Ovation Prime Endograft From TriVascular: Midterm Results And Advantages

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Ovation Prime™
Abdominal Stent Graft

Staged deployment of suprarenal stent
Polymere-filled sealing ring creates a custom seal and protects the aortic neck
Trimodular design
13-14 F Conformable iliac limbs

Background

A continuous aortic enlargement at the level of infrarenal aortic neck has been reported after endovascular repair (EVAR)

The amount of proximal device oversizing with self-expanding stent grafts (SESG) influences neck progression

Background

When aortic neck dilatation occurs, it is related to adverse mid-term outcomes

Nothing to disclose
Background

Aortic neck dilatation with balloon exp. stent graft


The Ovation stent graft (TriVascular, Santa Rosa – CA)

- New concept of sealing by non-expansive circumferential apposition of polymer-filled ring to the aortic wall

Trivascular Ovation Italian Registry (TOIS)

METHODS
- Retrospective, multicenter registry (Nov 2014)
- 13 Italian Centers of Vascular Surgery
- Only patients who had undergone implantation of a Trivascular Ovation at least 24 months previously (before Nov 2012)
- CT scans available at a minimum 2-year follow-up were collected and sent for blind reading to a centralized core laboratory.

Central database for the core lab review of morphological changes
- OsiriX MD (v.6.5.1 64-bit)
- 1 VS as single observer (intra-observer agreement 0.91)
- All vessel measurements after center line lumen (CLL) reconstructions (manual segmentation)

RESULTS
161 patients
mean age 74 ± 5
92% male
Median 32 months (range 24-50)
CT @ ≥ 24 moths 89 pts
**Trivascular Ovation Italian Registry (TOIS)**

**FOLLOW-UP**

- 17 pts died (no AAA-related death)
- 15 pts lost at follow-up

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**Survival**

<table>
<thead>
<tr>
<th>Month</th>
<th>Survival</th>
<th>Number of events</th>
<th>Number of deaths</th>
<th>Standard Error</th>
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<tr>
<td>1y</td>
<td>95.5%</td>
<td>4</td>
<td>13</td>
<td>0.086</td>
</tr>
<tr>
<td>2y</td>
<td>92.4%</td>
<td>13</td>
<td>14</td>
<td>0.075</td>
</tr>
<tr>
<td>3y</td>
<td>87.6%</td>
<td>2</td>
<td>52</td>
<td>0.027</td>
</tr>
<tr>
<td>4y</td>
<td>87.6%</td>
<td>0</td>
<td>3</td>
<td>0.027</td>
</tr>
</tbody>
</table>

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**Freedom from type 1 endoleak**

- 3 type IA endoleak
  - 1 aortic cuff, 1 balloon-expandable stent, 1 coil and glue embolization
- 4 iliac limb occlusion
  - 1 bypass, 3 surgical thrombectomy
- 1 type II endoleak
  - coil embolization

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**Morphological changes**

- Core lab: 89 CT scans
- Zone A: Patency of visceral arteries in Zone A was 100%
- Zone B deployment: The mean stent-graft landing distance to the lowest renal artery was 3.13 ± 0.45mm (SE 0.45)
Morphological changes

Zone B & C
- No Neck enlargement (≥2mm)
- No Stent graft migration (≥3mm)

Zone B
The mean change was -0.32 ± 0.87 mm (SE 0.09)

Zone C
The mean change in diameters -0.06 ± 0.97 mm (SE 0.1)

Morphological changes_Summary

Neck evolution
- Zone A +0.18 ± 0.22 mm
- Zone B -0.32 ± 0.87 mm
- Zone C -0.06 ± 0.97 mm

Spearman correlation test (Zone B vs Zone C)

Spearman correlation test (Zone B vs Zone A)

Correlation Zone B vs Zone A

Correlation Zone B vs Zone C
Conclusions

- No aortic neck dilatation occurred in patients treated with TriVascular Ovation stent graft at CT scan after a minimum 24-month follow-up.

- This may suggest that aortic neck evolution is not associated to EVAR at mid-term follow-up when an endograft with no chronic outward radial force is implanted.

Acknowledgment

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