Article published online: 2021-03-23

Original Article

Percutaneous Transhepatic Biodegradable Stent Placement for Benign Anastomotic Biliary Strictures: Short-Term Outcomes of a Single-Institution Experience

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Abstract

Purpose: The purpose of this study was to assess the safety and effectiveness of biodegradable stents in the management of benign anastomotic biliary strictures. **Materials and Methods:** This retrospective study included all consecutive adult patients who underwent percutaneous biodegradable stent insertion for benign anastomotic biliary strictures that were refractory to cholangioplasty or biliary drainage-dependent or preferred stent placement to avoid long-term tube dependence. Fourteen stents were used in 12 patients (9 males) with a mean age of 53 years (range: 23–72 years). Ten patients had liver transplant (7 – choledochocholedochal anastomosis and 3 – hepaticojejunal anastomosis). Two patients had primary sclerosing cholangitis with hepaticojejunal anastomosis. The mean time since surgery was 5.5 years (6 months–16 years). Ten patients had an average of three (range: 1–6) previous sessions of biliary dilatation. Two patients initially preferred stent placement to avoid long-term tube dependence. **Results:** Technical and clinical success was achieved in all cases. One patient died 2 months after stent insertion because of progressive liver cirrhosis. No re-intervention was required in 8 (72%) of the remaining 11 patients at a mean follow-up time of 234 days (96–539 days). Three liver transplant patients required re-intervention at a mean time of 287 days. There were one severe procedure-related complication (cholangitis and sepsis) and one mild complication (transient septicemia). Stent migration into the bowel occurred in one case a few days after insertion, but this required no re-intervention. No procedure-related mortality occurred. **Conclusion:** Biodegradable biliary stent may offer a safe and effective option to avoid tube dependence in patients with benign anastomotic biliary strictures.

Keywords: *Benign anastomotic strictures, biliary stent, biodegradable*

Introduction

Benign anastomotic biliary strictures in liver transplantation or after hepaticojejunostomy are likely to be induced by ischemia or extensive fibrosis. Anastomotic strictures can be resistant to treatment and often require repeated endoscopic or percutaneous interventions with serial balloon dilatation and internal/external drainage, with technical success in the range of 85%–95%.[1] Alternatively, multiple plastic stents or covered self-expandable metallic stents (CSEMSs) may be used. However, their use remains controversial because of the possibility of stent occlusion and the need for re-intervention and stent removal.[2-4] The use of biodegradable biliary stents has been introduced as an alternative method for the management of benign biliary strictures.[5-8] Early clinical experience has showed promising results in prolonging time to re-intervention and avoidance of drain dependence.[5-9]

Our study aims to assess the safety and effectiveness of biodegradable biliary stents in the management of anastomotic biliary strictures refractory to standard cholangioplasty and biliary drainage.

Materials and Methods

This single-institution retrospective study was approved by the institutional review board, and the need to obtain informed consent was waived. The study included all consecutive adult patients between July 2016 and February 2018 who had benign anastomotic biliary stricture that was refractory to cholangioplasty or biliary drainage-dependent or preferred stent placement to avoid long-term tube dependence. Patients with benign strictures

How to cite this article: Arabi M, Alrehaili B, Salman R, Qazi S, Bashir O, Abdullah K, *et al*. Percutaneous transhepatic biodegradable stent placement for benign anastomotic biliary strictures: Short-term outcomes of a single-institution experience. Arab J Intervent Radiol 2019;3:19-22.

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Access this article online

Website: www.arabjir.com

DOI: 10.4103/AJIR.AJIR_43_18

Quick Response Code:

related to pancreatitis or primary sclerosing cholangitis were not considered for biodegradable stent placement in our practice. All clinical, laboratory, and imaging data were reviewed. Twelve patients (9 males) were included with a mean age of 53 years (range: 23–72 years). Ten patients underwent liver transplant (7 – choledochocholedochal anastomosis and 3 – hepaticojejunal anastomosis). Two patients had primary sclerosing cholangitis with hepaticojejunal anastomosis. The median time since surgery was 30 months. All patients had anastomotic strictures managed by percutaneous biliary drainage before stent placement. Ten patients had an average of three (range: 1–6) previous sessions of biliary dilatation. Two patients initially preferred stent placement to avoid long-term tube dependence. Fourteen biodegradable stents (10 mm × 40 mm) (ELLA-CS, s. r. o., Hradec Kralove, Czech Republic) were used in 12 patients. These bare, self-expandable stents are made of polydioxanone absorbable surgical suture, which is a semi-crystalline polymer. The stent is radiolucent and mounted with radiopaque gold markers to indicate its proximal and distal ends. Stents were loaded on the deployment system using the compression tool at the time of procedure according to the manufacturer's instructions (online video) and were deployed by unsheathing the stent at the anastomotic stricture through percutaneous transhepatic access using a 12-Fr sheath. Postdeployment dilatation was done in all cases with 10 mm × 4 cm balloons inflated to nominal pressure. Patients received preprocedural antibiotics with 1 g cefazolin IV. Following stent placement, all patients had an external drainage catheter that is capped for 2–3 days. These catheters were removed after confirmation of stable liver functions and tube cholangiogram to document stent patency [Figure 1]. Technical success was defined as successful percutaneous placement of a biodegradable stent, and clinical success was defined as staying drain free after 1 month. Time to re-intervention was defined as the time interval between initial placement of the stent and any subsequent endoscopic or percutaneous interventions indicated by clinical or imaging evidence of stricture recurrence (not caused by liver transplant dysfunction or progression of underlying primary liver disease). Complications were evaluated according to the new adverse event classification published by the Society of Interventional Radiology Standards of Practice Committee.[10]

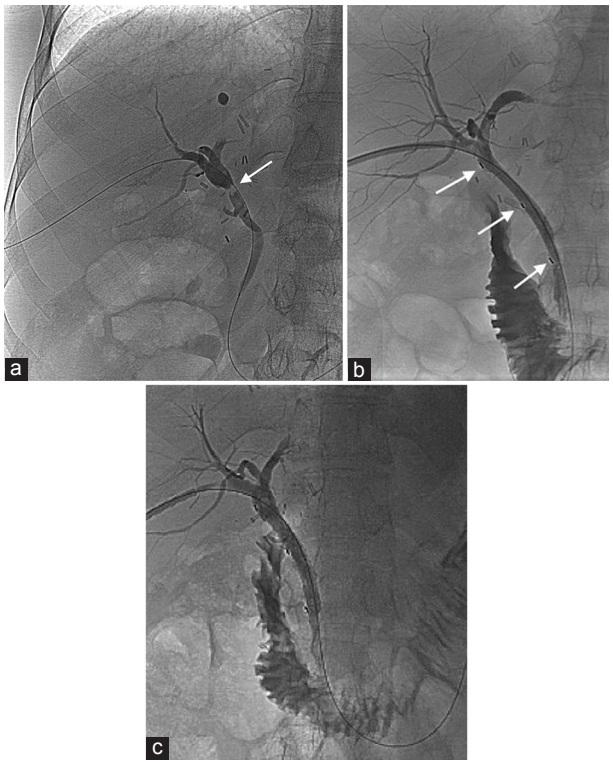

Figure 1: A 31-year-old male patient presented with elevated liver functions 1 year following liver transplant. The patient preferred biodegradable stent placement to avoid drain dependence. The patient remained drain free for 503 days when he required re-intervention for recurrent stricture. (a) Percutaneous transhepatic cholangiogram showed high-grade anastomotic stricture (arrow), (b) sheath cholangiogram done after predilatation with 10-mm balloon and biodegradable stent placement. Note the three radiopaque gold markers at the proximal, mid, and distal ends of the stent (arrows), (c) sheath cholangiogram 3 days later before removal of external drain shows patent stent

Results

Technical and clinical success was achieved in all cases. One patient died 2 months after the procedure because of progressive liver cirrhosis. No re-intervention was required in 8 (72%) of the remaining 11 patients at a mean follow-up time of 234 days (range: 96–539 days). Three liver transplant patients required re-intervention at a mean time of 287 days. One patient with hepaticojejunal anastomosis underwent biodegradable stent re-insertion after 214 days and ultimately had stricture recurrence 84 days after the second intervention. After 143 days, one transplant patient with choledochocholedochal anastomosis presented with recurrent obstructive jaundice caused by sludge, which was managed by endoscopic plastic stent placement. One patient had repeat percutaneous transhepatic drainage and balloon dilatation 503 days after the initial stent placement. Patients who required re-intervention had partial or complete stent dissolution at the time of recurrence, as indicated by disappearance of one or more gold marker.

There were one severe procedure-related complication (cholangitis and sepsis) and one mild complication (transient septicemia). One transplant patient required two stents for two separate hepaticojejunal anastomoses. One of these two stents migrated into the bowel a few days after insertion but required no re-intervention. No procedure-related mortality occurred [Table 1].

Discussion

Anastomotic biliary strictures are traditionally treated with balloon dilatation, multiple endoscopic plastic stents, or long-term drainage. However, there has been recent interest in the use of CSEMSs in attempts to minimize the need for re-intervention and associated costs. Several previous

studies, including randomized controlled trials,[2-4,11,12] have demonstrated that CSEMSs are equally effective in achieving stricture resolution and require fewer endoscopic interventions. However, the use of CSEMS appears to be associated with a higher risk of adverse events, ranging between 15% and 23%, particularly acute pancreatitis, which might be related to coverage of the pancreatic duct.

Biodegradable biliary stents were recently introduced to minimize the need for repeated biliary interventions for benign strictures. These stents act as a scaffold for the stricture and allow long-term dilatation without the need for additional interventions for stent removal or exchange.[9] Degradation occurs by hydrolysis; the stent loses 50% of its breaking strength after 3 weeks and is absorbed within 6 months.[5-8] These stents seem to be more biocompatible than metallic stents and produce fewer inflammatory reactions of the bile ducts.[7,13] Early clinical studies have indicated the safety and efficacy of these stents in the management of anastomotic strictures.[5,6,8,14]

In a study by Janousek *et al*., ten patients were randomized for intraoperative placement of biodegradable stents at duct-to-duct anastomosis. All five patients who underwent stent placement (1.5 cm long) had good patency with no leaks or no stone formation. All stents completely degraded, presumably within 6–8 weeks, with no adverse effects.[14]

In a multi-institutional retrospective study, 107 patients underwent biodegradable stent placement to treat refractory benign biliary strictures. Technical success was 100%, with no major complications reported. The estimated mean time to stricture recurrence was 38 months. The recurrence rate at 3 years was 29.4%.[6]

Dopazo *et al*. recently reported the outcomes of using biodegradable biliary stents in adult and pediatric patients for anastomotic and nonanastomotic strictures. Stent placement was successful in all cases through transhepatic approach. After a median follow-up of 23 months for the adult patients and 17 months for the pediatric patients, the overall clinical success was 75%. Stricture recurrence occurred in 2/4 (50%) of the nonanastomotic strictures and in 3/16 (82%) of the anastomotic strictures.[15]

Our study investigated percutaneous management of biliary anastomoses with biodegradable stents. Endoscopic

Table 1: Patients demographics and outcomes after biodegradable stent placement

Patient	Age	Gender	Indication for surgery	Type of anastomosis	Time to stent placement after surgery (months)	Previous cholangioplasty	Complications	Time to re-intervention or last follow up (days)	Outcome at last follow up
1	64	Male	Liver transplant	Hepaticojejunal	24	1	Cholangitis and sepsis	214	Re-intervention (stent re-insertion)
2	23	Male	Liver transplant	Choledochocholedochal	12	3	Transient septicemia	322	No recurrence
3	72	Female	Liver transplant	Choledochocholedochal	12	4		539	No recurrence
4	59	Male	Liver transplant	Choledochocholedochal	36	1		492	No recurrence
5	70	Male	Sclerosing cholangitis	Hepaticojejunal	108	0		60	Death due progressive liver cirrhosis
6	47	Male	Liver transplant	Choledochocholedochal	24	1		143	Re-intervention (ERCP plastic stent)
7	31	Male	Liver transplant	Hepaticojejunal	12	0		503	Re-intervention (PTC/ cholangioplasty)
8	56	Female	Sclerosing cholangitis	Hepaticojejunal	120	3		96	No recurrence
9	59	Female	Liver transplant	Choledochocholedochal	48	6		115	No recurrence
10	26	Male	Liver transplant	Hepaticojejunal	120	2	Stent migration	54	No recurrence
11	71	Male	Liver transplant	Choledochocholedochal	84	6		103	No recurrence
12	57	Male	Liver transplant	Choledochocholedochal	8	2		151	No recurrence

PTC: Percutaneous transhepatic cholangiography, ERCP: Endoscopic retrograde cholangiopancreatography

management was not possible in five patients (42%) with hepaticojejunal anastomosis. The remaining patients were initially managed by percutaneous transhepatic drainage and repeated balloon dilatation. The use of biodegradable stents in this cohort obviated the need for internal/external biliary drainage or repeated dilatation in a majority of patients. However, our study is inherently limited by its small size, retrospective nature, and the lack of comparison to other methods of management. The time of stent degradation could not be precisely determined because of a lack of long-term imaging follow-up; hence, its structural changes and effect on the stricture cannot be ascertained.

Conclusion

The use of biodegradable stents in the management of anastomotic biliary strictures is safe and may help to avoid long-term drainage. However, further study is warranted to obtain long-term results in larger cohorts with comparison to other methods of management in terms of quality of life improvement and associated costs.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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