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COMPARATIVE EFFECTIVENESS OF TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) VERSUS SURGICAL AORTIC VALVE REPLACEMENT (SAVR): A COMPREHENSIVE REVIEW

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Abstract
"Aortic stenosis" (AS) is a cardiac condition in which the aorta narrows down which creates a hindrance to the flow of blood. This ultimately leads to increased pressure in the left ventricle which increases the risk of heart failure. Aortic stenosis was previously managed as Surgical Aortic Valve Replacement which was the gold standard till the previous decade. Recently, a more innovative approach, Transcatheter Aortic Valve Replacement (TAVR) is used. The goal of both these treatment methods is to replace the dysfunctional valve with a functional substitute. TAVR has been shown to be a better alternative to SAVR. However, there is a scarcity of research comparing the outcomes of TAVR and SAVR. Limited research is available on the comparison between TAVR and SAVR. The purpose of this review article is to compare the outcomes of TAVR vs SAVR in various studies.

Introduction
Aortic stenosis is a coronary condition in which there is obstruction to the blood flow in the aorta. It affects almost 3% of the population older than 65 years, survival rate is more in asymptomatic

patients. It decreases rapidly after symptoms appear. This is because of compensation by left ventricular hypertrophy and atrial augmentation of preload in the asymptomatic phase. As the disease progresses, these compensatory mechanisms fail, leading to appearance of symptoms of heart failure, angina, or syncope (1). Treatment of aortic stenosis is aortic valve replacement, conventionally Surgical Aortic Valve Stenosis was performed. Currently, Transcatheter Aortic Valve Replacement is preferred. In 2012, FDA approved the use of TAVR in high risk patients (2). TAVR is performed under direct visualisation with fluoroscopy or transesophageal echocardiogram (TEE) guidance. The most preferred approach is the transfemoral approach which is least invasive. If not feasible, the procedure can be performed by subclavian, apical or trans-aortic approaches which are more invasive. Two types of valves are approved by the FDA, the SAPIEN valve and the CORE valve. The SAPIEN valves are made of bovine pericardial tissue and a chromium cobalt alloy frame and are balloon expandable. The newest generation of CORE valves is the EVOLUT-R which is composed of porcine tissue and a nitinol frame. It does not not require balloon expansion (self-expandable) and has the ability for repositioning after deployment (2). Surgical Aortic Valve Replacement involves the use of a heart lung machine to stop the heart and access the aortic valve. Traditionally median sternotomy was performed as it allows complete access to the cardiac structures (3). There is also a parasternal approach but it is avoided because of chest wall hernias (4). Other methods include the right mini thoracotomy approach by Benetti (5) and the mini sternotomy approach by Gundry (6). Possible complications associated with TAVR range from the need for a permanent pacemaker, to vascular injury, stroke, annular rupture, paravalvular leak, bleeding, left ventricular perforation, acute myocardial infarction, cardiac tamponade, acute kidney injury, infection, hypotension, and death (2)(7). Post SAVR complications include life-threatening or disabling bleeding, encephalopathy, atrial fibrillation, acute kidney injury, aortic dissection, and injury to other heart structures because of greater invasiveness (8). This review aims to analyse recent studies published on PubMed, to compare the effectiveness of TAVR and SAVR based on patient outcomes, procedural complications, and long-term survival.

Methodology

Data Sources and Search Strategy

To conduct this comprehensive review, we searched the PubMed database for relevant articles published up to May, 2024. The keywords included " Transcatheter Aortic Valve Replacement", " Surgical Aortic Valve Replacement", " Aortic Stenosis", " TAVR" and " SAVR" . Boolean expressions (AND, OR) were used to refine the search. The search was limited to articles published in English and involving human subjects only.

Inclusion Criteria

- Patients with severe aortic stenosis or aortic insufficiency
- Patients undergoing TAVR or SAVR for the first time
- Age $\geq$ 18 years
- Patients with complete medical records and follow-up data

Exclusion Criteria

- Patients with concomitant cardiac procedures (e.g., coronary artery bypass grafting, mitral valve repair)
- Patients with active endocarditis or cardiac tumor
- Pregnant or breastfeeding women
- Patients with severe comorbidities (e.g., advanced kidney disease, liver disease)
- Patients with incomplete medical records or missing follow-up data

Study Selection

Initial search presented 1245 articles. After removing the duplicates, 975 articles left. Two reviewers (R1 and R2) screened the title and abstract of the articles according to the inclusion and exclusion criteria after which 146 articles were found to be potentially eligible and underwent full text review. In the end, 54 articles met all the criteria and were included in the review.

Quality Assessment

The methodological quality of the studies was assessed using Newcastle Ottawa Scale (NOS) for observational studies and Cochrane Risk of Bias Tool for RCTs.

Review

Patient Outcomes

Mortality and Survival Rates

TAVR has proven to be more advantageous over SAVR in terms of mortality and survival rates, various studies have concluded that TAVR has more survival rate and less mortality rate as compared to SAVR. According to Fusari et al. (9), morbidity and mortality rates associated with TAVR are less as compared to those of SAVR. They included 187 patients out of which 81 were treated with SAVR and 106 were treated with TAVR. There were fewer ICU cases after TAVR. TAVR resulted in significant mean aortic gradient reduction and increased functionality (higher than SAVR). Although for the first year, survival was comparable between TAVR and SAVR , at later follow-up, there were significantly higher deaths because of cardiac reasons in SAVR. According to Smith (10), 30-day mortality rates in TAVR are less than SAVR. They randomly assigned 699 high risk patients of aortic stenosis to undergo either TAVR or SAVR and found that the 30-days mortality rate in TAVR was 3.4 % as compared to 6.5 % in SAVR. The mortality rate after 1 year was 24.2% and 26.8%, respectively. They concluded that both valve replacement procedures had similar survival rates at 1 year, indicating TAVR as a viable alternative to SAVR. Mack et al. (11) conducted a similar study in 2019. They randomly assigned patients with severe aortic stenosis with low surgical risk to undergo either TAVR or SAVR. The primary endpoint was composite of death, stroke or hospitalisation. They found that the rate of the primary composite endpoint at 1 year in the TAVR group was significantly lower than the SAVR group (8.5% vs. 15.1%). At 30 days, TAVR had a lower rate of stroke and lower rates of new-onset atrial fibrillation. TAVR also had a lower risk of a poor treatment outcome at 30 days (11). Khan et al. compared the efficacy of TAVR and SAVR. They extracted data from various reputable academic sources and primarily focused on assessing the mortality rates of the two procedures at 30 days and 12 months intervals (12). According to them, there was a 40.1% lesser risk of 30-days all-cause mortality in the TAVR approach.

Quality of Life and Functional Status

Researches suggest quality of life and achievement of functionality following TAVR is better than after SAVR. Fliegner et al. found that short term improvement was rapid post TAVR as compared to SAVR (13). They used HRQOL as a measure of recovery of the patient including the Medical Outcomes Survey Short-Form 36 (SF-36) (14), the Barthel Index (to measure functional status), self-reported perception of quality of life (QoL), and the EuroQoL (EQ-5D) (15). Using these instruments they found that TAVR is beneficial over SAVR at 1 month follow up. Similarly, Reynolds et al. conducted a study that measured HRQOL among high-risk patients after TAVR and SAVR and found that improvements in HRQOL after one year were similar in both (16). After 1-month follow-up, transfemoral-TAVR patients showed clinically relevant improvements in HRQOL as compared with SAVR (16). Quality of life studies of the PARTNER 2 cohort A clinical trials showed similar results, 1-month HRQOL benefits were significantly better for TF-TAVR than for SAVR patients, however, long term 1 and 2 years benefits for TAVR and SAVR were no different (17). Makkar et al. conducted a follow up study for 5 years, they selected 2037 patients with severe aortic stenosis and randomly assigned them to undergo TAVR or SAVR (18). The patients' ECG and health-status outcomes were followed for 5 years. They concluded that in the long term, after 5 years, there was no significant difference in the mortality rates of the TAVR group and the SAVR group (18). Baron et al. reported that TAVR resulted in greater QoL improvements in the short term, and long term over SAVR at 1, 6 and 12 months (19). They studied 1000 low risk patients with severe aortic stenosis who randomly underwent TAVR or SAVR and found that TAVR was associated with meaningful early and late health status benefits as compared with SAVR.

Procedural Complications

Vascular and Conduction Complications

According to Conte (8), vascular complications were higher in TAVR. Research suggests the most common vascular complications are vessel dissection, rupture, formation of pseudoaneurysms, and access site hematoma (20) (21). Mack et al. suggest that there is no significant difference in vascular complications between both groups (11). According to Lou et al. (22), TAVR has a higher associated risk of reintervention, major vascular complication, paravalvular leak, and PPM. Many studies suggest that TAVR increases the risk of permanent pacemakers. Lou et al. (22) found that the incidence of PPM in TAVR was 14.7% vs. 5.6% in the SAVR group. Saia et al. conducted a study on 73 patients who underwent TAVR, and found that 28.3% of the patients required PPM post TAVR (23).

Bleeding Complications

Studies suggest that SAVR is associated with more bleeding because of greater invasiveness. Généreux et al. (24) conducted a study to identify bleeding complications after SAVR and TAVR. They concluded that among high-risk patients enrolled in the PARTNER I randomised trial, bleeding complications were more common after SAVR than after TAVR and resulted in poor prognosis. Similarly, Lou reported 17 % incidence of bleeding after in TAVR vs 44.3 % in the SAVR group.

Stroke and Acute Kidney Injury

According to the literature comparing TAVI vs. SAVR in patients with severe aortic stenosis , the risk of stroke with TAVI was lower. Siemieniuk et al. (25) in their systemic review concluded that transfemoral (TF) TAVR is more beneficial as compared to SAVR because of low risk of stroke, atrial fibrillation and acute kidney injury. However, SAVR is more beneficial as compared to transapical (TA) TAVR in terms of these factors. Compared with SAVR, transfemoral TAVR had reduced risk of stroke (-20, -37 to 1, moderate certainty), atrial fibrillation (-178, -150 to -203, moderate certainty), and acute kidney injury (-53, -39 to -62, high certainty). Compared with SAVR, transapical TAVI had higher risk of stroke (45, -2 to 125, moderate certainty) (25). Similarly, Khan et al. (12) found that patients who underwent TAVR had a 36% reduced risk of 30-day stroke incidence RR 0.64 (95% CI: 0.38 - 1.9, $P = 0.10$) and 56% reduced risk of acute kidney injury, RR 0.43 (95% CI: 0.35 - 0.54, $P < 0.001$).

Cost of treatment

According to Baron et al. , the total procedural cost of TAVR is approximately 20,000 $ more than SAVR (26). However, breaking down the cost on the basis of types of valves used, index hospitalisation for Sapien XT valve TAVR is $2,888 higher, and for Sapien 3 valve TAVR is $4,155 lower. With reduced hospital stay durations and follow up needs, TAVR reduces the lifetime cost by 8000-10000$ while increasing the quality adjusted survival by 0.15 to 0.27 years (26). Hence TAVR is proving to be more cost effective than SAVR.

Hospital stay and Rehospitalization

Many studies suggest that the length of stay, LOS of TAVR is less than SAVR. In 2012, a study found that the mean LOS for TF-TAVR was 6 days less than SAVR (27). In another study, Brescia found that LOS for TAVR was shorter as compared to SAVR (6.2 ± 5.6 for TAVR vs 10.2 + 7.5 days for SAVR) (28). A 2020 suggested similar result concluding that TAVR had “significantly shorter (median) LOS " at six days, compared with SAVR's eight days (29). Despite shorter LOS, the readmission rates of TAVR are higher than SAVR (30). According to this study, 17.9 % of patients after TAVR were readmitted to hospital within 30 days. Goldsweig et al., (31) found that the average number of unplanned admission days for SAVR was 2.0 and for TAVR was 3.0.

Conclusion

Both TAVR and SAVR approaches have their advantages and limitations. TAVR offers lesser mortality risk, lesser bleeding, stroke and kidney complications, and improved quality of life, thus is a better option for high risk patients. However, SAVR still remains a robust option with lower risk of vascular and conduction complications. Ongoing advancements in TAVR technology will be crucial in improving outcomes.

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