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Application of Fully Covered Self-Expandable Metallic Stents with and without Antimigration Waist Versus Repeated Plastic Biliary Stent Placement in Management of Anastomotic Biliary Strictures After Orthotopic Liver Transplantation

Authors' Contribution:
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Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Bakground: Standard methods for endoscopic retrograde cholangiopancreatography (ERCP) management of anastomotic strictures (AS) after OLT includes repeated balloon dilation of the stricture with subsequent insertion of a plastic biliary stent (PBS). In post-OLT patients not responding to standard endoscopic treatment, the placement of fully covered self-expanding metal stents (FCSEMS) is a valid alternative to surgical treatment. The aim of this study was to compare the results of new FCSEMS implantation with the standard ERCP stricture management protocol and with conventional FCSEMS insertion.

Material/Methods: This retrospective study involved 39 post-OLT patients with confirmed diagnosis of biliary AS. Enrolled subjects were divided into 2 groups: the FCSEMS group (study group) and the PBS group (control group). The study group was divided into 2 subgroups: the conventional FCSEMS group and the new-type FCSEMS group.

Results: Stricture recurrence after PBS placement was observed in 36.36% of controls and in only 9.52% of study group members (P=0.170). Recurrence rates in patients after conventional FCSEMS and new type FCSEMS implantation was similar (10% *vs.* 9.09%; P=0.501). The applied treatment was successful in 82.61% of study group members and only 43.75% of controls (P=0.029). Success rates of conventional FCSEMS and new-type SEMS insertion did not differ significantly (81.82% *vs.* 83.33%, P=0.649). There was no statistically significant difference in complication rates between groups (P=0.879).

Conclusions: Implantation of FCSEMS is more effective than repeated balloon dilatation of AS with subsequent PBS placement and is they have similar complication rates. Application of new-type FCSEMS gives results comparable to conventional FCSEMS.

MeSH Keywords: **Cholangiopancreatography, Endoscopic Retrograde • Cholestasis • Liver Transplantation**

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Background

Since Starzl et al. first performed a liver transplantation in 1963 [1], the incidence of biliary complications has been reduced significantly due to improvements in organ selection, retrieval, preservation, and standardization of biliary reconstruction methods [2].

Despite advances in the field of organ transplantation, biliary complications remain a common source of morbidity and mortality in patients after orthotopic liver transplantation (OLT). Among complications of the biliary tract, biliary leaks and strictures are considered the most common. The reported incidence of biliary strictures after cadaveric donor OLT varies from 5% to 15% [3]. Fibrotic healing, local ischemia, and surgical complications are believed to play a role in the pathogenesis of biliary strictures [4]. Post-transplant biliary strictures are classified into 2 major categories: anastomotic strictures (AS) and non-anastomotic strictures (NAS). Among liver transplant recipients, AS are observed more frequently; the incidence of AS in OLT recipients within 1 year of surgery varies from 5% to 10% [5].

Traditionally, surgical repair has been the standard of care for treating biliary strictures in post-OLT patients. Due to advances in endoscopy, the non-operative management of biliary strictures has become standard practice, obviating the need for surgery in most patients [3,5].

Compared with NAS, AS are relatively short in length and are usually isolated; hence, endoscopic treatment success rates are higher for AS [5]. Success rates up to approximately 80% are reported for endoscopic intervention in the treatment of AS for deceased donor OLT [6,7].

Standard methods for endoscopic retrograde cholangiopancreatography (ERCP) management of AS include repeated balloon dilation of the stricture with subsequent insertion of a plastic biliary stent (PBS) 3 months later [4,5]. Recent studies show that in post-OLT patients not responding to standard endoscopic treatment, the placement of self-expanding metal stents (SEMS) is a valid alternative to surgical treatment [8,9]. Moreover, implantation of partially covered stents or fully covered self-expanding metal stents (FCSEMS) as a first approach in the management of benign biliary strictures including AS was found to be related to good stricture resolution rates [4,10]. However, stent migration after FCSEMS implantation occurs in some patients [11–13] Hence, Kaffes et al., in conjunction with Taewoong Medical, introduced a new FCSEMS that is short and has a long removal string and a central antimigration waist [4,14]. A prospective, randomized, multicenter study of a newly designed FCSEMS *vs.* PBS in anastomotic biliary strictures after OLT showed promising results [4].

The aim of the present study was to compare the results of the new FCSEMS implantation with the standard ERCP stricture management protocol and with conventional FCSEMS insertion.

Material and Methods

The study involved 39 post-OLT patients with confirmed diagnosis of biliary AS who received endoscopic management between January 2010 and January 2017 at the Provincial Hospital in Szczecin, Poland. The inclusion criteria were: a newly detected biliary AS after OLT, age ≥18 years, and FCSEMS insertion or balloon dilatation with subsequent PBS placement in endoscopic management of AS. The exclusion criteria were: isolated bile leak without AS, NAS, hilum involvement, intrahepatic strictures, hepatic artery thrombosis, and balloon dilatation without subsequent PBS placement. All data were collected retrospectively.

Enrolled subjects were divided into 2 groups: the FCSEMS group (study group) and the PBS group (control group). The study group was divided into 2 subgroups: conventional FCSEMS group and new-type FCSEMS group.

All ERCP procedures were performed by the same experienced endoscopist using an Olympus duodenoscope model EVIS EXERA II TJF-Q180V (Olympus Co., Tokyo, Japan). Procedures were performed under propofol sedation in the semiprone position.

In the PBS group, patients underwent balloon dilatation of the stricture followed by PBS placement. After selective biliary cannulation (SBC) using sphincterotome rather than cannula, a biliary balloon dilatator was introduced over a guidewire. All dilatations were performed with the Maxpass Biliary Balloon Dilator B-400N-0640 (Olympus Co., Tokyo, Japan). Subsequently, PBS was inserted, preferably a 10 Fr calibre Advanix™ Biliary Stent or Flexima™ Biliary Stent (Boston Scientific Corporation, Natick, MA, USA). After 3 months, ERCP was repeated, the stent was removed, and the stricture was assessed again. If the stricture persisted, the whole procedure was repeated; otherwise, the patient was placed on clinical follow-up.

In the FCSEMS group, once SBC was achieved, a guide wire was inserted across the stricture. Then, the SEMS was placed into position and deployed. At approximately 6 months after first ERCP, the stent was removed to assess the stricture. If the stricture had resolved, the patient was placed on clinical follow-up. If the stricture did not resolve, further stenting was performed, in some cases with additional balloon dilatation.

In the new-type FCSEMS subgroup, stenting was performed using the KAFFES™ Biliary Stent (Taewoong Medical, Seoul, Korea), which was designed to treat AS after liver transplantation.

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Table 1. Demographic characteristics of study group and control group.

<table>
<tr><th rowspan="2"></th><th colspan="2">SEMS</th><th rowspan="2">PBS</th><th rowspan="2">P</th></tr>
<tr><th>Conventional SEMS</th><th>New type FCSEMS</th></tr>
<tr><td rowspan="2">Number of patients (n)</td><td>11</td><td>12</td><td rowspan="2">16</td><td rowspan="2">–</td></tr>
<tr><td colspan="2">23</td></tr>
<tr><td rowspan="2">Men (n%)</td><td>10 (90.91)</td><td>8 (66.67)</td><td rowspan="2">13 (81.25)</td><td rowspan="4">0.860</td></tr>
<tr><td colspan="2">18 (78.26)</td></tr>
<tr><td rowspan="2">Women (n%)</td><td>1 (9.09)</td><td>4 (33.33)</td><td rowspan="2">3 (18.75)</td></tr>
<tr><td colspan="2">5 (21.74)</td></tr>
<tr><td rowspan="2">Mean age ±SD (years)</td><td>51.36±15.14</td><td>50.17±13.46</td><td rowspan="2">49.69±13.74</td><td rowspan="2">0.921</td></tr>
<tr><td colspan="2">50.74±13.97</td></tr>
<tr><td rowspan="2">Age range (years)</td><td>22–64</td><td>24–66</td><td rowspan="2">24–63</td><td rowspan="2">–</td></tr>
<tr><td colspan="2">22–66</td></tr>
<tr><td rowspan="2">Time of stricture presentation after transplant (median in months)</td><td>1.3</td><td>2.6</td><td rowspan="2">1.4</td><td rowspan="2">0.853</td></tr>
<tr><td colspan="2">2</td></tr>
<tr><td rowspan="2">Time of stricture presentation after transplant (range)</td><td>14 days to 6 months</td><td>13 days to 13 months</td><td rowspan="2">13 days to 22 months</td><td rowspan="2">–</td></tr>
<tr><td colspan="2">13 days to 13 months</td></tr>
</table>

Made from Nitinol with polytetrafluoroethylene covering, the KAFFES™ Biliary Stent has 3 radio-opaque markers with a diameter of 10 mm at either end, a gradual narrowing into the center to 8 mm diameter marked with middle radio-opaque marker, and a long 10-cm removal string. Implantation of this stent is similar to other SEMS, but positioning of the middle marker adjacent to the stricture is required before stent deployment. In the new-type FCSEMS group, stents were removed at approximately 6 months after implantation and the stricture was assessed. If the stricture had resolved, the patient was placed on clinical follow-up and no further stenting was performed. The same protocol was applied in the conventional FCSEMS group. However, in the conventional FCSEMS group, WallFlex™ Biliary RX Stents (Boston Scientific Corporation, Natick, MA, USA), BUMPY™ Biliary Stent (Taewoong Medical, Seoul, Korea), and X-Suit NIR™ biliary metallic stents (Olympus Co., Tokyo, Japan) were used.

Statistical analysis was performed using the χ^2 Pearson's test, Student's t-test, and Mann-Whitney test. A P value of less than 0.050 was considered significant.

Results

A total of 39 patients with AS after OLT were included in this study. A total of 23 subjects were assigned to the study group, which was divided into 2 subgroups: conventional FCSEMS group and new-type FCSEMS group, which consisted of 11 and 12 patients, respectively. The control group comprised 16 patients.

No significant differences in demographic characteristics were found between the groups. The data on demographic characteristics of all subjects are outlined in Table 1. No significant difference in indication for orthotopic liver transplant was observed between groups, as shown in Table 2.

The stricture resolution rate was 91.30% in the study group and 68.75% in the controls, but the difference was not statistically significant (P=0.167). In patients in whom conventional FCSEMS was inserted and in subjects treated with new-type FCSEMS AS resolution rate was similar, at 90.91% *vs.* 91.67%, respectively (P=0.499) (Table 3). Control group members in whom stricture resolution was not achieved despite repeated balloon dilatation followed by PBS insertion were treated surgically (1 hepaticojejunostomy and 1 retransplantation) or with FCSEMS implantation (2 patients). One control died before further treatment was applied. Study group patients not responding to endoscopic management were referred for surgical treatment (1 hepaticojejunostomy and 1 retransplantation).

Stricture recurrence after PBS placement was observed in 36.36% of control subjects. In the study group, AS reoccurred only in 9.52% of subjects; however, the difference did not reach statistical significance (P=0.170). Recurrence rates in patients after conventional FCSEMS and new-type FCSEMS implantation were similar (conventional FCSEMS subgroup 10% *vs.*

Table 2. Indications for liver transplant in both groups.

<table>
<tr><th rowspan="2"></th><th colspan="2">SEMS</th><th rowspan="2">PBS</th><th rowspan="2">P</th></tr>
<tr><th>Conventional SEMS</th><th>New-type FCSEMS</th></tr>
<tr><td rowspan="2">Alcoholic liver cirrhosis n (%)</td><td>1 (9.09)</td><td>1 (8.33)</td><td rowspan="2">2 (12.5)</td><td rowspan="2">0.879</td></tr>
<tr><td colspan="2">2 (8.7)</td></tr>
<tr><td rowspan="2">Hepatitis C n (%)</td><td>4 (36.36)</td><td>3 (25)</td><td rowspan="2">6 (37.5)</td><td rowspan="2">0.909</td></tr>
<tr><td colspan="2">7 (30.43)</td></tr>
<tr><td rowspan="2">Hepatocellular carcinoma n (%)</td><td>3 (27.27)</td><td>4 (33.33)</td><td rowspan="2">4 (25)</td><td rowspan="2">0.999</td></tr>
<tr><td colspan="2">7 (30.43)</td></tr>
<tr><td rowspan="2">Wilsons disease n (%)</td><td>1 (9.09)</td><td>0 (0)</td><td rowspan="2">0 (0)</td><td rowspan="2">–</td></tr>
<tr><td colspan="2">1 (4.35)</td></tr>
<tr><td rowspan="2">Drug-induced acute liver failure n (%)</td><td>0 (0)</td><td>1 (8.33)</td><td rowspan="2">2 (12.5)</td><td rowspan="2">0.742</td></tr>
<tr><td colspan="2">1 (4.35)</td></tr>
<tr><td rowspan="2">Hepatitis B n (%)</td><td>0 (0)</td><td>1 (8.33)</td><td rowspan="2">0 (0)</td><td rowspan="2">–</td></tr>
<tr><td colspan="2">1 (4.35)</td></tr>
<tr><td rowspan="2">Cryptogenic n (%)</td><td>2 (18.18)</td><td>2 (16.67)</td><td rowspan="2">2 (12.5)</td><td rowspan="2">0.975</td></tr>
<tr><td colspan="2">4 (17.39)</td></tr>
</table>

Table 3. Results of endoscopic treatment in both groups.

<table>
<tr><th rowspan="2"></th><th colspan="3">SEMS</th><th rowspan="2">PBS</th><th rowspan="2">P</th></tr>
<tr><th>Conventional SEMS</th><th>New type FCSEMS</th><th>P</th></tr>
<tr><td rowspan="2">Anastomotic stricture resolution n(%)</td><td>10/11 (90.91)</td><td>11/12 (91.67)</td><td>0.499</td><td rowspan="2">11/16 (68.75)</td><td rowspan="2">0.167</td></tr>
<tr><td colspan="3">21/23 (91.30)</td></tr>
<tr><td rowspan="2">Recurrence n(%)</td><td>1/10 (10)</td><td>1/11 (9.09)</td><td>0.501</td><td rowspan="2">4/11 (36.36)</td><td rowspan="2">0.170</td></tr>
<tr><td colspan="3">2/21 (9.52)</td></tr>
<tr><td rowspan="2">Successful treatment n(%)</td><td>9/11 (81.82)</td><td>10/12 (83.33)</td><td>0.649</td><td rowspan="2">7/16 (43.75)</td><td rowspan="2">0.029</td></tr>
<tr><td colspan="3">19/23 (82.61)</td></tr>
<tr><td rowspan="2">Complications n</td><td>1 (1 cholangitis)</td><td>1 (1 cholangitis)</td><td>0.499</td><td rowspan="2">2 (1 cholangitis, 1 haemobilia)</td><td rowspan="2">0.879</td></tr>
<tr><td colspan="3">2</td></tr>
</table>

new-type FCSEMS subgroup 9.09%; P=0.501); 1 patient was treated with liver retransplantation, and 1 underwent FCSEMS reinsertion (new-type FCSEMS placement in a conventional FCSEMS subgroup patient). In 2 control subjects, hepaticojejunostomy was performed after AS recurrence and the others (2 subjects) were managed endoscopically with new-type FCSEMS insertion (Table 3).

The overall success rate was significantly higher in the study group (percentage of patients in whom stricture resolution was achieved and no recurrence observed). The treatment was successful in 82.61% of study group subjects and in only 43.75% of controls (P=0.029). Success rates of conventional FCSEMS and new-type SEMS insertion did not differ significantly (81.82% *vs.* 83.33%, P=0.649) (Table 3).

There was no statistically significant difference in complication rates between groups (P=0.879). Post-ERCP cholangitis was observed in 3 cases, 1 after PBS placement and 2 after FCSEMS insertion. In 1 control subject, hemobilia was observed after the procedure. All complications were treated conservatively (Table 3).

Discussion

Currently, ERCP is the treatment of choice in the management of postoperative AS after OLT. Despite necessity of repeating the procedure, AS dilatation followed by PBS placement is considered standard in post-OLT patients [4]. However, reports on FCSEMS are rising and the relevance of FCSEMS insertion in AS management is growing [4,8,9,12–14]. Compared with balloon dilatation with subsequent PBS placement, FCSEMS implantation is associated with similar or higher resolution rates, often over 80% [4,7,8,12]. However, SEMS application is related to some specific complications, including stent migration, secondary stricturing, and stent impaction. Hence, many attempts were made to improve and adjust FCSEMS to anastomotic biliary strictures management [4,12,14]. The newly designed removable FCSEMS presented by Kaffes et al. has an antimigration mid-waist, a short stent length, and a long removal string, that allows the entire stent to be placed completely inside the duct [4].

While failure to remove the biliary stent and secondary strictures are considered uncommon, stent migration occurs in 0–41% of cases treated with FCSEMS [4,12]. In a randomized trial of new-type FCSEMS *vs.* PBS in the treatment of AS, Kaffes et al. did not observe any cases of stent migration [4]. In the present study, stent migration also did not occur in patients in whom new-type FCSEMS was inserted. Moreover, there were no stent migration episodes after endoscopic management with conventional FCSEMS.

The reported stricture resolution rate after repeated balloon dilatation with PBS placement varies from 63% [15,16] to 100% [17]. According to a review conducted by Lee et al., average AS resolution rate after PBS insertion was 87.2%, which is significantly higher than resolution rates reported after FCSEMS implantation (87.2 *vs.* 61.8%; P=0.003) [5]. The range of AS resolution rates in post-OLT patients treated with FCSEMS observed recently was 53% [18] to 81% [8]. However, resolution rates reported by Kaffes et al. after treatment with new-type FCSEMS was 100%.

Stricture resolution rates observed in this study are lower than results reported by Kaffes et al. In the quoted paper, the resolution rate in the study group compared to controls was approximately 10% higher (100% *vs.* 91.30% and 80% *vs.* 68.75%, respectively). In the study conducted by Kaffes et al., there was no significant difference in stricture resolution rates between PBS insertion and new-type FCSEMS treatment. In our study, resolution of AS was observed in 91.30% of the study group patients and in only 68.75% of controls; however, the difference was not statistically significant (P=0.167). However, the quoted study assessed only the cases treated with balloon dilatation of AS with PBS insertion and patients in whom new-type FCSEMS was applied [4]. There was no difference in stricture resolution rates between new-type FCSEMS and conventional FCSEMS in our study (91.67% *vs.* 90.91%). The stricture resolution rates after new-type FCSEMS and conventional FCSEMS insertion were similar to the results of previously conducted studies on FCSEMS use in benign biliary strictures (resolution of the stricture in approximately 90% of cases) [9,12].

According to Lee et al., AS reoccurs in 0% [17] to 37% [16] subjects treated with multiple PBS placement [5]. The recurrence rate after FCSEMS placement ranges from 7% [8] to 25% [18]. However, the average stricture recurrence rates in patients treated with PBS and FCSEMS are not significantly different (13.3% and 14.5%, respectively; P=0.8) [5].

Compared with the outcomes of the randomized trial of new-type FCSEMS versus PBS in post-OLT anastomotic biliary strictures, the AS recurrence rate in our study was similar in controls (30% and 36.36%, respectively). The authors of the quoted paper did not observe any AS recurrence after new type FCSEMS implantation; however, the discrepancy in recurrence rate between PBS and FCSEMS placement was not significant [4]. In the presented study, stricture recurred in 1 patient after KAFFES™ FCSEMS implantation and after 1 conventional SEMS insertion (9.09% *vs.* 10%); there was no difference in AS recurrence rate between the PBS group and FCSEMS group.

Despite small the sample size, the statistical analysis revealed a statistically significant difference in overall success rates between groups (82.61% in FCSEMS group, 43.75% in PBS group; P=0.03). Similar results with FCSEMS implantation in post-OLT patients were reported by Traina et al. (success rate 81.25%), who assessed efficacy and safety of FCSEMS in biliary complications after OLT, but they also included patients with bile leaks [8].

The difference in success rates between patients treated with FCSEMS and PBS observed in our study was greater than in outcomes reported by Kaffes et al., who found the overall success rate of applied treatment in the study group (FCSEMS) was 70% and 50% in controls (PBS), but the difference was not statistically significant (P=0.18) [4].

Higher success rates of standard treatment in comparison to our results were observed also in previous studies. The total success rate of applied endoscopic treatment reported by Shah was 62% after cadaveric OLT [19].

Post-ERCP complications in AS treatment include cholangitis, pancreatitis, bleeding, pain, and stent migration [5]. The reported occurrence of complications after multiple balloon dilatation with subsequent PBS placement in patients with post-OLT anastomotic strictures ranges from 1.5% [20] to as high

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as 67% [21]. In most papers, the observed complication incidence after PBS placement is below 20% [5]. In patients treated with FCSEMS, insertion complications occur in 26% [21] to 46% [18] of patients; however, cases of stent migration considerably contribute to the high incidence of complications in these subjects.

Complication rates reported by Kaffes et al. were 50% in the PBS group (40% cholangitis, 10% pain) and 10% (cholangitis) in patients treated with new-type of FCSEMS. However, the difference in complication rates was not statistically significant [4].

In our study, complications occurred less frequently in subjects treated with multiple PBS implantation compared with the study conducted by Kaffes et al. (12.5%; 6.25% cholangitis, 6.25% bleeding). In the FCSEMS group in the present study, the incidence of complications was similar to outcomes reported by the quoted authors (8.7%). However, discrepancies in complication incidence may be due to the retrospective character of this study; cholangitis not requiring hospital admission may be overlooked.

Conclusions

In comparison to standard endoscopic management of post-OLT anastomotic strictures, FCSEMS implantation is more effective than repeated balloon dilatation of AS with subsequent PBS placement and has a similar complication rate. Application of new-type FCSEMS gives results comparable to conventional FCSEMS. However, further prospective studies are required to confirm outcomes of this study due to its small sample size and retrospective character of the study.

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