Sutureless Aortic Valve: Where do they stand in the Era of TAVI?

Hani K. Najm MD, Msc, FRCSC,, FACC, FESC
Chair, Congenital and Pediatric Heart Surgery
Cleveland Clinic Children’s
Cleveland, Ohio
• No Disclosure
Are we doing well with SAVR?
% of patients with severe PPM

- TAVI
- SAVR-ST
- SAVR-SL

16–18 (n=18)
19–20 (n=66)
21–22 (n=48)
23–25 (n=18)

Follow-up
Discharge

Annulus size (mm)

P = 0.049 at discharge; P = 0.007 at follow-up (TAVI vs. SAVR-ST and SAVR-SL)

P = NS
Why change standard AVR

- The need for bioprosthetic AV has become more due aging population, in some centers reaches 80% of total AVR

- Hemodynamic performance of standard stented bioprostheses are suboptimal in particular in small aortic roots leading to “PPM” which may necessitate ARE with increased risk in frail patients

- Combined procedures such as CABG and AVR has increased due to aging population

- Calcified aortic sinuses presents a surgical challenge

- Smaller access and mini-invasive procedures proven efficacious and useful

- Ample evidence is available correlating longer CPB and myocardial ischemic time to increased M&M
Is TAVI the answer for these cases?

- Aortic valve is not excised therefore the possibility of coronary obstruction
- Peripheral access still has substantial M&M
- Significant paravalvular leak is detrimental to survival
- Long term results are still awaited
- Cost vs benefit has been questioned
- Pacemaker implantation can be substantial
- Crimping of the valve may affect long term SVD
- May not be suitable for bicuspid AV
What are Sutureless AV

- Stent mounted
- Rapid deployment
- Self anchoring
  - AT annulus
  - At sinuses
  - At ST junction
Advantages of Sutureless Valve

- Complete excision of the diseased valve.
- Anatomical tailoring to individual patient anatomy.
- Atraumatic introduction with no crimping of the the valve
- Valves are self anchoring at annulus/sinuses/ST junction, self expanding for easy implantation
- Due to rapid deployment leads to shorter CPB and ischemic time
- Permits minimally invasive cardiac surgery procedures while delivering gold standard surgical outcome.
Sutureless Aortic Valves

- Perceval S
- Intuity
- Enable 3f
Examples of Standard Aortotomies

Transverse

Hockey Stick

Lazy S
Leaflet Excision
Annular Debridement

- Calcification removed
Fig 1: Valve design features: button holes. Button holes allow correct axial-rotational positioning in the native aortic root.
(LC = left coronary, NC = noncoronary, RC = right coronary.)

Fig 2: Valve design features: dual collar design, with supra-annular and infra-annular sealing collars.
Perceval S – the design

Outflow Ring: at the STJ level

Sinusoidal Struts: anchoring into Valsalva Sinuses

Straight commissural struts: supporting the valve

Inflow tissue ring
Perceval S – collapsing system

Collapsed Outflow Ring

Valve Leaflets are creaseproof

Collapsed Inflow Ring
INTUITY VALVE SYSTEM

Figure 1. Rapid-deployment aortic valve: EDWARDS INTUITY Valve System, Model 8300A (Edwards Lifesciences LLC, Irvine, Calif).
Anatomic and Valve Considerations For Sizing

Supra-annular
Intra-annular
Sub-annular
Guiding Suture Placement in the Annulus

- Conventional suture techniques, such as non-evert ing mattress, figure of eight or simple can be used with this valve.
- Three annular sutures equally spaced and placed in the middle of each sinus to guide the valve onto the annulus.
- Non-pledgetted, braided sutures are recommended.

Non-Everting

Figure of Eight
Guiding Suture Placement on the Valve

- First inspect the valve before implant for evidence of extreme temperature exposure or other damage
- Secure valve by holding distal handle
- Place each suture through the sewing ring in positions corresponding to the annular suture positions
- Avoid inserting too deeply through sewing ring
Valve Inspection

- Confirm valve seating
- Confirm valve position
- Close the aortotomy
Perceval Clinical Experience

Perceval has the broadest clinical history available in sutureless technology. Over 15,000 Perceval implants ytd and ~9 years clinical experience.

Total of 124 publications since the FIM in 2007:
- 2008: 1
- 2009: 2
- 2010: 2
- 2011: 2
- 2012: 17
- 2013: 20
- 2014: 24
- 2015: 46
- 2016: 10

FDA APPROVED

Cleveland Clinic Children’s
Perceval Clinical Studies Roadmap

<table>
<thead>
<tr>
<th>Enrolment status</th>
<th>Completed</th>
<th>Completed</th>
<th>Completed</th>
<th>Completed</th>
<th>Ongoing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients and centers</td>
<td>30 pts 3 EU centres</td>
<td>150 pts 9 EU centres</td>
<td>658 pts 26 EU centres</td>
<td>300 pts 18 centers</td>
<td>(465 Perceval)</td>
</tr>
<tr>
<td>Endpoints</td>
<td>Feasibility 30 days safety</td>
<td>3-6 months safety and effectiveness</td>
<td>12 months safety and effectiveness</td>
<td>Composite valve success &amp; safety</td>
<td>Observational. Real world performance</td>
</tr>
<tr>
<td>Indications</td>
<td>≥ 75 years</td>
<td>≥ 75 years</td>
<td>≥ 65 years</td>
<td>≥ 18 years</td>
<td>As per IFU</td>
</tr>
<tr>
<td>Follow-up</td>
<td>5 years completed</td>
<td>5 years completed</td>
<td>Up to 5 years ongoing</td>
<td>Up to 5 years ongoing</td>
<td>As per IFU Up to 10 years</td>
</tr>
</tbody>
</table>
Early and intermediate outcome after aortic valve replacement with a sutureless bioprosthesis: Results of a multicenter study.

- Retrospective analysis of 314 pts
- **Perceval S** valve at 5 European centers.
- Mean age: 77.9 ± 5.0 years.
- Mean euroSCORE II: 9.0% ± 7.6%.
- AVR + CABG: 94 patients.
- Isolated AVR: 220 patients.
- Procedure success rate: 99.7%.

Early outcome; Sutureless AVR.

- Mean aortic cross-clamp time:
  - Isolated AVR: 39 ± 15 minutes.
  - AVR + CABG: 52 ± 26 minutes.

- Severe paravalvular leak: 2 patients (0.6%)

- In-hospital mortality:
  - Overall: 3.2%.
  - Isolated AVR: 1.4%.
  - AVR + CABG: 7.4%

- In-hospital mortality not affected by
  - euroSCORE <10% vs >10% (p = .558).
  - Age > 80 vs < 80 years (p = .125).
  - Full vs mini sternotomy (p = .921).

Observed v/s Predicted Mortality.
Sutureless AVR + CABG.

Trans-valvular gradients (mmHg) after sutureless AVR.

LV mass and LV mass indexed by visit - 3y

Perceval S experience

Cleveland Clinic Children’s
One-year outcomes of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) trial.

- 17 surgeons from 6 European centers.
- 146 consecutive patients with aortic stenosis had successful implantation of Intuity sutureless aortic bioprosthesis.
- Mean age: 75.5 ± 6.7 years
- 59% had isolated aortic valve replacement.
- 41% had concomitant procedures.
- Mini- sternotomy: 49%.
- Cross-clamp time (isolated AVR): 41.1 ± 10.6 minutes.

Early outcome; Sutureless AVR (Intuity)

- Early valve-related mortality: 1.4% (2/146).
- Mean follow-up: 9.8 ± 5.1 months.
- Cumulative survival: 92.5%.
- Mean aortic valve gradient at 1 year: 8.4 ± 3.4 mm Hg.

Sutureless aortic valve replacement as an alternative treatment for patients belonging to the “gray zone” between transcatheter aortic valve implantation and conventional surgery: A propensity-matched, multicenter analysis (Perceval S)

- Multicenter, propensity matched study.
- From April 2008 to May 2011.
- 468 transapical-TAVIs performed in 20 centers.
- 51 Sutureless valves performed in 3 centers
- Based on a propensity score analysis,
- 2 groups with **38 matched pairs** were created.

Early results.
Sutureless AVR vs TA- TAVI *(Perceval S)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>TA-TAVI (n = 38)</th>
<th>SU-AVR (n = 38)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital mortality, n (%)</td>
<td>2 (5.3)</td>
<td>0 (0)</td>
<td>.49</td>
</tr>
<tr>
<td>ARF requiring CVVH, n (%)</td>
<td>1 (2.6)</td>
<td>2 (5.3)</td>
<td>1.00</td>
</tr>
<tr>
<td>AMI, n (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1.00</td>
</tr>
<tr>
<td>Stroke, n (%)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1.00</td>
</tr>
<tr>
<td>Bleeding (life-threatening/disabling, major), n (%)</td>
<td>2 (5.3)</td>
<td>1 (2.6)</td>
<td>1.00</td>
</tr>
<tr>
<td>PPM implantation, n (%)</td>
<td>2 (5.3)</td>
<td>2 (5.3)</td>
<td>1.00</td>
</tr>
<tr>
<td>Mean transaortic gradient, mm Hg</td>
<td>10.25 ± 5.03</td>
<td>10.95 ± 3.72</td>
<td>.59</td>
</tr>
<tr>
<td>AR at discharge (at least mild), n (%)</td>
<td>17 (44.7)</td>
<td>6 (15.8)</td>
<td>.001</td>
</tr>
<tr>
<td>LVEF at discharge, % (IR)</td>
<td>60 (55-60)</td>
<td>60 (54-65)</td>
<td>.75</td>
</tr>
<tr>
<td>New-onset atrial fibrillation, n (%)</td>
<td>7 (18.4)</td>
<td>16 (42.1)</td>
<td>.04</td>
</tr>
<tr>
<td>Orotracheal intubation time, hours (IR)</td>
<td>4 (0-5)</td>
<td>5.5 (4-8)</td>
<td>.21</td>
</tr>
</tbody>
</table>

*(J Thorac Cardiovasc Surg 2012;144:1010-8).*
Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: A propensity-matched analysis of 2 strategies in high-risk patients

- From January 2010 to March 2012.
- 122 patients (age 79.4 ± 5.3 years, logistic euroSCORE 12% ± 8.4%) underwent minimally invasive sutureless aortic valve replacement.
- 122 (age 84.6 ± 6.2 years, logistic euroSCORE 20.9 ± %2.5%) underwent TAVI.
- After propensity matching, 37 matched pairs were available for analysis.

Early results; **(Perceval S) AVR vs TAVI.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Sutureless AVR (n = 37)</th>
<th>TAVI (n = 37)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital mortality</td>
<td>0</td>
<td>3 (8.1%)</td>
<td>.24</td>
</tr>
<tr>
<td>ARF requiring CVVH</td>
<td>0</td>
<td>2 (5.4%)</td>
<td>.25</td>
</tr>
<tr>
<td>Stroke</td>
<td>2 (5.4%)</td>
<td>2 (5.4%)</td>
<td>&gt;.999</td>
</tr>
<tr>
<td>Permanent PM implantation</td>
<td>4 (10.8%)</td>
<td>1 (2.7%)</td>
<td>.18</td>
</tr>
<tr>
<td>Mean transaortic gradient (mm Hg)</td>
<td>13.3 ± 3.9</td>
<td>14.2 ± 5.8</td>
<td>.564</td>
</tr>
<tr>
<td>AR at discharge (at least mild)</td>
<td>0</td>
<td>5 (13.5%)</td>
<td>.027</td>
</tr>
</tbody>
</table>

*(J Thorac Cardiovasc Surg 2014;147:561-7).*
Kaplan-Meier survival curve. (Perceval S) AVR vs TAVI.

(J Thorac Cardiovasc Surg 2014;147:561-7).
# 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Developed in Collaboration With the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons

## Practice Guideline

### Table: Risk Stratification for Interventional Procedures

<table>
<thead>
<tr>
<th>Low Risk (Must Meet ALL Criteria in This Column)</th>
<th>Intermediate Risk (Any 1 Criterion in This Column)</th>
<th>High Risk (Any 1 Criterion in This Column)</th>
<th>Prohibitive Risk (Any 1 Criterion in This Column)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STS PROM*</td>
<td>&lt;4% AND</td>
<td>&gt;8% OR</td>
<td>Predicted risk with surgery of death or major morbidity (all-cause) &gt;50% at 1 y OR</td>
</tr>
<tr>
<td>Frailty†</td>
<td>4%-8% OR</td>
<td>≥2 Indices (mild) AND (moderate to severe) OR</td>
<td></td>
</tr>
<tr>
<td>Major organ system compromise not to be improved postoperatively‡</td>
<td>1 Index (mild) OR</td>
<td>No more than 2 organ systems OR</td>
<td>≥3 Organ systems OR</td>
</tr>
<tr>
<td>Procedure-specific impedance§</td>
<td>Possible procedure-specific impedance OR</td>
<td>Possible procedure-specific impedance OR</td>
<td>Severe procedure-specific impedance OR</td>
</tr>
</tbody>
</table>

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Treating the patients in the ‘grey-zone’ with aortic valve disease: a comparison among conventional surgery, sutureless valves and transcatheter aortic valve replacement

Claudio Muneretto, Gianluigi Bisleri*, Annalisa Moggi, Lorenzo Di Bacco, Maurizio Tespili, Alberto Repossini and Manfredo Rambaldini

612 intermediate-high risk patients

Group 1: Surgical AVR 204 pts

Group 2: Sutureless valve 204 pts

Group 3: TAVR 204 pts

Division of Cardiac Surgery – University of Brescia Medical School
INTRA-OPERATIVE DATA

- CPB
- CROSS-CLAMP

Prostheses Size (mm)

- AVR
- SUTURELESS
- TAVR

p<0.001
POST-OPERATIVE Gradient / AR

**post-op PEAK GRADIENT (mmHg)**

- **AVR**
- **PERCEVAL**
- **TAVR**

\( p = 0.01 \)

**post-op MEAN GRADIENT (mmHg)**

- **AVR**
- **PERCEVAL**
- **TAVI**

\( p = \text{NS} \)

**AR ≥ Grade II**

- **AVR**
- **PERCEVAL**
- **TAVR**

\( p = 0.028 \)

\( p < 0.001 \)
Overall Survival

TAVR vs SUTURELESS

TAVR vs AVR, p<0.001

Follow-Up (Months)

Patients at Risk

<table>
<thead>
<tr>
<th>Group</th>
<th>0</th>
<th>4</th>
<th>8</th>
<th>12</th>
<th>16</th>
<th>20</th>
<th>24</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR</td>
<td>137</td>
<td>167</td>
<td>155</td>
<td>141</td>
<td>132</td>
<td>120</td>
<td>108</td>
</tr>
<tr>
<td>SUTURELESS</td>
<td>192</td>
<td>149</td>
<td>131</td>
<td>122</td>
<td>105</td>
<td>78</td>
<td>41</td>
</tr>
<tr>
<td>TAVR</td>
<td>184</td>
<td>145</td>
<td>112</td>
<td>108</td>
<td>78</td>
<td>61</td>
<td>29</td>
</tr>
</tbody>
</table>
Sutureless AVR experience
King Abdulaziz Cardiac center

May 2011 to July 2014.

65 patients with severe aortic stenosis underwent aortic valve replacement with suture-less bio-prosthesis.

Average age: 72.6 years.

Male : Female ratio: 60% : 40%.

Mean euro score 11.5
Patient Profile  
(Suture-less AVR) number 65

- Concomitant diseases:
  - Coronary artery disease: 57%
  - Severe mitral regurgitation: 9%
  - Severe tricuspid regurgitation: 6%

- Elevated RV systolic pressure: 83%
- Severe pulmonary hypertension: 23%
- Bicuspid aortic valve: 15%
Type of Prosthesis Used (Suture-less AVR)

- Perceval: 50 patients
- Intuity: 15 patients
- 3f Enable: 5 patients

Total: n = 65 patients
Operative Procedures
(Suture-less AVR)

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isolated AVR</td>
<td>7.5%</td>
<td>5</td>
</tr>
<tr>
<td>CABG+AVR</td>
<td>8.5%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Re-do CABG+AVR</td>
<td>2%</td>
<td>2</td>
</tr>
<tr>
<td>Mitral repair+AVR</td>
<td>53%</td>
<td>42.5%</td>
</tr>
<tr>
<td>Tricuspid repair+AVR</td>
<td>2%</td>
<td>57.5%</td>
</tr>
<tr>
<td>Septal myectomy</td>
<td>2%</td>
<td>n = 65</td>
</tr>
</tbody>
</table>
Bypass & Cross-clamp Times (Suture-less AVR)

- Average bypass time
- Average cross-clamp time

All patients: n = 52
Combined procedures
Operative Results
(Suture-less AVR)

- Mortality: 1/52 (2%), unrelated to valve function.
- Average mean trans-prosthetic gradient: 8.9 mmHg.
- Prosthetic regurgitation:
  - No regurgitation: 42 (89.49%).
  - Mild regurgitation: 5 (10.6%).
- Para-prosthetic leak:
  - No leakage: 45 (95.7%).
  - Mild leakage: 2 (4.3%).
Follow-up Data
(Suture-less AVR)

- Follow-up period:
  Mean follow-up: 24 months.
  (Range: 1 month to 48 month).
- Peak gradient (average): 27mmHg.
- Mean gradient (average): 15mmHg.
- Prosthetic regurgitation: Mild 5 (10.6%).
- Para-prosthetic leak: Mild 5 (10.6%).
Clinical results:

- Low and stable transvalvular gradients up to 5 years
- 0% SVD reported
- Early and late all cause mortality: 3.4% and 7%
- 0% thrombosis
- Early and late stroke rate: 1.6% and 0.8% (comparable to what reported for traditional AVR)
- Early and late major PVL rate: 1.4% and 1.0% (comparable to what reported for traditional AVR)

No valve dislodgement or migration reported.
Sutureless and TVR: Early Mortality comparison

Sutureless aortic valve replacement may improve early mortality compared with transcatheter aortic valve implantation: A meta-analysis of comparative studies

Hisato Takagi (MD, PhD)*, Takuya Umemoto (MD, PhD) for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

Department of Cardiovascular Surgery, Shizuka Medical Center, Shizuka, Japan


<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Sutureless AVR Events</th>
<th>Total</th>
<th>TAVI Events</th>
<th>Total</th>
<th>Weight</th>
<th>Odds Ratio IV, Random, 95% CI</th>
<th>Odds Ratio IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biancari 2015* [7]</td>
<td>2</td>
<td>144</td>
<td>10</td>
<td>144</td>
<td>22.4%</td>
<td>0.19 [0.04, 0.88]</td>
<td></td>
</tr>
<tr>
<td>D’Onofrio 2012 [8]</td>
<td>0</td>
<td>38</td>
<td>2</td>
<td>38</td>
<td>5.6%</td>
<td>0.19 [0.01, 4.08]</td>
<td></td>
</tr>
<tr>
<td>Doss 2012 [9]</td>
<td>3</td>
<td>27</td>
<td>5</td>
<td>29</td>
<td>22.4%</td>
<td>0.60 [0.13, 2.80]</td>
<td></td>
</tr>
<tr>
<td>Kamperidis 2015 [6]</td>
<td>1</td>
<td>48</td>
<td>10</td>
<td>221</td>
<td>12.3%</td>
<td>0.45 [0.06, 3.59]</td>
<td></td>
</tr>
<tr>
<td>Miceli 2015* [5]</td>
<td>0</td>
<td>37</td>
<td>3</td>
<td>37</td>
<td>5.9%</td>
<td>0.13 [0.01, 2.64]</td>
<td></td>
</tr>
<tr>
<td>Muneretto 2015 [10]</td>
<td>3</td>
<td>53</td>
<td>6</td>
<td>55</td>
<td>25.5%</td>
<td>0.49 [0.12, 2.07]</td>
<td></td>
</tr>
<tr>
<td>Santarpino 2014 [11]</td>
<td>0</td>
<td>37</td>
<td>3</td>
<td>37</td>
<td>5.9%</td>
<td>0.13 [0.01, 2.64]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td></td>
<td>384</td>
<td>561</td>
<td>100.0%</td>
<td>0.33</td>
<td>[0.16, 0.69]</td>
<td></td>
</tr>
<tr>
<td>Total events</td>
<td>9</td>
<td>39</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Tau² = 0.00; Chi² = 2.31, df = 6 (P = 0.89); I² = 0%
Test for overall effect: Z = 2.97 (P = 0.003)

Forest plot of odds ratios for early mortality among patients assigned to sutureless aortic valve replacement (AVR) versus transcatheter aortic valve implantation (TAVI).
1, confidence interval; IV, inverse variance.
Online-published ahead of print.
## Table 3. Intraoperative and Postoperative Outcomes of the Propensity-Matched Population

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Sutureless (n = 82)</th>
<th>Stented (n = 82)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time, min</td>
<td>145 ± 36</td>
<td>173 ± 57</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cross-clamp time, min</td>
<td>47 ± 16</td>
<td>59 ± 23</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>For isolated AVR, min</td>
<td>35 ± 12 (n = 57) 49 ± 16 (n = 62)</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>CPB time, min</td>
<td>71 ± 11</td>
<td>92 ± 33</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ventilation time, h</td>
<td>9.5 ± 4.6</td>
<td>16.6 ± 6.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intensive care unit, d</td>
<td>2 ± 1.2</td>
<td>2.8 ± 1.3</td>
<td>0.040</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>5 (6.1)</td>
<td>7 (8.5)</td>
<td>0.360</td>
</tr>
<tr>
<td>Reexploration for bleeding</td>
<td>2 (2.4)</td>
<td>5 (6.1)</td>
<td>0.221</td>
</tr>
<tr>
<td>Paroxysmal AF</td>
<td>3/74 (4.1)</td>
<td>12/76 (15.8)</td>
<td>0.015</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>3 (3.7)</td>
<td>11 (13.4)</td>
<td>0.024</td>
</tr>
<tr>
<td>Stroke/TIA</td>
<td>3 (3.7)</td>
<td>6 (7.3)</td>
<td>0.248</td>
</tr>
<tr>
<td>Respiratory insufficiency</td>
<td>2 (2.4)</td>
<td>10 (12.2)</td>
<td>0.016</td>
</tr>
<tr>
<td>Blood transfusion units</td>
<td>1.2 ± 1.3</td>
<td>2.5 ± 3.7</td>
<td>0.005</td>
</tr>
<tr>
<td>Exitus, 30 d</td>
<td>2 (2.4)</td>
<td>3 (3.7)</td>
<td>0.650</td>
</tr>
<tr>
<td>Hospital stay, d</td>
<td>10.9 ± 2.7</td>
<td>12.4 ± 4.4</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*Continuous data are presented as mean ± standard deviation and categorical data as number (%)*.  
AF = atrial fibrillation; AVR = aortic valve replacement; CPB = cardiopulmonary bypass; TIA = transient ischemic attack.

### Results

- **Traditional Sutured**
  - ICU stay (Days): 2.8
  - Transfusion (Blood units): 2.0
  - Ventilation (Hours): 16.6

- **Perceval**
  - ICU stay (Days): 2.5
  - Transfusion (Blood units): 1.2
  - Ventilation (Hours): 9.5

**Source:** Better Short-Term Outcome by Using Sutureless Valves: A Propensity-Matched Score Analysis
Key recommendations regarding PATIENTS INDICATIONS:

- Sutureless or rapid deployment as an alternative to stented valves in patients requiring aortic replacement following the current guidelines for biological valve.
- Sutureless can be more beneficial in redo cases or delicate aortic wall conditions as calcified root, porcelain aorta, or prior implantation of aortic homograft or stenteless valve.
- Sutureless valves are the first choice in case of concomitant procedures (including multiple valves) or small annulus to reduce XCT
- Implantation possible in bicuspid valves type 1 and 2
- Contraindications for Bicuspid valve type 0
- Contraindications for annular abscess or destruction due to endocarditis
Sutureless Consensus paper
key recommendations from an international panel of 31
international renowned experts

KEY TECHNICAL recommendations:

- **Proctoring and education** are necessary
- **Careful but complete decalcification** of the aortic root
- **Oversizing** with sutureless valves is not beneficial
- **Intraoperative transoesophageal echocardiography**
- In case of **multiple valves procedures**, it is recommended to remove the native aortic valve prior to the mitral procedure and to implant the sutureless aortic valve after reconstruction of the mitral valve
- **Proximal anastomoses** of concomitant CABG during single aortic clamp period or side clamping when possible
- **No specific recommendations** on the use of anticoagulation or antiplatelet therapy after the implantation. The institutional protocol on bioprosthetic valves should be followed
Important Issues

- The fate of paravalvular leak
- Can Sutureless valve be explanted, early or late?
- Can VIV be performed?
- Can DVR be performed, repair or replacement?
- Long term outcome?
- Would one type of sutureless aortic valve be enough for all AVR?
Indications for Sutureless AVR

AVR patients ideal for sutureless AVR

- Small Aorta
- Small Annuli
- Calcified Aortic root
- Compromised pre-operative contractile function
- Higher-risk patients requiring concomitant procedure (CABG)
- Respiratory disorders (COPD)
- Patients previously implanted with “stentless” prosthesis

Subjects of age $\geq$ 65 years;
Subjects with aortic valve stenosis or steno–insufficiency
Conclusions

- Sutureless aortic valve replacement is safe and has excellent early and mid outcome
- Suitable for small aortic roots, calcified roots and higher risk patients
- Reduces ischemic and pump time
- Paravalvular leak is low and may not affect mortality
- Long term outcome is still awaited.
SUTURELESS VALES