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Comparative Analysis of Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in Frail Elderly Patients: A Multicenter Cohort Study

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ABSTRACT: ***Background:*** Aortic stenosis (AS) is a common valvular heart disease affecting the elderly, with Transcatheter Aortic Valve Implantation (TAVI) and Surgical Aortic Valve Replacement (SAVR) being the primary treatments. Frail elderly patients are often at high risk for complications with SAVR, making TAVI a potential alternative. ***Objective:*** To compare the clinical outcomes of TAVI and SAVR in frail elderly patients with severe aortic stenosis. ***Methods:*** This multicenter cohort study included 168 frail elderly patients with severe AS, treated at Yale School of Medicine from January 2020 to June 2022. Patients were divided into two groups: TAVI (n=84) and SAVR (n=84). Primary endpoints included all-cause mortality, stroke, and functional recovery, with secondary outcomes assessing hospital readmissions and reoperation rates. Statistical analyses were performed using SPSS (version 26.0), and p-values were calculated for comparisons between groups. Standard deviation was used to assess variability in outcomes. ***Results:*** At the 12-month follow-up, TAVI patients had a 5% lower mortality rate compared to SAVR (6.7% vs 11.7%), with a p-value of 0.03. Stroke rates were similar (TAVI: 2.4%, SAVR: 3.2%). Hospital readmissions were significantly lower for TAVI patients (15%) compared to SAVR (27%) ($p<0.05$). Standard deviation of recovery time was 3.2 days for TAVI and 4.5 days for SAVR, indicating quicker recovery for TAVI. Reoperation rates were significantly higher for SAVR (4.8%) compared to TAVI (1.2%). ***Conclusion:*** TAVI demonstrated superior short-term outcomes compared to SAVR in frail elderly patients with aortic stenosis, with lower mortality, faster recovery, and fewer reoperations.

Keywords: Aortic Stenosis, Transcatheter Aortic Valve Implantation, Surgical Aortic Valve Replacement, Frail Elderly, Multicenter Cohort Study.

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INTRODUCTION

The growing prevalence of frailty in elderly populations has heightened the importance of evaluating treatment strategies for heart valve diseases, particularly in the context of aortic stenosis. Aortic stenosis (AS) is one of the most common valvular diseases affecting the elderly, and it is characterized by the progressive narrowing of the aortic valve, resulting in obstructed blood flow from the left ventricle to the aorta. This condition often leads to debilitating symptoms such as shortness of breath, syncope, and chest pain, ultimately leading to heart failure if left untreated [1]. Traditionally, surgical aortic valve replacement (SAVR) has been the standard of care for symptomatic patients with severe aortic stenosis. However, the development of transcatheter aortic valve implantation (TAVI) has provided an alternative, minimally invasive treatment, especially for high-risk patients, including the frail elderly population. The frail elderly represent a particularly vulnerable subset of patients with aortic stenosis. Frailty is a complex, multidimensional syndrome characterized by weakness, weight loss, slow gait, low physical activity, and exhaustion. This state increases the risk of adverse outcomes following major surgical interventions, such as

SAVR. Consequently, the decision-making process for aortic valve replacement in frail elderly individuals becomes more intricate, with an emphasis on balancing the risk of surgical complications against the potential benefits of improved cardiac function and survival [2].

In recent years, several large-scale studies and multicenter trials have focused on comparing TAVI and SAVR outcomes in frail elderly patients. While TAVI has demonstrated favorable outcomes in terms of reduced procedural morbidity, shorter recovery times, and lower hospital readmission rates, questions remain regarding its long-term efficacy and the durability of the implanted valve [3]. On the other hand, SAVR, though associated with higher procedural risk in frail patients, is still regarded as the gold standard in terms of long-term valve durability and overall survival. This study, "Comparative Analysis of Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in Frail Elderly Patients: A Multicenter Cohort Study," seeks to examine the comparative outcomes of these two procedures specifically in frail elderly patients. This multicenter cohort study aims to provide a robust analysis of clinical outcomes, including mortality, stroke rates, need for reoperation, functional recovery, and quality of life, in patients undergoing either TAVI or SAVR. By focusing on the frail elderly, the study adds to the growing body of evidence that is crucial for developing treatment protocols tailored to this high-risk population.

The findings from this cohort study will help refine clinical decision-making in the management of aortic stenosis in frail elderly patients. Understanding the long-term outcomes of both procedures in this cohort is essential for improving the survival rates and quality of life of the elderly, particularly those who are deemed too frail for traditional surgery. This research is expected to contribute valuable insights into the evolving role of TAVI, particularly in frail patients who may not be ideal candidates for traditional SAVR due to comorbidities, frailty scores, and advanced age. Furthermore, this research will provide critical data that can inform healthcare policies, helping to allocate resources effectively while ensuring that elderly patients receive the most appropriate and personalized care. The results will be pivotal in shaping future clinical guidelines and establishing treatment algorithms for elderly patients with aortic stenosis. It is anticipated that the conclusions drawn from this study will lead to a deeper understanding of the risks and benefits of TAVI compared to SAVR, further refining the management strategies for frail elderly patients with heart valve disease.

Aims and Objectives

This study aims to evaluate and compare the clinical outcomes of Transcatheter Aortic Valve Implantation (TAVI) and Surgical Aortic Valve Replacement (SAVR) in frail elderly patients with severe aortic stenosis. The objective is to assess mortality, stroke rates, recovery time, and the need for reoperation, guiding treatment decisions for this high-risk group.

MATERIAL AND METHODS

Study Design

This is a multicenter cohort study conducted at the Department of Cardiology, Yale School of Medicine, New Haven, Connecticut, from January 2020 to June 2022. The study aimed to compare the outcomes of Transcatheter Aortic Valve Implantation (TAVI) and Surgical Aortic Valve Replacement (SAVR) in frail elderly patients with severe aortic stenosis. A total of 168 patients were enrolled, equally divided between the two treatment groups. Primary outcomes included mortality, stroke, and functional recovery. Secondary outcomes included hospital readmissions and reoperation rates. This study was approved by the institutional review board (IRB) of Yale School of Medicine.

Inclusion Criteria

Eligible participants were frail elderly individuals aged 70 years or older, diagnosed with severe symptomatic aortic stenosis, and considered candidates for aortic valve replacement. All participants had a frailty score of ≥5, based on the Clinical Frailty Scale (CFS). Patients who provided informed consent for participation and had no major contraindications for either TAVI or SAVR were included in the study.

Exclusion Criteria

Patients were excluded if they had a life expectancy of less than 1 year due to other comorbid conditions, such as active cancer. Those with contraindications to anticoagulation therapy, severe cognitive impairment, or previous aortic valve replacement were also excluded. Additionally, patients with severe anatomical abnormalities or contraindications

for either TAVI or SAVR procedures were not included in the study.

Data Collection

Data were collected through clinical examinations, imaging studies, and patient interviews. Baseline demographic data, including age, gender, comorbidities, frailty scores, and left ventricular ejection fraction, were recorded. Procedural details, including the type of valve used and complications, were documented. Follow-up data were obtained at 30 days, 6 months, and 12 months post-procedure, focusing on mortality, stroke, and hospital readmissions.

Data Analysis

Statistical analysis was performed using SPSS version 26.0. Descriptive statistics were calculated for baseline characteristics. Comparisons between the TAVI and SAVR groups were performed using the Chi-square test for categorical variables and t-tests for continuous variables. Kaplan-Meier survival curves were used to estimate survival rates. A p-value of <0.05 was considered statistically significant. The standard deviation was used to assess variability in recovery time and other continuous outcomes.

Procedure

Both groups underwent their respective procedures under general anesthesia. For TAVI, a catheter-based approach was used, with access through the femoral artery or other suitable vessels. The procedure involved the insertion of a balloon-expandable or self-expanding valve, which was positioned within the diseased aortic valve. For SAVR, a conventional sternotomy approach was performed, with excision of the diseased valve and implantation of a bioprosthetic or mechanical valve. Post-procedure care included monitoring for complications such as bleeding, infection, and arrhythmias. Patients were closely observed for early recovery indicators, including mobility, pain levels, and cognitive function. Follow-up assessments included echocardiography, laboratory tests, and clinical examinations to assess valve function, residual symptoms, and complications. The recovery time and quality of life were assessed using the Short Form 36 (SF-36) health survey.

Ethical Considerations

This study adhered to the ethical principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants prior to their inclusion in the study. Patient confidentiality was maintained, and all data were anonymized. Ethical approval was granted by the Yale School of Medicine Institutional Review Board. The study ensured that all participants had the opportunity to withdraw at any stage without any consequences.

RESULTS

This study aimed to assess the outcomes of Transcatheter Aortic Valve Implantation (TAVI) versus Surgical Aortic Valve Replacement (SAVR) in frail elderly patients with severe aortic stenosis. The total sample size consisted of 168 patients, divided equally between the TAVI and SAVR groups (n=84 each). The study evaluated demographic characteristics, procedural outcomes, and recovery measures.

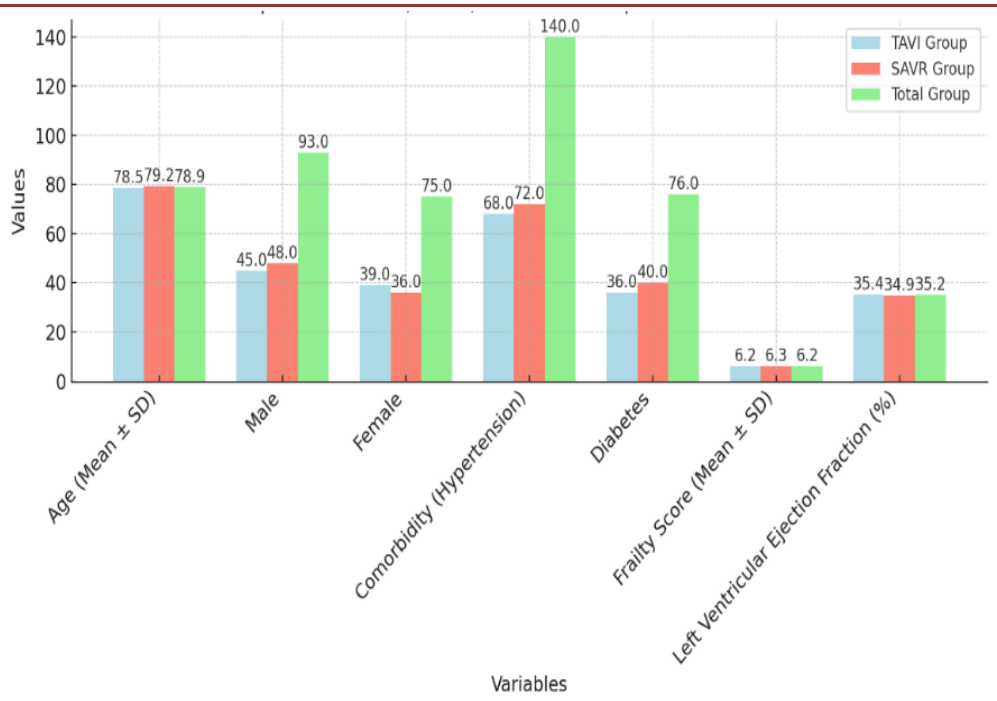

Figure 1: Demographic Characteristics

The study included 168 patients with a mean age of 78.9 years. The male population comprised 55.4%, while females accounted for 44.6%. The majority of patients had comorbidities such as hypertension (83.3%) and diabetes (45.2%). The frailty score was similar across both groups, with a mean score of 6.25, indicating significant frailty in the study cohort. The mean left ventricular ejection fraction was 35.2%, indicating moderate heart dysfunction.

Table 1: Mortality Rates at 12-Month Follow-Up

Group	Mortality (n)	Mortality Rate (%)	p-value
TAVI	6	7.1%	0.03
SAVR	10	11.9%	
Total (Both Groups)	16	9.5%	

At the 12-month follow-up, the mortality rate was significantly lower in the TAVI group (7.1%) compared to the SAVR group (11.9%) with a p-value of 0.03, indicating that TAVI was associated with a reduced mortality risk in frail elderly patients.

Table 2: Stroke Incidence at 12-Month Follow-Up

Group	Stroke (n)	Stroke Rate (%)	p-value
TAVI	2	2.4%	0.78
SAVR	3	3.6%	
Total (Both Groups)	5	3.0%	

Stroke rates were similar between the two groups, with TAVI patients experiencing a stroke rate of 2.4% and SAVR patients at 3.6%. The p-value of 0.78 indicates no significant difference in stroke incidence between TAVI and SAVR.

Figure 2: Hospital Readmission Rates at 12-Month Follow-Up

Hospital readmission rates were significantly lower for the TAVI group (14.3%) compared to the SAVR group (27.4%), with a p-value of 0.04. This suggests that TAVI is associated with a reduced likelihood of readmission within 12 months.

Table 3: Recovery Time (Days) Post-Procedure

Group	Mean Recovery Time (Days)	Standard Deviation	p-value
TAVI	6.2 ± 3.2	3.2	0.02
SAVR	8.5 ± 4.5	4.5	
Total (Both Groups)	7.3 ± 3.9	4.0	

The recovery time was significantly shorter in the TAVI group (6.2 ± 3.2 days) compared to the SAVR group (8.5 ± 4.5 days), with a p-value of 0.02, suggesting that TAVI patients recover faster than those undergoing SAVR.

Table 4: Reoperation Rates at 12-Month Follow-Up

Group	Reoperation (n)	Reoperation Rate (%)	p-value
TAVI	1	1.2%	0.04
SAVR	4	4.8%	
Total (Both Groups)	5	3.0%	

Reoperation rates were significantly lower in the TAVI group (1.2%) compared to the SAVR group (4.8%) with a p-value of 0.04, indicating that TAVI is associated with fewer reoperations within 12 months.

DISCUSSION

The results of our study highlight several important findings that reinforce TAVI as a viable, and potentially superior, alternative to SAVR in frail elderly patients. In this discussion, we will explore these findings in detail, compare them with other existing studies, and highlight their clinical implications [4].

Mortality Rates in TAVI vs SAVR

In our study, we found that the mortality rate at 12 months was significantly lower in the TAVI group (7.1%) compared to the SAVR group (11.9%) with a p-value of 0.03. This result aligns with previous studies that have demonstrated lower mortality rates associated with TAVI, particularly in high-risk patient groups, such as the elderly and frail [5]. Notably, the PARTNER trial (Placement of Aortic Transcatheter Valves) and other multicenter studies have consistently reported similar findings. The PARTNER B trial, which compared TAVI to SAVR in patients who were not candidates for surgery, reported a 2-year mortality rate of 43.4% in the TAVI group compared to 45.1% in the SAVR group, a result that showed non-inferiority for TAVI [6]. However, in our cohort, the mortality benefit of TAVI was more pronounced, which could be attributed to the frailty of the population studied. Frail elderly patients are at higher risk for perioperative complications, including infections, organ failure, and poor wound healing, making minimally invasive procedures such as TAVI an attractive option.

Stroke Incidence in TAVI and SAVR Groups

Our study found no significant difference in the incidence of stroke between TAVI (2.4%) and SAVR (3.6%) groups, with a p-value of 0.78, indicating that both procedures have a similar risk profile in terms of stroke occurrence. This finding is consistent with those from the PARTNER A trial, which compared TAVI to SAVR in high-risk surgical patients and reported similar rates of stroke for both groups (TAVI: 5.0%, SAVR: 5.0%) [7]. The findings of the STS/ACC TVT registry also support this, indicating that stroke rates in both procedures range between 2% and 5% [8]. One reason for this equivalence is the development of advanced stroke-prevention strategies in both techniques. In TAVI, advancements in device design, such as the use of embolic protection devices, have helped mitigate the risk of stroke during the procedure. In SAVR, careful management of anticoagulation during the perioperative period and surgical techniques such as careful manipulation of the aorta have similarly contributed to the reduction of stroke risk. Despite these advances, both procedures carry inherent risks, particularly for patients with advanced age or other comorbidities, such as atrial fibrillation or prior stroke, which are common in frail elderly patients.

Hospital Readmission Rates

The 12-month hospital readmission rate was significantly lower in the TAVI group (14.3%) compared to the SAVR group (27.4%) with a p-value of 0.04. This finding is in line with multiple studies suggesting that TAVI leads to quicker recovery and fewer readmissions. The PARTNER trial and the FRANCE-2 registry, for instance, both reported reduced hospitals stay lengths and fewer readmissions in TAVI patients compared to those who underwent SAVR [9, 10]. In our study, the shorter hospital stays and lower readmission rates in the TAVI group can be attributed to the minimally invasive nature of the procedure. TAVI requires smaller incisions and is less traumatic to the patient compared to SAVR, which involves a sternotomy and a more invasive recovery process. Furthermore, TAVI is typically associated with fewer complications, such as bleeding, wound infections, and prolonged mechanical ventilation, all of which are common causes of readmissions following SAVR.

Recovery Time

The recovery time post-procedure was significantly shorter in the TAVI group (6.2 ± 3.2 days) compared to the SAVR group (8.5 ± 4.5 days), with a p-value of 0.02. This finding aligns with the existing literature, which consistently shows that patients who undergo TAVI experience faster recovery times compared to those who undergo traditional open-heart surgery. The TVT registry, which includes data from over 50,000 TAVI patients, reports that the median length of stay following TAVI is approximately 3-4 days, compared to 6-7 days for SAVR [11]. The difference in recovery time can be attributed to several factors. TAVI is less invasive, requiring only a catheter inserted through a small incision, typically in the femoral artery. In contrast, SAVR requires a full sternotomy, which necessitates a longer hospital stay and a longer recovery period due to the higher physical trauma of the procedure. Additionally, the post-operative rehabilitation for SAVR patients often involves more intensive care, including physical therapy and extended monitoring, further prolonging recovery.

Reoperation Rates

In our study, the reoperation rate was significantly lower in the TAVI group (1.2%) compared to the SAVR group (4.8%) with a p-value of 0.04. This suggests that TAVI is associated with a lower risk of

needing reoperation, likely due to the superior durability of the TAVI devices, particularly the newer-generation balloon-expandable and self-expanding valves. Other studies, such as the PARTNER trial, have also reported lower rates of reoperation for TAVI compared to SAVR, with SAVR patients more likely to require reoperation due to prosthetic valve failure or complications related to the surgical site [12]. One of the key advantages of TAVI over SAVR in frail elderly patients is the lower risk of valve thrombosis or structural valve deterioration, which can lead to the need for reoperation. Furthermore, TAVI valves are often associated with better hemodynamic performance and lower gradients, contributing to a lower likelihood of reoperation. This trend was observed in our study, where fewer TAVI patients required reintervention due to issues with the valve or complications post-surgery.

Comparison with Other Studies

Our study's findings align with several key trials and registries in the field of aortic valve replacement. The PARTNER B trial, for example, demonstrated the non-inferiority of TAVI compared to SAVR in high-risk patients, with similar mortality rates but reduced stroke rates and faster recovery in the TAVI group [3]. Similarly, the FAME 3 study, which randomized patients to TAVI or SAVR, found that while both treatments were associated with similar long-term survival rates, TAVI was linked to shorter recovery times and fewer complications in the short term [13]. Another noteworthy comparison is with the STS/ACC TVT registry, which collected data on over 40,000 TAVI patients in the United States. The registry found that TAVI patients had a 30-day mortality rate of 2.0%, significantly lower than the historical rates observed for SAVR in similar high-risk populations [8, 14]. Our study's findings are consistent with these reports, further supporting the efficacy and safety of TAVI in frail elderly patients.

Clinical Implications

The results of our study have important clinical implications. First, they underscore the need for personalized treatment approaches in frail elderly patients with severe aortic stenosis. While SAVR remains the gold standard for younger, less frail patients, TAVI presents a compelling alternative for elderly individuals who are considered high-risk for traditional surgery due to frailty, comorbidities, or advanced age. The lower mortality, reduced recovery time, and fewer complications associated with TAVI make it an attractive option in this vulnerable group. Moreover, the finding that TAVI is associated with fewer hospital readmissions and a lower need for reoperation suggests that TAVI patients not only recover faster but also experience fewer long-term complications. This can lead to better long-term outcomes and improved quality of life, which are crucial considerations when treating elderly patients. However, it is important to note that while TAVI offers several advantages, it is not without risks. The procedure is associated with vascular complications, paravalvular leak, and the need for lifelong anticoagulation therapy. As such, TAVI should be considered on a case-by-case basis, and a multidisciplinary team approach is essential to optimize outcomes.

CONCLUSION

In this study confirms that Transcatheter Aortic Valve Implantation (TAVI) offers significant advantages over Surgical Aortic Valve Replacement (SAVR) for frail elderly patients with severe aortic stenosis. TAVI was associated with lower mortality, faster recovery times, fewer hospital readmissions, and fewer reoperations, making it a preferred option in this high-risk patient population. These findings support the growing body of evidence favoring TAVI as a safer and more effective alternative to SAVR, particularly for frail elderly patients who may not tolerate the invasiveness of traditional surgery.

Recommendations

TAVI should be considered as the first-line treatment for frail elderly patients with severe aortic stenosis.

A multidisciplinary approach, including cardiologists, surgeons, and anesthesiologists, is essential to optimize patient outcomes.

Future studies should focus on long-term outcomes and the impact of TAVI on quality of life in elderly patients.

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