CMJ, 2024;46(2): 129-135
DOI: 10.7197/cmj.1474981

Cumhuriyet Medical Journal

| cmj.cumhuriyet.edu.tr | Founded: 2004 Available online, ISSN:1305-0028 Publisher: Sivas Cumhuriyet Üniversitesi

Two-year Experience with balloon-Expandable Transcatheter Aortic Valve Replacement in Severe Aortic Stenosis at a Tertiary Center

Anıl Şahin[1,a,*], Ahmet Caner Canpolat[1,b], Enes Gül[2,c], İdris Buğra Çerik[3,d], İbrahim Gül[1,e]

[1]*Department of Cardiology, Sivas Cumhuriyet University, Medical School, Sivas, Türkiye.*
[2]*Department of Radiology, Sivas Cumhuriyet University Medical School, Sivas, Türkiye.*
[3]*Department of Cardiology, Ordu University Medical School, Ordu, Türkiye.*
**Corresponding author*

Research Article

History

Received: 29/04/2024
Accepted: 08/06/2024

ABSTRACT

Objective
Aortic stenosis (AS) is the most common valvular heart disease requiring intervention, particularly in developed countries. Transcatheter aortic valve replacement (TAVR) is indicated for patients with a high surgical risk and a post-procedural survival expectancy of more than 12 months. Over the years, the TAVR method has emerged as a significant treatment option for patients with symptomatic severe AS and has begun to be implemented in our country as well. The objective of this study was to evaluate the short and long-term outcomes of patients undergoing TAVR at our center, as well as to assess our institution's experience with the TAVR procedure.

Methods
This retrospective, single-center analysis included 16 consecutive patients with symptomatic AS who underwent TAVR between March 2022 and February 2024. All patients included in the study underwent implantation of a balloon-expandable TAVR valve. In the study, the demographic characteristics of patients preoperatively and during post-procedural follow-ups, their clinical status preoperatively and postoperatively, and echocardiographic findings were evaluated and compared.

Results
The mean age of the entire population was 78.3 ± 8.7 years, and 50% were women. Transfemoral access was used in 93.8% of patients. Implantation success was achieved in all cases. During the TAVI procedure, 12.5% of patients required permanent pacemaker implantation. The mean length of hospital stay for the entire cohort was 4.5±2.3 days. There wasn't show in-hospital deaths occurred before hospital discharge. During the follow-up, it was observed that 3 patients died from all-cause mortality. The mean follow-up duration of the study was 552 days, with the longest follow-up being 666 days. The significant improvement was noted in all echocardiographic parameters and functional capacity. No cases with moderate or severe aortic regurgitation, necessitating additional procedures.

Conclusion
Our center results with TAVR over a 2-year span consistent with broader studies. Despite some procedure-related complications, advancements in devices and techniques are expected to reduce these, enhancing outcomes with increased procedural experience. With medicine favoring less invasive approaches, TAVR is poised to become a more prevalent alternative to surgery across diverse patient cohorts.

Keywords: Aortic stenosis, complications, follow-up, transcathater aortic valve replacement

Şiddetli Aort Darlığında Tersiyer Bir Merkezde Yapılan Transkateter Aort Kapak Replasmanının İki Yıllık Sonuçları

Araştırma Makalesi

Süreç

Geliş: 29/04/2024
Kabul: 08/06/2024

ÖZET

Amaç
Aort darlığı (AD), özellikle gelişmiş ülkelerde müdahale gerektiren en yaygın kapak hastalığıdır. Transkateter aort kapak replasmanı (TAVR), yüksek cerrahi risk taşıyan ve işlem sonrası 12 aydan fazla sağkalım beklentisi olan hastalarda endikedir. Yıllar içinde, TAVR yöntemi semptomatik ciddi AD'li hastalar için önemli bir tedavi seçeneği olarak ortaya çıkmış ve ülkemizde de uygulanmaya başlanmıştır. Bu çalışmanın amacı, merkezimizde TAVR geçiren hastaların kısa ve uzun vadeli sonuçlarını değerlendirmek ve TAVR prosedürü ile kurum deneyimimizi değerlendirmektir.

Yöntem
Bu retrospektif, tek merkezli analiz, Mart 2022 ile Şubat 2024 arasında TAVR geçiren 16 ardışık semptomatik AD'li hastayı içerdi. Çalışmaya dahil edilen tüm hastalar, balon genişletilebilir bir TAVR kapak implantasyonu geçirdi. Çalışmada, hastaların preoperatif ve postoperatif takiplerinde demografik özellikleri, klinik durumları ve ekokardiyografik bulguları değerlendirilip karşılaştırıldı.

Bulgular
Tüm popülasyonun ortalama yaşı 78.3 ± 8.7 yıl idi ve %50'si kadındı. Hastaların %93.8'inde transfemoral erişim kullanıldı. İmplantasyon başarısı tüm vakalarda sağlandı. TAVI işlemi sırasında hastaların %12.5'ine kalıcı kalp pili implantasyonu gerekti. Tüm kohort için hastanede kalış süresinin ortalama uzunluğu 4.5 ± 2.3 gün idi. Hastane taburculuğundan önce hiçbir hastanede ölüm olmadı. Takip sırasında, 3 hastanın tüm nedenlere bağlı olarak öldüğü görüldü. Çalışmanın ortalama takip süresi 552 gün olup, en uzun takip süresi 666 gündü. Tüm ekokardiyografik parametrelerde ve fonksiyonel kapasitede belirgin bir iyileşme gözlendi. Ek prosedür gerektiren orta veya şiddetli aort yetersizliği vakası bulunmadı.

Sonuç
Merkezimizdeki TAVR sonuçları, daha geniş çalışmalarla tutarlıdır. Bazı prosedürle ilgili komplikasyonlara rağmen, cihaz ve tekniklerdeki ilerlemelerin bunları azaltması ve prosedür deneyimi arttıkça sonuçların geliştirilmesi beklenmektedir. Tıbbın daha az invaziv yaklaşımları tercih etmesiyle, TAVR'in farklı hasta grupları arasında cerrahiye alternatif olarak daha yaygın bir seçenek haline gelmesi beklenmektedir.

Anahtar Kelimeler: Aort darlığı, komplikasyon, takip, transkatater aortik kapak replasmanı

[a] *dr.anil.sahin@gmail.com* *0000-0003-3416-5965*
[b] *ahmetcanercanpolat@gmail.com* *0009-0006-9395-5325*
[c] *enesguldr89@gmail.com* *0000-0002-5562-2697*
[d] *cerikbugra@gmail.com* *0000-0003-1419-3950*
[e] *dribrahimgul@hotmail.com* *0000-0003-1007-0961*

How to Cite: Şahin A, Canpolat AC, Gül E, Çerik İB, Gül İ. Two-year experience with balloon-expandable transcatheter aortic valve replacement in severe aortic stenosis at a tertiary center, Cumhuriyet Medical Journal. 2024;46(2): 129-135.

Introduction

Aortic stenosis (AS) is the most common valvular heart disease requiring intervention, particularly in developed countries.[1] Degeneration resulting from calcification is the most common cause of AS, and its prevalence is increasing with the ageing population.[2] In a community-based echocardiographic study, severe calcific AS was found in 2% of adults aged 65 and older, while aortic valve sclerosis associated with ageing but without significant stenosis was detected in 29%.[3] Approximately two-thirds of all cardiac valve surgical interventions are aortic valve replacements (AVR), with the aetiology mostly being aortic stenosis.[1]

In patients with valvular aortic stenosis, the decision for medical or interventional treatment is based on identifying the underlying cause and grading the severity of the valve stenosis.[4] In asymptomatic AS patients, once symptoms occur, regardless of the symptom level, survival worsens if the stenosis is not relieved. The time from the onset of symptoms to death in untreated patients can be as short as 2 years. In symptomatic severe AS patients, effective treatment that improves symptoms increases survival, and enhances exercise capacity is surgical or transcatheter aortic valve replacement (AVR).[5] The choice of intervention type in patients planned for aortic valve replacement depends on a comprehensive evaluation of patient characteristics, scoring systems, and comorbidities that pose surgical risk. Transcatheter aortic valve replacement (TAVR) is indicated for patients with a high surgical risk and a post-procedural survival expectancy of more than 12 months.[4] Randomized controlled trials have shown that in symptomatic severe AS patients who are inoperable surgically, TAVR reduces both mortality and hospitalizations compared to standard treatment.[6,7]

Over the years, the TAVR method has emerged as a significant treatment option for patients with symptomatic severe AS and has begun to be implemented in our country as well. Since 2022, the TAVR procedure has been initiated in our centre for all eligible patients. Considering that the success of the TAVR procedure increases with centre experience and comprehensive evaluation of the patient by the heart team, we aimed to evaluate the short and long-term follow-up results of patients undergoing TAVR in our centre and assess our centre's experience in this study.

Material and Methods

The study included patients who underwent TAVR with a diagnosis of severe AS at the Cardiology Clinic of Sivas Cumhuriyet Faculty of Medicine Hospital between March 2022 and February 2024. Our study was conducted in accordance with the Helsinki Declaration, and written consent was obtained from all patients with approval from the Sivas Cumhuriyet Ethics Committee with approval number 2024/03-19.

The interventional procedures for patients were performed by operators in our hospital's Cardiology Clinic. The diagnosis of severe aortic stenosis was established through echocardiographic evaluation (using GE Healthcare Vivid S70N GE Ultrasound, Norway) and clinical assessment by current guidelines. Patients diagnosed with symptomatic severe aortic stenosis were evaluated by the cardiology-cardiovascular surgery council to determine the intervention method. All patients were assessed by the Heart Team with the use of validated score systems including the Society of Thoracic Surgery (STS) risk score, and determined patient suitability for SAVR, TAVI or medical therapy. During the preoperative period, patients underwent coronary angiography performed by an invasive cardiologist. Significant coronary artery disease (CAD) was defined as ≥50% stenosis. Patients with ≥70% stenosis and deemed suitable for percutaneous coronary intervention underwent coronary revascularization. The aortic valve structure, degree of calcification, aortic anatomy, and peripheral arteries of the patients were evaluated by angiographic imaging using multidetector computed tomography (MDCT) by an expert radiologist. Planned valve measurements were calculated using the 3Mensio program guided by CT images. All patients were informed about the TAVR procedure before undergoing it, and consent was obtained from them or their relatives.

In the study, the demographic characteristics of patients preoperatively and during post-procedural follow-ups, their clinical status preoperatively and postoperatively, and echocardiographic findings (left ventricular end-systolic and end-diastolic diameters [LVESD, LVEDD], left ventricular ejection fraction [LVEF], left atrial diameter, systolic pulmonary artery pressure, aortic valve area [AVA], aortic valve gradients, and velocities) were evaluated and compared. Procedural characteristics and any complications that occurred were recorded. Patients were assessed at regular outpatient clinic visits using echocardiographic, clinical, and laboratory parameters. Parameters at the last follow-up were compared with preoperative parameters. Mortality data occurring within the hospital or during follow-ups were recorded.

Implantation Procedure

The TAVR procedure was performed in the catheterization laboratory with the presence of an anesthesiologist, a cardiovascular surgeon, and an invasive cardiologist, under full sedation. Sedaoanalgesia was initiated with midazolam (0.1 mg/kg/dose by slow intravenous infusion, maximum 10 mg) and continued with ketamine (1 mg/kg/dose by slow intravenous bolus, maximum 100 mg). The transfemoral route was prioritized for intervention in patients. In one patient deemed unsuitable for femoral access, the procedure was performed via the left subclavian artery approach. At the beginning of the procedure, sheaths were inserted into the femoral artery and femoral vein of the patients. Surgical cut-down incisions were not made during femoral artery interventions. All procedures were performed using vascular closure devices. A temporary pacemaker electrode was inserted into the right ventricle through the femoral vein. Following the crossing of the aortic valve, balloon-expandable MyVal TAVR valves of appropriate sizes were deployed in all patients under rapid pacing. Post-dilatation with a balloon was performed in patients showing non-central aortic regurgitation (AR) on aortography. Hemostasis was achieved in the femoral artery using vascular closure devices, and the procedures were concluded. Patients were closely monitored in the intensive care unit post-procedure to monitor for the development of temporary pacemaker requirements, pericardial effusion, or hemodynamic deterioration. Patients continued to receive aspirin and clopidogrel as antiplatelet therapy in the postoperative period.

Statistical Analysis

Statistical analyses were conducted using the SPSS program (version 29.0, Inc., Chicago, Illinois). Clinical and laboratory data of patients were expressed as mean ± standard deviation, median (interquartile range), and percentage (%). Wilcoxon test, a nonparametric test, was used for comparing pre- and post-procedural parameters, while the Student's t-test was utilized for comparing means of parametric variables.

Results

The study included 16 patients who underwent TAVR at our centre, with a mean age of 78.3 ± 8.7 years. Eight (50%) of the patients were female. The median follow-up duration was found to be 552 days. The demographic characteristics of patients, comorbidities, and medications used during the preoperative period are presented in Table 1. Hypertension (HT) and coronary artery disease (CAD) were present in 15 (93.8%) of the patients, heart failure (HF) in 7 (43.8%), and atrial fibrillation (AF) in 5 (31.3%). Among the patients, 9 (56.3%) were using beta-blockers, 8 (50%) were on loop diuretics, 7 (43.8%) were taking renin-angiotensin system inhibitors (RASi), and 4 (25%) were on oral anticoagulant therapy.

When evaluating the preprocedural echocardiographic characteristics of the patients, the mean LVEF was found to be 52% ± 8, the mean aortic jet velocity was 4.1 ± 0.6 m/s, the mean aortic valve gradient was 54.4 ± 15.0 mmHg, and the mean aortic valve area was 0.78 ± 0.14 cm^2 (Table 2). The mean QRS duration pre-procedure was 100 ± 30 ms, and the mean PR duration was 97 ± 52 ms (Table 2). Pre-procedural laboratory parameters of the patients are summarized in Table 2.

All patients included in the study underwent implantation of a balloon-expandable TAVR valve. Transfemoral access was used in 15 (93.8%) patients, while subclavian access was utilized in 1 patient. The most common valve size chosen was 26mm (56.3%). Post-dilatation was performed in 6 (37.5%) patients due to paravalvular AR observed after implantation. Positive inotropic agents were used in 3 (18.8%) patients due to hypotension or bradycardia during the procedure. No mortality, malign tachycardia, or need for resuscitation occurred in any patient during the procedure. Pericardial effusion not causing hemodynamic compromise was observed in 4 (25%) patients during follow-up. None of these patients underwent pericardiocentesis and were conservatively managed. Two patients required temporary hemodialysis during the in-hospital period post-procedure, but their hemodialysis needs ceased upon discharge. Atrioventricular block requiring pacemaker implantation was observed in 2 patients post-procedure. Permanent pacemaker implantation was performed without complications in these patients. Detailed procedural information and post-procedural complications are shown in Table 3. In our study, one patient required percutaneous coronary intervention due to coronary artery disease (non ST elevation myocardial infarction) during the follow-up period, 3 months after valve implantation, and successful left anterior descending artery revascularization was performed. The patient was discharged without any complications after the procedure.

The postoperative and follow-up echocardiographic findings of the patients are presented in Table 2. According to this, no patient had severe AR during follow-up after the procedure, while mild AR was observed in 2 patients. It was noted that NT-proBNP values decreased and QRS and PR intervals were slightly prolonged compared to pre-procedure values, but this did not have clinical significance and did not require additional intervention.

During the follow-up, it was observed that 3 patients died from all-cause mortality. The cause of death was sudden cardiac death in two patients, while one patient died due to septic shock and multiorgan failure that developed after pneumonia. The mean follow-up duration of the study was 552 days, with the longest follow-up being 666 days. Among the deceased patients in the study, the earliest mortality was observed on the 178th day.

Table 1. Clinical characteristics of patients

Baseline characteristics	
Age (years)	78.3 ± 8.7
Female, n (%)	8 (50.0)
Hypertension, n (%)	15 (93.8)
Heart failure, n (%)	7 (43.8)
Diabetes mellitus, n (%)	8 (50.0)
Coronary artery disease, n (%)	15 (93.8)
Dyslipidemia, n (%)	11 (68.8)
Atrial fibrillation, n (%)	5 (31.3)
Chronic obstructive pulmonary disease, n (%)	7 (43.8)
Cerebrovascular disease, n (%)	10 (62.5)
Chronic kidney disease, n (%)	2 (12.5)
Periferal artery disease, n (%)	3 (18.8)
Preprocedure medications	
Beta-blocker, n (%)	9 (56.3)
Renin-angiotensin system inhibitors, n (%)	7 (43.8)
Mineralocorticoid receptor antagonists, n (%)	1 (6.3)
Sodium-glucose cotransporter-2 inhibitors n (%)	4 (25.0)
Loop diuretics, n (%)	8 (50.0)
Oral anticoagulants, n (%)	4 (25.0)
Statins, n (%)	8 (50.0)

Table 2. Echocardiographic and laboratory findings before the procedure and at the last follow-up

	Preprocedure	Follow-up
Left ventricle ejection fraction (%)	52 ± 8	52 ± 9
LVDD (mm)	47.7 ± 4.3	47.2 ± 4.7
Left atrium diameter (mm)	45.5 ± 3.6	46.3 ± 4.4
IVS (mm)	12.9 ± 2.8	12.3 ± 1.4
Aortic velocity (m/s)	4.1 ± 0.6	2.0 ± 0.4
Maximum aortic gradient (mmHg)	86.6 ± 23.9	19.7 ± 5.1
Mean aortic gradient (mmHg)	54.4 ± 15.0	10.6 ± 2.6
Aortic valve area (cm^2)	0.78 ± 0.14	
Aortic annulus diameters (mm)*	24.3 ± 2.8	
sPAP (mmHg)	43.7 ± 15.2	33.5 ± 12.2
Moderate-Severe AR, n (%)	3 (18.8)	0 (0.0)
QRS duration (msn)	100 ± 30	122 ± 36
PR duration (msn)	97 ± 52	118 ± 54
Hemoglobine (g/dL)	12.2 ± 1.8	11.3 ± 1.7
Platelet	262 ± 95	200 ± 63
NT-proBNP (pg/ml)	4,252 (274-7,919)	2,329 (787-7,754)
LDL	95 ± 37	91.2 ± 35.3

AR: aortic regurgitation, IVS: interventricular septum, LDL: low density lipoprotein, LVDD: left ventricle diastolic diameter, NT-proBNP: N-terminal pro–b-type natriuretic peptide, sPAP: systolic pulmonary artery pressure.
*: calculated with computed tomography

Table 3. Procedural specifics and outcomes in individuals undergoing TAVR

Procedure details	
STS Score	4.4 ± 1.3
Acces site, n (%)	
- Right femoral	14 (87.5)
- Left femoral	1 (6.3)
- Subclavian	1 (6.3)
Valve diameter	
- 21.5 mm	1 (6.3)
- 23 mm	2 (12.5)
- 24.5 mm	3 (18.8)
- 26 mm	9 (56.3)
- 27.5 mm	1 (6.3)
Postdilatation, n (%)	6 (37.5)
Periprocedure inotropic support, n (%)	3 (18.8)
Procedure related complications and outcomes	
Pericardial effusion, n (%)	4 (25.0)
Hemodialysis, n (%)	2 (12.5)
Pacemaker implantation, n (%)	2 (12.5)
Blood transfusion, n (%)	2 (12.5)
Aortic regurgitation, n (%)	
- Mild	2 (12.5)
- Moderate	0 (0.0)
- Severe	0 (0.0)
Percutaneous coronary intervention, n (%)	1 (6.3)
Major bleeding, n (%)	0 (0.0)
Major vascular complication, n (%)	0 (0.0)
Coronary obstruction, n (%)	0 (0.0)
Annular rupture, n (%)	0 (0.0)
Device embolization, n (%)	0 (0.0)
Inhospital mortality, n (%)	0 (0.0)
Mean follow-up time (day)	552

Discussion

In our study, we evaluated the pre- and post-procedural clinical, laboratory, and echocardiographic characteristics of 16 patients who underwent TAVR procedures at our centre over approximately more than 2 years. Additionally, we investigated perioperative and postoperative complications as well as short and long-term mortality development. The mean age of the patients included in the study was 78.3 ± 8.7 years, and they had significant comorbid conditions accompanying them.

When compared to current TAVR studies, our study had similar characteristics in terms of mean age and comorbid conditions.[6,8,9] Current guidelines prioritize TAVR procedures, especially in the elderly population, but increasing age and comorbidities also increase procedural complications, thus increasing procedural risk factors.[4] In our study group, hypertension, coronary artery disease, and dyslipidemia were the most common comorbid conditions, with heart failure diagnosed in 7 patients. It is well-known that mortality and morbidity significantly worsen with the onset of symptoms related to heart failure, especially as symptoms of heart failure emerge in patients with severe aortic stenosis.[10] Therefore, it is crucial to assess the symptomatic status of the patient before deciding on valve interventions. Similarly, the development of heart failure is a parameter that predicts adverse outcomes both related to the disease and the TAVR procedure.

The mean LVEF was found to be 52 ± 8 in our patient's pre-procedure. When symptoms, findings, and LVEF were evaluated together in the patients included in the study, it was possible to classify the majority as having AS-HF. The relatively high LVEF in our study patients may have contributed to the low mortality and peri-procedural complication rates.

In our study, the pre-procedural and follow-up echocardiographic findings of patients were compared. The most important parameters determining the success of the TAVR procedure are the normalization of the aortic valve gradient and an increase in the effective aortic valve orifice area.[11,12] In this regard, a significant decrease in both maximum and mean aortic gradients was observed in our patients. The durability of the valve is currently one of the biggest concerns in TAVR procedures. In the current literature, there is no apparent degeneration reported in follow-ups extending up to 10 years.[13,14] In our 2-year follow-ups, there were no findings suggestive of degeneration associated with gradient increase.

The presence of paravalvular AR post-TAVR is a key determinant of procedural success and long-term outcomes. Reports exist in the literature indicating that moderate or severe paravalvular AR is observed in 1-10% of cases with balloon-expandable valves.[15] Factors such as proper valve sizing, the application of predilation or postdilatation in necessary cases, and the degree of aortic root calcification are fundamental predictors of post-procedural AR formation. In our patient group, there were no patients with moderate to severe AR observed post-procedure or during follow-up. This could be explained by relatively less calcification burden, optimal valve sizing, and the application of postdilatation in selected patients (37.5%).

Currently, there are two main types of valves available for TAVR procedures: balloon-expandable and self-expandable. Although there are some differences between valve types in terms of procedural complications and success, no significant differences have been observed in outcomes.[16,17] We performed all our procedures using balloon-expandable valve systems. It is known that in balloon-expandable valve procedures, complications requiring pacemaker placement due to conduction disturbances occur less frequently.[18] Consistent with current literature, in our study, conduction disturbances requiring permanent pacemaker placement were observed in 12.5% of cases post-procedure.

Current guidelines recommend transfemoral access as the preferred vascular access route for TAVR procedures. It is known that complication rates increase with the use of alternative vascular access routes. The most significant factor preventing the use of femoral access is the presence of peripheral artery disease. Although three (18.8%) of our patients had significant peripheral artery disease, only one procedure was performed using an alternative subclavian access route. In a study by Van Mieghem et al., the risk of major vascular access site complications was found to be above 10%, with arterial sheath size and female gender being significant determinants.[19] In our patients, no major bleeding or major vascular complications were observed either peri-procedurally or post-procedurally. The absence of bleeding complications, especially, is thought to be associated with the use of post-procedural vascular closure devices.

In large randomized controlled trials regarding transcatheter aortic valve implantation, the 30-day mortality rates have been found to range from 3.3% to 9.8%, while the 1-year mortality rates range from 14.2% to 30.7%.[20,21] In our study, with an average follow-up period of 550 days, the overall mortality rate was found to be 18.8%. This rate is consistent with current literature data. It is evident that careful preoperative preparation, proper management of comorbidities, and increased procedural experience will lead to a decrease in both postoperative complications and mortality. Therefore, TAVR procedures should be performed carefully in experienced centres. Although the results of our initial experiences with TAVR procedures, both procedure-related outcomes and follow-up results, are quite satisfactory, it is important to note that during the follow-up period, patients undergoing TAVR may require additional cardiac and non-cardiac interventions and treatments, given their age and other comorbid conditions. In our study, one patient required percutaneous coronary intervention due to coronary artery disease during the follow-up period, and successful revascularization was performed. There is a consensus that the use of balloon-expandable valves facilitates

coronary access. It should not be forgotten that TAVR patients may require additional cardiac and non-cardiac interventions and treatments during the follow-up period, considering both their age and other comorbid conditions.

With the development of new devices and increased experience, complications following TAVR have decreased compared to the beginning. The most lethal complications are associated with myocardial and major vascular injuries. Left ventricular perforation leading to cardiac tamponade occurs in approximately 2.5% of transfemoral TAVR procedures, requiring emergency pericardiocentesis and often emergency sternotomy. The frequency of wire perforations, mostly seen in early experiences, decreases as experience increases.[22] In our study, pericardial effusion developed in 4 patients (25%) after the procedure, but tamponade did not occur during follow-up. None of these patients underwent pericardiocentesis and were conservatively monitored.

In a study conducted by Uguz and colleagues involving patients who predominantly had two different valves implanted via the transfemoral route, it was reported that female gender, arterial calcification, and the sheath/iliofemoral artery ratio were independent risk factors for predicting vascular adverse events.[23] This study, conducted at an experienced center and including 211 patients, found a major vascular complication rate of 5.7%. The patients included in this study had a mean logistic EuroSCORE value of 21.04. In our study, which included a smaller patient group, no major vascular complications occurred. This can be explained by the selection of relatively lower-risk patients and the use of percutaneous closure devices in all patients. Therefore, in patients undergoing TAVI, the presence of conditions such as arterial calcification or peripheral arterial disease warrants greater caution regarding the risk of major vascular complications.

Following TAVR, a decrease in left ventricular end-diastolic pressure and gradients is expected to result in decreased myocardial strain and a consequent reduction in natriuretic peptide levels. It is known that natriuretic peptide (NP) levels decrease after TAVR in the absence of major complications.[24] In our study, a significant decrease in NP values was observed when comparing pre-and post-procedural values. This phenomenon can be associated with both the relaxation of the myocardium functionally and hemodynamically and with improvements in functional capacity and symptoms.

Our study has some limitations. Firstly, presenting a single-centre experience results in a limited number of patients. Additionally, the use of a single type of valve system for TAVR procedures is another limitation. Although there were no follow-up losses in our study, the lack of standardized follow-up periods for all patients may have affected the standardization of follow-up. Furthermore, the data regarding medical treatments used during follow-up are not clear.

Conclusion

According to current guidelines, patients with indications for AVR who are deemed inoperable or at high surgical risk, but with a life expectancy of more than 1 year, are recommended to undergo TAVR. The decision for transcatheter aortic valve implantation should be made by a heart team, taking into account factors such as surgical risk, individual risk, technical feasibility of TAVR, and patient preference. Our center adheres to these recommendations, and the results of TAVR procedures performed within a 2-year period are consistent with the findings of other studies in this field. Despite the development of some procedure-related complications, it is anticipated that with the use of new devices and procedural techniques, these complications will decrease, and better outcomes will be achieved as experience with the procedure increases. Considering the shift towards less invasive treatment modalities in medicine, we believe that TAVR will be used more frequently as an alternative to surgical treatment in different patient groups in the future.

Declaration of interests

The authors declare no conflicting interests.

Acknowledgements

None.

Funding

None.

References

1. Lung B, Baron G, Butchart EG, et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. Eur Heart J. 2003;24(13):1231-1243. doi:10.1016/s0195-668x(03)00201-x
2. Joseph J, Naqvi SY, Giri J, Goldberg S. Aortic Stenosis: Pathophysiology, Diagnosis, and Therapy. Am J Med. 2017;130(3):253-263. doi:10.1016/j.amjmed.2016.10.005
3. Alipour MS, Shah PA. Diagnosis of aortic stenosis in the elderly: role of echocardiography. Am J Geriatr Cardiol. 2003;12(3):201-206. doi:10.1111/j.1076-7460.2003.02067.x
4. Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease [published correction appears in Eur Heart J. 2022 Feb 18;:]. Eur Heart J. 2022;43(7):561-632. doi:10.1093/eurheartj/ehab395
5. Okumus N, Abraham S, Puri R, Tang WHW. Aortic Valve Disease, Transcatheter Aortic Valve Replacement, and the Heart Failure Patient: A State-of-the-Art Review. JACC Heart Fail. 2023;11(8 Pt 2):1070-1083. doi:10.1016/j.jchf.2023.07.003
6. Leon MB, Mack MJ, Hahn RT, et al. Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk. J Am Coll Cardiol. 2021;77(9):1149-1161. doi:10.1016/j.jacc.2020.12.052
7. Mack MJ, Leon MB, Smith CR, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. Lancet.

2015;385(9986):2477-2484. doi:10.1016/S0140-6736(15)60308-7
8. Surman TL, Abrahams JM, Williams-Spence J, et al. Clinical Outcomes in Surgical and Transcatheter Aortic Valve Replacement: An ANZSCTS Database Review 2001-2019. Heart Lung Circ. 2022;31(8):1153-1165. doi:10.1016/j.hlc.2022.04.047
9. Duran Karaduman B, Ayhan H, Keleş T, Bozkurt E. Evaluation of procedural and clinical outcomes of transcatheter aortic valve implantation: A single-center experience. Tek merkeze ait transkateter aort kapak implantasyonunun işlem ve klinik sonuçların değerlendirilmesi. Anatol J Cardiol. 2020;23(5):288-296. doi:10.14744/AnatolJCardiol.2020.03942
10. Tadic M, Sala C, Cuspidi C. The role of TAVR in patients with heart failure: do we have the responses to all questions?. Heart Fail Rev. 2022;27(5):1617-1625. doi:10.1007/s10741-021-10206-6
11. Veulemans V, Afzal S, Papadopoulos G, et al. TAVR-related echocardiographic assessment - status quo, challenges and perspectives. Acta Cardiol. 2020;75(4):275-285. doi:10.1080/00015385.2019.1579979
12. Zajarias A, Cribier AG. Outcomes and safety of percutaneous aortic valve replacement. J Am Coll Cardiol. 2009;53(20):1829-1836. doi:10.1016/j.jacc.2008.11.059
13. Pibarot P, Ternacle J, Jaber WA, et al. Structural Deterioration of Transcatheter Versus Surgical Aortic Valve Bioprostheses in the PARTNER-2 Trial. J Am Coll Cardiol. 2020;76(16):1830-1843. doi:10.1016/j.jacc.2020.08.049
14. Case BC, Khan JM, Rogers T. Early Leaflet Thickening, Durability and Bioprosthetic Valve Failure in TAVR. Interv Cardiol Clin. 2021;10(4):531-539. doi:10.1016/j.iccl.2021.05.005
15. Takagi H, Umemoto T; ALICE (All-Literature Investigation of Cardiovascular Evidence) Group. Impact of paravalvular aortic regurgitation after transcatheter aortic valve implantation on survival. Int J Cardiol. 2016;221:46-51. doi:10.1016/j.ijcard.2016.07.006
16. Lanz J, Möllmann H, Kim WK, et al. Final 3-Year Outcomes of a Randomized Trial Comparing a Self-Expanding to a Balloon-Expandable Transcatheter Aortic Valve. Circ Cardiovasc Interv. 2023;16(7):e012873. doi:10.1161/CIRCINTERVENTIONS.123.012873
17. Sa YK, Choi IJ, Chang K, et al. Balloon-Expandable Versus Self-Expandable Valve in Transcatheter Aortic Valve Replacement: A Nation-Wide Study. Am J Cardiol. 2024;213:119-125. doi:10.1016/j.amjcard.2023.12.007
18. Sammour Y, Krishnaswamy A, Kumar A, et al. Incidence, Predictors, and Implications of Permanent Pacemaker Requirement After Transcatheter Aortic Valve Replacement. JACC Cardiovasc Interv. 2021;14(2):115-134. doi:10.1016/j.jcin.2020.09.063
19. Van Mieghem NM, Tchetche D, Chieffo A, et al. Incidence, predictors, and implications of access site complications with transfemoral transcatheter aortic valve implantation. Am J Cardiol. 2012;110(9):1361-1367. doi:10.1016/j.amjcard.2012.06.042
20. Haussig S, Linke A. Patient selection for TAVI 2015 - TAVI in low-risk patients: fact or fiction? EuroIntervention. 2015;11 Suppl W:W86-W91. doi:10.4244/EIJV11SWA27
21. Thogata H, Garikipati S, Reddy S S, Abhinav Reddy P, Kumar Jella H. Long-Term Prognosis and Predictors of Mortality in Patients Undergoing Transcatheter Aortic Valve Replacement: A Retrospective Analysis. Cureus. 2023;15(8):e44432. Published 2023 Aug 31. doi:10.7759/cureus.44432
22. Seiffert M, Conradi L, Baldus S, et al. Severe intraprocedural complications after transcatheter aortic valve implantation: calling for a heart team approach. Eur J Cardiothorac Surg. 2013;44(3):478-484. doi:10.1093/ejcts/ezt032
23. Uguz E, Gokcimen M, Ali S, et al. Predictability and Outcome of Vascular Complications after Transfemoral Transcatheter Aortic Valve Implantation. J Heart Valve Dis. 2016;25(2):173-181.
24. O'Leary JM, Clavel MA, Chen S, et al. Association of Natriuretic Peptide Levels After Transcatheter Aortic Valve Replacement With Subsequent Clinical Outcomes. JAMA Cardiol. 2020;5(10):1113-1123. doi:10.1001/jamacardio.2020.2614