TAVR for low-risk patients in 2017: not so fast.

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Conflicts of Interest

• Consultant and proctor for Edwards Lifesciences (Irvine, CA, US)
• Consultant for Comed (Bolsward, The Netherlands)
TAVR

• Transcatheter Aortic Valve Replacement

• Balloon-expandable or self-expandable valves

• Indication: severe AS, failed bioprosthesis (VinV)

• Available accesses: TF, TA, TAO, trans-subclavian, trans-carotid

• EVOLVING TECHNOLOGY: repositionable/retrievable valves, low-profile delivery systems, new valve design to prevent PVL
TAVR in 2017

• Proven efficacy in inoperable and high-risk patients
• Proven efficacy in failed bioprosthesis (VinV)
• Incoming data are showing good results in moderate-risk patients
• Proven hemodynamics over the years

WHY NOT PERFORMING TAVR IN LOW-RISK PATIENTS AS WELL?
Agenda

1. Vascular and access-site related complications
2. Paravalvular leak
3. PM implantation
3. Valve durability
1. Vascular and access-site related complications
2. Paravalvular leak
3. PM implantation
3. Valve durability
Preoperative vascular assessment
Vascular complications

Never force the indication for TF
Vascular complications in TAVR

• Drop in access-site related major/life-threatening vascular complication rate with “low-profile” devices (32Fr → 14Fr sheath)

• Vascular complications: 5-11% (dissection, rupture)

• (SAVR: <2%)

• TF >> TA = TAO

• New devices will further decrease the risk

• Choice of the right TAVR access-site is the key factor to further decrease vascular complications (Heart-Team)

1. Vascular and access-site related complications
2. Paravalvular leak
3. PM implantation
3. Valve durability
PLV

PVL ++

Re-ballooning

PVL +
PVL and mortality
SAPIEN 3

- Enhanced frame geometry for ultra-low delivery profile
- Low frame height
- Bovine pericardial tissue
- Outer skirt to reduce PVL
SAPIEN 3

Paravalvular Leak (AT)

Paravalvular Leak: S3HR & S3i
(Valve Implant Patients)

Percent of Evaluable Echocardiograms

N =
1 Year 92
2 Years 73
3 Years 48
4 Years 32
5 Years 16

Percent of evaluable echos

None/Trace    Mild    Moderate    Severe

No. of Echos

30 Days 1504
Repositionable valves

LOTUS Valve (996pts)
- repositioned: 29.2%
- Severe PVL: 0%
- Moderate PVL: 0.3%

Evolut R (151pts, 317pts)
- repositioned: 22.1%
- Moderate to Severe PVL: 0-8%

PVL after TAVR

- Moderate to severe PVL rate after TAVR: 0.3-11%
  (SAVR: 0-2%; sutureless valves: 0.4-2.5%)
- Moderate PVL > severe PVL
- New valve design to decrease the risk of PVL
- Balloon pre-dilation increases the risk of PVL (RR: 0.59)
- No BAV, choice of the right TAVR-valve, Positioning, sizing, post-TAVR re-balloonning and bailout VinV are key factors to further decrease the risk of PVL post-TAVR

1. Vascular and access-site related complications
2. Paravalvular leak
3. PM implantation
3. Valve durability
PM after TAVR

Pacing after cardiac surgery, transcatheter aortic valve implantation and heart transplantation

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
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<tbody>
<tr>
<td>1) High degree or complete AV block after cardiac surgery and TAVI. A period of clinical observation up to 7 days is indicated in order to assess whether the rhythm disturbance is transient and resolves. However, in case of complete AV block with low rate of escape rhythm this observation period can be shortened since resolution is unlikely.</td>
<td>I</td>
<td>C</td>
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<tr>
<td>Sinus node dysfunction after cardiac surgery and heart transplantation. A period of clinical observation from 2 to 4 weeks is indicated in order to assess whether the disturbance resolves.</td>
<td>I</td>
<td>C</td>
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<tr>
<td>Sinus node dysfunction after cardiac surgery and transplantation. Cardiac pacing should be considered in symptomatic patients with atrioventricular block. Pacemaker implantation improves the quality of life in these patients.</td>
<td>II</td>
<td>C</td>
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Predictors for new PM after TAVR


STS/EACTS Latin America Cardiovascular Surgery Conference 2017
PM after TAVR

- New PM after TAVR: 6-30% (SAVR: 2.3-8.5%; sutureless valves: 1.8-7.7%)
- Lotus > CoreValve > Sapien
- Balloon pre-dilation seems not to increase the risk of PM
- Positioning, sizing, and choice of the right TAVR-valve, are key factors to decrease the risk of new PM implantation (less oversizing, better re-positioning: “not-too-low”)

1. Vascular and access-site related complications
2. Paravalvular leak
3. PM implantation
3. Valve durability
SAVR bioprosthesis

• FU > 20 years
• Proven age-related durability

Hancock II Bioprosthesis for Aortic Valve Replacement: The Gold Standard of Bioprosthetic Valves Durability?

Tirone E. David, MD, Susan Armstrong, MS, and Manjula Mangati, MS
Division of Cardiovascular Surgery of Peter Munk Cardiac Centre, Toronto General Hospital and University of Toronto, Toronto, Ontario, Canada.

Background. This study examined the long-term durability of the Hancock II bioprosthesis (Medtronic, Minneapolis, MN) in the aortic position.

Methods. From 1982 to 2004, 1,134 patients underwent aortic valve replacement (AVR) with Hancock II bioprosthesis and were prospectively monitored. Mean patient age was 67 ± 11 years; 302 patients were younger than 60, 402 were 60 to 70, and 528 were older than 70. Median follow-up was 12.5 years and 99.2% complete. Valve function was assessed in 94% of patients. Freedom from adverse events was estimated by the Kaplan-Meier method.

Results. Survival at 20 and 25 years was 19.2% ± 5% and 4.7% ± 3%, respectively, with only 31 and 3 patients at risk. Survival at 20 years was 34.9% ± 4.4% in patients younger than 60, 22.7% ± 3.3% in those 60 to 70, and 2.4% ± 1.5% in those older than 70 (p = 0.05). Structural valve deterioration developed in 67 patients aged younger than 60, in 18 patients aged 60 to 70, and in 2 patients older than 70. The freedom from structural valve deterioration at 20 years was 63.4% ± 4.2% in the entire cohort, 59.2% ± 5.7% in patients younger than 60 years, 62.5% ± 3.7% in patients aged 60 to 70, and 99.8% ± 0.2% in patients older than 70 (truncated at 19 years). Repeat AVR was performed in 104 patients (7.6% for structural valve failure, 18 for endocarditis, and 34 for other reasons). At 20 years, overall freedom from AVR was 63.1% ± 4% for any reason, 28.8% ± 5.4% in patients younger than 60 years, 58.6% ± 3.2% in patients 60 to 70, and 98.3% ± 0.6% in patients older than 70.

Conclusion. Hancock II bioprostheses is a very durable valve in patients 60 years and older and is probably the gold standard of bioprosthetic valve durability in this patient population.

(Am J Thorac Surg 2010;139:775-83) © 2010 by The Society of Thoracic Surgeons

Fig 3. Freedom from reoperation due to structural valve deterioration is shown for (A) all patients (dotted lines on either side of solid line represent upper and lower 95% confidence interval) and (B) according to age group.
• FU > 20 years
• Proven age-related durability
TAVR valve durability

• 5 year follow-up shows good results with low degeneration rate
• Limited number of “survivors” from first cohorts of patients.
• Long-term durability can be limited by:
  • Underexpansion
  • Crimping
  • Calcium in native leaflets

Discussion

• In TAVR, incidence of PVL, vascular complications and new PM implantation is still high compared to SAVR
• Long-term TAVR valve durability is still not yet proven

• Hospital mortality and stroke after TAVR are low and more related to the patients’ comorbidities than to the procedure itself
• Next generation TAVR devices will overcome the limits of the available valves.
Conclusion

• In 2017, TAVR has higher risks of PVL, vascular complications and new PM implantation compared to SAVR.

• While waiting for next-generation devices and long-term results, TAVR in low-risk patients should only be considered in selected cases.