



The Status of SEMS Versus Plastic Stents for Benign Biliary Strictures

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Abstract

Purpose of Review Benign biliary strictures can be treated with plastic stents and self-expandable metal stents (SEMS). This review article delineates the latest scientific evidence for their usage.

Recent Findings Despite evolving literature on both type of stents as treatment modalities of benign biliary strictures, which encompass mainly anastomotic strictures and strictures related to chronic pancreatitis, no final conclusions can be drawn regarding the superiority of a particular stent. SEMS tend to have higher stricture resolution rates and fewer procedural requirements which are partly offset by higher stent migration and stricture recurrence rates compared with plastic stents.

Summary Additional studies focusing on new SEMS types with anti-migration features as well as cost-effectiveness calculations are necessary for clinical decision-making when treating patients with benign biliary strictures.

Keywords Benign biliary strictures · Review · Plastic stent · Metal stent

Benign Biliary Stricture Overview

The term benign biliary strictures (BBS) encompass a multitude of stricture etiologies. A large proportion of BBS requiring endoscopic interventions are iatrogenic, including post-orthotopic liver transplantation (OLT) anastomotic strictures and complications following cholecystectomy. BBS related to chronic pancreatitis are caused by inflamed and fibrotic parenchyma compressing the intra-pancreatic portion of the common bile duct. Less common etiologies of BBS include autoimmune conditions like primary sclerosing cholangitis (PSC), IgG4-related sclerosing cholangitis, and infectious etiologies such as AIDS cholangiopathy [1, 2].

From an endoscopic perspective, treatment algorithms for BBS focus initially on the exclusion of an underlying malignant process followed by endoscopic dilation with or without placement of biliary stents. During endoscopic retrograde cholangiography (ERC) biliary stents are placed with the goals of relieving cholestasis, assuring patency of the bile duct

and applying continuous radial force on the stricture. Historically, plastic biliary stents were the mainstream of treatment, adequate treatment often necessitating placement of multiple plastic stents during ERC. Since the introduction of self-expandable metal stents (SEMS), considerable attention has been drawn towards the utility of SEMS for treatment of BBS. Initial generations of SEMS were uncovered stents. Their utility for BBS treatment was hampered by stent in-growth from granulation tissue leading to recurrent biliary occlusion and their inability to be removed, rendering uncovered SEMS an inappropriate treatment for BBS. These stents remain suitable for palliation of unresectable hepatopancreaticobiliary malignancies. Subsequent generations of SEMS known as covered SEMS are better suited for treatment of BBS; the synthetic material bridging the interstices of the SEMS prevents tissue ingrowth and allows for their removal following stricture resolution. All SEMS discussed in this article are fully covered SEMS.

There is a relative paucity of data documenting the effectiveness of plastic stents as a treatment modality for BBS. An advantage of plastic stents is their lower cost relative to SEMS. Their main disadvantage is the need for frequent ERC given higher rates of stent occlusions, particularly with single plastic stent placement, as compared with SEMS which feature a larger stent diameter resulting in longer patency rates and consequently exert a greater radial expansion force in comparison with plastic stents. This purported advantage of

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SEMS over plastic stents is partly outweighed by the higher cost of SEMS and a reported higher migration rate [3, 4].

This review article focuses on the technical considerations for using plastic stents versus SEMS based on type of BBS, and the advances made over the last 3 years. Historical publications and landmark studies are also reviewed in order to provide a well-rounded synopsis. The main limitation of the literature is that most studies are uncontrolled and often retrospective, incurring inherent risk of bias. Further, most studies included heterogeneous patient populations with a multitude of BBS etiologies, which limits their conclusions and generalizability.

Historically, single 10 French size plastic stents were placed bridging the BBS. During subsequent ERC, BBS were slowly upsized with dilation every 3 months [5]. However, currently favored plastic stent protocols for BBS favor placement of a maximal number of plastic stents that can be accommodated across the BBS following dilation. This so-called “aggressive multiple plastic stent placement” strategy theoretically achieves a more sustained anastomotic dilation and results in long-term high stricture resolution rates [6]. Tabibian and colleagues demonstrated that successful resolution of anastomotic BBS was directly related to the number of plastic stents placed during ERC. [5, 7] Dilation protocols with SEMS for BBS are less well studied. Most authors place SEMS for 3–6 months with subsequent stent replacement until BBS resolve. Several authors suggested a longer SEMS indwelling time; however, this is limited to local expertise [Khashab, indwelling time article].

Cantu and colleagues reported the current status of the usage of plastic stents and SEMS for BBS in a nationwide Italian survey that included 19 endoscopy units. Out of a total of 7679 ERCPs performed in 2013, 560 ERCPs were performed to treat anastomotic BBS following liver transplantation. Forty-two percent of the centers used SEMS in conjunction with plastic stents whereas 58% centers utilized only plastic stents [8].

Biliary Strictures After Liver Transplantation

The majority of attention assessing the utility of plastic stents and SEMS over the last 3 years has been directed towards anastomotic strictures following liver transplantation. Liver transplantation encompasses deceased donor liver transplantation (DDLT) as well as living donor liver transplantation (LDLT). The preferred biliary anastomosis is a duct-to-duct biliary reconstruction. In comparison with DDLT, the biliary anastomosis in LDLT utilizes smaller bile ducts, has a higher surgical complexity, and is associated with a higher proportion of anastomotic strictures and bile leaks, reported to be as high as 36% and 29%, respectively. [9–15] In a direct comparison between DDLT with LDLT at a single institution, anastomotic

strictures occurred in 7.6% and 33.3%, and bile leaks in 1.7% and 13.3%, respectively. Stricture dilation as the main treatment modality for anastomotic strictures was more successful in DDLT, with a 100% clinic success rate versus 40% in LDLT. [16]

Several recent randomized controlled trials (RCT) and meta-analyses compared the treatment outcome of anastomotic BBS related to liver transplantation utilizing plastic stents and SEMS. Tal and colleagues reported a European randomized prospective multicenter trial including 48 patients with complete follow-up who were randomized to receive plastic stents versus SEMS. Treatment success, defined as stricture resolution, was reported in 95.8% in the plastic stent versus 100% in the SEMS group. SEMS were associated with a high migration rate of 33.3%, of which half occurred in resolved strictures. Fewer ERC (2 vs 4, $p < 0.001$) were necessary in the SEMS group compared with the plastic stent group to achieve stricture resolution [17]. SEMS outcomes appeared less favorable in a Brazilian study by Martins and colleagues, in which 162 patients with anastomotic BBS following liver transplantation were randomized to SEMS placement for 6 months or placement of multiple plastic stents with an exchange at every 3 months for a total of 1 year. Stricture resolution was reported in 83.3% in the SEMS versus 96.5% in the plastic stent group ($p = 0.19$) after a mean of 2 versus 4.9 ERC (no p value reported), respectively. SEMS had a higher stricture recurrence rate compared with patients receiving plastic stents (32% vs 0%) and a higher adverse event rate of 23.3% and 6.4% ($p < 0.01$), respectively, mainly acute pancreatitis. Stent migration was also more frequently reported in the SEMS group (10% versus 2.8%, no p value reported) [4]. Of interest, a recent randomized controlled multicenter study performed in eight US endoscopic referral centers assessed if SEMS placement for 6 months is non-inferior to plastic stent placement with stent exchange every 3 months. The authors included patients with BBS following liver transplantation ($n = 73$); however, patients with chronic pancreatitis ($n = 35$) and BBS following post-operative injury ($n = 4$) were also included. SEMS demonstrated higher stricture resolution rate compared with the plastic stent group (92.6% vs 85.4%, $p < 0.001$) with less ERC needed (2.14 vs 3.24; $p < 0.001$) and shorter time to stricture resolution (181 vs 225 days; $p < 0.006$). Interestingly, in contrast to the previous studies, this study did not show a significant difference in stent migration which occurred in 14 patients following SEMS (16 SEMS) and 9 patients following plastic stent (10 plastic stents) placement. A subgroup analysis controlling for the impact of the etiology of BBS on the outcomes following SEMS vs plastic stents could not be performed [18].

Cost-effectiveness analyses must account for the relatively higher costs of SEMS in addition to the fewer number of procedures needed to achieve resolution of BBS. Kaffes and colleagues reported a cost analysis of

20 patients with BBS after liver transplantation who were randomized into a SEMS versus plastic stent placement. Of note, 2 versus 4.5 ERC were performed to achieve stricture resolution in the SEMS and plastic stent groups, respectively ($p = 0.0001$). Complications occurred in 50% of the plastic stent group, mainly cholangitis, compared with 10% in the SEMS group. No stent migration was reported in either group. The authors concluded that SEMS were more cost effective than the placement of multiple plastic stents with a cost difference of 10,830 AUS\$ versus 23,580 AUS\$ ($p = 0.02$) [3]. Comparable results were reported by Martins and colleagues with a median treatment cost of 6903 USD versus 16,095 USD ($p < 0.01$), favoring SEMS placement [4].

In light of the outcomes of RCTs, several meta-analyses were performed addressing the utility of plastic stent and SEMS in BBS. An early and frequently cited meta-analysis included mainly uncontrolled retrospective and prospective studies, with their obvious inherited biases, compared multiple plastic stent placement versus SEMS for anastomotic BBS following liver transplantation and reported similar stricture resolution rates in both cohorts. Of note, SEMS migration rate was 16% [19]. A more recent meta-analysis by Landi and colleagues included three randomized control trials and one retrospective cohort which were mentioned earlier in this review [3, 17, 18, 20, 21]. Patients with anastomotic BBS (most commonly following orthotopic liver transplantation) were included; 179 were treated with plastic stents and 119 patients with SEMS placement. In the pooled data analysis, SEMS and multiple plastic stents achieved comparable rates of stricture resolution (92% vs 91%, respectively) whereas stricture recurrence occurred more often in the SEMS cohort (23% vs 0.5%) although results were non-significant. In line with prior studies, patients in the SEMS cohort required less ERC to achieve stricture resolution, with a mean difference of 1.69 ERC (ERC $p < 0.00001$) [21]. A subsequent meta-analysis by Zhang and colleagues which included six randomized control trials with mainly anastomotic BBS from liver transplantation demonstrated similar results, with SEMS being slightly more favorable in terms of stricture resolution (OR 1.05) but with a higher likelihood of stricture recurrence (OR 1.39). There was a non-significant trend towards more stent migration with SEMS (OR 1.71) [22].

In summary, current data from RCTs and meta-analyses confirm that SEMS achieve comparable or marginally better stricture resolution rates compared with the placement of multiple plastic stents for BBS. SEMS consistently required fewer ERC interventions to achieve resolution of BBS. However, one needs to account for a higher stent migration rate of SEMS, a complication that tends to be higher in anastomotic BBS than in alternate BBS etiologies. Other adverse events, mainly acute pancreatitis and cholecystitis did not differ by stent type [18].

Benign Biliary Strictures in Chronic Pancreatitis

Chronic pancreatitis can be complicated by BBS. Historically, the mainstay treatment was the placement of multiple plastic stents that were exchanged every 3 months until stricture resolution, with reported success rates averaging 65.2% [2, 23, 24]. Since the introduction of SEMS, multiple authors have addressed their utility to treat chronic pancreatitis related BBS; however, these reports commonly include heterogeneous patient populations with a variety of BBS etiologies. An early retrospective multicenter study including 133 patients with chronic pancreatitis, anastomotic strictures or gallstone-related BBS reported stricture resolution following SEMS placement in 80.7% of chronic pancreatitis cases and 91.6% of anastomotic strictures [25]. Comparable data was reported in a retrospective study of 145 patients with BBS treated with SEMS, which the authors divided into extrinsic and intrinsic stricture causes. Most extrinsic causes were due to chronic pancreatitis (97%, 73/75 patients), whereas intrinsic causes included choledocholithiasis and anastomotic strictures. Successful stricture resolution was achieved in 48 patients with chronic pancreatitis (66%) whereas the intrinsic stricture resolution rate was significantly higher (87%). The lower stricture resolution rate for extrinsic biliary compression was also demonstrated in a multivariate analysis (OR 0.115, $p = 0.004$) [26]. Similarly, the interpretation of two recent studies from five US centers and from Europe with 123 and 92 patients, respectively, who underwent treatment of BBS with SEMS, is hampered by the inclusion of several BBS etiologies, including chronic pancreatitis (24–45%) and biliary stones (30–39%). Stricture resolution rate was reported as high as 94.7% in chronic pancreatitis and 87.9% in anastomotic strictures. Reported complications included stent migration in 9.7% and 25%, respectively, as well as acute pancreatitis in 3.3%. In line with previous reports, a longer SEMS dwell time was more likely to achieve stricture resolution [27, 28]. In order to compare the utility of plastic stents with SEMS in BBS due to chronic pancreatitis, Haapamaki and colleagues performed a randomized multicenter study with 60 patients. Plastic stents were reassessed every 3 months whereas SEMS were placed for 6 months. At a 2-year follow-up, overall success rate was 88% in the plastic stent and 91% in the SEMS group. Cholangitis accounted for most adverse events in the plastic and SEMS groups, 23% and 29% ($p = 0.767$), respectively, whereas stent migration occurred only in 10% and 7% ($p = 1$), respectively [29].

Several meta-analyses address SEMS placement for BBS in chronic pancreatitis; however, these are mostly based on low-quality data. Zheng and colleagues analysis of 37 studies (total 1677 patients) included 552 patients with chronic pancreatitis and 563 patients with liver transplant-related strictures. Overall stricture resolution and recurrence rates

following SEMs placement were 83% and 11%, respectively. A subgroup analysis, of which the specifics were not delineated in detail, revealed no significant difference in stricture resolution rate when comparing chronic pancreatitis with other BBS etiologies [30]. Addressing both SEMs and plastic stents for BBS, Sikki and colleagues reported a meta-analysis of 218 patients with chronic pancreatitis, 308 liver transplant recipients, and 420 patients with other BBS etiologies. The 12-month clinical success rate in patients with chronic pancreatitis was significantly higher in patients treated with SEMs than plastic stents (77% versus 33%). A difference was not found for other BBS etiologies (87% and 85%, $p = 0.9$). Moreover, late complications including stent occlusion and stent migration occurred less frequent in patients following SEMs placement at 4.6% versus 14% ($p = 0.006$) [31]. Comparable results were reported in another meta-analysis with 1298 patients from observational and randomized control studies, including 470 patients with chronic pancreatitis, 264 liver transplantation, and 173 patients with strictures related to choledocholithiasis [32]. SEMs placement was associated with 83% stricture resolution, 85% in patients following liver transplantation, and 75% in chronic pancreatitis. Data from the included RCTs demonstrate a stricture resolution rate of 89%, with a pooled relative risk of 1.08 compared with plastic stents, but this SEMs advantage was not statistically significant ($p = 0.79$). The total number of ERC to achieve stricture resolution favored the SEMs cohort with a pooled difference in the mean number of ERC of 1.71 ($p = 0.05$), but stratification according to BBS etiology was not reported [32].

In summary, SEMs placement is feasible in BBS related to chronic pancreatitis. The clinical outcomes are less successful compared with those reported for SEMs in anastomotic strictures following liver transplantation. This is likely related to the fact that BBS in chronic pancreatitis tend to be longer and more complex than BBS seen in anastomotic strictures. On a positive note, these features might explain why SEMs tend to have a lower migration rate in chronic pancreatitis (reported to be as low as 4.6%) than in BBS related to anastomotic strictures. It remains unclear whether SEMs can decrease the number of ERC required to achieve stricture resolution in BBS related to chronic pancreatitis and whether SEMs are cost effective in this setting.

Primary Sclerosing Cholangitis

Primary sclerosing cholangitis (PSC) is associated with chronic intra- and extra-hepatic biliary strictures. Particular attention is drawn to so-called dominant strictures which are defined as strictures with a diameter of less than 1.5 mm in the common bile duct or less than 1 mm in the hepatic ducts. These strictures are common in PSC and have a high risk for harboring malignancy. Following sampling and exclusion of

malignancy, dominant strictures were historically treated with biliary dilation with or without biliary plastic stent placement, although earlier studies suggesting that patients do worse with plastic stents after dilation. In a recent landmark study by Ponsioen and colleagues, patients with dominant strictures were randomized to ERC with balloon dilation alone or dilation plus plastic stent placement. The dilation group had significantly fewer complications than patients undergoing balloon dilation and plastic stent placement, with reported severe events in 6.7% versus 45%, respectively ($p = 0.001$) [33]. As such, plastic stents are not favored in patients with PSC-related dominant strictures. Extrapolating these results, one might expect that these patients are unlikely to derive benefit from SEMs placement as well, though there is a paucity of data to assess SEMs in PSC patients.

Treatment of Biliary Strictures—Recent Innovations

According to the studies reviewed above, SEMs have a comparable or higher stricture resolution rate for BBS and may require fewer ERC procedures in comparison with plastic stents. Higher stent migration rates remain a significant drawback of SEMs, however, particularly in patients with anastomotic strictures following liver transplantation. Decreasing the rate of SEMs migration and optimizing stent dwell time has inspired several innovations in SEMs technology. This is particularly important, as longer SEMs dwell time was associated with a lower stricture recurrence rate when comparing stent placement for 6 months compared with 3 months [27, 34]. Extrapolated from esophageal SEMs, biliary SEMs with anti-migration anchoring fins and flaps [35, 36] (e.g., GORE VIABIL Biliary Endoprosthesis, Gore, USA) and different shapes, including cone shaped (e.g., Leufen Medical, Berlin, Germany) and double cone shaped stents, have been proposed to decrease SEMs migration rate [37]. New stent innovations allow intraductal placement without bridging the ampulla and creation of bilio-enteric anastomosis (e.g., KAFFESS Biliary stent, Niti-S SEMs, Taewoong Medical, S Korea). The rationale for intraductal SEMs placement is based on decreased biliary reflux of duodenal contents which might promote infection and SEMs occlusion, and possibly a lower risk of migration [38].

Aeppli and colleagues reported 29 patients with BBS following liver transplantation who were treated with intraductal SEMs placement. The SEMs used in this study had an attached string to facilitate the stent removal. Reported stricture resolution was 100%, with stricture recurrence in 24%. Of interest, only 1 out of 36 stents migrated [39]. No significant difference was reported in another study by Wu and colleagues when comparing intraductal SEMs with plastic stents in 69 patients with BBS (following orthotopic liver

transplantation in the majority). Stricture resolution rate was achieved in 84.4% and 83.8% ($p = 0.947$), respectively, however with less ERC required in the SEMS cohort. Only one case of SEMS migration was reported [40].

In terms of innovations in the shape of SEMS, Walter and colleagues reported a multicenter prospective cohort study utilizing SEMS with flared ends and a highly conformable middle stent segment (Niti-S biliary bumpy stent, Taewoong Medical, South Korea) placed for 3 months in 38 patients with mostly chronic pancreatitis and postsurgical strictures. Stricture resolution was achieved in 80% of patients but decreased to 63% during follow-up at a median of 265 days following stent removal. Despite the anti-migration features, stent migration occurred in 11 of 35 (31%) of patients [41]. Weigt and colleagues reported the outcome of a double-coned SEMS (Leufen Medical, Berlin, Germany) placed in 11 patients with BBS mainly due to chronic pancreatitis. Strictures resolved in all patients and no stent migration following a mean stent treatment of 170 days was reported [37•].

Another known method to decrease stent migration for BBS was reported by Parlak and colleagues in patients with anastomotic BBS following living donor liver transplantation. In addition to SEMS deployment, plastic pigtail stents were inserted into secondary bile duct branches with the rationale that this might decrease stent migration and avoid obstruction of small bile duct branches by the SEMS. This resulted in a stricture resolution rate of 17/19 patients (89.5%) and a stricture recurrence in 3 patients (17.6%), without reported SEMS migrations [42].

Biodegradable stents have the advantage that stent removal becomes obviated by spontaneous stent disintegration. They have been introduced as a potential treatment modality for BBS. Case reports suggest feasibility and successful stricture resolution; however, no recent case series exist to document the outcome of biodegradable stents for the treatment of established BBS [31]. Janousek and colleagues reported a small randomized trial in which biodegradable stents were placed intraoperatively across the duct-to-duct biliary anastomosis during liver transplantation, in an effort to prevent formation of anastomotic strictures. The treatment arm had no reported strictures or leaks following liver transplantation, with complete stent absorption and no stent related adverse effects [43]. These results require further exploration, as a prior study utilizing intraoperative plastic stents for bridging the duct-to-duct anastomosis reported a higher odds ratio (74%) of requiring post-operative ERC for biliary complications [44]. Another RCT comparing intraductal stenting versus no stenting in patients undergoing living donor liver transplantation found higher rates of bile leak (35.5% vs 12.1%, $p = 0.034$) and need for biliary procedures (OR 5.27) in patients with intraoperative anastomotic stent compared with no stent [45].

Another important concern related to SEMS for BBS is infection, which warrants ERC with stent exchange. In general, the risk of cholangitis related to biliary stent placement increases with longer stent dwell times. To decrease the risk of biliary infection after SEMS placement, silver nanoparticle-coated biliary SEMS that have antibacterial properties have been developed. Such SEMS have not been clinically applied yet; however, they might find their niche particularly for small diameter stents which have a higher risk of stent occlusion [46].

Tissue ingrowth or hyperplasia, a problem inherent to uncovered biliary SEMS, can also be seen in fully covered SEMS as well. Tringali and colleagues reported their experience with five patients who developed tissue ingrowth which hampered stent removal. In each case, another SEMS was placed into the previously placed SEMS for 2 weeks, facilitating stent removal in all five patients [47]. Generally, most current protocols for treating BBS with SEMS utilize dwell times of 3–6 months. Some studies show that SEMS can be left in place longer, but long SEMS dwell times are associated with greater risk of stent occlusion and migration [48]. The optimal timing for SEMS placement remains currently unclear.

Summary

Considering the evolving body of literature comparing plastic stents versus SEMS for treatment of BBS, no final conclusions can be drawn regarding the absolute superiority of one approach over the other. Both techniques have relatively comparable stricture resolution rates, although SEMS tend to have higher resolution rates and fewer procedural requirements when used for anastomotic strictures. These advantages are offset by higher stent migration and stricture recurrence rates following SEMS placement in this setting. The optimal timing of SEMS replacement and the role of unique mechanical SEMS specifications (different shapes, incorporation of anti-migration features, and so forth) remain unknown. There is conceptual rationale for longer SEMS dwell time, larger SEMS diameters, and incorporation of anti-migration properties when treating BBS, but the rate of complications (cholangitis, cholecystitis, and pancreatitis) might eclipse the potential benefits of using SEMS. Placement of a multiple stent plastic stents in BBS remains a viable (and common) strategy for treating BBS, but is limited by more frequent ERC procedures for stent replacement (performed every 3 months in many centers). Additional studies regarding the cost-effectiveness of the two strategies (multiple plastic stents versus SEMS) for each unique type of BBS (chronic pancreatitis, anastomotic, other) would also positively influence clinical decision-making when selecting an approach for treating patients with BBS.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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