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Research

Transcatheter Aortic Valve Implantation: A Tertiary Center Experience

Transkateter Aortik Kapak İmplantasyonu: Üçüncül Merkez Deneyimi

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ABSTRACT

Objective: Transcatheter aortic valve implantation (TAVI), which is an actual treatment method for advanced aortic stenosis (AS) in high-risk patients, has been applied to many patients in our clinic. This study aimed to show whether the mortality and morbidity results of the TAVI procedure performed in our clinic were similar to those in the literature.

Methods: Patients who underwent TAVI for severe AS between April 2012 and February 2019 were evaluated. Society of Thoracic Surgeons scores were calculated. Biochemical parameters before and after the procedure and change in echocardiographic parameters after the procedure were determined.

Results: The mean age of the patients was 78 (62-89) years and 56.82% (n=25) were female. The average mean gradient of the patients before and after the procedure were 42 (20-72) and 10 (0-26) mmHg, respectively (p<0.001). In-hospital mortality rate was 9.09% (n=4), peri-procedural mortality rate was 15.9% (n=7). There was only one record of death in TAVI procedures performed after 2015. The Edwards Sapien valve was implanted in 50% (n=22) of patients, while Portico, Corevalve and Evolute valves were implanted in 25% (n=11), 18.18% (n=8) and 6.81% (n=3) of patients, respectively. Thirty (68.18%) patients had TAVI implantation without balloon pre-dilatation. There was no difference in peri-procedural mortality between patients who had and had not balloon pre-dilatation (n=2, 6.7%, and n=2, 14.3%; p=0.581, respectively). Two patients showed moderate aortic regurgitation after valve implantation. Eight patients had stage 1 acute kidney failure (AKF), whereas one patient had stage 2 AKF. One patient required permanent pacemaker implantation because of complete heart block.

Conclusion: When the studies in the literature were examined, the relatively high mortality rates were observed when TAVI procedure was first used. The number of deaths in our clinic has decreased significantly over the years, in accordance with the literature.

Keywords: Aortic stenosis, implantation, mean gradient

ÖZ

Amaç: Cerrahi açıdan yüksek riskli hastalarda ileri aort darlığı (AD) için geliştirilen güncel bir tedavi yöntemi olan transkateter aort kapak implantasyonu (TAVI) işlemi kliniğimizde de birçok hastaya uygulanmıştır. Bu çalışmanın amacı kliniğimizde uygulanan TAVI işleminin mortalite ve morbidite sonuclarının literatürdeki çalışmalar ile benzer olup olmadığınının gösterilmesidir.

Gereç ve Yöntem: Çalışma kapsamında Nisan 2012-Şubat 2019 tarihleri arasında ileri AD sebebi ile TAVI uygulanan hastalar incelendi. Göğüs Cerrahları Dernek skorları hesaplandı. İşlem öncesi ve sonrası biyokimyasal parametreleri, ekokardiyografi sonuçlarının işlem sonrası nasıl değiştiği belirlendi.

Bulgular: Hastaların ortalama yaşı 78 (62-89) yıl idi ve %56,82'si (n=25) kadındı. Hastaların işlem öncesi ve sonrası ortalama gradiyenti sırası ile 42 (20-72) ve 10 (0-26) mmHg idi (p<0,001). Hastane içi ve periprosedurel mortalite oranı %9,09 olarak bulundu. Hastaların %50'sine (n=22) Edwards Sapien marka kapak, %25'ine (n=11) Portico, %18,18'ine (n=8) Corevalve, %6,81'ine ise (n=3) Evolute marka kapak takıldı. Otuz hastaya (%68,18) balon predilatasyonu uygulanmadı. Balon uygulanan ve uygulanmayan hastalarda periprosedurel mortalite açısından fark saptanmadı (sırası ile, n=2, %6,7 ve n=2, %14,3; p=0,581). İki hastada işlem sonrası orta derecede aort yetersizliği gelişti. Sekiz hastada evre 1 akut renal hasar, bir hastada ise evre 2 akut renal hasar gelişti. Bir hastaya tam kalp bloğu nedeni ile kalıcı pacemaker implante edildi.

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Sonuç: Literatürde yer alan çalışmalara bakıldığında TAVI işlemi ilk kullanılmaya başlandığında göreceli olarak yüksek mortalite oranları görülmüştür. Ancak ölüm sayısı literatür ile uyumlu şekilde yıllar içinde belirgin azalma göstermiştir.

Anahtar Kelimeler: Aort darlığı, implantasyon, ortalama gradient

INTRODUCTION

Calcific degeneration of the aortic valve is complicit in the pathogenesis of aortic stenosis (AS). It affects persons over the age of 75 years with an estimated prevalence of 3.4% (1). Classically, longstanding increase in pressure overload leads to left ventricular hypertrophy and ultimately heart failure. These patients are generally older and have comorbidities that can worsen their outcomes. If left untreated, symptomatic AS has an annual mortality rate of up to 25% (2,3).

Although surgical aortic valve replacement (SAVR) is the mainstay of treatment, transcatheter aortic valve implantation (TAVI) has become a novel treatment modality for the management of high risk patients with AS. First TAVI operation was performed in 2002, and in 2012, Food and Drug Administration approved TAVI for treating patients with AS who had a prohibitive risk of surgery. Clinical decision whether to perform TAVI or SAVR depends on various factors including patients' comorbidities, operator's experience and prosthesis factors. TAVI has been a non-inferior alternative of SAVR in extreme high-risk patient population; furthermore, it was found to be superior compared to medical treatment (4-6). Vascular-neurological complications and post-procedural aortic regurgitation (AR) are the most frequently reported complications in TAVI patients (4). After its promising results in high-risk patients, its performance in intermediate and low-risk patients have been evaluated. Nordic Aortic Valve Intervention trial assessed CoreValve transcatheter heart valve with SAVR using a sample of 280 patients with intermediate to low-risk profile. Primary endpoints, including myocardial infarction, stroke and mortality, were found to be similar in both groups. Acute kidney injury (AKI), bleeding was higher in SAVR, whereas paravalvular leakage and pacemaker implantation were higher in the transcatheter heart valve arm (7). A large-scale trial, Placement of Aortic Transcatheter Valves (PARTNER) IIA, compared balloon-expandable SAPIEN XT valve with SAVR in intermediate risk group patients. The primary end-point was similar in both treatment groups at two years follow-up. In this study transfemoral approach was superior to the surgical treatment (8). Furthermore, recent studies conducted in low risk patients with AS showed that TAVI was a non-inferior alternative to surgical treatment (9,10). Based on the results of clinical studies, current European valvular guideline advocates TAVI as class I indication for patients with AS who are older than 75 years have Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM)/score EuroSCORE II greater than 8 or unsuitable for surgery (11). For the patients who are under 75 years of age and have a low surgical risk, SAVR is recommended. The remaining patients should be assessed according to their clinical and procedural features, including valve durability and life expectancy of the patient.

In our country, the number of TAVI procedures has increased since it was first carried out in 2009 (12). Although clinical trials and registries performed on patients with AS provide real world data in terms of procedural success, complications, short-and mid-term outcomes, patient selection and operator experience differ from center to center (13-15). It is well known that operator experience and center size have a positive impact on the outcome of patients (16). Therefore, obtaining homogenous data that are drawn from a single population may be important owing to non-uniform data collected from different centers. In this context, we evaluated whether mortality and morbidity results of TAVI procedure performed in our hospital were similar to those in the literature.

METHODS

This retrospective study included 44 patients who underwent TAVI procedure between April 2012-February 2019 in the cardiology department of a tertiary hospital in Türkiye. Patients' data, including age, comorbidities, presence of atrial fibrillation, beta blocker use, biochemical variables, pre and post-procedural systolic and diastolic blood pressure, electrocardiogram, implanted valve type and size were obtained from hospital records.

Echocardiography, Multislice Computed Tomography and Coronary Angiography

All the patients underwent echocardiographic examinations with the using of vivid 9 device, which had a sector transducer of 3.2 MHz (Horten, Norway). Echocardiographic assessments complied with the current guidelines (17). The diagnosis of severe AS was diagnosed if the patient had an aortic valve area of less than 1 cm^2, mean transaortic gradient of more than 40 mmHg, mean transaortic jet velocity of more than 4 m/s, or indexed aortic valve area of 0.6 cm^2/m^2. Pre-procedural and post-procedural aortic valvular gradient, presence and degree of AR, ejection fraction, left atrial, left ventricular diastolic and ascending aorta diameters

were assessed. Cardiac CT was performed for each patient to delineate the anatomical and functional properties of the aortic valve. Aortic root structural parameters such as perimeter, area and diameter; coronary hinge points, degree and distribution of aortic valve calcification, ascending aorta diameter were estimated. Coronary angiographic imaging of each patient was provided. If the patient had more than 70% stenosis in one of the major coronary arteries, that stenosis was classified as severe stenosis. For the left main coronary artery, severe stenosis was described as more than 50% occlusion of the artery.

STS scoring system was used for the operative risk assessment of the patients (18). Patients were high, intermediate and low risk if they had risk score of more than 8%, 4-8%, and less than 4%, respectively. The decision regarding performing SAVR or TAVI was made by heart team which included invasive cardiologist, cardiovascular imaging specialist, and a cardiovascular surgeon. If the patient had a high STS risk score and/or associated co-morbidities decision in favor of TAVI was made. If the patient had concomitant coronary artery disease, bicuspid aorta, moderate/severe AR, severe other valve disease, aortic annulus size less than 18 mm and/or more than 35 mm, the decision was made in favor of SAVR. Ethical Committee of University of Health Sciences Türkiye, Bakırköy Dr. Sadi Konuk Training and Research Hospital approved the study and it was directed in conformity with the declaration of Helsinki (decision no: 2019-05-12, date: 04.03.2019).

The suitability of the peripheral vasculature to the procedure was assessed by multi-slice computed tomography. The vascular acces route, tortuosity of the vessels, presence and extent of calcification in the peripheral arteries were determined. All procedures were done by transfemoral approach. Sheath sizes were adapted according to the valve size. The type of valve implanted was left to the operator's preference. Edwards Sapien, Portico, Corevalve and Evolute valves were implanted during the study period. All patients underwent temporary pacemaker implantation concomitant with TAVI operation under conscious sedation. At the end of the operation, percutaneous closure devices were used to provide femoral hemostasis. For assessing complications (mortality, neurological events, bleeding and renal complications) Valve Academic Research Consortium-3 was used (19). Periprocedural mortality was described as death within 30 days of valve implantation. In hospital and periprocedural mortality rates of the patients were calculated. Neurological events were classified as ischemic stroke, hemorrhagic stroke, or transient ischemic attack. AKI is classified into four stages. Stage 1 AKI was described as an increase in creatinine level 1.5-2 times the baseline within seven days or more than 0.3 mg/dL increase within 2 days after the procedure. Stage 2 AKI was described as 2-3 times increase in creatinine levels compared with baseline within 7 days after the procedure. Stage 3 AKI was described as an increase in serum creatinine levels 3 times of baseline within 7 days of procedure or serum creatinine level of more than 4 mg/dl with an increase of more than 0.5 mg/dL. Stage 4 AKI is described as temporary or permanent renal replacement therapy (19).

Statistical Analysis

Categorical variables were expressed as frequency and percentages. Normality testing of continuous variables was done by Kolmogorow-Smirnow test. Since all data showed a non-normal distribution, continuous variables were expressed as median, minimum and maximum. Comparison of pre-procedural and post-procedural variables was done by Kruskall-Wallis H test. Agreement between pre-procedural and post-procedural AR was evaluated by Fleiss Kappa analysis. Lastly, a comparison of STS scores of patients who deceased during the first 24 h of TAVI, deceased during indeterminate time from TAVI and living patients was made using Kruskal-Wallis H test. $P<0.05$ was considered as significant. All statistical analyses were done using Number Cruncher Statistical System, 2017 Statistical Software.

RESULTS

The average age of the study population was 78 (62-89) years, 19 of (43.18%) were male and 25 of (56.82%) were female, 29.55% were diabetic, 75% were hypertensive, 54.55% had ischemic heart disease. The demographic characteristics of the patients are given in Table 1. Mean STS score and mean-implanted valve size was 4 (2.49-11) and 26.5 (23-35) mm, respectively. Clinical characteristics are given in Table 2. Mean pre-procedural ejection fraction and aortic valve area were found to be 56.5 (20-65) and 0.8 (0.4-1.2) cm^2, respectively. Pre-procedural echocardiographic findings are given in Table 3. The Edwards Sapien valve was implanted in 50% (n=22) of patients, while Portico, Corevalve and Evolute valves were implanted in 25% (n=11), 18.18% (n=8) and 6.81% (n=3) of patients, respectively. Thirty (68.18%) patients had TAVI implantation without balloon pre-dilatation. We did not find any difference in peri-procedural mortality between patients who had and had not balloon pre-dilatation (p=0.581).

The mean aortic gradient decreased from 42 (20-72) mmHg to 10 (0-26) mmHg after TAVI procedure ($p<0.0001$) (Table 4). According to Fleiss Kappa analysis, there was no

significant agreement regard to the degree of AR before and after the procedure (Table 5). Four patients died or within 24 of the procedure. Two patients died from cardiac arrest and 2 patients died from ischemic stroke (in-hospital mortality=9.09%). Of the 4 deceased patients, three patients underwent TAVI procedure between 2012 and 2015, whereas one patient died in 2017. The mean STS score of the deceased patients was 5.63. Seven patients died within one month after the procedure (peri-procedural mortality n=7, 15.9%). Since we accessed deceased patients' information from government database system, we couldn't identify the cause of death. We found no differences with respect to STS scores between deceased and alive patients. Table 6 shows the in-hospital mortality of the study population.

Twenty-two patients had balloon expandable bioprostethic valve implantation. Of these patients 6 patients had mild, 4 patients had mild-to-moderate and only one patient had moderate AR before TAVI implantation. After valve implantation, only one patient who had moderate AR who mild AR before TAVI. No patient had severe AR after the procedure. Of 22 patients who underwent self-expandable valve implantation, 3 patient had mild, 6 patients had mild-to-moderate and 3 patients had moderate AR. After self-expandable valve implantation, only one patient had moderate AR, who had mild regurgitation before the procedure. No patient had severe regurgitation after self-expandable valve implantation.

Table 1. Demographic characteristics of the patients

	n	%
Male	19	43.18
Female	25	56.82
DM	13	29.55
HT	33	75
COPD	6	13.64
PCS	10	22.73
IHD	24	54.55
B-blocker use	24	54.55
AF	9	20.45

DM: Diabetes mellitus, HT: Hypertension, COPD: Chronic obstructive pulmonary disease, PCS: Previous cardiac surgery, IHD: Ischemic heart disease, AF: Atrial fibrillation

Table 2. Clinical characteristics of the patients

	Median (minimum-maximum)
Age (years)	78 (62-89)
Valve size (mm)	26.5 (23-35)
STS score	4 (2.49-11)
Hct (%)	32.65 (25.8-45.58)
Plt (×10^3/L)	207.5 (106-482)
MPV (fl)	9.17 (6.88-15.1)
Urea (mg/dL)	53.5 (22-158)
Uric acid (mg/dL)	6.47 (0-11.1)
TC (mg/dL)	192 (6.11-290)
LDL-C (mg/dL)	115 (50.8-226)
HDL-C (mg/dL)	49.5 (21-86)
TG (mg/dL)	101 (32-300)

STS: Society of Thoracic Surgeons, Plt: Platelelet, Hct: Hematocrit, MPV: Mean platelet volume, TC: Total cholesterol, LDL-C: Low-density lipoprotein cholesterol, HDL-C: High-density lipoprotein cholesterol, TG: Triglyceride

Table 3. Echocardiographic parameters of the study population

	Median (minimum-maximum)
EF (%)	56.5 (20-65)
LA (mm)	41.5 (29-54)
IVS (mm)	13 (9-18)
PW (mm)	12 (8-14)
LVD (mm)	49 (35-70)
AVA (cm^2)	0.8 (0.4-1.2)
Pre-procedural maximum gradient (mmHg)	71.5 (38-150)
Pre-procedural mean gradient (mmHg)	41(20-72)
Ascending aortic diameter (mm)	35 (27-46)

EF: Ejection fraction, LA: Left atrium, IVS: Interventricular septum, PW: Posterior wall, LVD: Left ventricular end diastolic diameter, AVA: Aortic valve area

Table 4. Pre-procedural and post-procedural clinical variables of the patients

	Pre-procedural	Post-procedural
SBP	120 (100-163)	122.5 (83-172)
DBP	70 (54-90)	64 (42-91)
Hgb	10.7 (8.21-15.9)	10 (7.7-14.3)
WBC	7.11 (4.8-14.79)	10.15 (6.28-24.1)
Creatinine	1.13 (0.6-6.55)	1.21 (0.58-7.09)
Mean aortic gradient (p<0.0001)	42 (20-72)	10 (0-26)

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, Hgb: Hemoglobin, WBC: White blood cell

Table 5. Comparison of pre and post-procedural aortic regurgitation

		Post-procedural aortic regurgitation					
		Absent (n,%)	Mild (n,%)	Mild-moderate (n,%)	Moderate (n,%)	Total (n,%)	p/Kappa
Pre-procedural aortic regurgitation	Absent	5 (38.46)	6 (46.15)	2 (15.18)	0 (0)	13 (100)	0.347/0.100
	Mild	2 (22.22)	4 (44.44)	1 (11.11)	2 (22.22)	9 (100)	
	Mild-moderate	2 (20.00)	8 (80.00)	0 (0)	0 (0)	10 (100)	
	Moderate	0 (0)	4 (100)	0 (0)	0 (0)	4 (100)	
	Total	9 (25)	22 (61.11)	3 (8.33)	2 (5.56)	36 (100)	

Table 6. Peri-procedural mortality of the patients

	Death (n=16) (36.36%)	Alive (n=24) (54.55%)	In-hospital mortality (n=4) (9.09%)	p
STS score median (min-max)	4.46 (2.49-8.74)	3.54 (2.99-11.00)	4.19 (3.81-10.34)	0.558

STS: Society of Thoracic Surgeons, min: Minimum, max: Maximum

Eight patients had increase in creatinine level more than 0.3 mg/dL, indicating stage 1 AKF. Only one patient had more than 2 times increase in creatinine level compared with baseline (pre-procedural creatinine: 1.25 mg/dL versus post-procedural creatinine: 3.12 mg/dL). No patient required temporary or permanent renal replacement therapy. One patient required permanent pacemaker implantation because of complete heart block.

DISCUSSION

Since the first implantation in 2002, TAVI has become an established treatment for patients with severe AS who have a high or moderate surgical risk. When TAVI was first introduced to medical practice, its mortality rate was comparable to that of SAVR (6). Overtime, improvements in both operator experience and technical equipment have resulted in decreased procedural risk and mortality (9). Our in-hospital and periprocedural mortality rates were 9.09% and 15.9%, respectively and mean implanted valve size was 27.2 mm. The mean STS score of our study population was 4.99%; four patients died during or within 24 h after the procedure. Three patients died between 2012-2015 and one patient died in 2017, after that time no patient was lost during the hospital stay. There was no difference in STS score of deceased and alive patients.

After all data were collected, we performed a review of literature to compare our results with already published studies. Surgical Replacement and Transcatheter Aortic Valve Implantation trial randomized 1660 intermediate patients with AS to TAVI or surgical procedure. Mean age and STS score of the enrolled patients were 79.8 years 4.5%, respectively. After 24 months, composite death from any cause or disabling stroke was 12.6% for the TAVI arm and 14% for the surgical arm. Peri-procedural mortality of the study population was 2.2% (20). In the PARTNER IIA study, 1011 and 1021 severe patients with AS with intermediate surgical risk were assigned to TAVI and SAVR, respectively. The mean STS score was 5.8%. The composite end point did not differ between two groups of patients. The incidences of all-cause mortality and disabling stroke at two years were 19.3% and 21.1% for TAVI and surgical arm, respectively. This study did not specifically note the peri-procedural mortality rate (8). Thourani et al. (21) compared intermediate risk patients with AS who received the third generation SAPIEN 3 valve with the surgical arm of the PARTNER IIA trial. In that study, the mean STS score was 5.2±1.7%, technical success was attained in 98% of patients. One year mortality and stroke rate was significantly lower with the use of third generation valve (p=0.0038) (21). Similarly, PARTNER III trials, which has been performed on low risk patients with AS (STS score: 1.9%) revealed that TAVI was superior to SAVR in terms of composite death, stroke and rehospitalization (9). Duran Karaduman et al. (22) reported their experience with 556 patients. The mean STS score of the patients was 6.0%±3.5%. In the hospital and one-year mortality of the study group were 3.9% and 12.3%, respectively (22). Dağdelen et al. (23) reported early and mid-term results of ten high-risk patients with AS who underwent Edwards Sapien bioprosthetic valve implantation. During early and mid-term follow-up no patient died or had stroke (23). Results

of randomized trials and observational studies showed that peri-procedural mortality of TAVI ranges from 13.30 (Engager) to 0.69 (SAPIEN 3) (24). The mortality rate at our hospital has declined in accordance with the literature. Our in-hospital and periprocedural mortality rates were 9.09% and 15.9%, respectively. Of the 4 patients who died during the hospital stay, two of them died from cardiovascular arrest and the other two died of a cerebrovascular event. There has been only one in-hospital death after 2015. This reduction in mortality was greatly due to decrease in sheath size and peripheral vascular complications, increased operator experience, and the use of second generation valves. In our study mean STS score was relatively low (median=4, minimum=2.49, maximum=11). That could be attributed to a long period of study time. Our study period began in April 2012 and ended in February 2019. During the initial period of study time, patients with high STS scores were underwent TAVI procedure, however with the operator experience and expansion of indications, patients with intermediate and even low STS scores underwent the procedure with favorable clinical results. Besides, our heart team evaluated each patient and not only the STS scores of the patients were evaluated but also other comorbidities were considered.

We also estimated post-procedural AR. Two patients who had no AR pre-procedurally, developed mild-moderate AR after the procedure. Likewise, 2 patients with mild AR, developed moderate AR after the procedure. Of the patients who developed moderate AR, one patient underwent balloon expandable valve and the other patient underwent self-expandable valve implantation. Mild-moderate AR regressed to mild AR in 8 patients and moderate AR mild AR in 4 patients. The Edwards Sapien valve was the most commonly implanted valve in our study, in addition we did not find any difference with respect to peri-procedural mortality in patients who underwent balloon pre-dilatation compared to those who did not undergo balloon pre-dilatation.

CONCLUSION

In conclusion, our TAVI experience was increased over time and the mortality rate of our clinic was decreased significantly in accordance with the literature. Mean STS score of our study group was 4 indicating an intermediate risk group of patients. TAVI is a reliable alternative of SAVR in high and intermediate risk groups of patients, moreover, it could have a future potential in low-risk patients.

The major limitations of our study were as follows; the study had a small sample size, we did not know the exact cause of death during long-term follow-up and the incidence of TAVI related para-valvular AR could not exactly estimated.

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ETHICS

Ethics Committee Approval: Ethical Committee of University of Health Sciences Türkiye, Bakırköy Dr. Sadi Konuk Training and Research Hospital approved the study and it was directed in conformity with the declaration of Helsinki (decision no: 2019-05-12, date: 04.03.2019).

Informed Consent: Retrospective study.

Authorship Contributions

Concept: F.F., E.O., C.Y., İ.F.A., Design: F.F., E.O., İ.F.A., Data Collection or Processing: F.F., E.O., İ.F.A., Analysis or Interpretation: F.F., E.O., C.Y., İ.F.A., Literature Search: F.F., E.O., C.Y., İ.F.A., Writing: C.Y.

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