One-year outcomes after Transcatheter Mitral Valve Implantation: Results from the CHOICE-MI registry

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on behalf of the CHOICE-MI Investigators
Potential conflict of interest

Speaker's name: Alison Duncan, London

☑ I have the following potential conflicts of interest to report:

Receipt of honoraria or consultation fees:
Abbott, Edwards Lifesciences, Medtronic
Why this study?

- Transcatheter mitral valve implantation (TMVI) using dedicated devices

- Novel therapeutic alternative for patients with severe symptomatic mitral regurgitation (MR) unsuitable for
  - mitral valve surgery or
  - transcatheter edge-to-edge repair (TEER)

- Single device reports and outcomes

- Real-world outcome data of TMVI patients scarce
What did we study?

**CHOICE-MI**

The CHoice of OptImal transCatheter trEatment for Mitral Insufficiency Registry

- investigator-initiated
- multicentre
- international
- retrospective
- device-independent
- 05/2014 – 03/2021

**CHOICE-MI inclusion criteria:**

- significant MR
- unsuitable for standard therapy
  - high risk for surgery
  - suboptimal TEER anatomy
- screening for TMVI

Baseline characteristics (clinical, echo, CT)

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PMR  SMR  Mixed PMR/SMR  MAC
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MVARC criteria

Clinical / echo outcome at 30-days and 1-year

Primary composite outcome: 1-year all-cause mortality or heart failure hospitalisation
How was the study executed?

**CHOICE-MI inclusion criteria:**
- screening for TMVI
- relevant mitral valve disease
- high risk for surgery
- suboptimal TEER anatomy

**CHOICE-MI Registry**
(N=767)

**TMVI Screening**

**Excluded:**
- MR <2+
- pure MS

**Pts. with ≥2+ MR**
(N=746)

**TMVI eligible**

**TMVI**

- CardiAQ™
- Cardiovalve™
- Cephea™
- Fortis™
- HighLife™
- Intrepid™
- Sapien M3™
- Tendyne™
- Tiara™

**N=229**

**TMVI ineligible**

**TEER**

- MitraClip™
- PASCAL™

**N=216**

**Surgery**

- Replacement
- Repair

**N=62**

**Medical therapy**

**N=240**

PCRLondonValves.com
## What are the results?

<table>
<thead>
<tr>
<th></th>
<th>All patients (N=229)</th>
<th>Primary MR (N=54) 28.8%</th>
<th>Secondary MR (N=118) 58.4%</th>
<th>PMR/SMR (N=20) 12.8%</th>
<th>MAC (N=27) (11.8%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>76.0 (71.0, 81.0)</td>
<td>77.5 (72.9, 83.1)</td>
<td>75.0 (70.0, 80.0)</td>
<td>77.0 (72.2, 80.0)</td>
<td>79.0 (71.2, 84.0)</td>
<td>0.043</td>
</tr>
<tr>
<td>Female gender</td>
<td>84 (36.7)</td>
<td>25 (46.3)</td>
<td>40 (33.9)</td>
<td>9 (45.0)</td>
<td>8 (29.6)</td>
<td>0.30</td>
</tr>
<tr>
<td>STS PROM (%)</td>
<td>5.7 (3.2, 8.6)</td>
<td>4.3 (2.9, 7.4)</td>
<td>5.5 (3.1, 8.3)</td>
<td>5.7 (4.4, 9.6)</td>
<td>7.8 (3.9, 12.4)</td>
<td>0.077</td>
</tr>
<tr>
<td>EuroSCORE II (%)</td>
<td>6.3 (3.6, 13.2)</td>
<td>6.0 (2.9, 8.9)</td>
<td>6.2 (3.7, 13.9)</td>
<td>5.8 (4.4, 14.0)</td>
<td>9.2 (5.0, 13.7)</td>
<td>0.26</td>
</tr>
<tr>
<td>NYHA class IV</td>
<td>54 (23.6)</td>
<td>8 (14.8)</td>
<td>38 (32.2)</td>
<td>4 (20.0)</td>
<td>3 (11.1)</td>
<td>0.024</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>119 (55.3)</td>
<td>28 (51.9)</td>
<td>62 (55.4)</td>
<td>10 (50.0)</td>
<td>18 (66.7)</td>
<td>0.59</td>
</tr>
<tr>
<td>Diabetes</td>
<td>57 (24.9)</td>
<td>11 (20.4)</td>
<td>31 (26.3)</td>
<td>7 (35.0)</td>
<td>6 (22.2)</td>
<td>0.60</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>82 (35.8)</td>
<td>17 (31.5)</td>
<td>43 (36.4)</td>
<td>8 (40.0)</td>
<td>9 (33.3)</td>
<td>0.88</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>40.0 (35.0, 54.0)</td>
<td>55.0 (45.7, 60.0)</td>
<td>37.0 (31.7, 43.0)</td>
<td>35.3 (30.8, 44.5)</td>
<td>50.0 (39.2, 60.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>LVEDV (mL)</td>
<td>153.4 (116.5, 198.0)</td>
<td>134.5 (100.9, 171.1)</td>
<td>167.0 (132.0, 214.0)</td>
<td>149.0 (101.6, 241.2)</td>
<td>150.0 (113.8, 237.7)</td>
<td>0.038</td>
</tr>
<tr>
<td>TAPSE (mm)</td>
<td>15.0 (12.0, 19.0)</td>
<td>16.0 (13.0, 18.1)</td>
<td>15.0 (12.0, 19.0)</td>
<td>17.5 (12.9, 20.1)</td>
<td>16.0 (13.8, 18.1)</td>
<td>0.43</td>
</tr>
<tr>
<td>EROA (cm²)</td>
<td>0.3 (0.2, 0.5)</td>
<td>0.4 (0.3, 0.6)</td>
<td>0.3 (0.2, 0.4)</td>
<td>0.2 (0.2, 0.3)</td>
<td>0.4 (0.3, 0.5)</td>
<td>0.0040</td>
</tr>
<tr>
<td>MVPG (mmHg)</td>
<td>3.0 (2.0, 4.0)</td>
<td>3.0 (2.0, 4.4)</td>
<td>2.0 (2.0, 3.0)</td>
<td>3.0 (2.7, 5.0)</td>
<td>4.0 (3.0, 5.8)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
What are the results?

MVARC 30-day outcomes

- Technical success: 95.2%
- Procedural mortality: 1.8%
- 30-day mortality: 9.9%

LVOT obstruction: 3.2%
Valve malposition: 3.7%
Conversion to surgery: 2.8%
Access site complications: 9.6%
Reintervention for bleeding: 7.5%
Disabling stroke: 3.1%
AKI: 15.4%

Median follow-up time: 1.94 (1.53-2.11) years

Primary composite endpoint of 1-year all-cause mortality or HF hospitalization: 39.2%
[no difference primary MR (44.1%), secondary MR (39.1%), mixed MR (20.0%) (p=0.68)]
What are the results?

Echocardiographic outcome

At discharge, MR eliminated (residual MR <1+) in **83.9%** patients treated with TMVI.

At 1-year, MR eliminated (residual MR <1+) in **72.2%** patients treated with TMVI.
Why is this study important?

• In this global multicenter registry

• **229 patients treated with ten different dedicated TMVI devices**
  • TMVI was associated with high technical success
  • low procedural mortality
  • low rates of procedural complications
  • regardless of MR aetiology
  • elimination of MR achieved in majority regardless of MR aetiology

• TMVI reasonable treatment alternative for patients unsuitable for standard MR therapy
Essentials to remember

• Real-world outcome data for patients treated with dedicated TMVI devices is scarce

• The global **CHOICE-MI registry**
  • included 767 MR patients unsuitable for standard therapy
  • all underwent evaluation for TMVI eligibility
  • 229 patients underwent TMVI with ten different dedicated TMVI devices

• Regardless of MR aetiology, TMVI was associated with
  • high technical success
  • low procedural mortality, low rates of procedural complications
  • durable MR elimination in the majority of patients

• TMVI may represent a complementary treatment for anatomically suitable patients with MR unsuitable for surgery or TEER