18 of our participants [44%] at baseline) and primary sclerosing cholangitis as the transplant indication (1 participant) are known risk factors for biliary adverse events after liver transplantation.[24] Immunosuppression was a predisposing factor to infections in this cohort, that is, OLT patients undergo intensive perioperative prophylactic immunosuppressive

induction therapy to prevent acute cellular rejection in the first months after transplantation, followed by maintenance immunosuppressive therapy for life.[25] Infection risk is lower with tapered immunosuppression by 12 months after transplant; however, a Finnish registry study with 3923 person-years of follow-up estimated that after the first year post-transplant, 1 in 15 liver transplant patients will have an episode of cholangitis or other severe infection each year.[26] Multivariate analyses in our study suggested that longer time since liver transplantation was associated with a lower risk of adverse events and of cholangitis specifically. Patients who develop BBS later in the post-transplant period might be expected to have a more benign course after surviving the immediate postoperative period when the risks of postoperative adverse events or graft failure are the highest.[2]

Our study had several limitations and considerations affecting interpretation. It was a small prospective study with limited power to estimate patient characteristics associated with the efficacy and safety endpoints and with no plastic stent comparator. Patients with prior plastic stent placement were eligible for the study and comprised approximately half of the OLT cohort. This could have caused selection bias favoring either strictures that had failed earlier treatment and were more difficult to treat or inclusion of more patients with a prior sphincterotomy (95% of our cohort) for whom stent migration might have been more likely compared with patients with a native papilla.[7] Because of the small study size, some findings regarding risk factors (eg, association between alcoholism as reason for transplant and stent migration) might have been spurious. The study was not designed to compare FCSEMSs with MPS placement or variants[27] that have also shown good efficacy. Some authors are employees of the sponsor of the study, some investigators were paid consultants for or have received research funding from the study sponsor, and some have received funding from another manufacturer of FCSEMSs. This might have influenced their willingness to participate in the study but would not change their ability to objectively collect data.

In conclusion, in OLT patients with anastomotic biliary stricture treated with FCSEMSs, the probability of remaining stent-free by 5 years was approximately 50% for all patients and over 70% for those with stricture resolution after a median 5.0 months of FCSEMS indwell time. All stricture recurrences occurred by 15 months after stent removal. FCSEMSs continue to show good efficacy and an acceptable level of safety for OLT patients who have post-OLT biliary stricture of their duct-to-duct anastomosis.

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Fondazione Policlinico Universitario A. Gemelli IRCCS, Digestive Endoscopy Unit, Università Cattolica del Sacro Cuore, Centre for Endoscopic Research Therapeutics and Training (CERTT), Rome, Italy (7), Department of Gastroenterology and Hepato-pancreatology, Hôpital Erasme, Université Libre de Bruxelles, Brussels, Belgium (8), The Center for Advanced Digestive Care, Division of Gastroenterology and Hepatology, Weill Cornell Medical College, New York, New York, USA (9).

Reprint requests: Jan-Werner Poley, MD, Erasmus MC, University Medical Center Rotterdam, Dept of Gastroenterology & Hepatology, Rotterdam 3000CA, Netherlands.

If you would like to chat with an author of this article, you may contact Dr Poley at j.poley@erasmusmc.nl.