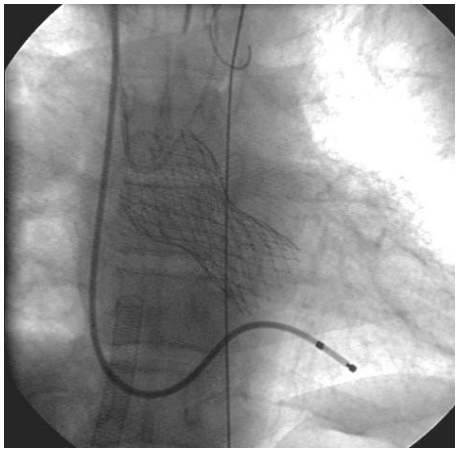
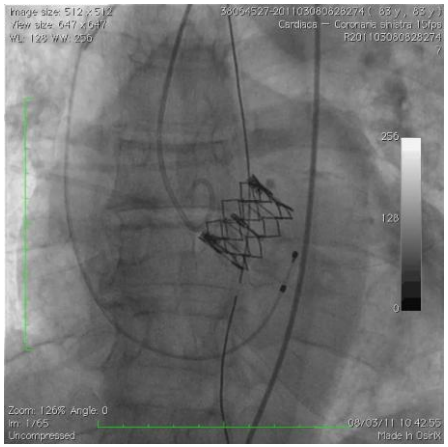
18th APRIL 23-26, COEX, SEOUL, KOREA

TCTAP 2013

Screening Candidates for TAVI

How to Chooce TAVI or SAVR





I Sheiban

University of Torino

Interventional Cardiology
Pederzoli Hospital
Peschiera D/G (Verona) / Italy

isheiban@yahoo.com

Patient selection for TAVI

EuroIntervention

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)

Alec Vahanian[1]*, Ottavio Alfieri[2]*, Nawwar Al-Attar[1], Manuel Antunes[3], Jeroen Bax[4], Bertrand Cormier[5], Alain Cribier[6], Peter De Jaegere[7], Gerard Fournial[8], Arie Pieter Kappetein[7], Jan Kovac[9], Susanne Ludgate[10], Francesco Maisano[2], Neil Moat[11], Friedrich Mohr[12], Patrick Nataf[1], Luc Pierard[13], José Luis Pomar[14], Joachim Schofer[15], Pilar Tornos[16], Murat Tuzcu[17], Ben van Hout[18], Ludwig K. Von Segesser[19], Thomas Walther[12]

EuroInterv. 2008;4:193-199

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**
  - **<u>10–20%</u> 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?

Patient selection for TAVI

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

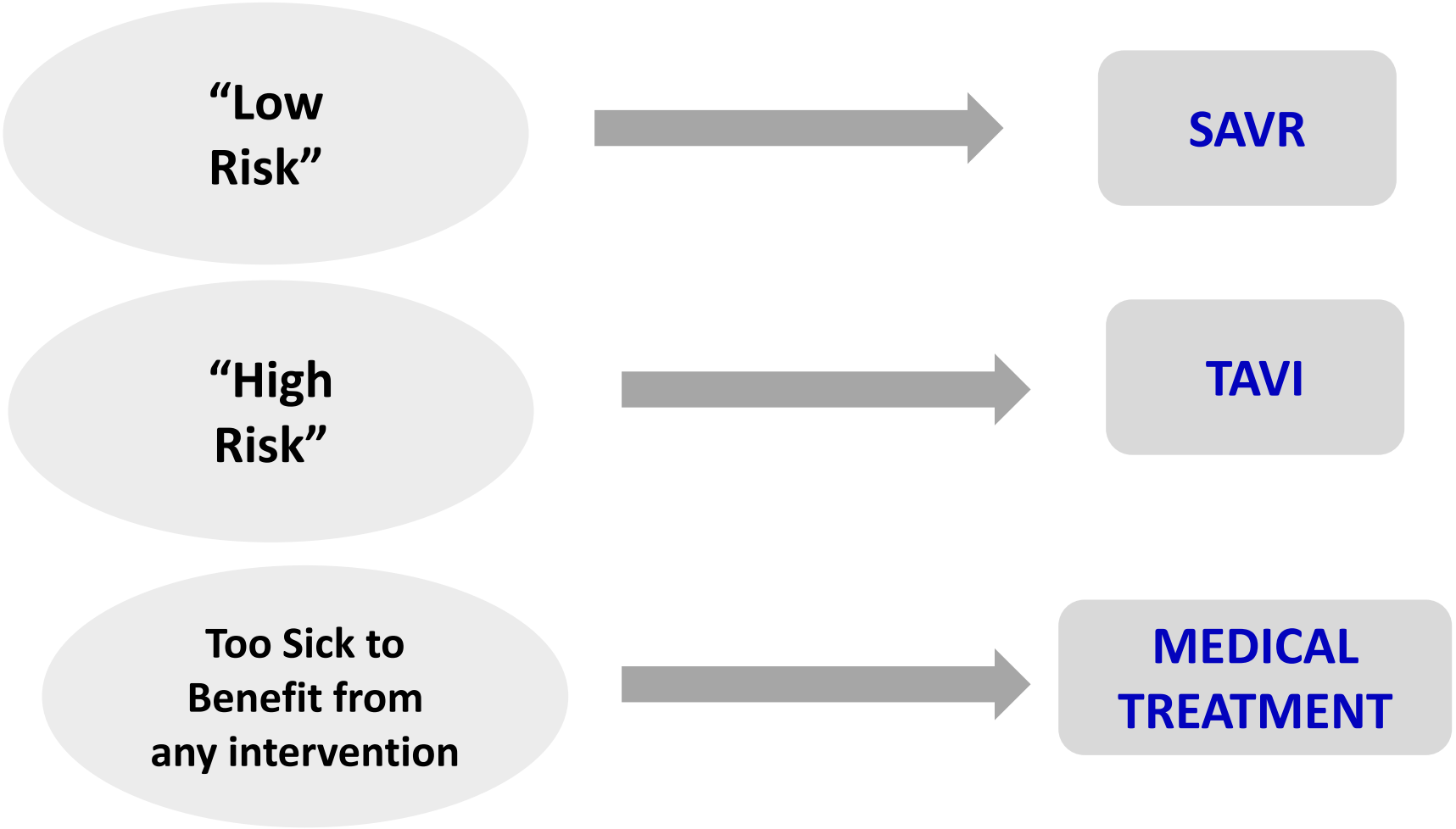
- **Clinical evaluation**
- **Frialty index**

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:



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)

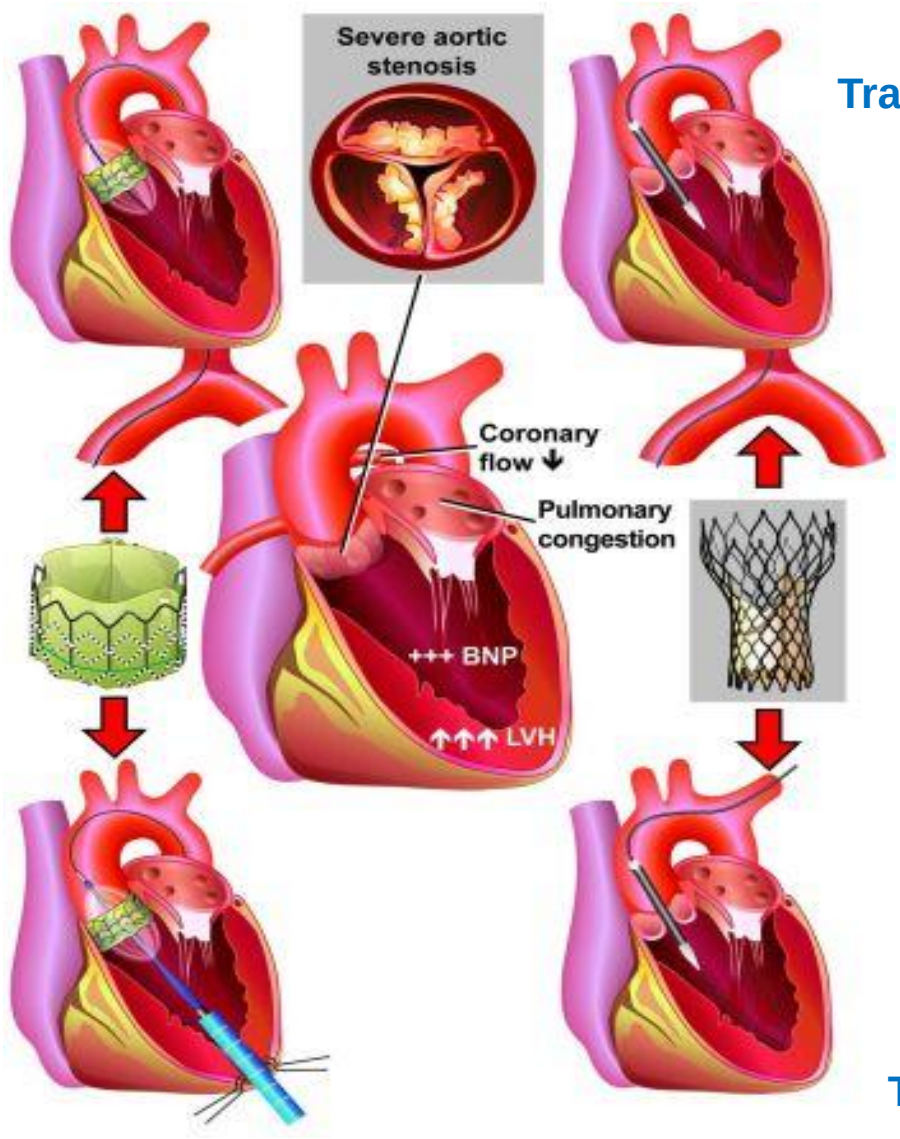
2) *Route selection:*

Transfemoral, trans-subclavian or Transapical?

Vascular Access

Trans-femoral

Trans-femoral



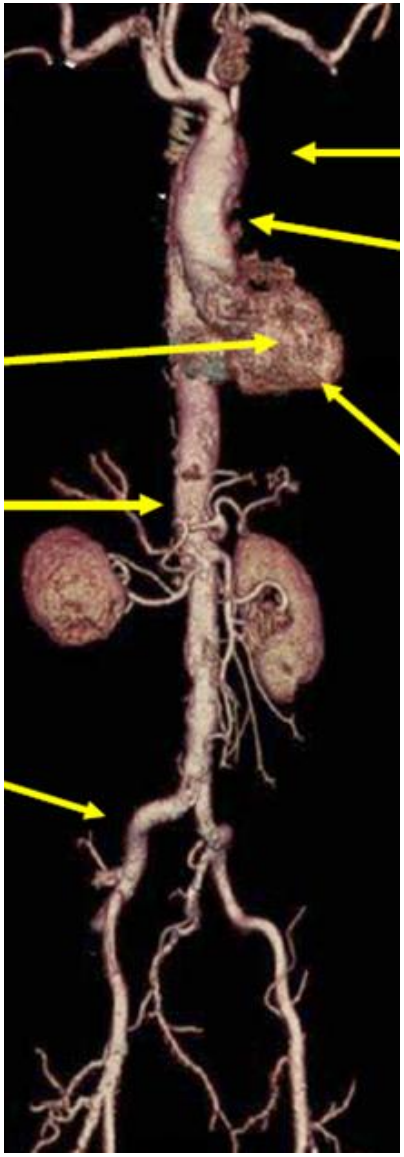
Edwards SAPIEN XT

Core Valve

Trans-Apical

Trans- Succlavian
Trans-aortic

Anatomical characteristics of the cardiovascular system



Aortic arch

Ascending aorta & aortic root

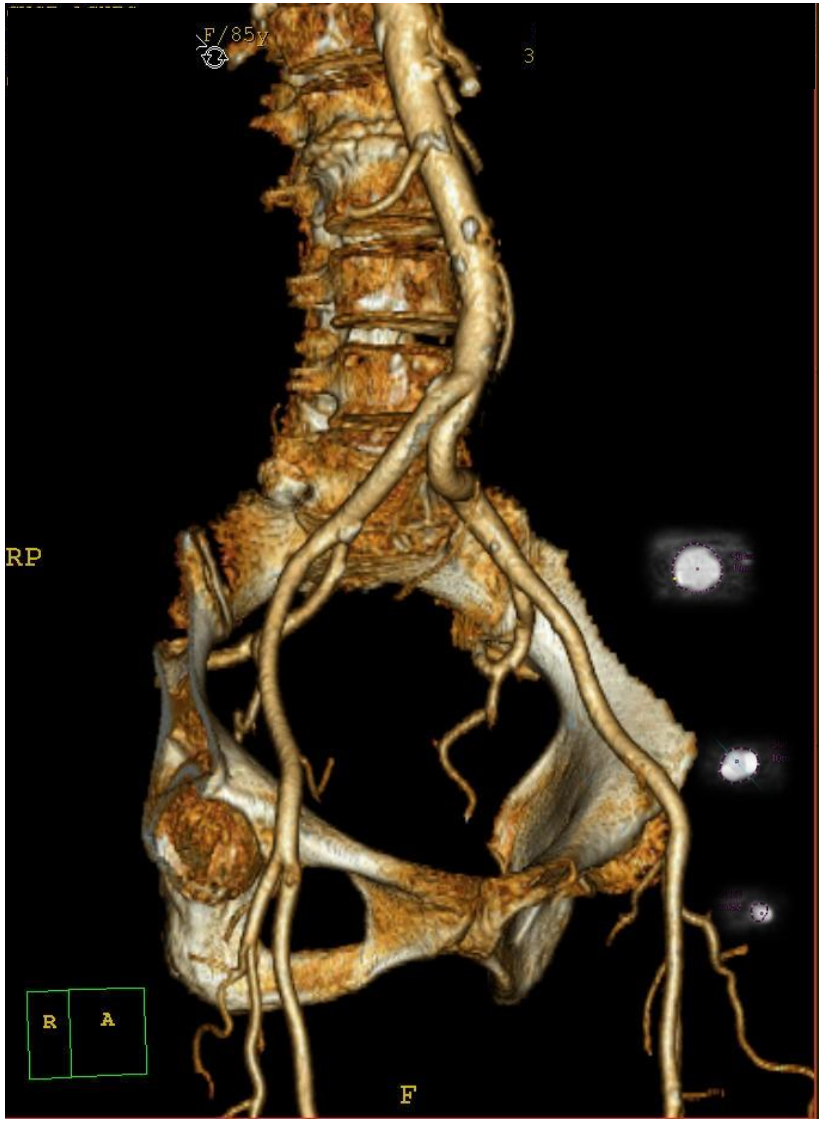
Coronary arteries

Left ventricle

Aorta

Ilio-femoral vessels

Vessels Diameters and calcifications for Transfemoral Approach



Patient Evaluation for TAVI : Aorto-iliac- femoral angiogram

- **Assess <u>tortuosity</u> and <u>calcification</u> from femoral to abdominal aorta**

  Critical to patient's candidacy for TAVI

- **<u>TORTUOSITY</u>**

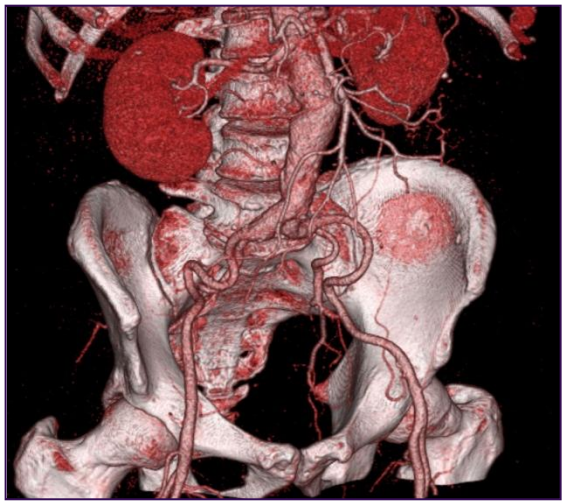
  Assess angulation of aortic bifurcation

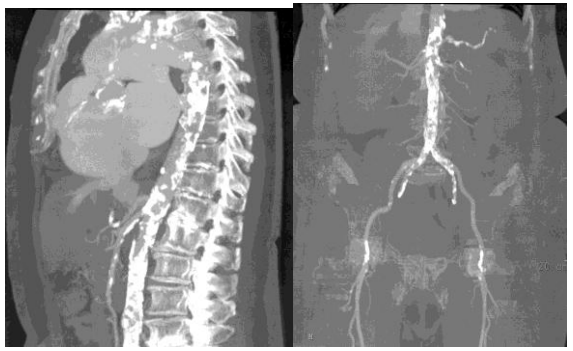
  Angulated takeoff of common iliac artery may increase risk of distal aortic perforation

- **<u>CALCIFICATION</u>**

  Measure both iliac and femoral arteries paying special attention to areas of narrowing

  Circumferential calcification should be examined



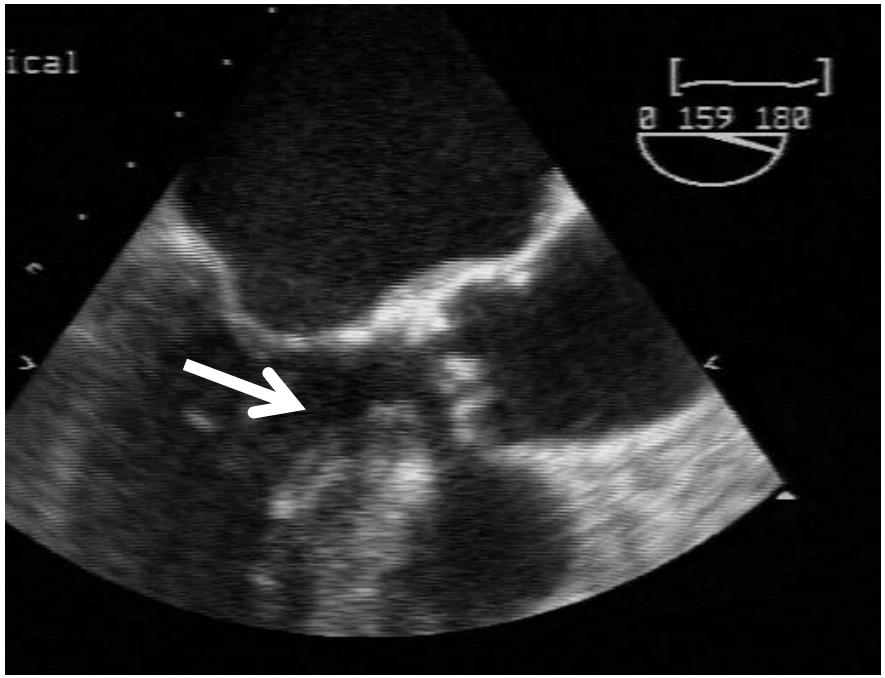


Very tortuous arteries (if not severely calcified) migth be adequately straightened with the use of super-stiff guidewire (ex: <u>COOK Lunderquist)</u>

(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:

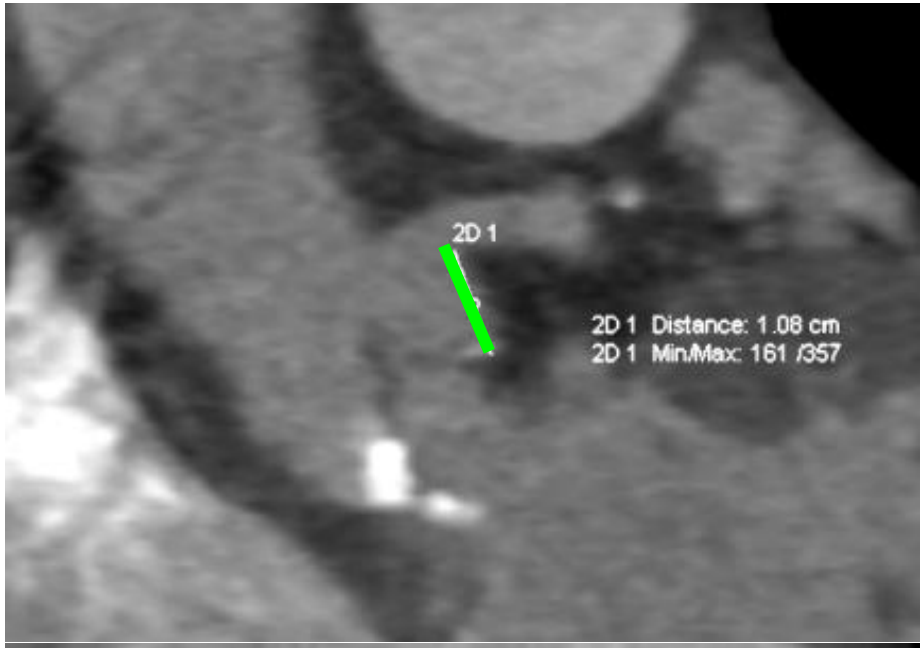
Measurements of valve area and flow-dependent indices

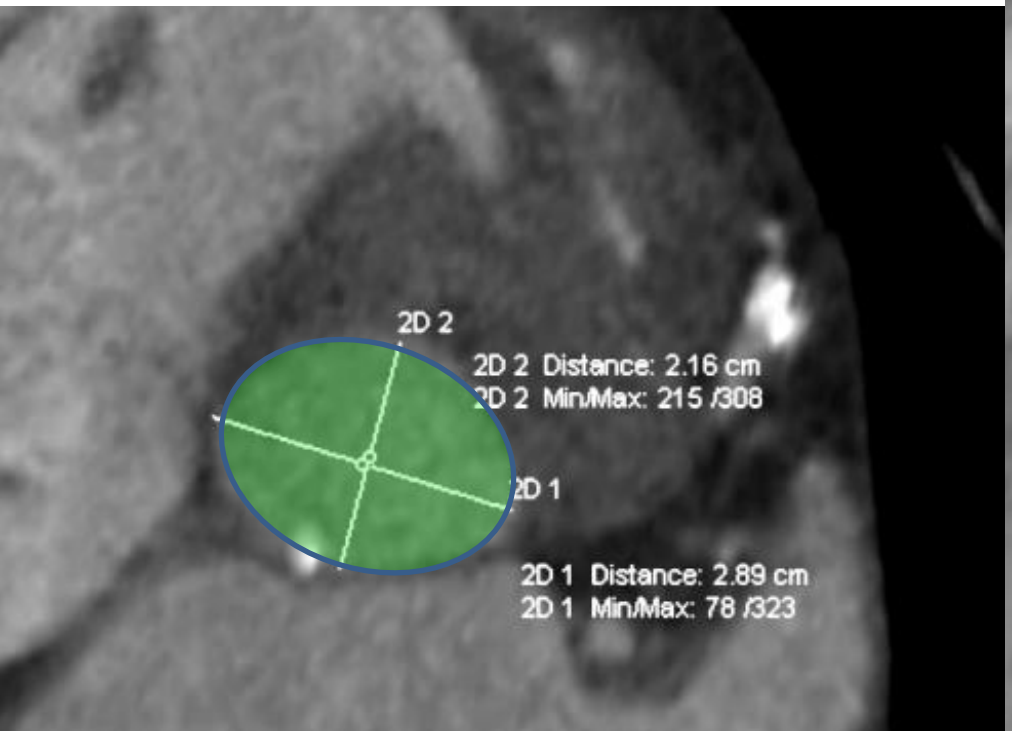
AVA < 0.8 cm² or < 0.6 cm²/m²

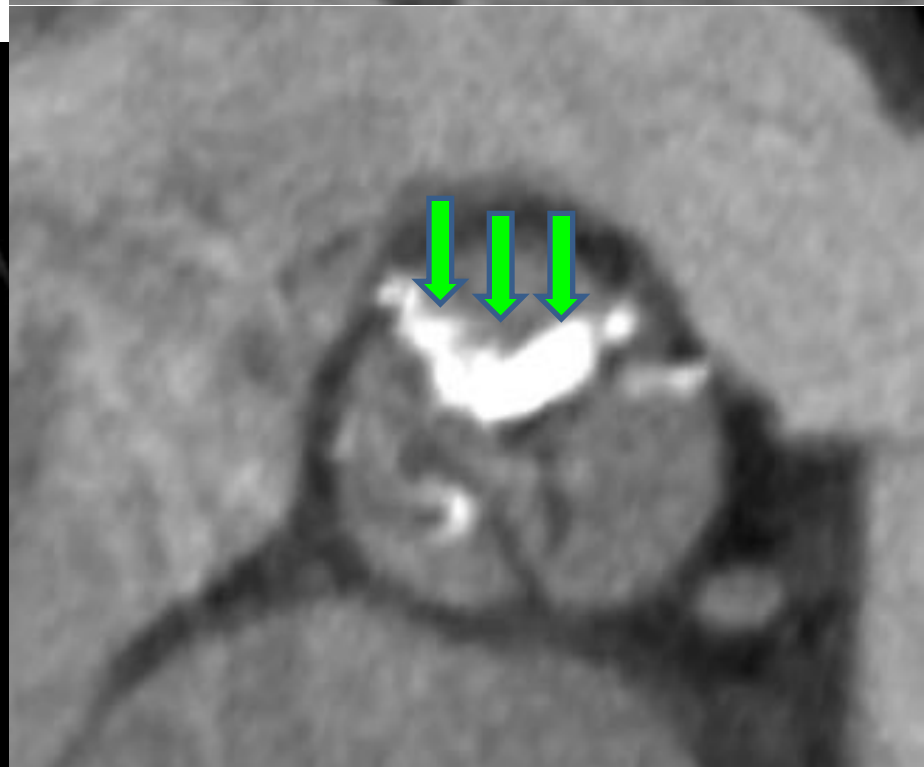
Low-dose dobutamine echo. useful to differentiate severe and pseudo severe AS (in pts with low EF and mean gradient)

MSCT for the evaluation of

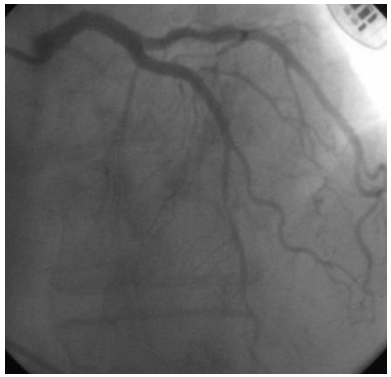
- aortic annulus
- aortic calcifications
- and distance between annulus and coronary artery ostium







Patient selection for TAVI



. Assessment of coronary anatomy:

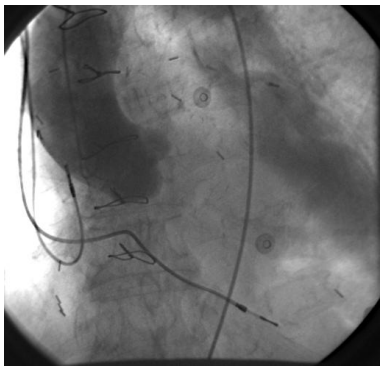
Coronary angiography: CAD ?, need for revascularisation?

. 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, tortuosities and calcifications

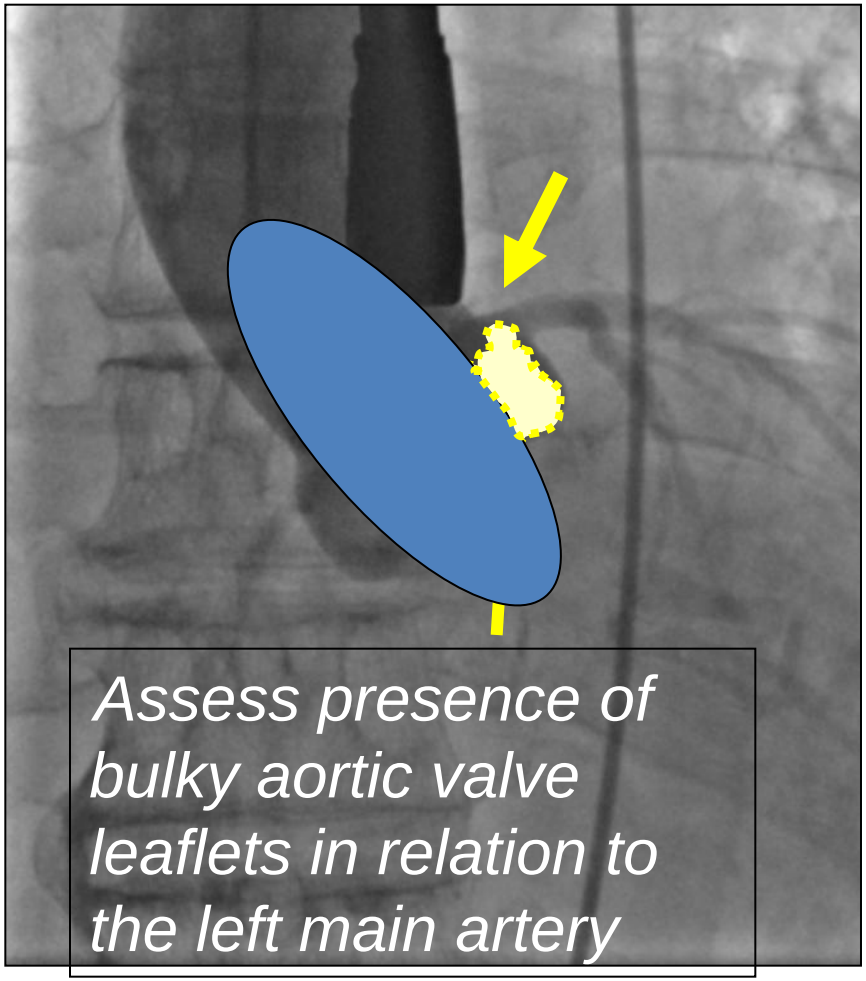
MSCT, **Angio**,

Patient evaluation for TAVI : Aortogram

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

Patient evaluation for TAVI : Aortogram

Aortogram during 23mm balloon inflation



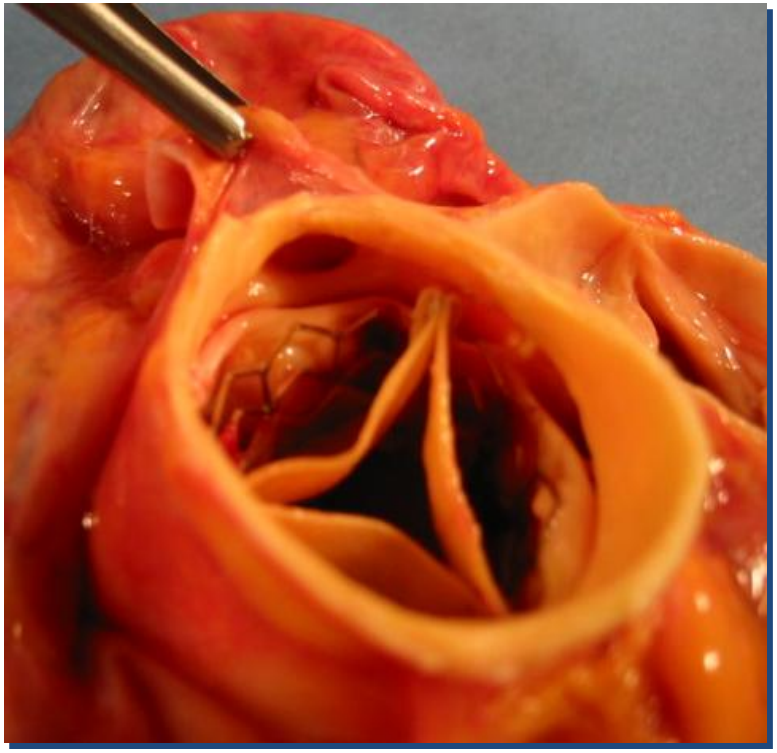
Will bulky calcific leaflets compromise left main artery?

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

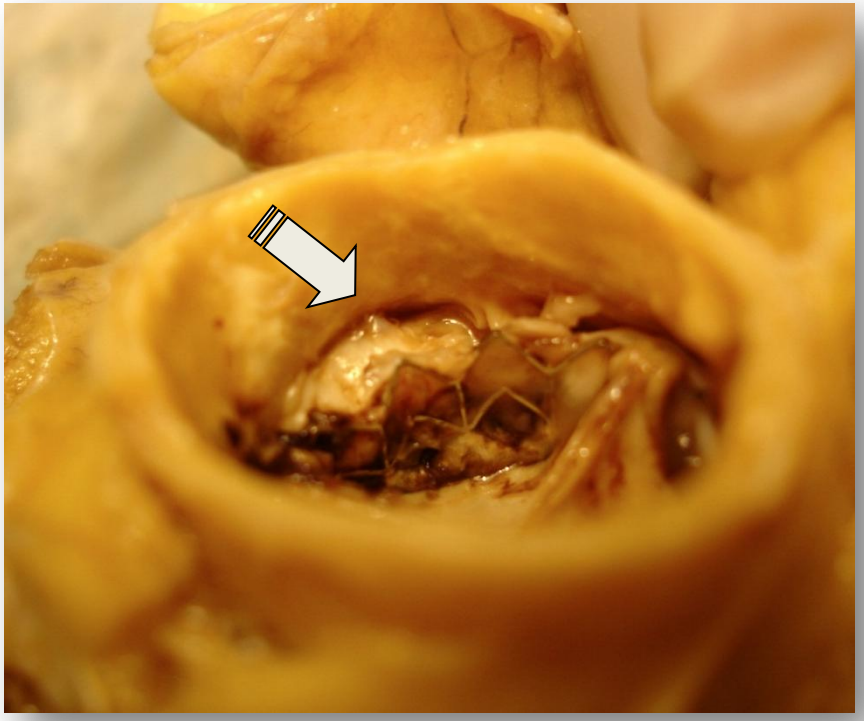
This patient should be excluded

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 controindication)

risk of incomplete deployment

. **Asymetric 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, tortuosities, small diameter, previous bypass

- **Aorta:**

***AAA, severe angulation, severe atheroma of the arch, coarctation, transverse asc*ending aorta**

Contraindications f transapical approach

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

Alternative approaches : Trans –aortic , Trans –subclaclavian

(for Self Expandable Valve)

Transcatheter Aortic Valve Implantation

Cardiac *-related Complications*

Left ventricular apical aneurysm

Conduction abnormalities

Cardiac arrhythmias

Endocarditis

Coronary artery occlusion

Aortic root dissection

Aortic regurgitation

Valve embolization

Cardiac perforation

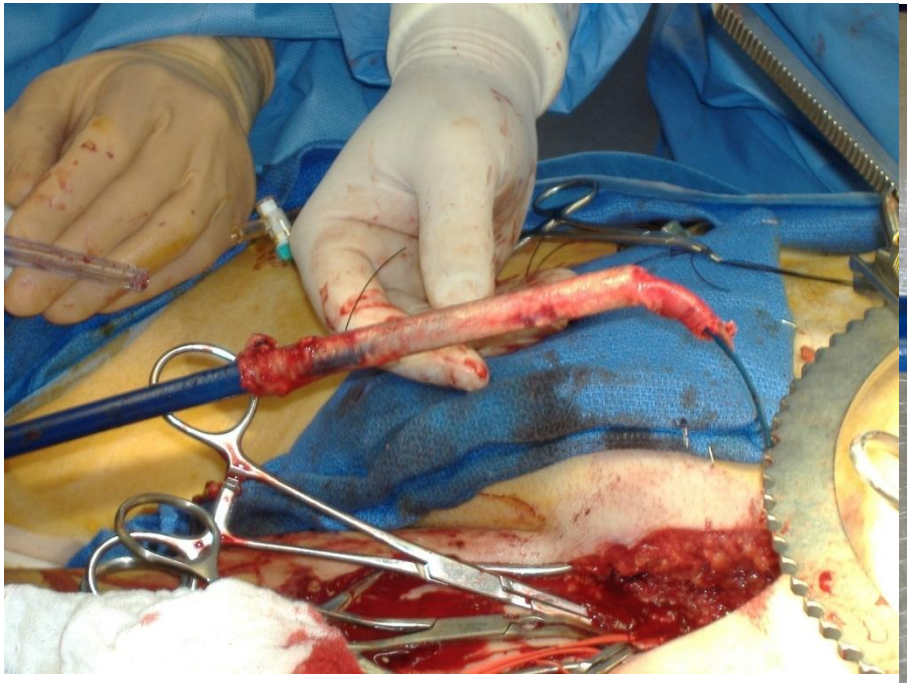
Ventricular septal defect

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

European Heart Journal (2012) **33**, 2451–2496
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES

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

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[a])
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

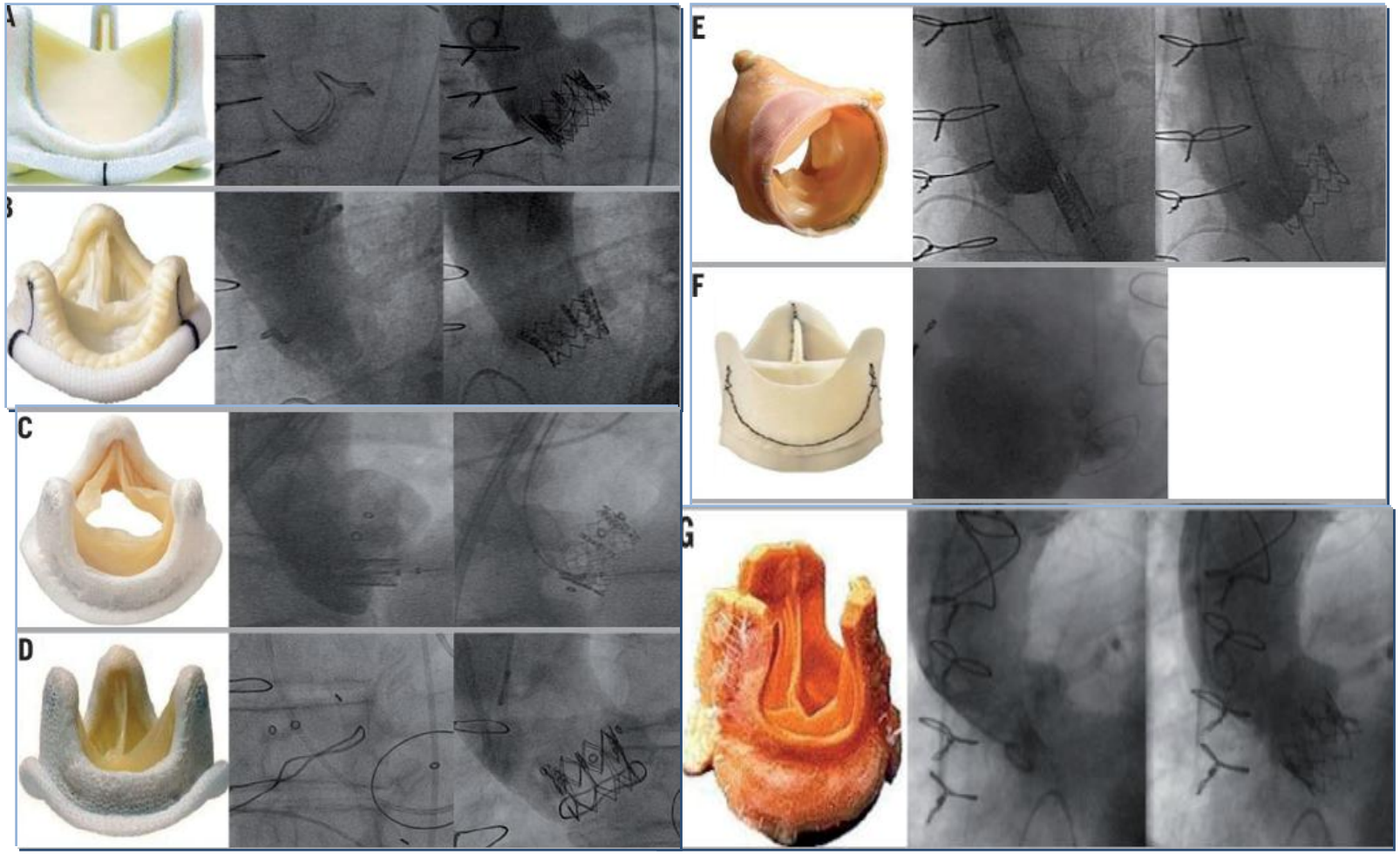
ESC Raccomandations for the use of transcatheter aortic valve implantation

Recommendations	Class [a]	Level [b]	Ref [c]
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C	
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.	I	B	99
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.	IIa	B	97

ESC Guidelines 2012 : Indications for SAVR in Aortic Stenosis

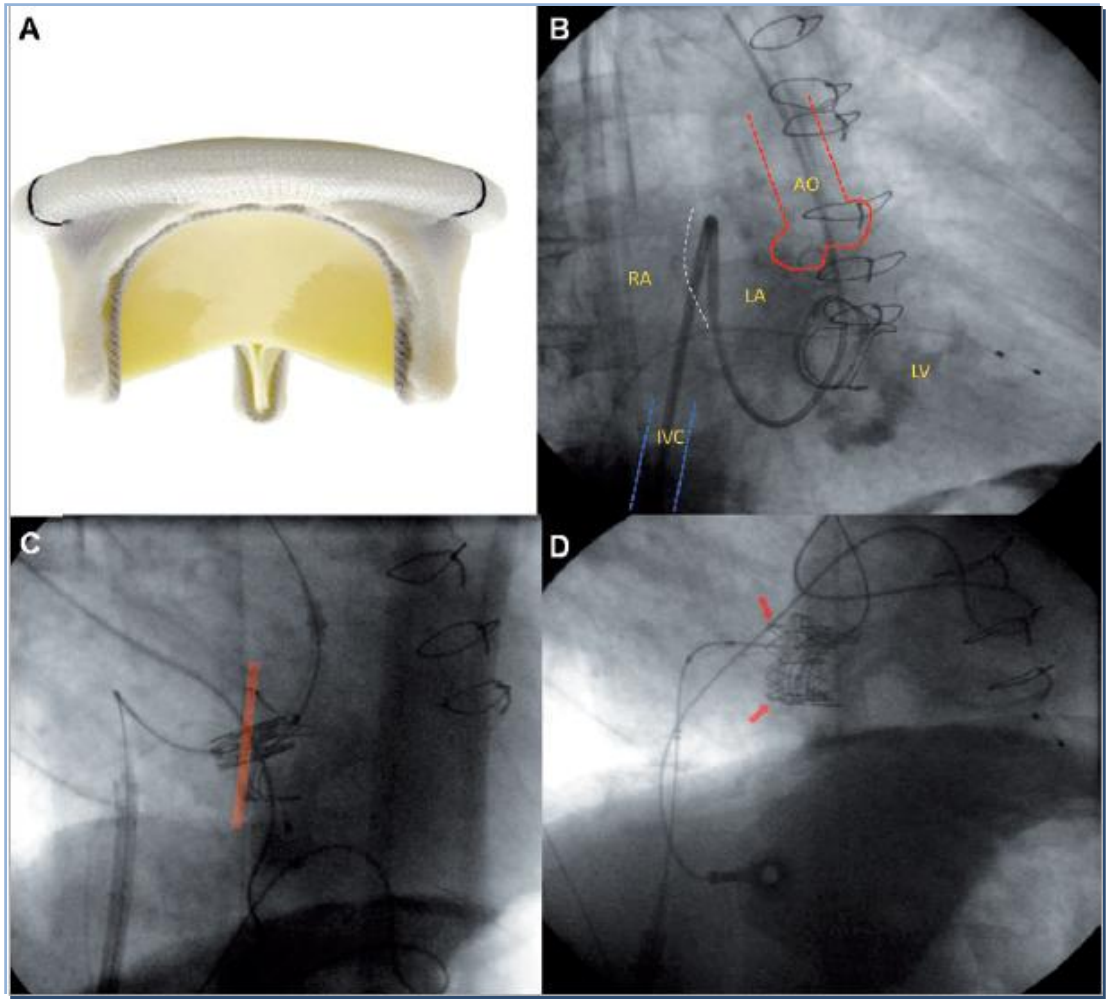
	Class[a]	Level[b]	Ref[c]
AVR is indicated in patients with severe AS and any symptoms related to AS.	I	B	12, 89, 94
AVR is indicated in patients with severe AS undergoing CABG, surgery of the ascending aorta or another valve.	I	C	
AVR is indicated in asymptomatic patients with severe AS and systolic LV dysfunction (LVEF <50%) not due to another cause.	I	C	
AVR is indicated in asymptomatic patients with severe AS and abnormal exercise test showing symptoms on exercise clearly related to AS.	I	C	
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.	IIa	B	
AVR should be considered in asymptomatic patients with severe AS and abnormal exercise test showing fall in blood pressure below baseline.	IIa	C	
AVR should be considered in patients with moderate AS[d] undergoing CABG, surgery of the ascending aorta or another valve.	IIa	C	
AVR should be considered in symptomatic patients with low flow, low gradient (<40 mmHg) AS with normal EF only after careful confirmation of severe AS.[e]	IIa	C	
AVR should be considered in symptomatic patients with severe AS, low flow, low gradient with reduced EF, and evidence of flow reserve.[f]	IIa	C	
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.[f]	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



Azeem Latib, et al : Transcatheter valve-in-valve implantation with the Edwards SAPIEN in patients with bioprosthetic heart valve failure: the Milan experience , EuroIntervention 2012;7:1275-1284

Valve-in Valve : Mitral position



Azeem Latib, et al : Transcatheter valve-in-valve implantation with the Edwards SAPIEN in patients with bioprosthetic heart valve failure: the Milan experience , EuroIntervention 2012;7:1275-1284

Final Remarks

- **Procedural Success and patients safety higly 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 conofirmed 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.**