Transcatheter aortic valve implantation
and
pre-procedural risk assessment

Alec Vahanian ,FESC, FRCP(Edin.)
Bichat Hospital
University Paris VII, Paris, France
## Disclosures

- **Relationship with companies who manufacture products used in the treatment of the subjects under discussion**

<table>
<thead>
<tr>
<th>Relationship</th>
<th>Manufacturer(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speaker's Honoraria</td>
<td>Edwards Lifesciences</td>
</tr>
<tr>
<td>Consultant (Advisory Board)</td>
<td>Abbott, Medtronic</td>
</tr>
<tr>
<td></td>
<td>Saint Jude Medical, Valtech</td>
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</tbody>
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#esc2012 www.escardio.org
• General comments on TAVI
• Pre-procedural risk assessment and indications for TAVI
• Pre-procedural risk assessment and feasibility of TAVI
• Conclusions
The Devices for TAVI

Medtronic CoreValve® TAV

Edwards SAPIEN™ THV

CE mark 2007

CE mark 2007

> 50000 patients treated
Procedural complications in SOURCE XT

<table>
<thead>
<tr>
<th>Events</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aborted Procedures - %</td>
<td>0.6</td>
</tr>
<tr>
<td>Unable to Cross Native Valve - %</td>
<td>0.04</td>
</tr>
<tr>
<td>Conversion to Surgery - %</td>
<td>0.4</td>
</tr>
<tr>
<td>Annular Dissection - %</td>
<td>0.4</td>
</tr>
<tr>
<td><strong>Coronary Occlusion - %</strong></td>
<td><strong>0.4</strong></td>
</tr>
<tr>
<td>SAPIEN-in-SAPIEN (Bailout) - %</td>
<td>1.1</td>
</tr>
<tr>
<td>Valve Embolization - %</td>
<td>0.7</td>
</tr>
<tr>
<td>Cardiac Tamponade - %</td>
<td>0.5</td>
</tr>
</tbody>
</table>

(Wendler; Vahanian @ EuroPCR 2012)
## Clinical outcome at 30 Days

<table>
<thead>
<tr>
<th></th>
<th>ADVANCE Transfemoral N=1015</th>
<th>SOURCE Transfemoral N = 1694</th>
<th>SOURCE Transapical N = 906</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause Mortality (%)</td>
<td>4.5</td>
<td>4.3</td>
<td>9.9</td>
</tr>
<tr>
<td>Any Stroke (%)</td>
<td>2.9</td>
<td>2.3</td>
<td>2.1</td>
</tr>
<tr>
<td>Aortic regurgitation ≥ 2/4(%)</td>
<td>-</td>
<td>5.8</td>
<td>3.5</td>
</tr>
<tr>
<td>Myocardial Infarction (%)</td>
<td>0.2</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>New Pacemaker (%)</td>
<td>26.3</td>
<td>8.0</td>
<td>10.9</td>
</tr>
<tr>
<td>Vascular Complication – Major (%)</td>
<td>10.7</td>
<td>7.3</td>
<td>3.6</td>
</tr>
<tr>
<td>Renal Failure with Temporary Dialysis (%)</td>
<td>5.7</td>
<td>1.2</td>
<td>4.0</td>
</tr>
<tr>
<td>Major Bleeding (%)</td>
<td>9.7</td>
<td>5.0</td>
<td>11.4</td>
</tr>
</tbody>
</table>

*(Bauernschmidt; Wendler @ EuroPCR 2012)*
Follow-up after TAVI

(Webb. Circulation 2009;119;3009-3016)
Impact of comorbidities on life expectancy

- Causes of death (30 days to 1 Year) in the Source Registry
- 1038 patients (TAVI using Sapien valve)
- Half of death were of non-cardiac cause

*(Thomas et al. Circulation 2011;124:425-33)*

<table>
<thead>
<tr>
<th>Cardiac</th>
<th>Non Cardiac</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>45 (25.1%)</td>
<td>88 (49.2%)</td>
<td>46 (25.7%)</td>
</tr>
</tbody>
</table>

- **Cardiac**
  - Heart Failure 28 (62.2%)
  - Myocardial Infarction 6 (13.3%)
  - Endocarditis 3 (6.7%)
  - Other* 8 (17.8%)

- **Non Cardiac**
  - Pulmonary*** 21 (23.9%)
  - Renal Failure 11 (12.5%)
  - Cancer 10 (11.4%)
  - Stroke 9 (10.2%)
  - Gastrointestinal 5 (5.6%)
  - Other** 32 (36.4%)

- **Unknown**
  - Sudden Death 18 (39.1%)
  - Renal Failure 11 (12.5%)
  - Cancer 10 (11.4%)
  - Stroke 9 (10.2%)
  - Other** 32 (36.4%)
Predictors of 1-year death after TAVI

**Non-cardiac**
- Age
- Logistic EuroSCORE
- STS Score
- COPD
- Chronic Kydney D.
- Diabetes
- Prior stroke
- Carotid stenosis
- Dyslipidemia
- HTN

**Cardiac**
- PHT
- NYHA Class IV
- Acute pulm.oedema
- CAD
- Severe MR
- M Valvuloplasty

**Procedural**
- Moderate/ severe AR
- Major vascular compl
- Stroke
- Kidney injury
- Experience
- Transapical
• General comments on TAVI
• *Pre-procedural risk assessment and indications for TAVI*
• Pre-procedural risk assessment and feasibility of TAVI
• Conclusions
The « Heart Team »

- SURGEONS
- CARDIOLOGISTS
- Anesthesiologists
- Imaging specialists (Echo, CT, MRI)
- Other specialists: Geriatricians ……

Treatment of Aortic Stenosis

With expertise in the treatment of valve disease
ESC/EACTS Guidelines for the Management of Valvular Heart Disease
Essential questions in the evaluation of a patient for valvular intervention

- Is valvular heart disease severe?
- Does the patient have symptoms?
- Are symptoms related to valvular disease?
- What are patient life expectancy and expected quality of life?
- Do the expected benefits of intervention (versus spontaneous outcome) outweigh its risks?
- What are the patient's wishes?
- Are local resources optimal for planned intervention?
Risk scores in valve surgery

- Good discrimination (low vs. high risk)
  C-index 0.75-0.78
- But poor calibration (predicted vs. observed risk)


- Euroscore II
  Better calibration but no specific data in high-risk patients
Risk scores in PARTNER

• Contra indication for surgery (Partner B)
  – 358 patients
  – Logistic Euroscore: 28%
  – STS score: 12%

• High-risk for surgery but operable (Partner A)
  – 699 patients
  – Logistic Euroscore: 29%
  – STS score: 12%

Risk factors not Captured in the Traditional Risk Scores

- Liver disease/cirrhosis
- “Porcelain” aorta
- Chest irradiation
- Chest wall deformities
- Oxygen dependence
- Neurocognitive dysfunction
- Frailty
- ........
Subjective assessment of frailty

Eye-ball test

Severe frailty

Frailty

Flexibility
Objective assessment of frailty

Katz Index of Activities of Daily Living

How many of these activities do you require help?

- 1. Bathing
- 2. Dressing
- 3. Toileting
- 4. Transferring
- 5. Continence
- 6. Feeding

Score 0 or 1 (Dependence vs. Independence)

Total score <4: positive for frailty
“SURTAVI model”

« Top ten » Risk factors

- Significant CAD
- Frailty
- Left Ventricular dysfunction
- Neurological dysfunction
- Pulmonary disease
- Peripheral vascular disease
- Renal disease
- Redo cardiac surgery
- Pulmonary hypertension
- Diabetes mellitus

(Van Mieghem, EuroIntervention 2012 Online March 2012)
### “SURTAVI model”

<table>
<thead>
<tr>
<th>Low risk</th>
<th>Intermediate risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 70 yrs, &lt; 2 risk factors</td>
<td>≥ 70 yrs, 2 or 3 risk factors</td>
<td>≥70 yrs, &gt; 3 risk factors</td>
</tr>
<tr>
<td>≥ 75 yrs, no risk factors</td>
<td>≥ 75 yrs, 1 or 2 risk factors</td>
<td>≥75 yrs, &gt; 2 risk factors</td>
</tr>
<tr>
<td>≥ 80 yrs, ≤ 1 risk factor</td>
<td></td>
<td>≥80 yrs, &gt; 1 risk factor</td>
</tr>
</tbody>
</table>

*(Van Mieghem, EuroIntervention 2012 Online March 2012)*
“The Model” for the Prediction of the Risk of AVR @ TAVI

- Simple score based on a limited number of variables
- Inclusion of indices of functional and/or cognitive capacities
- Specific evaluation in valve patients
- Elaborated from a broad spectrum of operative risks
- External validation in high- and low-volume centers
- Updated on a regular basis
- Consider specific model for high-risk patients

Working group recommendations
Currently available risk scores should not be used as an isolated decision tool but as part of an integrated approach, which includes complete clinical evaluation, reference to local resources and surgical results, and the preferences of the patient and their family. Risk scores are not a substitute for clinical experience in the management of patients with VHD.
In the absence of a perfect quantitative score, the risk assessment should mostly rely on the clinical judgement of the heart team in addition to a combination of scores.
## Indications for transcatheater aortic valve implantation

<table>
<thead>
<tr>
<th>TAVI should only be undertaken with a multidisciplinary “heart team” including cardiologists and cardiac surgeons and other specialists if necessary.</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>C</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TAVI should only be performed in hospitals with cardiac surgery on-site.</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>C</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a “heart team” and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>B</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TAVI should be considered in high risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a “heart team” based on the individual risk profile and anatomic suitability.</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIa</td>
<td>B</td>
<td></td>
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</table>
Management of severe aortic stenosis

Severe AS

Symptoms

- No
  - LVEF < 50%
    - No
      - Physically active
        - No
          - Re-evaluate in 6 months
        - Yes
          - Exercise test
            - No
              - Presence of risk factors and low/intermediate individual surgical risk
                - No
                  - Re-evaluate in 6 months
                - Yes
                  - AVR
          - Yes
            - Symptoms or fall in blood pressure below baseline
              - No
                - Presence of risk factors and low/intermediate individual surgical risk
                  - No
                    - Re-evaluate in 6 months
                  - Yes
                    - AVR
              - Yes
                - Contraindication for AVR
                  - No
                    - High risk for AVR
                      - No
                        - AVR
                      - Yes
                        - AVR or TAVI
                  - Yes
                    - Short life expectancy
                      - No
                        - Med Rx
                      - Yes
                        - TAVI

• General comments on TAVI
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## 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 ostium, 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.
Multi-Modality screening of the aortic root before TAVI

Echo/CT/MRI?

Measurement of aortic annulus

Calcium distribution

Aortic root
The choice of the type and size of the prosthesis should be multifactorial and also take into account other factors such as:

- Patient’s size and gender,
- Height of coronary ostia,
- Aortic root calcification…

**Predictors of aortic regurgitation**

(Edwards SAPIEN)

**Detaint et al.**

*JACC Interv 2009;2:82107*

- “Cover Index” (TEE)
- Operator experience

**Delgado et al.**

*Circulation 2009;120:S957*

- Annulus size (MSCT)
- Degree of valve calcification (MSCT)
Other contraindications

**LV apical thrombus**
Contrast echo, MSCT

**Dynamic subaortic Obstruction**
Echocardiography

**Severe organic MR**
is a contraindication but functional MR is not
Vascular access

- Conventional angio + **MSCT**
  - Sagittal + transversal views

Judgement based on the combination of:

- **Minimal diameters**
  - 18 Fr: 6mm
  - 22 Fr: 7mm
  - 24 Fr: 8mm

- **Calcification (grading)**
- **Tortuosity**

→ *Choice of the approach*
Coronary artery disease

Decision based on
• Clinical presentation
• Location of lesions
• Myocardium at risk
• Suitability for PCI

Options
• TAVI + medical Rx
• PCI pre > per TAVI
• Reconsideration of surgery
• Give up any intervention
Left ventricular dysfunction

- BAV as a Bridge?
- TAVI?
- Cardiac assist for pts in Shock?

(Clavel. Circulation 2010;122:1928-36.)
Bicuspid valves

Case by case decision

- annulus: shape/diameter
- amount/distribution of Ca
- specific valve design?
Conclusions

- Pre-procedural risk / benefit assessment is crucial in the performance of TAVI

- A dedicated “Heart Team” should determine the indications for TAVI and thereafter the feasibility of the procedure

- All of this relies on a comprehensive evaluation of cardiac and extra-cardiac conditions, combining clinical assessment, multimodality imaging and other investigations if needed

- Further research is needed on risk stratification models for AVR and TAVI, evaluating mortality and functional results