



The safety and efficacy of the percutaneous balloon-expandable biodegradable magnesium biliary stents in patients with liver transplant

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PURPOSE

This study aims to present our institutional experience with the use of percutaneous balloon-expandable biodegradable magnesium biliary stents (MBS) in the treatment of benign, refractory anastomotic strictures (AS), where initial percutaneous or endoscopic approaches fail or are ineffective, after liver transplantation (LT).

METHODS

In this retrospective single-center study, 13 patients with clinically refractory AS who underwent MBS placement between July 2021 and August 2024 were evaluated. Statistical analyses included Kaplan–Meier survival analysis for patency and Spearman's correlation for recurrence risk. Primary outcomes included stricture recurrence and time to reintervention during follow-up.

RESULTS

The median age of patients was 35 years [interquartile range (IQR): 22–48], and 11 were male (85%). Living donor LT was performed in 12 (92%). The MBS were placed at a median of 8 months post-transplant (IQR: 5–44), with a technical success in all cases (100%). Before MBS placement, patients underwent a median of one endoscopic retrograde cholangiopancreatography (IQR: 0–3) and three percutaneous transhepatic biliary drainage procedures (IQR: 1–8). The median follow-up was 25 months (IQR: 15–33). The MBS patency rates were 93%, 85%, and 67% at 6, 12, and 24 months, respectively. Stricture recurrence occurred at a median of 30 months post-placement (95% confidence interval: 23.6–36.3). A moderate positive correlation was observed between the number of pre-stent interventions and recurrence risk ($\rho: 0.582, P = 0.023$). Post-procedural complications (cholangitis) occurred in 1 patient.

CONCLUSION

Balloon-expandable biodegradable MBS may provide a safe and effective treatment for refractory AS following LT. Early placement of MBS, particularly after fewer prior interventions, appears to be associated with improved patency and longer stricture-free survival.

CLINICAL SIGNIFICANCE

Early use of biodegradable magnesium stents after LT may reduce the need for multiple interventions and improve long-term biliary patency.

KEYWORDS

Biodegradable stent, magnesium, benign biliary anastomotic stricture, biliary stent, percutaneous transhepatic biliary drainage, liver transplantation

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Biliary anastomotic strictures (AS) represent one of the most frequent and clinically significant complications following liver transplantation (LT).¹ These strictures typically arise from factors such as surgical technique, graft-recipient bile duct size mismatch, or ischemic injury to the biliary epithelium, and they contribute substantially to post-transplant morbidity and mortality.² The reported incidence of AS varies by transplant type, occurring in approximately 15% of patients after deceased donor LT (DDLT) and ranging from 19% to 40% following living donor LT (LDLT), where biliary reconstruction is often more technically challenging.³

In patients with AS following LT, the first-line treatment is typically endoscopic retrograde cholangiopancreatography (ERCP) with balloon dilatation and plastic stent placement.^{4,5} When ERCP is unsuccessful or not feasible—such as in patients with altered anatomy or inaccessible anastomoses—percutaneous transhepatic biliary drainage (PTBD) combined with bilioplasty and stent insertion is employed as a more invasive but effective alternative.^{6,7} Although these interventions are generally efficacious, they often require multiple sessions or prolonged catheterization, which can negatively impact the patient's quality of life and increase the risk of complications.^{8,9}

Biodegradable stents (BS) have been successfully employed in the management of benign gastrointestinal and vascular conditions, and their application in the biliary system represents a relatively recent and innovative therapeutic approach.^{10,11} Compared with conventional non-degradable stents, BS are associated with lower complication rates, including reduced risks of infection, stent occlusion, migration, and chronic inflammation. Moreover, they eliminate the need for a secondary intervention for stent removal, as the material gradually degrades *in situ*.¹² Given the high incidence of AS and

the frequent need for repeated biliary interventions following LT, BS represent a promising alternative to traditional endobiliary devices. Magnesium biliary stents (MBS) biodegrade naturally, eliminating the need for retrieval while maintaining biocompatibility and optimal mechanical properties.¹³⁻¹⁷ Their degradation products are safely excreted and may provide anti-inflammatory, antimicrobial, and healing benefits.^{13,15,18} This study presents our institutional experience with magnesium-based BS in the treatment of post-transplant AS and aims to evaluate their safety and efficacy.

Methods

Study design

This single-center retrospective study was approved by İnönü University Ethics Committee (approval number 2025/6784, date: 03.01.2025). Written informed consent was obtained from all patients prior to interventional procedures. Thirteen patients treated for AS following LT between July 2021 and August 2024 were included. The inclusion criteria were as follows: patients with clinically and radiologically confirmed benign AS following LT; failure of previous endoscopic or percutaneous management to maintain long-term patency. The exclusion criteria were as follows: evidence of hepatic artery thrombosis; malignant strictures; or inadequate follow-up data. No patients were lost to follow-up. All percutaneous procedures were performed by the same interventional radiologist.

Patient management and intervention protocol

Management decisions were determined through a multidisciplinary approach involving interventional radiologists, transplant surgeons, and gastroenterologists. AS were confirmed by ultrasonography (US) and magnetic resonance cholangiopancreatography (MRCP) in patients with clinical or laboratory suspicion of biliary complications.

When feasible, ERCP was attempted as the first-line intervention. If ERCP failed or clinical improvement was not achieved after repeated sessions, PTBD was performed; furthermore, PTBD was the first-line treatment in patients with hepaticojejunostomy (HJ)-type biliary anastomosis. Refractory AS was defined as persistent stricture after multiple PTBD sessions, and BS placement was considered in these cases.

All PTBD procedures were performed under sterile conditions with intravenous sedation and analgesia, with the patient

in the supine position. Access to the biliary system was obtained via a transhepatic approach using a 0.018-inch guidewire and a coaxial access system (Accustick, Boston Scientific, Marlborough, MA, USA) through an appropriate intercostal space, under US and fluoroscopic guidance.

After access, contrast cholangiography was used to delineate biliary anatomy and stricture severity. In the initial session, an internal-external biliary drainage catheter (Flexima, Boston Scientific) was placed for decompression. Drainage output was monitored daily, with routine catheter flushing and maintenance.

In subsequent sessions, under anesthesia, balloon dilatation of the stricture was performed using angioplasty balloons inflated to 18–20 atmospheres for approximately 2 minutes. A multi-hole internal-external catheter was then reinserted. The balloon diameter was selected to match the normal proximal (upstream) bile duct caliber, and drainage catheter size was chosen accordingly to avoid overdistension while ensuring sufficient scaffolding.

If the stricture persisted during follow-up, a balloon-expandable biodegradable MBS (UNITY-B, Q3 Medical, Dublin, Ireland; CE certified) was deployed. One patient with two HJ anastomoses and dual strictures received two stents.

Technical success was defined as the absence of residual stricture on completion of cholangiography after stent placement.

The percutaneous catheter was not immediately removed post-stent placement, allowing early complication management. It was withdrawn within 24–48 hours after confirming normal findings on follow-up cholangiography and clinical assessment.

Follow-up and outcome measures

All patients were followed at 1 month post-procedure, then every 3 months during the 1st year in the absence of symptoms. After the 1st year, visits were scheduled every 6 months. Routine follow-up included liver function tests and hepatobiliary US. In the presence of clinical signs of cholangitis, abnormal laboratory values, or biliary dilatation on US, MRCP was performed to assess for stricture recurrence.

Recurrence of AS was defined as a new anastomotic-level stricture on MRCP requiring intervention. Clinical success was defined as BS patency without AS recurrence during follow-up.

Main points

- Percutaneous balloon-expandable biodegradable magnesium biliary stents (MBS) are effective and safe for treating biliary strictures after liver transplantation.
- Biodegradable MBS placed after fewer interventional procedures demonstrate higher patency rates and longer stricture-free intervals.
- Early placement of biodegradable magnesium stents in refractory anastomotic strictures is associated with improved clinical outcomes and reduced recurrence risk.

Statistical analysis

Statistical analyses were performed using the SPSS 22.0 software (IBM Corp., Armonk, NY, USA) package. The Kolmogorov–Smirnov test was used to assess the normality of the data distribution. As the data did not follow a normal distribution, quantitative variables were presented as median [interquartile range (IQR)]. Due to the violation of parametric test assumptions, the Mann–Whitney U test or the Wilcoxon signed-rank test was used for comparisons of quantitative variables within dependent groups. Correlations between two quantitative variables were analyzed using Spearman's rho coefficient. Categorical variables were expressed as frequencies and percentages (%). The recurrence rate of AS was assessed using the Kaplan–Meier method. A *P* value of <0.05 was considered indicative of statistical significance in all analyses.

Results

A total of 13 patients (11 men, 2 women; ratio 5.5:1) were included. The median age at the time of LT was 35 years (IQR: 22–48). LDLT was performed in 12 patients (92%), and DDLT in 1 patient (8%). Indications for LT included hepatitis B (*n* = 6), hepatitis C (*n* = 3), fulminant liver failure (*n* = 2), and hepatocellular carcinoma (*n* = 2). The type of biliary anastomosis was duct-to-duct in 7 patients and HJ in seven anastomoses (1 patient had two HJ anastomoses). Table 1 presents the demographic and clinical characteristics of the study population. Stent placement occurred at a median of 8 months after LT (IQR: 5–44). The technical success rate was 100%. Figures 1–3 demonstrate representative cholangiographic images before and after MBS placement.

Pre-stent interventions included a median of one ERCP session (IQR: 0–3) and three PTBD procedures (IQR: 1–8). The median follow-up period after MBS placement was 25 months (IQR: 15–33) (Figure 4). Stricture recurrence occurred at a median of 30 months post-stenting (standard error: 3.2; 95% confidence interval: 23.6–36.3) (Figure 5). The BS patency rates were 93% at 6 months, 85% at 12 months, and 67% at 24

months. Among patients with recurrence, the shortest stent patency was 6 months, and the longest was 35 months. Three patients remained recurrence-free throughout follow-up (7, 36, and 45 months) (Figure 6, Table 2). There was a moderate positive correlation between the total number of interventional procedures prior to BS placement and stricture recurrence (Spearman's rho: 0.582, *P* = 0.023).

Table 1. Demographic characteristics and clinical information of the patients

Variables	
Age (median, IQR) (years)	35 (22–48)
Sex (male/female)	11/2
Liver transplantation indication	Hepatitis B (<i>n</i> = 6), Hepatitis C (<i>n</i> = 3), Fulminant liver failure (<i>n</i> = 2), Hepatocellular carcinoma (<i>n</i> = 2)
Type of transplant	
LDLT	12
DDLT	1
Biliary anastomosis	
DD	7
HJ	7

Continuous data are expressed as median. IQR, interquartile range; LDLT, living donor liver transplantation; DDLT, deceased donor liver transplantation, DD: duct-to-duct; HJ, hepaticojejunostomy.

Table 2. Procedural details and clinical outcomes of the patients

Variables	
Time from LT to BS (median, IQR) (months)	8 (5–44)
Number of ERCP(s) before BS (median, IQR)	1 (0–3)
Number of PTBD(s) before BS (median, IQR)	3 (1–8)
Clinical success rate (%)	
6 months	92%
12 months	85%
24 months	67%
Follow-up without recurrence after BS	3 patients (7, 36, 45 months)
Complications (<i>n</i>)	1 (cholangitis)

Continuous data are expressed as median. IQR, interquartile range; LT, liver transplantation; BS, biodegradable stent; ERCP, endoscopic retrograde cholangiopancreatography; PTBD, percutaneous transhepatic biliary drainage.

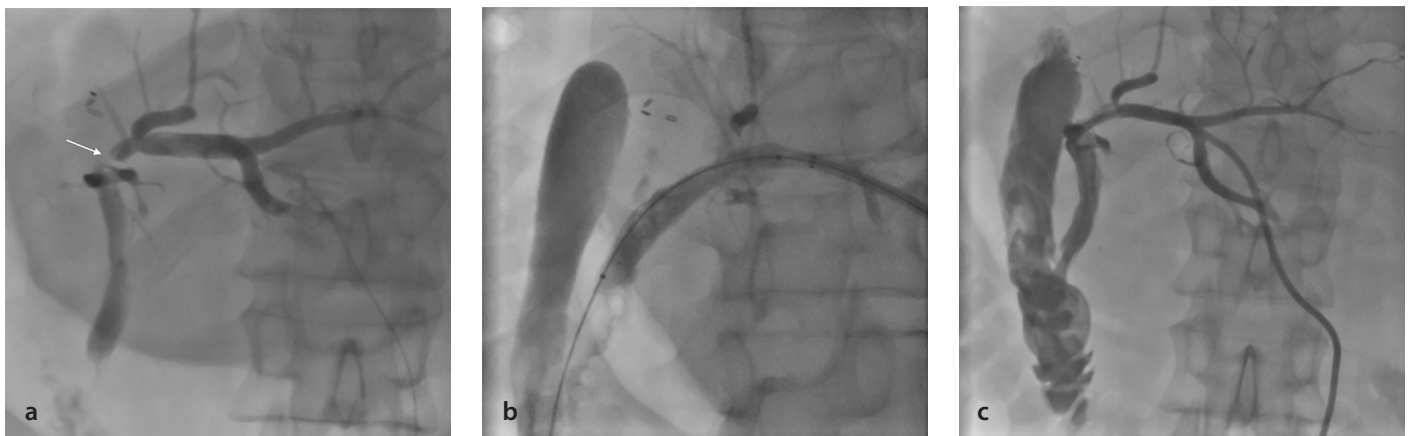


Figure 1. Cholangiogram of a left lobe recipient living donor liver transplantation patient demonstrating a significant duct-to-duct anastomosis stenosis (white arrow) (a). Implantation cholangiogram showing successful deployment of balloon-expandable biodegradable magnesium biliary stent (b). Cholangiogram after placement of an internal-external biliary drainage catheter for safety, demonstrating a reduction in the biliary dilatation (c).

Among a predefined list of potential complications (pancreatitis, bleeding, perforation, stent migration, bile duct or duodenal abrasion, misplacement, severe pain, bile occlusion, and cholangitis), only one case of cholangitis was observed. No major complications, such as stent migration, bleeding, or ductal injury, occurred.

There was a statistically significant decrease in both total bilirubin and direct bilirubin levels from the time of BS placement to 1 month post-placement ($P < 0.05$). Although alanine transaminase, aspartate transaminase, alkaline phosphatase, and gamma-glutamyl-transpeptidase levels also decreased, these changes were not statistically significant ($P > 0.05$) (Table 3).

Discussion

BS have shown promise in the treatment of benign gastrointestinal, coronary, and peripheral vascular stenoses.¹⁶ Their application in the biliary tract, however, is relatively recent. BS can be categorized into two groups: organic stents, which are made from materials such as polycaprolactone and polylactic acid, offering benefits such as biocompatibility, elasticity, and flexibility; and metallic stents, built from magnesium, iron, and zinc, providing advantages in biocompatibility and superior mechanical properties.^{13,16}

Currently, three Conformité Européenne-marked biodegradable biliary stents are commercially available: Ella (Ella-CS, Czech Republic), Archimedes (Q3 Medical, Ireland), and UNITY-B (Q3 Medical, Ireland). The Ella stent has been evaluated in several small studies for benign biliary strictures and shown to have good clinical outcomes, with low rates of epithelial proliferation and stent-related complica-

tions.¹⁹⁻²² However, evidence remains limited regarding the use of BS—particularly magnesium-based BS—in the setting of AS following LT. The mid- and long-term performance of these devices in this specific population remains underexplored.

There is currently no standardized protocol for managing AS after LT. The primary goal of treatment is to achieve long-term biliary patency while minimizing reintervention, prolonged catheterization, and the need for surgical revision.³ Although both endoscopic and percutaneous interventions are effective, multiple sessions for catheter

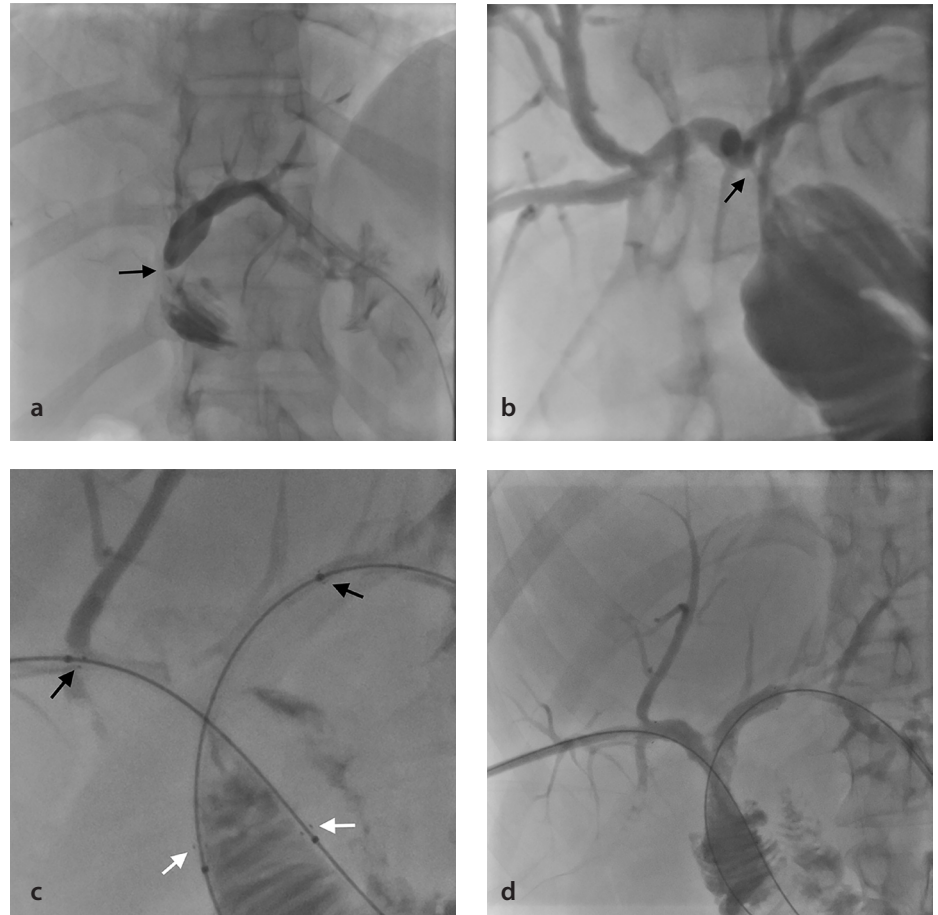


Figure 2. Cholangiograms showing significant stenoses (black arrows) in the left (a) and right (b) main hepatic duct to hepaticojejunostomy anastomosis in a cadaveric liver transplant recipient. Simultaneous implantation of two stents was performed in the patient (black arrows point to the proximal and white arrows point to the distal ends of the stents) (c). Post-implantation control cholangiogram demonstrates complete resolution of stenoses and patency of implanted stents (d).

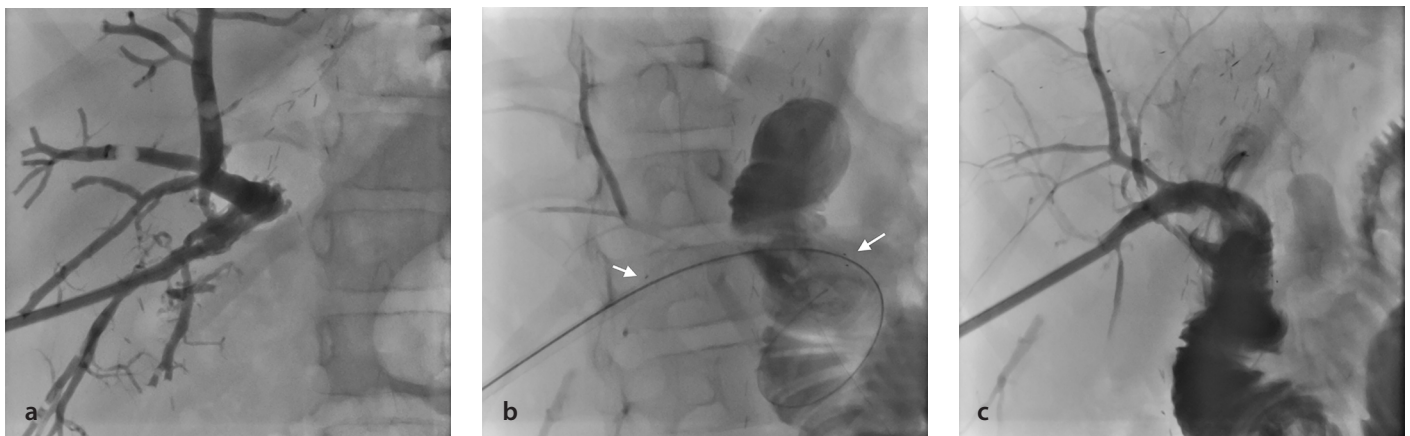


Figure 3. Cholangiogram showing marked dilatation and stenosis of hepaticojejunostomy (HJ) anastomosis in a pediatric patient who underwent a right lobe living donor liver transplantation (a). A biodegradable magnesium biliary stent (white arrows) was implanted through the HJ anastomosis (b). Post-implantation control cholangiogram showing resolution of stenosis and normal caliber of intrahepatic bile ducts (c).

exchanges, stent removals, or repeat dilations negatively affect quality of life and increase the risk of procedure-related complications.^{23,24} In this context, BS offer a significant advantage, especially in refractory cases.

Our study supports the feasibility and effectiveness of BS in this setting, with a 100% technical success rate, 85% clinical success within 1 year, and a median stent patency of 30 months. These outcomes are consistent with prior reports. For example, Dopazo et al.²⁶ reported a 40% recurrence over a median 23-month follow-up in 10 patients with LT treated with Ella stents, and Battistel et al.²⁵ reported a 72% success rate with minimal complications in 18 patients with LT with percutaneously placed BS. A large multicenter study (n = 159) demonstrated stent patency rates of 86%, 79%, and 78% at 12, 36, and 60 months, respectively, though only 4.6% of patients in that cohort had undergone LT.²⁷

Unlike previous studies, we used the UNITY-B stent, a balloon-expandable, hybrid BS consisting of a magnesium alloy core (MgNdMn21) with a polymer coating, designed for percutaneous and endoscopic implantation. The percutaneous version of the stent was used in the study. MBS degrade naturally *in vivo*, eliminating the need for retrieval and showing high biocompatibility, minimal inflammatory reaction, and low migration risk.^{13,17} They also exhibit favorable mechanical properties, including adequate radial force, thin strut profiles, and enhanced inner lumen area. Additionally, magnesium degradation products are safely excreted and may confer anti-inflammatory, antibacterial, and tissue healing properties.^{14,16} However, rapid corrosion in bile remains a significant challenge. The alkaline, enzyme-rich environment of bile accelerates magnesium degradation, potentially limiting stent durability. Advances in surface coatings and alloying elements (e.g., zinc, calcium) are necessary to enhance corrosion resistance and extend functional life in the biliary system.^{13,15,16}

Our study population was predominantly LDLT recipients (92%), a group known to have more complex biliary anatomy and stricter anastomoses than DDLT recipients. The finding in our study that there was a patient who developed AS recurrence 6 months after BS, as well as a patient who was followed up for 45 months without recurrence, supports that this situation is due to multifactorial factors, which may partially explain the reduced mid-term patency rates. The tim-

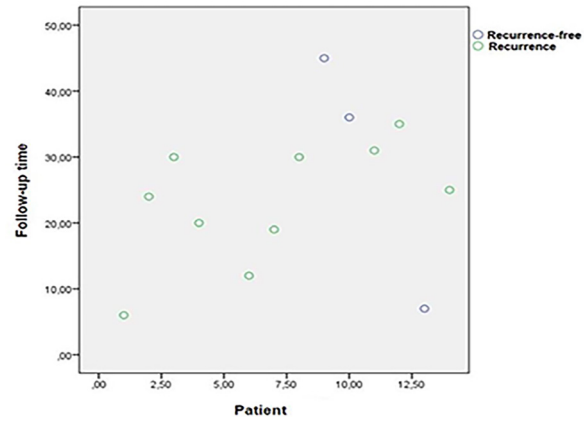


Figure 4. Scatter plot depicting individual patient follow-up time. Each data point represents a patient, categorized as either recurrence (green) or recurrence-free (blue).

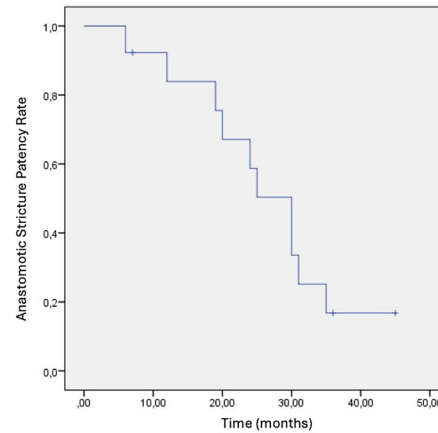


Figure 5. Graphical representation of anastomotic stricture patency rates after biodegradable stenting as estimated by Kaplan–Meier survival analysis.

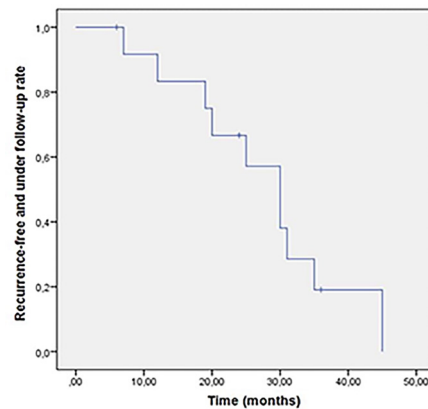


Figure 6. Graphical representation of recurrence-free and under follow-up rate after biodegradable stenting as estimated by reverse Kaplan–Meier survival analysis.

Table 3. Pre- and post-stent laboratory values of the patients

Laboratory tests	Time of BS placement	First month after BS placement	P
Total bilirubin, mg/dL	2.1 (0.8–2.3)	1.0 (0.7–1.3)	0.019
Conjugated bilirubin, $\mu\text{mol/L}$	0.7 (0.4–1.9)	0.3 (0.2–0.6)	0.034
AST, U/L	53 (38–78)	31 (24–64)	0.333
ALT, U/L	65 (45–122)	44 (29–84)	0.268
ALP, U/L	187 (131–268)	148 (111–259)	0.125
GGT, U/L	164 (96–237)	105 (42–187)	0.112

Continuous data are expressed as median interquartile range. BS, biodegradable stent; AST, aspartate transaminase; ALT, alanine transaminase; ALP, alkaline phosphatase; GGT, gamma-glutamyl-transpeptidase.

ing of BS placement also appears to influence outcomes; patients with earlier stent deployment after fewer failed interventions had longer stricture-free intervals. These findings suggest that early BS placement, rather than prolonged attempts at repeated ERCP or PTBD, may optimize clinical outcomes.

Complication rates were low and comparable with existing literature.² Only one patient developed cholangitis, and no serious adverse events, such as stent migration or bile duct perforation, were observed in the present study.

This study has several limitations. First, the small sample size limits the statistical power and generalizability of the results. In addition, variability in time from LT to BS placement and the number of prior procedures complicates analysis and underscores the need for standardized treatment pathways. Further analysis of risk factors for AS recurrence after BS placement was not possible with the available data set. As stent visibility was not the main focus of our study due to the retrospective design, we do not have precise information on stent visibility during the resorption process. In this context, future prospective studies may provide more comprehensive data to evaluate the biological lifecycle of BS. Finally, our study did not directly compare BS with other treatment strategies, such as repeat bilioplasty or surgery. Prospective, multicenter studies with larger sample sizes and longer follow-up are needed to fully establish the role of MBS in the treatment of AS after LT.

Magnesium-based biodegradable biliary stents appear to be a safe and effective treatment option for refractory AS following LT. Our findings suggest that earlier stent placement, particularly in patients with fewer prior interventions, may result in prolonged stent patency and extended stricture-free survival. Although further comparative studies are warranted, MBS may offer a promising minimally invasive alternative in the evolving management of post-transplant biliary complications.

Footnotes

Conflict of interest disclosure

Nurullah Dağ was not serving in any editorial role at the time of the manuscript's submission, evaluation, acceptance, or ahead of print publication. At the time of inclusion of the article in the regular issue, he is serving as Section Editor of the journal. Nurullah Dağ was not involved in the editorial evaluation, peer-review process, or publication decision

of this manuscript. The other authors declare no conflict of interest.

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