Hemorrhage Complication with Endovascular Treatment for Peripheral Artery Disease: from I-PAD Registry

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Introduction

- Endovascular treatment (EVT) is a less invasive form of treatment for peripheral artery disease (PAD) than bypass surgery, and tends to be performed as the first-line treatment instead of bypass surgery.

- Bleeding from Puncture site is common complication with EVT.

Aim

- To investigate hemorrhage complication in( of) EVT for patients with PAD.

I-PAD NAGANO registry

Improving prognosis of peripheral artery disease: patients undergoing endovascular treatment in NAGANO

- This registry is ongoing prospective multicenter registry.
- We will investigate systems clinical outcome after EVT for PAD.

Subject

- Patients had EVT for PAD from Aug 2015 to July 2016 in 12 institutes in Nagano prefecture in Japan.
- Patients had symptoms of intermittent claudication classified as Stage 2 or greater according to the Rutherford classification and had leg ischemia confirmed by means of noninvasive testing.
- Including 141 CLI cases.

Definition

- Bleeding complication was defined as need blood transfusion or need extra hospital stay.
- Over Bleeding Academic Research Consortium (BARC) type 2
- Under weight was defined as BMI less than 18.5.
- Worse than moderate frail was defined as frailty score over 5

Procedure strategy

- We use 6-7F system for iliac or superficial femoral artery (SFA) lesion Treatment.
- We use 4-5Fr system for below the knee (BTK) treatment.
- 1st line strategy for SFA is provisional stenting (If there was a residual stenosis ≥30%, or if there was residual flow limiting dissection, we placed a self-expandable stent).
- 1st line strategy for iliac lesion is using clopidogrel.
- We can't use stent for BTK lesion exclude bailout cases.
- IVUS guide EVT for iliac and SFA.
- All patients had EVT for BTK were CLI cases.
- 30 megml units of 1000 units was administrated before the procedure; thereafter, the active clotting time was maintained at ≥200 s.
- Each operator decided to use heparin device.
- Patients took oral cilostazole (100 mg/day) and clopidogrel (75 mg/day) for a minimum of 4 weeks after EVT. Oral intake of these drugs was also started at least 3 days prior to the procedure.

Univariate analysis of bleeding from puncture site

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iliac lesion</td>
<td>3.64 (0.99 - 13.25)</td>
<td>0.05</td>
</tr>
<tr>
<td>Thoracic aorta lesion</td>
<td>3.36 (1.15 - 9.6)</td>
<td>0.02</td>
</tr>
<tr>
<td>Diabetic mellitus</td>
<td>0.91 (0.58 - 1.42)</td>
<td>0.74</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>0.63 (0.4 - 1.01)</td>
<td>0.08</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.3 (1.01 - 1.66)</td>
<td>0.04</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>1.0 (0.63 - 1.52)</td>
<td>0.4</td>
</tr>
<tr>
<td>Prior history of bleeding</td>
<td>2.03 (1.04 - 3.96)</td>
<td>0.05</td>
</tr>
<tr>
<td>Total procedure</td>
<td>2.83 (1.34 - 5.98)</td>
<td>0.02</td>
</tr>
<tr>
<td>Total catheterization</td>
<td>1.43 (0.83 - 2.43)</td>
<td>0.2</td>
</tr>
<tr>
<td>Total access</td>
<td>0.83 (0.47 - 1.45)</td>
<td>0.51</td>
</tr>
<tr>
<td>Access procedure</td>
<td>0.37 (0.17 - 0.82)</td>
<td>0.02</td>
</tr>
<tr>
<td>Antegrade access</td>
<td>0.91 (0.42 - 1.98)</td>
<td>0.81</td>
</tr>
</tbody>
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Conclusion

In this study, real world bleeding complication with EVT was 1%. It is acceptable result. However, we should pay meticulous attention in brachial approach to patients who have calcification of target lesion and high frailty score.