TAVI current status and future perspective

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TAVI: **BIG BANG**

2002
Commitment to *Evidence* - Based Med.

The multi-disciplinary *Heart Team*

Rapid *Technology* Enhancement

*Simplification* of the Procedure

Striking *Reduction* in Complications

Commitment to **Evidence** - Based Med.

The multi-disciplinary **Heart Team**

- Rapid **Technology** Enhancement
- **Simplification** of the Procedure
- Striking **Reduction** in Complications

AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary
A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

<table>
<thead>
<tr>
<th>Year</th>
<th>Low Risk (Must Meet ALL Criteria in This Column)</th>
<th>Intermediate Risk (Any 1 Criterion in This Column)</th>
<th>High Risk (Any 1 Criterion in This Column)</th>
<th>Prohibitive Risk (Any 1 Criterion in This Column)</th>
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<td>2014</td>
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(2 days before SURTAVI)

Nishimura et al JACC 2014
SURTAWI Trial
Study Design

Symptomatic Severe Aortic Stenosis

Intermediate Surgical Risk
STS PROM ≥3% and <15%

Heart Team Evaluation
Assess inclusion/exclusion
Risk classification

Randomization n=1,746
Stratified by need for revascularization

TAVR only
TAVR + PCI
SAVR only
SAVR + CABG

Baseline neurological assessments

Screening Committee
Confirmed eligibility

TAVR N=864
age 79.9 – mean STS 4.4%

SAVR N=796
age 79.6 – mean STS 4.5%

I° EP: All-Cause Death or Disabling Stroke at 2 Years (non-inferiority)

Reardon M, ACC 2017
All-Cause Mortality or Disabling Stroke

Best 30-day AVR mortality EVER!! 1.7%

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<tr>
<th>Months Post-Procedue</th>
<th>SAVR</th>
<th>TAVR</th>
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<td>24</td>
<td>796</td>
<td>864</td>
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<td>18</td>
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24 Months

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<th>TAVR</th>
<th>SAVR</th>
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<tr>
<td>12.6%</td>
<td>14.0%</td>
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Difference (95% CI) –1.4% (–5.2%, 2.3%)
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2014

2017
(2 days before SURTAVI)

20XX

SURTAVI - PARTNER 3
NOTION 2 – EVOLUT PRO

Nishimura et al JACC 2014
Heart Team

CLASS I LoE C
The HEART TEAM
A *Deal* WITH THE *Devil*?

Cardiac Surgeon

Interventional cardiologist
Clinical characteristics favoring TAVI:

- STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)
- Presence of severe co-morbidity (not adequately reflected by scores)
- Age ≥75 years
- Previous cardiac surgery
- Frailty
- Restricted mobility and conditions that may affect the rehabilitation process after the procedure

Anatomical and technical aspects favoring TAVI:

- Favourable access for TF TAVI
- Sequelae of chest radiation
- Porcelain aorta
- Presence of intact CABG at risk when sternotomy is performed
- Expected patient-prosthesis mismatch
- Severe chest deformation or scoliosis
TAVI - EVOLUTIONs

- Commitment to Evidence-Based Med.
- The multi-disciplinary Heart Team
- Rapid Technology Enhancement
- Simplification of the Procedure
- Striking Reduction in Complications

Tarantini G, Nai Fovino L, Gersh B, European Heart Journal 2017
TAVI Systems
Global Inventory (#25)

- Sapien 3
- Evolute R
- Lotus
- Portico
- Jena Valve
- Centera
- Shangai Valve
- Trinity
- Colibri
- Inovare
- Thubrikar
- Valve Medical
- Syntheon Verso
- Triskele
- BioValve
- MyVal
- HLT
- NVT
- J-Valve
- Xeltis
- Zurich TEHV

GLOBAL LEADERS

FUTURE CONTENDERS
TAVI ACCESSORY DEVICES

LARGE BORE VASCULAR SHEATHS

Solopath

Expandable from 12 Fr to 18 Fr

LARGE HOLE VASCULAR CLOSURE

Prostar

Reduced hole size

Reduction of vascular complications from 15% to <5%
TAVI ACCESSORY DEVICES

NOVEL VALVULOPLASTY DEVICES

NEW MATERIALS
INCREASED STABILITY
NO NEED FOR PM
TAVI ACCESSORY DEVICES

NEUROEMBOLIC PROTECTION

Claret sentinel

Proximal Filter (Innominate Artery) 9–15 mm
Distal Filter (LCC Artery) 6.5–10 mm

Triguard
TAVI PROCEDURE ROOM

YESTERDAY

TODAY
Which therapy do you think is better?

SAVR Better
- Vascular complications
- Paravalvular leakage
- Pacemaker

TAVI Better
- Mortality
- Strokes
- AKI
- Bleeding
- New AFib
- Valve area
- 30-day QOL
- 30-day 6MWT
- Hospital stay

30-day QOL
30-day 6MWT
Hospital stay
EXPECTATIONS
EXPECTATIONS

- IMPROVED DISEASE AWARENESS AND ACCESS TO TAVR
- EXPLOSIVE GROWTH IN TAVI WORLDWIDE
- ACCELERATED INNOVATION OF TAVR PLATFORMS
- RE-DEFINING DISEASE STATE AND “TIMING/TRIGGER POINTS” FOR THERAPY
- REALIZATION OF NEW CLINICAL INDICATIONS

Tarantini G, Nai Fovino L, Gersh B, European Heart Journal 2017
TAVI GROWTH

Global TAVI Units

X4 growth in 10 years
NEW TRIGGER POINTS
AORTIC STENOSIS REDEFINED:
FUNCTIONAL CLASSIFICATION

Mild AS

Moderate AS Symptoms -

Moderate AS Symptoms +

TAVI – UNLOAD

Severe AS Symptoms -

EARLY TAVI

ACTIVE SURVEILLANCE

Severe AS Symptoms +

PARTNERS

LOW / INT / HIGH RISK

TAVI

2022

2017
Final thoughts on TAVI

**Survival of the Fittest**

“It is not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change.”

~Charles Darwin, 1809
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