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How to improve patient outcomes following TAVI in 2024? Recent advances

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ABSTRACT

Transcatheter aortic valve implantation (TAVI) has revolutionized the treatment of aortic stenosis, particularly among elderly patients. The first TAVI procedure in the world was performed in 2002, by Professor Cribier. It was subsequently approved for clinical use in Europe in 2007, followed by approval in the United States in 2011. Since it was introduced into clinical practice in Europe, there has been a remarkable increase both in the number of procedures and centers performing TAVI. Recent findings endorse its application in lower-risk populations as well, suggesting a transformative shift in the field of interventional cardiology. This review article thoroughly explores the recent advancements and key considerations aimed at enhancing patient outcomes following TAVI in 2024. Key areas of focus include valve durability, paravalvular leak management, valve-in-valve procedures, and the implications and management of coronary artery disease in these patients. The article highlights the importance of selecting valves with favorable hemodynamics, minimal coronary risk, and optimal durability, especially for younger, lower-risk patients. Paravalvular leak remains a significant concern; thus, pre-procedural planning and immediate corrective measures are crucial to mitigate its impact. The increasing need for valve-in-valve interventions underscores the importance of the strategic initial valve choice with a looking-forward perspective. Additionally, emerging strategies, such as transcatheter leaflet laceration to prevent coronary obstruction during reinterventions, are examined. This review synthesizes

current research and clinical practices, providing a roadmap for enhancing TAVI outcomes through technological advancements and strategic procedural planning. The findings and recommendations presented aim to optimize long-term patient prognosis, ensuring that TAVI remains a leading solution for aortic stenosis in an increasing variety of patients.

Key words: aortic stenosis, coronary access, durability, TAVI, valve-in-valve

INTRODUCTION

Aortic stenosis is the most common valvular heart disease. In the current valvular ESC guidelines transcatheter aortic valve implantation (TAVI) is recommended in older patients (≥75 years), or in those who are high-risk or unsuitable for surgery [1]. The American Heart Association guidelines recommend as a class 1 indication either transfemoral TAVI or surgical aortic valve replacement (SAVR) for patients 65 years or older [2]. Marzec et al. [3] analyzed outcomes and predictors of long-term mortality in patients undergoing TAVI and SAVR. They performed a retrospective analysis of patients with advanced aortic stenosis and found no significant differences regarding prognosis between TAVI and SAVR at 2-year follow-up.

However, and due to the increasing scientific evidence supporting TAVI, it has marked a significant shift in the management of these patients. Surgery is being surpassed as the best option, with percutaneous treatment now being the preferred choice, even for low-risk patients [4]. Several aspects must be considered when generalizing these procedures to younger patients to address their long-term prognosis: Durability, the risk of atrioventricular block, the need of future percutaneous procedures, and the coronary access. We need to address and anticipate the answers to those questions now, as the seeds we plant today will become the trees of tomorrow.

The purpose of this review is to summarize to summarize the key aspects that must be considered today to improve the prognosis and future of patients undergoing TAVI.

DURABILITY AND HEMODYNAMICS

If we consider extending TAVI to low-risk patients, the first procedure must be performed with a lifetime strategy plan. A young patient undergoing TAVI should ideally receive a

valve with a low coronary risk plane, large upper cells, commissural alignment, and optimal valve hemodynamics.

One of the main important concerns is durability.

Severe structural valve deterioration is defined as:

- Transprosthetic gradient of 30 mm Hg or more and an increase in transprosthetic gradient of 20 mm Hg or more.
- Severe new intraprosthetic regurgitation.

Bioprosthetic valve failure is defined as the composite rate of death from a valve-related cause or an unexplained death following the diagnosis of bioprosthetic valve dysfunction, aortic valve re-intervention, or severe structural valve deterioration [5].

Interactions between the TAVI stent frame and valve leaflets that occur during crimping and deployment may also accelerate structural valve degeneration [6].

The NOTION trial [7] was the first to randomize patients at lower surgical risk to TAVI CoreValve (Medtronic Inc.) or SAVR. The primary composite outcome (all-cause mortality, stroke, or myocardial infarction) showed no differences 10 years after treatment. The risk of severe bioprosthesis structural valve deterioration was lower after TAVI compared with SAVR, while the risk of bioprosthetic valve dysfunction was similar.

PARTNER 3 trial [8] demonstrated that, among low-risk patients with aortic stenosis, TAVI (balloon expandable) was superior to SAVR at preventing death, stroke, or rehospitalization at 1 year. This benefit was sustained to 5 years. Valve durability indicators were also stable over time with no differences in the incidence of bioprosthetic valve failure related to structural valve deterioration (1.4% vs. 2.0%) or reintervention rates (2.6% vs. 3.0%) between TAVI and SAVR at 5-year follow-up.

Technology continues to advance in pursuit of improved durability. The valve SAPIEN 3 Ultra RESILIA has an advance blocking-calcium technology that promises to improve durability, inspired by the surgical valve INSPIRIS RESILIA [9]. When comparing Sapien 3/Sapien 3 Ultra versus Sapien 3 Ultra RESILIA, echo-derived mean gradients are lower with RESILIA with larger effective orifice areas and less paravalvular leaks. The Japanese Ocean-TAVI Registry published similar results in this regard [10].

The Evolut Low Risk trial [4] showed that, at 4-year follow-up, TAVI patients had sustained improvement in hemodynamics as measured by echocardiography, with significantly lower aortic valve mean gradients and greater effective orifice area compared with SAVR.

How could we improve durability?

Several new polymer technologies have been developed in recent years in the hope of creating an ideal polymeric heart valve substitute that overcomes the limited durability of bioprosthetic valves [11]. Maybe we should focus on the material of the TAVI or the possibility of new designs with removable leaflets sewed to a stent, previously suggested for SAVR [12].

TAVI IN TAVI

The number of TAVI in TAVI implantations will increase significantly in the future, due to the expansion of the technique to young patients and the limited durability. There are some risks to envisage, such as impaired coronary access, residual gradients and durability. Sizing and positioning need to be standardized based on the prosthesis failure mechanism. The choice of the first prosthesis is crucial when planning the lifetime management of a patient as it has a significant impact on treatment options in the future. The first valve implantation impact significantly the second redo, both TAVI in TAVI or TAVI explant.

In the registry EXPLANTORREDO-TAVR [13], the authors sought to determine outcomes of TAVI surgical explant vs redo-TAVI. In this registry, TAVI-explant had a shorter median time to reintervention, with less structural valve degeneration, more prosthesis-patient mismatch, and similar paravalvular leak (PVL) rates compared to redo-TAVI. TAVI-explant had higher mortality at 30 days and 1 year.

Several aspects that must be carefully examined in the cardiac tomography (CT) to prevent coronary obstruction in TAVI in TAVI procedures [14]:

- The risk plane.
- The distance from the valve to the coronary artery.
- The commissural orientation of the first TAVI.
- The possibility of sinus sequestration.

New concepts are arising with the increasing need of VIV procedures, such as the height of the newskirt, the possibility of leaflet overhang (acceptable in cases of regurgitation as the main mechanism of degeneration) and the expansion of the first TAVI.

PARAVALVULAR LEAK

PVL after TAVI is prevalent and it means higher risk of all-cause mortality, rehospitalization, and cardiovascular mortality following TAVI [15].

The incidence of moderate to severe PVL has declined with improved valve design, implantation technique, and operator experience, but the latest generation devices implanted in low-risk populations still show moderate to severe PVL in 0.8% for balloon-expandable devices and in 3.4% for self-expanding devices at 30 days. The incidence of mild PVL is high after TAVI, with incidences of 29% in balloon-expandable vs. 36% in self-expanding devices at 30 days [8, 16]. Mild PVL is usually asymptomatic and there are conflicting results regarding its association with mortality. The negative impact of PVL on outcome after TAVI is attributed to the remodeling of the left ventricle in patients with aortic stenosis, resulting in a pressure-overloaded ventricle, in combination with an acute volume overload [17].

Predictors of PVL are annular eccentricity, severe calcification of the aortic valve, bicuspid aortic valves and type of prosthesis, being balloon-expandable devices associated with less PVL. PVL may be the consequence of an undersizing of the implanted device or an incomplete expansion of the prosthesis stent frame.

The use of CT for sizing the annulus reduced PVL compared with transesophageal echocardiogram [18]. Therefore, 3D measurements using multi-slice CT are considered the gold standard for sizing the annulus.

The aortic annulus is typically oval, while TAVI frames are circular, which may hinder full frame apposition. The eccentricity index (1 — minimal/maximal annular diameter) measures annular shape. In first-generation self-expanding devices, an eccentricity index >0.35 was associated to significant PVL [19], though other studies did not confirm this finding. In balloon-expandable devices, annular and left ventricular outflow tract eccentricity predicted PVL due to heterogeneous sealing zones. Additionally, an increased left ventricular outflow tract — ascending aorta angle influenced stent radial force, impacting PVL [20].

Procedural strategies to prevent PVL are needed. Accurate assessment of the aortic valve annulus before TAVI is mandatory to select the optimal valve size. Implantation depth, both too deep and too shallow, is associated with relevant PVL.

How could we reduce PVL?

In patients considered to have moderate or greater PVL after TAVI, an immediate corrective procedure should be considered. The management should be individualized, considering the balance between the vulnerability factors to aortic regurgitation (including absence of preexistent native aortic regurgitation, severe left ventricular concentric hypertrophy with small cavity, and advanced diastolic function) versus the risk factors (bulky calcific nodules) for complications (stroke, aortic annulus injury, coronary artery obstruction).

The optimal treatment of PVL is prevention. However, when prevention is unsuccessful, some treatment options can be considered. These include balloon postdilation, placement of a second valve, and percutaneous PVL closure by a vascular plug.

The first-line procedure to correct PVL is an additional postdilation [21]. A slightly oversized balloon (at least be equal to or >95% of the mean annulus diameter) is recommended to achieve further expansion of the prosthesis. Studies have shown that postdilation correction can be performed safely, with a decrease of the PVL in most patients. However, balloon postdilation correction has been associated with an increased risk of stroke, which is at least partly attributed to the worse baseline risk profile of the patients with PVL. It is important a careful sizing of the postdilation balloon according to the size and geometry of the transcatheter valve and consideration of lower deployment of the balloon to prevent leaflet injury [22].

A VIV procedure may be necessary in some cases of moderate to severe PVL in which postdilation correction failed, if the anatomic conditions allow the implantation of a second prosthesis [23]. It is successful in 90% of cases, either through lengthening of the sealing skirt in case of inadequate position or through further expansion of the index device. This procedure is used when the PVL is primarily related to a malposition of the first valve (in particular, too high position).

For the rare cases of persisting significant PVL after postdilation and/or a valve-in-valve correction, transcatheter closure of the PVL using vascular plugs may be an option in experienced centers and reduce mortality [24].

A comprehensive echocardiographic examination should be performed before hospital discharge. If PVL is greater than mild grade or the grading is doubtful, a cardiac magnetic resonance examination may be considered and a regurgitant fraction of 30% or greater should prompt additional corrective procedures.

CORONARY ARTERY DISEASE IN TAVI

The prevalence of coronary artery disease in patients with severe aortic stenosis varies widely, from 80% in high-risk trials to only 15% in more recent low-risk trials [4, 25]. Guidelines suggest that revascularization with coronary artery bypass grafting should be considered in patients undergoing SAVR [1]. Therefore, it is not surprising that the early trials of TAVI required coronary angiography before the procedure, and percutaneous coronary intervention of proximal and mid lesions in major coronary arteries was strongly recommended. Percutaneous revascularization has proven to be safely performed [26], but whether it offers clinical benefit remains unclear. To date, there have been no randomized trials addressing this issue.

Pre-TAVI CT has a high negative prognostic value for high-grade proximal stenosis of each coronary artery. As a result, CT could be used as a screening tool to rule out significant proximal coronary artery disease in patients undergoing TAVI [27].

Coronary obstruction in TAVI

Performing TAVI on a young person might have important implications on future interventions. Irrespective of valve durability, a young patient will likely receive one or multiple percutaneous interventions in the decades following the index procedure. The most dreadful complication in redo TAVI is represented by coronary obstruction [28].

Coronary height <10 mm, sinus of Valsalva width <30 mm, leaflet tips extending above the coronary ostia or the sinotubular junction, the distance between a virtual valve and the coronary ostium <4 mm, and/or at the sinotubular junction <2 mm have been identified as risk factors for coronary obstruction post TAVI [29–32]. In VIV cases, only the distance from the virtual valve to the coronary ostium <4 mm and valve type (stented with externally mounted leaflets or stentless) but not coronary height were identified as predictors of coronary obstruction [30].

Coronary access after TAVI

Techniques to improve success of cannulating coronary ostia and interventions have been refined, including using guide catheters with smaller curves (engaging the left coronary artery with a JL3 or EBU 3 from a radial approach or JL3.5/EBU 3.5 from a femoral approach), remote wiring and using guide extension catheters, and using the appropriate cells within the prosthesis to access the coronary ostia [33].

How could we minimize the risk of coronary obstruction?

A careful analysis of the CT will help to predict patients at high risk of coronary obstruction and be cautious. Commissural alignment is becoming an important parameter for procedure optimization in younger patients undergoing TAVI, and is essential to be able to engage the coronary ostium in the future [34].

Transcatheter leaflet laceration has emerged as a preventive technique to avoid coronary obstruction during TAVI procedures. The study of Kitamura et al. [32] confirms the efficacy and safety of this technique in a real-world setting, and provides further support for its extended application at experienced centers. Bailout strategies, such as chimney stenting, might also be helpful in reducing this risk.

RISK OF PACEMAKER

The risk is different in ballon expandable vs. self-expanding valves, being higher in the self-expanding, in general [35], although different for each type of valve. Preexisting right bundle branch block, first-degree atrioventricular block and low implantation depth have been identified as predictors of pacemaker following TAVI [36]. However, it is highly variable depending on the electrocardiogram at baseline and the height of implantation (the higher, the lower risk of disturbances) [37]. The need of pacemaker implies a worse prognosis in patients after TAVI [38].

RISK OF STROKE

TAVI for the treatment of aortic stenosis can lead to embolization of debris. Capture of debris by devices that provide cerebral embolic protection may reduce the risk of stroke.

The overall evidence confirms similar or lower rate of stroke in TAVI versus SAVR. Risk predictors for acute stroke after TAVI are generally related to procedural factors, whereas late stroke is mainly associated with patient characteristics, with a variable impact on cognitive function. The optimal choice for the antithrombotic treatment in TAVI for stroke prevention is yet to be determined. Current data do not support routine use of cerebral embolic protection devices during TAVI [39, 40]. In the review by Richter et al. [41], an overview of the available literature on cerebral embolic protection devices in patients undergoing TAVI and outline recent advances within this field is shown.

There are two main categories of cerebral embolic protection devices: filter devices, which capture embolic debris, and deflector devices, which redirect debris away from the cerebral circulation.

Sentinel (Boston Scientific): The most studied filter device, approved in the United States and Europe, uses two filters placed in the brachiocephalic trunk and left common carotid artery. Despite showing debris capture in 99% of procedures, clinical trials such as SENTINEL and CLEAN-TAVI yielded mixed results regarding reduction in stroke or lesion volume.

TriGuard (Keystone Heart): A deflector device covering three cerebral vessels, inserted via the femoral artery. Although showing promise in trials like DEFLECT III and REFLECT II, its efficacy in reducing stroke and new lesions remains inconclusive.

Embol-X (Edwards Lifesciences): Another deflector device that demonstrated smaller lesion volumes in a randomized trial.

Other devices like Emblok, Embrella, and PointGuard are in various stages of clinical evaluation, aiming to provide more comprehensive brain protection with novel designs and mechanisms.

Overall, while cerebral embolic protection devices show potential in reducing silent brain lesions, their impact on clinical stroke outcomes and long-term neurocognitive function needs further validation through larger, standardized trials.

CONCLUSION

We are currently making continuous advancements to mitigate the negative aspects associated with TAVI, specifically addressing valve durability, prosthetic degeneration, PVL, coronary access, conduction disorders, and the risk of stroke.

The key areas of research and development include:

- Valve durability: Innovations aimed at enhancing the durability of TAVI prosthesis, including the use of advanced materials and designs. Strategies to prevent calcification and other forms of degeneration, potentially involving biocompatible coatings and improved manufacturing techniques.
- PVL: Development of sealing mechanisms and skirt designs to minimize PVL.
- Coronary access: Designing valves with large cells to ensure unobstructed coronary access post-implantation.

- Conduction disorders: Reducing the impact on the cardiac conduction system through refined deployment techniques and valve positioning.
- Stroke risk reduction: Implementing procedural refinements and embolic protection devices to reduce the incidence of stroke during and after TAVI.

These advancements collectively contribute to the evolution of TAVI, aiming to create an ideal valve that combines optimal hemodynamics, minimal risk of coronary occlusion, effective sealing against PVL, and reduced impact on the conduction system. Improving patient prognosis with TAVI involves a holistic approach, considering all reviewed factors to select the valve best suited to the individual patient's characteristics.

Article information

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