The PRELIEVE trial: Final 1-year outcomes of the prospective atrial flow regulator study

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On behalf of PRELIEVE trial

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**Background:** Implantation of the Atrial Flow Regulator (AFR) with an 8 or 10mm interatrial fenestration reduces left sided filling pressures in symptomatic heart failure (HF). Here, we report the final one-year results on safety and efficacy of the AFR in HF patients.

**Methods:** PRELIEVE is a prospective, non-randomized, multi-center, single-arm study in HF patients with reduced (HFrEF) or preserved (HFpEF) ejection fraction. Patients with elevated fillings pressure at rest received an 8mm shunt device while those with exercise-induced rise in filling pressure received a 10mm AFR shunt device.

**Results:** Out of 109 enrolled patients 106 patients (n=62 HFrEF and n=44 HFpEF) received a successful device implantation (n=86 8mm AFR and n=20 10mm AFR). All-cause and cardiovascular mortality were 21% and 14% respectively in HFrEF and 7% and 0% respectively in HFpEF. HF hospitalization rate was 19% in HFrEF and 9% in HFpEF. In 85 patients (n=44 HFrEF and n=41 HFpEF) with completed follow-up, device patency was documented in all patients having adequate image quality at 1-year follow-up (n=78). NYHA class >1 increase was noted in 67.5% HFrEF and 63.7% HFpEF patients.

Quality of life assessed from the KCCQ score (overall summary score) increased from 49 + 23 to 72+24 in HFrEF and from 41+20 to 55+26 in HFpEF patients. Improved KCCQ >5 points was noted in 67.4% HFrEF and 44.7% in HFpEF patients. Six minute walking distance increased from 203+101m to 269+108m in HFrEF and from 228+121 m to 253+109m in HFpEF. Improved walking distance by either 50 m or by 50% was noted in 59.5% in HFrEF and 41.2% in HFpEF patients.

Among echocardiography parameters, right ventricular diameter tended to increase in patients receiving 10 mm shunt device (Delta 1year vs. baseline 3.1 +11.2 mm), no changes were observed in patients treated with 8 mm shunt device. Note, pacemaker presence or resting pulmonary vascular resistance were similar.

**Conclusions:** Implantation of AFR device with either 8 or 10 mm shunt size in HF patients was safe and feasible irrespective of baseline ejection fraction. Signals of clinical efficacy were observed in the majority of patients. This study warrants further clinical evaluation of the AFR device in HF.

**Table 1. Clinical efficacy parameters 6-minute walking distance (6MWD) and quality of life (KCCQ)**

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>6 months</th>
<th>12 months</th>
<th>Delta 12 months vs. baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>6MWD (m) HFrEF n=45</td>
<td>203 ± 101</td>
<td>258 ± 104</td>
<td>269 ± 108</td>
<td>67 ± 124</td>
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<tr>
<td>6MWD (m) HFpEF n=35</td>
<td>228 ± 121</td>
<td>273 ± 108</td>
<td>253 ± 109</td>
<td>29 ± 104</td>
</tr>
<tr>
<td>KCCQ (overall score) HFrEF n=43</td>
<td>49 ± 23</td>
<td>72 ± 17</td>
<td>72 ± 24</td>
<td>23 ± 29</td>
</tr>
<tr>
<td>KCCQ (overall score) HFpEF n=38</td>
<td>41 ± 20</td>
<td>60 ± 28</td>
<td>55 ± 26</td>
<td>16 ± 26</td>
</tr>
</tbody>
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Clinical efficacy parameters