ORIGINAL ARTICLE

Transcatheter aortic valve implantation with the Edwards Sapien 3 valve: First experiences in Turkey

Edwards Sapien 3 kapakla yapılan transkateter aort kapak implantasyonu: Türkiye'deki ilk deneyimler

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ABSTRACT

Objective: Transcatheter aortic valve implantation (TAVI) has shown promising results in patients with severe aortic stenosis (AS) at high risk for open heart surgery. We aimed to evaluate outcomes of patients who underwent TAVI with Edwards SAPIEN 3 Transcatheter Heart Valve (S3), a second-generation TAVI device.

Methods: Between November 2014 and June 2016, 31 high-risk patients received balloon-expandable S3 valve at Atatürk Training and Research Hospital that has the largest case series in Turkey.

Results: Mean age of the patients was 76.1±12.6 years. Mean Society of Thoracic Surgeons and logistic European System for Cardiac Operative Risk Evaluation scores were 7.8%±3.1 and 31.4%±17.6, respectively. S3 valve was implanted in 27 patients via transfemoral approach and via trans-subclavian approach in 4 patients under local (n=29) or general (n=2) anesthesia. Procedural success rate was 100% (23 mm, n=7; 26 mm, n=16; 29 mm, n=8). Paravalvular aortic regurgitation (PAR) was absent or trivial in 29 (93.6%) patients and mild in 2 (6.4%) patients. Permanent pacemaker implantation (PPI) was required in 2 (6.4%) patients during the procedure, and in-hospital mortality occurred in 1 (3.2%) of those 2 patients.

Conclusion: S3 valve is associated with higher rate of device success and lower incidence of PAR, peripheral vascular complications, and need for new PPI.

ÖZET

Amaç: Transkateter aort kapak implantasyonu (TAKİ) açık kalp cerrahisi için yüksek riskli olan ciddi aort darlıklı hastalarda yüz güldürücü sonuçlar sağlamıştır. Bu yazıda ikinci kuşak bir TAKİ cihazı olan Edwards SAPIEN 3 kapak ile TAKİ yapılan hastalardaki sonuçları değerlendirmeyi amaçladık

Yöntemler: Kasım 2014'den Haziran 2016'ya kadar geçen sürede, Türkiye'deki en fazla olgu çalışmasına sahip olan Atatürk Eğitim ve Araştırma Hastanesi'nde yüksek riskli 31 hastaya balonla-genişleyebilen S3 kapak takıldı.

Bulgular: Hastaların ortalama yaşı 76.1±12.6 yıl idi. Ortalama Göğüs Cerrahları Birliği (STS) ve lojistik Kardiyak Operatif Risk Değerlendirmesi için Avrupa sistemi (EuroSCORE) skorları sırasıyla %7.8±3.1 ve %31.4±17.6 idi. S3 kapak lokal (n=29) ve genel (n=2) anestezi altında 27 hastaya femoral yaklaşımla, 4 hastaya subklaviyen yaklaşımıyla yerleştirildi. İşlem başarı oranı %100 idi (23 mm, n=7, 26 mm, n=16, 29 mm, n=8). Paravalvüler aort yetersizliği (PAY) 29 (%93.6) hastada ya hiç yok ya da önemsiz derecede, 2 (%6.4) hastada ise hafif derecede idi. Kalıcı kalp pili implantasyonu (KKPİ) işlem esnasında sadece 2 (%6.4) hastaya yapıldı ve hastane-içi ölüm, işlem esnasında KKPİ de yapılan sadece 1 (%3.2) hastada gerçekleşti.

Sonuç: Edwards Sapien 3 kapak yüksek oranda cihaz başarısı ve düşük oranda PAY, periferik vasküler komplikasyon ve yeni KKPİ ihtiyacı ile ilişkilidir.

Received: April 18, 2016 *Accepted:* August 15, 2016

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Transcatheter aortic valve implantation (TAVI) has become the therapy of choice for severe, symptomatic aortic stenosis (AS) in inoperable patients, and is non-inferior to surgical aortic valve replacement (sAVR) in high-risk patients.[1–4] The procedure was first performed in 2002.[5] Since then, this technology has evolved profoundly. At present, primary issues related to TAVI that remain to be solved are high incidence of paravalvular aortic regurgitation (PAR), peripheral vascular complications, and need for permanent pacemaker implantation (PPI). So far, new types of transcatheter bioprosthetic valves have been the means to try to resolve these problems. Ideal aortic bioprosthesis must be durable and reduce risk of complications.

Edwards SAPIEN 3 Transcatheter Heart Valve (S3) (Edwards Lifesciences, Inc., Irvine, CA, USA) is newest generation of balloon-expandable valve. It obtained CE mark approval on January 27, 2014 and is commercially available in Europe. It incorporates a number of new and enhanced features intended to reduce risk of vascular injury and PAR, as well as to facilitate rapid and accurate deployment. Significant design improvements have been incorporated when compared with earlier SAPIEN XT valve. Lower profile delivery systems were introduced to enable less traumatic implantation via transfemoral, transapical, and transaortic access routes. More importantly, these changes were designed to facilitate percutaneous access and closure even in patients with smaller iliofemoral arteries.

The aim of this single-center study was to report outcomes of TAVI with S3 valve, which was designed to decrease major vascular complications, rate of paravalvular leak and to enhance valve positioning.

METHODS

Patient population

Of 294 patients, we prospectively included 31 patients who underwent TAVI with S3 valve system between November 2014 and June 2016 at our facility. Before the procedure, multi-modal cardiovascular imaging, including transthorasic echocardiography (TTE) and transesophageal echocardiography, cardiac and peripheral multi-slice computed tomography angiography (CTA), and invasive coronary and peripheral angiography, were performed on all patients. Cardiac CTA was especially important for accurate assessment of aortic valve anatomy and calcification, aortic annular sizing, subannular calcification, aortic root size and geometry, height of coronary ostia and septal bulging from aortic annular plane, and final valve sizing. Invasive coronary angiography was also important for preoperative assessment and determination of optimal position of aortic root during procedure. Invasive peripheral angiography was performed for accurate estimation of access site to ensure safe and successful procedure. TTE was performed just after procedure and again before hospital discharge. Decision to proceed with TAVI was made by multidisciplinary heart team, which included cardiovascular surgeons, invasive cardiologists, and anesthesiologists. Eligibility was based on calculated surgical risk scores (European System for Cardiac Operative Risk Evaluation [EuroSCORE] and the Society of Thoracic Surgeons [STS] risk score), other clinical (e.g., frailty) and technical issues (e.g., porcelain aorta, adherent bypass grafts). Written, informed consent was obtained from all patients and the present study was approved by Atatürk Training and Research Hospital ethics committee.

Abbreviations:

AR	*Aortic regurgitation*
AS	*Aortic stenosis*
AV	*Atrioventricular*
BMI	*Body mass index*
CABG	*Coronary artery bypass grafting*
CTA	*Computed tomography angiography*
HF	*Heart failure*
LBBB	*Left bundle branch block*
LV	*Left ventricle*
LVEF	*Left ventricular ejection fraction*
PPM	*Prior permanent pacemaker*
PAR	*Paravalvular aortic regurgitation*
PPI	*Permanent pacemaker implantation*
sAVR	*Surgical aortic valve replacement*
TAVI	*Transcatheter aortic valve implantation*
TEE	*Transesophageal echocardiography*
TIA	*Transient ischemic attack*

Transcatheter aortic valve implantation

All TAVI procedures were performed in catheterization laboratory under fluoroscopic guidance by dedicated team of invasive cardiologists, cardiovascular surgeons, and anesthesiologists. Depending on the patient's clinical condition and evaluation of the anesthesiologist, procedure was performed under general anesthesia or local anesthesia with mild sedation. Only device implanted was balloon-expandable S3 pericardial bioprosthesis. All patients had transvenous temporary cardiac pacing during procedure. Transfemoral route was used when feasible; alternatively trans-subclavian route was used. All trans-subclavian procedures were performed using surgical cutdown technique. In transfemoral procedures, however, per-

cutaneous closure with double Perclose ProGlide or ProStar XL percutaneous vascular surgical systems (Abbott Vascular, Inc., Santa Clara, CA, USA) was preferred. In all cases, aortic balloon valvuloplasty was performed under rapid ventricular pacing at 180-210 beats/min. Positioning and deployment of valve was done under fluoroscopic guidance. Immediately after valve implantation, fluoroscopy was used to confirm good position and identify any PAR. TTE was also performed to detect pericardial effusion and to assess valve function.

Adjunctive pharmacological therapy consisted of heparin during the procedure (activated clotting time between 250-300 s), acetylsalicylic acid (100 mg/d) indefinitely, and clopidogrel (75 mg/d) for 6 months after procedure.

Statistical analysis

Statistical analysis was performed using SPSS software, version 17.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean (range) ± 1 SD. Discrete variables were expressed as count and percentage. Categorical variables were compared using Pearson's chi-squared test. Statistical significance was defined as p value <0.05.

RESULTS

Total of 294 patients underwent TAVI between July 2011 and June 2016; 31 patients who received second-generation S3 valve were included in the present study. Baseline clinical characteristics of the study population are presented in Table 1. Mean age was 76.1±12.6 years (range: 57–100 years) and 14 were

Table 1. Baseline characteristics of the study population

Variables	n=31		
	n	%	Mean±SD
Age, (years)			76.1±12.6
Female	14	45.1	
Body mass index (kg/m²)			27.4±5.9
Hypertension	25	80.6	
Diabetes mellitus	12	38.7	
Hypercholesterolemia	21	67.7	
Coronary artery disease	24	77.4	
Previous percutaneous coronary intervention	11	35.4	
Prior coronary artery bypass grafting	11	35.4	
Previous myocardial infarction	9	29.0	
Previous stroke	3	18.8	
Atrial fibrillation	7	22.5	
Chronic obstructive pulmonary disease	14	45.1	
Renal impairment (Estimated glomerular filtration rate <60 mL/min)	12	38.7	
Serum creatinine (mg/dL)			1.4±1.2
New York Heart Association class III or IV	28	90.3	
Logistic European System for Cardiac Operative Risk Evaluation (%)			31.4±17.7
Society of Thoracic Surgeon score (%)			7.8±3.1
Echocardiographic findings:			
Aortic valve area (cm²)			0.67±0.11
Mean pressure gradient (mmHg)			49.0±13.4
Left ventricular ejection fraction (%)			53.0±12.0
Systolic pulmonary artery pressure (>60 mmHg)	8	28.8	

SD: Standard deviation.

female (45.1%). All patients had severe symptomatic AS with mean gradient of 49.0±13.4 mmHg and mean aortic valve area of 0.67±0.11 cm². There was severe systolic heart failure (HF) (left ventricle ejection fraction [LVEF] <30%) in 4 patients. Two patients with severe HF were diagnosed as having low flow-low gradient severe AS after dobutamin stress echocardiography. Mean body mass index (BMI) was 27.4±5.9 kg/m². One patient was morbidly obese with BMI of 52 kg/m². Mean logistic EuroSCORE was 31.4±17.7% and mean STS risk score was 7.8±3.1%. All patients but 3 had New York Heart Association (NYHA) class III or IV dyspnea. Rate of coronary artery disease was very high (n=24, 77.4%), with prior percutaneous coronary intervention in 11 (35.4%) and prior coronary artery bypass grafting (CABG) in 11 (35.4%) patients. Previous ischemic stroke was present in 3 patients: 1 transient ischemic attack (TIA) and 2 with major stroke and sequelae. There was chronic renal failure in 12 (38.7%) patients (1 in dialysis treatment for 4 years), with estimated glomerular filtration rate below 60 mL/min. Furthermore, there was history of Hodgkin's lymphoma and rectal carcinoma in 2 separate patients, both of whom were cured with chemotherapeutic drugs and surgery.

Procedural data of study patients is provided in Table 2. S3 valve was implanted in 27 (87.1%) patients via transfemoral access and in 4 (12.9%) patients via trans-subclavian access. Local anesthesia with mild sedation was used for 29 (93.6%) patients and general anesthesia was used for remaining 2 (6.4%) patients. In 7 (22.6%) patients, 23-mm prosthesis was implanted, while 26-mm prosthesis was used for 16 (51.6%) patients and 29-mm prosthesis for 8 (25.8%) patients. A 14-F sheath was used for 23-mm and 26-mm bioprostheses and 16-F sheath was used for 29-mm bioprostheses. Aortic balloon valvuloplasty was performed before valve deployment. For access site closure, percutaneous (n=27, 87.1%) or surgical cutdown (n=4, 12.9%) techniques were used. ProStar (n=2, 7.4%) or double Perclose ProGlide (n=25, 92.6%) vascular devices were used for percutaneous closure. Mean procedural time was 43.4±6.7 minutes. Mean quantity of contrast material used during procedure was 79.5±39.7 mL.

Procedural outcomes can be seen in Table 3. All patients were successfully treated with S3 valve; procedural success rate was 100%. No stroke or TIA was observed during or after the procedure in any patient. Permanent pacemaker was implanted in 2 (6.4%) patients due to development of complete atrioventricular (AV) block (n=1) and asystole (n=1) just after valve deployment. In-hospital death occurred in 1 patient (3.2%) due to acute pulmonary edema, not valve dysfunction or other procedure-related problem. Investigation of clinical and procedural features of this patient revealed previous history of CABG and severe HF (LVEF: 20%). Patient had received 29-mm bioprosthesis through transfemoral route and PPI was performed during procedure due to development of complete AV block.

Post-TAVI aortography and TTE were utilized to evaluate degree of PAR. Pigtail catheter was placed over bioprosthetic valve and post-TAVI aortography was performed with 20 cc opaque contrast agent delivered under 800 pci within 1.5 seconds at prime position. Hemodynamic data were obtained immediately post-TAVI, including measurement of LV end-

Table 2. Procedural data of the study population (n=31)

	n	%	Mean±SD
Anesthesia			
Local	29	93.6	
General	2	6.4	
Vascular access site			
Transfemoral	27	87.1	
Transsubclavian	4	12.9	
Diameter of e-sheath			
14 F	23	74.1	
16 F	8	25.9	
Valve size (mm)			
23	7	22.6	
26	16	51.6	
29	8	25.8	
Access site closure			
Percutaneous			
ProStar	2	6.5	
ProGlide	25	80.6	
Surgical	4	12.9	
Aortic balloon valvuloplasty	31	100	
Procedural time (min)			43.4±6.7
Contrast used (mL)			79.5±39.7

SD: Standard deviation.

Table 3. Procedural outcome of the study population (n=31)

	n	%	Mean±SD
Successful implantation rate (%)		100	
Post-procedural aortic regurgitation (angiography)			
None/trace	29	93.6	
Mild	2	6.4	
Moderate	0	0	
Severe	0	0	
Permanent pacemaker requirement	2	6.4	
Vascular complications	None	None	
Bleeding complications	None	None	
Stroke	None	None	
In-hospital death	1	3.2	
Maximum gradient after implantation (mmHg)			22.4±7.8
Mean gradient after implantation (mmHg)			11.4±5.7
Aortic valve area (cm²)			1.7±0.5
Post-procedural aortic regurgitation (echocardiography)			
None/trivial	29	93.6	
Mild	2	6.4	
Moderate	0	0	
Severe	0	0	
Left ventricular ejection fraction at discharge (echocardiography, %)			57.6±10.8
Days in intensive care unit			2.1±1.2
Days in hospital			5.8±1.8

SD: Standard deviation.

diastolic pressure and diastolic pressure, and were compared with pre-TAVI values, as in other studies.[6] There was none to trace quantity of PAR in 29 patients (93.6%) and mild PAR in 2 patients (6.4%). There was no more than mild PAR in any patient. TTE confirmed this result. Mean transaortic gradient was reduced from 49.0±13.4 mmHg to 11.4±5.7 mmHg and mean aortic valve area increased from 0.67±0.11 cm² to 1.7±0.5 cm² at discharge. When LVEF measurements from before and after procedure were compared, mild increase (53.0±12.0% vs 57.6±10.8%, respectively) was observed. Mean intensive care unit stay was 2.1±1.2 days and mean hospital stay was 5.8±1.8 days.

DISCUSSION

This is the first study in Turkey to report outcomes of TAVI performed with S3 valve system at a single center. Implantation with new, low-profile, balloon-expandable S3 valve system was successful in all patients. Clinical and hemodynamic outcomes were also excellent.

TAVI is well-established therapeutic option for severe degenerative AS in patients with high surgical risk.[7] Since first TAVI procedure in 2002, significant advances have been made in device technology, appropriate patient and valve selection, procedural technique, and post-procedural management. Placement of Aortic Transcatheter Valves (PARTNER) trial determined superiority of TAVI to medical treatment and non-inferiority to sAVR.[2] US CoreValve Pivotal Trial High Risk Study demonstrated better survival at 1 year with TAVI compared to sAVR.[4] However, despite these encouraging results, first-generation TAVI devices have several limitations, with post-procedural aortic regurgitation (AR) being one of the primary concerns.[8] Major advantages of S3 valve are its lower profile, facilitated positioning, and paravalvular seal-

ing cuff preventing PAR. Moreover, low-profile delivery system reduces potential vascular complications.

PAR after TAVI has been found to be associated with increased mortality rate.[9] Negative prognostic impact of post-procedural AR on patients undergoing TAVI has been extensively reported. In particular, occurrence seems to be associated with two- to threefold increase in 30-day and 1-year mortality.[8] Post-procedural AR was significant limitation of first-generation TAVI devices.[8] Therefore, new devices like S3 valve that can prevent or reduce rate of PAR were introduced into clinical practice. Binder et al.[10] reported none to trivial PAR in 73% of 15 patients who underwent TAVI with S3 valve and only mild PAR in the remainder. In the present study, PAR was absent or trivial in 93.6% of patients and mild in the rest. Most likely reasons for this lower rate of PAR are 1) outer skirt, which enhances paravalvular seal; 2) accurate positioning; 3) precise sizing with multi-modal imaging; and 4) proper patient selection. In this study, S3 valve was chosen especially for patients with high risk of PAR, including patients with bulky aortic calcification.

Vascular complications have been the most common cause of morbidity and mortality after TAVI.[1,11] Ratio of outer diameter of sheath to minimal lumen diameter of artery used for access site is strong predictor of vascular complications.[11] S3 valve system can be introduced with lower profile delivery system using 14-F and 16-F sheaths and therefore might facilitate transfemoral TAVI in patients previously considered unsuitable for femoral artery route.[12] In present study, TAVI with S3 valve was performed on 2 patients via transfemoral access after simultaneous common iliac artery stenting. There was no minor or major vascular complication in our study, consistent with reported results of Binder et al.[10] Absence of vascular complications can be explained by deployment of S3 valve with lower profile delivery system in addition to significant experience of our center.

Length of S3 valve is slightly greater than earlier SAPIEN and SAPIEN XT valves. Although difference is not large, this increase seems to facilitate optimal positioning within the native aortic valve and annulus. However, by potentially extending area of contact with the septum, increased size of valve might increase risk of AV block and thus, need for PPI. Complete AV block necessitating PPI is a major concern after TAVI. The large observational United Kingdom Transcatheter Aortic Valve Implantation Registry (UK TAVI)[13] and the French Aortic National CoreValve and Edwards (FRANCE 2)[14] registry reported need for new pacemaker rate at 24.4% and 24.2%, respectively, with CoreValve (Medtronic, Inc., Minneapolis, Minnesota) device versus 7.4% and 11.5%, respectively, with SAPIEN XT valves. In PARTNER trial,[15] prior permanent pacemaker (PPM), new PPM, and chronic left bundle branch block (LBBB) patients had worse clinical and echocardiographic outcomes compared with non-PPM patients, and presence of PPM was independently associated with 1-year mortality. Thus, reducing need for PPI as a specific aspect of clinical outcome after TAVI is of significant importance. Emerging data indicate rate of 13% to 30% PPI after TAVI with S3 valve.[16–18] Husser et al.[19] also reported rate of 12% PPI after S3 valve implantation. Interestingly, in our study, only 2 patients (6.4%) required new pacemaker, and S3 device did not result in higher rate of PPI during hospitalization.

In the present study, there was only 1 in-hospital death. Evaluation of this case revealed very high-risk patient with history of severe heart failure (LVEF of 20%), CABG (with left internal mammarian artery to left anterior descending artery graft), insulin-dependent diabetes mellitus, hypertension, and carotid artery disease (with history of endarterectomy). He received PPI during TAVI procedure due to development of complete AV block. In addition, LBBB was observed on electrocardiography and he received 29-mm S3 valve, both of which are thought to be indicator of high risk for new PPI.

Study limitations

Main limitation of the present study is sample size. Number of patients included in this study may prevent generalization of these results. However, all 31 patients underwent TAVI performed by the same heart team at highly experienced TAVI center after evaluation using multimodal imaging techniques.

Conclusion

Lower rate of PAR, peripheral vascular complications, and PPI were found compared with data from other clinics performing TAVI with S3 valves. This second-generation valve had high rate of device success. Therefore, we may conclude that S3 valve can be used confidently in all TAVI procedures.

Conflict-of-interest issues regarding the authorship or article: None declared

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Keywords: Aortic stenosis; Edwards Sapien 3 valve; permanent pacemaker; transcatheter aortic valve implantation.

Anahtar sözcükler: Aort darlığı; Edward Sapien 3 kapak; kalıcı kalp pili; transkateter aort kapak implantasyonu.