Off-label Application of Pipeline Embolization Device (PED) in the Treatment of Intracranial Aneurysms

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Poster ID: 41299
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The authors have no disclosure.

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Abstract:
In 2011, FDA approved the usage of Pipeline embolization device (PED) for particular intracranial aneurysms (see indications below).[1] However, the application of PED has shown utility in multiple off-label purposes.[2] Here we review all the off-label PED cases in a single institute in the past 6 years.

FDA approved indications:[1]
- Age ≥ 22
- Size ≥ 10 mm
- Neck ≥ 4 mm or dome/neck < 2
- Petrous to superior hypophyseal

Off-label applications:[2]
- Previously treated
- Acutely ruptured
- Small (< 10 mm)[3][4]
- Distal circulation
- Posterior circulation
- Fusiform
- Tandem
- Blood-blister like

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Methods:
This is a single institution, retrospective study of all the patients who underwent PED treatment since 2011, of which cases with off-label use were recruited for analysis. Of a total of 80 aneurysms treated with PED, 62 cases were off-label. All the clinical data including radiographic results were independently reviewed by two investigators (B.L. and W.L.).
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## Results:

<table>
<thead>
<tr>
<th>Total aneurysms treated by PED</th>
<th>62</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total PED procedures</td>
<td>54</td>
</tr>
</tbody>
</table>

### Demographic

<table>
<thead>
<tr>
<th>Gender</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>57</td>
</tr>
<tr>
<td>Male</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>54.26</td>
</tr>
<tr>
<td>Median</td>
<td>55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian/AA/Hispanic/Puerto Rican/Asian</td>
<td>40/11/6/4/1</td>
</tr>
</tbody>
</table>

### Symptoms

<table>
<thead>
<tr>
<th>Symptoms</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>44 (71%)</td>
</tr>
<tr>
<td>Vision changes</td>
<td>9 (14%)</td>
</tr>
<tr>
<td>Dizziness/vertigo</td>
<td>7 (11%)</td>
</tr>
<tr>
<td>CN III deficit</td>
<td>5 (8%)</td>
</tr>
</tbody>
</table>

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### Aneurysm characteristics

<table>
<thead>
<tr>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
</tr>
<tr>
<td>Right</td>
</tr>
<tr>
<td>P-Com/Ophthalmic/Supra-clinoid/Superior hypophyseal/Cavernous/Para-clinoid/Infra-clinoid/M1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ruptured</th>
<th>(14) (26%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute</td>
<td>(1)</td>
</tr>
<tr>
<td>Remote</td>
<td>(13)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Size (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (mm)</td>
</tr>
<tr>
<td>Median (mm)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Neck (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (mm)</td>
</tr>
<tr>
<td>Median (mm)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shape</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saccular/lobulated/tandem/blood blister-like/fusiform</td>
</tr>
</tbody>
</table>

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### Pre-operative status

<table>
<thead>
<tr>
<th>Status</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native/virgin</td>
<td>35 (57%)</td>
</tr>
<tr>
<td>Coiled</td>
<td>17 (27%)</td>
</tr>
<tr>
<td>Stented</td>
<td>6 (10%)</td>
</tr>
<tr>
<td>Clipped</td>
<td>4 (6%)</td>
</tr>
</tbody>
</table>

### Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding (cutaneous; medically managed)</td>
<td>6 (10%)</td>
</tr>
<tr>
<td>Facial droop and arm weakness (resolved)</td>
<td>1</td>
</tr>
<tr>
<td>Ischemic stroke (delayed resolution)</td>
<td>1</td>
</tr>
<tr>
<td>PED with vessel occlusion (asymptomatic)</td>
<td>1</td>
</tr>
<tr>
<td>Sub-arachnoid hemorrhage (no deficit)</td>
<td>2</td>
</tr>
<tr>
<td>Tandem aneurysms (one patient)</td>
<td></td>
</tr>
</tbody>
</table>

### Follow-up imaging

<table>
<thead>
<tr>
<th>Imaging Outcome</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-operative day</td>
<td>44 (71%)</td>
</tr>
<tr>
<td>Mean/median (day)</td>
<td>67-650</td>
</tr>
<tr>
<td>Complete aneurysm occlusion</td>
<td>36 (82%)</td>
</tr>
<tr>
<td>Partial aneurysm occlusion</td>
<td>7 (16%)</td>
</tr>
<tr>
<td>No effect</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

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**Results:**

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Discussion:
Studies have been reported worldwide for the off-label applications of PED. In our institute, off-label PED has been extensively used in 62 aneurysms since 2012, including that are small, previously treated, tandem, fusiform, blood blister-like, and posterior circulation, etc. The number of female cases is dramatically larger than male cases (11.4:1), likely due to higher medical care service utilization in women than in men.[5] Headache is the most common presentation. 76% patients were smokers, 66% had hypertension, and 8% had family history. All patients received dual anti-platelet therapy (Aspirin + Clopidogrel or Aspirin + Ticagrelor) pre-PED which were continued post-operatively. Though the aneurysm-based complication rate is 10% (6/62), the case-based complication rate would be 9.3% (5/54) since the SAH happened in one patient for tandem aneurysms (two). Of these complications, all patients’ symptoms resolved (mRS ≤ 1) during follow-up. Total occlusion rate was 82% among the 44 (71%) aneurysms with post-operative imaging results. The mortality rate is 0%.
Conclusion:
Off-label application of PED is an effective method for the treatment of intracranial aneurysms with an acceptable safety profile including low long-term complication rate.
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Summary points:
- Off-label PED applications are common worldwide
- Off-label PED use is effective
- Off-label PED use has a similar safety profile compared to on-label PED use

Reference: