Status of the LEOPARD Trial to Compare Outcomes of On-the-Bifurcation Fixation with the Endologix AFX EVAR Device to Current Proximally-Fixed EVAR Endografts

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Faculty Disclosures

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EVAR Is 23-Years Old

J.C. Parodi, J.C. Palmaz, and H.D. Barone,
Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysm

Historic EVAR Evidence is 10-years Old (and does not reflect current practice)

What Have We Learned About EVAR?

• Lower perioperative mortality
• No sustained long-term mortality benefit
• No consensus on cost-effectiveness

BUT

• Older studies
• Old devices
• Mostly on-IFU patients

And Close to 40% Are Treated Outside of the IFU

J.C. Parodi, J.C. Palmaz, and H.D. Barone,
Transfemoral Intraluminal Graft Implantation for Abdominal Aortic Aneurysm

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Published Data Sets Are at Best “Hypothesis-generating”

- Retrospective analyses
- Individual centers
- Multiple generations of devices
- Inconsistent results

Economic Pressures Are Rising

Cost-effectiveness of conventional and endovascular repair of abdominal aortic aneurysms: Results of a randomized trial

LEOPARD Study
Looking at EVAR Outcomes by Primary Analysis of Randomized Data

- Prospective, randomized, multicenter study
- Real-world patient population
- Head-to-head comparison on commercially available endograft systems
  - Outcomes
  - Costs

Basis for Randomization

- AFX® versus alternative EVAR devices
- Unique design of AFX
  - Anatomic fixation suppresses graft migration independent of anatomy of the neck
  - Sealing zones defined by highly conformable ePTFE graft material
  - Preservation of native bifurcation

Primary Endpoint
Survival in the absence of Aneurysm Related Complications (ARC) at 12 months. ARC is a composite of most relevant EVAR related outcomes:

- Periprocedural death (<30d)
- Rupture
- Conversion to Open Surgical Repair
- Endoleak
- Migration >10 mm
- Aneurysm Enlargement >5 mm
- Occlusions
- Secondary Endovascular Procedure for Device or Aneurysm Related Indication

All Endoleaks Impact EVAR Success

All endoleaks impact EVAR success.
Economic Burden of Endoleaks


Distribution of Endoleaks, By Type*

<table>
<thead>
<tr>
<th>Type</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Type I</td>
<td>17%</td>
</tr>
<tr>
<td>Type II</td>
<td>59%</td>
</tr>
<tr>
<td>Type III</td>
<td>24%</td>
</tr>
</tbody>
</table>

*19.9% (27/136 pts) total endoleak rate

5-year Cumulative Post-implant Costs

- Patients without endoleak: $5,706
- Patients with endoleak: $26,739

Study Design

- Prospective, randomized, multi-center, “all-comers” design
- Independent core lab analysis and event adjudication
- Sample size: 800
- Sites: 80 Sites maximum
- Enrollment: 18 months
- Follow-up: 5 years
- Powered for two-staged hypothesis testing
  - Non-inferiority followed by superiority

Study is Powered To Show Superiority of AFX

- MAEs at 30 days, 12 months and annually
- Aneurysm-related complications (ARC) post 12 months, up to 5 years
- Aneurysm-related mortality (ARM)
- Endoleaks classified by type
- Loss of neck apposition
- AAA-related secondary procedures up to 5 years
- Device integrity throughout study
- Component utilization
- Total radiation exposure
- % bilateral PEVAR
- Access-related complications

Planned Economic Sub-Studies

- Economic Sub-study
  - Subset of the study population will be part of an economics outcomes assessed by site specific billing information
- Patient Related Outcomes
  - Subset of the study population will be assessed for certain patient-related outcomes indicative of patient satisfaction and QoL

Modern Cost and Comparative Effectiveness*

SUMMARY

- Critical need for Level 1 evidence in contemporary, real-world patient population using commercially available EVAR devices
  - Understanding the outcomes
  - Guiding treatment strategies
  - Therapy cost analysis
  - Solid reference for future therapy developments
- LEOPARD
  - Robust, statistically powered study design
  - Independent core-lab and CEC
  - Landmark data set for future EVAR-EVAS comparison

* Independent analysis