MAVERIC: 6-Month Outcomes of Transcatheter MV Repair in Patients With Severe Secondary Mitral Regurgitation

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Potential conflicts of interest

Speaker's name: Stephen Worthley

☑️ I have no potential conflict of interest to report

☒ I have the following potential conflict(s) of interest to report:

Type of affiliation / financial interest:

• Receipt of honoraria or consultation fees Medtronic and Abbott
Functional Mitral Regurgitation: The Clinical Problem

- The global annual incidence of FMR is estimated to be >2,500,000
- Left untreated, the 3 year survival rate for those with mod/severe MR is ~ 55%
The ARTO™ System
Transcatheter Annular Reduction Therapy (TART)

- Immediate and Direct A-P Diameter Shortening to Treat FMR
- No compression of LCX or other coronary artery
- Venous Based Delivery Under Fluoroscopic Imaging
- Acutely Reversible or Removable
- 12 Fr Delivery System
- No residual ASD, no trauma to native MV leaflets or chords
- Ample room for future septal access
- Procedure generally takes <90 mins
MAVERIC STUDY DESIGN

Multi-Centre, Single Arm 45 Patient Safety and Efficacy Study

30 day, 6 month, 1, 2 and 3 year clinic/echo visit follow-up

Primary Outcome Measures:
• Safety: Major Adverse Events at 30 days
• Efficacy: Mitral Regurgitation Grade at 30 days

Secondary Outcome Measures
• NYHA Class
• HF Hospitalization
• Device success measures

Major Inclusion Criteria:
• MR Grade ≥ 2+
• NYHA Class II-IV
• Optimized medical therapy

Major Exclusion Criteria:
• Significant structural abnormality of the mitral valve
• Known need for any cardiac surgery
• Life expectancy <1 year

Echo Core Lab: CERC
Study Mgmt: CERC
All Events CEC Adjudicated
## Safety at 6 months

<table>
<thead>
<tr>
<th>CEC Adjudicated Event</th>
<th>30 days N=45 N(%)</th>
<th>6 months N=42 N(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Composite Endpoint at 6 months*</td>
<td>2(4.4)</td>
<td>7(16.0)</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>3(7.2)</td>
</tr>
<tr>
<td>Cardiovasc</td>
<td>0</td>
<td>3(7.2)</td>
</tr>
<tr>
<td>Non-cardiovasc</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>1(2.3)</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mitral Operation/Intervention</td>
<td>0</td>
<td>1(2.3)</td>
</tr>
<tr>
<td>Cardiac Tamponade</td>
<td>1(2.2)</td>
<td>1(2.2)</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>1(2.2)</td>
<td>3(6.9)</td>
</tr>
</tbody>
</table>

*Death, Stroke, MI, cardiac tamponade, device related cardiac surgery, renal failure*
MR Grade Reduction at 6 months

Paired Data N=38
P<0.0001

Pre-procedure

6 Months

0-Trace | 1+ | 2+ | 3+ | 4+
---|---|---|---|---
31.6 | 31.6 | 36.8 | 13.2 | 18.4
29.0 | 39.5 | 13.2 | 18.4
18.4 | 39.5 | 29.0 | 13.2
13.2 | 39.5 | 29.0 | 13.2

NYHA Class Improvement at 6 months

Paired data N=41
P<0.0001
MAVERIC: Reduced Volumes and Indices at 6 months

- Paired data

![Graphs showing regurgitant volume by PISA, EROA, AP Annulus Diameter, and LVEDV (index)]
MAVERIC CONCLUSIONS

• MR Grade, AP Diameter, NYHA Class and RVols after the ARTO procedure were all significantly reduced at 6 months and improvements evident and maintained from 30 day outcomes

• The primary safety composite endpoint was low at 16%, as was mortality (7.2%) with no deaths attributed to the device or procedure

• Importantly, the rate of hospitalization for heart failure and heart failure or death were both low at 9.3% and 16.2% respectively

• This study demonstrates the 6 month efficacy and safety of the ARTO System for the treatment of FMR