Randomized Comparison of a CrossBoss First vs. Standard Wire Escalation Strategy for Crossing Coronary Chronic Total Occlusions: the “CrossBoss First” trial

Emmanouil S. Brilakis, MD, PhD
on behalf of the CrossBoss First Trial Investigators
Disclosure Statement of Financial Interest

Consulting/speaker honoraria: Abbott Vascular, Amgen, Asahi, CSI, Elsevier, GE Healthcare, Medicure

Employment (spouse): Medtronic

Grants: Boston Scientific, Osprey VA CSP#571
1. Planned antegrade crossing
2. No primary retrograde
3. No ostial lesions (<5 mm)
Study flowchart

966 patients were assessed for eligibility between 2015 and 2017 at 11 US hospitals

686 were ineligible

280 met eligibility criteria

34 were not enrolled

246 were enrolled and underwent randomization

122 were assigned to CrossBoss group
119 underwent initial crossing attempt with CrossBoss
0 lost to follow-up
122 (100%) were included in the analysis of the primary and secondary clinical outcomes

124 were assigned to the guidewire group
122 Underwent initial crossing attempt with antegrade wire escalation
0 lost to follow-up
124 (100%) were included in the analysis of the primary and secondary clinical outcomes
# Crossing strategies

<table>
<thead>
<tr>
<th>Variable</th>
<th>CrossBoss (n=122)</th>
<th>Guidewire (n=124)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical Success, %</td>
<td>88.5</td>
<td>87.1</td>
<td>0.846</td>
</tr>
<tr>
<td>First Crossing Strategy, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Antegrade wire escalation</td>
<td>22</td>
<td>98</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>▪ Antegrade dissection and re-entry</td>
<td>77</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>▪ Retrograde</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Successful Crossing Strategy, %</td>
<td></td>
<td></td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>▪ Antegrade wire escalation</td>
<td>24</td>
<td>51</td>
<td></td>
</tr>
<tr>
<td>▪ Antegrade dissection and re-entry</td>
<td>50</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>▪ Retrograde</td>
<td>18</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>▪ None</td>
<td>8</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>
Primary endpoints

Crossing time

- **CrossBoss**
  - Median crossing time: 56 (33, 93) minutes
- **Guidewire**
  - Median crossing time: 66 (36, 105) minutes

Procedural MACE

- **CrossBoss**
  - Procedural MACE: 3.28%
- **Guidewire**
  - Procedural MACE: 4.03%

**P values**

- Crossing time: p = 0.323
- Procedural MACE: p = 1.000

**Standardized mean difference:** 0.094

Variable (n=122) | CrossBoss | Guidewire | P value
---|---|---|---
Crossing time (min) | 56 (33, 93) | 66 (36, 105) | 0.323

*b: median (interquartile ranges)*
Primary endpoints: ISR cases

Crossing time

<table>
<thead>
<tr>
<th>Variable</th>
<th>CrossBoss (n=25)</th>
<th>Guidewire (n=24)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crossing time (min)</td>
<td>41 (23, 58)</td>
<td>66 (32, 111)</td>
<td>0.046</td>
</tr>
</tbody>
</table>

Standardized mean difference: 0.534
### Procedural characteristics and outcomes

<table>
<thead>
<tr>
<th>Variable</th>
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<th>Guidewire (n=124)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedural Success, %</td>
<td>85.3</td>
<td>83.1</td>
<td>0.634</td>
</tr>
<tr>
<td>Total procedural time (min)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>109 (78, 185)</td>
<td>109 (75, 161)</td>
<td>0.670</td>
</tr>
<tr>
<td>Total fluoroscopy time (min)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>40 (28, 66)</td>
<td>37 (24, 65)</td>
<td>0.339</td>
</tr>
<tr>
<td>Total AK radiation dose</td>
<td>2.18 (1.23, 3.56)</td>
<td>2.34 (1.23, 3.91)</td>
<td>0.752</td>
</tr>
<tr>
<td>Contrast volume&lt;sup&gt;b&lt;/sup&gt;</td>
<td>260 (168, 350)</td>
<td>250 (155, 329)</td>
<td>0.492</td>
</tr>
<tr>
<td>Fluoroscopy time (min)&lt;sup&gt;b&lt;/sup&gt; at crossing</td>
<td>20 (11, 44)</td>
<td>25 (12, 48)</td>
<td>0.638</td>
</tr>
<tr>
<td>AK radiation dose at crossing</td>
<td>0.88 (0.48, 1.97)</td>
<td>1.08 (0.33, 2.44)</td>
<td>0.644</td>
</tr>
</tbody>
</table>

<sup>b</sup>: median (interquartile ranges)
Equipment costs

Guidewire cost (USD)

Balloon cost (USD)

Microcatheter cost (USD)

CrossBoss and Stingray cost (USD)

Stent cost (USD)

Overall cost (USD)
Conclusions

• As compared with a primary wire escalation strategy, upfront use of the CrossBoss catheter for crossing CTOs was associated with:
  - similar crossing time
  - similar success and procedural MACE rates
  - similar equipment utilization and costs

• Further studies are needed to determine whether some subgroups (such as in-stent occlusions) are better suited for crossing using the CrossBoss catheter.