Chapter

Transcatheter Aortic Valve Replacement: Clinical Indications and Outcomes

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Abstract

Severe calcific aortic stenosis (AS) is commonly seen in the elderly population, and as human longevity increases, the prevalence of severe AS is bound to increase. Symptomatic severe AS, if left untreated, carries high mortality with 2-year survival below 50%. Surgical aortic valve replacement (SAVR) had been the standard of care for such patients with excellent outcome. As the patient's comorbidities increase, so does surgical risk for SAVR. Since its first human use in 2002 and commercial approval in 2007 (CE mark, Europe), transcatheter aortic valve replacement (TAVR) has come up as an excellent alternative to SAVR in patients with higher surgical risk profile. Iterations in device design added to enhanced operator experience can be attributed towards improved clinical outcomes. Indications for TAVR continues to expand and now includes patients with intermediate surgical risk as well. This chapter discusses indications and evidence for TAVR and touches upon patient selection and complications after TAVR.

Keywords: severe aortic stenosis, transcatheter aortic valve replacement, indications of TAVR, complications of TAVR, trials on TAVR

1. Introduction

A population-based study done by Eveborn et al. demonstrated an increase in the prevalence of AS with age, from 0.2% at 50–59 years to 9.8% at 80–89 years [1].

Prevalence of any AS and severe AS from pooled data involving multiple studies was shown to be 12.5 and 3.4% respectively among people of age >75. Approximately half to one-third of patients with severe AS may be asymptomatic at the time of diagnosis [2].

Due to long asymptomatic period associated with severe Aortic stenosis, patients may not report any overt symptoms, or compensate for their decreased exertional capacity by slowing down their daily activities attributing it to normal aging. Addressing symptom onset in patients with severe AS is extremely important as the onset of symptoms markedly decreases survival unless aortic valve replacement is performed.

Early observation done by Ross and Braunwald [3] showed that patients with angina have a 50% 5-year survival rate without AVR, those with syncope have 50% 3-year survival. Heart failure carries worse prognosis with mean survival rate of less than 2 years without AVR.

1) As a bridge to future definitive therapy: a) Hemodynamically unstable, b) Bridge to TAVR/SAVR in patients with reversible comorbidities, c) Need for percutaneous coronary intervention 2. As a palliative measure for symptomatic severe AS with poor life expectancy due to non-cardiac comorbidities who are considered poor candidates for TAVR/SAVR 3. Combined with TAVR, as in balloon expandable valves 4. Symptomatic patient before undergoing emergent non cardiac surgery 5. To assess contribution of AS for symptom status in presence of severe concomitant pulmonary involvement 6. Patients with congenital aortic stenosis 7. Symptomatic severe aortic stenosis in pregnant patients when optimal medical therapy fails.

Table 1.
Indications for balloon aortic valvuloplasty (BAV).

While SAVR is considered standard of care for management of symptomatic severe aortic stenosis, one-third of patients with severe AS with indications for SAVR may be denied surgery in view of advanced age and comorbidities.

Catheter-based balloon aortic valvuloplasty (BAV) was developed in 1985 as a less invasive solution for patients with symptomatic severe AS who were denied SAVR.

High rates of recurrence (80%) at 1 year associated with BAV hindered its widespread adaptability and search for other less invasive therapeutic option for severe AS patients was continued.

Contemporary indications for BAV are listed in **Table 1**. Currently, BAV is reserved for use as a bridge-to-decision to provide more definitive therapy for AS and for patients with contraindications for TAVR in whom relief of Aortic obstruction will improve quality of life.

2. TAVR: early concepts

To circumvent restenosis after BAV, a combination of stent frame and valve within was thought as an alternative. This arrangement could potentially implant an aortic valve in place of diseased native aortic valve using minimally invasive catheterization technique, thus avoiding high morbidity and mortality associated with high risk SAVR. Routine observation of high-pressure balloon inflation (4–5 atmospheres) leading to opening of all calcified aortic valves in a circular fashion led to the concept of TAVR [4].

In 1992, Andersen and colleagues [5], used a hand-made porcine valve contained within a metallic mesh and successfully implanted at various cardiac sites in a pig model. This was the first evidence of use of a stented valve.

In 1999 percutaneous valve technologies (PVT) designed early models of balloon expandable transcatheter heart valve (THV) [4].

The first human implantation of a percutaneous stented valve to a degenerated right ventricle-to-pulmonary artery conduit was done in 2000 by Bonhoeffer and colleagues [6]. This was a bovine jugular valve mounted on stent platform.

After initial success with the sheep model, Dr. Alain Cribier and his team performed the first successful TAVR in human using a balloon expandable THV on 16th April 2002 as a bailout procedure after failed emergency BAV [4].

3. Evolution of TAVR: indications and clinical trial evidence for TAVR

After initial success with the Sheep model, first human implantation with the balloon expandable Edwards valve was done on 16th April 2002 after failed emergency BAV as a bailout procedure [4].

After encouraging initial results, Dr. Cribier and team were able to recapitulate TAVR in a few patients. Worldwide demonstrations of this innovative therapy led to its increased acceptance. TAVR was transforming from a crazy idea to a viable therapy option. The Cribier valve technology was acquired by Edwards Lifesciences (Irvine, CA) for further development, and the THV was further marketed as Edwards Sapien valve.

Simultaneously scientists from Europe were working on a self-expandable valve (CoreValve, Medtronic, Inc.; Minneapolis, MN) platform as an alternative to balloon expandable valve since 2004 and human implantations were being done successfully.

As the number of TAVR implantations increased, data from multiple small studies and registries like SOURCE, ADVANCE, FRANCE I and FRANCE II showed procedural success (30 days survival) ranging from 67–92%.

With the available data, the European CE mark authorization was granted in August 2007 for the Edwards Sapien balloon expandable THV with the transfemoral RetroFlex delivery system and in January 2008 for use with the transapical Ascendra delivery device.

PARTNER was the first randomized trial that compared TAVR with standard therapy. Cohort B of this landmark trial demonstrated superiority of TAVR over medical therapy in patients with severe symptomatic AS who were considered extreme (or prohibitive) risk for SAVR. At 1 year follow up, absolute risk reduction in all-cause mortality of 20% was observed, a finding which held true even at 5 years follow up [7].

Cohort A of PARTNER trial compared TAVR with SAVR and showed that TAVR was non-inferior to SAVR in patients with high surgical risk (society of thoracic surgeons (STS) score >8%). CoreValve extreme risk trial data showed benefit of TAVR with reduction in all-cause mortality.

In November 2011, United States Food and Drug Administration (US FDA) approved TAVR as a treatment option for patients with symptomatic severe AS who were considered inoperable for SAVR. Favourable clinical data using self-expanding THV CoreValve (Medtronic) led to its USFDA approval in 2014 on similar patient subset.

With the available evidence from randomised control trials (RCTs) and multiple registry data, TAVR was given Class I LOE B recommendation in patients with prohibitive (not suitable for SAVR) and increased surgical risk by ESC guidelines [8] and Class I LOE A by ACC/AHA guidelines [9].

Another important observation noted in PARTNER 1 trial was diminishing survival benefit of TAVR with higher STS score. This led to stress more importance on patient selection.

Intermediate surgical risk (STS score ≥4–8%) patients with symptomatic severe AS were enrolled in PARTNER 2 trial comparing TAVR using second generation Sapien valve (Sapien XT) with SAVR along with subgroup analysis of transfemoral and transthoracic cohorts. All-cause mortality in TAVR arm was non-inferior to SAVR at 2 years with comparable stroke and permanent pacemaker rates.

The SURTAVI (surgical replacement and transcatheter aortic valve implantation) trial used Self-expandable CoreValve and enrolled patients with symptomatic severe AS with intermediate surgical risk and showed all-cause mortality in TAVR group non-inferior to SAVR at 1 and 2 years.

PARTNER 2 and SURTAVI trials also showed a favourable decreasing trend in all-cause mortality and post-procedure stroke rates (refer to **Table 2**).

ACC/AHA has given Class II LOE (level of evidence) A recommendation for TAVR in intermediate-risk population [9].

With the availability of 5-year data on TAVR showing good valve durability, focus of attention shifted to extend the benefit of TAVR to low-risk population with severe AS.

NOTION trial [10] and low-risk TAVR trial [11] evaluated the role of TAVR in low-risk population (STS score <4%).

NOTION trial is one of the earliest randomized trials, started recruiting patients in 2009 in a single centre. NOTION trial enrolled patients with symptomatic severe AS with low surgical risk and randomized them to TAVR versus SAVR. All-cause mortality at 1 year seen in this study was lower in TAVR arm compared to SAVR, an effect that persisted at 5 years.

The post-procedure permanent pacemaker implantation (PPI) rates and PVL (paravalvular leak) were higher in the TAVR group. Despite higher PPI and PVL rates, the all-cause mortality was lower with TAVR than SAVR. Higher PPI rates were because of an overenthusiastic approach for pacemaker implantation in view of lack of experience during those days.

The above-mentioned trials showed a consistent reduction in 30 days all-cause mortality attributed to improved technical advances, procedural skills and better patient selection (refer to **Table 2**).

SURTAVI 2012	PARTNER 2 2011	PARTNER B 2007	PARTNER A 2007	**Clinical Trial**
Severe AS with intermediate risk (STS ≥3 and ≤15)	Severe AS with intermediate risk (STS ≥4)	Severe AS with high risk and not suitable for SAVR. (Assessed by 2 CT surgeons and 1 Cardiologist)	Severe AS with high risk (STS PROM ≥10%)	**Population studied**
TAVR(879) vs SAVR(867) Core valve	TAVR (1011) vs SAVR(1021) Sapien XT valve	TAVR (179) vs Medical (179) 1st gen Edward Sapien	TAVR (348) vs SAVR (351) 1st gen Edward Sapien	**Comparator& valve used**
All-cause mortality TAVR vs. SAVR At 1 year 8.1% vs 8.8%	All-cause mortality TAVR vs. SAVR At 1 year 14.5% vs 16.4% At 2 year 19.3% vs 21.1%	All-cause mortality TAVR vs. medical therapy At 1 year 30.7% vs 50.7% At 2 years 43% vs 68% At 5 years 38.9% vs 66.7%	All-cause mortality TAVR vs. SAVR At 1 year 24.3% vs 26.8% At 2 year 33.9% vs 35%	**Primary end point**
At 1 year 8.2% vs 8.6% At 2 years 10% vs 11%	At 30 days 5.5% vs 6.1% At 1 year 10.1% vs 9.7%	At 1 year 11.2% vs 5.5% At 2 year 13.8% vs 5.5% At 5 year 16% vs 18.2%	At 1 yr. 8.7% vs 4.3% At 2 yrs. 11.2% vs 6.5%	**Stroke**
At 30 days 25.9% vs 6.6%	At 2 years 11.8% vs 10.3%	At 2 years 6.4% vs 8.6%	At 2 years 6.4% vs 7.2%	**Permanent pacemaker**
At 1 year 5.3% vs 0.8% At 2 years 5.8% vs 1.2%	Mod to severe PVL in At 1 yr. 3.4% vs. 0.4%	10% at 30 days had Moderate to severe PVL in TAVR	11.8% at 30 Days had Moderate to Severe PVL	**Paravalvular leak**

Core valve High risk 2011	Core valve extreme risk 2011	NOTION 2009	**Clinical Trial**
Severe AS determined as high risk by heart team (STS>15% and risk of death within 30days of surgery <50%)	Severe AS determined as high risk by heart team (STS>15% and risk of death within 30days of surgery >50%)	Severe AS, candidate suitable for TAVR and SAVR by multidisciplinary team	**Population studied**
TAVR (394) vs SAVR (401) Core valve	TAVR (506) Vs Prespecified Objective goal	TAVR (145) Vs SAVR (135) Core valve	**Comparator and** **Valve used**
All-cause mortality TAVR vs. SAVR At 1 year was 14.2% vs 19.1%	All-cause mortality at 1 year 8.4%TAVR vs. 24.3%OPG	All-cause mortality TAVR Vs. SAVR At 30 days 2.1% Vs. 3.7%. At 1 year 4.9% vs 7.5%	**Primary end point**
At 30 days 4.9% vs 6.2% At 1 year 8.8% vs 12.6%	Stroke was 4% at 30 days and 7% at 1 year	At 30 days 2.8% Vs 3% At 5 year 10.5% Vs 8.2%	**Stroke**
At 30 days 19.8% vs 7.1% At 1 year 22.3% vs 11.3%	At 30 days 21.6%	At 30 days 34.1% Vs 1.6%	**Permanent pacemaker**
At discharge 7.7% vs 0.3% At 1 year 6.1% vs 0.5%	10.7% at discharge and 4.3% at 1 year	15.7% Vs 0.9% at 1 year	**Paravalvular leak**

Table 2.
Clinical trials data.

A valve in valve (ViV), by virtue of the procedure being a re-do sternotomy, with patients typically in their 70 and 80s age, they usually fall into an intermediate risk category for surgical treatment. Most of the patients with degenerated bio prosthetic aortic valve qualify for TAVR.

The main issues with ViV are under expansion of the valve leading to higher gradients and a higher risk of coronary obstruction.

Bicuspid aortic valve (BiV), not approved, TAVR had been used off-label in BiV.

Issues related to the use of TAVR in BiV are:

Large annulus with severe and asymmetric calcification or presence of raphe can hinder with positioning and expansion of the valve that can lead to PVL or annulus rupture.

Increased risk of aortic dissection or rupture in view of concomitant aortopathy.

In view of relatively young patients with longer life expectancy, the durability of TAVR valve is still a concern.

A study by Ravi et al., which included 435 patients with BiV, showed higher 30 days all-cause mortality with off label TAVR (8.5%) when compared with on label TAVR (6.1%) [12].

Outcomes are not as favourable as tricuspid valve, still a valid alternative in patients with higher surgical risk profile.

4. Patient selection for TAVR

Patient evaluation is directed towards identifying patients where significant improvement in the quality and duration of life is expected with AVR and avoid unnecessary intervention where the benefit is unlikely due to other confounding co-morbidities.

Extreme comorbidities that overwhelm the benefit of TAVR may render the procedure futile as shown in PARTNER cohort B.

The essential components for patient selection include:

1. Clinical risk stratification with emphasis on heart team
2. Geriatric risk stratification
3. Anticipated clinical benefit and
4. Assessment of patient's goals and preferences
5. Anatomic assessment: MDCT as standard. 3D TEE as an alternative.
    a. Accurate valve sizing
    b. Vascular access planning

4.1 Clinical risk stratification

Important components of clinical risk stratification are mentioned in **Table 3**.

STS-PROM and Euroscore II are the two most commonly used integrated risk scoring calculators used to assess surgical risk.

STS risk scoring system had been extensively utilized in clinical decision making for TAVR. SAVR, components of which are showed in **Table 4**.

STS score <4% is low risk.

≥4%, <8% is intermediate risk.

>8% is high risk.

- **Age**
- **Number of comorbidities**
- **Severely reduced left ventricular function**
- **Low flow (low stroke volume index, <35 ml/m2)**
- **Severe myocardial fibrosis**
- **Severe concomitant mitral and/or tricuspid valve disease**
- **Severe pulmonary hypertension (PASP ≥60 mmHg)**
- **Severe lung disease, particularly oxygen dependent**
- **Advanced renal impairment (stages 4 and 5)**
- **Liver disease**
- **Very high STS score (predicted risk of mortality >15%)**

Table 3.
Clinical predictors of increased risk.

Age, gender, ethnicity	
Anaemia	
Renal function	Prior CABG
Sleep Apnoea	
Associated co-morbidities like DM, Lung disease	Peripheral artery disease COPD
Drug abuse	Frailty
Pneumonia	Porclein aorta
Home Oxygen	
MI	Chest wall irradiation
Heart Failure	
NYHA class	Chest wall deformity
Cardiogenic Shock	
Tachyarrhythmia's	
Bradyarrhythymias	
Steroids use	
previous cardiac arrest	
Number of Diseased Vessels	
Ejection Fraction	
Aortic Stenosis	
Valvular pathology in addition to AS	

Table 4.
Variables included in STS PROM and variables not included in STS PROM.

Concept of heart team: doctors from various specialties as a team need to evaluate TAVR patients.

Multidisciplinary team approach provides an opportunity for active participation of doctors from multiple specialties and share views on different aspects of patient health care and also to counsel patient relatives on an anticipated line of management.

The team should consist of referring physician, Clinical Cardiologist, Interventional cardiologist, cardiothoracic surgeon, Cardiac anaesthesiologist, dedicated cardiac imaging specialist, Valve clinic coordinator, dedicated nursing and catheterisation laboratory team.

4.2 Geriatric risk stratification

Beyond the traditional co-morbidities like DM and HTN, the elderly population also need particular attention in terms of advanced frailty, disability in activities of daily living, malnutrition, mobility impairment, low muscle mass and strength, cognitive impairment and mood disorders.

The commonly used assessment tools are shown in **Table 5**.

4.3 The anticipated benefit of TAVR

Trial evidence consistently shows, treatment with TAVR in patients with symptomatic severe AS results in reduction of all-cause mortality, improved duration of survival.

Patients symptomatic because of severe AS not because of other comorbidities have the greatest symptomatic benefit.

Patient pre-operative symptom status can be assessed by Kansas city cardiomyopathy questionnaire (KCCQ) [13] and can be followed up linearly.

• Frailty
5-meter gait speed
Fried's frailty scale
• Disability
Activities of daily living (ADL)
Instrumental activities of daily living (IADL)
• Cognitive impairment
Mini-Mental Status Examination (MMSE)
• Mood disturbance
Geriatric Depression Scale (GDS)
• Malnutrition
Albumin
Mini-nutritional assessment
• Charlson comorbidity index

Table 5.
Geriatric assessment tools.

4.4 Patients goals and preferences

The assessment of futility must include consideration of patient's values, goals, and preferences.

Shared decision-making requires both patient and provider share information, work toward a consensus and reach agreement on the course of action.

In the TAVR population, when benefit in symptom relief aligns with a patient's goals, care may not futile.

However, when life prolongation and symptom relief is not anticipated, care may be futile.

TAVR is not recommended in patients with a life expectancy of <1 year, or if the benefit of TAVR will be less obvious in the backdrop of multiple co-morbidities.

4.5 Anatomic assessment

Assessment of valve calcification, valve anatomy, annulus size, coronary height, an angle of implantation, size of sinuses of Valsalva, ascending aorta and peripheral vascular access by multidetector computerized tomography scan (MDCT) is an integral part of pre TVAR work up.

4.5.1 Aortic annulus

Annulus is a virtual ring formed by basal hinge points of the valve cusps. The measurement of annulus size is a very important step as it determines the size of the TAVR valve.

Prosthesis undersizing causes the risk of significant Paravalvular leak (PVL) or valve embolization, if oversized, disruption of the aortic root and cause annular rupture or impingement on conduction system and may cause bundle branch block or complete heart block.

Cardiac complications:	**TEE related**
Conduction abnormalities	Dental trauma
Tachyarrhythmia's	Oral bleeding
Paravalvular leak	Oesophangeal injury
Coronary obstruction	Oesophageal rupture
Valve embolization	
Valve thrombosis (clinical or subclinical)	
Cardiac tamponade	**Anaesthesia related**
Annular rupture	
Aortic dissection	
Non cardiac complications:	**Vascular**
Renal dysfunction	Dissection or perforation
Stroke	Retro-peritoneal hematoma
Major bleeding	Pseudo aneurysm
Acute kidney injury	
Access site related infection	

Table 6.
Complications of TAVR.

3D TEE and MDCT are the two most commonly used imaging methods for annulus measurement.

MDCT is a non-invasive procedure, the ability to measure annulus during any part of the cardiac cycle and provide additional information like valve calcification, distribution of valve calcification, sizes of sinus of valsalva (SOV), coronary ostia distance from the annulus, makes it imaging of choice unless contraindicated in view of kidney injury [14].

4.5.2 Vascular access planning

MDCT because of excellent resolution provides a virtual roadmap for vasculature and allows identification of vessel size, tortuosity, calcification, and luminal diameter, which allows the planning of access routes with a view to minimizing vascular complication rate.

5. Complications of TAVR

TAVR has seen an overall decline in peri-procedural complications over time, partly owing to newer technology and expertise.

Complications associated with TAVR are as listed in **Table 6**.

According to transcatheter valve therapy (TVT data), 30-day in-hospital mortality has decreased from 7.5% in 2012 to 4.6% in 2015 [15].

This part of the chapter briefly reviews about important complications post TAVR.

5.1 Major vascular access site complications

Access site complications incidence depends upon the method of localization and the location of the puncture site, the need for multiple punctures and the size of the sheath used. The incidence of major vascular complications showed a decreasing trend attributed to technical innovations reducing sheath size and valve delivery systems.

The overall major vascular complication rate was 17% in PARTNER 1 trial, decreased to 2.5% in low-risk TAVR trial [11], 2018 due to improvements in the sheath and valve delivery systems.

5.2 Permanent pacemaker implantation (PPI)

Need for PPI arises due to a complex interaction of the valve with the conduction system.

The incidence of PPI has not decreased as expected, compared with other complications. Changes in the valve design to prevent PVL and position of valve implantation contributed for PPI.

PPI incidence appears to increase with the oversizing of the valve and changes in valve design to prevent PVL. Shallow implantation and improvement in technical skill could decrease the incidence of PVL as shown in the REPRISE trial.

PPI frequency varies in relation to the valve type used. Balloon Expandable valve has a relatively less incidence of PPI at the cost of higher valvular gradients.

The incidence of new PPI post-TAVR was 6–10% in PARTNER 1 and PARTNER 2 trials which is similar to 5% seen in low-risk TAVR study [11].

The requirement of PPI has been associated with increased hospital stay and financial burden but has not been shown to increase mortality conclusively.

5.3 Paravalvular leak (PVL)

PVL occurs because of the difference in the shape of the valve which is circular compared to the elliptical aortic annulus.

The incidence of PVL is consistently shown to be higher with TAVR than SAVR in all landmark trials of TAVR.

Valve size, aortic valve distribution of calcium and implantation depth were predictive of post TAVR PVL [16].

Precise annulus sizing by appropriate aortic imaging pre-TAVR is fundamental to prevent PVL. With the use of newer imaging technology and understanding of the factors involved the incidence of moderate or severe PVL decreased 12.5% in PARTNER B to <1% in low-risk TAVR data [11]. Out of 12.5% moderate to severe PVL in PARTNER cohort B only 0.7% have severe leak, severe PVL causing an increase in mortality or need for re-intervention is very rare.

5.4 Stroke

Stroke is one of the most devastating complication post-TAVR, it causes an increase in mortality, significant worsening of quality of life and disability.

A stroke occurs due to the embolization of plaque contents from atheroma disrupted during delivery system manipulations. Early trial PARTNER 1 used a balloon-expandable valve with a 22-24F delivery catheter and showed a 30-day stroke risk of 5.5–6.2% [7].

The risk of stroke decreased over the years with increasing operator experience, advancements in valve technology, and improvement in patient selection.

PARTNER 2 and CoreValve studies used Sapien XT and CoreValve which used 18F delivery catheter and showed a 30-day risk of stroke around 4% [17–19].

A study on the timing of stroke post-TAVR by Samir et al. showed that of strokes occurring within 30 days post-TAVR, 64% were diagnosed within 2 days and 85% were diagnosed within 1 week, the risk of stroke after the initial peri-procedural period is not high [20]. More balloon post dilations and lack of dual antiplatelet therapy before the procedure were associated with a higher risk of early stroke [20].

Newer advances like Sentinel cerebral protection system are recently approved by the US FDA and are commercially available.

The Sentinel study investigated the role of Sentinel CPS (cerebral protection system) but failed to show a reduction in the median total new lesion volume on MRI. So In view of the lack of robust evidence regarding the efficacy of CPS, the choice of using neuroprotection in TAVR requires an individualized risk-benefit analysis.

Investigations therapies like protecting aortic arch vessels with CPS, excluding the LAA and refining post procedural antithrombotic strategy may aid in a further reduction in stroke incidence.

5.5 Durability

Structural valve deterioration is defined as any change in valve function resulting from an intrinsic abnormality leading to an intervention.

Increase in a mean gradient to >20 mm Hg or increase >10 mm Hg from baseline, an appearance of new valvular regurgitation constitutes SVD.

Rising interest for the use of TAVR in low-risk population makes durability of valve an important concern where the life expectancy of the patients would be more than 15 years. Five-year data from PARTNER 1 trial showed stable valve area and mean transvalvular gradient throughout the follow-up. The mean valve area was 1.52 cm^2 and the mean gradient was 10 mm Hg at 5 years and no events of clinical thrombosis of the TAVR valve [7].

Any increase in valvular gradients should warrant imaging workup for valve thrombosis. Data from multicentre registry showed, an incidence of VHD of 4.5% (overall VHD) and 2.8% within the first year (early VHD) [21].

Makkar et al. reported hypo-attenuated leaflet thickening (HALT) and reduced leaflet motion (RELM) in transcatheter valves, evaluated by four-dimensional volume-rendered computer tomography [22]. The effect of this finding on clinical outcomes needs further investigation.

Walksman et al. reported a 14% incidence of HALT and 11.2% RELM at 30 days post-TAVR, but were asymptomatic clinically.

Multivariate analysis showed the absence of anticoagulation at discharge, valve size <23 mm, a valve in valve procedure and greater BMI as predictors of transcatheter valve hemodynamic deterioration post-TAVR [21].

5.6 Miscellaneous

5.6.1 Annular rupture

Non-existent with self-expandable valves except in cases where pre or post-dilation is performed.

Because of the use of newer imaging modalities accurate sizing of the balloon, an annular rupture is a very rare phenomenon.

5.6.2 Valve embolization

Device embolization was defined as, Movement of valve prosthesis during or after deployment such that it loses contact with the aortic annulus. A study by Makkar et al., out of 2,554 patients who underwent TAVR, valve embolization was noted in 1% of patients. Technical factors like undersized valve and complex aortic valve anatomy, incomplete balloon inflation, and pacing failure were associated with valve embolization [23].

5.6.3 Coronary obstruction

Symptomatic coronary obstruction following TAVR is rare but a life-threatening complication. Multicentre registry data shows an incidence of 0.6%. It was observed more frequently with balloon expandable valve and in those with a previous surgical prosthesis [24]. Low lying coronary ostium and shallow sinus of Valsalva were anatomical factors associated with the risk for coronary obstruction [24].

5.6.4 Trans oesophageal echo (TEE) related complications

The incidence of complications with TEE is <1%. Dental trauma, oral bleeding, oesophageal erosions and rarely oesophageal rupture.

5.6.5 Anaesthesia-related complications

Respiratory dependence, hypotension, nausea and vomiting are among common, complete description of anaesthesia related complications is beyond the scope of this chapter.

6. Conclusion

TAVR, a novel approach started as an impossible idea, witnessed a remarkable journey and now is an established therapy in management of symptomatic severe Aortic stenosis patients. Outcomes post TAVR are bound to get better as technology improves and expertise increases. "TAVR first approach may be the future."

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Conflict of interest

There are no conflicts of interest.

Appendix

AS	aortic stenosis
STS PROM	society of thoracic surgeons, predicted risk of mortality
MI	myocardial infarction
V tach/V fib	ventricular tachycardia/ventricular fibrillation
CT surgeon	cardiothoracic surgeon
PPI	permanent pacemaker implantation
PVL	paravalvular leak
VARC	valve academic research consortium
CPS	cerebral protection system
LAA	left atrial appendage

VHD	valve hemodynamic deterioration
SVD	structural valve degeneration
TAVR	transcatheter aortic valve replacement
HALT	hypo attenuated leaflet thickening
RELM	reduced leaflet motion
COPD	chronic obstructive pulmonary disease
CABG	coronary artery bypass graft
BAV	balloon aortic valvuloplasty
THV	transcutaneous heart valve
PVT	percutaneous valve technologies
PARTNER	placement of aortic transcatheter valve trial
SOURCE	Sapien aortic bioprosthesis European Outcome Registry
NOTION	Nordic aortic valve intervention trial
SURTAVI	surgical replacement and transcatheter aortic valve implantation
SOV	sinus of valsalva
TVT	transcatheter valve therapy
TEE	trans oesophageal echo

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