Expansion of TAVR to lower risk populations

Dharam J. Kumbhani, MD, SM, MRCP, FACC, FAHA, FSCAI

Assistant Professor of Medicine, Interventional Cardiology
UT Southwestern Medical Center, Dallas, TX
Inoperable
High
Intermediate
Low
Considerations

• Short and long-term efficacy

• Complications and safety

• Durability

• Cost and cost-effectiveness

• Patient preference
Inoperable
High
Intermediate
Low

Valve
Access/sheath

Numerical scores (STS, EuroSCORE)
Other factors (frailty)
Inoperable patients

PARTNER 1B

**In an age and gender matched US population without comorbidities, the mortality at 5 years is 40.5%.**
Inoperable patients

CoreValve: Extreme Risk

- All-Cause Mortality
- Cardiovascular Mortality

Mortality 0 – 1 Year:
- 18.3%

Mortality 1 – 2 Years:
- 24.3%
- 16.1%

TCT 2014
Inoperable patients

PARTNER IIB XT

HR [95% CI] = 0.93 [0.66, 1.33]

p (log rank) = 0.706
High-risk patients

PARTNER 1A

HR [95% CI] = 1.04 [0.86, 1.24]

p (log rank) = 0.76

TAVR 348
SAVR 351

67.8%
62.4%

0% 20% 40% 60% 80% 100%
0 12 24 36 48 60
Months post Randomization

TAVR 262 228 191 154 61
SAVR 236 210 174 131 64

SAPIEN
2006
High-risk patients
CoreValve: High Risk

- Transcatheter:
  - 0% at 0 months
  - 5% at 6 months
  - 10% at 12 months
  - 14.1% at 18 months
  - 22.2% at 24 months

- Surgical:
  - 0% at 0 months
  - 5% at 6 months
  - 10% at 12 months
  - 18.9% at 18 months
  - 28.6% at 24 months

Log-rank P = 0.04

Δ = 6.5

No. at Risk:
- Transcatheter: 391, 378, 354, 334, 219
- Surgical: 359, 343, 304, 282, 191
High-risk patients

PARTNER II S3HR

Mortality: 30 days

O:E = 0.26
(STS 8.6%)

All-Cause  Cardiovascular

S3HR

2.2  1.4
High-risk patients
Evolut CE study

Mortality

- 30-day
- 1-year

0 6.7

Evolut R
Intermediate-risk patients

PARTNER II S3i

Mortality: 30 days

O:E = 0.21
(STS 5.3%)
Low-risk patients

STACCATO

Mortality: 30 days

SAVR

TA-TAVR

0

8.8

0

30-day
Low-risk patients

MORTALITY

1 year 2 year

SAVR TAVR

7.5 6.7 9.8 8.0

EuroPCR 2015
Complications
• Vascular complications

• Stroke

• Paravalvular aortic regurgitation

• Pacemaker

• Others
Strokes: 30 days

<table>
<thead>
<tr>
<th>Device</th>
<th>Risk</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1B (TF)</td>
<td>6.7%</td>
<td>179</td>
</tr>
<tr>
<td>P1A (Overall)</td>
<td>5.6%</td>
<td>344</td>
</tr>
<tr>
<td>P2B XT (TF)</td>
<td>4.3%</td>
<td>284</td>
</tr>
<tr>
<td>S3HR (Overall)</td>
<td>1.5%</td>
<td>583</td>
</tr>
<tr>
<td>S3i (Overall)</td>
<td>2.6%</td>
<td>1076</td>
</tr>
<tr>
<td>CoreValve HR</td>
<td>4.9%</td>
<td>395</td>
</tr>
<tr>
<td>Evolut CE</td>
<td>0%</td>
<td>60</td>
</tr>
<tr>
<td>NOTION</td>
<td>1.4%</td>
<td>145</td>
</tr>
</tbody>
</table>
Moderate to severe PVL: 30 days

- PARTNER I B TF: 12.0%
- PARTNER I A: 13.2%
- PARTNER II B TF: 24.2%
- PARTNER II S3HR: 2.5%
- CoreValve HR: 7.8%
- Evolut CE 1 year: 4.3%
- NOTION 1 year: 15.7%
Pacemaker: 30 days

3.4%  PARTNER I B TF
3.8%  PARTNER I A
6.4%  PARTNER II B TF
13.2%  PARTNER II S3HR
19.8%  CoreValve HR
11.7%  Evolut CE
34.1%  NOTION

Pacemaker: 30 days
Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

Indication creep?

STS scores

- PARTNER I B TF: 11.6%
- PARTNER I A: 11.7%
- PARTNER II B TF: 10.3%
- CoreValve HR: 7.4%
- NOTION: 3.0%
- TVT 2011-13: 7.0%
- GARY: 5.0%

Indication creep?
Conclusions

• Robust data for TAVR in high-risk and inoperable patients – standard of care

• Data in lower risk populations still accruing

• Several considerations regarding extension of TAVR to lower risk populations

• Stakeholders need to work together to optimize utilization of TAVR in clinical practice
GO BACK. WE MESSED UP EVERYTHING.
First TAVR 2002
Evolution of Edwards THV

Cribier-Edwards 2002
SAPIEN 2006
SAPIEN XT 2009
SAPIEN 3 2013

* Sheath compatibility for a 23 mm valve
Evolution of Medtronic THV

CoreValve
2005

CoreValve Evolut R
2013

18 F

14 F