Preclinical Evaluation of a Novel Solid Core Pressure Guidewire in a Porcine Model

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BACKGROUND

- Use of a pressure guidewire during PCI decision-making for intermediate-severity lesions has proven long-term clinical benefits and a IA recommendation in recent guidelines.
- The major limitation of pressure guidewires at present is their poor technical performance compared to standard coronary guidewires.
- Whereas state-of-the-art coronary guidewires have a solid core for enhanced control, current pressure guidewires have a hollow tube design to accommodate the pressure leads/fibers.
- A novel pressure guidewire has been designed with the pressure fibers embedded into a solid guidewire core.

OBJECTIVE

To compare operator performance assessment of a novel solid core design pressure guidewire versus standard hollow tube pressure guidewires.

METHODS

- A total of 9 swine were used to assess 3 different wire models by 3 experienced physicians.
- Each physician was blinded to wire model and performed randomly assigned PCI procedures (e.g.: wire vessel navigation; pressure measurement; device delivery of an imaging catheter, stent, or balloon) in coronary and peripheral vasculature.
- 18 wires from each model were tested.
- Upon procedure completion, users evaluated five mechanical performance features of each wire on a 1 to 5 scale (maneuverability/steerability, stiffness/torque, delivery, kink resistance, functionality/trackability)
- An average score was generated for each wire and compared using a T-test.
- Six vessels in which only a pressure guidewire from each model (n=6 of each model) was passed were subjected to a histological vessel injury analysis by a blinded pathologist.

LIMITATIONS

- This study was sponsored by Philips. B.A.B. reports grant support: Pfizer, Ionis, AstraZeneca, Abbott Vascular; Consulting fees: Philips, Abbott Vascular, Servier, Daiichi-Sankyo, Janssen, Quark. B.A.B is a member of the TIMI Study Group, which has received institutional grant support through the Brigham and Women’s Hospital from: Abbott, Amgen, AstraZeneca, Bayer HealthCare, Pfizer, Proxel, Quark Pharmaceuticals, Roche, Takeda, The Medicines Company, Zora Biosciences.

CONCLUSIONS

- A novel, solid core design pressure guidewire had significantly higher performance scores than did standard hollow tube design pressure guidewires.
- The solid core pressure guidewire resulted in numerically less vessel injury, though with limited power to detect a statistically significant difference.

Table 1. Blinded operator performance assessment

<table>
<thead>
<tr>
<th>Wire Model</th>
<th>Average Score</th>
<th>p-value (T test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid core guidewire</td>
<td>4.44 ± 0.55</td>
<td>--</td>
</tr>
<tr>
<td>Hollow core guidewire 1</td>
<td>3.92 ± 0.73</td>
<td>--</td>
</tr>
<tr>
<td>Hollow core guidewire 2</td>
<td>3.92 ± 0.73</td>
<td>--</td>
</tr>
<tr>
<td>Solid core vs Hollow core 1</td>
<td>&lt;0.0001</td>
<td>--</td>
</tr>
<tr>
<td>Solid core vs Hollow core 2</td>
<td>&lt;0.0001</td>
<td>--</td>
</tr>
<tr>
<td>Hollow core 1 vs Hollow core 2</td>
<td>0.993</td>
<td>--</td>
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