Screening Candidates for TAVI

How to Choose TAVI or SAVR

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Patient selection for TAVI

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

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Patient selection for TAVI

3 major steps

1. To set–up Heart Team: crucial
2. To establish that procedure is needed
3. To evaluate the feasibility of the procedure
Patient selection for TAVI

1. The Heart Team:

*Multidisciplinary team approach*

- Clinical cardiologist
- Echocardiographist
- Interventional cardiologist
- Cardiac surgeon
- Anaesthesiologist
- Geriatrician
Patient selection for TAVI

• **Why the Heart Team is crucial for success**
  – Patient selection requires multidisciplinary collaboration
    • *Risk scores have limitations*
    • *Good clinical judgement is essential*
  – Heart Team = unbiased patient information
  – Prevents self referral
  – 10–20% of patients referred to TAVI are redirected to SAVR
Patient selection for TAVI

2. The need for the procedure is established by:

- Demonstration of severe AS
- Identification of symptoms related to AS
- High risk for SAVR (Scoring System)
- Life expectancy > 1 year
Patient selection for TAVI

3. Evaluation of the procedure feasibility
   - Echo
   - CT-angio
   - Coronary angio
Patient selection for TAVI

Steps:

1. Confirmation of aortic stenosis severity
2. Evaluation of symptoms
3. Analysis of risk for cardiac surgery
4. Evaluation of life expectancy
5. Assessment of the feasibility and exclusion or contraindication for TAVI
Patient selection for TAVI

Steps:

1. Confirmation of aortic stenosis severity
2. Evaluation of symptoms
3. Analysis of risk for cardiac surgery
4. Evaluation of life expectancy
5. Assessment of the feasibility and exclusion or contraindication for TAVI
Patient selection for TAVI

Analysis of the risk of surgery

Assessment of cardiac and extracardiac factors:

- Scores (7 scores in literature)
- EuroScore and New Euroscore, STS Predicted Risk of Mortality score...

But ..

- Value of individual scores in this high risk population?
- Predictive value of these scores for morbidity and long-term results?
Analysis of the risk of surgery

The risk of surgery is based on

• Clinical judgement,

• Global appraisal of the patient,

• Risk factors not covered in scores (chest radiation, previous CABG with patent grafts, porcelain aorta, liver cirrhosis...)

• Scores (expected mortality >20% by EuroScore and >10% by STS score)

• Local environment (results in the given institution)
Patient selection for TAVI

Surgical risk scores are used to guide but not to dictate patient selection.
Patient selection for TAVI

Steps:

1. Confirmation of aortic stenosis severity
2. Evaluation of symptoms
3. Analysis of risk for cardiac surgery
4. **Evaluation of life expectancy**
5. Assessment of the feasibility and exclusion or contraindication for TAVI
Patient selection for TAVI

Evaluation of life expectancy and quality of life:

The evaluation of life expectancy is most significantly influenced by comorbidities

- Clinical evaluation
- Frailty index

TAVI/SAVR should not be performed if life expectancy is < 1 year
CONTRAINDICATIONS

1. Non-valvular aortic stenosis
2. Congenital aortic stenosis, unicuspid or bicuspid aortic valve
3. Non-calcified aortic stenosis
4. Evidence of intracardiac mass, thrombus or vegetation
5. Active bacterial endocarditis or other active infections
6. Untreated clinically significant coronary artery disease requiring revascularization
7. Severe ventricular dysfunction with ejection fraction < 20%
8. Unstable angina during index procedure
9. Myocardial infarction within 1 month
10. Cerebrovascular accident (CVA)
11. Patient unable to tolerate anticoagulation therapy
12. Severe coagulation problems
13. Hypertrophic cardiomyopathy with or without obstruction (HOCM)
14. Recent pulmonary emboli
15. Severe deformities of the chest
Treatment options for AS:

- **“Low Risk”** → **SAVR**
- **“High Risk”** → **TAVI**
- Too Sick to Benefit from any intervention → **MEDICAL TREATMENT**
Patient selection for TAVI

Steps:

1. Confirmation of aortic stenosis severity
2. Evaluation of symptoms
3. Analysis of risk for cardiac surgery
4. Evaluation of life expectancy
5. Assessment of the feasibility and exclusion or contraindication for TAVI
Patient selection for TAVI

High Risk Patient for SAVR....

1) Is the patient a good candidate for TAVI?
   (Inclusion / exclusion criteria)

2) Route selection:
   Transfemoral, trans-subclavian or Transapical?
Two different approaches:

1. Edwards SAPIEN XT
2. Core Valve

Vascular Access:

- Trans-femoral
- Trans-Apical
- Trans-Suclavian Trans-aortic
Anatomical characteristics of the cardiovascular system

- Aortic arch
- Ascending aorta & aortic root
- Left ventricle
- Coronary arteries
- Aorta
- Ilio-femoral vessels
Vessels Diameters and calcifications for Transfemoral Approach
Patient Evaluation for TAVI: Aorto-iliac-femoral angiogram

- Assess **tortuosity** and **calcification** from femoral to abdominal aorta
  
  *Critical to patient’s candidacy for TAVI*

- **TORTUOSITY**
  
  Assess angulation of aortic bifurcation
  
  Angulated takeoff of common iliac artery may increase risk of distal aortic perforation

- **CALCIFICATION**
  
  Measure both iliac and femoral arteries paying special attention to areas of narrowing
  
  Circumferential calcification should be examined

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**Very tortuous arteries (if not severely calcified) might be adequately straightened with the use of super-stiff guidewire (ex: COOK Lunderquist)**

(can be assessed at the time of diagnostic procedure)
Patient evaluation for TAVI: Echo

- LV function and hypertrophy
- LVEF < 30%:
  - Increases the risk of the procedure
  - Myocardial contractility reserve should be assessed *(stress ECHO or BAV as a bridge to THV)*
  - Relative contra-indication of trans-apical approach
Patient selection for TAVI

Confirmation of the severity of AS:
TAVI should be performed only in patients with severe A.S.

Echocardiography:
Measurements of valve area and flow-dependent indices
AVA < 0.8 cm² or < 0.6 cm²/m²
Low-dose dobutamine echo. useful to differentiate severe and pseudo severe AS (in pts with low EF and mean gradient)
MSCT for the evaluation of
- aortic annulus
- aortic calcifications
- and distance between annulus and coronary artery ostium
Patient selection for TAVI

. **Assessment of coronary anatomy:**
  
  *Coronary angiography*: CAD ?, need for revascularisation?

. **Measurement of aortic annulus:**
  
  for correct sizing
  
  to minimize risk of valve migration and paravalvular leakage
  
  TEE > TTE, MSCT, Aortography

. **Evaluation of anatomy of iliac and femoral arteries:**
  
  size, tortuositities and calcifications
  
  MSCT, Angio,
Patient evaluation for TAVI: Aortogram

- Assess bulky leaflet
- Left main distance from annulus
- Horizontal aorta?
- Porcelain aorta?
- Define view: LAO / RAO °, CRAN / CAUD °
This patient should be excluded

Stenting a bulky aortic valve can result in displacing a calcific nodule and a possible occlusion of the coronary ostium.

Assess presence of bulky aortic valve leaflets in relation to the left main artery.

Will bulky calcific leaflets compromise left main artery?

Patient evaluation for TAVI: Aortogram
Complications

Left Main Coronary Obstruction

Normal positioning of TAVI and LCA

Bulky calcified nodule compressing LM origin by TAVI
Patient selection for TAVI

Procedure-related contraindications

- Size of aortic annulus
  <18mm or >29 mm
- Bicuspid valves: (relative contraindication)
  risk of incomplete deployment
- Asymmetric heavy valvular calcification:
  compression of coronary arteries, paravalvular leak
- Size of aortic root:
  >45mm for self expandable device
- Apical LV thrombus
- Subaortic obstruction
  Severe septal hypertrophy for self expandable device
Patient selection for TAVI

Contraindications of transfemoral approach
- Iliac arteries:
  severe calcifications, tortuosity, small diameter, previous bypass
- Aorta:
  AAA, severe angulation, severe atheroma of the arch, coarctation,
  transverse ascending aorta

Contraindications of transapical approach
Previous surgery of LV using a patch
Calcified pericardium
Severe respiratory insufficiency
Non-reachable LV apex

Alternative approaches: Trans-aortic, Trans-subclavvian
  (for Self Expandable Valve)
Transcatheter Aortic Valve Implantation
Cardiac-related Complications

- Conduction abnormalities
- Aortic regurgitation
- Cardiac perforation
- Valvular endocarditis
- Left ventricular apical aneurysm
- Endocarditis
- Aortic root dissection
- Valve embolization
- Coronary artery occlusion
- Aortic regurgitation
- Cardiac perforation
- Ventricular septal defect
- Cardiac arrhythmias
Transcatheter Aortic Valve Implantation
Non Cardiac -related Complications

- Vascular complications (access and other)
  - esp. major (vessel perforation a/o requiring surgery)
- Renal failure
  - esp. RIFLE criteria (e.g. renal replacement Rx)
- Neurologic events
  - esp. major and irreversible (clinically significant)
Complications

Iliac Perforation

Sheath removed surgically with external iliac and common femoral artery ("artery on a stick"); sheath was "scored" due to severe calcification; ileo-femoral bypass graft placed and patient recovered fully
Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian (Chairperson) (France)*, Ottavio Alfieri (Chairperson) * (Italy), Felicita Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Iung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)
ESC Guidelines 2012: Contraindications for transcatheter aortic valve implantation

<table>
<thead>
<tr>
<th>Absolute contraindications</th>
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<tbody>
<tr>
<td>Absence of a ‘heart team’ and no cardiac surgery on the site</td>
</tr>
<tr>
<td>Appropriateness of TAVI, as an alternative to AVR, not confirmed by a ‘heart team’</td>
</tr>
<tr>
<td>Clinical</td>
</tr>
<tr>
<td>Estimated life expectancy &lt; 1 year</td>
</tr>
<tr>
<td>Improvement of quality of life by TAVI unlikely because of comorbidities</td>
</tr>
<tr>
<td>Severe primary associated disease of other valves with major contribution to the patient’s symptoms, that can be treated only by surgery</td>
</tr>
<tr>
<td>Anatomical</td>
</tr>
<tr>
<td>Inadequate annulus size (&lt;18 mm, &gt;29 mm²)</td>
</tr>
<tr>
<td>Thrombus in the left ventricle</td>
</tr>
<tr>
<td>Active endocarditis</td>
</tr>
<tr>
<td>Elevated risk of coronary ostium obstruction (asymmetric valve calcification, short distance between annulus and coronary ostium, small aortic sinuses)</td>
</tr>
<tr>
<td>Plaques with mobile thrombi in the ascending aorta, or arch</td>
</tr>
<tr>
<td>For transfemoral/subclavian approach: inadequate vascular access (vessel size, calcification, tortuosity)</td>
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<table>
<thead>
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<th>Relative contraindications</th>
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<tbody>
<tr>
<td>Bicuspid or non-calcified valves</td>
</tr>
<tr>
<td>Untreated coronary artery disease requiring revascularization</td>
</tr>
<tr>
<td>Haemodynamic instability</td>
</tr>
<tr>
<td>LVEF &lt; 20%</td>
</tr>
<tr>
<td>For transapical approach: severe pulmonary disease, LV apex not accessible</td>
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</table>
ESC Raccomandations for the use of transcatheter aortic valve implantation

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVI should only be undertaken with a <strong>multidisciplinary heart team</strong> including cardiologists and cardiac surgeons and other specialists if necessary.</td>
<td>I</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>TAVI should only be performed in hospitals with cardiac surgery on-site.</td>
<td>I</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td><strong>TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR</strong> 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.</td>
<td>I</td>
<td>B</td>
<td>99</td>
</tr>
<tr>
<td>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.</td>
<td>IIa</td>
<td>B</td>
<td>97</td>
</tr>
</tbody>
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# ESC Guidelines 2012: Indications for SAVR in Aortic Stenosis

<table>
<thead>
<tr>
<th>Indications</th>
<th>Class</th>
<th>Level</th>
<th>Ref</th>
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<tbody>
<tr>
<td>AVR is indicated in patients with severe AS and any symptoms related to AS.</td>
<td>I</td>
<td>B</td>
<td>12, 89, 94</td>
</tr>
<tr>
<td>AVR is indicated in patients with severe AS undergoing CABG, surgery of the ascending aorta or another valve.</td>
<td>I</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>AVR is indicated in asymptomatic patients with severe AS and systolic LV dysfunction (LVEF &lt;50%) not due to another cause.</td>
<td>I</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>AVR is indicated in asymptomatic patients with severe AS and abnormal exercise test showing symptoms on exercise clearly related to AS.</td>
<td>I</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td><strong>AVR should be considered in high risk patients with severe symptomatic AS who are suitable for TAVI, but in whom surgery is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.</strong></td>
<td>IIA</td>
<td>B</td>
<td></td>
</tr>
<tr>
<td>AVR should be considered in asymptomatic patients with severe AS and abnormal exercise test showing tachycardia in blood pressure below baseline.</td>
<td>IIA</td>
<td>C</td>
<td></td>
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<tr>
<td>AVR should be considered in patients with moderate AS undergoing CABG, surgery of the ascending aorta or another valve.</td>
<td>IIA</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>AVR should be considered in symptomatic patients with low flow, low gradient (&lt;40 mmHg) AS with normal EF only after careful confirmation of severe AS.</td>
<td>IIA</td>
<td>C</td>
<td></td>
</tr>
<tr>
<td>AVR should be considered in asymptomatic patients with severe AS, low flow, low gradient with reduced EF, and evidence of flow reserve.</td>
<td>IIA</td>
<td>C</td>
<td></td>
</tr>
</tbody>
</table>
| AVR should be considered in asymptomatic patients, with normal EF and none of the above mentioned exercise test abnormalities, if the surgical risk is low, and one or more of the following findings is present:  
  - Very severe AS defined by a peak transvalvular velocity >5.5 m/s or,  
  - Severe valve calcification and a rate of peak transvalvular velocity progression ≥0.3 m/s per year. | IIA   | C     |           |
| AVR may be considered in symptomatic patients with severe AS low flow, low gradient, and LV dysfunction without flow reserve. | IIb   | C     |           |
| AVR may be considered in asymptomatic patients with severe AS, normal EF and none of the above mentioned exercise test abnormalities, if surgical risk is low, and one or more of the following findings is present:  
  - Markedly elevated natriuretic peptide levels confirmed by repeated measurements and without other explanations  
  - Increase of mean pressure gradient with exercise by >20 mmHg  
  - Excessive LV hypertrophy in the absence of hypertension. | IIb   | C     |           |
Valve-in Valve: Aortic position

Final Remarks

- Procedural Success and patients safety highly depend on adequate patients selection and details. Team Work (HEART TEAM) is Crucial (Cardiac Surgeon, Anesthesiologist, Clinician, Echo.....)
- As with PCI and CABG for coronary artery disease, conventional SAVR and TAVI will likely be offered to different groups of patients: SAVR is still considered as first option in low-risk patients and TAVI as a valid alternative in high-risk patients and those with previous valve surgery (valve-in-valve).
- If results will be confirmed overtime, in the future conventional AVR will be the treatment of the choice in low-risk or younger (<60-65 years) patients, while TAVI will be offered to the moderate- to high-risk and (and may be also in low-risk) in relatively elderly patients.