The initial efficacy of the Pipeline Embolisation Device in the treatment of intracranial aneurysms: A single centre experience

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Purpose

The Pipeline Embolisation Device (PED) is a newly established treatment option in the previously difficult to treat intracranial aneurysms (IAs). The PED works to treat IAs through the mechanisms of:

- Flow diversion
- Endothelial repavement
- Preservation of perforated or branching vessels

Internationally there have been a number of clinical trials to establish the PED’s efficacy and safety in the treatment of IAs:

<table>
<thead>
<tr>
<th>Trial</th>
<th>No. patients</th>
<th>No. IAs</th>
<th>Occlusion rate 6 months</th>
<th>Mortality/major morbidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>PUFS¹</td>
<td>104</td>
<td>106</td>
<td>81.1%</td>
<td>5.6%</td>
</tr>
<tr>
<td>PITA²</td>
<td>31</td>
<td>31</td>
<td>93%</td>
<td>6.5%</td>
</tr>
<tr>
<td>Buenos Aires³</td>
<td>53</td>
<td>63</td>
<td>93%</td>
<td>0%</td>
</tr>
<tr>
<td>Budapest⁴</td>
<td>18</td>
<td>19</td>
<td>94%</td>
<td>5.3%</td>
</tr>
<tr>
<td>Belgium⁵</td>
<td>20</td>
<td>27</td>
<td>77%</td>
<td>15%</td>
</tr>
<tr>
<td>Australia⁶</td>
<td>54</td>
<td>57</td>
<td>85.7%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Table 1: Comparison of Pipeline Embolisation Device Trials

To date there have been a limited number both single and multicentre studies conducted in Australia. These have shown that the PED is an efficacious and safe intervention for difficult to treat unruptured IAs⁶,⁷.

The purpose of this study was to evaluate the initial efficacy and safety of the PED in the treatment of IAs at the Royal Brisbane and Women’s Hospital. In particular those IAs that are unfavourable for coiling intervention and/or have failed previous treatment.
Methods and Materials

All cases of Pipeline Embolisation Device (PED) intervention over a 17 month period at the Royal Brisbane and Women's Hospital were retrospectively reviewed. This included patients that had unfavourable aneurysm anatomy for coiling or had previously undergone coiling intervention of the target intracranial aneurysm (IA).

The following case information was collected:

- size of the target IA
- location of the target IA
- was there previous coiling intervention of the target IA?
- indication for the use of the PED in treating the target IA
- was intervention in the setting of acute/subacute arachnoid haemorrhage?

Comparison of pre and post Pipeline Embolisation Device (PED) intervention imaging was used to determine the efficacy of the procedure. Images used for comparison are up to approximately 6 months post intervention.

Efficacy was determined by the imaging criteria of (at 6 months):

- decrease in aneurysmal flow
- resolution of aneurysm
- no significant in-stent stenosis (<50% stenosis)

Determinants of a good/positive clinical outcome (at 6 months):

- decrease in size or resolution of the aneurysm treated with the PED
- no significant (< 50%) in-stent stenosis of the PED
- no rupture of the target IA
- no rupture of other IAs due to periprocedural anticoagulation
- decrease or resolution of mass effect of aneurysm if present
- decrease or resolution of significant symptoms related to the aneurysm
- no transient ischaemic attacks post intervention
- no morbidity related to the admission for the PED intervention
- no morbidity related to con-current treatments of the aneurysm
- no morbidity related to ongoing antiplatelet therapy
- no mortality
Results

Twenty-three intracranial aneurysms (IAs) in 22 patients were treated by 3 interventional neuroradiologists with the Pipeline Embolisation Device (PED) between May 2010 and September 2011.

Size of Target Intracranial Aneurysm

The distribution of the target IA size treated with the PED is as follows:

![Size Distribution of Target Intracranial Aneurysm](image)

*Fig. 1*: Chart displaying size distribution of target intracranial aneurysms treated with the Pipeline Embolisation Device

**References:** Royal Brisbane and Women's Hospital

Location of Target Intracranial Aneurysm
**Table 1.** Location distribution of target IAs treated with the PED.

<table>
<thead>
<tr>
<th>Location</th>
<th>Number of Aneurysms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior circulation aneurysms</td>
<td>15</td>
</tr>
<tr>
<td>Posterior circulation aneurysms</td>
<td>8</td>
</tr>
</tbody>
</table>

**Indication for Pipeline Embolisation Device**

**Table 2.** Indication for PED intervention in target IA

<table>
<thead>
<tr>
<th>Indication for PED insertion</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-occlusion with previous coiling intervention</td>
<td>7</td>
</tr>
<tr>
<td>Wide neck/unfavourable anatomy with no previous coiling</td>
<td>15</td>
</tr>
<tr>
<td>Adjacent to target IA where PED is indicated</td>
<td>1</td>
</tr>
</tbody>
</table>

Note that three patients were treated in the context of acute/subacute subarachnoid haemorrhage (SAH).

**Immediate Results of the Pipeline Embolisation Device**

In 10 of the 22 cases it was noted that there was a reduction in aneurysm flow of the target IA immediately after the insertion of the PED. Almost complete occlusion of the target IA was observed in 3 cases immediately post PED insertion (figures 2, 3, 5 and 6 provide a before and immediately after PED insertion example).

**Results at Follow up**

Patients received varying follow up in accordance with clinical need. This included follow up scanning with a single modality or various combinations of; Computerised Tomography Angiogram (CTA), Magnetic Resonance Angiography (MRA) or Digital Subtraction Angiography (DSA). Twenty-one patients had attended a definitive follow up scan by approximately 6 months (range 3 to 7 months) post the PED insertion. One
patient was lost to follow up for this study, as they did not attend definitive follow up until 1 year post intervention. A total of 22 aneurysms in 21 patients were reviewed at follow up scans, of these 18 of the 22 aneurysms (82%) showed no aneurysmal flow. This included 15 aneurysms (68%) that showed complete resolution. The remaining 4 cases displayed decreased aneurysmal flow but were not occluded by 6 months.

Varying sizes of IAs had differing rates of occlusion (detailed in Table 3). Of the 10 small aneurysms treated with the PED, all 10 aneurysms had complete angiographic occlusion at follow up. This is in comparison to the 4 giant IAs treated with the PED of which only 1 displayed complete angiographic occlusion at follow up (Figures 7-10)

Table 3: Distribution of IA size and occlusion of aneurysm post PED intervention

<table>
<thead>
<tr>
<th>Size of IA</th>
<th>Number of IA's</th>
<th>Number occluded at follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small (&lt;5mm)</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Medium (5-15mm)</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Large (15-25mm)</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Giant (&gt;25mm)</td>
<td>4</td>
<td>1</td>
</tr>
</tbody>
</table>

Seven patients had previously undergone coiling intervention for the target IA treated with the PED. Of these, 6 patients (86%) had complete occlusion of the aneurysm at initial follow up (ranging from 2-6 months).

In one further case a PED was inserted in the same procedure that coiling intervention was abandoned due to unfavourable anatomy (wide neck). This case had a favourable outcome with reduction in flow at 6 month follow up.

Two patients were identified to have minor/non-significant in-stent stenosis. One further patient was asymptomatic of a 50% in-stent stenosis at 6 month follow up.

The recurrence rate at follow up was 0%.

A favourable clinical outcome was achieved in 86% of all cases that had attended follow up at approximately 6 months.
Figures 7-20 demonstrate pre and post intervention of imaging of various cases.

**Mortality**

*There was 1 mortality in 21 patients (4.7%).*

This was related to a hospital acquired respiratory infection progressing to sepsis. This case received PED intervention in the setting of subacute SAH. A CTA 4 days post intervention showed the target IA had completely occluded.

**Morbidity**

*Morbidity occurred in 4 patients (19%).*

**Major morbidity in 2 of the 21 patients (9.4%).**

One patient suffered an ipsilateral acute occipitoparietal haematoma in the context of periprocedural anticoagulation post PED insertion for a left Internal Carotid Artery IA (Figure 21). This patient continued to experience transient ischemic attacks post intervention even though the target IA displayed decreased flow on CTA at 1 month follow up.

The second patient experienced extensive morbidity related to post PED aneurysm thrombosis and swelling. Corticosteroids were used as treatment. The complications were related to mass effect from the treated aneurysm (panhypopituitarism and bilateral blindness) and steroid-induced immune suppression (ventilator-dependant Pneumocystis carinii pneumonia). The patient eventually fully recovered. There was complete angiographic occlusion of the giant IA at follow up (Figures 7-10).

**Minor morbidity occurred in 2 of the 21 patients (9.4%).**

These 2 patients re-presented within two weeks of intervention with headache. Neither case was found to have acute intracranial haemorrhage on CT. Symptoms in both cases settled.
Images for this section:

Fig. 2: Patient A: DSA pre intervention demonstrating a Right Internal Carotid Artery aneurysm.

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**Fig. 3:** Patient A: DSA immediately post Pipeline Embolisation Device deployment. Note flow in the aneurysm has been immediately arrested.

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Fig. 4: Patient A: DSA at 7 months post Pipeline Embolisation Device deployment. There is no flow demonstrated flow in the Right Internal Carotid Artery aneurysm.

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**Fig. 5:** Patient B: DSA pre intervention. A small aneurysm is demonstrated at the Posterior Cerebral Artery near the termination of the Basilar Artery.

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Fig. 6: Patient B: DSA post Pipeline Embolisation Device deployment. There has been immediate decrease in flow of the aneurysm demonstrated in Figure 4.

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**Fig. 7:** Patient C: DSA shows a giant Right Internal Carotid Artery IA.

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**Fig. 8:** Patient C: DSA 6 months post PED intervention. The giant aneurysm demonstrated in Figure 7 has been completely occluded by the PED.

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Fig. 9: Patient C: CTA Head (Axial) demonstrating the giant right Internal Carotid Artery IA

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**Fig. 10:** Patient C: CTA Head (Axial) 1 month post PED intervention displays there is no flow into the giant IA demonstrated in Figure 9.

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Fig. 11: Patient D: DSA pre intervention demonstrates a small intracranial aneurysm from the Right Internal Carotid Artery.

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**Fig. 12:** Patient D: DSA post Pipeline Embolisation Device intervention demonstrates no flow in the previously demonstrated IA in Figure 6.

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Fig. 13: Patient E: DSA pre PED. Two aneurysms are demonstrated in the Left Internal Carotid Artery. The more distal aneurysm (red arrow) has previously undergone coiling intervention. There is a small proximal aneurysm (green arrow).

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**Fig. 14:** Patient E: DSA 7 months post PED intervention. There has been cessation in flow in both the proximal (green arrow) and distal (red arrow) aneurysms. One PED was deployed across both of the aneurysms demonstrated in Figure 8.

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Fig. 15: Patient F: DSA pre PED intervention demonstrates a medium aneurysm located in the Anterior Communicating Artery

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Fig. 16: Patient F: DSA post PED deployment demonstrates cessation in flow of the ACOM IA previously demonstrated in Figure 10 (red arrow)

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Fig. 17: Patient G: Non-contrast CT Head (Axial) of a patient that presented to the Department of Emergency with headache. The scan demonstrates a giant right intracranial aneurysm with active flow and surrounding vasogenic oedema.

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Fig. 18: Patient G: DSA pre intervention demonstrates the giant intracranial aneurysm.

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Fig. 19: Patient G: Non-contrast CT Head (Axial) post PED (red arrow). Compared to Figure 13, there is decrease in size of the right intracranial aneurysm and decrease in the surrounding vasogenic oedema.

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**Fig. 20:** Patient G: CTA (Axial) post PED deployment. The image demonstrates the minimal remaining flow in the right intracranial aneurysm (green arrow) and the PED stent in situ (red arrow)

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**Fig. 21:** Patient H: Non-contrast CT Head (Axial) 1 day post PED intervention. There is an left sided occipitoparietal haematoma that occurred in the context of periprocedural anticoagulation.

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Conclusion

*The Pipeline Embolisation Device is an effective endovascular treatment option for difficult or complex intracranial aneurysms.*

- 22 patients with 23 aneurysms were treated
- 1 patient did not attend follow up within the defined time frame
- At approximately 6 month follow up:
  - No IA flow was demonstrated in 82% (18 of 22 aneurysms) at approximately 6 months.
  - Complete resolution occurred in 68% (15 of 22 aneurysms).
  - 0% IA recurrence rate

A good clinical outcome occurred in 86% (18 of 21 patients).

Mortality/Morbidity

- Mortality occurred in 4.5% of cases (1 of 22 patients)
  - Death due pseudomonal sepsis.
- Major morbidity occurred in 9.4% (2 of 21 patients)
  - 1 ipsilateral cerebral haematoma due to periprocedural anticoagulation
  - 1 case of treated aneurysm mass effect and also steroid induced immunocompromise.
- Minor morbidity occurred in 9% (2 of 21 patients).
  - 2 unexpected representations for headache, with no sequelae.
Personal Information

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References


