India Live 2017

Update in Interventional Cardiology
India Live 2017

Update in Interventional Cardiology

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Preface

Perhaps no other discipline in medicine has seen such galloping strides as the field of interventional cardiology has. So fast is the evolution of the technology that it is difficult to keep pace with it. By the time you follow the recommended guidelines, the guidelines become obsolete in the light of new knowledge. Interventions in chronically occluded vessels, development of bioabsorbable stents—a new era, and intravascular imaging have changed the pattern of our practice.

The purpose of this update in interventional cardiology is manifold. It attempts at providing clear understanding of techniques from basic to beyond—to lay down principles that could allow the highest standards of safety and efficacy; to provide complete comprehensive run-down on any particular subject is beyond the scope of this book. What we have attempted is to emphasize the key points encompassing tips and tricks to fine-tune the skills of an interventional cardiologist.

With chapters on complications and high-risk PCI, the authors hope to provide wherewithal to bail out of a dreadful situation. The authors have poured in their years of experience to familiarize the reader with several practical methods of performing and troubleshooting the usual and unusual situations in the cathlab. In nutshell, the book will help in decision-making and executing the decisions in the cathlab.

This book has been possible with collaborative support of my co-editors and contributors. I hope the book empowers an interventionist with knowledge that would eventually acquire success, safety and efficacy while attempting the entire gambit of interventional procedures.

Ashwin B Mehta
This book is a culmination of consolidated efforts of a number of people. The most important ones are the contributors. Each one has made an outstanding contribution in their field, and despite their busy schedule, they have accepted our invitation and spared no efforts to come out with most illustrious and outstanding articles. We wish to deeply acknowledge their contribution from the bottom of our hearts.

Our sincerest thanks to the Directors of India Live, Dr Ashok Seth, Dr Upendra Kaul, Dr Mathew Samuel Kalarickal, and Dr Vinay K Bahl. Without their continuous encouragement and support, this task would not have been possible.

Several other members of our team have put in incessant efforts in correspondence, communication and synchronization amongst the various authors. Special mention for Mrs Kirti Talawadekar. Without her sincere efforts, the book would not have seen the light of the day within the specified time limit.

We would also thank the Jaypee Brothers Publishers team, especially Mr Sabarish Menon and Ms Kritika Dua for their continuous support and helping us in every way for timely publication of this book.

Ashwin B Mehta
Nihar Mehta
Rahul Chhabria
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Transcatheter Aortic Valve Replacement (TAVR)—Current Status

Ashwin B Mehta, Nihar Mehta

INTRODUCTION

The most common acquired valvular heart disease in adults in the developing world is aortic stenosis (AS), which has an increasing prevalence with age. Symptomatic severe AS, if treated medically inevitably leads to functional deterioration, heart failure and death. Although, surgical aortic valve replacement (SAVR) is the standard treatment with a Class 1 recommendation by ACC/AHA and ESC/EACTS guidelines in adults to alleviate symptoms and improve survival, SAVR entails considerable risks for some patients with severe co-morbidities and in some anatomical subsets. About 30% of patients do not undergo the procedure.

Since 2002, when the first transcatheter aortic valve replacement (TAVR) was performed by Dr Alain Cribier, this new technique has been used in many countries worldwide resulting in an additional option for these high-risk patients. In the subgroup of patients who are inoperable or high risk, TAVR is now the standard of care and is a valid alternative to surgery. In patients with severe symptomatic AS a multidisciplinary team approach is recommended to assess the individual risk of the patient and choose between the options of SAVR and TAVR.

INDICATIONS OF AORTIC VALVE REPLACEMENT (SAVR OR TAVR) (TABLE 1)

The following are the indications of AVR by SAVR or TAVR in patients with aortic stenosis.

- High gradient AS with symptoms on history or during exercise testing
- Symptomatic patients with a Low-flow low-gradient severe AS with a reduced left ventricular ejection fraction (LVEF)
- Symptomatic patients with a low-flow low-gradient severe AS who are normotensive and have a LVEF > 50% if it is determined that the obstruction is the most likely cause of symptoms.
Table 1: Recommendations of AVR

<table>
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<th>Recommendations</th>
<th>Class of recommendation</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVR is recommended for symptomatic patients with severe high-gradient as who have symptoms by history or on exercise testing (stage D1)</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>AVR is recommended for asymptomatic patients with severe AS (stage C2) and LVEF &lt;50%</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>AVR is indicated for patients with severe AS (stage C or D) when undergoing other cardiac surgery</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>AVR is reasonable for asymptomatic patients with very severe AS (stage C1, aortic velocity ≥ 5.0 m/s) and low surgical risk.</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>AVR is reasonable in asymptomatic patients (stage C1) with severe AS and decreased exercise tolerance or an exercise fall in BP</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>AVR is reasonable in a symptomatic patients with low-flow/low-gradient severe AS with reduced LVEF (stage D2) with a low-dose dobutamine stress study that shows an aortic velocity &gt; 4.0 m/s (or mean pressure gradient ≥ 40 mm Hg) with a valve area ≤ 1.0 cm² at any dobutamine dose</td>
<td>IIa</td>
<td>B</td>
</tr>
<tr>
<td>AVR is reasonable in symptomatic patients who have low-flow/low-gradient severe AS (stage D3) who are normotensive and have an LVEF &gt; 50% if clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>AVR is reasonable for patients with moderate AS (stage B) (aortic velocity 3.0 to 3.9 m/s) who are undergoing other cardiac surgery</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>AVR may be considered for asymptomatic patients with severe AS (stage C1) and rapid disease progression and low surgical risk</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

For the strength of recommendations: Class I means the procedure/treatment should be performed/administered. Class IIa means it is reasonable to perform the procedure/administer treatment. Class IIb means the procedure/treatment may be considered. Class III means that the procedure or treatment is not useful/effective and may be harmful.

For the level of evidence: Level A means multiple populations evaluated; data derived from multiple randomized clinical trials or meta-analyses. Level B means limited populations evaluated; data derived from a single randomized trial or nonrandomized studies. Level C means very limited populations evaluated; only consensus opinion of experts, case studies, or standard of care.

(AS: Aortic stenosis; AVR: Aortic valve replacement by either surgical or transcatheter approach; BP: Blood pressure; LVEF: Left ventricular ejection fraction).
The following are indications for AVR by SAVR in patients with aortic stenosis:

- *Asymptomatic* patients with severe AS and LVEF <50%
- *Asymptomatic* patients with severe AS and decreased exercise tolerance or fall in BP during exercise.
- *Asymptomatic* severe AS undergoing other cardiac surgery
- *Asymptomatic* very Severe AS (velocity >5 m/s) and a low surgical risk

**INDICATIONS FOR TAVR**

The indications for TAVR are evolving. TAVR can be used for native valve aortic valve stenosis or in bioprosthetic valve stenosis, regurgitation or a combination of both (the ‘valve in valve’ procedure).

- In native aortic valve stenosis: In patients with calcific aortic stenosis who meet the indications for an aortic valve replacement, the surgical risk

**Table 2: Recommendations for AS: Choice of SAVR or TAVR.**

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class of recommendation</th>
<th>Level of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical AVR is recommended in patients who meet an indication for AVR with low or intermediate surgical risk</td>
<td>I</td>
<td>A</td>
</tr>
<tr>
<td>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</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>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 &gt;12 mo</td>
<td>I</td>
<td>B</td>
</tr>
<tr>
<td>TAVR is a reasonable alternative to surgical AVR in patients who meet an indication for AVR and who have high surgical risk</td>
<td>Ila</td>
<td>B</td>
</tr>
<tr>
<td>Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS</td>
<td>Ilb</td>
<td>C</td>
</tr>
<tr>
<td>TAVR is not recommended in patients in whom existing comorbidities would preclude the expected benefit from correction of AS</td>
<td>III: No benefit</td>
<td>B</td>
</tr>
</tbody>
</table>

The above approach is similar to that in the 2014 AHA/ACC valve guideline. However, recommendation for TAVR in intermediate-risk patients are based on studies published after these guidelines.

(AVR: Aortic valve replacement by either surgical or transcatheter approach; TAVR: Transcatheter aortic valve replacement; AS: Aortic stenosis; SAVR: Surgical aortic valve replacement).
and co-morbidities are estimated. The choice between SAVR and TAVR is based on these risks.

TAVR is preferred in the presence of certain technical and anatomical subsets, which lead to a high risk for SAVR. These are as follows:
- Porcelain aorta
- Prior significant mediastinal radiation
- Prior pericardectomy with dense adhesions
- Prior sternal infection with complex reconstruction
- Patent left internal mammary graft lying beneath the sternum [as identified by computed tomography (CT) angiography].

- **Valve-in-valve TAVR**: In patients with a bioprosthetic aortic valve with symptomatic failure of the valve in the form of stenosis, regurgitation or both and a high surgical risk for SAVR.
- **Bicuspid aortic valve**: The anatomy of bicuspid aortic valves being asymmetrical with bulky leaflets predispose to suboptimal valve seating and deployment with a noncircular valve expansion. This increases the risk of paravalvular regurgitation and device migration. Whether newer valve designs will be able to account for these problems remains to be seen.

**Prerequisites for TAVR**

- To determine which patients are suitable candidates for TAVR, a multidisciplinary ‘Heart-Valve Team,’ including cardiologists, interventionists, cardiac surgeons, anesthetist and other specialists if necessary, should assess every patient on an individual basis.
- The hospital should have cardiac surgery on-site.
- These high risk patients should have a life expectancy of more than 1 year after considering the co-morbidities.
- They should be likely to have improvement in their quality of life.
- TAVR is recommended in patients who have a prohibitive surgical risk as deemed by the ‘heart team’.
- Among patients who have an intermediate or high risk but are still operable, TAVR may be performed if the heart team deemed that TAVR was favorable based on risk profile and anatomical suitability.

**RISK ASSESSMENT**

In patients with severe symptomatic calcific AS, the treatment decision between TAVR and SAVR is to be decided based on the risk assessment as well as the other co-morbidities and technical and surgical subsets (discussed above). The decision should be individualized by the Heart-Valve Team to optimize results.

The risk assessment is based on the Society of Thoracic Surgical – Predicted Risk of Mortality (STS-PROM) Risk Estimate (Table 3). Other scoring systems
Table 3: Risk assessment based on STS-PROM risk estimate, frailty, major organ system compromise and procedure specific impediment.

<table>
<thead>
<tr>
<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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<tr>
<td>STS PROM* &lt;4% AND 4 to 8% OR &gt;8% OR</td>
<td>Frailty¶ None AND 1 Index (mild) OR &gt;2 Indices (moderate to severe) OR</td>
<td></td>
<td>Predicted risk with surgery of death or major morbidity (all cause) &gt;50% at 1 year OR</td>
</tr>
<tr>
<td>Frailty¶ None AND 1 Organ system OR No more than 2 organ systems OR</td>
<td>Major organ system compromise not to be improved postoperatively*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure-specific impediment* None</td>
<td>procedure-specific impediment</td>
<td>Possible procedure-specific impediment</td>
<td>Severe procedure-specific impediment</td>
</tr>
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</table>

*Use of the Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM) to predict risk in a given institution with reasonable reliability is appropriate only if institutional outcomes are within one standard deviation of STS average observed/expected ratio for the procedure in question.

¶Seven frailty indices: Katz Activities of Daily Living (independence in feeding, bathing, dressing, transferring, toileting, and urinary continence) and independence in ambulation (no walking aid or assist required or 5-meter walk in &lt;6 s). Other scoring systems can be applied to calculate no, mild-, or moderate-to-severe frailty.

*Examples of major organ system compromise: Cardiac-severe LV systolic or diastolic dysfunction or RV dysfunction, fixed pulmonary hypertension; CKD stage 3 or worse; pulmonary dysfunction with FEVI &lt;50% or DLCO₂ &lt;50% of predicted; CNS dysfunction (dementia, Alzheimer’s disease, Parkinson’s disease, CVA with persistent physical limitation); GI dysfunction—Crohn’s disease, ulcerative colitis, nutritional impairment, or serum albumin &lt;3.0; cancer-active malignancy; liver—any history of cirrhosis, variceal bleeding, or elevated INR in the absence of VKA therapy.

•Examples: Tracheostomy present, heavily calcified ascending aorta, chest malformation, arterial coronary graft adherent to posterior chest wall, or radiation damage.

(CKD: Chronic kidney disease; CNS: Central nervous system; CVA: Stroke; DLCO₂: Diffusion capacity for carbon dioxide; FEV₁: Forced expiratory volume in 1 s; GI: Gastrointestinal; INR: International normalized ratio; LV: Left ventricular PROM: Predicted risk of mortality; RV: Right ventricular; STS: Society of Thoracic Surgeons; VKA: Vitamin K antagonist).

have also been used for risk assessment such as the logistic EuroSCORE (the European system for Cardiac Operative Risk Evaluation), Ambler Score and SURTAVI model.9,10
Based on the current evidence and the risk assessment, the following approach can be used for patients with severe symptomatic aortic stenosis:

- **Prohibitive surgical risk:** With a predicted post–TAVR survival of more than 12 months, TAVR should be the procedure of choice compared to medical therapy.
- **Intermediate to high surgical risk (STS-PROM Score more than 4):** Both, TAVR or SAVR can be viable options. The Heart-Valve Team should decide the optimal procedure based on individual patient factors, preferences, associated conditions like coronary disease, other valve lesions and other technical and anatomical subsets.
- **Low surgical risk (STS-PROM Score less than 4):** SAVR should be the procedure of choice.

**CONTRAINDICATIONS FOR TAVR (TABLE 4)**

**Types of TAVR Valves**

Currently, two different TAVR devices are widely used:

1. Balloon-expandable Edwards SAPIEN, SAPIEN XT or SAPIEN 3 Transcatheter Heart Valve (Edwards Lifesciences, Irvine, CA, USA)
2. Self-expanding Medtronic CoreValve or EvolutR (Medtronic, Minneapolis, MN, USA)

**Table 4: Absolute and relative contraindications for TAVR.**

<table>
<thead>
<tr>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Absolute contraindications</strong></td>
</tr>
<tr>
<td>- Absence of a Heart Valve Team or Cardiac surgery on-site</td>
</tr>
<tr>
<td>- Appropriateness of TAVR, compared to SAVR, not confirmed by the Heart Team</td>
</tr>
<tr>
<td><strong>Clinical</strong></td>
</tr>
<tr>
<td>- Estimated life expectancy &lt; 1 year</td>
</tr>
<tr>
<td>- Improvement in quality of life by TAVR unlikely due to co-morbidities</td>
</tr>
<tr>
<td>- Severe primary disease of other valves, contributing to symptoms, which can be treated by surgery only</td>
</tr>
<tr>
<td><strong>Anatomical</strong></td>
</tr>
<tr>
<td>- Inadequate annulus size—smaller than 18 mm (native valve) or 17 mm (bioprosthetic valve) or larger than 29 mm</td>
</tr>
<tr>
<td>- Severe aortic regurgitation (&gt;3+). (Not an exclusion when used to treat failed bioprosthetic valve for valve-in-valve procedure)</td>
</tr>
<tr>
<td>- Active endocarditis</td>
</tr>
<tr>
<td>- Increased risk of coronary ostial obstruction (small aortic sinuses, short distance between annulus and coronary ostium)</td>
</tr>
<tr>
<td>- For transfemoral or subclavian approach: inadequate access (size, tortuosity, calcification)</td>
</tr>
</tbody>
</table>

Contd...
Edwards Sapien XT and Sapien 3 Valve
Edwards SAPIEN XT valve is a trileaflet bovine pericardium valve mounted on a cobalt chromium frame. It is available in 20, 23, 26 and 29 mm sizes. It can be used via the retrograde route, transapical route or trans-aortic route (Fig. 1).
SAPIEN 3 valve has a very low delivery profile and an outer skirt to prevent para-valvular regurgitation. It is available in 23, 26 and 29 mm sizes (Fig. 2 and Table 5).

Medtronic CoreValve and EvoluteR Valve
CoreValve is trileaflet valve made up of porcine pericardial tissue and mounted in self expanding nitinol frame. It is available in 26, 29 and 31 mm sizes. All valves initially required 24 or 25 French sheath for delivery of prosthesis but recent changes in the delivery systems have lead to a decrease to 18 French sheath for delivery. CoreValve can be used via the retrograde, transaortic or subclavian routes (Fig. 3). The EvoluteR has a lower delivery profile and a 14 French sheath can be used for delivery. Recapturing of the valve before releasing can be done up to three times in case of suboptimal positioning of the valve. (Tables 6 and 7).

Approaches for TAVR (Figs. 4A to E)

1. Antegrade approach: Cribier initially used the antegrade approach. This involved percutaneous access to the femoral vein followed by a

Relative contraindications
- Bicuspid or Noncalcified valves
- Untreated coronary artery disease
- Acute myocardial Infarction within one month before procedure
- Stroke or transient ischemic attack within 6 months of procedure
- Left ventricular ejection fraction < 20%
- Hemodynamic instability requiring inotropes, mechanical ventilation or mechanical heart assistance within 30 days
- Severe mitral regurgitation
- Hypertrophic cardiomyopathy with or without obstruction
- Severe pulmonary hypertension and right ventricular dysfunction
- Intracardiac mass, thrombus or vegetation
- Atheroma (> 5 mm thick, protruding or ulcerated) ascending or arch of aorta
- Thoracic or abdominal aortic aneurysm (> 5 cm)
- Narrowing (especially with calcification or irregularities) or tortuosity of abdominal or thoracic aorta
- Any contraindication or hypersensitivity to anticoagulation
- Renal insufficiency or end-stage renal disease requiring chronic dialysis

(TAVR: Transcatheter aortic valve replacement; SAVR: Surgical aortic valve replacement).
Fig. 1: SAPIEN XT Valve.

Fig. 2: SAPIEN 3 Valve.

**Table 5:** Specifications for the SAPIEN 3 Valve according to size.

<table>
<thead>
<tr>
<th>Size</th>
<th>Transfemoral sheath</th>
<th>Minimum access vessel diameter</th>
<th>Native annulus size (TEE)</th>
<th>Native annulus area</th>
<th>Area derived diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>23 mm</td>
<td>14 F</td>
<td>5.5 mm</td>
<td>18–22 mm</td>
<td>338–430 mm²</td>
<td>20.7–23.4 mm</td>
</tr>
<tr>
<td>26 mm</td>
<td>14 F</td>
<td>5.5 mm</td>
<td>21–25 mm</td>
<td>430–546 mm²</td>
<td>23.4–26.4 mm</td>
</tr>
<tr>
<td>29 mm</td>
<td>16 F</td>
<td>6.0 mm</td>
<td>24–28 mm</td>
<td>540–683 mm²</td>
<td>26.2–29.5 mm</td>
</tr>
</tbody>
</table>

Fig. 3: Medtronic CoreValve.
trans-septal puncture. A wire was passed from the femoral vein and snared into the femoral artery to create a arteriovenous loop. The valve was crimped onto a balloon and introduced through the femoral vein, across the inter-atrial septum, across the mitral valve and finally across the aortic valve antegradely through the left ventricle. Since, this was technically challenging, the retrograde approach is preferred.

2. Retrograde/transfemoral approach: This is the preferred approach currently. The femoral artery is punctured and a balloon aortic valvuloplasty is done through a 14 F sheath. The sheath can be changed to an 18, 19 or 22 F sheath and the valve is positioned across the aortic valve retrogradely through the arch and ascending aorta.

3. Transapical approach: This involves a minimally invasive lateral thoracotomy, placement of an apical purse string suture, passing a stiff wire from the apex to the aortic arch, balloon aortic valvuloplasty during rapid ventricular pacing followed by deployment of the device.

4. Subclavian/transaxillary approach: It is a percutaneous approach, used in patients with an unfavorable ilio-femoral anatomy.

5. Transaortic approach: This involves a minimally invasive anterior thoracotomy allowing direct access to the aorta. It can be used in patients

---

**Table 6: Specifications for the EvoluteR Valve according to size.**

<table>
<thead>
<tr>
<th>Size</th>
<th>23 mm</th>
<th>26 mm</th>
<th>29 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annulus diameter</td>
<td>18–20 mm</td>
<td>20–23 mm</td>
<td>23–26 mm</td>
</tr>
<tr>
<td>Annulus perimeter*</td>
<td>56.5–2.8 mm</td>
<td>62.8–72.3 mm</td>
<td>72.3–81.7 mm</td>
</tr>
<tr>
<td>Sinus of Valsalva diameter (mean)</td>
<td>≥25 mm</td>
<td>≥27 mm</td>
<td>≥29 mm</td>
</tr>
<tr>
<td>Sinus of Valsalva height (mean)</td>
<td>≥15 mm</td>
<td>≥15 mm</td>
<td>≥15 mm</td>
</tr>
</tbody>
</table>

*Annulus perimeter = Annulus diameter × π

---

**Table 7: Differences between SAPIEN Valve and CoreValve.**

<table>
<thead>
<tr>
<th></th>
<th>Edward SAPIEN XT/SAPIEN 3 Valve</th>
<th>CoreValve/Evolute-R Valve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expansion</td>
<td>Balloon expandable</td>
<td>Self-expandable</td>
</tr>
<tr>
<td>Frame</td>
<td>Stainless steel</td>
<td>Nitinol</td>
</tr>
<tr>
<td>Valve material</td>
<td>Bovine</td>
<td>Porcine</td>
</tr>
<tr>
<td>Sheath size</td>
<td>21–24/16–18/14 F</td>
<td>18/14 F</td>
</tr>
<tr>
<td>Annulus size</td>
<td>&gt;18 mm, &lt;25 mm</td>
<td>&gt;20 mm, &lt;27 mm</td>
</tr>
<tr>
<td>Area</td>
<td>1.7 cm²</td>
<td>1.7–1.9 cm²</td>
</tr>
<tr>
<td>Repositioning</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Access site</td>
<td>Transfemoral, transapical</td>
<td>Transfemoral, subclavian, transaortic</td>
</tr>
</tbody>
</table>
Figs. 4A to E: Approaches for TAVR: (A) Transfemoral approach; (B) Transapical approach. After left lateral minithoracotomy, the deliver catheter is advanced through the LV apex; (C) Transaortic approach. After right or mid ministernotomy, the delivery catheter is advanced directly through the ascending aorta; (D) Subclavian approach; (E) Transaxillary approach.

with an unfavorable iliofemoral or subclavian anatomy as well due to factors like chest deformity, low ejection fraction or respiratory disease.

6. Carotid approach: It has been proposed, however, in such cases, it is crucial to evaluate the cerebral arteries, carotid and vertebral arteries, and circle of Willis, to assess the risk of ischemic stroke.
Chapter 19: Transcatheter Aortic Valve Replacement (TAVR)—Current Status

PATIENT SPECIFIC SELECTION OF TAVR VALVE

For most patients undergoing TAVR, the Edward SAPIEN or Medtronic CoreValve are suitable. Certain patient related problems may influence the selection of the valves.

- **Annulus size**: All valves do not cover all annulus sizes. Depending on the patient’s annulus size, the appropriate valve must be chosen.
- **Risk of annulus rupture**: Annulus rupture has been observed more commonly with a balloon expandable valve. Therefore with patients with a high risk of annulus rupture like small and calcified annulus, a self-expanding valve would be a better choice.
- **Risk of coronary obstruction**: Recapturable valves preferable in this subset of patients.
- **Valve-in-valve TAVR with a small bioprosthetic valve**: In this type, a supra-annular TAVR provides a greater effective orifice area.

CURRENT STATUS OF EVIDENCE

Several registries and randomized controlled trials have evaluated the outcomes of TAVR in patients with native aortic valve stenosis falling into different risk groups. Based on the evidence, the scope of TAVR has expanded from inoperable patients to patients with an intermediate or high risk.

PROHIBITIVE SURGICAL RISK (INOPERABLE) GROUP: TAVR VERSUS MEDICAL MANAGEMENT

*Partner 1B Trial*: The outcomes of TAVR were compared to medical management in inoperable patients with severe aortic stenosis using the Edward SAPIEN valve in the placement of aortic transcatheter valves (PARTNER) Trial Cohort B. The mean age of the patients was 83 years and the mean STS-PROM Score was 11.7%. At one and two years, the mortality rate of TAVR was significantly reduced compared to the medically managed group. The New York Heart Associate (NYHA) functional class was also significantly better in the TAVR group. This trend continued at five years as well (Fig. 5 and Table 8).

With regards to the side effects, the stroke rate was higher in the TAVR group at 30 days, 1 year and 2 years but the risk of stroke was similar in both groups at 5 years. Thus there was no continuous risk of stroke in the TAVR group after the initial procedure. In the TAVR group, moderate or severe paravalvular regurgitation was seen in 12.4 and 8.8% at 30 days and one year respectively but the PVR improved in 42.6% at two years.
Figs. 5A to D: Two-year outcomes of the PARTNER IB Trial.\(^7\)

**THE COREVALVE PIVOTAL EXTREME RISK ILEOFEMORAL STUDY**\(^9\)

The CoreValve Pivotal Extreme Risk Ileofemoral Study evaluated the safety and efficacy of the CoreValve in severe aortic stenosis with a extremely high risk of surgery (mean STS-PROM Score of 10.3%). The outcomes showed the rate of all cause mortality or major stroke at 12 months was 26%. With regards to the side effects, the 30 days rate of life threatening bleeding was 12.7%, major vascular complications was 8.2% and need of permanent pacemaker was 21.6%. The rate of moderate or severe paravalvular regurgitation improved at 12 months from 10.7 to 4.2% (Fig. 6).

**HIGH SURGICAL RISK GROUP: TAVR VERSUS SAVR**

*Partner 1A trial:* The outcomes of TAVR (using the Edward SAPIEN valve) were compared to SAVR for patients with severe aortic stenosis with a high surgical risk in the PARTNER Trial Cohort A.\(^20,21\) The mean age of the patients was 84 years and the mean STS-PROM Score was 11.7%. At 1, 2 and 5 years,
Table 8: One and two-year outcomes of the PARTNER IB TRIAL \(^{17}\)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>TAVR (N=179)</th>
<th>Standard therapy (N=179)</th>
<th>P Value</th>
<th>TAVR (N=179)</th>
<th>Standard therapy (N=179)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality—no. (%)</td>
<td>55 (30.7)</td>
<td>89 (50.7)</td>
<td>&lt;0.001</td>
<td>77 (43.3)</td>
<td>117 (68.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stroke—no. (%)</td>
<td>19 (11.2)</td>
<td>8 (5.5)</td>
<td>&lt;0.001</td>
<td>22 (13.8)</td>
<td>8 (5.5)</td>
<td>0.01</td>
</tr>
<tr>
<td>Rehospitalization—no. (%)</td>
<td>43 (27.0)</td>
<td>79 (53.9)</td>
<td>&lt;0.001</td>
<td>53 (35.0)</td>
<td>95 (72.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Death or rehospitalization—no. (%)</td>
<td>79 (44.1)</td>
<td>126 (71.6)</td>
<td>&lt;0.001</td>
<td>101 (56.7)</td>
<td>153 (87.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Death or stroke—no. (%)</td>
<td>63 (35.2)</td>
<td>90 (51.3)</td>
<td>&lt;0.002</td>
<td>82 (46.1)</td>
<td>117 (68.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cardiac death—no. (%)</td>
<td>35 (20.5)</td>
<td>75 (44.6)</td>
<td>&lt;0.001</td>
<td>50 (31.0)</td>
<td>100 (62.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>NYHA class III or IV—no./total no. (%)</td>
<td>28/118 (23.7)</td>
<td>48/79 (60.8)</td>
<td>&lt;0.001</td>
<td>16/95 (16.8)</td>
<td>23/40 (57.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Myocardial infarction—no. (%)</td>
<td>1 (0.8)</td>
<td>1 (0.7)</td>
<td>0.9</td>
<td>2 (1.6)</td>
<td>2 (2.5)</td>
<td>0.69</td>
</tr>
<tr>
<td>Creatinine &gt;3 mg/dL—no. (%)</td>
<td>2 (1.1)</td>
<td>5 (2.8)</td>
<td>0.4</td>
<td>2 (1.1)</td>
<td>5 (2.8)</td>
<td>0.45</td>
</tr>
<tr>
<td>Renal failure—no. (%)(^*)</td>
<td>4 (2.3)</td>
<td>7 (4.7)</td>
<td>0.2</td>
<td>5 (3.2)</td>
<td>9 (7.6)</td>
<td>0.15</td>
</tr>
<tr>
<td>Major bleeding—no. (%)</td>
<td>41 (24.2)</td>
<td>21 (14.9)</td>
<td>0.04</td>
<td>48 (28.9)</td>
<td>25 (20.1)</td>
<td>0.09</td>
</tr>
<tr>
<td>Balloon aortic valvuloplasty—no. (%)</td>
<td>2 (1.1)</td>
<td>138 (82.3)</td>
<td>&lt;0.001</td>
<td>4 (2.8)</td>
<td>140 (85.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Aortic-valve replacement—no. (%)</td>
<td>0</td>
<td>10 (7.6)</td>
<td>0.002</td>
<td>1 (0.9)</td>
<td>11 (8.9)</td>
<td>0.005</td>
</tr>
<tr>
<td>Endocarditis—no. (%)</td>
<td>2 (1.4)</td>
<td>1 (0.8)</td>
<td>0.6</td>
<td>3 (2.3)</td>
<td>1 (0.8)</td>
<td>0.32</td>
</tr>
<tr>
<td>New pacemaker—no. (%)</td>
<td>8 (4.7)</td>
<td>14 (8.6)</td>
<td>0.15</td>
<td>10 (6.4)</td>
<td>14 (8.6)</td>
<td>0.47</td>
</tr>
</tbody>
</table>

* Percentages shown are Kaplan-Meier estimates, and P values are point-in-time analyses, with the exception of the percentages for creatinine >3 mg/dL (265 umol/liter) and for New York Heart Association (NYHA) class III or IV which are straight frequencies, with P values calculated with the use of Fisher’s exact test. All events in this table were adjudicated by an independent clinic at events committee. TAVR denotes transcatheter aortic-valve replacement.

\(^*\)Renal failure was defined by the need for dialysis for any length of time.
the mortality rate of TAVR was comparable compared to the SAVR group. Improvement in the symptoms was more frequent in the TAVR group compared to the SAVR group at 1 year but was not statistically significant at 5 years (Fig. 7).
The rate of strokes and transient ischemic attacks was higher in the TAVR group at 30 days, one year and two years but were similar to the SAVR group at 5 years to which we can draw a similar conclusion of no continuous risk of stroke after the initial procedure. At 30 days, the TAVR group had more vascular complications where as the SAVR group had a higher incidence of atrial fibrillation and major bleeding. Moderate or severe paravalvular regurgitation was more in the TAVR group at 1, 2 and 5 years and was associated with an increased late mortality (Table 9).

### Table 9: Outcomes of the PARTNER IA TRIAL. 21

<table>
<thead>
<tr>
<th>Outcome</th>
<th>1 year Surgery (N=351)</th>
<th>TAVR (N=348)</th>
<th>P Value*</th>
<th>2 years Surgery (N=351)</th>
<th>TAVR (N=348)</th>
<th>P Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>From any cause</td>
<td>89 (26.8)</td>
<td>84 (24.3)</td>
<td>0.45</td>
<td>114 (35.0)</td>
<td>116 (33.9)</td>
<td>0.78</td>
</tr>
<tr>
<td>From cardiovascular causes</td>
<td>40 (13.0)</td>
<td>47 (14.3)</td>
<td>0.63</td>
<td>59 (20.5)</td>
<td>67 (21.4)</td>
<td>0.80</td>
</tr>
<tr>
<td>Repeat hospitalization</td>
<td>51 (17.7)</td>
<td>59 (18.6)</td>
<td>0.78</td>
<td>60 (21.7)</td>
<td>74 (24.7)</td>
<td>0.41</td>
</tr>
<tr>
<td>Death from any cause or repeat hospitalization‡</td>
<td>125 (37.7)</td>
<td>121 (34.9)</td>
<td>0.45</td>
<td>152 (46.5)</td>
<td>159 (46.6)</td>
<td>0.99</td>
</tr>
<tr>
<td>Stroke or TIA§</td>
<td>13 (4.3)</td>
<td>28 (8.7)</td>
<td>0.03</td>
<td>18 (6.5)</td>
<td>34 (11.2)</td>
<td>0.05</td>
</tr>
<tr>
<td>Stroke</td>
<td>10 (3.2)</td>
<td>20 (6.0)</td>
<td>0.08</td>
<td>14 (4.9)</td>
<td>24 (7.7)</td>
<td>0.17</td>
</tr>
<tr>
<td>TIA</td>
<td>4 (1.5)</td>
<td>8 (2.6)</td>
<td>0.32</td>
<td>5 (2.0)</td>
<td>10 (3.6)</td>
<td>0.26</td>
</tr>
<tr>
<td>Death from any cause or stroke§</td>
<td>95 (28.6)</td>
<td>95 (27.4)</td>
<td>0.74</td>
<td>119 (36.4)</td>
<td>127 (37.1)</td>
<td>0.85</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>2 (0.6)</td>
<td>0</td>
<td>0.16</td>
<td>4 (1.5)</td>
<td>0</td>
<td>0.05</td>
</tr>
<tr>
<td>Major vascular complication§</td>
<td>13 (3.8)</td>
<td>39 (11.3)</td>
<td>&lt;0.001</td>
<td>13 (3.8)</td>
<td>40 (11.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Major bleeding‡</td>
<td>88 (26.7)</td>
<td>52 (15.7)</td>
<td>&lt;0.001</td>
<td>95 (29.5)</td>
<td>60 (19.0)</td>
<td>0.002</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>3 (1.0)</td>
<td>2 (0.6)</td>
<td>0.63</td>
<td>3 (1.0)</td>
<td>4 (1.5)</td>
<td>0.61</td>
</tr>
</tbody>
</table>

Contd...
This study randomized high risk patients of severe aortic stenosis to TAVR using the CoreValve and SAVR. The mean age of the patients was 83.2 years and the mean STS-PROM Score was 7.4%. The mortality at 1 year was lower in the TAVR group compared to the SAVR group (Fig. 8).
Chapter 19: Transcatheter Aortic Valve Replacement (TAVR)—Current Status

The TAVR group had a higher frequency of major vascular complications, cardiac perforation and permanent pacemaker implantation whereas the SAVR group had a higher frequency of life threatening bleeding, acute kidney injury and atrial fibrillation. There was no increase in the risk of stroke in the TAVR group compared to the SAVR group.

INTERMEDIATE SURGICAL RISK GROUP: TAVR VERSUS SAVR

PARTNER 2A TRIAL\textsuperscript{23} was a randomized trial to compare TAVR using Edward SAPIEN Valve and SAVR in intermediate risk patients with severe aortic stenosis. The mean STS-PROM Score was 5.8%. The rate of death from any cause or disabling stroke was the same in the two groups at 1 year and 2 years (Fig. 9).

At 30 days, the TAVR group had a larger aortic valve area but also a higher frequency of major vascular complications. The SAVR group had a higher frequency of acute kidney injury, severe bleeding and atrial fibrillation. Moderate or severe paravalvular regurgitation was more in the TAVR group at 30 days and was associated with an increased late mortality at 2 years (Figs. 10A to C).

An observational study evaluated TAVR using the SAPIEN 3 valve in patients with severe aortic stenosis with an intermediate risk (mean STS-PROM Score of 5.2%). At one year, the all cause mortality of TAVR was 7.4%, disabling stroke was in seen 2% and moderate or severe paravalvular regurgitation was seen in 2%. TAVR was superior to SAVR for the composite end point of death from any cause, strokes and incidence of moderate or severe aortic regurgitation as well as for individual outcomes of death and stroke. SAVR caused less moderate or severe aortic regurgitation.\textsuperscript{24}

\hspace{\textwidth}{\textbf{Fig. 9:} Outcomes of PARTNER 2A Trial: Death from any cause or disabling stroke (%) at one year and two years.\textsuperscript{23}}
Figs. 10A to C: Echocardiographic outcomes of PARTNER 2A Trial.23 (A) The change in aortic-valve area from baseline to 2 years, and (B) the percentage of patients with paravalvular aortic regurgitation at 30 days, 1 year, and 2 years after the procedure. (C) Time-to-event curves for death from any cause according to the severity of paravalvular aortic regurgitation. The inset shows the same data on an enlarged y axis.

CoreValve Surtavi Trial to compare the safety and efficacy of TAVR using the CoreValve with SAVR in patients with severe aortic stenosis with intermediate risk is ongoing.
LOW SURGICAL RISK GROUP: TAVR VERSUS SAVR

The Nordic Aortic Valve Intervention Trial (NOTION Trial)\(^\text{25}\) evaluated the outcomes of patients with severe aortic stenosis with low or intermediate risk (average STS-PROM Score of 3%) receiving a TAVR using the CoreValve or undergoing SAVR. The composite primary outcome (death from any cause, stroke or myocardial infarction at one year) were similar in the TAVR and SAVR group (13.1% and 16.3% respectively). The TAVR group showed better valve hemodynamics at 1 year, with a lower effective orifice area compared to the SAVR group (Fig. 11). The TAVR group had a more frequent permanent pacemaker requirement, higher aortic regurgitation and lower NYHA functional class at 1 year. The SAVR group had more life threatening bleeding, cardiogenic shock, acute kidney injury and atrial fibrillation at one year (Table 10).

Although, data in this group is limited, the relative benefit of TAVR compared to SAVR is unlikely to be higher than the high-risk group. The long-term durability of the valve and paravalvular regurgitation are especially important since this subset of patients is likely to survive longer. Thus, current evidence favors SAVR in the low risk group of patients with severe aortic stenosis.

BALLOON-EXPANDABLE VERSUS SELF-EXPANDING VALVES IN TAVR

THE CHOICE TRIAL:\(^\text{26}\) The Comparison of Transcatheter Heart Valves in High Risk Patients with Severe Aortic Stenosis (CHOICE) trial compared the
balloon-expandable Edward Sapien XT valve with the self-expanding Medtronic CoreValve.

The early outcomes of device success favored balloon-expandable valves (95.9%) as compared with self-expanding valves (77.5%). However, this difference was caused by a lower frequency of greater-than-mild aortic regurgitation and lower need for implanting more than one valve in the balloon-expandable group.

At 1 year, the rates of all-cause mortality (17.4 vs 12.8%), cardiovascular mortality (12.4 vs 9.4%), stroke (9.1 vs 3.4), and repeat hospitalization for heart failure (7.4 vs 12.8) were similar in both groups (Figs. 12A and B).

<table>
<thead>
<tr>
<th>Index hospitalization* or 30 days</th>
<th>1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TAVR</strong></td>
<td><strong>SAVR</strong></td>
</tr>
<tr>
<td>Major, life threatening disabling bleeding*</td>
<td>16 (11.3)</td>
</tr>
<tr>
<td>Cardiogenic shock*</td>
<td>6 (4.2)</td>
</tr>
<tr>
<td>Major vascular complication*</td>
<td>8 (5.6)</td>
</tr>
<tr>
<td>Acute kidney injury stage II or III*</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>All-cause death†</td>
<td>3 (2.1)</td>
</tr>
<tr>
<td>Cardiovascular death†</td>
<td>3 (2.1)</td>
</tr>
<tr>
<td>Neurological events‡</td>
<td>4 (2.8)</td>
</tr>
<tr>
<td>Stroke‡</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Transient ischemic attack‡</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>MI‡</td>
<td>4 (2.8)</td>
</tr>
<tr>
<td>Valve endocarditis‡</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>New-onset or worsening AF†</td>
<td>24 (16.9)</td>
</tr>
<tr>
<td>Permanent pacemaker implantation†</td>
<td>46 (34.1)</td>
</tr>
</tbody>
</table>

*Rate during index hospitalization; data reported as number of patients with events (percentage) in each treatment group; p values were calculated by Fisher exact test or chi-square test, as appropriate.
†Rates determined at 30 days and 1 year; data reported as number of subjects (Kaplan-Meier estimates) at the specific time point, and they do not equal the number of patients with events divided by the total number of patients in each treatment group; p value was calculated by the log-rank test for all data through 30 days or 1 year.
Permanent pacemaker placement was more frequent in the self-expanding group (37.6% vs 17.3%). Greater-than-mild paravalvular regurgitation was more frequently seen in the self-expandable group (1.1% vs 12.1%).

COMPLICATIONS OF TAVR

<table>
<thead>
<tr>
<th>Common complications</th>
<th>Infrequent complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>Annulus rupture</td>
</tr>
<tr>
<td>Bleeding</td>
<td>Myocardial injury</td>
</tr>
<tr>
<td>Coronary artery obstruction</td>
<td>Low cardiac output</td>
</tr>
<tr>
<td>Strokes or Transient ischemic attacks</td>
<td>Acute kidney injury</td>
</tr>
<tr>
<td>Post-TAVR aortic regurgitation</td>
<td>Prosthetic valve thrombosis</td>
</tr>
<tr>
<td>Vascular complications</td>
<td>Infective endocarditis</td>
</tr>
<tr>
<td>Conduction defects</td>
<td>Valve migration/Strut fracture</td>
</tr>
</tbody>
</table>

- **Bleeding**: Early and late (more than 30 days postprocedure) bleeding after TAVR is common. However, in the PARTNER 1A trial, the risk of peri-procedural bleeding was higher in patients undergoing SAVR (Table 10).

  Major bleeding post-TAVR has been reported in 17–24% in extreme risk cases, 11% in high risk cases and 7–10% in registries. The most frequent types of major bleeds were gastrointestinal (40.8%), neurological (15.5%), and traumatic fall-related (7.8%). Early and late bleeding complications are independently associated with increased mortality at 30 days and one year.

- **Coronary artery obstruction**: Coronary artery obstruction is an uncommon but potentially fatal complication of TAVR and occurs in about 0.7% of procedures with risk factors being low coronary artery ostia height...
(<10 mm), small aortic sinuses, bulky asymmetric leaflet calcification, oversized prosthesis and high implantation. It is more common in women and with use of the balloon expandable valve. To avoid this complication, evaluation before TAVR must include CT scan or transesophageal echocardiography to measure the distance from the aortic annulus to the coronary ostia, the sinus size and valve calcification. Coronary obstruction may be treated by percutaneous intervention or coronary artery bypass graft surgery.

Coronary artery obstruction is more frequent with valve-in-valve TAVR compared with native valve TAVR (3.5% vs 0.7%) due to proximity of the coronary ostia to the bioprosthetic leaflets and posts.

- **Strokes/Transient ischemic attacks:** The 30 days risk of strokes following TAVR is observational studies and clinical trials is 2–5%. PARTNER Trial 1A and 1B showed that although the risk of stroke or transient ischemic attacks was higher than SAVR at 30 days, 1 year and 2 years, the risk was similar at 5 years which showed that there was no increased risk of stroke after the initial procedural risk.

Procedural and clinical factors that increase the risk of stroke are: manipulation of a wire or large catheter across the aortic arch, balloon aortic valvuloplasty, positioning the device, inadequate blood flow to the brain during rapid pacing and atrial fibrillation.

- **Post-TAVR aortic regurgitation**
  - **Paravalvular regurgitation (PVR):** PVR is a common complication after TAVR, the incidence being 7–70% for mild PVR and 0–24% for moderate or severe PVR. PVR is caused by incomplete apposition of the device with the aortic annulus due to calcific deposits that prevent adequate sealing or inadequate expansion of the device. The determinants of PVR are heavily calcified annulus, undersized prosthesis and improper valve positioning, inadequate balloon aortic valvotomy prior to deployment of a self-expanding valve. A meta-analysis found that moderate to severe PVR was associated with three times the 30 days mortality and 2.3 times the one year mortality after TAVR.
  - **Central regurgitation:** It is usually caused by improper valve sizing or deployment. It may be resolved by gentle probing of the leaflets with a wire. In case there is a severe central regurgitation, valve-in-valve deployment may be considered.

- **Vascular complications:** Vascular complications are common after TAVR with common vascular complications being
  - Arterial dissection,
  - Closure device failure,
  - Arterial closure device-induced stenosis, and
  - Hematoma at the puncture site.
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- Artery avulsion (‘artery on a stick’),
- Vessel perforation leading to retroperitoneal hematoma,
- Aortic dissection

The increased incidence is due to large sized catheters used and high risk characteristics of the patients. The main determinants of vascular complications are small vessel diameter, severe atherosclerotic disease, calcified access arteries and tortuosity. Vascular complications are a predictor of increased late mortality after TAVR.\(^{34}\)

- **Conduction disturbances**: Heart blocks are a common complications after TAVR, seen most commonly with the CoreValve than the Edward SAPIEN valve because of higher and long lasting radial force of the nitinol frame and deeper implantation site in the left ventricular outflow tract for the CoreValve. Left bundle branch block is the most common electrocardiogram (ECG) finding after TAVR. However, its long-term significance is unknown.

  The incidence of permanent pacemaker implantation after Edward SAPIEN valve is between 6.5% and 10% and after CoreValve is 25.8–37%. Risk factors for development of higher degree AV blocks are pre-existing right bundle branch block, complete AV block at the time of the procedure, small annulus diameter, improper implantation depth and the use of CoreValve device.\(^{35}\)

- **Other complications**: Less common complications of TAVR are annulus rupture, myocardial injury, low cardiac output, acute kidney injury, prosthetic valve thrombosis, infective endocarditis, etc.

Complications for native valve TAVR are similar to valve-in-valve TAVR with few exceptions. Annular rupture has not been reported in valve-in-valve TAVR. The rates of paravalvular regurgitation and permanent pacemaker requirement are lower in valve-in-valve TAVR. On the contrary, coronary artery obstruction is more frequent with valve-in-valve TAVR.\(^{30}\)

**INDIAN SCENARIO**

Although, TAVR is an accepted and established interventional method of treatment of severe aortic stenosis in several countries, there are several roadblocks to its widespread use in India. The Indian patient tends to be more frail, with possibly smaller sizes of access arteries and smaller annulus sizes. Associated valvular diseases like rheumatic heart disease would play a role in case selection. TAVR has a long learning curve for the operator. It also involves significant costs, majority of which have to be born by patients. Additionally, in a country where the young are not optimally treated, the elderly population is likely to take a back seat.
A few centers in India do perform TAVRs but we are nowhere near having the experience of our western colleagues. In order for the TAVR program to be more successful, TAVRs should initially be done in large volume centers, with experience in structural heart disease. Collaboration between cardiologists, interventional cardiologists, cardiothoracic surgeons, radiologists and anesthetists is essential to ensure success and good outcomes.

CONCLUSION

The mainstay of treatment for severe symptomatic aortic stenosis is SAVR or TAVR so as to improve symptoms and survival. A multidisciplinary team should collaborate to decide the best treatment option for each individual patient. For patients with who are inoperable, TAVR is recommended rather than medical therapy. Even in patients who have an intermediate or high surgical risk, TAVR is as effective as surgery. More data is required on TAVR in low risk patients.

Although, SAVR and TAVR are equally effective, TAVR has a greater risk of paravalvular aortic regurgitation, permanent pacemaker implantation and major vascular complications, whereas SAVR has a greater risk of major bleeding, acute kidney injury and atrial fibrillation.

The devices used during TAVR are the Edward SAPIEN Valve and the Medtronic CoreValve. The CoreValve has a high incidence of permanent pacemaker requirement and paravalvular regurgitation, but the long term outcomes of both valves are similar.

With the expanding indications of TAVR and continuous improvement in the hardware resulting in a reduction in complication rates, this non-invasive approach to replacing a heart valve is likely to become in procedure of choice over surgery for severe aortic stenosis.

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