Comparison of outcomes of endovascular treatment with stent placement in patients with early and late hepatic venous outflow obstruction (HVOO)

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Purpose

To retrospectively evaluate the long term results of stent placement in patients with early and late hepatic venous outflow obstruction (HVOO) after orthotopic liver transplantation (OLT).
Methods and Materials

1. Characteristics of the patient population
From January 1996 to February 2011, 16 patients with HVOO after OLT treated with self-expandable stents were retrospectively recruited. Informed consent for all the procedures performed was obtained, as well as the approval of the institutional review board.

The study group included 12 male and 4 female patients (mean age: 53.2 years, CI 95%: 31 to 65 years) who had undergone orthotopic cadaveric whole-liver transplantation. Pre-transplantation liver diseases included alcoholic cirrhosis (n=7), HCV cirrhosis (n=3), mixed cirrhosis (n=1), other causes (n=5).

2. Classification of HVOO
In 8 of 16 cases (50%) the obstruction was detected in the early postoperative period (in the first 30 days after surgery). This timing suggests an etiology of the obstruction related to technical factors such as torsion, kinking or compression.

In the other 8 of 16 cases (50%), the obstruction manifested in the late postoperative period (ranging from 1 month to 4 years after transplantation surgery). Intimal hyperplasia and fibrosis must be considered when assessing the etiology in this second group of patients.

Classification of HVOO is represented in Table 1 on page 6

3. Initial diagnosis of hepatic venous outflow obstruction
The diagnosis of HVOO was initially based on clinical and laboratory data, followed by imaging tests for characterization such as Doppler ultrasonography (US) and/or computed tomography (CT).

Clinical and laboratory manifestations assessed included abdominal pain, weight gain, ascites, lower-extremity edema, pleural effusion, hepato-splenomegaly and laboratory abnormalities indicative of hepatic dysfunction.

Doppler US examination was performed in all patients, using B-mode and color/pulsed Doppler imaging (Antares/Acuson S2000; Siemens Healthcare, Erlangen, Germany). CT examination was performed in 4 of the 16 patients (25%) in order to morphologically characterize the surgical connection and accurately locate the stenosis. Biphasic contrast material-enhanced CT examinations were performed with a standard liver protocol and 16/64 row multidetector computed tomography (MDCT; Somatom Sensation & Definition/Axiom; Siemens Healthcare, Erlangen, Germany). No complications related to iodinated contrast infusion were registered.

Most frequent findings of initial diagnosis are summarized in Table 2 on page 6.
4. Venographic and manometric study
After the initial diagnosis and characterization of HVOO, all 16 patients underwent a venographic and manometric study. The objectives of these tests were to confirm and accurately locate the site of obstruction and quantify the pressure gradients between the "wedged" and the "free" portal vein gradient as well as between the hepatic veins and the right atrium. These examinations revealed a pressure gradient >3 mm Hg in all the 16 cases and stenosis of the surgical connection in 11 cases. In 5 cases only indirect findings of stenosis were found.

The findings of the venographic and manometric studies are summarized in Table 3 on page 7.

5. Stent placement (Fig. 2 on page 8 Fig. 3 on page 9)
The stent placement was performed as primary treatment in 14 patients and as secondary treatment (after balloon angioplasty) in 2. All procedures were performed under general anesthesia (n=15) or under deep sedation (n=1).

For the selective catheterization of hepatic veins, a transhepatic approach (under ultrasound guidance) was chosen in 15 patients (93.75%) and a transfemoral approach with catheterization of 1 hepatic vein was preferred in 1 patient (6.25%). The number of catheterized hepatic veins ranged from 1 to 3 (mean 2). In all cases, either from the transjugular or transfemoral approach, a guidewire was placed transversing the affected IVC. Hepatic veins were punctured with a 21-gauge needle and a 0.035´´ guide wire (Terumo, Tokyo, Japan) was placed by using an Accustick II (Boston Scientific, Spencer, Indiana). A 4-7 F introducer (Cordis, Miami, FL,) sheath was then placed within the lumen of each hepatic vein. Each stenosis was then crossed from a transhepatic approach and guidewires were placed with their distal tip within the superior vena cava. Self expandable stents (Wallstent, Boston Scientific, Natick, MA) were deployed across the stenoses (hepatic veins alone or including the IVC) and subsequently dilated with size-appropriate angioplasty balloons (Diameter ranges between 6 and 18 mm, Boston Scientific, Galway, Ireland).

After stent placement, post-procedural angiographic control with contrast injection and pressure-gradient measurements in each hepatic vein and the right atrium were performed as a measure of technical response. Depending on the size of the dilator/sheath used to access the hepatic veins, coils of different lengths and diameters were deployed in the entry tract to avoid the risk of bleeding.

6. Success registration and patient follow up
Immediate postprocedure follow-up consisted of clinical, laboratory and Doppler US examinations that were performed within 24-72 hours after stent placement.
Long term follow-up was based on clinical and laboratory analyses that were performed every 1-3 months after placement and Doppler US at 1, 3, 6, 9 and 12 months for a 1-year period after the procedure. After completing 1 year, the frequency of clinical and US follow-up ranged from 3-6 months. CT and/or angiographic studies were performed when complications or recurrence were suspected.

**Outcomes assessed:**

- Technical success is defined as the angiographic resolution of the stenosis with improvement of blood flow after contrast injection and a significant reduction in the pressure gradient.

- Clinical success is defined as a significant improvement of the patient's condition assessed by an evaluation of signs and symptoms including abdominal pain, ascites, lower-extremity edema, and pleural effusion.

- Major procedure-related complications include not only those directly related to stent placement such as bleeding, pneumothorax, hemothorax or visceral injury, but also complications that can manifest a long time after the procedure as stent migration or occlusion.

- Recurrence is defined as the reappearance of clinical, US, CT, or angiographic findings suggestive of HVOO. The most frequent findings are persistent ascites, recurrence of significant pressure gradients in the hepatic veins or IVC and identification of previous or new stenosis.

- Primary patency is defined as the interval between the placement of the stent and the first time of appearance of findings of outflow obstruction that require percutaneous angiographic study.

**7. Statistical analysis**

Kaplan Meier tests were used to calculate the patency rate in patients with both early and late HVOO. A log rank test was used to compare the patency rates of both groups. Pearson's chi-squared test was used to compare patient survival, graft survival, technical success, clinical success, recurrence and complication rates. All statistical analyses were performed with the SPSS software package (version 15.0, SPSS, Chicago, IL). Statistical significance was defined as a P value < 0.05.
Table 1: Classification of HVOO

<table>
<thead>
<tr>
<th>Time to diagnosis (Cutoff 30 days)</th>
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<tbody>
<tr>
<td>Early</td>
<td>8 (50%)</td>
</tr>
<tr>
<td>Late</td>
<td>8 (50%)</td>
</tr>
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</table>

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Table 2: Initial diagnosis

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Table 3: Venographic and manometric findings

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Fig. 2: Stent placement: A- Selective catheterization of right and middle hepatic veins. An stenosis of the piggyback is demonstrated. B- Simultaneous deployment of stents in right and middle hepatic veins crossing the stenosis. C- Resolution of the stenosis.

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Fig. 3: A- Selective catheterization of right and middle hepatic veins. An stenosis of the piggyback is demonstrated. B- Stent placement in right and middle hepatic veins restore the hepatic venous outflow.

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Results

1. Description of the procedures
During the study period, 34 self-expandable stents were placed in 16 patients with OLT. Stents ranged in diameter from 10 to 20 mm (Mean: 16 mm) and in length from 60 to 100 mm (Mean: 60 mm).
13 patients (81.25%) required multiple stents to treat the HVOO, with 10 patients (62.5%) receiving 2 stents, 1 patient receiving 3 stents (6.25%) and 2 patients (12.5%) receiving 4 stents. Only 3 patients (18.75%) required the placement of just 1 stent.
According to the location of the stenosis, 15 stents were placed in the right hepatic vein (44.1%), 12 stents in the middle hepatic vein (35.3%), 2 were placed in the left hepatic vein (5.8%) and 5 in the inferior vena cava (14.7%).
Regarding with the access route, 33 of the stents (97%) were placed from a transhepatic approach and only 1 (3%) was placed from a transjugular approach.
In all cases the stent was placed in the selected area and there were no cases of immediate shortening or misplacement. In order to minimize these complications, a balloon dilatation of the stent was immediately performed.

Information about the procedures performed is detailed in Table 4 on page 13, Table 5 on page 13, Table 6 on page 14

2. Long-term follow up
The follow-up period of the study ranged between 21 and 5331 days with a median of 765 days. 6 of 16 patients (37.5%) were lost to follow-up before the stated date of end of the study due to demise or clinical transfer. Recurrence was diagnosed in 2 of 16 patients (12.5%)

Follow-up information is summarized in Table 7 on page 15

3. Technical and clinical success
The rate of technical success was lower in patients with early HVOO (7 of 8 patients - 87.5%) when compared to late HVOO (8 of 8 patients - 100%) but this difference was statistically not significant (p=1)
The clinical success rate was higher in patients with early HVOO (7 of 8 patients - 87.5%) compared to late HVOO (6 of 8 patients - 75%). This difference was statistically not significant (p=1)

4. Major procedure-related complications
The incidence of major complications in patients with early HVOO ( 6 of 8 patients - 87.5%) was the same as the one that was found in patients with late HVOO (6 of 8 patients - 75%), no existing differences.
Major immediate complications (# 24 hours after the procedure) were found included 1 case of pleural effusion with hematic characteristics and 1 case of intrahepatic hematoma.
Long-term procedure-related complications included 1 case of stent migration and 1 case of stent thrombosis.

5. Recurrence
The recurrence rate was lower in patients with early HVOO (0 of 8 patients - 0%) compared to late HVOO (2 of 8 patients - 25%), but the difference was statistically not significant (p=0.467)

6. Patient and graft survival
The rate of graft survival was higher in patients with early HVOO (8 of 8 grafts - 100%) compared to late HVOO (7 of 8 grafts - 87.5%) but the difference was statistically not significant (p=1)
The survival rate of patients with early and late HVOO was the same in both cases (7 of 8 patients - 87.5%; p=1)

7. Patency rates
Patency rates were calculated with Kaplan Meier tests.
In the group of patients with early HVOO the primary patency rates calculated at 3, 6, 12 and 60 months for the stents placed were 1.00, 1.00, 1.00 and 1.00.
In the group of patients with late HVOO the primary patency rates calculated at 3, 6, 12 and 60 months for the stents placed were 0.93, 0.93, 0.93 and 0.70.
A Log rank test was used to compare the primary patencies of early and late HVOO, obtaining a p value of 0.097. This result suggests that the higher primary patency rate of patients with early HVOO has trend to signification.

Results of technical and clinical success, major complications, recurrence, patient’s and graft’s survival and primary patency are summarized in Table 8 on page 16
Table 4: Endovascular treatment (I)

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Table 5: Endovascular treatment (II)

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**Table 6:** Endovascular treatment (III)

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<table>
<thead>
<tr>
<th>Location of the stents placed</th>
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<tbody>
<tr>
<td>Right hepatic vein</td>
<td>15</td>
</tr>
<tr>
<td>Middle hepatic vein</td>
<td>12</td>
</tr>
<tr>
<td>Left hepatic vein</td>
<td>2</td>
</tr>
<tr>
<td>Inferior vena cava</td>
<td>5</td>
</tr>
<tr>
<td>Immediate complications (shortening or misplacement)</td>
<td>0</td>
</tr>
</tbody>
</table>
Follow-up information

<table>
<thead>
<tr>
<th>Follow-up time (days)</th>
<th>21-5531 (Median: 765 days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss to follow-up</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
</tr>
<tr>
<td>No</td>
<td>10</td>
</tr>
<tr>
<td>Cause of loss to follow-up</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>2</td>
</tr>
<tr>
<td>Change of center</td>
<td>4</td>
</tr>
<tr>
<td>Recurrence of HVOO</td>
<td>2 (12,5%)</td>
</tr>
</tbody>
</table>

**Table 7:** Follow-up information

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Table 8: Results

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Conclusion

1. Endovascular treatment of HVOO with stent placement shows excellent outcomes.
2. There are no significant differences of long-term outcomes in patients with early and late HVOO.
3. There might be a trend to a slightly higher primary patency rate in the group of patients with early HVOO.
References


