ORIGINAL ARTICLE

Clinical efficacy of anti-migration features in fully covered metallic stents for anastomotic biliary strictures after liver transplantation: comparison of conventional and anti-migration stents

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Background and Aims: Anastomotic biliary strictures (ABSs) are one of the most frequent adverse events that occur after orthotopic liver transplantation (OLT). Multiple plastic stents (MPS) have been validated for this indication. More recently, fully covered self-expandable metallic stents (FCSEMSs) have been used with positive outcomes, but also have a higher rate of migration, which may limit success. Our primary objective was to compare stent migration rates observed with standard FCSEMSs (Std-FCSEMSs) and so-called anti-migration FCSEMSs (Am-FCSEMSs), which are newly designed with reversed proximal side flaps. Secondary objectives were to compare rates of stricture resolution and procedure-related morbidity.

Methods: We conducted a retrospective analysis of a subset of patients (FCSEMSs for post-OLT ABS) from 2 prospectively maintained databases of (1) OLT patients, and (2) ERCP and stent placement. Between January 2009 and January 2016, consecutive patients presenting with ABS after OLT referred to Cochin Hospital (Paris, France) for ERCP and receiving a FCSEMS were included. Exclusion criteria were any other cause of biliary stricture (ie, malignant stricture, ischemic origin), and biliary fistulae.

Results: One hundred twenty-five FCSEMSs (57 Am-FCSEMSs, 52 type 1 Std-FCSEMSs, and 16 type 2 Std-FCSEMSs) were used in 75 patients for ABS after OLT, with a planned stent placement period of 6 months in all patients. Patient characteristics and rates of previous endoscopic treatment or timing of ABS occurrence after OLT were not different between the groups. The rate of FCSEMS complete migration was 16% (20/125), consisting of 1.7% (1/57) for Am-FCSEMSs and 28% (19/68) for type 1 and 2 Std-FCSEMSs ($P < .0001$). All attempted stent removals (100% of patients) were successful. First follow-up ERCP after each FCSEMS highlighted a stricture resolution rate of 78.4% (98/125), including 93% (53/57) for Am-FCSEMSs and 66.2% (45/68) for type 1 and 2 Std-FCSEMSs ($P < .001$). After a median follow-up of 28 months after stent removal (range, 12-66 months), stricture recurrence was observed in 12.3% (range, 11%-17%) of patients treated with Am-FCSEMSs against 55.9% (range, 54%-56%) of those receiving Std-FCSEMSs ($P < .0001$).

Conclusions: In patients with ABS after OLT, the use of Am-FCSEMSs significantly decreased the risk of stent migration, improved stricture resolution at the time of stent removal, and reduced the rate of stricture recurrence during follow-up. Endoscopic removal success and procedure-related morbidity were similar for both standard and anti-migration stents. (Gastrointest Endosc 2018;■:1-10.)

Abbreviations: ABS, anastomotic biliary stricture; Am-FCSEMS, anti-migration FCSEMS; FCSEMS, fully covered self-expandable metallic stent; MPS, multiple plastic stents; OLT, orthotopic liver transplantation; PCSEMS, partially covered self-expandable metallic stent; Std-FCSEMS, standard FCSEMS.

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INTRODUCTION

Biliary adverse events may occur after orthotopic liver transplantation (OLT) and are responsible for significant morbidity, which may compromise the functionality of the transplanted tissue. Biliary strictures are the most commonly reported adverse events, occurring in 10% to 30% of patients after OLT from a cadaveric donor, and are located in the anastomotic region in nearly 85% of cases in patients with bilio-biliary anastomoses.[1-4]

In recent decades, endoscopic management by retrograde cholangiography has become the standard treatment for anastomotic biliary strictures (ABSs), with a lower morbidity rate compared with surgery and percutaneous techniques.[5] The sequential stenting method, which uses a gradually increasing number of plastic stents for a total calibration duration of at least 1 year is the most frequent choice for this indication.[6] According to previous studies, these multiple plastic stents (MPS) offer a high success rate for ABS resolution, estimated at between 65% and 94%.[7-10] However, this therapeutic option requires repeated endoscopic procedures with the patient under general anesthesia. Poley et al[10] demonstrated that on average, a median of 4 plastic stents implanted during 5 ERCP procedures were necessary for resolution of ABS, with long-term data demonstrating success rates of 70% to 100% for follow-up ranging from 4 to 70 months.[11]

More recently, the use of partially covered self-expandable metallic stents (PCSEMSs), and subsequently, fully covered self-expandable metallic stents (FCSEMSs), has become an interesting therapeutic option. These metallic stents have a greater diameter than the plastic stents, which allows for resolution of the ABS with a single device in a potentially shorter time of about 6 months.[12-14] This property also explains the lower risk of stent blockage compared with plastic stents. Several studies have demonstrated the feasibility of managing benign biliary strictures with FCSEMSs.[15-19] The most frequently identified adverse event after management with FCSEMSs is stent migration, which may be a limiting factor to its effectiveness, as shown by long-term success rates of 53% to 100% for follow-up periods ranging from 4 to 20 months.[11,12,20,21] To mitigate this risk, new FCSEMSs have been developed with a flared distal end and anti-migration proximal side flaps.

The primary objective of this study was to compare the migration rates between conventional FCSEMS and anti-migration FCSEMSs in the management of ABSs after OLT. The secondary objectives were to compare stricture resolution rates and morbidity with the different types of FCSEMS.

METHODS

Patients

We carried out a retrospective analysis of 2 databases containing prospectively collected data from the period between January 2009 and January 2016. This was within the framework of a collaboration between a liver transplantation center (Pitié-Salpêtrière Hospital) and an interventional biliary endoscopy center (Cochin Hospital). The first database concerned patients who underwent OLT, whereas the second concerned patients who had undergone ERCP with the implantation of a metallic biliary stent. Patients who were identified in both databases were eligible for inclusion in the present study.

The inclusion and exclusion criteria were the same for the various groups described hereafter. The inclusion criteria were a diagnosis of ABS after OLT with choledocho-choledochal anastomosis, whatever the type and indication for liver transplantation, and endoscopic treatment of this stricture by the implantation of an FCSEMS.

The exclusion criteria were as follows: all non-bilio-biliary anastomoses (ie, hepato-jejunal), early ABS occurring less than 30 days after OLT, malignant biliary strictures, intrahepatic cholangitis suggestive of an ischemic origin, a stricture extending to within less than 1 cm of the superior biliary confluence, the presence of plastic stents (ie, exchange of a plastic stent for an FCSEMS), or the existence of a biliary fistula.

Endoscopic procedures

All of the ERCPs were performed in a single university teaching hospital at the Cochin Hospital (Paris, France), with the aid of a large channel duodenoscope (Olympus TJF 160 or TJF-180, Olympus, Japan). After obtaining informed consent from the patient, each examination was performed with the patient under general anesthesia (propofol), often with orotracheal intubation. Systemic antibiotic prophylaxis was administered before ERCP. After selective biliary catheterization, a cholangiogram was obtained to assess the location and configuration of the stricture. In the absence of antecedent endoscopic treatment, a biliary sphincterotomy was performed to allow for complete expansion of the stent through the papilla, facilitate its future removal, and reduce the risk of acute pancreatitis, which may be triggered by duct obstruction caused by the stent. Hydrostatic 6-mm or 8-mm balloon dilatation was performed during the same endoscopic procedure if the operator deemed the stricture too tight for direct implantation of the stent. Whatever the type of metallic stent used, the placement of the FCSEMS was centered on the ABS, taking care to ensure that the proximal end of the stent was below the superior biliary confluence or placed at the confluence without blocking a hepatic duct, and that the distal end projected 10 to 20 mm into the duodenal lumen, through the papilla.

In the absence of any new symptoms (abdominal pain, fever, jaundice) and/or abnormal liver function tests (cholestasis) that would make an earlier follow-up necessary, the metallic stent was removed after 6 months with the aid of a foreign body clamp, generally through the