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Transcatheter Aortic Valve Implantation: First Applications and Short Term Outcomes in Our Clinic

Transkateter Aort Kapak Implantasyonu: Kliniğimizdeki İlk Uygulamalar ve Erken Dönem Sonuçları

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Abstract

Objective: The objective of this study is to evaluate the first applications and short term outcomes of transcatheter aortic valve implantation (TAVI) in our clinic, which is a new technology for the patients with high risk for surgical aortic valve replacement (SAVR).

Materials and Methods: Between January 2010 and December 2012, twenty five patients (16 males, 9 females; mean age 74.04±8.86 years) diagnosed with severe aortic stenosis, who were at high risk for surgery (EuroSCORE II: 5.58±4.20) and underwent TAVI in our clinic, were evaluated. The demographic and clinical characteristics of patients, anaesthetic management, complications during pre- and post-operative periods and the mortality rate in the first 30 days and six months were recorded.

Results: Edwards SAPIEN Valve prostheses were implanted by transfemoral approach (percutaneously in 10 patients and surgically in 15 patients) in all patients. The TAVI procedure was performed under general anaesthesia. The success rate of the TAVI procedure was 100%. Three patients had limited dissection of the femoral artery; however, intervention was not needed due to good distal perfusion rate. Permanent pacemaker was implanted to four patients because of long-term atrioventricular blockage. After the procedure, all patients were transferred to the Intensive Care Unit (ICU) and all patients were extubated in the ICU. The mean mechanical ventilation duration (minutes) was 166.20±39.32, the mean critical care unit stay (day) was 5.64±2.99 and the mean hospital stay (day) was 11.92±5.54. Acute renal failure was observed in one patient and stroke was observed in two patients on the first postoperative day. The mortality rate in the first 30 days and 6 months was found to be 4% and 16%, respectively.

Conclusion: Transcatheter aortic valve implantation is a great option for patients with severe aortic stenosis who are at high risk for SAVR. In our institute, procedural success and short term outcomes for patients underwent TAVI were found to be similar to the other studies in the national and international literature.

Keywords: Aortic valve stenosis, transcatheter aortic valve implantation, outcomes

Özet

Amaç: Bu çalışmanın amacı, cerrahi aort kapak replasmanı (SAVR) için yüksek risk taşıyan hastalarda yeni bir teknoloji olan transkateter aort kapak implantasyonunun, (TAVI) kliniğimizdeki ilk uygulamalarını ve erken dönem sonuçlarını ortaya koymaktır.

Gereç ve Yöntem: Ocak 2010 ve Aralık 2012 tarihleri arasında, şiddetli aort darlığı tanısı almış olup, cerrahi için yüksek riske sahip olmaları nedeniyle (EuroSCORE II: 5,58±4,20) kliniğimizde TAVI uygulanan 25 hasta (16 erkek, 9 bayan; ortalama yaş: 74,04±8,86 yıl) değerlendirildi. Hastaların demografik ve klinik özellikleri, anestezi yönetimi, preve post-operatif dönemlerdeki komplikasyonlar ile ilk 30 gün ve altı aydaki mortalite oranları kaydedildi.

Bulgular: Tüm hastalarda Edwards SAPIEN Valve protez transfemoral yaklaşımla (10 hastada perkutanöz, 15 hastada cerrahi yöntemle) yerleştirildi. Tüm hastalarda TAVI işlemi genel anestezi altında yapıldı ve transözefagial ekokardiyografi tüm hastalara uygulandı. TAVI işleminin başarı oranı %100 idi. İşlem süresince mortalite ve ciddi komplikasyon izlenmedi. Üç hastada femoral arterde sınırlı disseksiyon görüldü, ancak distal perfüzyonun iyi olması nedeniyle herhangi bir müdahale gerekmedi. Uzun süreli atriyoventriküler blokaj nedeniyle dört hastaya kalıcı pacemaker takıldı. İşlem sonrası, tüm hastalar Yoğun Bakım Ünitesi'ne (YBÜ) gönderildi ve tüm hastalar YBÜ'de ekstübe edildi. Ortalama mekanik ventilasyon süresi (dakika): 166,20±39,32, ortalama yoğun bakımda kalış süresi (gün): 5,64±2,99 ve ortalama hastanede kalış süresi (gün): 11,92 ±5,54 idi. Postoperatif birinci gün, bir hastada akut renal yetmezlik ve iki hastada inme izlendi. İlk 30 gündeki mortalite oranı %4 ve ilk 6 aydaki mortalite oranı %16 olarak bulundu.

Sonuç: Transkateter aort kapak implantasyonu, ciddi aort darlığı olup SAVR için yüksek risk taşıyan hastalarda mükemmel bir seçenektir. Enstitümüzde, TAVI uygulanan hastalardaki işlem başarısı ve kısa dönem sonuçlarının Türkiye'deki ve dünyadaki diğer çalışmalara benzer olduğu bulundu.

Anahtar Kelimeler: Aort kapak darlığı, transkateter aort kapak implantasyonu, sonuçlar

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Introduction

Aortic stenosis is a valvular heart disease affecting approximately 2% of the patients older than 65 years [1]. Aortic valve replacement (AVR) is needed in the presence of syncope, severe angina, congestive heart failure and severe dyspnoea [2]. Two methods, namely surgical aortic valve replacement (SAVR) and transcatheter aortic valve implantation (TAVI) have been developed for aortic valve replacement. TAVI is a less invasive method compared to SAVR for patients with aortic stenosis. Especially, elderly patients with aortic stenosis have high mortality (4%-18%) during SAVR due to the increased medical comorbidities such as severe left ventricular dysfunction, renal and respiratory disease [3, 4].

European System for Cardiac Operative Risk Evaluation (EuroSCORE) and the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) algorithms are usually used to evaluate the cardiac surgical risk. Scoring is done by evaluating multiple variables such as age, sex, preoperative state of the patient, serum creatinine levels, the presence of previous cardiac surgery and the presence of comorbid disease (active endocarditis, pulmonary, renal or peripheral vascular disease) [4].

Transfemoral, transapical, subclavian and iliac approaches have been described for the TAVI procedure. Coordinated multidisciplinary approach (cardiologist, cardiothoracic surgeon, anaesthesiologist, perfusionist and assistant health personnel) is essential for the success of TAVI. Careful anaesthetic management during TAVI reduces the recovery time after the procedure and the risk of potential complications such as extreme hypotension and hemodynamic instability [5, 6]. The purpose of a good anaesthetic management during TAVI is to achieve the optimal hemodynamic stability maintaining the preload, afterload and contractility [5]. General anaesthesia or local anaesthesia plus sedation may be used according to patient's characteristics, the presence of additional diseases and the preference of the surgical team [4].

The aim of this retrospective study is to evaluate the clinical and demographic characteristics of 25 patients underwent TAVI in our clinic between January 2010 and December 2012. We will also evaluate the anaesthetic management, complications during pre- and post-operative periods and the mortality rate in the first 30 days and six months in these patients.

Materials and Methods

The study was approved by the Ethics Committee of Ataturk University, Medical Faculty and written informed consents were obtained from all patients. Between January 2010 and December 2012, 25 TAVI procedures were performed at Ataturk University, Medical Faculty. The data of these patients were analysed with regard to clinical characteristics, anaesthetic management, pre- and post-operative complications and short term outcomes.

Surgical risk was evaluated using the EuroSCORE II [7] by a team including two cardiologist and cardiac surgeons. The patients with a high surgical risk for SAVR (EuroSCORE II>5) and inoperable patients (aged 65 years and over who suffered from at least one significant comorbidity such as liver cirrhosis, pulmonary hypertension, previous cardiac surgery and right ventricular failure) referred for the TAVI procedure. Transthoracic echocardiography was performed to detect the heart functionality, estimated ejection fraction rate of the left ventricle and pulmonary hypertension. Patients with an aortic annulus diameter >25 mm or <18 mm, asymmetric heavy valvular calcification, apical left ventricular thrombus on echocardiography were not referred to the TAVI procedure. In all patients, iliofemoral anatomy was evaluated with aortofemoral angiography and computed tomography, and coronary angiography was performed to assess the coronary anatomy and haemodynamic status. Transfemoral approach was initially planned for all patients. Subclavian approach was planned for the patients unsuitable for the femoral approach (such as with a severely calcified aortic arch and previous aortofemoral bypass). Edwards-SAPIEN valve (Edwards Lifesciences Inc, Irvine, CA) was used in all patients.

All TAVI procedures were performed in a hybrid operating room including adequate and sterile instruments for conventional open surgery accompanied by imaging methods [transesophageal echocardiography (TEE), high-resolution fluoroscopy, contrast aortography]. These imaging methods were used to detect the valve position, diagnose the complications and observe the heart functionality after the procedure. The procedure was performed by a team of two cardiologists, two anaesthesiologists, an assistant health personnel and a cardiac surgeon, and a perfusionist was available for the emergent surgery. All patients received acetylsalicylic acid (100 mg/day) (Aspirin®, Bayer, Istanbul, Turkey), intravenous cefazolin (Cefamezin®, Eczacibasi, Istanbul, Turkey), and clopidogrel (300 mg loading dose) (Plavix®, Sanofi-Aventis, Istanbul, Turkey) before the procedure. Additionally, patients received intravenous heparin (70-100 IU/kg) (Fraxiparine®, Sanofi-Dogu, Istanbul, Turkey]) to achieve an activated clotting time of 250-300 seconds during the TAVI procedure. At the end of the procedure, heparin was antagonized with protamine (Protamin®; Roche, Istanbul, Turkey) on a 1:1 basis. After the procedure, clopidogrel (75 mg/day, at least 6 months) and acetylsalicylic acid (100 mg/day, lifelong) were continued in all patients.

Two experienced anaesthetists evaluated all patients in terms of cardiovascular function and comorbidities which should be considered during the anaesthesia of the TAVI

procedure. General anaesthesia was preferred in all patients. A radial artery catheter was placed in the left radial artery for anaesthetic interventions. Before monitoring, premedication was provided with intravenous midazolam (0.01-0.02 mg/kg) (Dormicum®, La Roche, Basel, Fontenay, France) in all patients. All standard monitors including five-lead ECG, pulse oximetry, urinary catheter, bladder temperature, radial artery blood pressure, central venous pressure were performed. Urinary catheterization was performed to eliminate the accumulated contrast material in the bladder. A heating blanket placed beneath the patient to prevent hypothermia. A defibrillator was prepared in the procedure room to treat the ventricular fibrillation immediately. Every patient received an infusion of 500 mL crystalloid solution in 45 minutes and end-tidal oxygen concentration was maintained above 80% via a face mask before starting the induction.

The aim of the anaesthetic management during the procedure was to provide the optimal hemodynamic stability and maximal coronary perfusion maintaining an adequate preload, contractility and afterload. Induction of anaesthesia was made with bolus doses of propofol (2 mg/kg) (Propofol®, Fresenius, Istanbul, Turkey), remifentanyl (1 µg/kg) (Ultiva®, GlaxoSmithKline, Istanbul, Turkey) and rocuronium (Esmeron®, Organon, Istanbul, Turkey) (0.6 mg/kg). After tracheal intubation was performed with a single-lumen endotracheal tube, anaesthesia was maintained with oxygen (2 L/min), target-controlled infusion of propofol (target effect site concentration 1 µg/mL) and remifentanyl (target effect site concentration 1-3 ng/mL). TEE probe was inserted after the intubation to observe the left ventricular function and the volume status during the procedure. A triple-lumen central venous catheter was inserted through the right internal jugular vein for rapid volume administration in case of a severe hypotension and for monitoring the cardiac output during procedure. Two units of erythrocyte suspension were prepared for each patient preoperatively and the transfusion of erythrocyte suspension was performed in the case of haemoglobin levels <8 g/dL.

The surgical technique was applied according to the method described by the authors [8]. A pacing wire was placed in the right ventricular apex via the femoral vein. After the femoral artery was prepared percutaneously or surgically, the sheath (22F or 24F for Edwards-SAPIEN valve System) was inserted through the femoral artery observing with fluoroscopy. Then, native valve was dilated and the prosthesis was deployed by balloon inflation (to provide enlarged passageway for the prosthesis insertion) under rapid ventricular pacing (RVP). RVP providing temporary reversible cessation of the cardiac output was performed to facilitate the implementation of the balloon valvuloplasty following valve deployment.

Before starting RVP, MAP was increased above 90 mmHg using intravenous adrenaline or noradrenaline to prevent hemodynamic instability after stopping the pacing. Initial rate of RVP was 180-200 beats/min and then it was decreased to 20 beats/min sequentially until reliable capture was achieved. During RVP, the cardiac stand still duration was limited to less than 10 seconds to prevent possible myocardial ischemia. During the procedure, low heart rates (50-70 beats/min) were preferred to allow the adequate diastolic filling time and mean arterial pressure (MAP) was maintained above 65 mmHg. Hypotension (MAP <65 mmHg) was treated with intravenous crystalloid/colloid infusion and repeat bolus doses of epinephrine (5 µg) for the patients with impaired left ventricular function (ejection fraction <45%) and repeat bolus doses of norepinephrine (5 µg) for the patients with no regional wall motion abnormalities. Continuous infusions of inotropic agents were used in the case of unamended arterial hypotension (systolic arterial pressure <80 mmHg for more than 2 minutes despite optimal contractility and preload volume). Supraventricular arrhythmias and ventricular ectopy were controlled aggressively.

If ventricular fibrillation due to post-pacing myocardial ischemia was occurred during the procedure, electrical cardioversion was planned after completing the valve deployment to avoid the malposition of prosthesis and embolization. Total atrioventricular block was treated with permanent pacemaker implantation. Cardiopulmonary bypass was planned in the case of consistently low MAP despite the continuous infusions of inotropic agents or persistent ventricular fibrillation. After the implantation, valve position, whether paravalvular leakage or coronary artery, blood flow was controlled via TEE and aortic root angiography. Before the sheath was removed, stable valve position was detected and valve function was verified without any paravalvular leakage. In cases using the surgical approach, the access cites were closed surgically. Prostar XL device was used (Abbott Vascular Devices, Abbott Park Devices, IL) for percutaneous closure [8]. Procedural success was defined as the implantation of a properly functioning single prosthesis in the correct position. The procedure success was defined as a presence of bioprosthetic valve expanded in the proper position without valve or perivalvular significant leaks and major complications.

After the procedure, all patients were transferred to the Intensive Care Unit (ICU) for extubation and continuous postoperative electrocardiogram monitoring for three days. Early extubation was performed in all patients and postoperative analgesia was provided with paracetamol (1g every 6 hours) (Perfalgan®, Bristol-Myers Squibb, NY, USA). When hemodynamic and cardiac rhythm were stable (SpO_2 >94%, no significant arrhythmias, urine output ≥0.5 mL/kg/h and no intravenous inotropic or vasopressor requirement), the

patients were transferred to a general cardiac ward. The patients were discharged with a good hemodynamic stability, normal bowel function, no infection and normal feeding. Patients who were discharged from the hospital were called for routine screening and echocardiography examination at first, third and sixth months.

Demographic and clinical characteristics of the patients, duration of the total procedure (the time from premedication until the patient transfer to the ICU), the intervention time of the procedure (the time from femoral skin incision until the percutaneous closure of the vascular access site) and intensive care unit stay, needed for the transfusion of blood products were recorded in medical records. Serum creatinine levels, complications during and after the procedure, mortality rate (30-day mortality and 6-month mortality) and causes of death were also recorded through reviewing the medical records and telephone follow-up. Data was presented as mean±SD or percentages and SPSS software 12.0 (SPSS Inc.; Chicago, IL, USA) was used for the data analysis. Student t-test was used to compare the preoperative and postoperative parameters.

Results

A total of 25 patients underwent the TAVI procedure at the Anaesthesia Department of Ataturk University, Medical Faculty between January 2010 and December 2012. The demographic characteristics and comorbidities of all patients are presented in Table 1. Edwards SAPIEN Valve prostheses were implanted by transfemoral approach (percutaneously in 10 patients and surgically in 15 patients) in all patients. All patients had severe aortic stenosis and high risk for conventional surgery. The TAVI procedure was performed under general anaesthesia and TEE was applied to all patients. Continuous infusion of dobutamine (2-10 µgr/kg/min) was used in four patients due to unamended arterial hypotension. Some parameters and outcomes related to TAVI procedure were presented in Table 2. All bioprosthetic valves were properly functioned according to angiographic and echocardiographic examinations after the procedure. Serious paravalvular aortic regurgitation was not observed in all patients after the procedure. Complications related to the TAVI procedure were summarized in Table 3. There was no death during the procedure. Three patients had limited dissection of the femoral artery; however, intervention was not needed due to good distal perfusion rate. Homologous red blood cells were transfused to 12 patients. Permanent pacemaker was implanted to four patients because of long-term atrioventricular blockage.

After the procedure, all patients were transferred to the ICU and all patients were extubated in the ICU. The mean mechanical ventilation duration (minutes) was 166.20±39.32, the mean critical care unit stay (day) was 5.64±2.99 and the mean hospital stay (day) was 11.92±5.54 (Table 2). Acute

Table 1. Demographic characteristics and comorbidities of all patients

	All patients (n=25)
Age (years)	74.04±8.86
Male	16 (64%)
Female	9 (36%)
Body mass index (kg/m^2)	25.08±2.72
Coronary artery disease	9 (36%)
Prior cardiac surgery	3 (12%)
Prior cerebral ischemic event	4 (16%)
Pulmonary hypertension	5 (20%)
Diabetes mellitus	2 (8%)
Thyroid disease	5 (20%)
Chronic pulmonary disease	6 (24%)
Congestive heart failure	5 (20%)
Chronic anaemia	1 (4%)
EuroSCORE II	5.58±4.20
ASA classification	3.2±0.4

Data are presented as mean±SD or number (proportion). ASA: American Society of Anesthesiologists; Pulmonary hypertension: mean pulmonary artery pressure >45 mmHg; EuroSCORE II: European System for Cardiac Operative Risk Evaluation II

Table 2. Outcomes related to the TAVI procedure

	Mean±standard deviation
Crystalloid infusion (mL)	1300±125
Fresh frozen plasma infusion (n, %), units	(2, 8), 2±1.4
Homologous red blood cell transfusion (n,%), units	(12, 48), 2.5±1.2
Intervention time of procedure (min)	100.5±5.5
Total procedure duration (min)	180±6.6
Mechanical ventilation duration (min)	166.20±39.32
Length of critical care unit stay (days)	5.64±2.99
Length of hospital stay (days)	11.92±5.54
Preoperative ejection fraction (%)	42.40±6.72
Postoperative ejection fraction (%)	41.80±7.33
Preoperative creatinine levels (mg/dL)	1.0±0.30
Postoperative creatinine levels (mg/dL)	1.08±0.39

Data are expressed as mean±standard deviation, number (%). TAVI: Transcatheter aortic valve implantation

Table 3. Complications related to the TAVI procedure

	n (%)
Dissection of femoral artery	3 (12)
Permanent pacemaker implantation	4 (16)
Renal failure requiring dialysis	1 (4)
Major bleeding	2 (8)
Stroke	2 (8)
30-day mortality	1 (4)
6-month mortality	4 (16)

Data expressed in numbers (%). TAVI: Transcatheter aortic valve implantation

renal failure was observed in one patient and stroke was observed in two patients on the first postoperative day. During the 30-day and 6-month follow-up period, mortality rate was 4% and 16%, respectively. The patients' causes of death are presented in Table 4. Four patients died in the first 6 months and the functions of aortic valves of the other 21 patients were found to be good during the 6-month follow-up. Several fluoroscopic images taken during the procedure are presented in Figure 1.

Discussion

Transcatheter aortic valve implantation is less-invasive and an alternative procedure to SAVR for elderly patients with comorbidities, and it is also a suitable treatment method for inoperable patients [9]. There are numerous studies including the results of TAVI applications in many countries [10-14]. However, there are a limited number of studies on TAVI procedure in Turkey [15-17].

In this study, we presented the results of the first TAVI applications in our institute. Edwards-SAPIEN valve was implanted followed by balloon aortic valvuloplasty via transfemoral approach for all patients. All procedures were performed under general anaesthesia accompanied by TEE. There were no mortality and serious complications during the procedure. The success rate of the TAVI procedure was 100%.

EuroSCORE and STS-PROM algorithms are usually used to detect the surgical risk of the patients with aortic stenosis and select the appropriate patient for the TAVI procedure [9]. Recently, the EuroSCORE II has been used to assess the procedural risk and mortality for surgery and TAVI [7, 18]. Scoring of the EuroSCORE II algorithm is done according to certain characteristics of the patients such as ASA class, the level of left ventricular-function, the degree of pulmonary hypertension and renal impairment. It was found that 30-day mortality was best approximated by the EuroSCORE II in patients undergoing percutaneous TAVI procedure [7]. In this study EuroSCORE II was used to assess the risk of TAVI procedure and the patients with a score of ≥5 were evaluated as at high risk for the procedure. The total scores of all patients in this current study were ≥5.

Table 4. Causes of deaths in 4 patients underwent TAVI

Time	Death days	Death causes
In-hospital	20	Heart failure
After discharge	85	Pulmonary infection
After discharge	125	Sudden death
After discharge	160	Multi organ failure

TAVI: Transcatheter aortic valve implantation

Transcatheter aortic valve implantation may be performed via transfemoral, trans-subclavian/trans-axillary, trans-aortic or transapical approaches. Transfemoral approach has been performed in approximately 80% of all TAVI procedures nowadays [9]. In this study, all patients were appropriate for the transfemoral approach and success rate of procedure was high (100%). Similar to our results, Gul et al. [16] implemented the TAVI procedure on 33 patients via transfemoral approach and they reported high procedural success rate (97%). They also reported decreased mean NYHA (New York Heart Association) functional capacity after 3 months of the procedure compared with the previous values. In another study, Guinot et al. [6] analysed 62 patients treated with TAVI via the transfemoral approach. They also reported high procedural success rate (90%).

Anaesthetic management is very important for the success of the TAVI procedure. After the particular preoperative evaluation for the risk assessment, all procedures should be performed in a hybrid operation room including imaging systems such as angiography. Our anaesthetic management was similar to the previously reported studies [14-17]. Providing and maintaining the hemodynamic stability was the main objective of our anaesthetic management during the procedure. For this purpose, the procedure team especially anaesthesiologist was attentive and cautious for the estimated emergency situations (such as hypotension and ventricular fibrillation) causing hemodynamic deterioration which may require inotropic therapy, permanent pacemaker implantation and emergency SAVR.

RVP is used to minimize the cardiac motion and pulsatile trans-aortic flow during the procedure. Before starting RVP, MAP was increased above 90 mmHg in Bergmann et al.'s [19] study; above 65 mmHg in Fassl et al.'s [20] study. Similar to their procedures, blood pressure was increased before starting the RVP in this study. However, the number and duration of RVP episodes should be minimized during the procedure

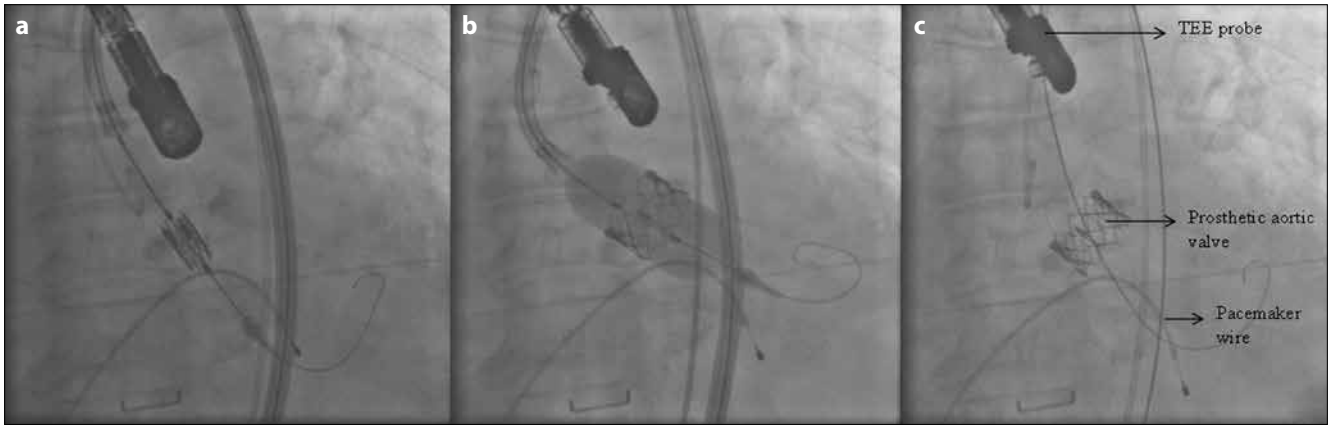

Figure 1. a-c. *Fluoroscopic images taken during the procedure: Insertion of the valve (Edwards-SAPIEN valve) system through the aorta (a); Transcatheter valve within the stent and inflated balloon (b); Demonstration of the valve after the deployment without aortic regurgitation (c). TEE: Transesophageal echocardiography.*

to avoid the myocardial ischemia [3, 4]. In this study, duration of the RVP was limited to less than 10 seconds and valve deployment was completed before the electrical cardioversion in case of a ventricular fibrillation due to ischemia. Because valve deployment improves cardiac output reducing left ventricular afterload and ventricular wall tension [21].

Patients' characteristics, comorbidities and the operator's experience should be taken into account in the selection of the appropriate anaesthetic technique for TAVI [3]. All patients in our study received general anaesthesia with endotracheal intubation because the procedure team preferred general anaesthesia in order to allow the use of TEE during the TAVI procedure. In a recent study, Gümüs et al. [17] evaluated 79 patients who underwent TAVI in a single centre in Turkey. Similar to our study, all patients in their study received general anaesthesia under fluoroscopic and TEE guidance. General anaesthesia had some advantages compared to local anaesthesia such as maintaining patient immobility, facilitating introducer sheath placement-removal and facilitating management of procedural complications allowing the use of TEE [22]. In our study, TEE was used during the procedure for all patients to provide continuous visualization of the aortic valve, to evaluate the ventricular function and rapid diagnosis of the complications such as pericardial effusion and iatrogenic mitral regurgitation during the TAVI procedure [20]. General anaesthesia had some disadvantages such as respiratory compromise and hemodynamic instability. On the other hand, local anaesthesia is associated with simple neurologic monitoring, short procedural time, improved patient satisfaction and reduced morbidity. But local anaesthesia had also some disadvantages such as patient discomfort due to local anaesthetic infiltration and catheters placement, patient's possible movements and increased risk for prosthesis misplacement [4].

Similar to our study, all approaches of TAVI were performed under general anaesthesia with fluoroscopic and TEE guidance in Guinot et al.'s [6] study. However, Dehedin et al. [12] analysed the data of the patients who underwent transfemoral TAVI with general or local/regional anaesthesia. They reported lower intraoperative requirement catecholamine and volume expansion, shorter procedure duration and shorter hospital stay in the local/regional anaesthesia group compared to general anaesthesia group. They found no differences in terms of pre-procedural outcome, 30-day mortality and length of the stay in the ICU between these groups. In another study, Bergmann et al. [21] reported no significant differences in terms of procedural or postoperative results (length of ICU stay, 30-day and 1-year mortality) between local/regional anaesthesia group and general anaesthesia group in the patients who underwent the TAVI procedure.

Another important issue in the TAVI procedure is the systemic anticoagulation. It is recommended that aspirin and clopidogrel (300 mg for both) should be administered before the procedure and aspirin 100 mg and clopidogrel 75 mg should be continued for 3-6 months after the procedure. Additionally, weight-adjusted intravenous heparin with a target of an activated clotting time of 250-300 seconds should be given during the procedure [3]. Patients in this study received systemic anticoagulation therapy as described above.

Although TAVI is a less-invasive procedure compared to SAVR, it is a harmless procedure. Atrioventricular block, vascular complications, aortic regurgitation, embolization, coronary artery occlusion, cardiac tamponed, acute renal failure and neurological complications may occur either during or after the TAVI procedure [20]. Even, Kim et al. [23] reported a mortal case with unexpected and fatal hemodynamic collapse during the transapical procedure despite a good

anaesthetic management. Permanent pacemaker implantation (16%), femoral artery dissection (12%), major bleeding (8%) and stroke (8%) were reported as the first three procedural complications of TAVI in this current study. The 30-day mortality rate was 4% and the 6-month mortality rate was 16% and there was no death during the TAVI procedure in our patients. Similar to our results, procedural mortality was 2.9% and permanent pacemaker implantation (11%), vascular complications (8.6%) and coronary obstruction (5.7%) were the first three procedural complications of TAVI in Gul et al.'s [16] study. 30-day mortality rate was 11.4% and nine-month mortality rate was 25.7% in their study. In a recent study [17], 30-day mortality following the TAVI procedure was reported as 9%. On the other hand, in Bergmann et al.'s study [19] the first three procedural complications for the patients who underwent TAVI under general anaesthesia were permanent pacemaker implantation (22%), femoral artery dissection (14%)renal failure requiring dialysis (8%), and 30-day mortality was 10% and 1-year mortality was 16%. These data were comparable to our findings.

The length of critical care unit stay and hospital stay (days) were 5.64±2.99 and 11.92±5.54, respectively in this study. Different periods for critical care unit stay and hospital stay were reported by Bergmann et al. [19] and Dehedin et al. [12] [(4.6±7.4, 15.4±14.2); (2±4, 7±14.5), respectively]. These differences may be caused by the clinical and demographic characteristics of the patients in the study groups.

The number of patients in this study was limited. This is a weakness of our study. However, TAVI was a novel procedure in our institute and we presented favourable short term clinical results of our initial cases.

In conclusion, TAVI is a great option for the patients with severe aortic stenosis who are at high risk for SAVR. However, a coordinated multidisciplinary approach is essential for the success of the procedure because the management of the procedure was complex. At the same time, the main objective of the anaesthetic management during the TAVI procedure is to provide and maintain the optimal hemodynamic stability. In our institute, procedural success and short term outcomes for the patients who underwent TAVI were found to be similar to previous studies, although the cases were our first TAVI experiences. Long-term randomized trials may be conducted to reveal the outcomes of the TAVI procedure.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of Ataturk University Medical Faculty (06.06.2013 No: 5/89).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

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