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Long-Term Observation of Specific Patient Groups After Transcatheter Aortic Valve Implantation

SUMMARY

Introduction:

Aortic valve stenosis (AS) is the most common valvular disease in the elderly, affecting one in eight individuals over 75 years of age. Advanced symptomatic AS is associated with a high risk of mortality, with half of the patients dying within two years of symptom onset. Transcatheter aortic valve implantation (TAVI) is now an established treatment option, particularly recommended for patients over 75 years old and those at high risk of complications from conventional surgical procedure. The decision to choose between TAVI and surgical aortic valve replacement should be made by a multidisciplinary team of specialists, the so-called Heart Team, based on a comprehensive assessment of the patient's clinical profile. While general guidelines for selecting the appropriate treatment method are well-defined, the decision is less straightforward in certain specific patient groups. Based on the clinical experience of our center, such groups include patients with bicuspid aortic valve (BAV) morphology and those with a history of immunosuppressive therapy.

Objective: The aim of this study was to evaluate in-hospital and long-term outcomes of TAVI in patients with BAV and those with a history of immunosuppressive therapy.

Methods: We developed a registry of patients who underwent TAVI procedures across five experienced academic centers in Poland. All patients included in the registry were qualified for TAVI by local multidisciplinary Heart Teams. The participating centers utilized standardized definitions for collecting clinical data. Long-term mortality data were obtained from the Polish National Health Fund database. For the BAV subgroup, the study population comprised patients with symptomatic, severe AS and bicuspid valve morphology. The control group included patients with tricuspid aortic valves (TAV) selected using propensity score matching at a 1:3 ratio. For the subgroup assessing the impact of immunosuppressive therapy, the study group consisted of patients who had been on chronic immunosuppressive therapy

for at least 30 days prior to the procedure. The control group comprised patients not receiving immunosuppressive therapy, selected using propensity score matching.

Results:

The registry included data from 1,451 patients who underwent TAVI. In the BAV analysis, two groups were identified: 130 patients with BAV and 390 patients with TAV. All-cause mortality was comparable between the groups up to 10 years post-TAVI (HR 1.09, 95% CI: 0.77–1.51). The rates of successful procedure completion and in-hospital mortality were similar (96% vs. 95%, $p = 0.554$ and 2.3% vs. 2.1%, $p = 0.863$, respectively). Moderate to severe paravalvular leak (PVL) at discharge was observed in both groups with similar incidence (2 vs. 2%, $p = 0.846$). We also noted a trend to higher stroke rates in patients with BAV (5 vs. 2%, $p = 0.078$). Among BAV patients, all-cause mortality was comparable between those receiving self-expanding and balloon-expandable prostheses (HR 1.02, 95% CI: 0.52–1.99). However, mortality was lower with new-generation prostheses compared to older-generation valves (HR 0.27, 95% CI: 0.12–0.62).

In the immunosuppression analysis, two matched groups were examined: 25 patients with a history of immunosuppressive therapy and 75 patients without such a history. Over a median follow-up period of 2.7 years post-TAVI, there were no significant differences in all-cause mortality between the groups ($p = 0.465$; HR = 0.73; 95% CI: 0.30–1.77). The incidence of major vascular complications was comparable (4.0% vs. 5.3%, $p = 1.000$). No statistically significant differences were observed in the composite endpoint comprising life-threatening or disabling bleeding, major vascular complications, stroke, and new pacemaker implantation (40.0% vs. 20.0%, $p = 0.218$).

Conclusions:

Patients undergoing TAVI for BAV-related AS demonstrated comparable long-term mortality to those with TAV up to 10 years post-procedure. Procedure success rates, in-hospital mortality, procedural complications, and the incidence of paravalvular leakage (PVL) were similar between the groups. The high rate of neurological complications (5%) among BAV patients warrants further investigation. There were no statistically significant differences in long term mortality and complications rates after TAVI in patients with the history of immunosuppressive treatment compared to patients without such history. Results of our study indicate that TAVI

can be safe and reliable treatment option in patients with BAV and history of immunosuppression.