EXCOR® Pediatric Update

Worldwide Clinical Experience with EXCOR® Pediatric

The EXCOR® Pediatric is the only paracorporeal ventricular assist device that can reliably support children from newborns to teenagers for weeks and months. For 22 years, EXCOR® Pediatric has been successfully used in increasing numbers at 147 pediatric heart centers in 35 countries worldwide.

1. More than 1,200 EXCOR® Pediatric Implantations documented in Database

2. Demography

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>4.7 years (2 d. - 17 y.)</td>
<td>2.0 years</td>
</tr>
<tr>
<td>Female</td>
<td>47%</td>
<td>53%</td>
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</tbody>
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3. Type of Support

<table>
<thead>
<tr>
<th></th>
<th>BVAD</th>
<th>LVAD</th>
<th>RVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>41%</td>
<td>58%</td>
<td>1%</td>
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</table>

4. Pre Operation Conditions*

- Most frequent diagnosis: 49% DCMP
- 29% emergency patients
- 94% NYHA level 4
- 33% on MCS
- 2.1 l/min/m² mean cardiac index
- 1.9 l/min mean cardiac output
- 19.3% LVEF

*of patients where data was given
5. Outcome

- Cumulative time on device: 314 years
- Mean time on device: 89.5 days (up to 1096 days)

Excellent Survival

Competing outcome of EXCOR® Pediatric patients for BVAD, LVAD and RVAD (n=1279).

Competing survival by support type of EXCOR® Pediatric patients (n=1248).

Overall survival of the most frequent diagnosis of EXCOR® Pediatric patients (n=1237).

Time on device of EXCOR® Pediatric patients (n=1279).

6. Ongoing Clinical Trials

- "Remaining activity of Carmeda® coating in EXCOR® blood pumps"
  Study design: International multi-center research project
  Objective: Evaluation of the activity of the remaining Carmeda® coating regarding durability after clinical use as measured by heparin bioactivity, heparin density and staining uniformity.
  Start enrollment: July 2011
  Investigator sites: Gothenburg (Sweden), Helsinki (Finland)

- Early Product Surveillance "EXCOR® Pediatric 15ml pump"
  Study design: European multi-center early product surveillance
  Objective: Evaluation of safety and utility of the EXCOR® Pediatric 15ml pump
  Start enrollment: February 2013
  Investigator sites: Bad Oeynhausen (Germany), Newcastle (UK), London (UK), Berlin (Germany)