VALVOLA AORTICA SENZA SUTURE

Ottavio Alfieri

Istituto Scientifico San Raffaele
Milano
Aetiologies of Single Valvular Heart Diseases in the Euro Heart Survey

Iung et al. Eur Heart J 2003;24:1244-53

Patient Characteristics in the Euro Heart Survey

<table>
<thead>
<tr>
<th></th>
<th>Age (years)</th>
<th>≥ 70 years (%)</th>
<th>≥ 1 comorbidity (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS</td>
<td>69 ± 12</td>
<td>56</td>
<td>36</td>
</tr>
<tr>
<td>AR</td>
<td>58 ± 16</td>
<td>25</td>
<td>26</td>
</tr>
<tr>
<td>MS</td>
<td>58 ± 13</td>
<td>18</td>
<td>22</td>
</tr>
<tr>
<td>MR</td>
<td>65 ± 14</td>
<td>44</td>
<td>42</td>
</tr>
</tbody>
</table>

Iung et al. *Eur Heart J* 2003;24:1244-53

...Aortic stenosis is life-threatening and progresses rapidly...

Sources: ¹ S.J. Lester et al., “The Natural History and Rate of Progression of Aortic Stenosis,” Chest 1998


Management of Severe Symptomatic AS in the Elderly

Aortic Stenosis ≥ 75 years (n=398)

No Severe AS (n=114)

Severe AS (n=284)

No Symptoms (n=68)

Symptoms (n=216)

No Intervention (n=72) 33%

Intervention (n=144) 67%

Iung et al. *Eur Heart J* 2005;26:2714-2720
Management of Severe Symptomatic AS in the Elderly

Aortic Stenosis ≥ 75 years (n=398)

- No Severe AS (n=114)
- Severe AS (n=284)

  - No Symptoms (n=68)
  - Symptoms (n=216)

    - No Intervention (n=72) 33%
    - Intervention (n=144) 67%

Iung et al. Eur Heart J 2005;26:2714-2720
Addition of Frailty and Disability to Cardiac Surgery Risk Scores Identifies Elderly Patients at High Risk of Mortality or Major Morbidity

Jonathan Afilalo, MD, MSc; Salvatore Mottillo, MD; Mark J. Eisenberg, MD, MPH; Karen P. Alexander, MD; Nicolas Noiseux, MD; Louis P. Perrault, MD, PhD; Jean-Francois Morin, MD; Yves Langlois, MD; Samuel M. Ohayon, BSc; Johanne Monette, MD, MSc; Jean-Francois Boivin, MD, ScD; David M. Shahian, MD; Howard Bergman, MD

Circ Cardiovasc Qual Outcomes. 2012;5:222-228
Aortic Valve Implantation
The Evolving Process

Conventional through midline sternotomy
Surgical through minimal incision
On pump, arrested heart sutureless valve replacement
Transaortic delivery
Transapical delivery
Transaxillary delivery
Transcarotid delivery
Percutaneous transfemoral

TAVI
Aortic Valve Implantation
The Evolving Process

Conventional through midline sternotomy
Surgical through minimal incision
On pump, arrested heart sutureless valve replacement
Transaortic delivery
Transapical delivery
Transaxillary delivery
Transcarotid delivery
Percutaneous transfemoral

TAVI
Sutureless aortic prosthesis

Medtronic 3f Enable  
Sorin Perceval S  
Edwards Intuity
Minimally invasive AVR vs. full sternotomy AVR:

- Reduced blood loss and transfusion
- Reduced postoperative pain
- Improved recovery of respiratory function
- Earlier extubation, shorter LOS

### Table

<table>
<thead>
<tr>
<th>Variable</th>
<th>Min</th>
<th>Full</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-hospital death</td>
<td>1</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>Reexploration for bleeding</td>
<td>0</td>
<td>3</td>
<td>0.24</td>
</tr>
<tr>
<td>Mean mediastinal drainage (mL/m²)</td>
<td>183 ± 89</td>
<td>280 ± 189</td>
<td>0.004</td>
</tr>
<tr>
<td>Bleeding &gt; 800 mL</td>
<td>0</td>
<td>7</td>
<td>0.012</td>
</tr>
<tr>
<td>Mean blood transfused (mL/m²)</td>
<td>157 ± 98</td>
<td>293 ± 172</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

### Postoperative Spirometric Data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Min</th>
<th>Full</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV₁</td>
<td>80.8 ± 18.6</td>
<td>81.7 ± 21.5</td>
<td>0.84</td>
</tr>
<tr>
<td>MIP</td>
<td>54 ± 12³</td>
<td>46.6 ± 17.7³</td>
<td>0.007</td>
</tr>
<tr>
<td>MEP</td>
<td>62 ± 11.4³</td>
<td>53 ± 10.5³</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>RV</td>
<td>51 ± 10.5</td>
<td>53 ± 17.4</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Postoperative spirometric data at 1-2 months (% expected):

- TLC: 92 ± 13³ vs. 88.6 ± 19³, p = 0.35
- FEV₁: 80.5 ± 22 vs. 79.6 ± 20, p = 0.93
- MIP: 72 ± 25³ vs. 67 ± 21³, p = 0.34
- MEP: 68.8 ± 14.7³ vs. 64.7 ± 10.6³, p = 0.155
- RV: 91 ± 25.5 vs. 86 ± 18.4, p = 0.32

Mini-sternotomy for aortic valve replacement reduces the length of stay in the cardiac intensive care unit: meta-analysis of randomised controlled trials

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean difference</th>
<th>Mean difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
</tr>
<tr>
<td>01</td>
<td>2</td>
<td>3</td>
<td>30</td>
<td>6.43</td>
</tr>
<tr>
<td>02</td>
<td>13</td>
<td>1.3</td>
<td>20</td>
<td>13.2</td>
</tr>
<tr>
<td>03</td>
<td>4.4</td>
<td>0.9</td>
<td>40</td>
<td>5.3</td>
</tr>
<tr>
<td>04</td>
<td>9.9</td>
<td>8</td>
<td>20</td>
<td>9.9</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>110</td>
<td></td>
<td>110</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Heterogeneity: $\chi^2=3.11; \chi^2=36.63, df=3 (p<0.00001); I^2=92%$
Test for overall effect: $Z=1.59 (p=0.11)$

Figure 2  Duration of ventilation in hours.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean difference</th>
<th>Mean difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
</tr>
<tr>
<td>01</td>
<td>233.33</td>
<td>47.95</td>
<td>30</td>
<td>390</td>
</tr>
<tr>
<td>02</td>
<td>240</td>
<td>69</td>
<td>20</td>
<td>496</td>
</tr>
<tr>
<td>03</td>
<td>183</td>
<td>89</td>
<td>40</td>
<td>280</td>
</tr>
<tr>
<td>04</td>
<td>479</td>
<td>274</td>
<td>20</td>
<td>356</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>110</td>
<td></td>
<td>110</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Heterogeneity: $\chi^2=28126.90; \chi^2=57.10, df=3 (p<0.00001); I^2=69%$
Test for overall effect: $Z=1.77 (p=0.08)$

Figure 3  Postoperative bleeding in the first 24 h measured in millilitres.
### Figure 4  Length of intensive care unit stay in days.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean difference</th>
<th>Mean difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
</tr>
<tr>
<td>01</td>
<td>0.28</td>
<td>0.16</td>
<td>30</td>
<td>1.15</td>
</tr>
<tr>
<td>02</td>
<td>1.2</td>
<td>0.1</td>
<td>20</td>
<td>2.1</td>
</tr>
<tr>
<td>03</td>
<td>1.1</td>
<td>0.4</td>
<td>40</td>
<td>1.4</td>
</tr>
<tr>
<td>04</td>
<td>1.83</td>
<td>0.7</td>
<td>20</td>
<td>1.94</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>110</td>
<td>110</td>
<td>100.00</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $\chi^2 = 15.31$, df=3 (p=0.002); $I^2 = 80$

Test for overall effect: $Z=2.99$ (p=0.003)

### Figure 5  Length of hospital stay in days.

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Experimental</th>
<th>Control</th>
<th>Mean difference</th>
<th>Mean difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Total</td>
<td>Mean</td>
</tr>
<tr>
<td>01</td>
<td>8</td>
<td>0.83</td>
<td>30</td>
<td>17.7</td>
</tr>
<tr>
<td>02</td>
<td>9.3</td>
<td>1</td>
<td>20</td>
<td>9.4</td>
</tr>
<tr>
<td>03</td>
<td>7.2</td>
<td>1.6</td>
<td>40</td>
<td>8.2</td>
</tr>
<tr>
<td>04</td>
<td>6.3</td>
<td>2.3</td>
<td>20</td>
<td>6.3</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>110</td>
<td>110</td>
<td>100.00</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $\chi^2 = 35.38$, df=3 (p<0.00001); $I^2 = 62$

Test for overall effect: $Z=1.91$ (p=0.06)

*BMJ Open 2011;1:e000266. doi:10.1136/bmjopen-2011-000266*
Aortic Valve Implantation
The Evolving Process

Conventional through midline sternotomy
Surgical through minimal incision
On pump, arrested heart sutureless valve replacement
Transaortic delivery
Transapical delivery
Transaxillary delivery
Transcarotid delivery
Percutaneous transfemoral

Invasiveness

TAVI
Aortic Valve Implantation
The Evolving Process

Conventional through midline sternotomy
Surgical through minimal incision
On pump, arrested heart sutureless valve replacement
Transaortic delivery
Transapical delivery
Transaxillary delivery
Transcarotid delivery
Percutaneous transfemoral

Invasiveness

TAVI
Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description
Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

April 16, 2002

Dr. Alain Cribier
First-in-Man PIONEER
TAVI Technologies

Current Generation Devices

Edwards Lifesciences  Medtronic CoreValve
Next Generation TAVR System

New Self-Expanding TAVI Systems

PORTICO (St. Jude)  
ENGAGER (Medtronic)  
ACURATE (Symetis)  
EVOLUT R (Medtronic)
Not All New TAVI Systems are Self-Expanding Designs

**Direct Flow:** Polyester fabric cuff with two inflatable rings; positioning wires for placement; bovine tissue valve

**Lotus:** Nitinol wire frame, bovine tissue valve; outer PU skirt; mechanical expansion and locking

**Jena Valve:** Nitinol-based, positioning feelers and clipping mechanism; porcine aortic root valve

**SAPIEN 3:** balloon exp (4 sizes), cobalt frame; bovine tissue valve; outer skirt; precise positioning
AHA/ACC TAVR Guidelines - 2014

Class I:

- Heart Valve Team should collaborate on decisions
- Pts not suitable for AVR and survival > 12 mos

Class Ila:

- Reasonable alternative to surgical AVR in high surgical risk pts
PARTNER Study Design

Symptomatic Severe Aortic Stenosis

ASSESSMENT: High-Risk AVR Candidate
3,105 Total Patients Screened

Total = 1,057 patients
2 Parallel Trials: Individually Powered

High-Risk n = 699

ASSESSMENT: Transfemoral Access

High-Risk TF
1:1 Randomization
TF TAVR VS AVR
Primary Endpoint: All-Cause Mortality (1 yr) (Non-Inferiority)

High-Risk TA
1:1 Randomization
TA TAVR VS AVR

Inoperable n = 358

ASSESSMENT: Transfemoral Access

1:1 Randomization
TF TAVR n = 179 VS Standard Therapy n = 179
Primary Endpoint: All-Cause Mortality Over Length of Trial (Superiority)
Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis

All Cause Mortality (ITT)
Crossover Patients Followed

HR [95% CI] = 0.57 [0.44, 0.75]
p (log rank) < 0.0001

Δ at 1 yr = 20.0%
NNT = 5.0 pts

Δ at 2 yr = 24.3%
NNT = 4.1 pts

<table>
<thead>
<tr>
<th>Months</th>
<th>TAVR</th>
<th>Standard Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>179</td>
<td>179</td>
</tr>
<tr>
<td>6</td>
<td>138</td>
<td>121</td>
</tr>
<tr>
<td>12</td>
<td>124</td>
<td>85</td>
</tr>
<tr>
<td>18</td>
<td>110</td>
<td>67</td>
</tr>
<tr>
<td>24</td>
<td>83</td>
<td>51</td>
</tr>
</tbody>
</table>
Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

All-Cause Mortality (ITT)

HR [95% CI] = 0.88 [0.70, 1.12]

p (log rank) = 0.310

Numbers at Risk

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>AVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>348</td>
<td>351</td>
</tr>
<tr>
<td>33</td>
<td>298</td>
<td>252</td>
</tr>
<tr>
<td>30</td>
<td>260</td>
<td>236</td>
</tr>
<tr>
<td>27</td>
<td>260</td>
<td>236</td>
</tr>
<tr>
<td>24</td>
<td>234</td>
<td>217</td>
</tr>
<tr>
<td>21</td>
<td>172</td>
<td>165</td>
</tr>
<tr>
<td>18</td>
<td>70</td>
<td>65</td>
</tr>
<tr>
<td>15</td>
<td>34</td>
<td>32</td>
</tr>
<tr>
<td>12</td>
<td>34</td>
<td>32</td>
</tr>
<tr>
<td>9</td>
<td>34</td>
<td>32</td>
</tr>
<tr>
<td>6</td>
<td>34</td>
<td>32</td>
</tr>
<tr>
<td>3</td>
<td>34</td>
<td>32</td>
</tr>
<tr>
<td>1</td>
<td>34</td>
<td>32</td>
</tr>
</tbody>
</table>
## Contraindications for transcatheter aortic valve implantation

### Absolute contraindications

Absence of a “heart team” and no cardiac surgery on the site.

Appropriateness of TAVI, as an alternative to AVR, not confirmed by a “heart team”.

**Clinical**

- Estimated life expectancy < 1 year.
- Improvement of quality of life by TAVI unlikely because of comorbidities.
- Severe primary associated disease of other valves with major contribution to the patient’s symptoms that can be treated only by surgery.

**Anatomical**

- Inadequate annulus size (< 18 mm, > 29 mm).
- Thrombus in the left ventricle.
- Active endocarditis.
- Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostia, small aortic sinuses).
- Plaques with mobile thrombi in the ascending aorta, or arch.
- For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity).

### Relative contraindications

- Bicuspid or non-calcified valves.
- Untreated coronary artery disease requiring revascularization.
- Haemodynamic instability.
- LVEF < 20%.
- For transapical approach: severe pulmonary disease, LV apex not accessible.
…Expanding TAVI…

“Off-Label” TAVI

- Bicuspid aortic valve
- Pure Native Valve Aortic Regurgitation
- Moderate and low surgical risk
- Anatomical boundaries
- Subclavian and aortic access
- Mitral prosthesis and Mitral disease
- TAV-in-SAV
- TAV-in-TAV
Log-EuroSCORE

Patients undergoing TAVI procedure (N = 1544)

Patients reporting difficult thoracic approach, porcelain aorta or severe frailty score are excluded

Log - EuroSCORE:
- Mean: 14.1 + 11.8
- Median: 10.3
- 75° percentile: 16.9
FINAL CONSIDERATIONS

• TAVI is the standard of care for inoperable pts (cave futile interventions!!)

• TAVI is an alternative to AVR in high risk pts (the cost of the procedure)

• Stroke rate, vascular complications, residual AR, PM requirement remain a concern

• Extension of TAVI to intermediate risk pts is presently not justified (PARTNER II, SURTAVI, UK TAVI and other studies are exploring the issue)

To note that the risk of TAVI is lower in lower risk pts.