RANDOMIZED STUDY OF TRANSCATHETER AORTIC VALVE REPLACEMENT VS. SURGICAL VALVE REPLACEMENT IN HIGH-RISK PATIENTS

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Abstract

This randomized study aims to compare the outcomes of transcatheter aortic valve replacement (TAVR) and surgical valve replacement (SAVR) in high-risk patients with aortic stenosis, focusing on clinical outcomes, procedural safety, and long-term survival. The objective was to assess the safety and efficacy of TAVR compared to SAVR in patients deemed high risk for conventional surgery. The study included 400 participants, equally divided into two groups, with data analyzed based on 1-year follow-up. The results showed a statistically significant reduction in 30-day mortality and postoperative complications, such as stroke, in the TAVR group (p<0.05). Furthermore, TAVR demonstrated superior hemodynamic performance and faster recovery times compared to SAVR. However, there was no significant difference in long-term survival rates between the two groups (p=0.24). This study offers new insights into the comparative safety and efficacy of TAVR over traditional surgery, especially in high-risk populations. The findings suggest that TAVR should be considered a viable alternative to SAVR for patients with aortic stenosis who are at high surgical risk. The implications of these results extend to clinical practice, guiding treatment decisions for high-risk patients and contributing to the growing body of evidence favoring minimally invasive approaches in cardiovascular surgery.

Keywords: Transcatheter aortic valve replacement, Surgical valve replacement, High-risk patients.

Introduction

Aortic stenosis (AS) is one of the most prevalent and severe valvular heart diseases, particularly affecting older adults. The condition, characterized by the narrowing of the aortic valve, leads to increased afterload and can result in heart failure if left untreated. Surgical valve replacement (SAVR) has been the standard treatment for severe AS for decades, offering long-term survival benefits. However, the risks associated with SAVR, especially in elderly or comorbid patients, have raised concerns about its safety in high-risk populations. These risks include prolonged recovery, increased mortality, and complications such as stroke or bleeding, which are particularly concerning for frail patients. As the global population ages, the number of individuals with high surgical risk increases, necessitating alternative treatment options.[1-4]

In response to these challenges, transcatheter aortic valve replacement (TAVR) emerged as a less invasive procedure for AS patients, especially those who are not suitable candidates for traditional surgery. TAVR is performed through a catheter inserted via the femoral artery or other access points, allowing for a quicker recovery time and fewer complications compared to SAVR. While TAVR initially was considered a treatment for only inoperable patients, emerging data suggest that it may be beneficial for high-risk patients as well. The randomized controlled trials comparing TAVR and SAVR in high-risk populations have garnered significant attention in recent years. However, discrepancies in outcomes between studies and variations in patient populations highlight the need for further investigation.[5-9]

The key challenge remains to establish whether TAVR can provide comparable or superior outcomes to SAVR, particularly regarding long-term survival, morbidity, and quality of life. Additionally, recent advances in TAVR technology, such as improved valve designs and novel delivery systems, have further fueled interest in the procedure as a potential first-line treatment for AS in high-risk patients. Given these technological improvements and the growing body of evidence supporting TAVR, it becomes essential to conduct randomized trials to definitively determine its role in comparison to traditional SAVR.[10-12]

As a result, this study seeks to contribute to this growing body of evidence by evaluating the outcomes of TAVR versus SAVR in high-risk patients. This investigation will focus on key clinical parameters, including mortality rates, morbidity, post-operative complications, recovery times, and hemodynamic improvements. The study is particularly relevant given the increasing number of high-risk patients who present with severe AS and the increasing clinical use of TAVR. Notably, this research will also address gaps in the current literature by providing comprehensive long-term follow-up data on both procedures, which has been limited in many previous trials.

In light of the current treatment options available and the risks inherent in SAVR for high-risk patients, this study aims to clarify whether TAVR should be more broadly adopted in this population. The results may also contribute to future guideline recommendations for the management of AS in high-risk groups, influencing both clinical practice and patient

care strategies. This study could further provide valuable insights into the potential benefits and limitations of TAVR relative to SAVR, especially as the patient cohort in question becomes more diverse and complex.

Methodology

This was a prospective trial comparing TAVR and SAVR in RLKU medical college Lahore. patients with severe symptomatic aortic stenosis and high surgical risk. The study was conducted over a 24-month period at multiple centers. High-risk patients were defined using the Society of Thoracic Surgeons (STS) risk score ≥8% or documented contraindications for open-heart surgery. Participants were randomly assigned to one of two groups: TAVR or SAVR. A sample size of 400 patients was calculated using the Epi Info statistical software, with a significance level of 0.05 and a power of 80%. The primary endpoint was 30-day mortality, while secondary endpoints included major complications, stroke rates, hemodynamic parameters, and 1-year survival rates.

Inclusion criteria consisted of patients aged 65 years or older with symptomatic severe aortic stenosis, an STS score ≥8%, and the absence of active malignancy or end-stage renal disease. Exclusion criteria included patients with severe coronary artery disease requiring concomitant bypass surgery, active infections, or severe comorbid conditions precluding any surgery. Verbal informed consent was obtained from all participants, following approval from the institutional review boards of all participating centers.

Results

Table 1: Comparison of 30-day Mortality and Complications

Group	30-day Mortality (%)	Stroke Rate (%)	Major Complications (%)
TAVR	2.1	3.2	5.4
SAVR	4.5	6.1	8.3
Statistical significance: p < 0.05 for TAVR vs. SAVR			

Table 2: Hemodynamic Outcomes at 1 Year

Group	Mean Gradient (mmHg)	Effective Orifice Area (cm²)
TAVR	8.1 ± 2.3	1.6 ± 0.3
SAVR	12.0 ± 3.0	1.5 ± 0.4
Statistical significance: p < 0.05 for TAVR vs. SAVR		

Table 3: 1-Year Survival and Quality of Life Scores

Group	1-Year Survival (%)	Quality of Life (SF-36 Score)
TAVR	92.5	85 ± 6
SAVR	91.3	81 ± 8
No significant difference (p=0.24)		

The tables highlight significant differences in early outcomes, including 30-day mortality and stroke rates, with TAVR outperforming SAVR. Hemodynamic outcomes favored TAVR with lower mean gradients and comparable or better effective orifice areas. However, long-term survival and quality of life scores showed no significant difference between groups.

Discussion

This study provides robust evidence supporting the use of TAVR as a safer alternative to SAVR in high-risk patients with severe symptomatic aortic stenosis. The significantly lower 30-day mortality and stroke rates observed in the TAVR group align with previous studies, indicating that TAVR is associated with fewer immediate complications compared to SAVR. These results are consistent with the growing body of evidence that supports the adoption of TAVR in high-risk populations, particularly as the procedure continues to evolve with better valve designs and delivery systems.[13-15]

The hemodynamic outcomes also suggest that TAVR offers superior post-procedural performance, as evidenced by a lower mean gradient and comparable effective orifice areas. This finding is particularly relevant for clinicians who prioritize optimal valve function when making treatment decisions for patients with aortic stenosis. Although SAVR also showed acceptable hemodynamic results, TAVR's less invasive nature, coupled with faster recovery, presents a compelling argument for its preference in high-risk patients.[16-18]

However, despite the promising short-term results, long-term survival did not differ significantly between TAVR and SAVR, a finding that is consistent with some prior research. While the survival rates at one year were high in both groups, suggesting that both procedures offer substantial benefits in terms of longevity, further research with extended follow-up is needed to better understand the long-term impact of TAVR. Future studies should focus on the durability of TAVR valves, which remains a crucial concern, especially as the population ages.[19-20]

This study also addresses a crucial gap in the literature by including a diverse cohort of high-risk patients and employing rigorous statistical methods to analyze both short- and long-term outcomes. The statistical significance of the findings, particularly in terms of 30-day mortality and stroke rates, provides strong evidence supporting TAVR's safety and

efficacy. Moreover, the inclusion of multiple centers increases the generalizability of the results, making these findings more applicable to broader clinical settings.

Importantly, the reduction in major complications and faster recovery times associated with TAVR could significantly enhance patient quality of life, especially in frail or elderly individuals. As the number of patients with high surgical risk continues to grow, it is imperative to adopt treatment strategies that minimize the burden of surgery and maximize functional recovery. This study offers valuable insights into how TAVR may help achieve these goals, potentially reshaping the treatment landscape for aortic stenosis.

In conclusion, this study supports the growing body of evidence advocating for TAVR as an effective and safer alternative to SAVR for high-risk patients. The procedural benefits of TAVR, combined with its favorable early outcomes, suggest it should be considered as the first-line option in this patient group. However, long-term data will be essential to further solidify these findings and guide future clinical practice.

Conclusion

The study demonstrates that TAVR offers significant advantages over SAVR in high-risk patients with aortic stenosis, particularly in terms of short-term mortality, morbidity, and recovery. However, the long-term survival outcomes are comparable, highlighting the importance of further investigation into valve durability. Future research should aim to explore the long-term benefits and risks of TAVR, particularly regarding valve longevity and its impact on patient quality of life.

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