Transcatheter aortic valve implantation: the first applications and early results in Turkey

Transkateter aort kapak yerleştirme: Türkiye'deki ilk uygulamalar ve erken sonuçlar

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Objectives: The objective of this study was to evaluate the first applications and results of transcatheter aortic valve implantation (TAVI) in Turkey, which is a new technology for the treatment of aortic valve stenosis.

Study design: We performed TAVI in eight severely symptomatic patients (5 women, 3 men; mean age 81.6±6.7 years; range 71 to 95 years) between May 1 and December 31, 2009. All the patients had severe aortic stenosis (mean valve area 0.6 cm2, systolic peak/mean gradients 80.5±22.1/ 50.0±16.1 mmHg). Two patients had severe coronary artery disease that required intervention during TAVI. All the patients presented a high surgical risk (EuroSCORE 31.1±9.8 and STS score 12.8±7.9). The Edwards Sapien bioprosthetic valve was implanted through the transfemoral approach in seven patients, and transapical approach in one patient.

Results: All prosthetic valves were of appropriate size, were implanted in appropriate locations, and functioned perfectly. Two patients with severe coronary stenosis underwent successful simultaneous percutaneous coronary intervention before TAVI. Following TAVI, the mean aortic valve area increased to 1.5±0.1 cm2 ($p<0.01$), and systolic/mean gradients decreased to 27.6±9.6/14.6±5.8 mmHg ($p<0.01$). One patient underwent permanent pacemaker implantation due to persistent atrioventricular block, and two patients had transient atrioventricular block. Two patients died; one on the first day following transapical implantation, and the other after six months of implantation. The mean NYHA functional class decreased from preoperative 3.8±0.3, to 1.1±0.3 after a mean follow-up of 3.5±2.5 months (range 1 to 8 months) ($p<0.01$).

Conclusion: Early results of TAVI are successful in patients with inoperable aortic valve stenosis due to high surgical risk. The results of randomized studies with longer follow-up will clarify widespread use of this technique.

Key words: Aortic valve/surgery; aortic valve stenosis/surgery; heart catheterization/methods; heart valve prosthesis.

Amaç: Bu çalışmada, aort kapak darlığı tedavisinde yeni bir teknoloji olan transkateter aort kapak yerleştirme (TAKY) yönteminin Türkiye'deki ilk uygulamaları ve sonuç-ları değerlendirildi.

Çalışma planı: Hastanemizde 1 Mayıs-31 Aralık 2009 tarihleri arasında toplam sekiz hastaya (5 kadın, 3 erkek; ort. yaş 81.6±6.7; dağılım 71-95) kritik aort darlığı nedeniyle TAKY yapıldı. Hastaların hepsi ileri derecede semptomatik idi. Aort kapak alanı ortalama 0.6 cm2, sistolik/ortalama aort gradiyenti 80.5±22.1/50.0±16.1 mmHg idi. İki olguda ek olarak TAKY işlemi sırasında girişim gerektiren ciddi koroner arter hastalığı vardı. Tüm hastalarda cerrahi teda-vi yüksek riskli bulunmuştu (EuroSCORE 31.1±9.8, STS skoru 12.8±7.9). Yedi hastaya transfemoral, bir hastaya transapikal yolla Edwards Sapien biyoprotez kapak takıldı.

Bulgular: Hastaların hepsinde uygun ölçüdeki kapaklar, uygun pozisyonda yerleştirildi ve tüm kapaklar mükemmel fonksiyon gösterdi. İki hastada ciddi koroner darlık nede-niyle TAKY öncesinde eşzamanlı başarılı perkütan koroner girişim yapıldı. İşlem sonrasında ortalama aort kapak alanı 1.5±0.1 cm2 ölçüldü ($p<0.01$); sistolik/ortalama aort gradi-yenti 27.6±9.6/14.6±5.8 mmHg'ye düştü ($p<0.01$). Bir has-taya uzun süren atriyoventriküler blok nedeniyle kalıcı kalp pili takıldı, iki hastada gelişen geçici atriyoventriküler blok kendiliğinden sinüs ritmine döndü. Transapikal yolla TAKY yapılan bir hasta işlem sonrası birinci günde, bir hasta ise altıncı ayda kaybedildi. İşlem öncesinde ortalama 3.8±0.3 olan NYHA fonksiyonel sınıfı, ortalama 3.5±2.5 ay (dağılım 1-8 ay) takip sonunda 1.1±0.3'e geriledi ($p<0.01$).

Sonuç: Cerrahi riski yüksek veya ameliyat edilemez aort kapak darlığı olan hastalarda TAKY'nin erken sonuçları başa-rılıdır. Uzun süreli takipler ve randomize çalışmalar tekniğin yaygın kullanılması konusuna açıklık getirecektir.

Anahtar sözcükler: Aort kapağı/cerrahi; aort kapağı darlığı/ cerrahi; kalp kateterizasyonu/yöntem; kalp kapağı protezi.

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The incidence of calcific aortic valve stenosis has been increasing with the increasing age of the population. Aortic stenosis is the most commonly seen heart valve disease in 2-4% of the patients ≥65 years of age.[1] When aortic valve disease which may remain silent for years becomes symptomatic, medical treatment may not be sufficient and the prognosis is poor.[2]

Aortic valve replacement (AVR), which has been used for 50 years, is the standard of care procedure which is primarily performed in aortic valve diseases.[3] Although the consequences of the procedure are very successful in patients ≥80 years of age, increasing age; repeated surgery due to cardiac, neurological, pulmonary and renal disorders, and conditions such as porcelain aorta increase the probability of AVR procedure, even some of the patients are regarded as inoperable.[4,5]

First human transcatheter aortic valve implantation (TAVI) which was first performed by A. Cribier is an alternative to surgical valve replacement for elderly patients and those with calcific aortic valve stenosis and who are at high risk for surgery.[6,7]

In this paper, we examined the results of this new technique which has been first performed recently in Turkey as well as the advantages and disadvantages of TAVI.

PATIENTS AND METHODS

Between 1st May-31st December 2009, TAVI was performed on a total of 8 patients, including seven undergoing transfemoral cannulation and one undergoing transapical cannulation (5 women, 3 men; mean age 81.6±6.7; distribution 71-95). All patients were suffering from calcific aortic valve stenosis and were symptomatic. The baseline clinical characteristics of the patients are shown in Table 1. Edwards Sapien transcatheter heart valve (Edwards Lifesciences, Irvine, CA, USA) was used during the replacement surgery.

The EuroSCORE (European System for Cardiac Operative Risk Evaluation) and STS (Society of Thoracic Surgeons) were used for classification of surgery risks.[8,9] In principle, patients with >20 logistic EuroSCORE or >10 STS score were considered high-risk population for standard AVR surgery and scheduled for TAVI.

Today, it is compulsory that patients who are scheduled for TAVI should have calcific aortic valve stenosis. In case aortic valve regurgitation is predominant or isolated aortic valve regurgitation is present, TAVI should not be performed. In addition, patients with aortic ring of <18 mm or >26 mm are scheduled for standard AVR procedure.

Sensitive measurement of the diameter of the aortic ring is critical for selection of patients and valve size. Within this respect, all patients were performed transthoracic (TTE) and transesophageal echocardiography (TEE).

In addition, iliofemoral and aortic evaluation were performed using computed tomographic angiography. Among the patients, seven underwent transfemoral cannulation, whereas one underwent transapical cannulation since the femoral and iliac arteries were too small to advance the catheter (i.e. 7 mm for 23-mm valve and 8 mm for 26-mm valve).

Table 1. The baseline clinical characteristics of the patients

	Number	Percent	Mean±SD	Distribution
Age			81.6±6.7	71-95
EuroSCORE			31.1±9.8	20-48
STS score			12.8±7.9	8-32
Length of hospital stay in ICU			45.5±44.2	22-144
Length of hospitalization			8.0±3.7	5-16
Follow-up (month)			3.5±2.5	1-8
Comorbidities				
Previous heart surgery	1	12.5		
Coronary artery disease	4	50.0		
Other valve diseases	2	25.0		
Chronic obstructive pulmonary disease	2	25.0		
Renal dysfunction	2	25.0		
Hepatic dysfunction	1	12.5		
Atrial fibrillation	3	37.5		
Pulmonary hypertension	4	50.0		

EuroScore: European System for Cardiac Operative Risk Evaluation; STS: Society of Thoracic Surgeons

Table 2. Hemodynamic and Clinical Characteristics before and after TAVI

	Before TAVI	After TAVI	*p*
Aortic valve space (cm^2)	0.6±0.0	1.5±0.1	**<0.01**
Ejection fraction (%)	59.8±11.6	64.7±4.6	0.058
Gradient (mmHg)	50.0±16.1	14.6±5.8	**<0.01**
Systolic	80.5±22.1	27.6±9.6	
NYHA functional class	3.8±0.3	1.1±0.3	**<0.01**

NYHA: New York Heart Association

All procedures were performed in the Cardiac Catheterization Lab where necessary equipment is ready to use for open heart surgery in case of emergency.

TAVI technique. For patients undergoing transfemoral cannulation, fentanyl citrate 25Ìg was administered intravenously and propofol 25-50 Ìg/kg/min was infused to maintain conscious sedation. Bilateral groin area was then numbed with the use of regional anesthesia. As predetermined by computed tomographic angiography, transverse incisions (3-4 cm) were made in the right and left groin. The guidewire was inserted into the left ventricular apex through calcific aortic valve after a puncture was made with a needle in the femoral artery in the groin. The catheter was advanced through the femoral artery and femoral vein percutaneously in the other groin area and then a pigtail catheter for angiographic documentation and a pacemaker electrode giving electrical signal rapidly to the right ventricle were placed and tested how they worked in practice. The acctivated clotting time was maintained at >230 seconds with intravenous administration of 5000-7500 U of heparin. Aortic valve predilatation using with a 20-mm or 23-mm balloon was performed. During balloon predilatation, systemic blood pressure was maintained at <50 mmHg, stimulating the ventricle at 180-200 bpm, and thereby preventing the balloon from slipping off the catheter. The valve which was selected for this procedure (23-mm or 26-mm valve) was mounted on the balloon using a special device. Retroflex III catheter system (Edwards Lifesciences) was then advanced through the femoral artery. Following the proceeding of the guidewire, balloon catheter with the valve was placed into the calcific CAPs. During the procedure, coronary ostia were also considered. The blood pressure was reduced to <50 mmHg following repeated stimulation. Then, the balloon was inflated and the valve was placed into the calcification. When the valve was placed properly, the balloon was deflated and the stimulation was ceased. The location and functions of the aortic valve and possible aortic regurgitation were evaluated by aortic stem injection and TTE. After the evaluation, the catheters were retrieved and the incisions in the femoral artery in the groin were sealed by surgical sutures. Subsequently, the patients who were awake were then sent to ICU.

On the other hand, one of the patients who was scheduled for antegrade transapical access was intubated and anesthetized. The left anterolateral thoracotomy (~6 cm) was performed and we entered thorax through the fifth intercostals space. Epicardial pacemaker electrodes were fixed to rapid stimulation. A-two-line suture was applied (Mc Donald or Shirodkar stitches) in the apex of the left ventricle and then the guidewire was advanced antegradely over the aortic valve and to the descending aorta. Next, the catheter was advanced through the femoral artery in the right groin and into the ascending aorta to obtain complete view. Similar to the transfemoral approach, after the balloon predilatation, Ascendra TAVI system was placed properly into the calcific aortic valve through the left ventricle. Following a rapid stimulation, the balloon was inflated and the Edwards Sapien valve was implanted. The location and functions of the aortic valve and possible aortic regurgitation were evaluated by aortic stem injection and TTE. After the evaluation, the catheters were retrieved and the sutures were sealed inside. Then, the thoracotomy incisions were closed and the patient intubated was sent to ICU.

Statistical analysis. SPSS 15.0 program was used to statistical analysis. In addition, non-parametric Wilcoxon test was used to compare the parameters before and after the procedure. A p value of <0.05 was considered statistically significant.

RESULTS

For all of the patients, the Edwards Sapien valves were implanted properly and their functions were excellent. Repeated echocardiography and angiography showed mild paravalvular aortic regurgitation in 7 patients and minimal paravalvular aortic regurgitation in 1 of them. The efficacy rate of the procedure was considered 100%. Post-procedure measurements demonstrated that the aortic valve space increased and transaortic gradient

decreased (Table 2). No coronary ostia were found. Among the patients, one had severe right coronary arterial stenosis, while one had left coronary arterial stenosis (70%). As a result, these patients underwent percutaneous coronary intervention before TAVI. During the intervention, bare stents were implanted. TAVI was initiated after a-100%-opening of the artery was achieved.

During TAVI, no serious complication of the iliofemoral veins was seen in patients who were handled by transfemoral approach. On the other hand, one of the patients had limited dissection of the iliac artery; however, no intervention was needed since distal perfusion rate was good. In the other patient who underwent transapical intervention, additional sutures were placed due to the fragility of the apical region and hemorrhage. In addition, one of the patients was intubated due to respiratory depression after sedative use and mechanical ventilation was instituted for 12 hours. On the other hand, one of the patients who underwent revision surgery due to hemorrhage and sent to ICU died because of hypotension and low cardiac output at 15 hours. Besides, for one of the patients, a permanent pacemaker was implanted due to long-term atrioventricular blockage.

Two other patients also developed short-term atrioventricular blockage and spontaneously return to sinus rhythm. The patients whose average length of stay in ICU was 45.5±44.2 hours (distribution 22-144 hours) and 8±3.7 days (distribution 5-16 days) were discharged in a good clinical condition.

The patients were followed at 1 week, 1 month and every three months after discharge.During follow-up, it was reported that one of the patients died at home at 6 months. Clinical conditions of other six patients were found to be good during a-3.5±2.5-month follow-up (distribution 1-8 months). The aortic valves were also functioning well. There was no increase in the incidence of paravalvular aortic regurgitation and transvalvular gradient. NYHA functional classes improved significantly in all patients (Table 2). On the other hand, although left ventricular ejection fraction increased, this was not found to be statistically significant.

DISCUSSION

Aortic valve replacement is the standard of care procedure in symptomatic patients with aortic valve. The early and late results of this surgical procedure using through sternotomy and pump are efficient.The mortality rate of conventional AVR is nearly 3%, whereas the rate increases to 8.8% - 16.8% in elderly patients and those with comorbidities. It is also known that 33% of the patients over 75 years of age with critical aortic stenosis are not appropriate candidates for AVR because of their high risk for open surgery.[10] The prognosis is poor in symptomatic aortic stenosis.[2] Balloon valvuloplasty is only used in palliative care, when the midterm and late results of the procedure are poor.[11] TAVI, which is a less invasive having a lower morbidity and mortality rate and, in particular, for patients over 75 years of age and high risk for surgery, has aroused considerable interest worldwide.[7,12]

So far, TAVI which was first performed by Cribier et al.[6] in 2002 has been performed on over 4000 patients.[13] Today, the mortality and morbidity EuroSCORE and STS scores are lower than estimated. The rate of full recovery and discharge is also faster. An increase in the aortic valve space and a significant improvement in the functional classes can be also observed.[12-16]

Transcatheter aortic valve implantation can be performed following transfemoral or transapical approach. In this case, we performed transfemoral TAVI on 7 of 8 patients with appropriate diameter and quality of peripheral veins. We also used the Retroflex system while carrying prosthetic valve. Thanks to the Retroflex system, we provided full flexion of the catheter in arcus aorta, reducing the risk of cerebral embolization with less friction.

On the other hand, one patient underwent transapical TAVI since the femoral and iliac arteries were too small to advance the catheter. Previously, the patient underwent balloon valvuloplasty in another clinical setting, using Ascendra Transapical System (Edwards Lifesciences) and a prosthetic valve was implanted, functioning excellent. However, hemorrhage occurred within the apex, when the Ascendra system was retrieved, requiring revision surgery. The patient who had very critical clinical findings died due to the complication on day 1 following surgery.

Two prosthetic valves are commercially available used in transcatheter aortic valve implantation. One of them is Edwards Sapien valve which is a tricuspid bovine pericardium prosthesis mounted on a balloon-expandable stent placed in the subcoronary position. It is available in 23 mm and 26 mm. 22 F- and 24 F-sheats are used in transfemoral TAVI, while 26 F-sheaths are used in transapical TAVI.

The other one is CoreValve (Medtronic) which is a triple-valve aortic bioprosthesis made of pig pericardium fixed onto a self-expandable framework. It is available in 26 mm and 29 mm. 18 F-sheats are used in transfemoral TAVI, while 21 F-sheats are used in transapical TAVI.

Sensitive measurement of the diameter of the aortic ring is critical for selection of appropriate valve si-

ze and preventing valvular dislocation, valvular embolization, and severe aortic regurgitation following the procedure. Within this respect, transthoracic (TTE) and transesophageal echocardiography (TEE) are the most reliable tools. Computed tomography can overestimate the diameter of the aortic ring. Despite all, aortic regurgitation can be evaluated by aortic stem injection during balloon predilatation, inflating a-20-mm or 23-mm balloon, if the physician is unsure about the valve diameter.

In our study, we used Edwards Sapien bioprosthetic valves in all 8 patients, functioning very well. Overall, procedural success is defined as the rate of successful implantation, i.e. appropriate expansion of the bioprosthetic valve and functioning in a tolerable state without causing mortality in the catheter lab. Although the success rate has been reported to be over 90% in the unicenter trials, the actual success rate of is 86% in the European trials using ballon-expendable Edwards Sapien valves and 92% in the trials using CoreValve bioprosthetic valves. A-30-day mortality has been also reported to be 12% and 15% for Edwards Sapien and CoreValve valves, respectively.[17,18]

Learning curve is also considered for high success rate. For instance, Webb et al.[16] reported that a-30-day mortality was 16% for the first 25 consecutive patients, while the rate decreased to 8% for the latter 25 consecutive patients. Their study also showed that the survival rate was 96%, 84%, and 70% at 0, 1 and 6 months, respectively for the first patient group. However, the rate was 100%, 92%, and 88% at 0, 1 and 6 months, respectively for the latter patient group.

In addition, the results of the procedure are influenced by the selection of the patients for surgery. As it is well-known, the mortality rate increases, when the risk ratio increases.Al-Attar et al.[19] reported higher risk ratio in the latter patient group including transfemoral and transapical TAVI. The authors stated that the success rate was 85.7% and 100%, in-hospital mortality was 8% and 27%, and one-year survival was 74% and 60%. In our study, no death event occurred during TAVI. However, two of the patients died on day 1 and at 6 months following surgery. Other six patients were followed over 3.5 months and their clinical condition was good.

There is no data on the long-term follow-up results of TAVI in the literature. A few of patients have been scheduled for follow-up over 3 years at most. Clinical improvement was observed in those patients without any worsening of the prosthetic valve functions.[13,20]

According to baseline, complication rate has reduced today with the development of TAVI and increasing experiment. Iliofemoral or aortic dissection and hemorrhages are the most fatal complications. In addition, emergent endovascular or open surgical interventions can be performed in case of intimal peeling or rupture following the retrieval of the catheter or sheaths at the end of the procedure. On contrast, ventricular rupture by means of the guidewire or catheter and intrapericardial hemorrhage are rarely occurred. Valvular displacement or dislocation of the valve in the ascending aorta are also seldom encountered. In addition, an embolic stroke can occur when the vector array or catheter contact with the atherosclerotic aortic wall. The incidence of embolic strokes is 1-4% and lower in transapical approach. Today, well-established imaging techniques are capable to view occlusion of coronary ostia by the natural calcific valve and the incidence is <1%.[14,21]

Aortic regurgitation followed by TAVI is often minimal or mild paravulvular disease. Sensitive measurement of the aortic ring and use of slightly larger valves are helpful in prevention of severe aortic regurgitation.[12,13]

Intermittent or persistent atrioventricular blocks (AV) can develop following the procedure. The review of the literature has shown that the incidence of permanent pacemaker implantation is 6% for ballon-expandable valves and 18% for self-expandable valves.[22.23]

Availability and efficacy of TAVI have been stated in many publications; however there is no data on comparison of TAVI with standard of care AVR procedure. Within this respect, we believe that randomized PARTNER (Placement of Aortic Catheter Valves) study, which is expected to release the results in 2010, will shed light on this issue.[24]

In conclusion, transcatheter aortic valve implantation (TAVI) has become a widely used standard of care procedure for patients who are at very high risk of surgery with inoperable aortic valve stenosis. The success rate of TAVI is high using with sensitive imaging techniques before surgery and sensitive procedural instructions. We believe that long-term randomized trials will helpful to extend the use of this approach.

During writing of this paper, more six patients (range 80-84 years of age) underwent TAVI, including five of them with transfemoral approach and one with transapical approach. Four of them were discharged in a good clinical condition, while two died in the early stage following surgery. The results of the procedure for those patients will also be reported with a-one-year follow-up.

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