

Research Article

Efficacy and Safety of Transcatheter Aortic Valve Replacement in High-Risk Patients

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ABSTRACT

Introduction: Transcatheter aortic valve replacement (TAVR) is becoming a more minimally invasive approach than surgical aortic valve replacement (SAVR) for high-risk patients with severe symptomatic aortic stenosis, with good procedural and clinical results.

Objectives: To assess the effectiveness and safety of TAVR in high-risk patients with severe aortic stenosis who have symptoms.

Materials and Methods: A Cross-sectional study was carried out from June 2025 to November 2025 at the Peshawar Institute of Cardiology, Peshawar, Pakistan. A total of 120 patients with high-risk were randomly assigned equally to TAVR or SAVR. Procedural success, hospital stay, complications, mortality, and echocardiographic outcomes were evaluated.

Results: TAVR achieved a procedural success rate of 96.7% and SAVR 93.3%. TAVR had a substantial impact on hospital stay and major bleeding. There was a trend toward a lower rate of mortality and stroke with TAVR and a higher rate of permanent pacemaker implantation. TAVR also resulted in beneficial hemodynamic and functional outcomes.

Conclusions: TAVR was an effective and relatively safe procedure for high-risk patients, and recovery was quicker and major bleeding events were less frequent than with SAVR.

Keywords: Transcatheter Aortic Valve Replacement (TAVR), Aortic Stenosis (AS), High-Risk Patients, Valve Replacement (SAVR).

INTRODUCTION

In elderly people and patients with multiple comorbidities, aortic valve disease is an emerging cause of cardiovascular morbidity and mortality. Aortic stenosis is a serious condition that leads to a progressive decrease in cardiac output, heart failure, syncope, angina, decreased functional capacity, and a poor prognosis if aortic valve surgery is not done. Transcatheter aortic valve replacement (TAVR) is therefore an important therapeutic approach that is not invasive. Transcatheter aortic valve replacement (TAVR) has been shown to offer equivalent clinical outcomes compared to surgical aortic valve replacement (SAVR) in Cross-sectional study across various surgical-risk categories, and has the advantage of avoiding the physiological stress of open-heart surgery and cardiopulmonary bypass (CPB) (1).

Clinical results have been encouraging for TAVR, and there has been significant advancement in the design of the valves, delivery systems, vascular access, imaging techniques, and peri-procedural management. The choice of the type of prosthetic valve is still clinically relevant in patients with high risk for severe symptomatic aortic stenosis, as there are differences between balloon-expandable and self-expanding valves in their frame design, radial force, implantation technique, hemodynamic performance, conduction-system effects and risk of paravalvular regurgitation. Comparative studies have therefore been focussed on whether either platform is superior in terms of safety or efficacy in vulnerable high-risk populations (2). While TAVR was originally designed for C-AoS, it has been used for other aortic valve disease as well. Systematic reviews

have focused more and more on the feasibility of transcatheter treatment for aortic regurgitation, especially in patients who are deemed to be poor surgical candidates (3).

The introduction of transcatheter treatment for pure aortic regurgitation is one example of the technological development of TAVR. Caution should be used when performing TAVR in patients with pure AR, and recent experience from a single centre has demonstrated acceptable procedural success and clinical outcomes in patients with limited valvular calcification and difficulty with prosthesis anchoring (4). Meanwhile, procedural complexity can be heightened in patients who are at risk of coronary obstruction, such as those with poor coronary anatomy, previous bioprosthesis failure, or restricted sinus size. Innovative technologies have thus been developed to maintain coronary flow during TAVR in anatomically challenging situations, and may expand this approach to more patients at high risk for procedural complications (5).

Recent data also suggest that the advantages of transcatheter valve therapy have transcended the high and prohibitive surgical risk populations. In the less severely aortic regurgitant population and other aortic valve disease populations, studies have shown promising short-term outcomes, which have helped to build confidence in transcatheter aortic valve interventions and the ongoing optimisation of patient selection (6). However, elderly patients undergoing TAVR often have heart failure, diabetes mellitus, renal dysfunction, and other systemic diseases which can impact recovery and long-term prognosis. Adjunctive pharmacological strategies to enhance outcomes after TVI are being evaluated, including heart failure and cardiometabolic risk therapies such as sodium-glucose cotransporter-2 inhibitors (7).

TAVR is still linked with clinically significant complications, although the procedure has come a long way. One of the main concerns is leaflet thrombosis, which could cause a reduction in valve motion, elevated transvalvular gradient, and/or structural valve dysfunction or thromboembolic events. Therefore, it is very important to understand the mechanisms, diagnosis, prevention and treatment of leaflet thrombosis to ensure good valve function and long-term safety (8). Another area of active investigation is antithrombotic management after TAVR. In patients without an established indication for chronic anticoagulation, use of direct oral

anticoagulants (DOACs) has been compared with conventional anti-thrombotic strategies, focusing on the potential for bleeding risk with DOACs in elderly and frail patients (9).

Durability and intermediate term performance of TAVR is also gaining increasing significance as the procedure is being made available to more patient populations. Comparative studies of TAVR and surgical aortic valve replacement in low- to moderate-risk patients have yielded important data on mortality, stroke, rehospitalisation, valve hemodynamics and procedure-related complications, which can also be used to contextualise outcomes in higher risk patients (10). Neurological events are still one of the most dreaded complications of T.V.I. because manipulation of calcified valves, as well as the aortic arch, can dislodge embolic material into the cerebral circulation. Cerebral embolic protection devices are, therefore, available to capture or deflect embolic debris, but efficacy has yet to be established in Cross-sectional study and meta-analyses (11).

Successful TAVR surgery is not the only requirement for recovery; it is also about restoring physical function and quality of life. In older, frail patients who are often candidates for TAVR, structured cardiac rehab, both pre- and post-valve intervention, may enhance exercise capacity, functional independence, and prognosis (12). Likewise, further assessment of embolic protection devices has focused on the need to identify the patients who are most likely to benefit from further embolic protection and the question of whether reducing embolic burden leads to significant reduction in disabling stroke (13). Among patients receiving TAVR with atrial fibrillation, both vitamin K antagonists and direct oral anticoagulants could be considered, making the decision to start an anticoagulant even more complicated, with a need to evaluate the risks of thromboembolism and bleeding (14).

Technological advances have also led to newer generation balloon-expandable aortic valves, such as the SAPIEN 3 system, to be investigated for aortic regurgitation in patients with difficult anatomy, extending the use of transcatheter valves beyond the traditional indications (15,16). Furthermore, comparisons of self-expanding versus balloon-expandable valves are continually improving prosthesis selection, examining the differences in mortality, vascular complications, pacemaker implantation, paravalvular leak, and hemodynamic performance (17). Peri-

procedural management is also crucial to safety, and in recent years, the use of less-invasive anesthetic techniques, such as conscious sedation in carefully selected patients, has been increasingly favored to ease early mobilization, minimize intensive-care needs and speed recovery (18). As a group, these advances reinforce the status of TAVR as a significant therapeutic advance for high-risk patients and highlight the ongoing importance of rigorous selection of patients for TAVR, as well as its safety, complications, and clinical effectiveness.

Objective: To determine the effectiveness and safety of TAVR in high-risk patients, including procedural success, clinical outcome, complications, mortality, and functional improvement in cardiac function and symptoms.

MATERIALS AND METHODS

Study Design: A Cross-sectional study.

Study Setting: Department of Cardiology and Cardiac Surgery at the Peshawar Institute of Cardiology, Peshawar.

Study Duration: The study was conducted over six months, from June 2025 to November 2025.

Inclusion Criteria: Severe symptomatic aortic stenosis, patients aged 65 years or older and deemed to be at high surgical risk by the multidisciplinary heart team, were included. Eligible patients had suitable anatomical characteristics for transfemoral TAVR and provided written informed consent.

Exclusion Criteria: Active IE, unsuitable vascular anatomy, significant severe uncontrolled comorbid illness, life expectancy <1-year, significant untreated coronary disease, contraindication to antithrombotic therapy, or refusal to participate.

MATERIALS

A multidisciplinary heart team consisting of interventional cardiologists, cardiac surgeons,

anesthesiologists, and imaging specialists were used to assess eligible patients. Baseline assessment included computed tomography angiography for aortic valve anatomy and vascular access, electrocardiography, routine laboratory tests, and transthoracic echocardiography. Patients who were eligible for the study were randomized to study groups based on the study protocol. The TAVR procedure was carried out transfemorally with an appropriately sized transcatheter heart valve guided fluoroscopically and echocardiographically. Success of the procedure, valve function, improvement of the hemodynamics, hospital stay and complications after the procedure were recorded. Vascular complications, bleeding, stroke, acute kidney injury, conduction abnormalities, permanent pacemaker implantation and mortality were monitored. Follow-up evaluations consisted of clinical evaluation and echocardiography to assess symptom resolution, functional status, transvalvular gradients, paravalvular regurgitation, and overall treatment success.

RESULTS

A total of 120 high-risk patients with symptomatic aortic stenosis were enrolled and randomized equally between the transcatheter aortic valve replacement (TAVR) group and surgical aortic valve replacement (SAVR) group, 60 patients in each group. Patients in the TAVR group had a mean age of 75.8 ± 6.4 years, while those in the SAVR group had a mean age of 75.1 ± 6.7 years. The percentages of males in the two groups were 56.7% and 58.3%. Baseline characteristics were similar across groups, and no significant differences between the groups were found in hypertension, diabetes mellitus, chronic kidney disease, and left ventricular ejection fraction.

Table 1. Baseline characteristics of study participants

Variable	TAVR (n=60)	SAVR (n=60)	P-value
Age, years	75.8 ± 6.4	75.1 ± 6.7	0.56
Male, n (%)	34 (56.7%)	35 (58.3%)	0.85
Hypertension, n (%)	45 (75.0%)	43 (71.7%)	0.68
Diabetes mellitus, n (%)	25 (41.7%)	23 (38.3%)	0.71
Chronic kidney disease, n (%)	14 (23.3%)	15 (25.0%)	0.83
LVEF, %	44.8 ± 7.6	45.2 ± 7.4	0.77

Procedural success was achieved in 58 patients (96.7%) undergoing TAVR compared with 56 patients (93.3%) undergoing SAVR. The TAVR group demonstrated a significantly shorter

mean hospital stay of 4.8 ± 1.7 days compared with 8.1 ± 2.4 days in the SAVR group ($p < 0.001$).

Table 2. Procedural and hospitalisation outcomes

Outcome	TAVR (n=60)	SAVR (n=60)	P-value
Procedural success	58 (96.7%)	56 (93.3%)	0.40
Hospital stay, days	4.8 ± 1.7	8.1 ± 2.4	<0.001
ICU stay, days	1.6 ± 0.8	3.2 ± 1.2	<0.001
30-day readmission	4 (6.7%)	7 (11.7%)	0.34

At 30-day follow-up, mortality occurred in 2 patients (3.3%) in the TAVR group and 4 patients (6.7%) in the SAVR group. Stroke occurred in 3.3% versus 5.0%, respectively.

Major bleeding was significantly less frequent following TAVR, whereas permanent pacemaker implantation occurred more frequently after TAVR.

Table 3. Thirty-day safety outcomes

Complication	TAVR (n=60)	SAVR (n=60)	P-value
Mortality	2 (3.3%)	4 (6.7%)	0.40
Stroke	2 (3.3%)	3 (5.0%)	0.65
Major bleeding	3 (5.0%)	10 (16.7%)	0.04
Acute kidney injury	4 (6.7%)	9 (15.0%)	0.14
Permanent pacemaker	7 (11.7%)	3 (5.0%)	0.19

Echocardiographic assessment demonstrated substantial improvement after valve replacement. At follow-up, the mean transvalvular gradient decreased to 10.2 ± 3.8 mmHg following TAVR compared with 12.6 ±

4.1 mmHg following SAVR (p=0.001). Improvement in NYHA functional class was observed in 88.3% of TAVR patients and 80.0% of SAVR patients.

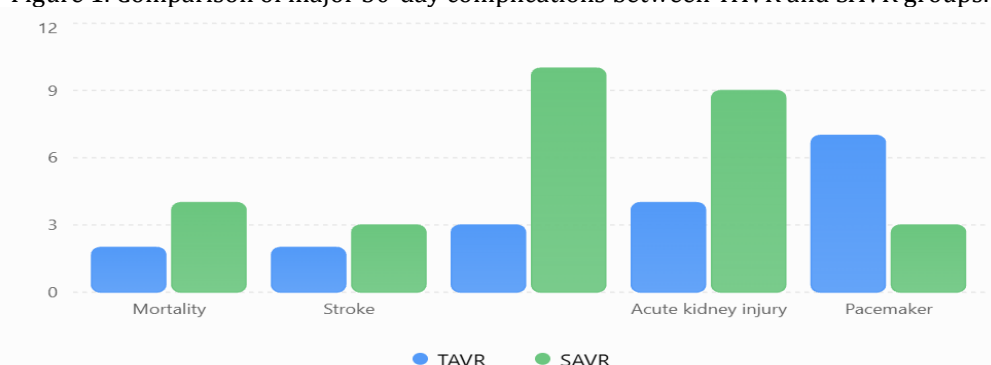
Table 4. Clinical and echocardiographic outcomes at follow-up

Outcome	TAVR (n=60)	SAVR (n=60)	P-value
Mean valve gradient, mmHg	10.2 ± 3.8	12.6 ± 4.1	0.001
LVEF, %	50.6 ± 6.8	49.1 ± 7.1	0.24
NYHA improvement	53 (88.3%)	48 (80.0%)	0.21
Moderate/severe paravalvular leak	3 (5.0%)	1 (1.7%)	0.31

Overall, TAVR demonstrated high procedural success, shorter hospitalization, favorable hemodynamic improvement, and lower major bleeding rates. Mortality and stroke were numerically lower after TAVR, although these

differences were not statistically significant. These findings suggest that TAVR may represent an effective and comparatively less invasive treatment option for appropriately selected high-risk patients.

Figure 1. Comparison of major 30-day complications between TAVR and SAVR groups.



DISCUSSION

The present study assessed the efficacy and safety of TAVR in high-risk patients with severe symptomatic aortic stenosis and found that

TAVR was associated with a high procedural success rate, shorter hospital and intensive care unit (ICU) length of stay, favourable hemodynamic performance, and reduced major

bleeding rates compared to surgical aortic valve replacement (SAVR). While there were no significant differences in mortality and stroke, there were a few numerical differences in these outcomes between the TAVR group and the other groups. The results align with the overall body of evidence that shows TAVR is a safe alternative to traditional surgery for patients who have a higher surgical risk. A meta-analysis of Cross-sectional study comparing TAVR and surgical valve replacement in the various risk groups also showed similar or even better results with TAVR, especially in those for whom surgery was clinically problematic (1).

The overall procedural success rate was 96.7% for the TAVR group and 93.3% for the SAVR group in this study. This impressive success rate is due to improvements in transcatheter valve technology, imaging, vascular access, and patient selection. Procedural and post procedural outcomes may be impacted by device characteristics. Senguttuvan et al. made a comparison between balloon-expandable and self-expanding transcatheter valves in high-risk patients and emphasized that both technologies can be effective, but there may be some differences in terms of specific complications and hemodynamic outcomes (2). Its use in aortic regurgitation (AR) is another testament to the continued growth of transcatheter valve therapy. Increasing evidence has been reported in a systematic review by Liu et al. favoring aortic regurgitation patients with limited treatment options, who could benefit from TAVR (3). Likewise, there is more recent experience using TAVR in pure aortic regurgitation (AR), which has demonstrated good procedural feasibility and clinical results in appropriately selected patients (4).

The shorter hospitalisation in the TAVR group is an important clinical benefit, especially in high-risk elderly and frail patients. The average length of hospital stay in this study was 4.8 days after TAVR versus 8.1 days after SAVR, and intensive care unit (ICU) length of stay was also significantly shorter. Avoid sternotomy and cardiopulmonary bypass for earlier mobilisation and recovery. Meanwhile, there are also technical issues with transcatheter procedures. While rare, coronary obstruction can have severe consequences. Techniques that attempt to reduce this risk in patients with high-risk anatomy who require transcatheter treatment of native or failing bioprosthetic valves have been investigated (5). The positive short-term results, which are now reported even in lower-risk patients with severe aortic valve disease,

continue to lend to the progressive maturity of the TAVR technology (6).

Treatment of associated cardiovascular and systemic diseases can also affect TAVR results. Most of the patients who are undergoing this procedure suffer from heart failure, diabetes, chronic kidney disease and other comorbidities. Therefore, pharmacological strategies for enhancing CV prognosis post-VI are becoming of increasing interest. The use of dapagliflozin in patients undergoing TAVI provides a good example of how the emphasis is shifting to maximising post-procedural medical therapy rather than valve implantation as a standalone therapy (7). In addition, the durability of the valve and the risk of thrombosis are significant issues. Leaflet thrombosis can lead to decreased motion of the leaflets, increased transvalvular gradients, and may also result in thromboembolic complications, warranting careful monitoring and suitable antithrombotic treatment. (8).

The rate of major bleeding was much lower in the current study than in TAVR patients. This finding has clinical importance for those who have high-risk factors, many of whom are elderly, frail, and prone to the complications of bleeding. The choice of post-TAVR antithrombotic therapy thus needs to consider the balance of bleeding and thromboembolic events. In patients without any other indication for anticoagulation, direct oral anticoagulants have been compared with routine antithrombotic strategies, with evidence suggesting that they should not be routinely used (9). Comparative studies of TAVR and SAVR in lower-to-moderate-risk patients have also shown differences in bleeding, vascular complications, valve performance, and recovery rates, which will help guide treatment selection based on patient-specific characteristics (10).

One of the most worrisome complications after TAVR is stroke. The difference in incidence of stroke between TAVR and SAVR patients in the present study was not statistically significant (3.3% vs. 5.0%). When positioning and deploying the valve, there is a risk of cerebral embolisation due to the possibility of dislodging calcific or atherosclerotic material. There is evidence from meta-analysis that CEDs can reduce embolic burden, but that this effect is not seen in clinically meaningful neurological events, which continues to be an area of further research (11). Functional recovery is also a significant issue, and cardiac rehabilitation has been shown to improve physical capacity and prognosis prior to and following transcatheter

valve replacement (12). Recent evaluations of embolic protection devices also highlight the need for judicious patient selection and the need for additional data before EPDs can be routinely recommended (13).

Another common comorbidity among elderly patients who receive TAVR is atrial fibrillation, which makes the selection of an appropriate anticoagulant a challenge. In patients with atrial fibrillation (AF) who have undergone TAVR, comparative evidence indicates that vitamin K antagonists (VKAs) and direct oral anticoagulants (DOACs) differences in both the risk of thromboembolism and bleeding should be taken into account when making treatment decisions (14). Newer generation transcatheter valves have also expanded the use of TAVR. Multicenter experience with the SAPIEN 3 valve in patients with aortic regurgitation has shown that today's valve systems can achieve satisfactory procedural and clinical results even in anatomically challenging patients (15).

High-risk patients often have significant non-cardiac co-morbidities that affect overall prognosis. Cancer is one such disease, and there is systematic evidence that malignancy should be part of multidisciplinary decision making as competing mortality and treatment-related factors may influence the anticipated benefit of TAVR (16). Prosthesis choice is still a factor. Comparative studies of self-expanding and balloon-expandable valves have shown that both platforms work equally well; however, differences in paravalvular regurgitation, permanent pacemaker requirement and hemodynamic performance could affect the choice of device (17). Permanent pacemaker implantation was numerically more prevalent following TAVR in the present study, consistent with the known risk of conduction disturbances following transcatheter valve deployment.

Last, but by no means least, anesthetic strategy is a key part of modern TAVR pathways. In the right patient population, these treatments may shorten recovery from the procedure, minimize the need for intensive care unit management and promote earlier discharge from the hospital than more aggressive anesthesia (18). The results of this study collectively suggest that TAVR is a useful and relatively safe intervention in high-risk patients with morbid aortic stenosis. In the elderly and frail patients, these benefits of reduced major bleeding, improved valve hemodynamics, and decreased hospital stay are especially pertinent. However, complications like vascular injury, conduction abnormalities, paravalvular leakage,

thrombosis and neurological events are significant. Thus, careful patient selection, heart team evaluation, proper selection of the prosthesis, optimized antithrombotic therapy and structured follow-up after the procedure are crucial to optimize the clinical benefits of TAVR.

CONCLUSION

TAVR was found to be statistically superior in terms of efficacy and safety in high-risk patients with aortic stenosis who have severe symptoms. TAVR was associated with a high procedural success rate and was associated with shorter hospital and intensive care unit stays, lower major bleeding rates, and significant improvement in valve hemodynamics and functional status compared with surgical aortic valve replacement in the present study. The TAVR group also had numerically less mortality and stroke rates, which were not statistically significant. While these advantages are present, there are also complications to consider, including conduction disturbances, permanent pacemaker requirement, paravalvular leakage, vascular complications, and thromboembolic events. Therefore, careful patient selection is essential, and this is achieved by a multidisciplinary heart-team approach. Overall, TAVR is a clinically and clinically useful, less invasive treatment option for high-risk patients, especially those with significant risks of cardiac surgery.

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