TAVI

REALITIES AND CONTROVERSIES

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HISTORY

The first catheter-based aortic valve was performed in 1965 by **Davies** in **canine** for temporary relief of aortic insufficiency.

Andersen performed the first contemporary transcatheter aortic valve replacement procedure in **pigs** in 1992.

Cribier in **2002** performed first TAVI in a patient with cardiogenic shock, failed BAV, and multiple co-mordibities.

Since that time, TAVI has become the standard of care in patients who are "inoperable" and is an important alternative in patients who are high risk for surgery .

Rouen, April 16, 2002
F.I.M THV implantation

57-yrs old man, cardiogenic shock, mutiple comorbidities
Aorto femoral BPGs occluded: Trans-septal approach

Circulation 2002;106:3006-8.

30 min post-implantation *8 days post-implantation*

Lessons from this FIM

1- Feasibility of TAVI
2- No THV embolization
3- No coronary occlusion
4- No MR
5- No AV-heart block
6- Mild AR (paravalvular)
7- Optimal valvular function
8- Immediate hemodynamic

Stupefaction and enthusiasm of the medical community !

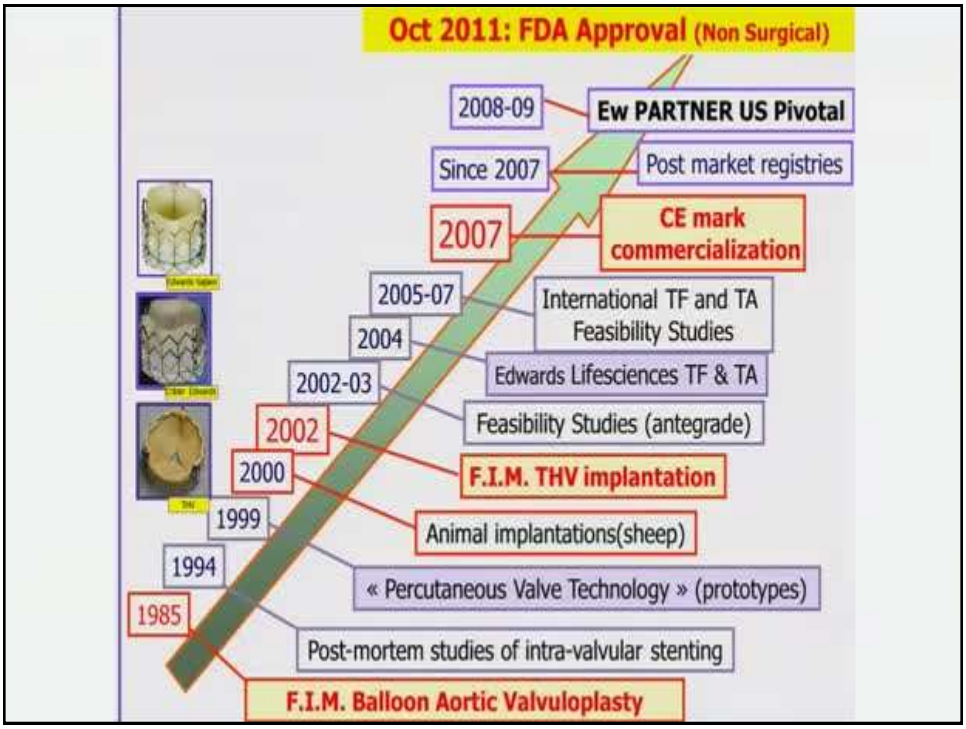
In July ***2004*** came the first implantation of the Core Valve ReValving System using a 25F delivery.

Within two years of the first case, the CoreValve delivery catheter was reduced to 18F.

06.24.2015

FDA Approves the CoreValve® Evolut® R System

The Evolut R System is approved for patients with severe aortic stenosis who are at high or extreme risk for surgery and for those with a failed surgical bioprosthesis (TAV in SAV). It is the first and only recapturable and repositionable device available in the U.S., setting a new standard for TAVR.



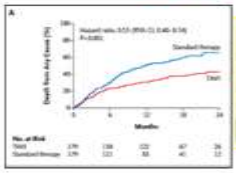
Trials and Registries

ESC/ACC/AHA Guidelines are based on the First Randomised Trials PARTNER 1

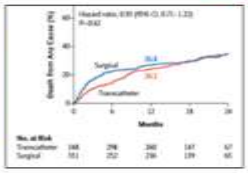
The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery	Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

M Leon et al; **2010**



C Smith et al; **2011**

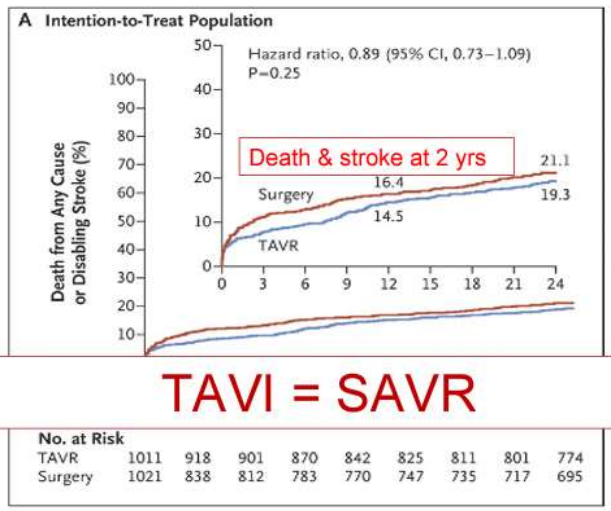


- Pts included between 2007 and 2009!
- SAPIEN, 1ere generation device
- Early TAVI experience
- Best cardiac surgeons

Randomized Trial in Intermediate risk patients: PARTNER 2A

New in 2016

Sapien XT



TAVI = SAVR

Leon et al
NEJM 2016

TAVI in Guidelines

Recommendations	Class [a]	Level [b]
TAVI should only be		
TAVI is indicated in patients		
1 year after consideration of their comorbidities.		

TAVI should only be undertaken with a multi-disciplinary team

TAVI should only be performed with surgery on-site

TAVI indicated in pts not suitable for AVR (Heart team)
With expected life-expectancy > 1-year
Likely to gain improvement in their quality of life

TAVI should be considered in High-Risk pts who may still be suitable for surgery but in whom TAVI is favored by the Heart Team based on the individual risk profile and anatomic suitability

AHA/ACC Guidelines 2014

TAVI vs. SAVR

Recommendations	COR	LOE	References
Surgical AVR is recommended in patients who meet an indication for AVR (Section 3.2.3) with low or intermediate surgical risk	I	A	(74,148)
For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate to provide optimal patient care	I	C	N/A
TAVR is recommended in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12 mo	I	B	(169,170)
TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR (Section 3.2.3) and who have high surgical risk (Section 2.5)	IIa	B	(171,172)

Complications

Complications

- vascular and access site complications
- bleeding
- stroke
- conduction system disease
- cardiac tamponade
- annular rupture
- peri-valvular aortic regurgitation
- device malpositioning or embolization

Stroke

Risk factors

- Older age, female
- prior cerebrovascular or peripheral vascular disease, diabetes, hypertension, prior cardiac surgery
- Need for balloon post-dilatation
- Post-TAVR atrial fibrillation

Ways to resolve

- Appropriate heparinization during procedure
- Appropriate pharmacologic treatment
- Anticoagulation when needed for atrial fibrillation
- Minimize unnecessary manipulations of the device in the aortic root
- Cerebral embolic protection devices (under investigation)

Vascular complications

Risk factors

- Small femoral artery luminal diameter
- Calcified arteries

Wayes to resolve

- Careful pre-procedural planning and evaluation of arterial access
- Confirm correct femoral artery placement (above bifurcation, below inferior epigastric) prior to large sheath dilatation
- Pre-closure of the arteriotomy site
  Iliac angiography at conclusion of the case
- Prompt endovascular or surgical repair of vascular injury

Conduction abnormalities

Risk factors

Pre-existing conduction system disease

Valve oversizing

Low valve implantation

Self-expandable devices
Calcified annulus

Ways to resolve

Consider active fixation, temporary pacemaker for highrisk cases and for self-expandable devices

Carefully monitor patients post-procedure for conduction system disease

Permanent pacemaker implantation when indicated

Limit device oversizing (must be weighed against risk of paravalvular regurgitation)

Aortic Regurgitation

Risk factors

- Asymmetric and calcified annulus
- Device undersizing

Ways to resolve

- Annular sizing and valve measurement by MSCT, cardiac MRI, or 3D transesophageal echocardiogram rather than single dimension sizing by 2D transthoracic echocardiogram
- Post-dilatation or placement of a second valve (must be weighed against risk of stroke or annular rupture)
- Central regurgitation requires placement of a second valve if not resolving

Cardiac Tamponade

Risk factors

- Temporary pacemaker perforation
- Guidewire perforation
- Annular rupture during valve deployment (more common in oversized valves, calcified annulus, with post-dilatation, and with balloon-expandable valves

Ways to resolve

- Careful wire management
- Limit device oversizing (must be weighed against risk of paravalvular regurgitation)
- Prompt diagnosis and management in the setting of hemodynamic instability
- Consider self-expanding device (less risk of annular rupture) for severely calcified annulus

Valve malposition

Ways to solve the problem

- Careful pre-procedural evaluation including annular size, and distance from annulus to coronary ostia

Scoring systems

Several different surgical risk algorithms are utilized by heart teams for the selection of patients for TAVR. The two most common risk assessment tools are the Society of Thoracic Surgeons (STS) score and the logistic EuroSCORE

many risk factors are not represented in the standard risk scores, including frailty, dementia, hepatic disease, and anatomic factors (e.g., porcelain aorta or "hostile" chest). These ignored or under-represented co-morbidities must be considered in new risk score

Durability

Half of transcatheter heart valves may undergo degeneration within 10 years, according to estimates from the first study investigating the long-term durability of these valves in patients undergoing TAVI reported at EuroPCR 2016 .

.a significant increase in degeneration rate was observed between 5-7 years after TAVI.

So that risk for structural valve degeneration after TAVI should be considered, especially when treating relatively young patients and those at lower surgical risk.

Future studies should explore long-term durability .

Minimalist strategy

To optimize safety with early-stage devices and to train practitioners, it was advisable to uniformly apply procedural "safeguards," including general anesthesia and intraprocedural TEE.

- More recently the focus has shifted toward simplification of the procedure; this strategy is now described as the "minimalist"

Components

- percutaneous transfemoral vascular Access
- monitored anesthesia control (i.e., conscious sedation) without general anesthesia.
- Reduction or elimination of intraprocedural TEE guidance.
- Reduction or elimination of balloon pre-dilation before valve implantation.
- Rapid ambulation and early hospital discharge.

hybrid strategy

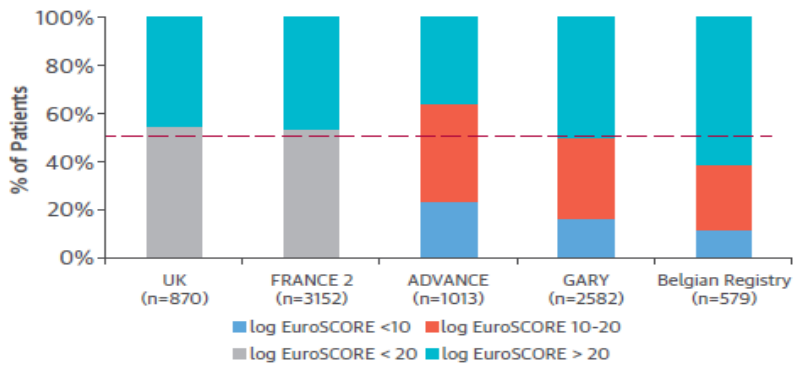
- Minimalist approach in straightforward cases with adequate imaging windows for transthoracic echocardiography,
- conventional approach in either high-risk or ambiguous cases, wherein the virtues of TEE guidance would be especially advantageous.

Controversies

I) Use of TAVR FOR low risk patients

Presently, several clinical research studies have acknowledged a downward risk "drift" and have begun to justify the use of TAVR in lower risk patients.

FIGURE 5 Risk Profile of European TAVR Registries



Distribution of log EuroScores in contemporary European TAVR registries (courtesy of Nicolo Piazza, MD, PhD). GARY = German Aortic Valve Registry; TAVR = transcatheter aortic valve replacement.

II) Valve-in-valve for bioprosthetic valve failure.

- clinical management of bioprosthetic valve failure in patients who are poor candidates for repeat surgical valve replacement is increasingly problematic.
- Transcatheter valve-in-valve implantation has emerged as a novel, less-invasive therapy for failed bioprosthetic surgical valves

- On the basis of clinical registry data, the self-expanding CoreValve and the balloon-expandable Sapien XT valve have been approved for use in high-risk patients with aortic bioprosthetic valve failure.

- In the largest international registry of transcatheter aortic valve-in-valve implants, using both balloon-expandable and self-expanding transcatheter valves, early hemodynamics findings were encouraging and 1-year survival was 83.2%.

- From a technical standpoint, compared with native valve TAVR, transcatheter valve-in-valve therapy results in more frequent coronary occlusions.
- More studies are still needed.

III) Bicuspid aortic valve disease.

bicuspid valves comprise approximately 20% of the surgical cases .

Why controversy

* more oval annulus shape * unequal leaflet size * heavy and uneven calcification *calcified raphes all these factors might interfere with optimal TAVR deployment and/ or lead to suboptimal hemodynamics.

- Recent data from a TAVR bicuspid valve registry, including 12 high-volume centers (139 patients) in Europe and Canada, support a preliminary finding that TAVR is safe, with a 5% 30-day and 17.5% 1-year mortality

- However, as predicted, a major concern in patients with bicuspid aortic valves is the higher incidence of PVR; post-implantation aortic regurgitation was found in 28.4% of patients

IV) Severe Aortic Incompetence

- The use of TAVR to treat patients with predominant aortic regurgitation and non-calcified aortic leaflets has been challenged because of the anatomical complexities.
- The need for large valve sizes and the management of associated aortic root disease are particular concerns.

- Few patients have thus far been treated for aortic regurgitation with self-expanding TAVR systems. Some dedicated TAVR devices for aortic regurgitation have been developed, and one, which clips to the native leaflets, has already been granted commercial approval in Europe.

Conclusion

- TAVI is efficient , feasable and reproducible.
- TAVI is considered an exciting therapy for patients with severe, symptomatic aortic stenosis who are at elevated risk for surgery, and the technology continues to evolve to include new valve designs, vascular access strategies, lower profile devices, and adjunctive methods to reduce the risk of procedural complications.
- Guidelines will be changed in future and we can dream to limit surgery for patients less than 65 years old and bicuspid calcific aortic valve

- Thank you