The ARCHYTAS worldwide post-market registry

Vincent Riambau, MD, PhD
Professor and Chief of Vascular Surgery
Hospital Clinic
University of Barcelona
Disclosure

Speaker name:

• V. Riambau, MD, PhD

I have the following potential conflicts of interest to report:

• Consulting:
  • Lombard Medical
  • Bolton Medical
  • Medtronic
  • W.L. Gore
  • Aptus
  • Cordis
  • Jotec
  • C.R. Bard
  • iVascular
ARCHYTAS Registry

**AAA Registry: Clinical outcomes of Highly angulated anatomy Treated with the Aorfix™ Stent graft.**

**Registry Rationale**

To prospectively quantify the global clinical outcomes of the Aorfix™ stent graft in real world EVAR cases.
ARCHYTAS Registry

Objective

- This Registry, is designed to **compliment Pythagoras IDE study** (Aorfix™ performance in neck angles of 0° to 90° and challenging anatomies) on a **global stage**.

Study Parameters and features

- **Inclusion/Exclusion criteria** as per IFU → More challenging anatomies
- Physician lead patient follow-up schedule → **Authentic and validated practice guidelines**
- **Core-lab** assessed pre-op imaging → Solid bases for forming analysis groups
- **Fully monitored data capture** → Robust dataset
- Up to **5 years follow-up** planned → Long term clinical performance of Aorfix™
- **Global patient recruitment** → True variability in patient cohort
Aorfix™ meets the challenge

On label choice

- Aorfix™ is the only endovascular stent graft with both CE mark and FDA approval to treat aneurysms in complex anatomies with neck angulations of up to 90°

- Approximately 4000 Aorfix™ stents implanted worldwide

- 6 years of clinical data in the US and over 10 years in Europe

Aorfix™ design allows clinicians to expand the reach of their EVAR practice.
<table>
<thead>
<tr>
<th>Year Completed</th>
<th>Patients</th>
<th>Neck Angle</th>
<th>Centres</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>First Patient</td>
<td></td>
<td></td>
<td>First in man</td>
</tr>
<tr>
<td>2004</td>
<td>24</td>
<td>0° to 65°</td>
<td>4</td>
<td>CE mark study</td>
</tr>
<tr>
<td>2009</td>
<td>30</td>
<td>60° to 90°</td>
<td>9</td>
<td>CE mark study for 90° necks</td>
</tr>
<tr>
<td>2012</td>
<td>218</td>
<td>0° to 90°</td>
<td>45</td>
<td>US IDE study – FDA approval in 2013</td>
</tr>
<tr>
<td>2014</td>
<td>234</td>
<td>0° to 90°</td>
<td>~50</td>
<td>US post-approval study (using VQI)</td>
</tr>
<tr>
<td>To Start 2015</td>
<td>500</td>
<td>0° to 90°</td>
<td>~50</td>
<td>Proposed Global Registry</td>
</tr>
<tr>
<td>Year Completed</td>
<td>Patients</td>
<td>Neck Angle</td>
<td>Centres</td>
<td>Comment</td>
</tr>
<tr>
<td>----------------</td>
<td>----------</td>
<td>------------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>2001</td>
<td>First Patient</td>
<td></td>
<td></td>
<td>First in man</td>
</tr>
<tr>
<td>2004</td>
<td>24</td>
<td>0° to 65°</td>
<td>4</td>
<td>CE mark study</td>
</tr>
<tr>
<td>2009</td>
<td>30</td>
<td>60° to 90°</td>
<td>9</td>
<td>CE mark study for 90° necks</td>
</tr>
<tr>
<td>2012</td>
<td>218</td>
<td>0° to 90°</td>
<td>45</td>
<td>US IDE study – FDA approval in 2013</td>
</tr>
<tr>
<td>2014</td>
<td>234</td>
<td>0° to 90°</td>
<td>~50</td>
<td>US post-approval study (using VQI)</td>
</tr>
<tr>
<td>To Start 2015</td>
<td>500</td>
<td>0° to 90°</td>
<td>~50</td>
<td>Proposed Global Registry</td>
</tr>
</tbody>
</table>
Registry Key Points

- Global Multi-centre nonrandomized single-arm prospective Registry
- Real world clinical Registry for Aorfex™
- 300 patients, 30 sites with an option to extend to 500 patients, 50 sites
- Overall Lead Registry PI – Prof. Riambau, Spain
- Country Level PIs
- Core lab image analysis
- Emphasis on data quality (monitored)
Expected Site Locations

EU: Spain, Germany, Poland, Czech Republic, Italy, UK
Russia
US
Latin America
Japan

Aorfix™ Registry will be expanded to further countries following local product approvals.
Registry Design

Reflects real-world, on-label practices through the following:

- Broad patient inclusion criteria per IFU
- Rigorous remote and on-site data entry and review (similar to clinical trial)
- Monitoring for defined outcomes
- Capture of primary and adjunctive interventions
- Physicians can dictate follow-up regimen per standard practices - expected norms are outlined in protocol
Imaging Guidelines

- Sites to follow standard of care for imaging
- Analysis by Independent Imaging Core Lab

<table>
<thead>
<tr>
<th>Imaging Type</th>
<th>Pre-Op</th>
<th>Discharge</th>
<th>Post-Op period to 6 months</th>
<th>12 months</th>
<th>Annually to 5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT*</td>
<td>✓</td>
<td>AR</td>
<td>AR</td>
<td>AR</td>
<td>AR</td>
</tr>
<tr>
<td>Duplex Ultrasound</td>
<td>AR</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>X-ray KUB (4-view)</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

* contrast enhanced (preferred not mandatory) spiral CT, <3 mm slices, overlapping images. AR= As Required
Primary Outcome Measures:
- Treatment success (12 months)
- Freedom from: sac expansion > 5mm, type I and III endoleaks requiring re-intervention, rupture, conversion to open surgery, graft migration, occlusion

Secondary Outcome Measures: (evaluated annually)
- Stent graft migration > 10 mm (12 months)
- Stent graft patency (12 months)
- Changes in aneurysm diameter (12 months)
- Stent graft endoleaks (post-op and 12 months)
- Aneurysm-related secondary procedures (12 months)
- Adverse device effects, Technical observations, Aneurysm-related mortality (12 Months)
- All-cause mortality (30 days and 12 months)
- Major Adverse Events (30 days)
Inclusion/Exclusion Criteria

Sites to screen and enroll consecutively

**Inclusion**

- Diagnosed abdominal aortic aneurysm with indication for endovascular repair
- Intention to electively implant the Aorfix™ Stent Graft System

**Exclusion**

- Patients unsuitable as outlined in IFU
- Unwilling or unable to return for follow-up visits
- Excludes use of Aorfix™ for re-do of competitor devices
Site Selection Criteria

- High Volume sites with annual case volume of approximately 30 AAA Stent Graft Procedures
- Ability to enroll 10 patients per year
- Adequate experience implanting the Aorfix™ device
- Resources to perform research-related tasks and follow-up patients for 5 years
- Regulatory/ethics approval (and patient informed consent or data-release authorisation) where required

Please contact Lombard Medical if you are interested in participating in the ARCHYTAS Registry:

www.lombardmedical.com
Active Sites at January 2015

- 21 active sites going through ethics committee approval across 6 countries

<table>
<thead>
<tr>
<th>Hospital 1</th>
<th>Hospital 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>H. Universitari Dr. Josep Trueta, Girona (SPAIN)</td>
<td>Bristol/Bath (UK)</td>
</tr>
<tr>
<td>Universitätsklinikum Leipzig (Germany)</td>
<td>Prague University Hospital (Czech Rep)</td>
</tr>
<tr>
<td>Bonifatius Hospital, Lingen (Germany)</td>
<td>Elisabeth-Krankenhaus Essen (Germany)</td>
</tr>
<tr>
<td>Nottingham University Hospital Queens Medical Centre (UK)</td>
<td>Auckland Hospital (New Zeland)</td>
</tr>
<tr>
<td>Ospedale Papa Giovanni 23, Bergamo (Italy)</td>
<td>Universitätsklinikum Würzburg (Germany)</td>
</tr>
<tr>
<td>Hospital Universitario Donostia (SPAIN)</td>
<td>Ospedale Sant'Andrea delle Fratte, Perugia, (Italy)</td>
</tr>
<tr>
<td>Norfolk &amp; Norwich University Hospital (UK)</td>
<td>Complexo Hospitalario Universitario de Ourense (SPAIN)</td>
</tr>
<tr>
<td>Klinikum Rechts der Isar der TU München (Germany)</td>
<td>Northwick Park Hospital (UK)</td>
</tr>
<tr>
<td>Sant'Anna, Como (Italy)</td>
<td>Hospital Clinic, Barcelona (SPAIN)</td>
</tr>
<tr>
<td>H. Marqués de Valdecilla, Santander (SPAIN)</td>
<td>H. Puerta del Mar. Cádiz (SPAIN)</td>
</tr>
<tr>
<td>Charité - Universitätsmedizin Berlin Campus Virchow-Klinikum (Germany)</td>
<td></td>
</tr>
</tbody>
</table>
Electronic Database

- Internet-based
- Secure
- Training & Support provided
- Remote and on-site monitoring
ARCHYTAS is a global registry aimed to evaluate the AORFIX performance in highly angulated anatomies, with on-label use basis and over 5-year follow up.
Thank you

Questions?
The ARCHYTAS worldwide post-market registry

Vincent Riambau, MD, PhD
Professor and Chief of Vascular Surgery Hospital Clinic
University of Barcelona