Acute and short term safety and feasibility of the new OPTIMIZER SMART-system: Is it reasonable to avoid an atrial lead?

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Background: Cardiac contractility modulation (CCM) is a device-based heart failure therapy that enhances contractile strength of the myocardium independent of the synchronization of myocardial contraction. CCM signals are non-excitatory high voltage electrical impulses that are applied during the absolute refractory period. The new OPTIMIZER™ SMART System delivers electrical stimuli without an atrial lead. This study is about the acute and short term feasibility and safety of the new OPTIMIZER™ SMART-SYSTEM.

Methods: 19 patients with standard indication for CCM have been enrolled in a single center in Germany, 91% male, BMI: 28.6 ± 4.1, EF = 24 ± 10.7%, 90% had a history of atrial fibrillation; all patients had two leads in the right ventricle without an atrial lead. The average number of hospitalizations due to heart failure in the past 12 months was 1.0 ± 0.7 per patient. Assessment of Echocardiographic parameters, NYHA class, BNP, QoL and device-related technical parameters was made before implant, at 2 and 4 weeks.

Results: During this short follow up period all 38 RV electrodes showed stable values without any significant changes in sensing or impedance. The average CCM output that was tolerated without sensations was 6.9 ± 1.2 V at baseline, 6.75 ± 1.3 V at 2 weeks and 6.2 ± 1.5 V at 4 weeks. The duration of daily therapy was 7.9 ± 0.3 h vs. 8.1 ± 0.6 h vs. 8.2 ± 0.4 h for each FU point of time. The rate of successful therapy delivery was 91.9 ± 9.6% vs. 89.7 ± 9.6% vs. 93.1 ± 5.9% (table1). The stability of effective CCM therapy showed a very good significance over time (Spearman rho: 0.810; p<0.001). Clinical changes were seen in a significant change in NYHA class from 3.17 ± 0.3 to 2.5 ± 0.7 (p<0.001) within 4 weeks after implantation. The QoL questionnaire showed a trend towards improvement with 49.9 ± 17.5 points vs. 44.4 ± 7.5 vs. 37.9 ± 21.0 but without being significant (p=0.137). Echo parameters and BNP did not show any significant changes during short term FU.

Conclusion: The new OPTIMIZER™ SMART-SYSTEM without an atrial lead showed an excellent stability of CCM therapy delivery with high rates of successful therapy. Delivery of therapy was over 90%, regardless of the underlying atrial rhythm. In this short term FU it seems reasonable to avoid the implantation of an extra atrial lead in these patients.

P317 Improvement of ventilatory efficiency and reduction of oscillatory breathing pattern by cardiac contractility modulation

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Introduction: Cardiac Contractility Modulation (CCM) is a treatment for patients with heart failure with reduced ejection fraction (HF-REF) providing improved myocardial molecular and biochemical characteristics and thus improved exercise tolerance and quality of life by application of electrical signals during the absolute refractory period.

Cardiopulmonary exercise testing is an ideal signature method to assess exercise tolerance in heart failure patients. The VE/VCO2-Slope (minute ventilation/carbon dioxide production) and an oscillatory breathing pattern have widely been demonstrated to have strong prognostic value for patients with chronic heart failure.

Methods: Between February 2017 and September 2017 10 patients (mean age 68 ± 9.9 years, NYHA 3.14 ± 0.38) with standard indication for CCM-therapy have been enrolled in a single center in Germany. Prior to implantation of the CCM-device, symptom-limited cardiopulmonary exercise testing was performed using a bicycle ramp protocol (25W-105W/min). The Follow-up was conducted 6 weeks post implantation.

The subjects were compared to a control group consisting of 12 patients (mean age 66 ± 8.1 years, NYHA 2.3 ± 0.78) with stable systolic heart failure and reduced ejection fraction. Statistical Analysis was performed by paired and unpaired t tests.

Results: 6 weeks after CCM-Implantation the VE/VCO2-Slope after CCM-Implantation showed a significant decrease (45,91 ± 11.72 vs. 41,47 ± 10,12; p<0.05) showing changes in ventilatory efficiency whereas the control-group showed a stable measurement with even an increasing tendency (31,8 ± 6,2 vs. 34,1 ± 9,4; p=0.148). The absolute change of the VE/VCO2-Slope between the CCM-group and control-group highlights the improvement after the intervention (-4,43 ± 5.23 vs. 2.38 ± 5.29; p<0.05). Additionally, the numbers of patients presenting an oscillatory breathing pattern only decreased for patients who received CCM therapy (9 out of 10 vs. 4 out of 10; p<0.05), whereas no changes were recorded in the control group (2 out of 10 vs. 2 out of 10).

In contrast, subjects showed no significant changes in watt-measurements (71,4 W ± 14,2 W vs. 73,6 W ± 17,2 W; p=0.647) or maximal oxygen uptake (969 ml/min ± 273 ml/min vs. 1308 ml/min ± 331 ml/min; p=0.281) compared to baseline. Similarly, the control-group showed stable measurements for external load (81,0 W ± 16,3 W vs. 77,0 W ± 17,5 W; p=0.220) and peak oxygen uptake (1072 ml/min ± 258 ml/min vs. 1116 ml/min ± 330 ml/min; p=0.345).

Conclusions: Cardiac Contractility Modulation provides improved ventilatory efficiency measures by VE/VCO2-Slope and reduces oscillatory breathing pattern during exercise after short term follow up. As the low ventilatory efficiency observed in patients with heart failure constitutes an important predictor of cardiovascular mortality these results provide an interesting insight of therapeutic effects of Cardiac Contractility Modulation apart from VO2-measurements.

P318 Day-case implant of complex pacing devices is safe and preferred by patients; a 2 year experience

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Background/Introduction: Across Europe, there is wide variation in length of stay of patients following pacemaker device procedures. Historically, device implantation required a one or two night hospital stay. Our unit has operated a Day-Case Implant service for simple pacing for many years, but patients undergoing implant of complex devices (Cardiac Resynchronisation Therapy (CRT) or Implantable Cardioverter Defibrillator (ICD)) stay overnight. However, our institution recently introduced an extensive policy of Day-Case procedures, including implant of complex devices. We report our experience of Day-Case Implant of complex devices, with focus on acceptability to patients.

Purpose: To assess the feasibility, acceptability and safety of Day-Case Implant of complex pacing devices.

Methods: A single-centre retrospective study. Questionnaires were distributed to patients who had received elective complex device implant in the preceding 24 months, before (Group A) and after (Group B) introduction of the Day-Case policy. Patients’ electronic medical records were reviewed and the presence or absence of complications at first follow-up-clinic (6 weeks) was recorded.

Results: One hundred and ten subjects were studied, 50 in Group A and 60 in Group B. Findings from the questionnaires are shown in Table 1. There were no adverse findings at 6 weeks that would have been avoided by or caused by overnight stay at implantation. Complications were recorded at 6 weeks in 5 subjects in Group A (10%) and 5 subjects (8.3%) in Group B. Between groups comparisons were made using Fisher’s exact test.

Abstract P318 Table. Patient responses to questionnaire.

<table>
<thead>
<tr>
<th>Group A (overnight stay)</th>
<th>Group B (Day-Case)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=50</td>
<td>n=60</td>
<td></td>
</tr>
<tr>
<td>Satisfied with discharge strategy, n(%)</td>
<td>45 (90)</td>
<td>57 (95)</td>
</tr>
<tr>
<td>Would have preferred the alternative strategy, n(%)</td>
<td>17 (34)</td>
<td>9 (16)</td>
</tr>
<tr>
<td>Satisfactory pre-discharge information, n(%)</td>
<td>48 (96)</td>
<td>55 (93.2)</td>
</tr>
<tr>
<td>Adequate analgesia, n(%)</td>
<td>49 (98)</td>
<td>50 (83.3)</td>
</tr>
<tr>
<td>Did the discharge strategy cause inconvenience for family / friends, n(%)</td>
<td>5 (10)</td>
<td>8 (13.3)</td>
</tr>
<tr>
<td>Long delay prior to discharge, n(%)</td>
<td>20 (40)</td>
<td>6 (10.1)</td>
</tr>
</tbody>
</table>

P319 Is the measurement of QRS duration valid and reproducible in patients with left bundle branch block?

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While this approach may not be suitable for all patients, we suggest that overnight stay for elective complex device implantation should be the exception. As well as being better for patients, there is a significant economic advantage of this approach.