Dissections Matter: Evidence for Post-PTA Dissections

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Disclosure

Speaker name: Ehrin J. Armstrong MD

I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Boston Scientific, Cardiovascular Systems, Gore Medtronic, Philips
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
Dissections Are the Mechanism of Angioplasty Leading to Luminal Gain

Balloon angioplasty uses multi-axis stress to increase arterial lumen, causing intimal rupture and variable deeper injury.
Angiographic Characterization of Dissections: NHLBI Modification

A. Minor radiolucent areas
B. Linear dissection
C. Contrast outside the lumen
D. Spiral dissection
E. Persistent filling defects
F. Total occlusion w/o distal antegrade flow
Fujihara et al, J Endovasc Ther 2017
Dissections Are Frequent and Often Severe

- Up to 84% of PTA results in a visible dissection\(^1,2\)
- Up to 42% of PTA results in Grade C or higher\(^1,2\)

\(^1\) Fujihara, *J Endovasc Ther* 2017
Dissection Severity is Often Underestimated

TOBA: Baseline Post-PTA Dissection Grade

Disparity between site-reported and core lab dissection grade

\[^1\] Bosiers J Vasc Surg 2016
Dissections Impact Clinical Outcomes After POBA

Hazard ratio for restenosis

Dissection Severity (NHLBI)²

<table>
<thead>
<tr>
<th></th>
<th>HR</th>
<th>[95% CI]</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>1.58</td>
<td>[0.79, 3.16]</td>
<td>0.193</td>
</tr>
<tr>
<td>A</td>
<td>1.81</td>
<td>[0.88, 3.73]</td>
<td>0.108</td>
</tr>
<tr>
<td>B</td>
<td>4.45</td>
<td>[1.22, 16.2]</td>
<td>0.024</td>
</tr>
<tr>
<td>C</td>
<td>6.37</td>
<td>[2.99, 13.6]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>D</td>
<td>22.9</td>
<td>[7.33, 71.6]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>E</td>
<td>297</td>
<td>[34.9, 2527]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

¹Fujihara, J Endovasc Ther 2017
²Manual of Operations NHLBI PTCA Registry 1985
Primary Patency After POBA of SFA

Fujihara et al, J Endovasc Ther 2017
TLR After POBA of SFA

B

Free from Clinically Driven TLR

0.0 0.2 0.4 0.6 0.8 1.0

Follow up period (months)

6 12 18 24

Nonsevere dissection
(Type None, A and B)

Severe dissection
(Type C-F)

p < 0.001 log-rank

Fujihara et al, J Endovasc Ther 2017
Fig 3. A, Primary patency rates at 24 months according to the types of angiographic dissection in superficial femoral artery lesions \( \leq 100 \) mm. B, Primary patency rates at 24 months according to the types of angiographic dissection in superficial femoral artery lesions \( >100 \) mm.
How To Treat Dissections?

- Prevention
  - “Optimal” vessel prep
  - Low atmosphere balloon inflations
  - Long duration of balloon angioplasty
  - Long balloons

- Stent Implantation

- Tack Implantation
Tack Endovascular System®

Tack® Implant
- **Adaptive Sizing™** fits vessel diameters 2.5 – 6.0mm
- Nitinol with gold RO markers for visibility
- Unique anchoring system prevents migration
- 6mm deployed length

Delivery System
- 6F/0.035”
- 6 implants pre-loaded on a single catheter
- Designed for highly accurate (≤1mm) deployment

CAUTION: Investigational device. Tack Endovascular System is limited by Federal (United States) law to investigational use. Not approved for sale in the United States. Tack Endovascular System is CE Mark authorized under EC Directive 93/42/EEC. Adaptive Sizing™ is a trademark of Intact Vascular, Inc. Tack Endovascular System® and Tack® are registered trademarks of Intact Vascular, Inc.
# Unique Characteristics of Tack Implant

<table>
<thead>
<tr>
<th></th>
<th>Tack Implant</th>
<th>Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Radial force</strong></td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td><strong>Inflammation</strong></td>
<td>Minimal</td>
<td>Chronic hyperplastic changes</td>
</tr>
<tr>
<td><strong>Pre-clinical study histology images</strong></td>
<td><img src="image" alt="Proximal Tack" /></td>
<td><img src="image" alt="Proximal Stent" /></td>
</tr>
<tr>
<td><strong>Sizing</strong></td>
<td>Adaptive Sizing allows a single Tack implant to fit a range of vessel diameters</td>
<td>Force increases with vessel diameter; requires precise sizing</td>
</tr>
<tr>
<td><strong>Metal burden</strong></td>
<td>Focal, biologically “silent” dissection repair therapy</td>
<td>&gt;70% more metal to treat the same dissection¹</td>
</tr>
</tbody>
</table>

¹Schneider, JACC: Cardiovasc Interv 2015  
²Bosiers, J Vasc Surg 2016
Conclusions

Dissections are common after POBA.

Increased severity of dissections is associated with higher risk of restenosis and need for repeat intervention.

   Even less severe dissections may require treatment, especially in longer lesions

Minimal data regarding which dissections need to be treated after DCB.

Emerging technologies including Tack device may change the paradigm and threshold for treating dissections.
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