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Advances in TAVR: A Review of Current Evidence and Clinical Implications

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ABSTRACT

Introduction: Transcatheter aortic valve replacement (TAVR) has taken place alongside surgical aortic valve replacement (SAVR) as an effective therapy for aortic stenosis – especially for patients with high and intermediate surgical risk. Subsequent developments have expanded these indications to include low-risk and other technically challenging subgroups. **Objective**: To evaluate the clinical outcomes and procedural success of TAVR in a tertiary care hospital in Pakistan. **Materials and Method**: This prospective observational study was conducted at Hayatabad Medical Complex Peshawar, Pakistan from January, 2024 to June, 2024. The inclusion criteria were symptomatic severe aortic stenosis patients, and they underwent TAVR with either balloon-expandable or self-expanding valves. **Results**: In 108 patients, the procedural success rate was 97.2%. Mean aortic valve area increased post-procedure, and there were low short-term adverse events mortality 1.9%, stroke 2.8%, and pacemaker implantation 10.2%. **Conclusion**: Real-world studies have shown that TAVR is a safe and effective approach for aortic stenosis in patients and supports procedural and clinical success.

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has become an appealing treatment modality in patients with aortic stenosis having intermediate or high surgical risk because it is as effective as surgical aortic valve replacement (SAVR). Continuous evolution in device technology, procedural techniques, and medical management has enhanced patient prognosis and expanded TAVR indication across a broader patient population. Initially introduced for treating patients who were considered nonsurgical candidates, TAVR has been increasingly used for low-risk patients and, in some subgroups, shows similar or better outcomes compared to SAVR (1). In recent years, highly effective evidence has introduced and established TAVR as a first-line therapy in many instances of severe aortic stenosis.

Another critical change observed with TAVR is its use in treating patients with bicuspid aortic valve (BAV) stenosis, which is anatomically more complex given its distinct morphology. New techniques, flexibility, and imaging and planning devices have made TAVR possible and more preferred in such patients, though the choice of patients should be carefully selected (2). In addition, comparisons of TAVR with SAVR in applied coronary subjects, including patients with left ventricular assist devices (LVADs), also highlight the clinical applicability of TAVR. Data presented in the study suggest that TAVR yields similar performance in this subset of patients, given its versatility in a wide range of clinical scenarios (3). Among low-risk patients, 5-year outcomes confirm sustained benefits of TAVR based on preserved hemodynamic results and similar mortality to SAVR, arguing for TAVR as a long-term treatment (4).

Another area of development in the TAVR process can be seen in valve-in-valve (ViV) cases in which TAVR is used to replace a previously implanted functional bioprosthesis that has experienced structural degeneration. Several meta-analyses demonstrate that ViV TAVR has emerged as a safer and more effective approach than redo-SAVR, especially in high-risk patients with lower reoperation complications and shorter recovery periods. Also, TAVR has been proven best suited for patients with moderate aortic stenosis who present with heart failure and are treated conservatively earlier. The TAVR UNLOAD trial provides specifics and demonstrates the benefit of early intervention and

improved functional status, especially in symptomatic patients with systolic heart failure (6). Similar approaches are also being considered in asymptomatic severe aortic stenosis. The EARLY TAVR trial looks at the outcome of early TAVR procedure compared to conservative management, which supports the shift towards more proactive interventional strategies to address potential disease progression and complications before they occur (7).

For individuals who have received previous TAVR and developed valve degeneration, the idea of TAVR-in-TAVR has received much attention. It has been proved to be technically practicable and safe based on systematic reviews, which supports its application for SVT for dealing with structural valve failure. However, durability data are still being collected (8). The landmark trials show favorable trends favoring TAVR regardless of the patient's risk profiles. Compared to surgical AVR, TAVR has been shown to have similar or better outcomes regarding mortality and stroke rate along with better quality of life, especially in patients with low surgical risk (9). Another vascular complication is a paravalvular leak, which has also been resolved by continuous innovations in TAVR technology (10). The OPERA-TAVI registry confirms the excellent performance of self-expanding and balloon-expandable next-generation valves, highlighting the effectiveness of TAVR in actual clinical practice (11).

However, TAVR has challenges that must be addressed to advance its development and implementation. Pulmonary hypertension, for instance, is another factor that falls under periprocedural risk factors that have been believed to be linked with unfavorable prognoses among TAVR patients. These factors are essential to minimize or manage to contribute positive modifiers for procedural success and survival (12). There are also emerging differences concerning TAVR intervention delivery. A report from France revealed that age and sex affect TAVR use by showing that aged male patients are more frequent users of TAVR than women, hence the need for TAVR equity (13). However, applying TAVR to patients with reduced ejection fraction and non-severe aortic stenosis has developed new clinical alternatives. There is preliminary data that TAVR may also be beneficial in this unusual population, but further confirmation is required (14).

Finally, issues like infective endocarditis continue to be a leading post-procedural complication. Recent reviews have discussed the incidence, risk factors, and management of TAVR-related endocarditis and emphasized interventions to prevent this often fatal complication as well as early diagnostic approaches (15). In combination, these works provide an overall view of TAVR as an impactful therapy for structural heart illness, highlighting the need for research, proper patient selection, and teamwork in cardiology.

Objective: To review the latest advancements in transcatheter aortic valve replacement (TAVR), evaluate current clinical evidence, and discuss its implications for patient outcomes, procedural strategies, and future directions in cardiology.

MATERIALS AND METHODS

Design: Retrospective Observational Study.

Study setting: Hayatabad Medical Complex Peshawar, Pakistan.

Duration: This study conducted in the duration from January, 2024 to June, 2024.

Inclusion Criteria

The study population included any patient with severe aortic stenosis aged 50 years and above who received TAVR during the study period. Patients of both genders were included in the study, and patients with low, intermediate, and high surgical risk were identified using Heart Team assessment. Patients who have undergone valve-in-valve or TAVR-in-TAVR therapies were also considered.

Exclusion Criteria

Exclusion criteria for the present analysis were patient records without a complete medical database, patients who were lost in our follow-up, patients with urgent or elective surgery for complicated significant cardiac abnormalities, and active infective endocarditis.

Methods

The data were collected from the case records of patients who received TAVR at Hayatabad Medical Complex Peshawar, Pakistan from January, 2024 to June, 2024 on a miscellaneous basis. Patients were evaluated regarding their demographic features, clinical presentation, echocardiographic diagnosis, those of the procedure, and their in-hospital course. The procedure was done through a transfemoral route with local or general anesthesia to the patient at the operator’s discretion. The choice of self-expanding or balloon-expandable valves depended on the anatomical compatibility of the patient, as assessed by imaging, including CT-angiography and transthoracic echocardiography before the procedure. Procedural success was assessed using the Valve Academic Research Consortium-3 (VARC-3) definitions. After the operation, all the patients were accompanied to the cardiac intensive care unit, and they received postoperative echocardiography and serial examination to evaluate the outcome of the valves as well as possible complications like a paravalvular leak or new conduction defects. Subsequent data were collected through outpatient clinic review or telephonic interviews assessing 30-day clinical events such as mortality, stroke, vascular complications, and rehospitalization.

RESULTS

Consequently, TAVR was performed on 108 patients at the Hayatabad Medical Complex Peshawar, Pakistan from January, 2024 to June 2024. They were 74.2 ± 8.6 years of age, and 61.1% were men. The baseline characteristics of the patients are presented in Table 1.

Table 1

Baseline Characteristics of Study Population

Parameter	Value (n = 108)
Age (mean ± SD)	74.2 ± 8.6 years
Male Gender	66 (61.1%)
Hypertension	89 (82.4%)
Diabetes Mellitus	51 (47.2%)
Chronic Kidney Disease	26 (24.1%)
Coronary Artery Disease	45 (41.7%)
Prior CABG	18 (16.7%)
Atrial Fibrillation	32 (29.6%)
LVEF < 40%	21 (19.4%)

Most patients received transfemoral TAVR (94.4%), but several patients required other access methods. Self-expandable valves were implanted in 62 (57.4%) patients, and balloon-expandable valves in the remaining 46 (42.6%) patients. The procedural success was achieved at 97.2%, with valves in three cases having intra-procedural complications of valve position and severe paravalvular regurgitation. An echocardiographic assessment done after the procedure showed an increase in the aortic valve area and a decrease in the mean gradient. It has been observed aortic valve area, which was 0.65 ± 0.12 cm² in pre-procedure, got raised up to 1.72 ± 0.24 cm² after the procedure. The mean aortic gradient was reduced from 46.1 ± 9.7 mmHg to 10.4 ± 3.6 mmHg.

Table 2

Procedural and Echocardiographic Outcomes

Outcome	Value
Transfemoral Access	102 (94.4%)
Self-expanding Valve Used	62 (57.4%)
Balloon-expandable Valve Used	46 (42.6%)
Procedural Success	105 (97.2%)
Aortic Valve Area (Pre vs. Post)	0.65 → 1.72 cm²
Mean Aortic Gradient (Pre vs. Post)	46.1 → 10.4 mmHg

Thirty-day clinical outcomes were favorable. Total mortality due to any cause was detected in two patients (1·9%). Three patients had a stroke (2.8%), while five patients had other major vascular complications (4.6%). Eleven patients (10.2%) received a permanent pacemaker, mainly for complete heart blockage. Six patients (5.6%) were readmitted within 30 days for heart failure or arrhythmic events.

Table 3

30-Day Clinical Outcomes

Outcome	Frequency (%)
All-Cause Mortality	2 (1.9%)
Stroke	3 (2.8%)
Major Vascular Complications	5 (4.6%)
Permanent Pacemaker Implantation	11 (10.2%)
30-Day Readmission	6 (5.6%)

These findings suggest that TAVR can be performed safely in a real-world Pakistani population with high procedural success, good hemodynamic improvement, and acceptable early follow-up risk.

DISCUSSION

The findings of this investigation affirm the increasing use and effectiveness of the TAVR procedure in a more diverse group of patients, acknowledging the trends in cardiovascular intervention. As postulated in previous studies, TAVR has become the standard of care for patients with inoperable or high surgical risk for surgical interventions and those with intermediate and low surgical risk (1). This study further validates TAVR from a clinical perspective, especially in developing settings, as demonstrated by comparable short-term results similar to large registries from more developed countries such as Pakistan. A significant advance in TAVR in the last decade has been the evolution of the technology to treat anatomically complex patients, particularly those with bicuspid aortic valve (BAV). In the present study, BAV data were not grouped separately, while new literature reveals that during recent years, due to the development of new device technologies and better imaging, outcomes in BAV are significantly better (2).

BAV anatomy, initially thought to be a relative contraindication due to asymmetric calcification and elliptical annulus, was treated with the relatively newer generation of valves and thus lays down success rates similar to those of tricuspid valve anatomy. The evaluation of the TAVR versus surgical aortic valve replacement (SAVR) remains a prominent area of concern among clinicians. The comorbidities, such as LVAD, also revealed that TAVR can provide results as effectively as SAVR or even better when regarding hospitalization time and perioperative mortality (3). Regarding this argument, the data reveal a high procedural success rate with minimal complications in a population with mixed risk. This is in agreement with previous long-term studies, including patients at lower surgical risk in which TAVR has shown durable valve implantation and relatively low mortality and stroke rates at 5 years, thereby validating its use in surgical candidates (4).

Valve-in-valve implantation and transcatheter aortic valve replacement – in transcatheter aortic valve replacement (TAVR-in-TAVR) procedures are expanding the possibilities of minimally invasive therapy in cases of structural valve degeneration. These are useful in the elderly or any complicated patient, especially when there is no need to open the chest again with low mortality and complications (5). Interventions

such as these are relatively rare in the practice due to the cost and availability of devices. Still, they are on the rise internationally, and one can anticipate them to become standard applications as procedural expertise is gained and follow-up data is collected. One such significant advance has been the application of TAVR in patients with moderate aortic stenosis and systolic heart failure. In this study, TAVR UNLOAD provided symptomatic and LV remodeling benefits in the subset and promoted the paradigm from a wellness approach to an intervention strategy (6). The EARLY TAVR trial raises the question of whether intervention before the onset of symptoms will reduce adverse events and decrease left ventricular dysfunction (7). Although not directly discussed in the study, these emerging paradigms impose new challenges into screening and decision-making within future clinic experience, particularly in the context of late-stage diagnosis.

Another emerging concept is TAVR-in-TAVR, a promising field that has been increasingly utilized recently. Given that the current TAVR practice expands the patient demographic to younger, lower-risk patients who will likely survive beyond their first bioprosthesis, it is essential. Data from clinical trials and registries suggest that repeating TAVR within an initial transcatheter valve is safe but requires careful consideration of anatomical features, such as the risk of coronary obstruction or elevated residual gradients (8). Follow-up works have also strengthened the prognosis of TAVR in terms of clinical applicability. These studies have demonstrated improved mortality, valve durability, and quality of life in low-risk patients, making TAVR even more suitable across the surgical risk spectrum. These are some of the long-term outcomes that are a result of continuous technological improvement and previous limitations like paravalvular leak, conduction disturbances, and access-related complications (10).

The OPERA-TAVI registry investigates the real-world outcomes of new-generation self-expanding and balloon-expandable valves. The preference for one device over the other depends on the accomplishments, size, and shape of the patient's anatomy. However, both present excellent results in specific categories of interventional procedures (11). This is in concordance with the current study's findings, the successful deployment rates of both types of valves, and the acceptable level of complications experienced across the different patient subsets. Therefore, regarding the comorbidities seen during the periprocedural period, TAVR constitutes one of the focal points of clinical consideration. For example, they have observed higher rates of post-procedural mortality and heart failure re-admission among patients with pulmonary hypertension (12). Researching and managing such coexisting conditions before TAVR can help enhance procedural efficiency and outcome. Age and Sex.Other socio-demographic factors also affect access to TAVR and its outcome. Preceding research conducted in France and other countries has revealed disparities between the referral and procedural rates of men and women, thus signaling the importance of having gender equality in healthcare (13).

While this study does not report outcomes based on the sex of the participants, understanding these differences can aid in developing future studies and policies that involve every sex of patients within the cardiovascular disease domain. Emerging data support TAVR in patients with reduced ejection fraction and non-severe aortic stenosis. Suppose TAVR is as effective in aortic stenosis with moderate symptoms and anatomy as in severe AS with left ventricular dysfunction. In that case, the current classification of AS severity may not entirely fit this group of patients, and a more objective measurement of seriousness may be needed (14). Lastly, the issue that deserves attention in the long-term follow-up of patients with TAVR is infective endocarditis. This is an infrequent complication, but it has a high morbidity and mortality rate. According to the reviewed studies, perioperative aseptic measures, administering antibiotics, and the early diagnosis of this complication are critical to preventing it (15). As the adoption of TAVR grows, infection control and early detection protocols should also be developed. Finally, these observations align with the current global trends that have shown that TAVR is indeed safe and efficacious and has continued to expand its role in managing patients with AS regardless of the situation. Recent updates in technology and imaging and improvements in patient selection have made it an essential tool in the day-to-day management of structural heart disease.

CONCLUSION

TAVR has been established as a revolutionary procedural intervention in the clinical management of AS comparable to surgical AVR, especially for patients considered at high risk for surgical procedures. The present study conducted at the Hayatabad Medical Complex Peshawar, Pakistan has shown procedural success, improvement in hemodynamics, and acceptable short-term complication rates, which supports the effectiveness of TAVR in the actual South Asian region. The results outlined here align with the global evidence concerning anatomical and clinical complexity in high-risk intermediate and low-risk patients undergoing PCI. New developments in device technology, procedural techniques, and patient selection will extend these benefits to younger and asymptomatic populations. More longer-term follow-up data and, importantly, the application of these techniques in low-resource environments provide a compelling vision for TAVR to enhance global cardiovascular medicine.

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