New Device Options for EVAR: What Advantages do they Provide?

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New Devices for EVAR

Focus has been on development of:
• Low profile devices to avoid access complications and allow for percutaneous delivery
• Minimize complexity of procedure to gain wider usage and applicability
• Address type II endoleaks in hope of reducing secondary interventions
• Reduce reliance of follow-up on contrast CT’s to minimize radiation exposure and cost

Conflicts of Interest

• I make a living practicing and promoting vascular surgery
• Consultant, physician training, grant support
  • Medtronic
  • Endologix (Nellix)
  • W. L. Gore
  • TriVascular

5-Year Costs Following EVAR ($US)

<table>
<thead>
<tr>
<th>Event</th>
<th>No</th>
<th>Yes</th>
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<tbody>
<tr>
<td>Endoleak</td>
<td>$5,706</td>
<td>$26,739</td>
</tr>
<tr>
<td>2’ Intervention</td>
<td>$3,668</td>
<td>$31,696</td>
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“Efforts aimed at minimizing cost should emphasize technical and device modifications aimed at reducing endoleaks and the need for secondary procedures.”

**Altura Endograft System**

Modular prosthesis with a flexible nitinol skeleton covered by a ribbed low porosity polyester fabric

- No need for contralateral gate canulation
- Suprarenal fixation and adjustable in situ iliac extensions
- Delivery through any 14 Fr sheath
- Semi-circular “kissing” aortic bodies

### Diagrams

- Partial Suprarenal Deployment
- Independent Renal Positioning
- Suprarenal Deployment

### Images

- 1st in Man – Santiago, Chile (May 5, 2011)
CT at 1 Year – Significant Sac Shrinkage

CT Reconstructions at 1 Year

23 patients enrolled
- 91% male
- Age 75.5 ± 7.4 years
- AAA diameter - avg 52.1 mm (46 – 68)

CTA follow up at 6 m (12 patients)
- All the devices remain patent
- Type I endoleak: 0
- Type II endoleak: 3
- No device migration or type III

CTA follow up at 1 year (8 patients)
- All the devices remain patent
- Type I endoleak: 1
- Type II endoleak: 1
- No device migration or type III

Aneurysm sac shrinkage during follow-up
Cardiatis Multilayer Aneurysm Repair System

Multi-layered stent induces “flow modulation” leading to thrombosis of the sac & laminar flow to side branches arising from the aneurysmal sac

CE marked
• Peripheral and visceral aneurysms
• Used in thoracic and abdominal aortic aneurysms
• Not to be used in rAAA

Cardiatis Multilayer Aneurysm Repair System (MARS)

A. Blood flow through a saccular aortic aneurysm
B. Saccular aortic aneurysm with an increased flow velocity
C. Saccular aortic aneurysm treated with a multilayer stent, which decreases the flow velocity into the aneurysm
D. Blood flow though the multilayer stent maintains flow to collaterals as the aortic aneurysm thromboses

Thursday, June 6, 2013
The first broadcast of a live case in the United States of a procedure using Cardiatis Multilayer Flow Modulation technology occurred on Thursday, June 6, 2013 at the New Cardiovascular Horizons conference in New Orleans. Miguel Montero-Baker, MD, performed the procedure at Hospital San Juan de Dios, San Jose, Costa Rica, on an 82-year-old male patient who had developed an aortic aneurysm.
Cardiatis -- Orebro Study

13 compassionate cases treated:
- 11 Thoracoabdominal aneurysms
- 2 Abdominal aortic aneurysms

4 of the above were symptomatic

5 mortalities:
- 3 Non-aneurysmal related
  - 2 cardiac / 1 unknown cause
- 2 Ruptures related to aneurysm

No decrease in aneurysm size at 15 months of follow-up, and 2 patients with significant increase in size

NELLIX DESIGN GOALS

Simplify EVAR procedure

- Simple & intuitive Steps
- Small inventory to treat all infrarenal AAA patients

Clinical Outcome Goals

- Eliminate secondary interventions
- Reduce required patient surveillance
**NELLIX ENDOBAG DESIGN**

- Durable polyurethane
- High strength PTFE sleeve
- Oversized to flow lumen
- Aortic Bags: 6.0cm diameter
- Seal aneurysm sac

**NELLIX STENT DESIGN**

- Cobalt chromium alloy
- Balloon-expandable
- Create flow lumens to iliacs
- Highly flexible
- Crush resistant
  - 1200 – 1400 mmHg
- Highly flexible

**BIOSTABLE POLYMER**

- Polyethylene Glycol (PEG) Diacrylate
- Viscosity of water
- Fills EndoBags to seal the sac
- Cures in 3 to 5 minutes
- Consistency of a soft pencil eraser

**ADVANCE CATHETERS OVER 0.035” GUIDEWIRES**

- Advance both Catheters over guidewires
- Position Catheters under fluoroscopy
- Pull back Catheter sheaths
- Reposition Catheters under fluoroscopy
Step 4: Shoot contrast through Angio-Tip to verify Seal

Allow Polymer to cure (3-5 minutes)

Adverse Aortic Neck Anatomy

Flow Model: Posterior view of aortic neck

NELLIX PRE & POST IMPLANT
CASE OVERVIEW:
6.0CM AAA WITH 10MM LENGTH NECK AND 3.5CM RCIAA

Pre-Operative: 6.3 cm AAA
Post-Operative: Type I Endoleak
30 days
60 days
Sac with limited rim enhancement and no outflow

Post Operative: 1 Year
Right Hypogastric Artery Preserved with a Nellix Extender

1 Year
EVAR for rAAA’s

- EVAR for r-AAA’s is gaining widespread use and acceptance as the best way to treat rAAA’s
- In the past general surgeons performed most of open repairs for rAAA’s
  - Today that is no longer the case
- Vascular fellows more are more comfortable performing EVAR than doing an open AAA repair
  - At a recent SVS meeting, vascular fellows felt their greatest challenge was doing open aortic procedures
- Balloon control has been found to be beneficial in open and endovascular treatment of rAAA’s

The Nellix sac sealing system appears ideally suited to treat rAAA’s

- Devices introduced via bilateral femoral access
- Balloons inflated with contrast
  - Controls bleeding & allows for fluid resuscitation
  - Outline of aneurysm sac is obtained
  - Angiogram performed from leading Nellix catheters to identify the renal arteries
- Devices are repositioned and endoframes are expanded
- Contrast in balloons is then exchanged for polymer

Balloon Expanded Endoframes

Contrast → PEG Filled Endobags

Aortogram

Nellix Single System: Rupture (4 year explant)
Excess polymer injected at implantation