Early Experience of Transcatheter Mitral Valve Replacement
Results from the Intrepid Global Pilot Study

Paul Sorajja, MD
for the Intrepid Global Pilot Study Investigators
Presenter Disclosure Information

• Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below


• Medtronic personnel performed all statistical analyses and verified the accuracy of the data, and assisted in the graphical display of the data presented.
Background

• Mitral regurgitation is common and associated with heart failure and a poor prognosis

• While surgery is the standard of care, transcatheter mitral valve replacement (TMVR) has recently emerged as a potential therapy

• However, the feasibility of TMVR remains uncertain
The Intrepid Prosthesis

Self-expanding, nitinol valve

43, 46, or 50 mm diameter

Houses a 27 mm tri-leaflet bovine valve

Transapical delivery system using 35 Fr access
Pilot Study Design

Study Aim

• To determine the feasibility of TMVR with the Intrepid valve

Analysis Cohort

• The initial 50 consecutively enrolled patients in the pilot study (06 May 2015 to 21 July 2017)

Clinical Endpoints

• MVARC criteria
• An independent physician committee reviewed adverse clinical events, including mortality, stroke, myocardial infarction, bleeding, re-hospitalization, and reoperation
Participating Sites

Abbott NW
Minneapolis, MN

Aurora St. Luke's
Milwaukee, WI

U of Michigan
Ann Arbor, MI

Mount Sinai
NYU/Langone
New York, NY

Barnes Jewish
St. Louis, MO

Baylor Heart and Vascular
Dallas, TX

Northwestern University
Chicago, IL

Piedmont
Atlanta, GA

Columbia University
New York, NY

Clinique Pasteur
Toulouse, France

The Alfred
Melbourne, Australia

Hygeia Hospital
Athens, Greece

Helsinki University Hospital
Helsinki, Finland

Barnes Jewish
St. Louis, MO

Northwestern University
Chicago, IL

Mount Sinai
NYU/Langone
New York, NY

Columbia University
New York, NY

John Paul II Hospital*
Krakow, Poland

*First in human

Houston Methodist
Houston, TX

Leeds Teaching Hospitals
Leeds, UK

Brighton and Sussex University Hospitals
Brighton, UK

Centre Hospitalier Regional Univeritaire de Lille
Lille, France

St. Thomas' Hospital
London, UK

Royal Prince Alfred Hospital
Sydney, Australia

Monash Heart
Melbourne, Australia

Monash Heart
Melbourne, Australia

Columbia University
New York, NY
Inclusion and Exclusion Criteria

Key Inclusion Criteria

• Symptomatic, severe mitral regurgitation
• Deemed high or extreme surgical risk by the local heart team
• Native mitral valve geometry and size compatible with the Intrepid™ TMVR
• Mild or no mitral valve calcification
• LVEF ≥ 20%

Key Exclusion Criteria

• Pulmonary hypertension (systolic pressure ≥ 70 mm Hg)
• Need for coronary revascularization
• Hemodynamic instability
• Need for other valvular therapy
• Severe renal insufficiency (Cr > 2.5 mg/dl)
• Prior MV surgery or intervention
### Baseline Demographics (n=50)

<table>
<thead>
<tr>
<th>n (%) or mean ± SD</th>
<th>n (%) or mean ± SD</th>
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<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td>72.6 ± 9.4</td>
</tr>
<tr>
<td>Men</td>
<td>29 (58.0%)</td>
</tr>
<tr>
<td>NYHA class III or IV</td>
<td>43 (86.0%)</td>
</tr>
<tr>
<td>HF hospitalization in past year</td>
<td>29 (58.0%)</td>
</tr>
<tr>
<td>COPD</td>
<td>25 (50.0%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>21 (42.0%)</td>
</tr>
<tr>
<td>Chronic renal insufficiency</td>
<td>29 (58.0%)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>29 (58.0%)</td>
</tr>
<tr>
<td>Sternotomies ≥1</td>
<td>22 (44.0%)</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>19 (38.0%)</td>
</tr>
<tr>
<td>Prior AVR</td>
<td>5 (10.0%)</td>
</tr>
<tr>
<td>Prior stroke</td>
<td>8 (16.0%)</td>
</tr>
<tr>
<td>Procedural Data</td>
<td></td>
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<tr>
<td>----------------</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>n (%) or median (IQR)</th>
<th>N=50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical procedure duration (min)</td>
<td>100.0 (80.0, 124.0)</td>
</tr>
<tr>
<td>Deployment time (min)</td>
<td>14.0 (12.0, 17.0)</td>
</tr>
<tr>
<td>Pacing time (sec)</td>
<td>29.0 (23.0, 36.0)</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>7.5 (5.1, 9.8)</td>
</tr>
<tr>
<td>Procedure aborted</td>
<td>1 (2.0%)</td>
</tr>
<tr>
<td>TMVR successfully implanted</td>
<td>48/49 (98.0%)</td>
</tr>
<tr>
<td>Device malfunction or failure</td>
<td>0/48 (0.0%)</td>
</tr>
<tr>
<td>Conversion to open MV replacement</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Intra-aortic balloon pump utilized</td>
<td>5 (10.0%)</td>
</tr>
<tr>
<td>ECMO support utilized</td>
<td>3 (6.0%)</td>
</tr>
</tbody>
</table>
## Clinical Outcomes

<table>
<thead>
<tr>
<th>n (%)</th>
<th>0-30 Days (n=50)</th>
<th>&gt;30 Days (n=41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>7 (14.0%)</td>
<td>4 (9.8%)</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Non-disabling stroke</td>
<td>2 (4.0%)</td>
<td>1 (2.4%)</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Acute renal impairment, stage 3</td>
<td>5 (10.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Reoperation for bleeding</td>
<td>5 (10.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>New-onset atrial fibrillation</td>
<td>7 (14.0%)</td>
<td>2 (4.9%)</td>
</tr>
<tr>
<td>Device embolization, hemolysis, or thrombosis</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Re-hospitalization for heart failure</td>
<td>4 (8.0%)</td>
<td>8 (19.5%)</td>
</tr>
</tbody>
</table>
Long-Term Survival (n=50)

Blue = surviving patients
Gray = deceased (n=11)
1-Year Survival

Survival

Months After TMVR

Number at risk:

50 41 21 10

76.5% [61.4 – 86.3]
All patients with mild or no MR in follow-up
New York Heart Association Classification

- Baseline (n=50)
  - NYHA I: 16.0%
  - NYHA II: 70.0%
  - NYHA III: 14.0%
  - NYHA IV: 0%

- 30 Days (n=42)
  - NYHA I: 2.4%
  - NYHA II: 54.8%
  - NYHA III: 21.4%
  - NYHA IV: 0%

- Last Follow-Up (n=43, Median 173 days)
  - NYHA I: 20.9%
  - NYHA II: 44.2%
  - NYHA III: 34.9%
  - NYHA IV: 0%

- MLHFQ (n=13)
  - Baseline: 56 ± 27
  - Follow-up: 32 ± 22
  - Improvement: p=0.01

10/13 patients improved

TCT.17
Intrepid Global Pilot Study
Data Summary (n=50)

• Device implant success in 48/49 (98%)
• 30-day mortality = 14%
  – 3 from apical bleeding, 3 from CHF, 1 from malposition
• One-year survival = 77%
  – 3 SCDs in patients with low EF and no ICDs
  – No death after 180 days
• No device malfunction, hemolysis, or thrombosis
• No or mild MR in all survivors
• 79% of patients in NYHA class I or II in follow-up
Conclusions

• TMVR with the Intrepid valve was feasible and resulted in correction of MR in symptomatic patients at high or extreme surgical risk

• Stable valve function was observed, and a majority of patients experienced symptom improvement

• Further investigations will determine the role of this therapy in a broader patient population, compared with surgery and other transcatheter techniques
Highlights

• First patient implant in the APOLLO Trial was October 2017
• Transfemoral is anticipated for initial human use in 2018
• Paper in press today:

Early Experience of Transcatheter Mitral Valve Replacement: Results from the Intrepid Global Pilot Study

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