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**Systematic Review Article**

# Surgery and risks of transcatheter aortic valve replacement (TAVR) in Low Surgical Risk patients with aortic stenosis

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**Abstract:**
Transcatheter aortic valve replacement (TAVR) has been shown to be a valid alternative to surgical aortic valve replacement (SAVR) in high operative risk patients with severe aortic stenosis (AS). Evidence on the benefits and harms of TAVR in patients at low risk of surgery, however, is still scarce. In this study, we planned to review the literature on all aspects of transcatheter aortic valve replacement (TAVR) as a newly introduced method. In our review, TAVR was found to be safe in low-risk patients with symptomatic severe aortic stenosis in terms of low procedural complication rates, short hospital stays, zero mortality and risk of stroke that may leave 3 permanent sequelae. TAVR, both TAVR and SAVR carry similar stroke risks for intermediate-risk patients, suggesting that no procedure is inherently safer. Healthcare providers should take this into account when counselling individual patients, considering the benefits and disadvantages of each procedure. The present study focusses specifically on low-risk individuals, so the results for the intermediate-risk patients who may come before us may not be universally applicable.

## 1. Introduction

Diseases of the aortic valve will increase as the population ages. Aortic stenosis has been shown to increase exponentially in those older than 70 and 80 years, with a rapid increase in those older than 85 years. Surgical aortic valve replacement has been the treatment of choice for decades, albeit with significant limitations and risks. Transcatheter aortic valve replacement for those who were too frail to undergo surgical aortic valve replacement became the answer to a large and significant medical and scientific question [1-3]. Transcatheter aortic valve replacement began with inoperable patients, followed by those at increased surgical risk. In 2016, transcatheter aortic valve replacement was approved for intermediate risk patients with equally favourable outcomes in the short and mid-term compared with surgical aortic valve replacement. With the proper growth of our knowledge, low surgical risk has become an increasingly interesting and intellectually challenging subject [4-8]. The trial looking at the procedures of surgical aortic valve replacement and transcatheter aortic valve replacement aimed to assess differences in complications between transcatheter aortic valve replacement and surgical aortic valve replacement patients using low surgical risk patients with severe symptomatic aortic stenosis as the control group. Specifically, we were interested in the number of long-term complications and/or differences we could see between the groups that would indicate a disproportionate number of common comorbidities and other issues [9]. The results of the three inconclusive trials led to numerous radically opposing conclusions. Aside from the flaws in the absolute numbers, none of the three trials revealed a major difference between transcatheter aortic valve replacement and surgical aortic valve replacement. However, general guidelines should be based on both short and long-term outcomes at this time [10, 11].

### 1.1. Background and Significance

Aortic stenosis is an extremely common valvular heart disease that leads to decreased life expectancy. Aortic stenosis patients are mainly elderly, comprising a higher percentage of the female population, and the number continues to rise with an increase in geriatric populations [12]. It follows that hopefully; aortic stenosis is set to become a more prevalent disorder worldwide in the future [13]. Traditional surgical aortic valve replacement is the treatment of choice for aortic stenosis of any

pathology and is recommended in clinical guidelines as a class 1 indication when a stenotic valve starts showing symptoms or left ventricular decompensates. The old standard valve replacement surgery brought with it significant morbidities and mortalities; conversely, transcatheter-based aortic valve replacement has generated interest as an alternative approach, as it can be performed through a less invasive procedure compared to old surgery [14, 15]. Robust evidence was developed in intermediate and high surgical risk categories on the basis of several clinical trials which compare transcatheter-based aortic valve replacement with traditional surgery. The possibility of using transcatheter-based aortic valve replacement instead of traditional surgery indicated the low-risk indications of "real or perceived low risk [13, 16]." Part of the rationale for research is to ensure it is better understood what kind of patients qualify for transcatheter-based aortic valve replacement. As the sample size of transfemoral patients has increased in these studies, this could lead to a more educated decision [17, 18]. This process is more complicated with the need to consider each potential transfemoral uncovered access separately, examining any statistical interaction between the uncovered and inbuilt tip positions of the device [15, 19].

## 2. Aortic Stenosis and Treatment Options

Aortic stenosis manifests due to the inadequate opening of the aortic valve that connects the left ventricle to the aorta. Aortic valve calcification is the most frequent cause of aortic stenosis, observed mostly in the geriatric population. Patients suffering from aortic stenosis usually present with symptoms such as chest pain, shortness of breath, asthenia, lower extremity oedema, or sometimes light-headedness during exertion [20]. When untreated, aortic stenosis gradually progresses to ventricular hypertrophy and ultimately to heart failure or myocardial infarction, leading to approximately 50% mortality within 2 years [21]. Two alternative surgical methods are performed for the treatment of severe aortic stenosis, including the traditional surgical aortic valve replacement using cardiopulmonary bypass and transcatheter aortic valve replacement via alternate pathologic aortic valve culverts. Surgical aortic valve replacement is the most frequently offered procedure to symptomatic patients with intermediate and high surgical risk profiles, while transcatheter aortic valve replacement is the first recommendation for high surgical risk category patients. Clinical decision-making for symptom-free severe aortic stenosis patients is based on guideline-directed data, the patient's health status, comorbidities, and the patient's needs [22, 23]. Both types of procedures, surgical aortic valve replacement and transcatheter aortic valve replacement, have their own treatment-related advantages and problems. The treatment-related key endpoint of all-cause death and major stroke is comparable between the two available treatment modalities in patients with severe aortic stenosis. For an individual with aortic stenosis, a decision regarding how to treat aortic stenosis should be based on several factors [24, 25]. Existing medical literature guides the recommendation not to treat asymptomatic patients having severe aortic stenosis. In patients with severe aortic stenosis and relevant symptomatology, a guideline-directed transcutaneous valve intervention should be performed in accordance with heart team decision-making [26]. Given the heterogeneity in clinical presentation, a single trial result should not be relied upon in isolation for decision-making. Individual patient characteristics, including age, clinical presentation, expected prognosis, concomitant comorbidities, risks of a therapeutic option, and also the patient's choice and preferences, should be core guiding factors influencing therapeutic decision-making [27, 28].

### 2.1. Pathophysiology of Aortic Stenosis

Aortic stenosis represents an anatomic valvular lesion that over time translates to a hemodynamic consequence of left ventricle pressure and volume increase. In particular, the impeded left ventricle ejection into the aorta characterizes the low pressure to peak ejection rate third phase of left ventricle contraction, while the excessive cardiac work due to the chronic peripheral arterial resistance elevation progressively causes left ventricular hypertrophy, diastolic and then systolic left ventricular impairment, which may remain entirely asymptomatic for a long time [29]. Progressive anatomical reduction of effective aortic area resulting in increased left ventricle contractile effort on a geometrically increased left ventricular mass implies an increase of intracavitary left ventricle pressure that, in some conditions, might compromise left atrial driving pressure and lead to left ventricle inflow obstruction [30, 31]. Multiple pathologic risk factors are typically responsible for any possible or pathological aortic valve stenotic disease involving either the valvular walls or the aortic distal orifice. Calcific aortic valve stenosis is the most frequently recorded severe aortic stenotic disease entity across all age ranges [32]. On the other hand, while different new primary binder compounds need to be studied to counterbalance or treat its leading clinical risk factors, severe aortic stenosis might be associated with either low, normal, or slightly increased cardiac output, for a wide range of aortic

mean gradients, not necessarily depending on the left ventricle ejection fraction value [33]. The cranio-caudal pressure gradient is indicated between the upstream stenotic ventricular corner and right heart cavities. Given these premises, the highest aortic mean gradient equals the shortest mean pressure-time of contact for cutting actions. The implications of isthmus stenosis for body injury from aortic and bicuspid valve magnetic forces cannot be forgotten [34, 35].

### 2.2. Surgical Aortic Valve Replacement (SAVR)

Surgical aortic valve replacement (SAVR) has been regarded as the gold standard intervention for severe aortic stenosis. Eligible patients may be symptomatic with aortic stenosis in the form of angina and congestive cardiac insufficiency or may be asymptomatic but found to have severe aortic stenosis primarily during screening with echocardiography and graded to severe aortic stenosis by an experienced valvular heart team. Surgery can be carried out only after other surgical intervention is done if the surgical risk is not high enough for the patients or the patients themselves deemed unsuitable candidate for surgical intervention [36]. SAVR can be performed as the classic sternotomy or the less invasive procedure, the minimal access aortotomy, where also the peri-areolar approach known as hemi-sternotomy, has been considered. Of course, the choice of surgery also depends on the location of the incision required for the surgical procedure. Under some circumstances SAVR returns less than optimal results, resulting in compromised function if the body system after surgery and reduces the prospective patient's quality of life. The evolution of other minInvasive surgical approaches leads clinicians to find solutions that are different from the traditional intervention that is transvacuolar or apical interventions [37]. Lack of prospective data for a direct head-to-head comparison highlights one of the limitations of using the trial data. After the operation, some complications of concern were post-operative infection until recovery due to pain and complaints and limitations of the speed of recovery and the limitations alive and young is a quality of radiation after surgery. Preoperative patient assessment is important in exploring these limitations to prevent definitive results. Focus on patient care postoperatively and with a good rehabilitation pathway to facilitate the long-term outcome of patients after surgery. The long-term outcome of patients with severe aortic stenosis who undergo SAVR with a surgical standard is good with a 15-year reported survival more than 30% to 40%, is similar to those who undergo TAVR. These records of surgery give the point to know why the prognosis and quality care of SAVR TAH patients are the same with TAVR with regards to the quality of life and a better prognosis than conservative treatment. The importance of surgery in an increasing alternative strategy with endovascular surgery for patients with severe aortic stenosis a low standard of surgery and prospects in TAVR evolves accordingly, with exposure to newer technology generating a foreseeable clinical behavior system approach shortly after hybrid, surgical and PCI settings [38, 39].

### 2.3. Transcatheter Aortic Valve Replacement (TAVR)

Percutaneous treatment of aortic stenosis: Transcatheter Aortic valve replacement Transcatheter aortic valve replacement (TAVR), also known as transcatheter aortic valve implantation, was introduced in 2002 with the first human case. It replaces a defective aortic valve without removing the old, damaged valve. Instead, it wedges a replacement valve into the aortic valve's place. This procedure focuses on providing options for those who are considered high- or inoperable-risk patients for surgical aortic valve replacement [40]. The general steps for TAVR are similar among centres and delivery devices, although there are some differences. It is a minimally invasive procedure, during which the valve is replaced by a catheter and is designed for patients at intermediate or higher surgical risk, or inoperable for surgical procedures to replace their aortic valve. In addition to devices using trans-femoral implantation, there are devices and delivery systems using trans-apex, subclavian, direct aortic, or transcatheter devices. The prerequisites for selecting patients with aortic stenosis are developed by relevant professional organizations [41, 42].

The recent studies have shown the effectiveness and safety of TAVR with the SAPIEN 3 valve in comparison with open-heart surgery in intermediate and low surgical risk patients. Consequently, TAVR with SAPIEN 3 is now another alternative to open-heart surgery in patients with severe aortic stenosis with a low level of evidence [43, 44]. Major complications of percutaneous technological intervention are death, myocardial infarction, infection, renal failure, cerebrovascular accident, and other bleeding, leading to a small gait deviation. The incidence of major complications greatly depends on the complexity of the patients treated. Moreover, TAVR's indications have been expanding and becoming more sophisticated thanks to the advancements and increasing number of TAVR substitution valves that are performed with the currently approved devices in adult patients [45, 46].

## 3. Low Surgical Risk Patients

Low Surgical Risk: Low surgical risk is defined in contradistinction to moderate and high surgical risk; the absence of definitions for moderate and high surgical risks changes the definition of low surgical risk. Adult patients with severe symptomatic aortic stenosis (often with AVA ≤1.0 cm²), who would not be considered low risk by contemporary guidelines and expert consensus for surgical AVR, but who have STS-PROM, Lillehei-Konstantinou, or EuroSCORE II of <4% are considered in this category. Patients for whom existing risk models do not meet the defined cut-off values of <4% should not be considered low surgical risk and should be categorized by providers and the heart team into a category that represents their procedural risk [47, 49]. Low Surgical Risk Clinical Assessment: Evaluation of low surgical risk includes, but is not limited to, evaluation of higher risk surgical features. Decision-making is based on multiple clinical parameters and assessment tools; the heart team and procedural site should have an active program for coronary artery disease evaluation and assessment for myocardial infarction, coronary disease revascularization options, and sudden death primary and secondary preventative measures [50, 51]. In the United States, TAVR is indicated for patients falling into these categories with specific devices. Pre-treatment aortic peaks, means, ratios, etc. are considerations in assessing the overall risk of the procedure and should be determined for all patients pre-procedure in keeping with societal and/or institutional guidelines. Low surgical risk patients considered dilated prior to TAVR require a heart team discussion about the risk-benefit aspects of continuing with TAVR or converting to SAVR. Long-term management includes all populations. Given that these subsets of patients are younger and have lower comorbidity burden than typical patient populations, extra attention to patient outcome is appropriate [52, 53].

### 3.1. Definition and Criteria

Low-risk patients are defined as patients with an estimated perioperative risk of surgical AVR < 3% by contemporary risk scoring predicted mortality. Many surgical risk scoring systems and guidelines are available to help clinicians evaluate the risk of AVR. Thus, it is not only the predicted risk of surgical modalities but also the assessment of the comprehensive clinical status measured with defined thresholds in a scoring system or a sum of evaluations to judge the treatment strategies for aortic stenosis on a broad level, such as estimation of survival benefit or treatment strategy in valve intervention. This information is important for healthcare providers and strengthens the evidence on the risk stratification level and the definition of the patient population in the clinical AS trials [40, 54, 55]. However, the low surgical risk patient is not solely an officially accepted surgical score or guideline. Reevaluating aortic stenosis in the era of transcatheter aortic valve replacement requires discussion on clinical definitions and criteria as directly referred to the mortality assessment published in clinical TAVR trials for officially defined patients. A better understanding is necessary to perform a risk-benefit analysis, anticipate long-term outcomes, and monitor with further results [56].

## 4. Risks and Complications of TAVR in Low Surgical Risk Patients

We have to remain vigilant about the identified as well as yet unknown risks and uncertainties in LSRs undergoing TAVR, especially at ages <. These patients undergo TAVR with the intention of increasing the durability of the valve, providing them with better results when they require intervention. Concerns about the procedure and device-related complications are also necessary because of the TDF [57].

Surgical Aortic Valve Replacement surgery in LSR is associated with relatively good patient outcomes with low surgical risk in LSR. Many of the problems of TAVR are due to the interaction of people with their prosthesis and disputes and not the surgical procedure performed for SAVR. There are acute as well as long-term complications seen with TAVR including bleeding, damage to blood vessels, device embolization, the impact of anesthesia, potential damage to the conduction system of the heart and the subsequent need for permanent pacemaker, stroke, worsening of heart function, the impact on the kidneys, valve complications, problematic aortic root enlargement with long term outcomes, effect on the nervous system and lifespan of the valve. It is important to note that Europe is now implanting the 4th generation of TAVR valves.

It is essential to remain vigilant and monitor outcomes, however, to draw firm conclusions, therefore, would be not warranted given the relatively small number enrolled in non-randomized registries [58]. Full informed consent in such a complex field is challenging and involves ascertaining that patients have understood the potential risk of multiple dimensions of the assessment.

Ethical issues, as well as clinicians, may struggle to explain if artificial devices provide any advantage in treatment for a disease for which one must also die [59].

### 4.1. Procedural Risks

Transcatheter aortic valve implantation has become established as an alternative treatment for patients at high or excessive risk for conventional aortic valve replacement. With expanded clinical experience and technical improvement, TAVR has been tested in patients at low surgical risk with promising clinical results. These favorable results of TAVR in low surgical risk patients were also confirmed in recent larger randomized controlled trials. However, it is worth mentioning that TAVR is not free of complications and necessitates long-term adoption of antiplatelet therapy and surveillance. The aim of this text is to update the current evidence for defining both procedural and long-term risks of TAVR in patients with aortic stenosis. Also, strategies for risk assessment and minimization of complications are highlighted [40, 60]. The occurrence of procedural complications is an inevitable consequence during any TAVR procedure and, in general, compromised 20.7% of patients in large TAVR data registries or randomized controlled trials. Major procedural complications typically occur during the per-operative time, mainly at the access site and skin incision and at the perioperative time. Patient-related factors such as comorbidities, frailty in terms of valvular or non-valvular heart failures, chronic obstructive pulmonary disease, reduced left ventricular ejection fraction, diabetes, and previous cardiac surgery compose the anatomy of the valvular disease itself [61, 62]. The treatment protocol for postviral diseases should also be analysed in detail [63]. In addition, the physical ability to tolerate the procedural complications mainly contributes to the incidence of these TAVR complications. However, those patients who had transcatheter treatment for aortic stenosis should be properly counseled and then comprehensively evaluated by a heart team involving valve surgeons, interventional cardiologists, and, when needed, other subspecialists before subsequent transcatheter treatment can be established [64, 65].

### 4.2. Long-term Outcomes

Clinical Efficacy: Long-term survival with TAVR in low surgical risk patients was reported to be approximately 95%, without significant late differences with SAVR. These results were confirmed in a group of patients who completed a 5-year follow-up with a low 5-year incidence of valve-related hemodynamic prosthesis deterioration in TAVR (moderate or severe aortic regurgitation in 1.1% and stenosis in 0.9%). As with the majority of TAVR trials, clinical outcomes seem to improve with time due to survival bias, with higher event rates in the initial periods. Therefore, a surveillance of the population was performed to prove higher medical event rates compared to the trial, suggesting a progressive increase in pacemaker needs (as high as 20% in 5 years) [66]. Improvement in Patients' Quality of Life: Functional improvements and symptom relief after TAVR, along with a reduction in hospitalization, have been constant in the trials. SAVR was associated with higher morbidity and longer recovery. An important trend towards better quality of life in TAVR recipients due to lower mortality in the first year was described in both trials. Long-term results of these trials showed a trend-like separation between TAVR and SAVR groups in HRQoL improvement that may be underestimated due to the sample size. Symptom improvements (NYHA functional class), based on all patients enrolled in major trials and the long term reported, were very high immediately after the first month in nearly 90% of the population and remained such over time. Long-term rates of disabling strokes remained stable and generally low [67]. The rates of new pacemaker implantation and subsequent atrioventricular conduction were relatively higher after TAVR compared to SAVR, ranging from 11.5% to 21.2% (at 1 year) in low surgical risk patients enrolled in contemporary TAVR trials. The majority of pacemakers are delivered outside of the initial discharge during the longitudinal follow-up, suggesting a gradual conduction deterioration. The homogeneity of the averaged new pacemaker rates likely masks binary outcomes for each prosthesis. In long-term studies, TAVR stroke rates remained stable and low, between 2.5% and 4% under DAPT and 4.3% overall. The majority occurred during the first year. New RBBB (intraventricular conduction delay) increased over time, but half resolved with conservative therapy [68].

## 5. Conclusion and Future Directions

In conclusion, we have synthesized evidence focusing on transcatheter aortic valve replacement (TAVR) in low surgical risk patients with aortic stenosis, uncovering a few important reflections. Firstly, TAVR is effective and can improve symptoms and reduce the risk of subsequent aortic valve-related hospitalization or mortality. It has a lower surgical risk than surgery and has inherent risks of vascular and myocardial complications. Cardiac membrane rupture during TAVR is an uncommon complication that can lead to death and therefore should be anticipated and managed judiciously. The landscape of cardiac surgery is rapidly evolving, with TAVR now being an established technique that can treat most patients with aortic stenosis, and considerations of surgical candidacy have shifted from technical feasibility to individual patient factors and preferences [69].

Future directions include ongoing study of the effects of TAVR on long-term valve function, atrial fibrillation, aortic stenosis progression, myocardial recovery, and hemodynamics, and exploring the role of valve interventional techniques such as TAVR and balloon valve dilatation for patients with bicuspid aortic valve. These may open research in valve-in-ring and sutureless valve-in-mitral annulus, which promise to be novel alternatives for patients at all surgical risk with degenerated biological mitral and bypass grafts. The proportion of patients with aortic stenosis undergoing TAVR rather than surgery is increasing. It is important that patients are adequately informed about the potential benefits of TAVR, the risks of TAVR or surgery, and alternative interventions specific to their condition and mindset, and that evidence is integrated into guidelines and policy [70]. Emerging evidence suggests that TAVR may be a suitable alternative to surgery for selected patients at low surgical risk. However, longer-term data on structural valve deterioration, valve thrombosis, endocarditis, and valve failure are required. The trend extends to contraindication to anticoagulation as a precautionary measure not to push patients to surgery for these procedures [40, 71].

## Author Statements:

- **Ethical approval:** The conducted research is not related to either human or animal use.
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