2-year outcomes of EVAS and Ch-EVAS in abdominal aortic aneurysms based on calculated neck length: a single center study

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Disclosure

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest
Editor’s Choice — Mid-term Migration and Device Failure Following Endovascular Aneurysm Sealing with the Nellix Stent Graft System — a Single Centre Experience

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WHAT THIS PAPER ADDS
Endovascular aneurysm sealing in the treatment of abdominal aortic aneurysm (AAA) via the Nellix stent graft is reported. A year’s post implant. Stent failure is specifically related to the role of such technology in the mainstream practice.

Objective: Endovascular aneurysm sealing (EVAS) with the Nellix stent graft is reported. There are few data describing the long-term outcomes following EVAS in a single centre. This is a retrospective review of all patients treated with the Nellix stent graft at our institution.

Methods: Factors that are described as device failure are surgical procedures for treatment of endoleak, or major migration of the stent graft. The 4-year freedom from graft failure was 92.3% (95% CI 89.8%–94.3%). The 5-year freedom from graft failure was 87.1% (95% CI 83.6%–90.5%).

Results: A total of 161 patients had been treated with the Nellix stent graft. There were 14 patients who had undergone surgical procedures for treatment of endoleak, or major migration of the stent graft. The 4-year freedom from graft failure was 92.3% (95% CI 89.8%–94.3%). The 5-year freedom from graft failure was 87.1% (95% CI 83.6%–90.5%).

Conclusions: Failure of aneurysm sealing following EVAS is anticipated and can occur due to aortic rupture. Post-operative features of failure:

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Anders Wanhammar, Fabio Verzini, Isabelle Van Herzeel, Eric Allaire, Matthew Bown, Tina Cohner, Florian Dick, Joost van Herwaarden, Christos Karkos, Mark Koelemay, Tilo Kößler, Ian Loftus, Kevin Mani, Germano Melissano, Janet Powell, Zoltán Szeberin

ESVS Guidelines Committee, Gert J. de Borst, Nabil Chakfe, Sebastian Debus, Rob Hinchliffe, Stavros Kakkos, Igor Koncar, Philippe Kohl, Jes S. Lindholm, Mélina de Vega, Frank Vermassen


Endologix Announces Recall of Nellix EVAS System, Restricting Use to Prescreened Patients Within Current Indications

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January 4, 2019—Endologix, Inc. announced a voluntary recall of all existing Nellix endovascular aneurysm sealing (EVAS) systems and the stoppage of unrestricted sales and use of the device, effective immediately.

The decision to initiate the recall is to ensure optimal patient outcomes through the most appropriate use of the device, according to the company’s announcement.

Endologix noted it has determined that off-label use is occurring at an unacceptable level, with the consequence of suboptimal results.
Purpose

• two-year outcomes of EVAS and Ch-EVAS in patients with infra- or juxtarenal AAA
• treatment method based on calculated neck length (CALCL), an alternative to the traditional centerline neck length (CL) method.
Methods

- between December 2013 and December 2018
- retrospective analysis
- outcomes of patients treated with EVAS and Ch-EVAS for AAA
- Primary endpoints: mortality, major adverse events and durability.
- Patients were surveilled with CTA and CEUS.
- Effective seal length after implantation was compared to migration risk.
Neck length calculations

- geometrical analysis of neck anatomy
- 3D coordinates in R3 were used to calculate vector lengths, angles, planes
- complex mathematical calculations to predict the position of the stentgrafts in the aortic neck.
Results

- 104 patients with AAA treated with EVAS,
  - 64 with infrarenal EVAS and 40 with Ch-EVAS
- Median follow-up: 31 mo (0 – 62)
- Lost to FU: 8
- Age: 72 y
- Male proportion: 87 %
- Aneurysm diameter: 57 mm
## EVAS / Ch-EVAS

<table>
<thead>
<tr>
<th>All Patients</th>
<th>EVAS</th>
<th>Ch-EVAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>64</td>
<td>40</td>
</tr>
<tr>
<td>Age</td>
<td>72.4</td>
<td>71.8</td>
</tr>
<tr>
<td>Male</td>
<td>84%</td>
<td>90%</td>
</tr>
<tr>
<td>Aneurysm Diameter</td>
<td>56.7</td>
<td>56.2</td>
</tr>
<tr>
<td>target vessels</td>
<td></td>
<td>91</td>
</tr>
<tr>
<td>Chimney grafts</td>
<td></td>
<td>75</td>
</tr>
<tr>
<td>PTA visceral vessels</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>1 vessel chimney</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>2 vessel chimney</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>3 vessel chimney</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>renal arteries</td>
<td>68</td>
<td></td>
</tr>
<tr>
<td>access. renal art.</td>
<td>1</td>
<td></td>
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<tr>
<td>SMA</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Nellix gen. 1</td>
<td>45</td>
<td>13</td>
</tr>
<tr>
<td>Nellix gen. 2</td>
<td>19</td>
<td>27</td>
</tr>
</tbody>
</table>
Neck length

• EVAS
  – CL: 33.2 mm
  – CALCL: 27.7 mm
  – diff: 5.5 mm NS

• Ch-EVAS
  – CL: 8.9 mm
  – CALCL: 3.8 mm
  – diff: 5.1 mm p<0.05

12 patients would have been deemed on-IFU based on CL measurement

neck loss (-) or gain (+) after treatment:
EVAS: -5.3 mm
Ch-EVAS: 15.6 mm p<0.05
## Follow-Up

<table>
<thead>
<tr>
<th></th>
<th>All Patients</th>
<th>EVAS</th>
<th>Ch-EVAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-Up</td>
<td>1044 (6-1861)</td>
<td>584 (20-1659)</td>
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</tr>
<tr>
<td>Lost to FU</td>
<td>5</td>
<td>3</td>
<td></td>
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<tr>
<td>30d-Mortality</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>6</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>FU</td>
<td>849 (179-1288)</td>
<td>379 (52-796)</td>
<td></td>
</tr>
<tr>
<td>Cancer</td>
<td>0</td>
<td>2</td>
<td></td>
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<tr>
<td>Cardiac</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>CVA</td>
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<td>0</td>
<td></td>
</tr>
<tr>
<td>Unknown</td>
<td>4</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Explantation*</td>
<td>1</td>
<td>0</td>
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</tr>
<tr>
<td>EVAS repair</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Migration &gt; 5 mm</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Type I EL</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

*Explantation: sac infection after nephrectomy for cancer*
All Cause Mortality

\[ p = 0.10 \text{ NS} \]
All Event (Mortality + repair)

\[ p = 0.09 \text{ NS} \]
All events / IFU

All criteria:
- on IFU: 30 (28.8 %)
- out IFU: 74

p = 0.06 NS

Neck criteria:
- on IFU: 54 (51.9 %)
- out IFU: 50

p = 0.40 NS
Target vessel patency

- Chimney stenosis: 1 successful PTA
- Chimney occlusion: 1 successful PTA
- primary patency target vessels: 89/91
- primary patency CG: 73/75
Reasons for migration

- 4 migrations in EVAS patients
- 2 technical failures:
  - displacement too low in 2 patients (EL)
  - association tapered neck + high thrombus burden in 2 cases

<table>
<thead>
<tr>
<th>CL</th>
<th>CALCL</th>
<th>dist. R-NX</th>
<th>uncovered</th>
<th>remaining shortest NL</th>
<th>migration during FU</th>
<th>EL during FU</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>9</td>
<td>-8</td>
<td>5</td>
<td>-4</td>
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<tr>
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<td>13</td>
<td>-9</td>
<td>5</td>
<td>-1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>20</td>
<td>16</td>
<td>4</td>
<td>4</td>
<td>16</td>
<td>1</td>
<td>0</td>
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<td>43</td>
<td>43</td>
<td>0</td>
<td>5</td>
<td>38</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

- 1 migration in 1-vessel Ch-EVAS
- short remaining neck length in angulated neck
Conclusion

- Patient selection according to straight position sealing length for EVAS or Ch-EVAS correlated with satisfactory two-year outcomes.
- CL neck length measures leads to false on-IFU decision
- Treatment of short and angulated necks with Ch-EVAS is a safe method.
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