Outcomes of the Initial Experience with Commercial Transcatheter Mitral Valve Repair in the U.S.

A report from the STS/ACC TVT Registry

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None
Degenerative MR is common, affecting ~600,000 persons in the U.S.

Surgery is the standard of care, and is indicated for patients with symptoms or LV dysfunction.

However, there are patients in whom the risk of surgery is prohibitive.
Transcatheter Mitral Valve Repair

The MitraClip System

- Commercial approval October 24, 2013
- Indicated for symptomatic patients with primary MR $\geq 3$ and prohibitive surgical risk
TMVR with MitraClip in the U.S.

Over 100 sites activated
Outcomes of commercial experience unknown
Study Objective

To analyze and report the initial commercial experience of TMVR with the MitraClip System in the U.S.
STS/ACC TVT Registry

Transcatheter Mitral Valve Repair

• Collaboration of STS, ACC, CMS, hospitals, medical industry
• Patient-level data with DCRI as analytic center
• Participation satisfies NCD*

*patients may not reflect all procedures during this study period
Methods

- All commercial TMVR cases with MitraClip enrolled in TVT registry through August 31, 2014 were identified (n=564)

- Examined in-hospital and 30-day outcomes for procedure success, complications, and device-related events.
Outcome Definitions

• **Procedure success**
  
  Post-implant MR grade ≤2, without CV surgery and without in-hospital mortality

• **Procedure complications**
  
  cardiac perforation, major bleeding, stroke, MI, mitral injury, or death

• **Device-related adverse events**
  
  Single leaflet device attachment, complete clip detachment, device thrombosis, device or delivery component embolization
Surgical Risk and Cases
564 patients at 61 hospitals

No. Cases

STS-PROM for mitral repair
Study Population
564 Patients

- Median age (% men)……………………………………… 83 yrs (56%)
- NYHA III/IV……………………………………………… 83.9%
- HF hospitalization prior yr…………………………… 51.8%
- Atrial fibrillation………………………………………… 62.6%
- Prior CVA………………………………………………… 8.7%
- Diabetes…………………………………………………… 25.0%
- Prior CABG………………………………………………… 32.4%
- Prior MI…………………………………………………… 24.6%
- Creatinine ≥2 g/dl………………………………………… 16.7%
- O2-dependency………………………………………….. 14.7%
- Median STS-PROM MV repair………………………… 7.9% (4.7, 12.2)
- Median STS-PROM MV replacement………………… 10.0% (6.3, 14.5)
Other Procedure Indications

- Frailty .......................................................... 57.2%
- Hostile chest .................................................... 6.0%
- Porcelain aorta ................................................. 3.4%
- RV dysfunction with severe TR ......................... 2.3%
- Immobility ......................................................... 1.2%
- Severe liver disease (MELD >12) ...................... 0.5%
- IMA at high risk of injury ................................. 1.4%
- Unusual extenuating circumstance ............. 25.3%
Echocardiographic data

- LV ejection fraction: 56% (45, 63%)
- MR severity grade 3 or 4: 94.0%
- LV EDD: 5.2 cm (4.6, 5.8 cm)
- LV ESD: 3.6 cm (3.0, 4.5 cm)
- Degenerative MR: 85.5%
  - Posterior prolapse: 28.9%
  - Posterior flail: 28.0%
- Functional MR: 14.4%
- Mitral annular calcification: 38.4%
- Leaflet calcification: 17.2%
- Mitral gradient ≥5 mmHg: 8.0%
- MVA <4 cm²: 19.7%
- Severe TR: 14.7%
Change in Mitral Regurgitation

Clip implantation occurred in 94%

Mitral Regurgitation

Baseline

Post-implant

Grade 4

Grade 3

Grade 2

Grade 1

93% MR ≤2

63.7% MR ≤1

p < 0.001
Clinical Outcomes

• Procedure success.... 91.8%
• Complications........ 7.8%
• Length-of-stay.......... 3 d (1,6 d)
• Home discharge........ 81.9%
Adverse Events

- In-hospital mortality .......................... 2.3%
- 30-day mortality .............................. 5.8%
- Cardiac surgery ............................... 0.5%
- Stroke ........................................ 1.8%
- Myocardial infarction ....................... 0%
- Major bleeding ............................... 3.9%
- Cardiac perforation ......................... 0.7%
- Device-related events ....................... 2.7%
  - Single leaflet device attachment ....... 1.1%
  - Device embolization ..................... 0.4%
  - Other ....................................... 1.2%
Clinical Variables and Residual MR

Univariate Odds Ratios for MR grade ≤2

- EDD  \( p=0.03 \)
- Baseline MR  \( p=0.03 \)
- A2-P2 clip site  \( p=0.01 \)
- Case vol. (per 2)  \( p=0.01 \)

Odds Ratios

More MR  \( \leftarrow \)  1  2  3  Less MR  \( \rightarrow \)
Commercial TMVR with MitraClip

Data Summary

• Prohibitive risk population with 86% DMR
• 91.8% procedure success
• Device-related adverse events: 2.7%
• Mortality: 2.3% in-hospital, 5.8% at 30-days
• Procedure complications: 7.8%
• EDD, MR, volume, clip site related to success
## U.S. vs. Other Registries

<table>
<thead>
<tr>
<th>Registries</th>
<th>Age (yrs)</th>
<th>DMR</th>
<th>MR ≤2</th>
<th>In-hospital death</th>
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</thead>
<tbody>
<tr>
<td>STS/ACC TVT (US)</td>
<td>83</td>
<td>86%</td>
<td>93%</td>
<td>2.3%</td>
</tr>
<tr>
<td>SENTINEL (EU)</td>
<td>74</td>
<td>28%</td>
<td>95%</td>
<td>2.9%</td>
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<td>ACCESS (EU)</td>
<td>74</td>
<td>23%</td>
<td>91%</td>
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<td>TRAMI (DE)</td>
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<td>MitraSwiss (CH)</td>
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<td>38%</td>
<td>85%</td>
<td>4.0%</td>
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<td>France (FR)</td>
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<td>88%</td>
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<td>GRASP (IT)</td>
<td>72</td>
<td>24%</td>
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<td>Netherlands (NL)</td>
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<td>18%</td>
<td>93%</td>
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<tr>
<td>MARS (Asia)</td>
<td>71</td>
<td>46%</td>
<td>94%</td>
<td>4.2%</td>
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<td>EVEREST I</td>
<td>71</td>
<td>79%</td>
<td>74%</td>
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<td>EVEREST II RCT</td>
<td>67</td>
<td>51%</td>
<td>77%</td>
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<td>EVEREST II HRS</td>
<td>76</td>
<td>30%</td>
<td>86%</td>
<td>2.6%</td>
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</tbody>
</table>
Conclusions

1) In this first report of the U.S. commercial experience with TMVR, procedure success, clinical outcomes, and adverse events were favorable in comparison to pre-approval studies and other national registries.

2) These data demonstrate effectiveness and safety of TMVR with MitraClip for the treatment of prohibitive risk patients with symptomatic MR.
Clinical Variables and Residual MR

- Age (↑) 0.12
- Male gender 0.17
- FMR 0.07
- EDD (↑) 0.03
- ESD (↑) 0.29
- Baseline MR (↑) 0.03
- A2-P2 implant 0.01
- > 1 clip placed 0.12
- MAC 0.90
- Mitral gradient (↑) 0.33
- MVA <4 cm² 0.23
- Severe TR 0.43
- Case volume (↑) 0.01

Odds Ratio for MR grade ≤2

STS/ACC TVT Registry

The Society of Thoracic Surgeons

AMERICAN COLLEGE OF CARDIOLOGY
Surgical Risk and Cases

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