Nellix: Lessons Learned from the EVAS Forward Global Registry and the Future Role of Polymer Sealing in AAA Management

Andrew Holden, MBChB, FRANZCR, EBIR
Director of Interventional Radiology
Auckland, New Zealand

LINC 2018
Disclosure

Speaker name: Andrew Holden.

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [X] Other – Clinical Investigator for ELGX
- [ ] I do not have any potential conflict of interest
Concept of *EndoVascular Aneurysm Sealing (EVAS)* with Nellix®

- Different method of aneurysm treatment with “active sac management”
- Analogous to open surgical repair with sac ablation
- Aim is to prevent endoleak of any type
- So how has it performed, what are the lessons learned and what is its potential in the future?
Validating EVAS with Clinical Data


**EVAS FORWARD GLOBAL REGISTRY**

- **N=300**
- 30 Centers (29 EU, 1 NZ)
- Enrollment Completed Sept, 2014
- 1 YR FU 2 YR FU 3 YR FU

No prospective screening, procedural steps not optimized

**EVAS FORWARD IDE**

- **N=180**
- 29 Centers (26 US, 3 EU)
- Enrollment Completed Nov, 2014
- 30 DAY FU 1 YR FU 2 YR FU

Strict IFU compliance, procedural steps evolved
Spontaneous Resolution of Type II Endoleak

Low Volume 0.1 – 0.4 mL

99.2% Freedom From Type II Endoleak
Freedom From Type II Endoleak

No Secondary Interventions for Type II Endoleak
Freedom From All Persistent Endoleak @ 2 Years

All Endoleak 1.8% (5) (N = 277)

<table>
<thead>
<tr>
<th>Type</th>
<th>Frequency</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type Ia</td>
<td>0.4% (1)</td>
<td></td>
</tr>
<tr>
<td>Type Ib</td>
<td>0.4% (1)</td>
<td></td>
</tr>
<tr>
<td>Type II</td>
<td>0.7% (2)</td>
<td></td>
</tr>
<tr>
<td>Type III</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Type Unknown</td>
<td>0.4% (1)</td>
<td></td>
</tr>
</tbody>
</table>

Mean follow-up 25 mo (0-35 mo)
Similar Positive Results - EVAS FORWARD IDE @ 2 Years

97% FREEDOM FROM TYPE II EL

99% FREEDOM FROM RUPTURE

Freedom from Type II Endoleak

Freedom from Rupture
Similar Positive Results - EVAS FORWARD IDE @ 2 Years

99% FREEDOM FROM CARDIOVASCULAR MORTALITY

94% FREEDOM FROM ALL CAUSE MORTALITY
Cross Trial Comparison @ 1 Year

<table>
<thead>
<tr>
<th>Classification</th>
<th>≤30 days</th>
<th>31d – 1yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Cause Death</td>
<td>3 (1.1%)</td>
<td>11 (4.0%)</td>
</tr>
<tr>
<td>Peri-operative mortality</td>
<td>3 (1.1%)</td>
<td>-</td>
</tr>
<tr>
<td>AAA-related mortality</td>
<td>-</td>
<td>1 (0.4%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persistent Endoleaks</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Endoleak (total T1ELs detected - 17)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1A</td>
<td>3 (1.1%)</td>
<td>1 (0.35%)</td>
</tr>
<tr>
<td>Type 1B</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 2</td>
<td>2 (0.4%)</td>
<td>1 (0.35%)</td>
</tr>
</tbody>
</table>

**Freedom from re-intervention @ 1 year = 92.3%**

<table>
<thead>
<tr>
<th>Classification</th>
<th>0-30 days</th>
<th>0 – 365 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Cause Death</td>
<td>1 (0.7%)</td>
<td>6 (4.0%)</td>
</tr>
<tr>
<td>Peri-operative mortality</td>
<td>1 (0.7%)</td>
<td>-</td>
</tr>
<tr>
<td>AAA-related mortality</td>
<td>1 (0.7%)</td>
<td>2 (1.3%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persistent Endoleaks</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Endoleak (total T1ELs detected - 2)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1A</td>
<td>1 (0.7%)</td>
<td>-</td>
</tr>
<tr>
<td>Type 1B</td>
<td></td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Type 2</td>
<td>8 (5.6%)</td>
<td>3 (2.3%)</td>
</tr>
</tbody>
</table>

**Freedom from re-intervention @ 1 year = 96.3%**

IFU compliance does influence re-intervention.
Continued Evolution of Nellix® EVAS

- Despite the excellent results @ 2 years, late complications noted in clinical practice and trials, predominantly after 2 years
- These are migration, type IA endoleak and aneurysm sac growth
- To mitigate these complications, there has been evolution in the procedure, device and IFU
Continued Evolution of Nellix ® EVAS
Nellix EVAS: A Procedure in Evolution

Patient **SELECTION**
Proper **POSITIONING** of the Nellix Device
Establishment of a Durable **SEAL**
Nellix EVAS: A PROCEDURE in Evolution

- Inflate Nellix balloons to nominal pressure (7 ATM) for AT LEAST 30 seconds
- Leave balloons up during unfurling, pre-fill and polymer – avoids stent displacement and bowing

### Proximal Neck Utilization

**Reduced Reintervention Risk**

<table>
<thead>
<tr>
<th></th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal Endoleak</td>
<td>0.946</td>
<td>0.884, 1.013</td>
<td>0.1121</td>
</tr>
<tr>
<td>Proximal Reintervention</td>
<td>0.339</td>
<td>0.891, 0.990</td>
<td><strong>0.0195</strong></td>
</tr>
</tbody>
</table>
Nellix EVAS: A PROCEDURE in Evolution

- Complete endobag filling is vital to achieve optimum seal
- Unfurling of the endobag before deployment of the stents allows optimum endobag conformability
- Pre-fill of the endobags after stent deployment with dilute contrast saline allows optimum positioning and calculation of endobag fill volume
Nellix EVAS: A DEVICE in Evolution

Gen2 Nellix

- Distal Endobag Attachment
- Integrated angiography holes
- Longer stents
- More flexible inner core
- Ability to exchange guidewire
- Polymer disposable dispenser
- Simplified console design

≥ 10mm seal
Revised Anatomic IFU for Most Predictable Outcomes

96% 2 Year Freedom from Type IA Endoleak, Migration, or Sac Growth

1. Aortic Proximal Neck Diameter
   - From 18-32 mm diameter
   - To 18-28 mm diameter
   - IA Endoleak
   - Migration

2. Aortic Neck Diameter Change
   - From ≤20%
   - To ≤10%
   - IA Endoleak

3. Aortic Aneurysm Diameter_{Max}
   - Aortic Blood Lumen Diameter_{Max} ≤1.40 ratio
   - Migration

4. Distal Seal Zone
   - • Iliac Artery Inner Wall Diameter
   - • Distal Iliac Artery Seal Zone ≥10 mm length
   - IB Endoleaks
   - Aneurysm Enlargement
IFU Impact on Longer Term Data

IFU REFINEMENT AND TYPE IA ENDOLEAK

- Single Centre audit of 115 consecutive cases
- Auckland Hospital
- Minimum follow up 2 years
- Mean follow up 3.5 years
Prospective Evaluation of Revised IFU

- 300 patient trial in Europe and Asia-Pacific
- Follow up out to 5 years

First Global FORWARD 2 Registry Patient

- Up to 90 patients, 28 US sites
- Follow up out to 5 years
Endovascular Bailout Options Now Approved
So, Who Do I Treat with Nellix in 2018?

- **Patients who are on the revised IFU:**
  - Part of a clinical trial
  - Expect outstanding outcomes in terms of freedom from any endoleak, migration and re-intervention
  - Morbidity/mortality benefits of “active aneurysm sac”

- **Patients with large aortic side branches (high risk of T2EL):**
So, Who Do I Treat with Nellix in 2018?

- Patients who concomitant iliac aneurysm disease:
  - Short common iliac arteries
  - CIA aneurysms with preservation of the internal iliac artery
So, Who Do I Treat with Nellix in 2018?

- Patients with failed EVAR and open repair:
  - Endobag sealing excellent treatment for T1 and T3 endoleaks
  - Two tube repair particularly suitable for short body grafts (avoids AUI)

**Type 1A Endoleak Repair**

- Excluder
- Anaconda
- Talent

**Type 3A Endoleak Repair**

- Courtesy of Francesco Torrella, MD, Liverpool, UK
- Courtesy of JP de Vries, MD, PhD, Nieuwagen, NL
- Courtesy of Michel Reijnen, MD, PhD, Arnhem, NL

**Type 1A Endoleak Repair - ChEVAS**

Andrew Holden MD, Auckland NZ
So, Who Do I Treat with Nellix in 2018?

- Hostile neck anatomy with ChEVAS:
  - Especially patients declined for FEVAR or need urgent treatment

- More imaginative use of parallel grafts:
Conclusions

- EVAS is a disruptive technology providing unique “active sac management”
- Not surprisingly, there have been challenges in achieving a durable seal but these are now well understood with strategies to avoid and treat complications now developed
- Outstanding results should be possible with compliance with the revised IFU – this will be prospectively tested in EVAS FORWARD 2 and EVAS 2 IDE
- There are some clear indications for EVAS in 2018
- Exciting developments in the future
Nellix: Lessons Learned from the EVAS Forward Global Registry and the Future Role of Polymer Sealing in AAA Management

Andrew Holden, MBChB, FRANZCR, EBIR
Director of Interventional Radiology
Auckland, New Zealand

LINC 2018