Clinical Outcomes at 1-year after Commercial Transcatheter Mitral Valve Repair in the United States

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STS/ACC TVT Registry™
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The views expressed in this presentation represent those of the authors, and do not necessarily represent the official views of these organizations. Learn more about the STS/ACC TVT Registry at www.tvtregistry.org.

The number of MitraClip procedures in this study may not reflect all such procedures performed during the study period. These data were obtained from hospitals who participated in the TVT Registry during the study period. It is possible that cases were performed at non-participating hospitals or that certain patients cases were excluded due to missing or incomplete information.
Disclosures

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STS/ACC TVT Registry™
Transcatheter Mitral Valve Repair
MitraClip™

24 Fr, transseptal system for leaflet apposition and reduction in MR

>40,000 patients worldwide

Approval in U.S. in October 2013 with 250 current sites

STS/ACC TVT Registry™
Study Objective

To examine the acute, 30-day, and one-year clinical outcomes of commercial transcatheter mitral valve repair with MitraClip in the U.S.

STS/ACC TVT RegistryTM
Methods

- Enrolled all commercial patients from the STS/ACC TVT registry through September 2015
- Linked patient records to CMS claims data for 30-day and one-year outcomes
Data Analysis

- Patient characteristics, procedural, and in-hospital events sourced from TVT registry (n=2,952)
  - Acute procedural success defined as post-procedural MR ≤2, without surgery or death
- 30-day and 1-year events from linked CMS claims data (n=1,867 or 63%)
  - Examined death, MV surgery, and re-hospitalization for heart failure

STS/ACC TVT Registry™
Patients

- Median age: 82 yrs (74, 86 yrs)
- Male gender: 55.8%
- NYHA III or IV: 85.0%
- Grade 3 or 4 MR: 93.0%
- Degenerative MR only: 85.9%
- Functional MR only: 8.6%
- DMR and FMR: 8.9%
- Frailty: 50.3%
- STS-PROM (MV repair): 6.1% (3.7%, 9.9%)
- STS-PROM (MV replacement): 9.2% (6.0%, 14.1%)
Acute Procedural Results

- 92.8% with post-procedural MR ≤2
- SLDA, 1.5%
- In-hospital mortality = 2.7%
- 85.9% discharged home
- Median LOS, 2 days (1, 5 days)

Acute procedure success = 91.8%
Clinical Outcomes at One-Year

- Either: 37.9%
- Death: 25.9%
- HF re-hospitalization: 20.2%
- Repeat Mitraclip = 6.2%
- MV surgery = 2.1%

Cumulative incidence (%) vs. Follow-up (months)

No. at risk:
- 1867 1095 723 464 263
- 1867 1293 889 570 336
- 1867 1095 723 464 263
Etiology of MR and Outcome

Cumulative incidences

Death

Death/ HF hosp

FMR

DMR

Follow-up (months)

No. at risk for Death

FMR 297 196 123 73 40

DMR 1485 1024 726 472 287

p = 0.028

p = 0.002
Impact of Tricuspid Regurgitation

Cumulative incidence of death

Impact of Tricuspid Regurgitation

<table>
<thead>
<tr>
<th>Severe</th>
<th>Moderate</th>
<th>Mild/none</th>
</tr>
</thead>
<tbody>
<tr>
<td>38.5%</td>
<td>23.5%</td>
<td>23.4%</td>
</tr>
</tbody>
</table>

Follow-up (months)

<table>
<thead>
<tr>
<th>No. at risk</th>
<th>0</th>
<th>2</th>
<th>4</th>
<th>6</th>
<th>8</th>
<th>10</th>
<th>12</th>
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<tbody>
<tr>
<td>Severe</td>
<td>298</td>
<td>198</td>
<td>141</td>
<td>83</td>
<td>47</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>666</td>
<td>451</td>
<td>307</td>
<td>203</td>
<td>131</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild/none</td>
<td>883</td>
<td>631</td>
<td>431</td>
<td>277</td>
<td>153</td>
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<td></td>
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</tbody>
</table>

\( p < 0.0001 \)
Post-Procedural MR and Survival

Cumulative incidence of death

No. at risk

Follow-up (months)

Grade III/IV
Grade II
Grade 0/I

III/IV  591  65  47  25  17
II  114  408  278  168  104
0/I  1146  810  559  373  213

p<0.0001
Multivariate Models for 1-yr Mortality

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hazard Ratio</th>
<th>Adjusted p values</th>
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</thead>
<tbody>
<tr>
<td>Age (per 5 yrs)</td>
<td></td>
<td>0.005</td>
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<tr>
<td>Dialysis</td>
<td></td>
<td>0.004</td>
</tr>
<tr>
<td>Moderate or severe lung disease</td>
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<td>0.02</td>
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<tr>
<td>LVEF (per 5%)</td>
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<td>&lt;0.0001</td>
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<tr>
<td>Severe TR</td>
<td></td>
<td>&lt;0.0001</td>
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<tr>
<td>Residual MR = III/IV*</td>
<td></td>
<td>0.004</td>
</tr>
<tr>
<td>Residual MR = 0/1*</td>
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<td>0.005</td>
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</tbody>
</table>

*vs. residual MR grade = 2

STS/ACC TVT Registry
Data Summary

- Acute procedural success in 92.8%, including in-hospital mortality of 2.7%
- At 1-year, mortality = 25.9%, HF re-hospitalization = 20.2%; either = 37.9%
- The one-year outcomes varied according to baseline characteristics and procedural results
- Significant co-variates in models for one-year outcomes were age, dialysis, moderate-severe lung disease, LVEF, severe TR, and residual MR
## Comparative Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Age (yrs)</th>
<th>DMR</th>
<th>Acute success</th>
<th>1-yr Mortality</th>
<th>1-yr HF hosp.</th>
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<tbody>
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<td>STS/ACC TVT</td>
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<td>85.9%</td>
<td>92.8%</td>
<td>25.9%</td>
<td>20.2%</td>
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<td>SENTINEL</td>
<td>74</td>
<td>28.0%</td>
<td>95.4%</td>
<td>15.3%</td>
<td>22.8%</td>
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<td>ACCESS-EU</td>
<td>74</td>
<td>20.6%</td>
<td>91.7%</td>
<td>19.2%</td>
<td>19.8%</td>
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<tr>
<td>EVEREST II HRS</td>
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<td>29.9%</td>
<td>86.0%</td>
<td>22.8%</td>
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<td>EVEREST PR</td>
<td>82</td>
<td>100%</td>
<td>95.3%</td>
<td>23.6%</td>
<td>18.0%</td>
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STS/ACC TVT Registry™
Conclusions

- Our study demonstrates the acute effectiveness and safety of transcatheter MV repair in the U.S.
- A subset of these high-risk patients have mortality or heart-failure re-hospitalization by one year
- Certain clinical variables (age, LVEF, severe TR, lung disease, dialysis) and the degree of MR reduction are significant predictors of these long-term clinical outcomes.

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