Background: Ultra-Low Temperature Cryoablation (ULTC) using near-critical nitrogen (-196°C) has been shown to produce durable, contiguous, transmural lesions in ventricles of animal models.

Objective: To evaluate safety and performance of ULTC for ablation of ventricular tachycardias (VTs).

Methods: The CryoCure-VT (NCT04893317) is a multi-center, prospective, single-arm, first-in-human, clinical trial, enrolling patients with recurrent monomorphic VTs of both ischemic (ICM) and non-ischemic (NICM) etiologies scheduled for endocardial ablation who also have implantable defibrillators. The endpoints include acute safety (Major Adverse Events during and up to 30-days post-procedure) and performance (via end-of-procedure VT inducibility), as well as freedom from sustained VT (>30 sec or requiring therapy) during 6-mo follow-up. The mapping and ablation strategies include substrate mapping and/or mapping in preference to ramp ATP to improve the termination rate of VT, and pace mapping (n=6).

Results: The first six patients (5 ICM/1 NICM), mean age of 63±9 years and mean EF=34±12% underwent VT ablation based on the combination of substrate-based mapping (n=6) and pace mapping (n=4). Mean procedure time was 182±60 minutes. An average of 8.3 lesions (range 1-16) were delivered per patient with mean freeze duration of 3.2±1.2 minutes/lesion, and total freezing time of 27.0±14.8 minutes (range 4-42 minutes). Post-ablation, 2 patients had no inducible VTs, 2 had inducible non-clinical VTs, 1 had elimination of 3 out of 4 clinical VTs, and 1 did not undergo inducement due to hemodynamic instability. A post-procedural ventricular pseudo-aneurysm occurred in one patient with ablation performed in ventricular tissue as thin as 2 mm which resolved 14 days post-procedure without clinical sequela. We will report on an additional 10 patients by the time of HRS.

Conclusion: The first experience using ULTC for VT ablation delivered by the Adagio Medical (Laguna Hills, CA) VT cryoablation system.

Methods: Twenty-five patients with ischemic and non-ischemic cardiomyopathy, with recurrent monomorphic drug-refractory VT which had failed a prior catheter ablation underwent SERF ablation in 3 different centers in Canada. After a voltage map, the mapping catheter was replaced with the needle-tipped ablation catheter, which was located perpendicular to the myocardium and extended either 6 or 8 mm into the tissue. Sterile saline solution was infused with a flow rate of 10 ml/min and 60°C and 50 watts of RF was used.

Results: LVEF was 33.3%±8.6, mean age was 69.5±6.4 years; 92% were male. From 43 clinical VT induced, 42 were attempted and 266 (SERF lesions were delivered (10.6±4.9 per patient). At the end of the case, 41 VT were non-inducible (98%) and 24 patients (96%) had their VT eliminated. At 6 months follow-up, VT burden was reduced by 87%. Complications included 2 strokes, 2 pericardial effusion and one patient had ischemic bowel and 1 died.

Conclusion: SERF ablation is feasible and permits control of symptomatic monomorphic VT in drug-refractory patients with a prior failed ablation.
Objective: We sought to evaluate the optimal ATP strategy for patients with VT with a cycle length >400 msec.

Methods: The success or the initial ATP attempt and incidence of ICD shock dependent on whether the initial ATP was burst vs ramp was assessed from patients who had been enrolled in the RAFT trial.

Results: 12,311 VT episodes from 1,798 patients were included. For VT CL >400ms, burst ATP terminated 53.8% (592/1101) of episodes of VT whereas ramp ATP terminated 50.6% (79/156) of episodes of VT (p = 0.507). For VT CL <400ms, 66.8% (5410/8095) of episodes of VT were terminated with burst ATP whereas 33.4% (698/2092) of episodes of VT were terminated with ramp ATP (P < 0.001). Following an unsuccessful burst and ramp ATP, 53.8% and 72.7% of episodes received a shock for VT CL >400ms, respectively (p < 0.001) and 59.5% and 77.2% of episodes received a shock for VT CL <400ms, respectively (p < 0.001).

Conclusion: Although inferior for VT with CL <400ms, the efficacy of ramp ATP is not significantly different to burst ATP at terminating VT with a cycle length >400ms. However, the rate of ICD shock following an unsuccessful ramp ATP is significantly higher than that for burst at all VT cycle lengths.

Table 1 – ATP Success with Burst and Ramp at Different Cycle Lengths

<table>
<thead>
<tr>
<th>Cycle Length</th>
<th>ATP Success</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;4000ms</td>
<td>Burst 53.8%</td>
<td>0.507</td>
</tr>
<tr>
<td></td>
<td>Ramp 50.6%</td>
<td></td>
</tr>
<tr>
<td>≤4000ms</td>
<td>Burst 66.8%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Ramp 33.4%</td>
<td></td>
</tr>
<tr>
<td>Shock following unsuccessful ATP &gt;4000ms</td>
<td>53.8%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>72.7%</td>
<td></td>
</tr>
<tr>
<td>Shock following unsuccessful ATP ≤4000ms</td>
<td>59.5%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>77.2%</td>
<td></td>
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CE-540-02

NONINVASIVE CARDIAC RADIOABLATION FOR VENTRICULAR TACHYCARDIA: PRELIMINARY RESULTS OF THE PROSPECTIVE STARNL-1 TRIAL

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Background: Radioablation or stereotactic arrhythmia radiotherapy is a promising new last-resort treatment modality for patients with recurrent ventricular tachycardia (VT) who are considered therapy refractory. Experience with radioablation is steadily growing worldwide as result of promising efficacy and safety results. Prospective trials are needed to confirm these results.

Objective: To prospectively evaluate the efficacy and safety of cardiac radioablation in patients with therapy-refractory ventricular tachycardia.

Methods: The prospective STARNL-1 trial is a single-arm, pre-post, intervention study. In 6 patients, the pro-arrhythmic cardiac region was identified and treated with a single stereotactic radiotherapy fraction of 25 Gy. Patients who were considered therapy-refractory, with recurrences after (multiple) VT ablations and high doses of class 1-3 anti-arrhythmic drugs, were included. For this analysis, patients who completed the 6-months follow-up were selected and the number of treated VT-episodes 6-months before and after treatment, excluding events in the 6 week blanking period, were compared. Safety analysis included evaluation of (serious) adverse events, echocardiography and lung function tests.

Results: Five of the 6 (83%) patients included in the STARNL-1 trial completed the 6 month follow-up and were selected. All patients were male (age range 55-83 years) and had an ischemic cardiomyopathy (median ejection fraction: 42% [range 32-52]). The median planning target volume was 163ml (range 93-233) and radiation beam-on times were all below 6 minutes. The median number of treated VT episodes significantly reduced from 28 (range: 15-107) in the 6 months before treatment to 3 (range 0-15) after treatment, p = 0.043. The median reduction percentage was 86.7% (range 85-100%). No serious treatment related adverse events occurred during follow-up. Comparing 3 months after treatment with baseline, the median change in ejection fraction was +7% (range: -27 to +28) and the median reduction in 1 second forced expiratory volume (FEV1) and diffusion capacity (DLCO) were both below 10%.

Conclusion: The results of the prospective STARNL-1 evaluating radioablation for therapy-refractory VT patients are very promising with regards to efficacy and safety.

CE-540-03

IMPROVEMENT IN PSYCHOSOCIAL SYMPTOMS AFTER ENROLLMENT IN A COMBINED ELECTROPHYSIOLOGY-PHYCHOSOCIAL VENTRICULAR ARRYTHMIA CLINIC

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Background: Patients with ventricular arrhythmias (VAs) often experience psychological symptoms and poor quality of life (QOL). Patient-reported outcome measures (PROMs) are validated questionnaires used to quantitate physical and psychosocial symptom burden.

Objective: To analyze changes in PROMs after initial visit to a multidisciplinary (EP + psychologist) VA clinic for patients with prior sudden cardiac arrest, sustained ventricular arrhythmias or implantable cardioverter-defibrillator (ICD) shocks.

Methods: At each clinic visit, patients completed 3 general health PROMs (New York Health Association class and visual analogue scales for physical health status and QOL) and 4 psychosocial PROMs (Hospital Anxiety and Depression Scale (HADS-A and -D), Cardiac Anxiety Questionnaire (CAQ), Florida Shock Anxiety Scale (FSAS), and Florida Patient Acceptance Scale (FPAS)). We compared baseline PROM scores prior to first appointment (A), at second clinic visit (B), and at most recent visit (C) using paired t-tests for repeated measures within subject. Clinical variables hypothesized to influence change in PROM scores were evaluated using t-test and 2-tailed correlation analysis.

Results: Sixty-two patients (age 57 ±15 years, 84% male) had at least two clinic visits. Between visits A and B, general health PROMs demonstrated a trend toward improvement, but all 4 psychosocial PROMs improved significantly (all p values < 0.01; Table 1). Prevalence of patients with moderate-severe anxiety symptoms (HADS-A ≥ 8) decreased from 28% to 13%, moderate-severe depression symptoms (HADS-D ≥ 8) from 10% to 4%, and moderate-severe ICD shock anxiety (FSAS ≥ 31) from 16% to 8%. Results were similar when comparing visits A and C, noting stable improvement in PROM scores. No baseline clinical variables (Table 1) correlated with PROM improvement.