The Coronary Sinus Reducer
A Device Based Therapy for Refractory Angina: Efficacy and Safety
Results from the Ongoing Open Label Registry

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Introduction:
An increasing number of patients with advanced coronary artery disease have refractory angina pectoris with poor quality of life despite optimal medical therapy. Treatment of chronic refractory angina remains an every-day challenge for the cardiologist. Patients with refractory angina pectoris are limited in their exercise capacity, have poor quality of life and have an increased level of anxiety and depression.

The CE Marked CS Reducer is currently enrolling patients in the Coronary Sinus Reducer for Treatment of Refractory Angina (COSIRA) Study and the REDUCE-1 Registry.

**COSIRA** is a prospective, multicenter, randomized, double-blind, sham-controlled clinical trial, with severe refractory angina who are not candidates for revascularization

**REDUCE-1** is an open label, multicenter, nonrandomized, prospective registry in EU and Israel, to evaluate the safety and efficacy of the CS Reducer in patients suffering from severe angina despite medical therapy.

We present here the current results of the first 11 patients of the Reduce-1 Registry who completed the 6-months follow up.

Methods:
Baseline (before CS Reducer implantation) and 6 months follow-up evaluations consist of clinical assessment, CCS (Canadian Cardiovascular Society) score, and objective evaluation of ischemia by stress test (exercise duration, time to chest pain and time to ST depression, Duke Score), dobutamine echocardiography (calculated wall motion score index, LV ejection fraction), and stress thallium scan (summed rest score and summed stress score).

All 11 patients completed the clinical evaluation at 6 months follow up. To date, only 6 patients have completed the full objective ischemia evaluation at 6 months follow up.

The difference between baseline and 6 months post Reducer implantation results were compared using Wilcoxon Signed Ranks for paired results. Data is presented as median and Interquartile Range (IQR) values.
Results:

Eleven patients have been evaluated at baseline and 6-months after CS Reducer implantation. No complications or any cardiac adverse events were recorded during the peri-procedural and the follow-up periods.

- Clinical parameters: CCS angina score and sublingual nitro daily consumption improved significantly 6 months after Reducer implantation, (Table 1, Figure 4).
- Exercise stress test parameters including exercise duration, time to 1mm ST segment depression and Duke Score were all improved, (Table 1).
- Thallium SPECT parameters, including summed rest score (SRS) and summed stress score (SSS) improved significantly after Reducer implantation, (Table 1).
- Echo dobutamine: Six months after Reducer implantation stress wall motion score improved and median LVEF values improved from 50% to 60% following dobutamine infusion.

Table 1:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Baseline parameters before CS Reducer (Median and IQR)</th>
<th>6 months after CS Reducer (Median and IQR)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCS angina score</td>
<td>3.0 (2-4)</td>
<td>1.0 (1-3)</td>
<td>0.004</td>
</tr>
<tr>
<td>Daily sub-lingual nitro</td>
<td>3.5 (0-10)</td>
<td>0.0 (0-6)</td>
<td>0.068</td>
</tr>
<tr>
<td>Exercise duration (min)</td>
<td>3.12 (1-6)</td>
<td>5.0 (3-8)</td>
<td>0.075</td>
</tr>
<tr>
<td>Time to ST segment depression (min)</td>
<td>2.04 (0-3)</td>
<td>4.53 (1-6)</td>
<td>0.66</td>
</tr>
<tr>
<td>Duke Score</td>
<td>-7.70 (-30 - -2)</td>
<td>-5.94 (-13-8)</td>
<td>0.23</td>
</tr>
<tr>
<td>SPECT SRS</td>
<td>7.5 (5-12)</td>
<td>3.0 (2-8)</td>
<td>0.043</td>
</tr>
<tr>
<td>SPECT SSS</td>
<td>19 (8-29)</td>
<td>9.5 (3-12)</td>
<td>0.027</td>
</tr>
<tr>
<td>Wall motion score (stress)</td>
<td>1.8 (2-3)</td>
<td>1.15 (1-2)</td>
<td>0.066</td>
</tr>
<tr>
<td>LVEF at rest and at peak dobutamine infusion (%)</td>
<td>50-50 (45-55)</td>
<td>50-60 (50-65)</td>
<td>0.08</td>
</tr>
</tbody>
</table>
Figure 4:
CCS Angina Score before and 6 months after implantation of the Neovasc CS Reducer

Conclusions:
These preliminary results from the Reduce-1 registry show that the use of percutaneous transvenous implantation of the Coronary Sinus Reducer in patients with refractory angina is safe, simple, and uneventful.

Clinical improvement was observed in all patients 6 months post CS Reducer implantation with a significant reduction in CCS angina score and in the utilization of sub-lingual nitro.

The observed improvement in the objective measured parameters of myocardial ischemia is very encouraging.

References: