IMPORTANCE OF GOOD SEAL ZONES AND PROCEDURAL ACCURACY IN GETTING GOOD RESULTS WITH NELLIX ENDOGRAFTS AND EVAS

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Disclosure
Matt Thompson.
✓ I have the following potential conflicts of interest to report:
Consulting
✓ Employment in industry
✓ Shareholder in a healthcare company
✓ Owner of a healthcare company
Other(s)
I do not have any potential conflict of interest

PROMISING RESULTS, DESPITE PUSHING IFU (GLOBAL REGISTRY)

FF TYPE II ENDOLEAK, RUPTURE, ARM, ACM

2015
2018-2019
2017
2016
2020-2022

GLOBAL REGISTRY: N=300, ALL-COMERS (37% OFF-IFU)
IDE: N=333, CONTROLLED

2013-2014

ROOT CAUSE ANALYSES
Clinical
Imaging
Engineering
Statistical

1Y FREEDOM FROM ENDOLEAK, REINTERVENTION, RUPTURE
2Y EVENTS

TYPE IA ENDOLEAK
MIGRATION
SAC GROWTH

ACHIEVED SEAL ZONE AND OUTCOMES

19 patients met revised IFU – 6 “graft failures”

REFINED IFU AND OUTCOMES

Endologix products and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability.
Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only.
CAUTION: The Nellix® EndoVascular Aneurysm Sealing System is an investigational device. Limited by federal (or United States) law to investigational use only.

RECENT PUBLICATIONS

Anatomical Predictors of Endoleaks or Migration After Endovascular Aneurysm Sealing

ACHIEVED SEAL ZONE AND OUTCOMES

- Initial thoughts on EVAS procedure were to “seal the aneurysm”
- Review of “on label” targets with “events” suggested an analysis of achieved vs available seal zones
- Initial logistic regression using sac expansion and “on label” subjects as proof of concept, expanded to all events in all subjects
- Anatomical parameters still strongest predictor of adverse events
- Achieved seal zones and low placement of devices also associated with adverse events
### ACHIEVED SEAL ZONE AND OUTCOMES – LOGISTIC REGRESSION

<table>
<thead>
<tr>
<th>Population</th>
<th>Outcome</th>
<th>Predictor</th>
<th>OR (95% CI)</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-target</td>
<td>Sac Expansion</td>
<td>Achieved proximal seal zone</td>
<td>0.935 (0.877, 0.996)</td>
<td>Every mm increase in achieved seal, odds of experiencing an event went down by 6.5%.</td>
</tr>
<tr>
<td>Entire study</td>
<td>Migration</td>
<td>Achieved proximal seal zone</td>
<td>0.954 (0.927, 0.981)</td>
<td>Every mm increase in achieved seal, odds of experiencing an event went down by 4.6%.</td>
</tr>
<tr>
<td>Entire study</td>
<td>Sac Expansion</td>
<td>Achieved proximal seal zone</td>
<td>0.965 (0.930, 0.992)</td>
<td>Every mm increase in achieved seal, odds of experiencing an event went down by 3.5%.</td>
</tr>
<tr>
<td>Entire study</td>
<td>Sac Expansion</td>
<td>Achieved distal seal zone</td>
<td>0.955 (0.922, 0.989)</td>
<td>For every millimeter increase in achieved seal, the odds of experiencing an event went down by 4.5%.</td>
</tr>
<tr>
<td>Entire study</td>
<td>Low stent placement</td>
<td></td>
<td>1.132 (1.025, 1.25)</td>
<td>For every millimeter below the renales, the odds of experiencing an event goes up 13%.</td>
</tr>
</tbody>
</table>

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EVAS AND TECHNICAL PROCEDURE

- Continuing to understand a new therapy after initial learnings
- Anatomical parameters still strongest predictor of adverse events
- Technical adequacy of procedure is important and training for EVAS2 reflects this
- Despite fundamental differences between EVAS and EVAR, importance of seal zones analogous to EVAR

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