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Review

Transcatheter Aortic Valve Implantation/ Replacement (Tavi/ Tavr): How It Started, How Its Going, Where Its Going

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Abstract

Transcatheter Aortic Valve Implantation/ Replacement (TAVI/TAVR) has come a long was since the first in human implant done by Prof Cribier & colleagues in 2002. Initially a consideration in inoperable/ high surgical risk patients, TAVI is now indicated in patients with severe tricuspid aortic stenosis and suitable anatomy aged 70 or higher. This has been possible due to improvements in pre procedural planning, performance upgrades & evolution of transcatheter heart valve (THV) systems and increasing operator experience. Considering improving longevity and relatively younger ages at index implantation, complexities of redo TAVI planning and methods to improve THV durability are the next frontiers. This review summarizes these advancements while emphasizing on pre procedural planning, current guidelines, individualized device selection with a brief note on polymeric heart valves - developed to overcome the disadvantageous bioprosthetic dysfunction seen with current THVs.

Keywords: transcatheter aortic valve implantation (TAVI); transcatheter aortic valve replacement (TAVR); aortic valve stenosis; aortic stenosis; CT TAVI planning; transcatheter heart valve (THV)

How It Started

The development of percutaneous aortic valves stemmed from the poor long term results & high re stenosis rates of balloon aortic valvuloplasty in high risk inoperable patients with severe native aortic valve stenosis, culminating in the first implant by Cribier and colleagues in 2002 . Initial skepticism of these devices revolved around the displaced heavily calcified in situ native valve leaflets posing a coronary obstruction risk, transcatheter heart valve (THV) leaflet damage during the crimping process and perceived peril of embolization of the percutaneously placed prosthesis, in the absence of anchoring sutures.

Alain Cribier's early work had shown that a balloon expandable stent deployed & fixed in the native aorta could withstand up to 2 kg tension. Working in close association with Percutaneous Valve Technologies, later acquired by Edwards in 2004, led to the initial Cribier Edwards Valve, available in sizes of 23, 26mm thru introducer sheaths of 22, 24F. The valve was originally implanted thru an antegrade transeptal approach necessitating crossing of the mitral valve, until the development of a retrograde transfemoral trans-aortic implantation technique with a deflectable pusher sheath. As an alternative and in the face of the large femoral sheaths of the time, a trans apical access was initiated as a "front door approach". However, with an almost double 30 day mortality, it fell out of favour.

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Meanwhile, on the back of successful animal implants, Eberhard Grube performed the first human implants of the self expanding CoreValve prothesis in 2005 - the company would subsequently be acquired by Medtronic in 2009. [1]

The initial trials – PARTNER B using a Balloon Expanding Valve (BEV) and CoreValve Pivotal Trial using a Self Expanding Valve (SEV) – showed decreased mortality at one year and in *inoperable* severe AS patients who underwent TAVI vs those who were on medical therapy, validating the role of TAVI as a therapeutic intervention in Aortic Stenosis. [2]

A major milestone however was reached with the PARTNER A (2011) and CoreValve High Risk Study (2014), which showed non- inferiority of TAVI (with a BEV and SEV respectively), with regards to all cause mortality at 30 days and 1 year, when compared to Surgical Aortic Valve Replacement (SAVR) with a bioprosthesis, in patients at *high surgical risk*. [2]

Risk stratification was done on the basis of the EUROSCORE or Society of Thoracic Surgeons predicted risk of mortality score (STS Score) [2]

Interestingly these trials also highlighted the differences in complications between TAVI and surgical aortic valve replacement (SAVR) with the vascular complications, para valvular regurgitation (PVR) & permanent pacemaker implantation being more associated with the former and acute kidney injury (AKI), major hemorrhage and atrial fibrillation (AF) being more common in the latter. [2]

The trials that followed – PARTNER 2 and SURTAVI – involved patients with severe AS and intermediate surgical risk. [3,4]

In PARTNER 2, 2032 patients with severe AS & intermediate surgical risk were randomized to undergo SAVR or TAVI using the Sapien XT prosthesis (with around 76% patients selected for transfemoral – TF – TAVI). With regards to the primary outcome, death from any cause or disabling stroke at 2 years, TAVI was found to be non- inferior to SAVR (P = 0.0001 for non inferiority). Furthermore, those patients who underwent TF TAVI had lower rates of death & disabling stroke vs those who underwent SAVR. TAVI also resulted in increased aortic valve areas (AVA), lower rates of AKI, severe bleeding and AKI while fewer rates of para valvular leaks (PVL) and vascular complications were noted in the SAVR group. [3]

The SURTAVI trial also involved intermediate risk patients with severe AS with 1746 patients randomized to SAVR or TAVI (with CoreValve prosthesis used in 84%, Evolut R in 16%). TAVI was non inferior to surgery at 2 years with regards to the primary outcome – death from any cause or disabling stroke. The pattern of complications was similar to those seen in PARTNER 2, with lower rates of AF & transfusion but higher rates of residual aortic regurgitation (AR) in the TAVI group. Additionally noted were the higher rates of the need for permanent pacing in the TAVI group. [4]

Evidence of comparable efficacy in severe AS patients with low surgical risk was obtained in the subsequent PARTNER 3 and Evolut Low Risk Trials. [5,6]

PARTNER 3 randomized 1000 such patients to either SAVR or TF TAVI with the Sapien 3 valve. The primary end point, a composite of death, stroke or hospitalization at 1 year was markedly lower in the TAVI group (8.5% vs 15.5%; difference -6.6 percentage points, P< 0.001 for non inferiority). Patients who underwent TAVI had a shorter index hospitalization and additionally, at 30 days, TAVI also showed reduced rates of death or stroke and new onset AF. [7]

The Evolut Low Risk trial, which randomized 1468 patients with severe AS & low surgical risk to either SAVR or TAVI with a self expanding prosthesis (CoreValve 3.6%, Evolut R 74.1% and Evolut Pro 22.3%), primarily looked at death from any cause and disabling stroke at 24 months. At 30 days, noted in the TAVI group were lower rates of disabling stroke, bleeding complications, acute kidney injury (AKI) and AF with higher rates of moderate to severe AR and permanent pacemaker implantation, compared to the SAVR group. At 12 months, the TAVI group had lower gradients (8.6 vs 11.2 mm Hg) and larger effective orifice areas (2.3 cm^2 vs 2.0 cm^2). [6]

A timeline of these developments & landmark trials is illustrated in Figure 1

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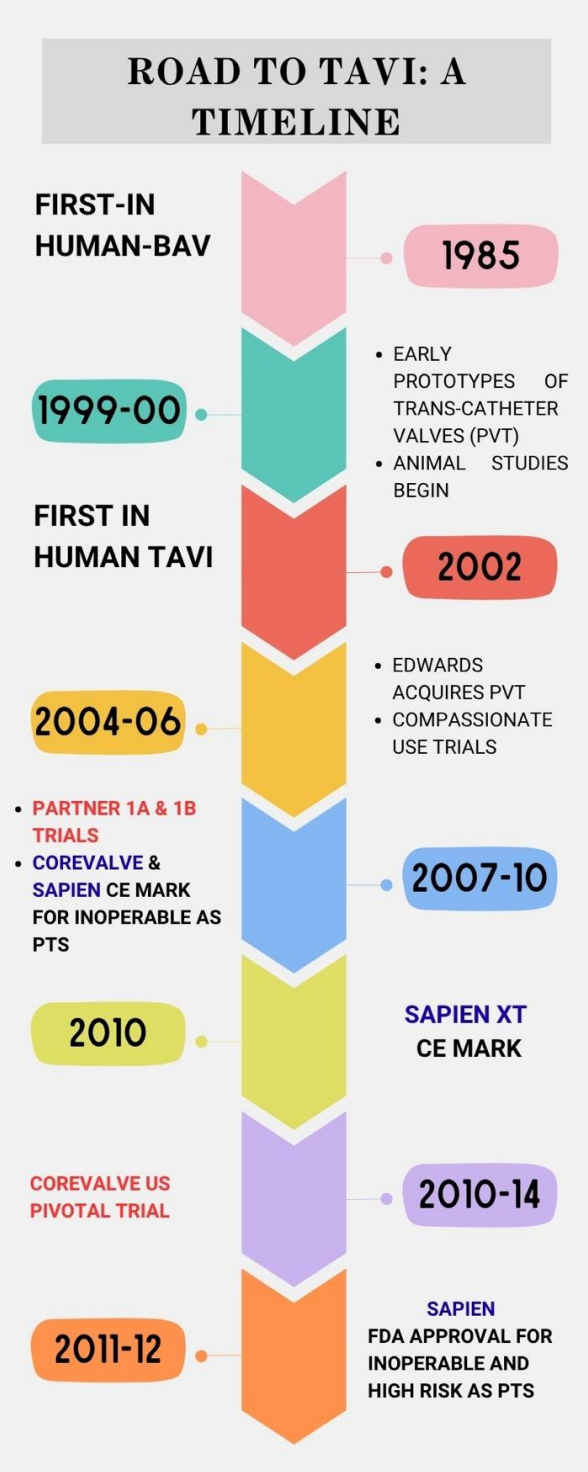

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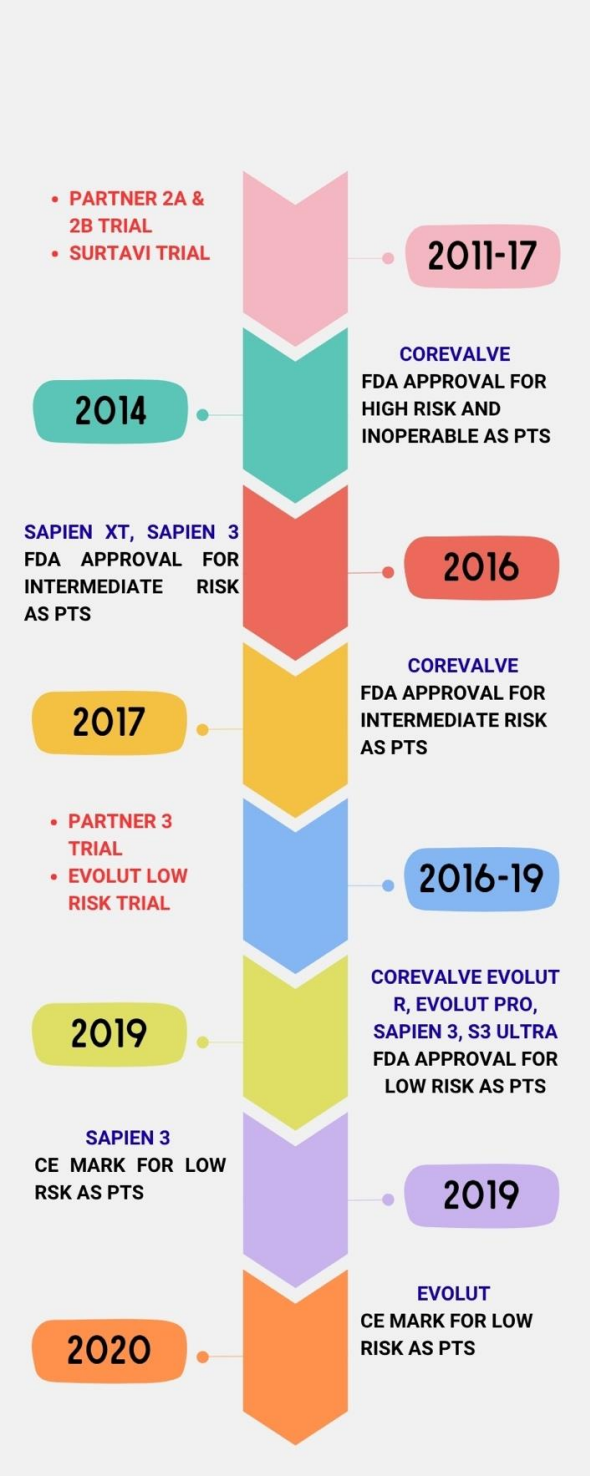

Figure 1. A brief timeline revealing the sequence of events from the first BAV to TAVI trials and subsequent THV approvals (major trials are in red, approved valves in blue) [35].

Over time, owing to improvements in procedural planning with computed tomography (CT), vascular access closure, improvements in valve technologies & operator experience have resulted in lower rates of procedural complications, stroke, moderate to severe AR and death. [8–10]

Procedural Planning Using CT

The aortic root is an extension of the left ventricular outflow tract (LVOT) extending from the basal attachment of the aortic valve cusps to their peripheral attachment at the sino tubular junction

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(STJ) level. It is composed of the Sinuses of Valvsalva (SoV), the fibrous interleaflet traingles and the valve cusps themselves.

The luminal contour on CT within the virtual plane that passes thru the basal attachment point of each cusp represents the aortic annulus. [11] (See Figure 2)

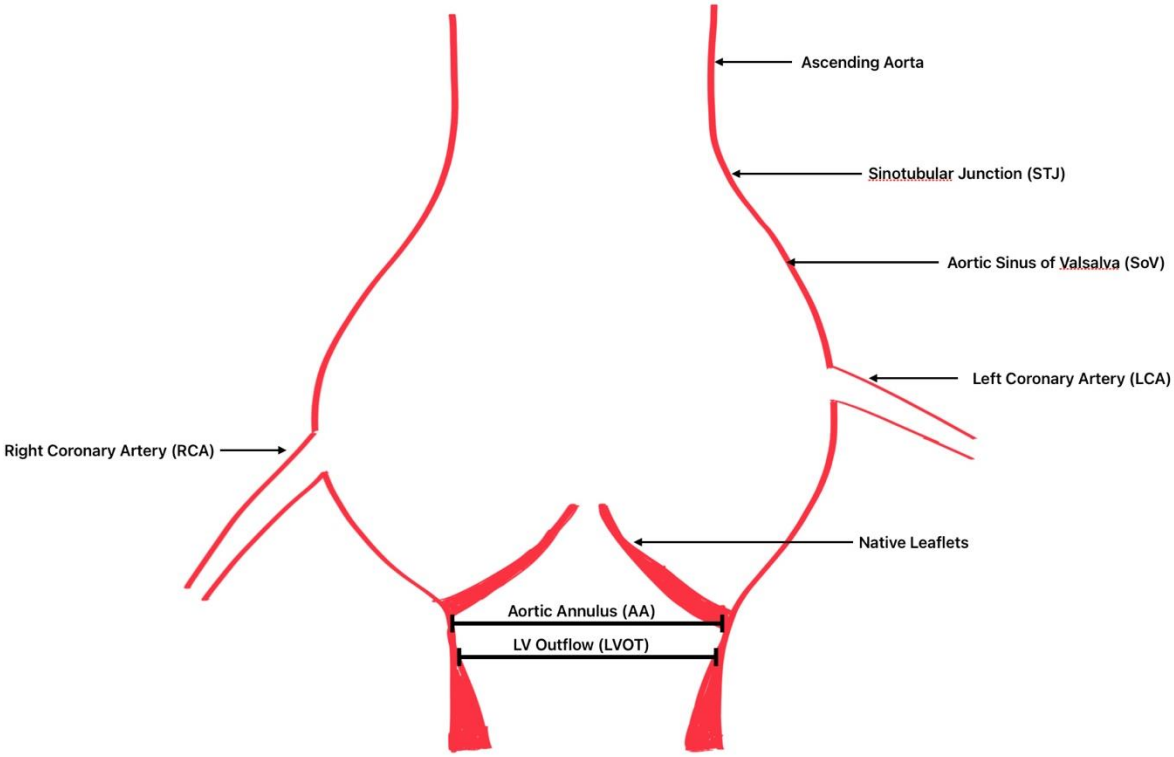

Figure 2. Aortic Root Anatomy.

The earlier Scoiety of Cardiovascular Computed Tomography (SCCT) expert consensus on CT prior to TAVI published in 2012 recommended CT imaging prior to TAVI specifically ECG synchronised imaging of the aortic root, preferably in systole (in view of dynamic changes in annular size & slightly larger dimensions noted in systole) with additional imaging of the entire aorta from the aortic arch to below the groin, going past the common femoral bifurcation thus enabling ileo femoral assessment. In adition ot measurements of the aortic root (at annular, SoV & STJ levels), measurements included those of the LVOT and Coronary heights. Interpretation jointly with a member of the TAVI team was recommended. [12]

Vascular access planning on CT involves peripheral vasculature assessment to determine minimal luminal size, tortuosity and calcifcation to determine suitability of access & predict probablilty of vascular complications. Ileo femoral assessment (given experince with & preference for TF TAVI), and if un suitable, other sites of vascular access can be evaluated in this manner. [8]

The updated SCCT consensus document expanded the role of CT in evaluation of the transcatheter heart valve (THV) post TAVI, mentioning its role in assessement of suspected structural deterioiration, valve thrombosis and infective endocarditis, as an ajunct to echocardiography. It also described the concept of "HALT" – Hypoattenuated Leaflet Thickening – which, when seen on post

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TAVI CT scan combined with restricted leaflet motion, may indicated leaflet thrombus formation. [11]

Furthermore the updated guidelines throw light on CT planning in "Valve in Valve" (TAVI in SAVR) procedures which centers around defining the risk of coronary artery obstruction. [11]

In recent years, "Redo TAVI" (TAVI in TAVI/ TAVI in THV) procedures are also becoming more common given the evolution of TAVI guidelines to include younger patients and patient survival exceeding THV durablitiy as a consequnece.

In Redo TAVI, CT is the lynchpin in planning & allows the delineation of the "neo skirt" and "coronary risk" planes, in order to determine the risk of coronary artery obstruction. [13]

While PARTNER 1 and 2 used echocardiography for measurments and sizing, in the PARTNER 3 trial annular mesurements were done on one of three 3D imaging modalities – CT, magnetic resonance imaging (MRI) and trans esophageal echocardiography (TEE). [3,7,14]

The CoreValve, SURTAVI and Evolut Low Risk trials however extensively used CT for aortic root and ileo femoral assessment. [4,6,15]

Improvements in Vascular Access & Closure

Transfemoral access remains the option of first choice with the most experince and better results. The role of CT in assessing access site suitability cannot be overstated. [3,8]

Yet vascular access site complications remain one of the most common complications encountered in TAVI, seen in as high as 14% patients. Available data suggests greater benefit with ultrasound guided perctuanoeus femoral access when compared to fluroscopy guided access. [16]

There has been a reduction in vascular complications and major bleeding over this time period, for eg. vascular complication & major bleeding rates of 16.8 & 22.3% respectively seen in PARTNER 1B were down to 2.8 & 7.7% respectively in PARTNER 3. This could be attributable in part to improving hardware with reduction in sheath sizes from upto a 24F sheath used in PARTNER 1 to the smaller 14F sheath in PARTNER 3. [3,7,8,14]

Access site closure has also evolved. Here too, ultrasound guided vascular closure is beneficial, allowing for visualisation of the closure device & especially intra luminal conditions enabling precise closure device deployment at the site intended. [17]

Furthermore, recent evidence has shown that a vascular closure device (VCD) strategy invloving a suture (Prostyle™/ Proglide™ – Abbott Vascular) & plug based (Angioseal® - Terumo) was superior to the traditional suture based VCD strategy alone using two Prostyles/ Proglides. [9]

How It's Going

The recently published outcomes of the PARTNER 3 cohorts showed that, at 7 years, among low risk patients with symptomatic severe AS, no significant differences were observed with respect to the primary composite endpoints consisting of of death, stroke & hospitalisation, between those who had undergone TAVI and those who had undergone SAVR. [18]

The 5 year outcomes of the Evolut low risk trial similarly showed, that amongst patients with severe AS & low surgical risk who were treated with either TAVI or SAVR, rates of all couse mortality or disabling stroke were comparable. [19]

Taken together, these data indicate that, in the short & intermediate terms, hard outcomes including all cause mortality, are similar in patients with severe AS & low surgical risk who underwent TAVI as compared to those who underwent SAVR. [18,19]

Long term data is also now being published. The NOTION trial which randomized 280 patients with severe AS and low surgical risk (STS Score <4%) to either TAVI with the self expanding CoreValve prosthesis (Medtronic®) vs SAVR with a bio prosthesis, had shown no differences in both groups with respect to the primary composite outcome, consisting of all cause mortality, stroke or myocardial infarction (MI) at 1 year. 10 year outcomes of these patients reveal that the original results still hold no significant differences in the primary composite outcome. [20,21]

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What is also important to note is, that the above mentioned intermediate and long term outcomes showing parity of TAVI with SAVR, involve the previous generation of these THVs. These have since undergone further evolution & upgrades, demonstrating improved performance. [18–23]

While the role of TAVI in symptomatic severe AS is established, recent evidence has shown potential benefit in asymptomatic severe AS. This is inferred from the findings of the Early TAVR trial, in which 455 patients with asymptomatic severe AS were randomized to undergo TF TAVI with a BEV or clinical surveillance, with the primary end point being a composite of death, stroke or unplanned hospitalization from cardiovascular causes. A primary endpoint occurred in 26.8% patients in the TAVR group vs 45.3% patients in the clinical surveillance group (HR 0.50, P<0.001). [24]

Current Guidelines

Symptomatic Severe AS has poor prognosis without intervention. Early intervention (TAVI or SAVR) is strongly recommended in all such patients with an estimated life expectancy of more than year. [25]

A diagnosis of severe AS is established on 2D Echocardiography criteria:

- Peak velocity & mean gradient across aortic valve > 4 m/s and > 40 mmHg respectively with the calculated aortic valve area (AVA) being < 1 cm^2 or indexed AVA < 0.6 cm^2/m^2.
- In case of discordant data – other measurements indicative of flow (LV Stroke Volume Index, <35 ml/m^2 indicative of low flow) and LV systolic function (LVEF, < 50%being used as the cut off) are noted which guide further testing in the form of Dobutamine Stress Echocardiography (DSE) and/ or Aortic Valve Calcium Score on CT (>2000 AU in males & >1200 AU in females indicative of severe AS)

The guidelines also throw light on the features that favor TAVI as a choice of intervention in these patients. These include

Age >= 70 years

Anatomic features

- Transfemoral access suitable for TAVI
- Porcelain aorta
- Intact coronary artery bypass grafts
- Severe chest deformity/ scoliosis

Concomitant Conditions

- Co morbidities/ cardiac conditions which may increase surgical risk
- Frailty
- Sequalae of chest radiation

Finally, the decision on selecting modality of intervention at the index procedure and valve type should be made keeping in mind the lifetime management of the disease and anticipating the possibility of a repeat intervention & risks therein (Redo SAVR vs SAVR after TAVI vs TAVI after SAVR – ViV TAVI vs Redo TAVI). [25]

Basics of THV Design & Currently Available Devices

The key elements of a THV include

1. A metallic frame
2. Leaflets
3. Inner skirt
4. Outer skirt [26]

Based on mechanism of THV deployment, THVs are classified into two groups –

- Balloon expanding valves (BEVs)
- Self expanding valves (SEVs)

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Furthermore, in the SEV group, the position of leaflets leads to a sub classification of supra annular SEV or intra annular SEV. [27]

The metallic frame may be made of either a multi phase cobalt based alloy, or, as in the case of SEVs – Nitinol (an alloy of nickel and titanium). The self expanding nature of these valves comes from the unique properties of nitinol – super elasticity and shape memory. Nitinol thus can be deformed and remain deformed at lower temperatures but as ambient temperature increases, nitinol assumes its original state. [26]

Leaflets can be derived from either bovine or porcine pericardial tissue. As described above, leaflet position can be intra annular (if within the annular plane) or supra annular. Supra annular leaflets, being not constrained by the rigid annulus, provide greater post implant internal diameter and better hemodynamics. [26]

However, supra annular leaflet design may add complexity in case of a redo TAVI procedure is anticipated in the future, by raising the neo skirt plane (NSP). [28]

Lastly, some valves have a skirt sewn at the ad-luminal surface of the metallic frame, proximal to leaflet insertion – the inner skirt. Some valves even have an additional outer skirt, sewn onto the ab-luminal surface of the proximal metallic frame. Skirts are made of either polyethene tetraphthalate (PET) or fabric or pericardial tissue & function to reduce paravalvular leaks (PVLs). [26]

The Sapien 3 & S3 Ultra (Edwards Lifesciences®)are tri leaflet BEVs with bovine pericardium derived leaflets mounted on a cobalt chromium frame.

The Evolut (Medtronic®) is a supra annular tri leaflet SEV with leaflets derived from porcine pericardium, mounted on a nitinol frame. [27]

A picture of recently available TAVI/ TAVR devices is shown in Figure 3

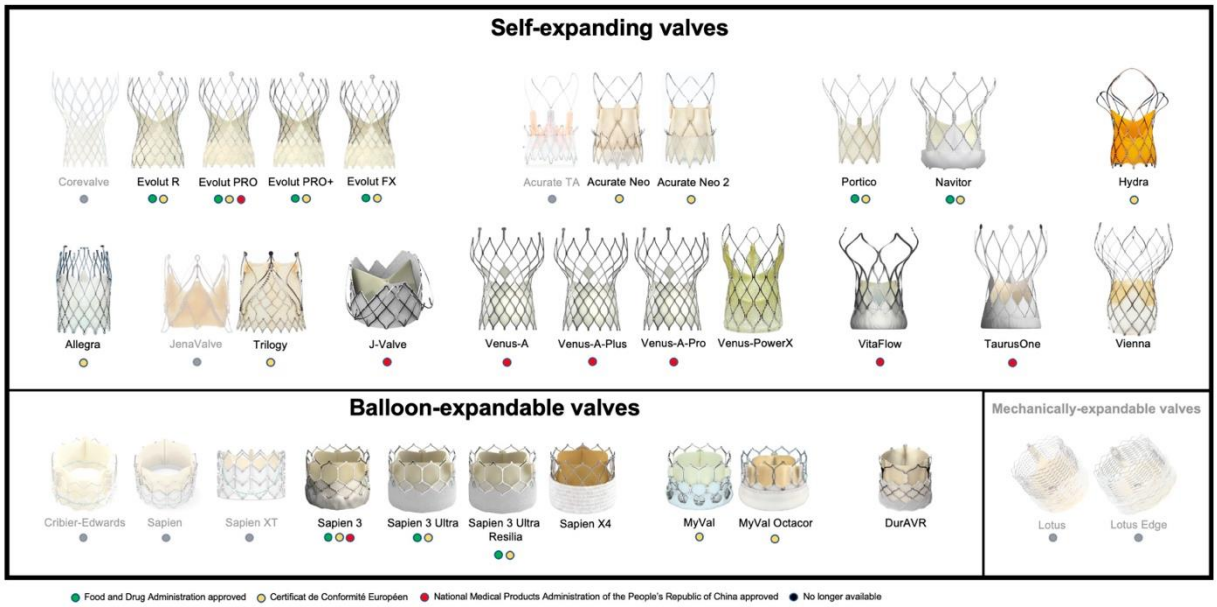

Figure 3. Recently available TAVR devices (Picture reproduced with permission [29]).

THV Selection

As described above, there is now a plethora of devices from the initial two that were available [29] This has lead to individualization of device selection, keeping in mind anatomy, patient characteristics and operator experience for optimal management & improving outcomes. [27]

A short frame BEV is preferred when the following are noted:

- Coronary artery disease
- Large aortic annulus
- Horizontal aorta

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- Pre existing conduction abnormalities increasing risk of post TAVI permanent pacing

Whereas, a tall frame SEV is preferred in the following situations:

- Intolerance to rapid pacing
- Peripheral vascular disease
- Aortic annular calcification
- ViV procedures
- Risk of patient prosthesis mismatch, small aortic annuli

These are not absolute criteria & valve selection must be individualized. [27]

Where Its Going

Indications for which TAVI has been considered, beyond severe tricuspid aortic stenosis, include

- Severe bicuspid aortic valve stenosis
- Severe native aortic valve regurgitation
- Moderate aortic stenosis

Bicuspid aortic valve disease is marked by early valve deterioration with patients presenting with severe stenosis at a younger age and associated aortopathy ,in up to half these patients. A decision regarding TAVI in this group therefore needs to be made keeping in mind lifetime management of the disease, with a potential redo procedure. TAVI in bicuspid valve disease was initially limited to in operable or high surgical risk patients with severe bicuspid aortic stenosis. Additionally, trials that compared TAVI with SAVR largely excluded patients with bicuspid aortic valve disease, with the exception of the UK TAVI 7 Notion 2 trials.

In the NOTION 2 trial, the composite end point (all cause mortality, stroke or procedure/ valve/ heart failure) was higher in the sub group of patients with bicuspid aortic valve disease (and low surgical risk) who underwent TAVI (49 patients), compared to those who underwent SAVR (51 patients) at 3 years. While these results did not achieve statistical significance, this has to be understood in the context of the trial being insufficiently powered to gain a meaningful result in this sub group.

Current guidelines recommend SAVR as the treatment of choice in patients with bicuspid aortic valve disease. However, TAVI is superior to medical therapy alone in high risk in operable patients with severe bicuspid AS.

Two upcoming trials, NAVIGATE Bicuspid & BELIEVERS, will directly compare TAVI to SAVR in patients with bicuspid aortic valve disease. [30]

TAVI in severe native aortic regurgitation may be considered if the patient is ineligible for surgery per the heart team and if the anatomy is suitable (IIb). [25]

The ALIGN AR was a prospective multi centre single arm study that looked at effectiveness of treating native moderate-to-severe aortic regurgitation, in patients deemed to be at high surgical risk by the heart team, with the Triology trans catheter heart valve (JenaValve Technologies®). Both, the 30 day endpoint compared for non inferiority with a prospective performance goal of 40.5% & primary efficacy endpoint with a non inferiority goal of 25% were met. This demonstrated the safety & effectiveness of treating severe native AR using a dedicated THV system. [31]

At the present time, there is not enough evidence to prove efficacy of TAVI in patients with moderate AS with surgical intervention recommended only if patient is undergoing concomitant CABG. [25]

The TAVR UNLOAD trial randomized 178 patients with moderate AS (AVA </= 1.5 cm^2 or iAVA <1.0 cm^2 or not meeting criteria for severe AS on DSE) with HFrEF (LVEF 20-50%, NYHA II-IV, receiving appropriate and stable GDMT for at least 1 month) to TAVI with a BEV vs clinical surveillance. While TAVI resulted in a greater improvement of the KCCQ overall summary score, it was deemed to be not superior to clinical surveillance with regards to the primary end point – a hierarchical occurrence of all cause death, disabling stroke, disease related hospitalizations & HF equivalents and change in the baseline KCCQ overall summary score. [32]

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Bioprosthetic Valve Dysfunction and Improving THV Durability as Part of Lifetime Management

While current guidelines recommend consideration of TAVI in patients with severe aortic stenosis and suitable anatomy aged 70 years and above, TAVI use has skyrocketed in patients less than 65 years of age with implantation rates increasing 8 times – from 7.1% in 2013 to 54.7% in 2021. [25,33]

Increasing numbers of younger patients undergoing TAVI coupled with increasing patient survival is likely to result in more patients outliving their first THV, downstream effects of which include redo TAVI planning and its associated complexities. [13,28]

It is paramount therefore to understand mechanisms of THV (bioprosthetic) dysfunction and also durability & performance of THVs beyond a 10-15 year period.

Bioprosthetic valve dysfunction, which may be further sub divided into structural vs non structural dysfunction, occurs due to one of the following pathologic mechanisms:

- Pannus formation
- Para valvular regurgitation
- Patient prosthesis mismatch
- Endocarditis or thrombosis

Subclinical leaflet thrombosis (SLT), defined as presence of leaflet thickening with reduced motion (on echocardiography or CT) without hemodynamic dysfunction/ cardiac symptoms or TIA (VARC 3) has been reported in as high as 30% of post TAVI patients at 1 year.

SLT may escalate toward clinically significant thrombosis, which has been shown in meta-analysis to be associated with a 3 time increased risk of stroke.

Despite this systematic use of oral anticoagulants – OACs – has not been found useful after TAVI. Trials done in this regard did show a reduction in SLT, however this was counter balanced by an increased risk of major complications and death. [33]

Recent efforts have focused on development of TAVI valves with novel materials that enhance durability. The bio prosthetic valve dysfunction seen with current THVs has led to the demand to create non thrombogenic durable polymeric heart valves (PHVs). For this purpose, poly (carbonate urea) urethanes (PCU) have been found to be a viable class of polymeric compounds. Leaflets made from these materials resist oxidative and hydrolytic degradation. Additionally, it is postulated that they create a non thrombotic environment by polymer endothelialisation.

The Foldax Tria valve was one the the initial PHVs to be tested in humans, although via surgical implantation. At 1 year follow up, out of the 14 patients who underwent implantation, 2 patients died due to valve related causes. However, hemodynamic performance and NYHA class was maintained throughout the follow up period. [33]

A study published in April 2026 demonstrated the safety and efficacy of TAVI with the Sikelia transcatheter heart valve – a self expanding valve featuring leaflets made from polyurethane materials. At discharge, out of the 12 patients who underwent TAVI, no patients reported death, stroke or required permanent pacemaker implantation. At 1 year the mean pressure gradient improved substantially (6.33 +/- 2.54 mmHg vs 47.5 +/- 13.82 mmHg). No moderate severe PVL and no evidence of SLT was noted on CT during follow up. While a favorable hemodynamic performance and acceptable safety profile was noted at 1 year, long term follow up would be needed to assess durability and consideration for treatment of patients with severe AS. [34]

Conclusion

TAVI has come a long way from the initial implantations done in inoperable patients, aided by improvements in pre procedural planning (CT), THV technologies and operator experience.

Current indications now extend to patients with symptomatic severe tricuspid aortic stenosis aged 70 or more while use in aortic regurgitation and bicuspid aortic valve disease requires further evidence.

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The current paradigm involves valve selection from the available BEVs & SEVs individualized to the patient's unique anatomical features on CT.

Lower ages at initial implantation have resulted in an emphasis on redo TAVI planning and methods to improve THV durability. Polymeric heart valves (PHVs) developed for this purpose appear promising although larger trials and long term assessment are needed.

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