

Outcomes of the Transaortic Valve Implantation Procedure in North Cyprus

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Abstract

BACKGROUND/AIMS: In Europe, aortic stenosis ranks first when examining patients requiring surgery or percutaneous interventions for the aortic valve. The aging population will bring along aortic stenosis that requires more percutaneous interventions, and transcatheter aortic valve implantation (TAVI) may become a routine procedure in the future. Statistical studies may increase the quality of interventions and reduce complication rates. There are no studies on TAVI in our country. In statistical terms, this study will provide detailed information about the TAVI procedures in North Cyprus and will be a source for future studies.

MATERIALS AND METHODS: In this study, we evaluated 94 patients who underwent TAVI procedures in North Cyprus between 2016 and 2021. Complication, mortality, and morbidity rates from hospitalization to discharge are reported. Echocardiography was performed on all patients with GE Vivid T8 (product year: 2015).

RESULTS: The 7-day mortality rate was found to be 5.31% in 94 patients with TAVI performed in our hospital. Complications related to the peripheral arteries were observed in 20.2% of the patients. The pacemaker implantation rate after TAVI was 9.6%.

CONCLUSION: It would be beneficial for each TAVI center to calculate mortality and morbidity rates regularly and compare them with the world literature. In this way, mortality and morbidity rates can be reduced and better procedural results can be achieved.

Keywords: TAVI, heart valve disease, mortality and morbidity rate of TAVI

INTRODUCTION

Aortic stenosis ranks first when aortic valve patients require surgical or percutaneous intervention in Europe.¹ The one-year mortality rate of symptomatic aortic stenosis increases up to 50% if untreated. The prevalence of the diseases increases parallel to the increase in the length of life.² According to the European Society of Cardiology (ESC) guidelines, mean gradient ≥ 40 mmHg, peak velocity ≥ 4.0 m/s, valve area ≥ 1 cm² indicate severe aortic stenosis.³ The ESC guidelines also recommend class I level b treatment (surgical or percutaneous) for symptomatic severe aortic stenosis.⁴ Findings of the randomized studies and complications rates may not always show in real life.^{1,2-5} Therefore, transcatheter aortic valve implantation (TAVI) centers should conduct

retrospective studies to determine complication rates and compare their findings with those of other studies. Such attempts may increase the quality of interventions and reduce complication rates.⁶⁻⁹

MATERIALS AND METHODS

In total, 94 patients underwent TAVI procedures between 2016 and 2021 in North Cyprus at a state hospital, and this study included all of these patients. Patients were analyzed with regard to mortality and morbidity rates from the procedure to hospital discharge. Our hospital is the largest heart center in North Cyprus, and most of the TAVI procedures performed all over the country have been performed at this hospital since 2016.

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All TAVI procedures, which were performed from 2016 to 2021 and recorded at the angiography laboratory of the state hospital, were retrospectively analyzed. Medical histories, clinical information, multislice CT scans, electrocardiograms, blood tests, and echocardiography records of 94 patients who underwent the TAVI procedure were analyzed. In addition, puncture sites during interventions, aortic valve type and size, pre- and post-dilatation rates, and methods of closing the puncture site were analyzed. Mortality and morbidity rates during the TAVI procedure and/or until patient discharge were evaluated. Cardiac death, major vascular complications, cerebrovascular events, need for permanent pacemaker implantation, and contrast media nephropathy were examined.

This study was approved by the Dr. Burhan Nalbantoğlu Ethics Committee (approval number: 67/21). Informed consent was obtained from all participants.

Statistical Analysis

All analyses were performed using the Statistical Product and Service Solutions (SPSS) software package (version 25.0, SPSS-IBM, Armonk, NY, USA) at the 95% confidence level and $p < 0.05$ significance level. Quantitative variables were reported as the mean and standard deviation; qualitative variables were described as numbers and percentages. Quantitative variables were analyzed using Friedman analysis for dependent groups. Subgroup analysis was performed using Wilcoxon analysis and interpreted using Bonferroni correction. The independent groups were compared using chi-square analysis.

RESULTS

Patients who underwent the TAVI procedure were mostly female (63.8% female, 36.2% male). The mean age was 78.64 years and the mean aortic gradient was 51.6 mmHg. New York Heart Association (NYHA) class III heart failure was observed in 84 patients, whereas advanced heart failure symptoms (NYHA class IV) were evident in 10 patients. 29.8% of the patients had obstructive coronary artery disease and percutaneous coronary intervention, and 8.5% had coronary bypass histories. 8.5% of the patients had pacemakers or implantable cardioverter defibrillators. One patient had severe mitral stenosis, whereas eight patients had severe mitral insufficiency. 15.9% of the patients had left bundle branch block and 4.25% had right bundle branch block.

Of the 94 TAVI procedures, 89 were implanted in the right femoral artery, 4 in the left femoral artery and 1 in the axillary artery. Three of the transfemoral TAVI procedures were closed by surgery and 91 were closed percutaneously (ProGlide). A self-expandable valve was used in 58.52% of the patients, whereas a balloon expandable valve was used in the remaining 41.48%. One TAVI procedure was valve-in-valve implantation. The mean EuroSCORE 2 score was 14.17. We analyzed all 94 TAVI procedures performed at the state hospital between 2016 and 2021. All patients with TAVI had severe symptomatic aortic stenosis. Procedures were performed after consultation with the Cardiology and Cardiovascular Surgery Council. The patients were slightly sedated by the anesthesia team during the procedure. During the procedure, valve implantation was performed in all patients with rapid stimulation by a temporary pacemaker placed in the right ventricle or by an existing pacemaker.

Three patients died during the procedure. Two deaths occurred due to coronary obstruction, whereas one death occurred due to valve

dislocation. Consequent pericardial tamponade due to temporary pacemaker lead-induced right ventricle perforation developed in 6 patients, and 1 patient died due to this cause. One patient died because of acute renal failure and metabolic causes.

Peripheral vascular complications were the most frequent complications with a percentage of 20.2%. Of these complications, 68.4% were treated with percutaneous transluminal angioplasty or stent and 31.6% were treated surgically. Cerebrovascular accident occurred in 1 patient, but there was no sequela during discharge. Nine (9.6%) patients had an advanced heart block after the TAVI procedure. A pacemaker was implanted in these 9 patients. Pacemaker implantation percentages in self-expandable TAVI was 10.9% and in balloon expandable TAVI was 7.7%.

The 7-day mortality rate was found to be 5.31% in 94 patients with TAVI performed in our hospital. Considering the causes of death of these patients, 2 patients died due to coronary obstruction, 1 patient died due to valve dislocation, and 2 patients died due to pericardial tamponade and related metabolic causes.

The peripheral complication rate was 20.2%, and the pacemaker implantation rate after TAVI was 9.6%. Eighty-nine patients were discharged from the hospital in good health, and no problem was encountered in the evaluation at the end of 7 days.

DISCUSSION

Aortic stenosis and TAVI procedures are more common in the contemporary world due to the aging population. TAVI procedures have been performed in North Cyprus since 2016. However, only one study has been conducted on mortality and morbidity rates after TAVI procedures in Cyprus. This study revealed the complication rates in TAVI procedures performed in North Cyprus and compare them with the findings in other TAVI centers.

This study analyzed the mortality and morbidity rates of TAVI procedures performed in North Cyprus between 2016 and 2022.¹ A comparison of our findings with the literature reveals similar mortality and morbidity rates. Inpatient hospital death rates in the meta-analysis ranged from 2.2 to 5.3.¹⁰ This ratio increased in patients with higher EuroSCORE 2 scores.^{11,12} On the other hand, the one-year mortality rate in patients who underwent transfemoral TAVI in Cyprus Republic between 2015 and 2020 was 2.6%, which was lower than our findings in North Cyprus.^{13,14} This difference may be explained with reference to the EuroSCORE 2 scores. In our study, 85.1% of patients were high-risk patients. Given that mortality risk is higher in patients with higher EuroSCORE 2 scores, mortality rates in our study were higher than those in the former study.^{15,16}

Vascular complications with a percentage of 20.21% were the most frequent complications, similar to those reported in the literature.¹⁷⁻¹⁹ The primary reasons behind these complications are calcified artery and wrong puncture site.²⁰⁻²² Risk factors for vascular complications include calcified vessels, advanced age, chronic kidney failure, and coronary artery disease.²³⁻²⁵

High-grade heart blocks requiring pacemaker implantation were the second most frequent complications. Pacemaker demand was more frequent in patients of advanced age, coronary artery disease, and diabetes mellitus. In addition, parallel to the literature, pacemaker

demand was lower in patients with balloon expandable valves.²⁶⁻²⁸ Perforation due to a temporary pacemaker lead in the right ventricle and consequent pericardial tamponade was another complication observed in this study. A right ventricle lead for more than 24 h increases the perforation risk. In addition, left ventricular stimulation via TAVI stiff wire may reduce ventricular perforation risk caused by temporary pacemaker.²⁹⁻³¹

Similar to the literature, mortality and morbidity rates of TAVI patients with chronic kidney failure were higher in our study.³²⁻³⁴ Morbidity and mortality rates in this study were similar to those reported in the literature.³⁵ We hope that these findings will be used to develop strategies to reduce mortality and morbidity rates in TAVI procedures.

CONCLUSION

It would be beneficial for each TAVI center to calculate the mortality and morbidity rates regularly and compare them with the world literature. In this way, mortality and morbidity rates can be reduced and better procedural results can be obtained. When we look at the statistics in our hospital, it is seen that the complications of peripheral artery injury and pericardial tamponade are high. The risk of pericardial tamponade can be reduced with left ventricular pacing. In addition, we think that angiographic imaging of the puncture site or puncture under ultrasound to reduce peripheral artery injuries will reduce the complication rates.

MAIN POINTS

- This study revealed the complication rates in TAVI procedures performed in North Cyprus and compare them with the findings in other TAVI centers.
- There are no studies on TAVI in North Cyprus. This study may help to reduce the mortality and morbidity rates during and after the TAVI procedure and will be a source for the next studies.
- In this study, 94 TAVI procedures performed in a state hospital in North Cyprus between 2016 and 2021 were examined, and the mortality and morbidity rates from hospitalization to discharge were calculated and the results were reported.
- The 7-day mortality rate was found to be 5.31% in 94 patients with TAVI performed in our hospital.
- The most frequent complications observed in TAVI patients were peripheral vascular complications, and insertion of 5F sheath may be helpful for safety.

ETHICS

Ethics Committee Approval: This study was approved by the Dr. Burhan Nalbantoğlu Ethics Committee (approval number: 67/21).

Informed Consent: Informed consent was obtained from all participants.

Peer-review: Externally peer-reviewed.

Authorship Contributions

Concept: A.Ö., C.C., Design: A.Ö., C.C., Data Collection and/or Processing: A.Ö., C.C., Analysis and/or Interpretation: A.Ö., C.C., Literature Search: A.Ö., C.C., Writing: A.Ö., C.C.

DISCLOSURES

Conflict of Interest: No conflict of interest was declared by the authors.

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