What The ROVER Registry Tells Us About The Magellan Robot System And How It Has Facilitated Endo Procedures That Have Failed Standard Manual Attempts

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Disclosures
• WL Gore - Consultant
• Cook Medical - Speaker

Evidence-Based Approach

Continuum of Evidence

Pre-Clinical - First-in-Man - Carotid Stenting - Uterine Artery Embolization - ROVER Registry

Evidence-Based Approach

Pre-Clinical
First-in-Man
Specific Procedural Applications
Comprehensive Registry

Magellan™ Clinical Experiences

CE Mark & FDA 510(k) clearance for Peripheral intervention
Approaching 1000 cases
Currently in 17 centers globally
Multi-disciplinary platform:
- Vascular Surgeons
- Interventional Radiologists
- Interventional Cardiologists

Procedures Performed with Magellan
- Thoracic Aneurysm Repair (TEVAR)
- Vascular Procedures
- Embolization Procedures (EVAR)
- Renal Artery Angioplasty and Stenting
- Mesenteric Artery Angioplasty and Stenting
- Splenic Artery Aneurysm Treatment
- Hepatic Chemoembolization (TACE)
- Hip Arterial and Venous
- Internal Iliac Embolization
- Uterine Artery Embolization (UFE)
- Prostate Artery Embolization (PAE)
- Crossing of Chronic Total Occlusions
- SFA Angioplasty and Stenting

ROVER Registry Design

Robotic Vascular and Endovascular Registry (ROVER)
- Post-market registry
- Data collection: retrospective/prospective
- Multicenter, single arm, non-blinded
- Number of subjects: 500
- Length of follow-up: 14 day and 30 day

Clinical Results from the ROVER Registry
(Data Freeze: September 2015)

• Data from the initial 6 clinical sites is included in the analysis.

• 100 subjects were identified who had undergone robotic navigation to deliver (or assisted) therapeutic intervention to 119 vascular targets.
ROVER Registry Data

Contributing Centers: Initial 100 pts.  
Prospective Cases Only

Houston Methodist Hospital, Houston, Texas, Jean Bismuth, M.D. (Study PI)  
Miami Cardiac & Vascular, Miami, Florida, Barry Katzen, M.D.  
Miami Valley Hospital, Dayton, Ohio, John Matsuura, M.D.  
University of Southern California, Los Angeles, California, Sung Ham, M.D.  
Good Samaritan Hospital, Cincinnati, Ohio, Patrick Muck, M.D.  
University Hospital Strasbourg, Strasbourg, France, Nabil Chakfe, M.D.

ROVER Registry

Baseline Patient Characteristics

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years (mean ± SD)</td>
<td>69.3 ±12.3</td>
<td>(n=100)</td>
</tr>
<tr>
<td>Gender</td>
<td>Female: 31% (31)</td>
<td>Male: 69% (69)</td>
</tr>
</tbody>
</table>

ROVER Registry

Therapy Targets%

- IVC Filter Extraction: 1%
- Hepatic: 3%
- Other Venous and Various Arterial: 4%
- Endograft (Fenestrated and non-Fenestrated): 11%
- Carotid Artery: 10%
- Mesenteric (Renal, Splenic, SMA, Hypogastric, Celiac): 20%
- Lower Extremity (Femoral, Femoral, Popliteal): 20%

Therapy Frequency

- Carotid: 20%
- Femoral: 15%
- Lower Extremity: 15%
- Other: 15%
- Angioplasty: 15%

ROVER Registry

Procedural Outcomes, 119 Targets

- Treatment Success: Defined as the ability to successfully navigate to and cannulate the target vessel(s)  
  - 110*/119 (92%)

  Note: 9 pts
  - (3) unable to cross bifurcation
  - (1) catheter diameter too large
  - (4) could not cannulate target (or cross CTO)
  - (1) catheter issue

ROVER Registry

Serious Adverse Events

<table>
<thead>
<tr>
<th>Serious Adverse Events</th>
<th>Relationship to Magellan Robotic System</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>CVA</td>
<td>Not Related</td>
<td>1</td>
</tr>
<tr>
<td>Vascular Injury</td>
<td>Not Related</td>
<td>1</td>
</tr>
<tr>
<td>Access Site Infection</td>
<td>Not Related</td>
<td>1</td>
</tr>
<tr>
<td>Access Site Complication (hematoma)</td>
<td>Possibly Related</td>
<td>1</td>
</tr>
</tbody>
</table>

(1) device related adverse event reported per the safety endpoint.
### ROVER Registry

**Manual to Robotic Conversions**

<table>
<thead>
<tr>
<th>Manual to Robotic Conversions</th>
<th>N/Description</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Conversions (reported in the database)</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Treated w. Magellan (post conversion to robotic procedure)</td>
<td>15</td>
<td>75%</td>
</tr>
<tr>
<td>Reason for Conversion to Robotic Procedure (top 5)</td>
<td>Complexity of Arterial Anatomy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FEVAR Complexity</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radio Embolization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Coil, Other Embolic Material Placed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unable to Cross Bifurcation</td>
<td></td>
</tr>
<tr>
<td>Attempted Treatment but not successful</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>(*)</td>
<td>1 patient lesion could not be crossed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4 patients target could not be reached</td>
<td></td>
</tr>
</tbody>
</table>

### Case Example

- ROVER is the platform to give us a glimpse into strengths and weaknesses of technology.
- Retrospective data will have a number of missing data points but will provide “real world” feedback.
- First publication to be published in upcoming year.

### Conclusion

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