International Journal of Research in Medical Sciences
Shah R et al. Int J Res Med Sci. 2018 Jun;6(6):1847-1855
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: http://dx.doi.org/10.18203/2320-6012.ijrms20182261

Review Article

Impressive journey of TAVI so far, but miles to go

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Received: 08 March 2018
Revised: 02 May 2018
Accepted: 05 May 2018

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ABSTRACT

Valve replacement is mandatory for AS patients owing to its progressive nature leading to continuous valve degeneration. However, surgical replacement cannot be opted for majority of patients due to old age and affiliated co-morbidities. Over the recent years, AS treatment in high-risk patient population favors a newer, less-invasive method of transcatheter aortic valve implantation (TAVI). The main objective of this review is to revisit all the relevant aspects of TAVI to treat AS in high-risk patients and to assess its possibility as a first-line treatment approach even for low-risk AS patients. We searched PubMed, Google Scholar, Medline and ClinicalTrials.gov to identify all the relevant randomized controlled trials (RCTs) assessing the outcomes of TAVI vs. surgical mode of valve replacement. This method is found to be very safe and reproducible in many landmark clinical trials involving high-risk patients, demonstrating superior or, at least, comparable outcomes vs. surgical mode of treatment. This led to a trend of testing TAVI in lower-risk patient population as well to expand its treatment indication profile.

Keywords: Aortic stenosis, Generation heart valve, Surgical aortic valve replacement (SAVR), Transcatheter aortic valve implantation (TAVI)

INTRODUCTION

Aortic valve degeneration is the most common cause of aortic stenosis (AS). Surgical aortic valve replacement (SAVR) remained a favoured approach to treat severe AS for a prolonged period. However, SAVR was associated with a high operative mortality rate of 7-10% in high-risk groups. Moreover, 30-40% of elderly patients do not opt to go for this surgery. Transcatheter aortic valve implantation (TAVI) was developed to address these unmet needs.[1] TAVI revolutionized the treatment of severe AS.[2] With more than 100,000 implants performed worldwide, TAVI is stated to change the paradigm in the treatment of AS.[3]

The feasibility of TAVI was first confirmed in the first decade of 21st century.[4] Over the years, a fast-paced development seen in prosthetic valve designing significantly improved procedural success and outcomes of TAVI, with a substantial reduction in complications.[5]

Isolated AS is reported to be as high as 7.3% in Indians, with the vast majority in geriatric population.6 As per recent Indian demographic data, nearly 3 lac AS patients are estimated to be eligible for TAVI in the near future. Thus, TAVI is stated to become a popular procedure amongst aged Indians as well.[2]

Pre-TAVI workup in patients and selection for TAVI

The pre-TAVI workup is best achieved in a systematic manner. However, the procedure may not always follow the same line.[7]

It may be claimed that TAVI is the treatment of choice in inoperable patients, and an effective alternative in high-risk patients considering the outcomes of recent randomized controlled trials.[9] However, over the last few years, there appears to be a trend to favor the treatment of even lower risk patients with TAVI.[9]

Patient evaluation before TAVI should be conducted by a multidisciplinary team. Current guideline recommendations for TAVI patient selection in AS have been explained below in Figure 1.[10]

Table 1: Pre-TAVI evaluations.

Key evaluations	As needed evaluations/additional details
Initial Assessment	
AS symptoms and severity	
Symptoms	Intensity, Acuity
AS severity	Echocardiography and other imaging
Baseline clinical data	
Cardiac History	Prior cardiac interventions
Physical examination and labs	Routine blood tests, PFTs
Chest Irradiation	Access issues, other cardiac effects
Dental Evaluation	Treat dental issues before TAVI
Allergies	Contrast, latex, medications
Social Support	Recovery, transportation, post-discharge planning
Major CV co-morbidity	
Coronary artery disease	Coronary angiography
LV systolic dysfunction	LV ejection fraction
Concurrent valve disease	Severe MR or MS
Pulmonary hypertension	Assess pulmonary pressures
Aortic disease	Porcelain aorta (CT scan)
Peripheral vascular disease	Prohibitive re-entry after previous open heart surgery (CT scan), Hostile chest, Imaging for PVD
Major non-CV comorbidity	
Malignancy	Remote or active, life expectancy
Gastrointestinal and liver disease, Bleeding	IBD, cirrhosis, varices, GIB-ability to take anti-platelets/anticoagulation
Kidney disease	eGFR <30 cc/min/1.73m^2 or dialysis
Pulmonary disease	Oxygen requirement, FEV_1 <50% predicted or DLCO <50% predicted
Neurological disorders	Movement disorders, dementia
Functional Assessment	
Frailty and disability	
Frailty assessment	Gait speed (<0.5 m/s or <0.83 m/s with disability/cognitive impairment), Frailty (Not frail or frail by assessments)
Nutritional risk/status	Nutritional risk status (BMI <21 kg/m2, albumin <3.5 mg/dl, >10-lb weight loss in past year, or ≤11 on MNA)
Physical function	
Physical function and endurance	6-min walk <50 m or unable to walk
Independent living	Dependent in ≥1 activities
Cognitive function	
Cognitive impairment	MMSE <24 or dementia
Depression	Depression history or positive screen
Prior disabling stroke	
Futility	
Life expectancy	<1year life expectancy
Lag-time to benefit	Survival with benefit of <25% at 2 years

Patient selection for TAVI as per risk scores

The decision for SAVR or TAVI in AS also rely on the calculation of risk scores for cardiac surgery (including SAVR): the STS-PROM and the EuroSCORE model. When the STS-PROM score exceeds 10% or when the logistic EuroSCORE is ≥20%, referral for TAVI should be considered.[5]

However, some patients as listed in Table 2 have been contraindicated to TAVI procedure as per the established clinical evaluation regime.

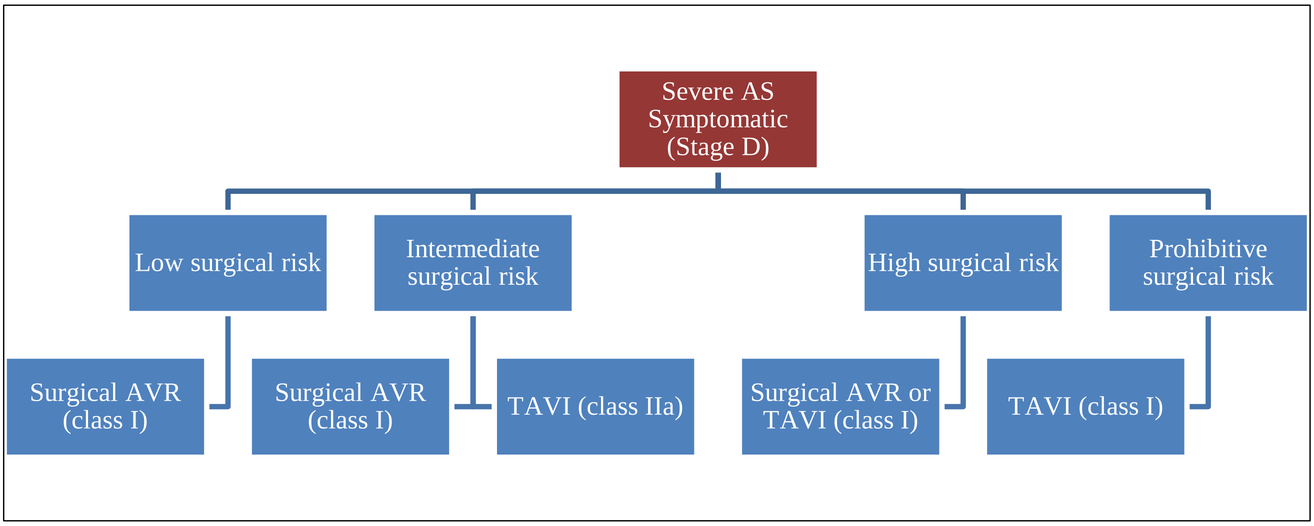

Figure 1: Choice of TAVR vs. surgical AVR in the patient with severe symptomatic AS.

Table 2: Contraindications for transcatheter aortic valve implantation.

Type of contraindications	Particulars
Absolute Contraindications	Absence of heart team or surgery
	Appropriateness of TAVI not confirmed by a "Heart Team"
	Clinical
	Estimated life expectancy <1 year.
	Unlikely improved quality of life by TAVI.
	Severe primary associated disease of other valves.
	Anatomical
	Inadequate annulus size (<18 mm, >29 mm)
	Thrombus in the left ventricle Active endocarditis
	Elevated risk of coronary ostium obstruction
	Plaques with mobile thrombi in the ascending aorta, or arch
	Inadequate vascular access
Relative Contraindications	Bicuspid or non-calcified valves
	Untreated coronary artery disease requiring revascularization
	Hemodynamic instability
	LVEF < 20%
	For transapical approach: severe pulmonary disease, LV apex not accessible

Note: LVEF, left ventricular ejection fraction

Overview of valve types

Historical valves

- The Percutaneous Heart Valve™ comprised a balloon-expandable stainless steel stent initially covering a polyurethane valve.[13]
- The Paniagua Heart Valve™, consisted a balloon-expandable stent with a bovine pericardium valve.[14]
- The Cribier-Edwards THV™ comprised an equine pericardium valve mounted on a balloon expandable tubular slotted stainless steel stent framework.[15]

Commercially available First-Generation transcatheter valves

Edwards SAPIEN THV™

- Bovine pericardium treated to remove calcium-binding sites.
- Updated RetroFlex 1™.
- Shortened nose cone to minimize injury to the left ventricle.
- Available for transapical delivery via the 24Fr Ascendra™ catheter.[16]

Medtronic CoreValve™

- Supra-annular bovine or porcine pericardium valve.
- Self-expanding nickel-titanium alloy frame working on a 'cell' design.
- Leaflet positioning minimizes disruption of leaflet configuration and co-aptation
- High loop strength and radial force of the central portion.

- The stent's cell structure also facilitates conformation to anatomical discrepancy and functions to minimize coronary ostia obstruction.[16]

Comparison of Edwards SAPIEN THV™ and Medtronic CoreValve™

- Found to produce similar clinical outcomes with a few notable exceptions.
- The Medtronic CoreValve™ -
- Significantly higher rates of conduction disturbances and the need for post-procedural PPM.[17]
- Higher moderate to severe regurgitation and requirement for repeat procedures.[18]
- Edwards SAPIEN THV™
- Significantly higher rate of surgical conversion and a higher incidence of major vascular complications.
- Both valves cannot be retrieved or repositioned following deployment.[17]

Selection of the optimal transcatheter bio-prosthetic valve

Number of modifications have been made to existing devices in attempts to overcome the limitations of earlier-generation valves.[17]

Table 3: Limitations of first-generation TAVI valves.

Limitation	Associated negative outcomes
Inability to reposition, retrieve, or resheath valves	Device embolization or malpositioning
Paravalvular leak	Increased mortality at two-year follow-up
High radial forces associated with aggressive oversizing of the valve prosthesis	Risk of annular rupture
Subsequent pacemaker requirement	Atrioventricular conduction abnormality
Placement of large-bore sheaths in femoral arteries	Vascular complications and associated bleeding
Coronary ostial obstruction by the valve and leaflet tissue and embolization	Consequent myocardial infarction
Embolization of friable material at the time of intervention	Risk of stroke
Complex delivery processes	Multiple operator requirement limiting accuracy of deployment

Current (second) generation of valves

Currently, 2 major valves available for commercial use.[19]

- The Edwards SAPIEN XT
- Balloon expandable
- Valve can be crimped into a smaller profile.
- 3 sizes - 23 mm, 26 mm and 29 mm.
- The Medtronic CoreValve
- Self-expanding nitinol based valve
- Tri-leaflet porcine pericardial leaflets
- 3 sizes - 26, 29 and 31 mm.[19]
- Innumerable other valves aiming to be smaller in profile, reduce paravalvular leaks and retrievable.[19]

Medtronic Evolut™

- Second-generation CoreValve™ retaining most of the earlier features.
- Reduced overall size
- 10 mm shortening of the outflow tract
- Tailored shape to improve fit and valve retrieval capacity.[17]

JenaValve™

- Porcine aortic root valve mounted on a low-profile self-expandable nickel-titanium alloy frame for anterograde transapical implantation.
- It relies on clip fixation of the prosthesis to native aortic valve leaflets to reduce the requirements for high radial forces and larger contact area.[17]

Sadra Lotus™ (Boston Scientific)

- Repositionable and fully retrievable valve
- Facilitates accurate primary positioning, early valve function, and hemodynamic stability during deployment.
- Minimizes paravalvular regurgitation in patients with severe AS at high or extreme SAVR risk.[20]

Other investigational devices

A number of new investigational devices have been listed in the following Table 4.

Selection of access route/valve delivery

Transfemoral route

- Current recommendations strongly advocate the femoral route as the preferred TAVI access site.
- Performed under loco-regional anesthesia.
- Following TAVI deployment, anticoagulation state needs to be restored.[23]

Transapical route

- Purpose-specific Ascendra delivery catheter
- Replaced by the Ascendra 2 system that can accommodate the SAPIEN-XT valve.[24]

Transaxillary/subclavian route

- Proved particularly advantageous for the CoreValve procedure.
- Initial concerns with the Novaflex system seem to have been alleviated.[24]
- Access to the axillary artery has generally been accomplished in an open fashion, due to the thin friable wall of this artery.[24]

Transaortic route

- Generally, been performed with the standard Edwards or Medtronic transarterial delivery system.
- Favorable in patients with compromised arterial access.[24-26]

Table 4: Newer/investigational TAVI devices.

Valve type	Direct flow medical valve	Heart leaflet technology	Medtronic engager	Edwards centera	Edwards Sapien 3	Colibri heart valve	Boston scientific lotus valve	Aor Tx	Acurate ® (Symetis)	Portico ® (St Jude)	Jena Valve®
Size (mm)	25, 27	21, 23	23, 26	23, 26	20, 23, 26, 29	26	23	-		18, 24 mm	23, 25, 27 mm
Height (mm)	17 - 18	-	-	17.5, 20	20	-	-	-		-	-
Leaflet	Bovine	Porcine	Bovine	Bovine	Bovine	Bovine (dehydrate)	Bovine	-	Porcine native aortic leaflets	Porcine	Porcine
Frame	Polymer	Nickel-titanium alloy	Nickel-titanium alloy	Nickel-titanium alloy	Cobalt chromium	Nickel-titanium alloy	Nickel-titanium alloy	Nickel-titanium alloy	Nitinol frame 23, 25, 27 mm	Nitinol	Nitinol
Sealing cuff	Polyester	Polyester	Polyester	PET	PET	Porcine	Polyureth-ane			-	-
Delivery	18Fr, 22Fr (TF)	18Fr (TF)	29Fr (TA)		Commander 14Fr (TA)	14Fr	18Fr	24Fr	28 Fr	18, 24 Fr TF, Tao, TA, SC	32 Fr TA
Expansion	Inflation	Self-expand-able	Self-expanda-ble	Self-expanda-ble	Balloon-expandable	Balloon-expandable	Mechanical	Self-expanda-ble	Self-expanda-ble	Self-expanda-ble	Self-expanda-ble
Reposition	Yes	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes
Retrievable	Yes	Yes	No	Yes	No	No	Yes	Yes	No	Yes	Yes
Resheathable	No	Yes	-	-	Yes	-	No	-	Sheathless	-	Sheathless
Trials conducted	Discover	-	Engager™ CE pivotal trial	Feasibility study, 26 mm, 200-2012, Edwards Centera system clinical trial	The partner II trial the sapien 3 study	-	Reprise II	-	Acurate TA® trial Acurate Neo and TF® trial	First-in-human experience	JUPITER registry
Approved /CE mark	CE mark in 2013	-	CE mark in 2013	Under evaluation	CE mark in 2014	-	CE mark in 2013	-	CE mark in 2011	CE mark in 2012	CE mark, 2012 for AS 2013 for AR
References	17, 21,22	17,22	17,22	17,22	17,22	17,22	17, 20,22	17,22	22	22	22

DISCUSSION

TAVI: Published evidence

TAVI in severe senile calcific aortic stenosis: inoperable patients

- In 2010, the first landmark study of TAVI-PARTNER trial B cohort was published.
- 358 symptomatic patients with severe calcific AS not considered for SAVR.
- Randomized to TAVI using the Edwards SAPIEN valve or medical therapy.
- Medically managed non-surgical patients-50% mortality rate in one year.
- All-cause mortality was reduced by an absolute 20% at one year.
- >50% reduction in the incidence of NYHA III or IV symptoms with TAVI.
- Thus, patients who are not candidates for SAVR should be strongly considered for TAVI.[27,28]

TAVI in severe senile calcific aortic stenosis: surgical candidates

- In 2011, PARTNER A trial results were published.
- 699 symptomatic severe calcific AS patients at high but still acceptable risk for SAVR were randomized to TAVI using SAPIEN valve or SAVR.
- Mortality at 30 days and one year was similar with TAVI and SAVR.[27,29]
- In 2014, the U.S. CoreValve High Risk Study was published with similar outcomes.
- Primary endpoint of all-cause death in the intention-to-treat analysis was 13.9% vs. 18.7% in the SAVR group ($p<0.001$ for non-inferiority, $p=0.04$ for superiority).
- No significant differences between the two groups with respect to functional status and quality of life.
- Strict adjudication of stroke identified no increased risk in the TAVI arm vs. SAVR at 30 days and one year.[27,30]
- SURTAVI trial
- 1660 patients with a mean age of 79.8 years at intermediate risk for surgery
- TAVI was non-inferior to surgery in patients with severe aortic stenosis at intermediate surgical risk, with a different pattern of adverse events associated with each procedure.[31]

Table 5: Summary of landmark TAVI trials.

Study	Valve used	Design	Control	No. of TAVI patients	Inclusion criteria	Conclusions
PARTNER 1A (2011)	Edwards SAPIEN	RCT	SAVR	348	Severe AS Symptomatic (NYHA ≥II) high surgical risk	TAVI is non-inferior to AVR in patients with severe AS and high surgical risk.
PARTNER 1B (2010)	Edwards SAPIEN	RCT	SMT (including BAV)	179		TAVI is superior to SMT for patients with severe AS who are unable to undergo AVR.
VIVID Registry (2012)[39]	Edwards SAPIEN Medtronic CoreValve	TAVI experience registry		202 (patients with degenerated bioprosthetic valves)	1-4 previous SAVR, median time from last SAVR to VIV procedure of 9 years	The valve-in-valve procedure is clinically effective in patients with degenerated bio-prosthetic valves. Safety and efficacy concerns include device malposition, ostial coronary obstruction, and high gradients after the procedure
US CoreValve (2014)	Medtronic CoreValve	RCT	SAVR	390	Severe AS Symptomatic (NYHA ≥II) High surgical risk	TAVI is associated with improved 1-year vs. SAVR for patients with severe AS at high surgical risk.
PARTNER 2 (2016)	Edwards SAPIEN XT	RCT	SAVR	1011	Severe AS Symptomatic (NYHA ≥II) Intermediate surgical risk	TAVI is non-inferior to SAVR in patients with severe AS and intermediate surgical risk.
SURTAVI (2017)	Medtronic CoreValve and Evolut R	RCT	SAVR	864		

TAVI in Severe Bicuspid Aortic Valve Stenosis

- Bicuspid aortic valve (BiAV) degeneration is the most common cause of AS in patients under 65, and accounts for 20% of severe AS cases in octogenarians.
- TAVI has traditionally been considered contraindicated in BiAV stenosis.

- Furthermore, patients with BiAV tend to be younger, leading to concerns about bioprosthesis durability.[27]

TAVI in low flow, low gradient severe AS

- Patients with reduced left ventricular ejection fraction (LVEF) and low flow, low gradient AS have a poor prognosis with medical therapy and a high peri-operative mortality with SAVR.
- Patients with classical LF-LG AS patients had better 2-year survival with TAVI compared to medical therapy. (PARTNER B)
- Two-year survival with TAVI was also similar to SAVR in the randomized PARTNER A trial.
- Better recovery of LVEF has been observed with TAVI vs. SAVR.
- TAVI also provides a therapeutic alternative to SAVR in patients with severe LF-LG AS with preserved LVEF.[27,32]

TAVI in severe native aortic valve regurgitation

TAVI in patients with native aortic valve regurgitation (NAVR) has unique technical challenges related to device anchoring. However, new transcatheter valve designs like JenaValve are addressing these challenges.[27]

TAVI for failed aortic bioprostheses

Concept of a valve-in-valve (ViV), delivered via a catheter, constitutes an attractive alternative. The VIVID registry has recently reported the feasibility and safety of TAVI in 459 patients with a failing aortic bioprosthetic valve.[27]

Off-Label indications for TAVI

- As per the new NCDR STS/ACC TVT Registry, in the US, off-label TAVI is used in approximately 9.5% of patients.
- This registry concluded that approximately 1 in 10 patients in the United States have received TAVI for an off-label indication.
- After adjustment, 1-year mortality was similar in these patients to those receiving TAVI for an on-label indication.[33]

Future of TAVI

TAVI for patients at lower surgical risk

- Current strategy revolves around evaluating TAVI for use in patients at lower surgical risk.
- As per a recent propensity score analysis, use of the SAPIEN 3 THV was associated with significantly lower rates of death, stroke, or moderate or severe aortic regurgitation at 1 year of follow-up vs. SAVR.
- These data prompted the FDA to approve the SAPIEN 3 THV for treating patients with severe AS at intermediate surgical risk.[34]
- Notes of the efficacy of TAVI in patients at low surgical risk were also seen in the NOTION trial.[35]
- Ongoing RCT such as PARTNER 3, Evolut R Low Risk and NOTION 2 have the capacity to establish TAVI as a first line treatment for AS patients even with low surgical risk.[34]
- However, the long-term durability of these THVs will determine whether TAVI can be used in younger patients or not.

Limitations of TAVI to be addressed in the future

Conduction system disturbances requiring permanent pacemaker implantation after TAVI. However, there has been a dramatic reduction in the rates of stroke and other major vascular complications and a consistent improvement in rates of paravalvular aortic regurgitation.[34]

Aortic regurgitation and bicuspid aortic valve disease

- Though the patient proportion is just 2-6%, bicuspid aortic valve disease is a unique anatomical challenge during TAVI. [34]
- In case of a systemic review in aortic regurgitation (AR), including a total of 237 patients with pure native AR from 13 TAVI studies
- CoreValve system were used in 79% of the patients.
- Device success was variable between studies and ranged from 74% to 100%.
- The need for a second valve occurred in up to 7% of patients
- Incidence of moderate-to-severe residual AR was 9%.
- Of note, the stroke rate was extremely low (0%), and 30-day mortality was 7% (3-13%).[37]

Imaging issues

Utility of imaging to improve prediction of TAVI-related outcomes is an emerging issue, particularly for patients with particular characteristics rendering them at greater risk of procedural complications and suboptimal outcomes. Fusion imaging and simulation of device implantation will probably have an increasing role in future TAVI. [34] The future of TAVI seems bright, with upcoming trials expected to increase the safety and efficacy of the procedure, reducing potential making TAVI a viable and a turning point procedure to treat most patients with severe aortic valve disease.

CONCLUSION

The establishment of TAVI rudimentarily changed the management of AS. The continuous improvement in existing valve design and the introduction of novel devices enabled a continued extension of this field. Further, as the results improve, and valve durability is determined, an extended application of this technology to lower-risk patients is also projected.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Shah R, Dave B. Impressive journey of TAVI so far, but miles to go. Int J Res Med Sci 2018;6:1847-55.