Aortic Valve Stenosis

TAVI: from compassionate to high-surgical-risk patient treatment

Speaker - 15'

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Milestones in TAVI/TAVR

2002  Alain Cribier, 1st TAVI, Circul 2002

2004  Alain Cribier reports 6 cases anterograde (balloon expandable valve), JACC 2004

2005  Eberhard Grube, 1st case of retrograde TAVI (self expandable valve), Circul 2006

2006  John Webb reports 18 cases of retrograde TAVI (balloon expandable valve), Circul 2006
Actual Practices: >30% of patients are not referred for surgery

Bouma et al. Heart 1999;82:143-148
Iung et al. Eur Heart J 2005;26:2414-2720
Pellikka et al. Circulation 2005;111:3290-3295
Charlson et al. J Heart Valve Dis 2006;15:312-321
• Of 369 patients with severe AS, 191 (52%) did not undergo AVR. Of these, 126 (66%, 34% of total) had symptoms consistent with AS.

• The most common reasons cited for absent intervention were comorbidities with high operative risk (61 patients [48%]), patent refusal (24 patients [19%]), and symptoms unrelated to AS (24 patients [19%]).

• Operated patients had a lower Society of Thoracic Surgery–calculated perioperative mortality risk than unoperated patients (1.8% [interquartile range, 1.0 to 3.0%] versus 2.7% [interquartile range, 1.6 to 5.5%], P0.001).

• However, 28 (24%) of 126 unoperated symptomatic patients had a calculated perioperative risk less than the median risk for patients who underwent AVR.

• Only 57 (30%) of 191 unoperated patients were evaluated by a cardiac surgeon.
Two questions are sequentially answered

Is TAVI Appropriate?

Feasible?
Is TAVI Appropriate?

- Surgical aortic valve replacement in Centers with 30 days mortality < 2% remains the gold standard because it guarantees “proven durability of the valve” and “no residual aortic insufficiency”. In some high risk patients mortality is high or very high.

- TAVI is usually feasible at an acceptable risk in patients with 30 days surgical mortality of 10% or higher.

- Regarding patients with a lower risk the debate is still open.
Is TAVI Appropriate?

Patient Family

Patient Team

Cardiologist
Interventional Cardiologist
Anesthesiologist
Cardiac Surgeon
Medical Team
Is TAVI Appropriate?

The Medical Team will evaluate the risk benefit of standard surgical procedure vs. TAVI taking into account the “limitations and advantages of each of them”

- **the main reason not to perform** standard surgical replacement will be the surgical risk (death or complications) and the impact of the procedure on the future quality of life.

- **the main reason to perform** TAVI is that the risk of death or complications are estimated lower than standard surgical risk.
Is TAVI Appropriate?

Except for “specific” situations the Patient/Family team should not over rule the suggestions of the Medical Team.
Risk profile: Clear Cut for TAVI

85 yrs old lady, severe COPD; prior CABG (LIMA+SVG), creatinine 2 mg/100ml, 75 kg., 165 cm., no diabetes, no prior CVA, stable angina.

Standard Euroscore: 16;
Logistic Euroscore: 66%

STS score: mortality 8%, mortality and morbidity 31%, length of stay 20 days, risk of stroke 2.5%, postprocedure renal failure 6%, prolonged ventilation 28%.

Not captured by EuroScore or STS score: Porcelain aorta, General Frailty, Dementia etc.
Risk profile: Clear Cut
but not captured by the Scores

85 yrs old lady, no prior surgery, no diabetes, no COPD, no renal failure, no prior CVA, 65 kg., 165 cm., stable angina
Risk Profiles: Debatable

- 95 yrs old lady, no prior surgery, no diabetes, no COPD, no renal failure, no prior CVA, 65 kg., 165 cm., stable angina.

- 75 yrs old lady, no prior surgery, no diabetes, no COPD, no renal failure, no prior CVA, 65 kg., 165 cm., stable angina. SEVERE DEMENTIA at home assisted by the Family.

- 90 yrs old lady, no prior surgery, no diabetes, no COPD, no renal failure, no prior CVA, 65 kg., 165 cm., stable angina. SEVERE DEMENTIA in a Nursing Home since 5 yrs.
Is TAVI Feasible?

1. Suitability of the patient to undergo an invasive procedure

2. Size of the aortic annulus: more than 18 mm and less 25-27 mm;

3. Size and condition of femoral or axillary vessels: 18/19 French introducer

4. Transapical (Sapien) or Supraaortie (Core Valve) alternative approaches when vascular access is inadequate: Need for general anesthesia
Screening and decision making

Multislice CT with ecg-gating and contrast injection to evaluate: annulus, coronaries, aorta, iliacs and femorals arteries

Transesophageal echo to evaluate: annulus, ventricular function

Coronary arteriography when needed
The variation in annulus size measurements made in the same patient using different investigative modalities.

TTE: Parasternal long-axis view

TEE: Left ventricular long-axis view

MSCT: Sagittal view

CT: Oblique transverse view
Larger size valve: rationale

PHV23MM

PHV26MM
Symptomatic Severe Aortic Stenosis

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

High-Risk

n = 699

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

High-Risk TF

ASSESSMENT: Transfemoral Access

High-Risk TA

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

1:1 Randomization

TF TAVR n = 179 VS Standard Therapy n = 179

Inoperable

n = 358

ASSESSMENT: Transfemoral Access

Primary Endpoint: All-Cause Mortality Over Length of Trial (Superiority)
Inoperable pts
Figure 3c. Two-year stroke Kaplan-Meier curve in PARTNER trial cohort 1A. Adapted from Kodali and colleagues.\

Hazard Ratio [95% CI]\
1.22[0.67,2.23]\
P=0.5165

Number at risk:\
TAVR:348  287  249  224  162  65  28\
AVR:351  246  230  211  160  62  31
In PARTNER Trial Cohort A

Core lab evaluation of aortic regurgitation:

10% of patients had moderate to severe AR
40% of patients had mild AR

Moderate, severe and mild AR were associated with higher mortality at FU
### Mortality According to Presence/Severity of Aortic Regurgitation

<table>
<thead>
<tr>
<th>Aortic regurgitation</th>
<th>None/trace</th>
<th>Mild</th>
<th>Moderate/severe</th>
<th>P (log rank)</th>
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<td>1-y mortality (%)</td>
<td>14.5</td>
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<td>2-y mortality (%)</td>
<td>24.8</td>
<td>39.2</td>
<td>41.1</td>
<td>&lt;0.001</td>
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When calcifications are massive we should expect more residual aortic insufficiency.
Strokes in PARTNER trial (B, inoperable pts.)
At 1 yr. in PARTNER IA any neurological event occurred in 4.3% of patients treated with surgery versus 8.3% of patients treated with TAVI.

Transapical access was a predictor of stroke in TAVI
Embolic Material
STS mortality risk ≥4% and ≤10%

Heart Team Evaluation
Confirm Inclusion/Exclusion & Intermediate Risk Classification

Randomization
Stratified by need for revascularization

- Medtronic CoreValve® TAVR
- SAVR
PARTNER II

Symptomatic Severe Aortic Stenosis

ASSESSMENT by Heart Valve Team

Intermediate Risk

ASSESSMENT: Individually Powered

Yes

ASSESSMENT: Transfemoral Access

No

Transfemoral (TF)

1:1 Randomization

TF TAVR Sapien XT

VS

Primary Endpoint: All-Cause Mortality + Major Stroke at Two Years (Non-inferiority)

Transapical (TA)

1:1 Randomization

TA TAVR Ascendra 2

VS

Primary Endpoint: All-Cause Mortality + Major Stroke + Repeat Hospitalization at One Year (Non-inferiority)

Inoperable

ASSESSMENT: Transfemoral Access

Yes

TF TAVR Sapien XT

VS

No

Not In Study
2 years mortality in inoperable patients (PARTNER B)

In very high risk pts. TAVI may be futile
FRANCE 2 TAVI Registry 3195 pts.
Gilard et al. NEJM 2012

Death According to EuroSCORE

- 20–30% vs. <20%: hazard ratio, 1.19 (95% CI, 0.95–1.49); P=0.13
- >30% vs. <20%: hazard ratio, 2.04 (95% CI, 1.67–2.48); P<0.001

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No. at Risk

- <20%: 1686, 1301, 636, 208
- 20–30%: 749, 582, 300, 113
- >30%: 717, 518, 269, 81
Two important studies in intermediate risk populations have been launched: SURTAVI with CoreValve and PARTENER II with Sapien XT.