Correction of Mitral Valve Regurgitation by Off-Pump, Transapical Placement of Artificial Chordae Tendinae. Results of the European TACT Trial

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Disclosure Statement of Financial Interest

G. Speziali and R.C. Daly: co-inventors of Neochord technology with royalty fees per Mayo Foundation policy, consultant fees, travel expenses for lab studies and clinical proctoring

Sponsor: NeoChord, Inc., Minneapolis, MN
TACT Trial
Transapical Artificial Chordae Tendinae

European Multi-center, prospective, single arm study

- 30 patients underwent mitral valve repair by implantation of ACT(s)
- Primary end-point:
  - MR $\leq 2+$ at 30-days
- 1, 6, 12 and 24 month echo follow-up
Key Inclusion Criteria:

- Severe MR ≥ grade 3+
- Isolated posterior prolapse
- No concomitant procedures

Key Exclusion Criteria:

- Functional or ischemic MR
- LVEF < 25%, LVEDD > 6.5 cm
- Severe annular dilatation
## TACT Trial Centers

<table>
<thead>
<tr>
<th>Site</th>
<th>Investigators</th>
<th>Enrolled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vilnius, Lithuania</td>
<td>A Aidietis; K Rucinskas</td>
<td>13</td>
</tr>
<tr>
<td>Leipzig, Germany</td>
<td>F Mohr; M Borger; J Seeburger</td>
<td>6</td>
</tr>
<tr>
<td>Turin, Italy</td>
<td>M Rinaldi; S Salizzoni</td>
<td>5</td>
</tr>
<tr>
<td>Aarhus, Denmark</td>
<td>S Nielsen</td>
<td>2</td>
</tr>
<tr>
<td>Munich, Germany</td>
<td>R Lange; S Bleiziffer</td>
<td>2</td>
</tr>
<tr>
<td>Milan, Italy</td>
<td>O Alfieri; F Maisano</td>
<td>1</td>
</tr>
<tr>
<td>Bad Nauheim, Germany</td>
<td>T Walther; M Schoenburg</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>30</strong></td>
</tr>
</tbody>
</table>
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ± SD / N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>64 ± 12</td>
</tr>
<tr>
<td>Gender (Female)</td>
<td>12 (40)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26 ± 4</td>
</tr>
<tr>
<td>MR Grade</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>3 (10)</td>
</tr>
<tr>
<td>4</td>
<td>27 (90)</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>22 (73)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>16 (53)</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>3 (10)</td>
</tr>
<tr>
<td>Stroke</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>3 (10)</td>
</tr>
</tbody>
</table>
No chords deployed
Acute Procedure Success (APS)

- Attempted Procedures: 30 procedures
- Implanted: 26
- No APS (converted to SOC): 4

30-days
- <2+ MR Grade: 17
- >2+ MR: 3
- Death: 1
- Indeterminate echo: 1

Acute Procedure Success 26/30 (87%)

30 Day Achieve Primary Endpoint of APS 17/26 (65%)
Standard of Care (SOC) outcomes:

- Four (4) patients—no APS
  - Three intraoperative conversions
  - One surgery within 7 days
  - All 4 MV repairs

- Four (4) patients with APS, MR >2+ within 30 days
  - 3 MV Repair
  - 1 MV Replacement
12/17 (71%) of successful patients have ≤1+ MR Grade
Learning curve: 30 days results

Last 15 patients:

- 100% Acute Procedure Success rate
- 86% Primary end-point at 30 day follow-up

*One patient with an indeterminate echo at 30 days is not included
Procedural Modifications

From 1 to 2+ chordae

From LV apex to PL insertion
30Day Results Per # of Chordae Implanted

Patients

1 chord | 2 chords | 3 chords | 4 chords

0% | 67% | 75% | 100%

www.aats.org
<table>
<thead>
<tr>
<th>Condition</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>Open surgery</td>
<td>8 (26.7%)</td>
</tr>
<tr>
<td>Transfusion &gt;2 units</td>
<td>5 (16.7%)</td>
</tr>
<tr>
<td>Ventilation &gt;48 hr</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 (3.3%)</td>
</tr>
<tr>
<td>MI</td>
<td>0</td>
</tr>
<tr>
<td>Emergent surgery</td>
<td>0</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>0</td>
</tr>
<tr>
<td>Deep wound infection</td>
<td>0</td>
</tr>
<tr>
<td>New onset perm. AF</td>
<td>0</td>
</tr>
<tr>
<td>Sepsis</td>
<td>0</td>
</tr>
<tr>
<td>Any MAE*</td>
<td>8 (26.7%)</td>
</tr>
</tbody>
</table>
30 Day Safety By Cohort

- Entire cohort, n=30: 27%
- Multiple chords, n=28: 25%
- Mult. chords plus Posterolat. Fix., n=15: 7%

Pts. with any MAE, %

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6 Mo. Durability Data (Core Lab)
Conclusions: TACT Trial

- Acute procedural success (APS) in 26 of 30 pts (87%)
- 30 day primary end-point in 17 pts (65% of APS)
- Second half of trial (n=15): 100% APS, 86% at 30 day
- Improvement with: multiple chords, PL position of chord fixation, patient selection, experience
- Average procedure time was 2 hour 11minute
- 6 month durability data show stable results
Overview…

- Enroll 50 Patients in 5-7 European Centers
- Registry Overview:
  - DMR patients with profile similar to TACT Trial,
  - ..plus expansion to High Surgical Risk Patients
  - Follow-ups at 1 month, 6 month and 1 year

Possible inclusion of FMR patients (edge-to-edge Repair)

Application of Augmented Reality Imaging Technology for Procedural Guidance
Pledgeted Edge to Edge Repair

"Supported"
Aortic annulus: RED
Mitral annulus: GREEN

Axes for device trajectory

NEONAV: Virtual Imaging integrated with real-time TEE
Thank you