Role of Biodegradable Stents as Part of Treatment of Biliary Strictures after Pediatric and Adult Liver Transplantation: An Observational Single-Center Study

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ABSTRACT

This brief report presents the results of 20 adult and pediatric patients treated with the use of biodegradable SX-Ella biliary stents placed by means of a transhepatic approach for the treatment of benign biliary strictures after liver transplantation. Stent insertions were always feasible (100%), and only 1 case of acute pancreatitis was observed (5%). The overall clinical success rate of the procedure, including anastomotic and nonanastomotic strictures, was 75%, and was higher in the anastomotic stricture group (81.25%) than in the non-anastomotic stricture group (50%).

ABBREVIATIONS

cSEM = covered self-expandable metal stent, LT = liver transplantation, MRCP = magnetic resonance cholangiopancreatography

Biliary anastomotic strictures are the most frequent complication after liver transplantation (LT), and worldwide consensus on the best therapeutic management is lacking (1). Several studies have reported endoscopic treatment with maximal plastic stent placement (2) or covered self-expandable metal stents (cSEMs) (3) as the criterion-standard treatment. The success rates of these procedures range from 60% to 80%, with 30% morbidity (gastrointestinal bleeding and pancreatitis) and a recurrence rate ~20% (4). A transhepatic approach has proved to be a valuable therapeutic alternate to endoscopic procedures, with similar morbidity and recurrence rates (5). However, multiple sessions of balloon dilation or long-term external biliary drainage may be required to achieve satisfactory clinical results.

Nonanastomotic strictures are considered to be a different and challenging biliary complication after LT, because they may occur at multiple locations in the biliary tree, usually owing to hepatic artery thrombosis, leading to retransplantation in most cases owing to the suboptimal results of endoscopic and percutaneous techniques (6,7).

The past 2 decades have seen relevant advances in the development of biodegradable materials for medical applications. These materials have been used to remedy the limitations associated with metal and plastic stents, such as higher migration rates, less flexibility, and less expansive radial force (8). A small number of cases using biodegradable polydioxanone stents placed percutaneously in the biliary tract have been described, showing lower morbidity,

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Table 1. Adult and Pediatric Patient Characteristics

Adult Patients						Pediatric Patients					
Patient	Age (y)	Sex	Indication for LT	Graft	Time After LT of Biliary Complication (mo)	Patient	Age (y)	Sex	Indication for LT	Graft	Time After LT of Biliary Complication (mo)
1	65	M	HCC	Whole liver	194	1	1	F	Biliary atresia	Living donor	31
2	60	M	HCC	Whole liver	50	2	9	F	Wilson disease	Whole liver	31
3	49	M	Alcohol	Whole liver	26	3	1	M	Familial cholostatic disease	Split liver	10
4	59	M	Alcohol	Whole liver	19	4	6	M	HCC	Living donor	26
5	54	F	HCC	Whole liver	4	5	1	M	Hepatoblastoma	Living donor	1
6	61	M	HCC	Whole liver	11	6	1	F	Alagille syndrome	Living donor	7
7	68	M	HCC	Whole liver	2	7	5	F	Biliary atresia	Living donor	7
8	61	M	Alcohol	Whole liver	4	8	8	M	Familial cholostatic disease	Living donor	4
9	61	M	HCV	Whole liver	2	9	4	M	Hepatoblastoma	Living donor	1
10	60	M	HCC	Whole liver	6	10	1	F	Biliary atresia	Living donor	1

F = female; HCC = hepatocellular carcinoma; HCV = hepatitis C virus; LT = liver transplantation; M = male.

migration, and recurrence rates than endoscopic procedures (9–14), although no results on the treatment of biliary complications after LT have been reported.

The purpose of the present study was to evaluate the feasibility and safety of the novel use of biodegradable SX-Ella biliary stents placed by a transhepatic approach as part of the treatment of post-LT benign biliary strictures.

MATERIALS AND METHODS

This was an observational retrospective single-center study from a prospectively obtained database. The study was approved by our Institutional Review Board and conducted in compliance with the provisions of the Declaration of Helsinki and Good Clinical Practice guidelines. Written informed consents for each procedure were obtained from all patients.

From August 2014 to September 2017, 20 patients (10 adults and 10 children) with symptomatic benign biliary strictures after LT treated with the use of biodegradable SX-Ella biliary stents were included. The biliary strictures were confirmed on magnetic resonance cholangiopancreatography (MRCP).

Two types of biliary strictures after LT, according to radiologic findings, were differentiated (6): anastomotic strictures, defined as segmental or focal narrowing around a biliary anastomosis; and nonanastomotic strictures, defined as multiple and diffuse strictures of the intra- and/or extrahepatic bile ducts with or without patency of the hepatic artery unrelated to biliary anastomosis.

The median patient age in the adult group was 60 years (range, 49–68). All received a whole graft from brain-dead donors, and the biliary reconstruction was end-to-end choledocho-choledochostomy. Seven patients developed anastomotic strictures and 3 nonanastomotic strictures. Two of the 3 patients with nonanastomotic strictures had thrombosed hepatic artery and in 1 the hepatic artery was patent. The biliary complications appeared after a median time of 8 months (range, 0.8–194) after LT (Table 1).

In the pediatric population, the median age was 2.5 years (range, 1–9). Nine patients received partial grafts (1 split-liver and 8 living-donor) with hepatojejunostomy performed in all of them. One patient received a whole graft, and an end-to-end anastomosis was done. Nine patients presented anastomotic stricture and 1 nonanastomotic stricture with thrombosed hepatic artery in a median time of 7 months (range, 0.2–31) after LT (Table 1).

In all of these patients, percutaneous transhepatic balloon dilatation was the first step in the treatment of biliary stenosis, with ensuing stent placement after failure of percutaneous cSEMs. Before August 2014, cSEMs were routinely used, and they were replaced thereafter by biodegradable biliary stents.

The SX-Ella BD stent (Ella-DV biliary stent, Ella-CS; Hradec Králové, Czech Republic; Fig 1) used in this series is made of polydioxanone, which is a semicrystalline biodegradable polymer of the polyester family, a material used for sutures for many years. Hydrolytic processes degrade the polydioxanone, and the stent loses 50% of its strength after 4 weeks and is completely absorbed within 3–6 months. There are 2 platinum markers to allow for fluoroscopic visibility, which can be visualized for up to 6 months.

All patients underwent percutaneous transhepatic cholangiography under local anesthesia and mild sedation (1 mcg/Kg of fentanyl, 0.05 mg/Kg of midazolam, and 0.5 mg/Kg of propofol) with the use of ultrasound and fluoroscopic guidance according to standard micropuncture technique. When the biliary stricture was proven, a first dilation with the use of an 8–10-mm high-pressure balloon