Increased Pressure Gradients Within an Aortic Arch Endograft are Associated with Rapid Development of In-stent Stenosis in a Porcine Model

Daniel Silverberg, MD, FACS, Marcel Goodman MD, FRACS, Edward Woo, MD, Eliaha Martinez, Udi Willenz, DVM, Moshe Halak, MD, David Planer, MD, Msc

Department of Vascular Surgery, The Chaim Sheba Medical Center, Tel Hashomer, Israel, University of Western Australia, Asat Harofe Medical Center, Israel, Medstar Washington Hospital Center and Medstar Georgetown University Hospital, PA, EndoSpan Ltd, Israel; The Institute of Animal Research, Kibbutz Lahav, Israel; The Heart Institute, Hadassah, Hebrew University Medical Center, Jerusalem, Israel

Introduction

• Domestic pigs are frequently used in preclinical phases of aortic arch stent graft development.
• Advantages of porcine models:
  - Large iliac vessels suitable for large bore sheaths and delivery systems
  - Large aorta diameters
  - Resistant to hemodynamic and neurological insults
• Several limitations exist with porcine models, as the anatomy and physiology do not completely parallel that of humans (table 1) (figure 1).
• Reported experience with experimental fenestrated arch stent graft in pigs is limited, and the physiological response to stent implantation is unknown.
• We report our mid term observations with 2 designs of a novel fenestrated stent graft (Nexus™) for the aortic arch.

Table 1: Human vs. domestic pig anatomy

| Parameter | Human | Pig
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Age (days)</td>
<td>170 kg</td>
<td>30 kg</td>
</tr>
<tr>
<td>Ascending aorta diameter</td>
<td>32 mm</td>
<td>32 mm</td>
</tr>
<tr>
<td>Ascending aorta length</td>
<td>30 mm</td>
<td>32 mm</td>
</tr>
<tr>
<td>Arch mobility during cardiac cycle</td>
<td>1 mm</td>
<td>15 mm</td>
</tr>
<tr>
<td>Thrombophilia</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Methods

• Five large ( >170 kg) domestic pigs underwent implantation of the prototype Nexus aortic arch stent graft (HG).
• Five additional pigs underwent implantation of a modified Nexus device with improved hemodynamics (SPS).
• Following implantation, blood pressure readings were documented in the thoracic aorta and in each of the branches.
• Angiography performed at 1, 3, and 6 months.
• Pigs were sacrificed after 6 months.

Results

• Modular, self-expandable stent graft
• Nitinol framework, polyester inner graft
• Tapered main module from BCT to DTA
• 20mm AA fenestration
• 8mm AA fenestration
• Module in AA
• Module in LSA
• Modular attachment with HG configuration

Table: Comparison of HG versus SPS designs

<table>
<thead>
<tr>
<th>Design</th>
<th>Day 0</th>
<th>3 months</th>
<th>6 months</th>
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<tbody>
<tr>
<td>HG</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>SPS</td>
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</table>

Conclusions

• Pressure gradients across all modular attachments were severely elevated in HG group. These gradients were eliminated in SPS Group (figure 2).
• Follow up angiograms revealed severe in-stent stenosis within BCT and LSA stents in HG group and no in-stent stenosis was seen in SPS group (figure 3).
• Gross pathological and histological examination of stents revealed dense fibrous tissue layer lining the stent graft in BCT and LSA of HG group. These findings were not observed in SPS group (figure 4.5).

• Elevated pressure gradients observed in the aortic arch following stent graft implantation are associated with rapid development of in-stent stenosis in the porcine model.
• Hemodynamic disturbances within the arch may be caused by narrowings or clutering of hardware within the arch.
• These hemodynamic disturbances should be taken into consideration when planning experimental aortic arch devices.
• Care should be taken to eliminate pressure gradients in order to avoid development of in-stent stenosis in this animal model.