Memorial CVI Symposium
The era of TAVR

Isaac Yepes, MD
PGY-1 Internal Medicine
• 81 y.o female, completely independent on her daily living activities

• History of
  • CAD $\rightarrow$ s/p PCI of the PDA with two cypher stents in 2011
  • Non obstructive carotid artery disease
  • Hypertension
  • Hyperlipidemia

• History of aortic stenosis
  • Followed up with Cardiology for two years
  • Presented with fatigue, dyspnea and lower limb edema with moderate exertion (carrying packages to the car)
  • Initial evaluation revealed moderate to severe AS and intervention was delayed
  • While dyspnea was considered multi factorial, symptoms progressed and follow up echo 2/23/18 revealed severe AS with a MG 68 mmHg
Cardiac Cath on 3/2018
  - Severe aortic stenosis (mean gradient 53mmHg, aortic valve area 0.7 cm²)

Single vessel CAD:
  - LAD: 35% proximal narrowing.
  - CIRCUMFLEX: 40% ostial narrowing.
  - RCA: Dominant. The right PDA is occluded proximally in stent. This is unchanged compared with angiography December

The patient was advised to undergo TAVR as she fulfilled criteria for intervention

5/9/2018 she had TAVR (23mm Sapien 3 valve-trans femoral approach) with conscious sedation

On 5/10/2018 the patient was discharged home
Time course of calcific aortic stenosis

For decades the only available option for AS treatment was SAVR

In 2002 First TAVR/TAVI was performed

**In High-risk symptomatic patients**
- PARTNER trial Cohort A
- CoreValve High Risk Study

**Intermediate-risk patients**
- PARTNER 2A Trial
- SURTAVI Trial

**Low-risk symptomatic patients**
- Evolut Low Risk trial
- PARTNER III Trial
• **PARTNER trial Cohort A**  ➔ 699 patients
  
  • Balloon expandable TAVI (femoral approach) Vs SAVR
  
  • Mortality at 30 days, one year, two and 5 years was similar
  
  • Combined stroke/TIA more frequent after TAVI at 30 days and one year, borderline significant difference at 2 years and no difference at 5 years
  
  • > patients referred improvement of symptoms after 30 day with TAVI but at one year it was similar for TAVI and SAVR
  
  • TAVI associated more frequently with major vascular complications
  
  • SAVR more commonly associated with major bleeding & new onset A.fib
  
  • Mod-severe para-valvular regurgitation TAVI>SAVR after 30 day, one and two years ➔ Associated with increased late mortality
• **CoreValve High Risk Study** ➔ 795 patients with severe AS with high estimated surgical risk --> Randomly assigned to self-expanding TAVI Vs SAVR.
  
  • Mortality at 1 and 2 year TAVR<SAVR
  • Death & Major stroke significantly lower with TAVI at 1, 2 and 3 years
  • Major vascular complications, Cardiac perforation and permanent pacemaker were more frequent after TAVI
  • Life threatening or disabling bleeding, AKI and new onset or worsening A.fib were more common after SAVR
• **PARTNER 2A Trial** → Randomized 2032 intermediate-risk patients with severe AS --> TAVI (balloon-expandable) Vs SAVR

• Mean STS-PROM score was 5.8.

• 76.3% trans-femoral access & 23.7% transthoracic access (transapical/transthoracic)
  
  • Death or disabling stroke --> TAVI = SAVR at 2 years (TAVI <SAVR in trans-femoral cohort)
  
  • TAVI --> Larger aortic valve areas
  
  • TAVI < 30 day rates, AKI, severe bleeding and new onset A.fib
  
  • SAVR < paravalvular AR & lower rates of major vascular complications
  
  • TAVI Pt with moderate-severe AR at 30 d --> Higher mortality at 2 year f/u
- **SURTAVI Trial**  ➔ Randomized 1746 patients with symptomatic severe AS with intermediate surgical risk

- Mean STS PROM 4.5%

- **TAVI (Self-expanding – 93.6% iliofemoral access) Vs SAVR**
  - Death from any cause or disabling stroke at 24 months --> TAVI = SAVR
  - NYHA symptoms & quality of life (KCCQ) --> Significant improve in both groups at 24 month f/u -- At 1 months KCCQ score improvement TAVI > SAVR
  - AKI, A.fib and transfusion requirement at 30 day SAVR > TAVI
  - Major vascular complications & pacemaker need for permanent pacemaker at 30 day TAVI > SAVR
  - Moderate to severe paravalvular AR at 1 year TAVI > SAVR
  - Mean prosthetic valve gradients were lower & Aortic valve areas in TAVI
Low-risk symptomatic patients

- **Evolut Low Risk trial** → Randomized 1468 patients with severe AS and low surgical risk (STS-PROM 1.9±0.7).

- TAVI (self-expanding valve – 99% transfemoral access) Vs SAVR
  - Death or disabling stroke at 2 years --> Non-inferiority threshold met
  - At 30 day disabling stroke, bleeding complications, AKI, A.fib --> TAVI < SAVR
    But higher rates of moderate-severe AR & permanent pacemaker implantation
    with no significant difference in mortality.
  - At 1 year hospitalizations for HF & prosthetic aortic valve gradients --> TAVI < SAVR. No significant difference in Mortality
• **PARTNER III Trial** ➔ Randomized 1000 patients with severe AS and low surgical risk (STS-PROM 1.9±0.7)

• TAVI (balloon-expandable valve) Vs SAVR
  - Death, stroke or rehospitalization at 1 year --> Significantly lower in TAVI than in SAVR
  - At 30 days --> Rates of stroke and A.fib --> TAVI < SAVR with no significance difference in the frequency of permanent pacemaker insertion or moderate-severe paravalvular AR. No significant difference in Mortality
  - At 1 year prosthetic valve mean gradients and frequency of moderate-severe paravalvular AR --> Similar in TAVI & SAVR as well as mortality.
2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Requirements for Transcatheter Aortic Valve Replacement
CLASS IIa (MODERATE)  Benefit >> Risk

- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other
- Comparative-Effectiveness Phrases‡:
  - Treatment/strategy A is recommended/indicated in preference to treatment B
  - Treatment A should be chosen over treatment B

Suggested phrases for writing recommendations:
- Is reasonable
- Can be useful/effective/beneficial
- Comparative-Effectiveness Phrases‡:
  - Treatment/strategy A is probably recommended/indicated in preference to treatment B
  - It is reasonable to choose treatment A over treatment B

CLASS IIb (WEAK)  Benefit ≥ Risk

- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

LEVEL B-R  (Randomized)

- Moderate-quality evidence‡ from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR  (Nonrandomized)

- Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

LEVEL C

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

LEVEL E

Consensus of expert opinion based on clinical experience when evidence is insufficient, vague, or conflicting
• Grade I Level of Evidence A
  • Surgical AVR or TAVR is recommended for symptomatic patients with severe AS (Stage D) and high risk for surgical AVR, depending on patient-specific procedural risks, values, and preferences.
  • TAVR is recommended for symptomatic patients with severe AS (Stage D) and a prohibitive risk for surgical AVR who have a predicted post-TAVR survival greater than 12 months.
• Grade IIA  Level of Evidence B-R
  • TAVR is a reasonable alternative to surgical AVR for symptomatic patients with severe AS (Stage D) and an intermediate surgical risk, depending on patient-specific procedural risks, values, and preferences.

• Grade IIB Level of Evidence C
  • Percutaneous aortic balloon dilation may be considered as a bridge to surgical AVR or TAVR for symptomatic patients with severe AS.

• Grade III (No benefit)
  • TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS.
Memorial Cardiac and Vascular Institute data with TAVR

- TAVR -> 327 cases
- Valve in valve 19
  - Aortic 9
  - Mitral 9
  - Tricuspid 1
  - Mitral valve ring 1