Two Years' Experience in Transapical Aortic Valve Implantation

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ABSTRACT

Objectives: To describe the results of transcatheter aortic valve implantation in high-risk patients with aortic stenosis using the transapical approach.

Methods: From September 2006 till March 2010, with the mean follow up of 2 years, forty-five patients with severe symptomatic aortic stenosis were treated with transapical - transcatheter aortic valve implantation using the Edwards SAPIEN valve, because of high surgical risk or contraindications to surgery. Mean age was 81±10 years, mostly in New York Heart Association classes III/IV, the predicted surgical mortality was (12±16%) using the European System for Cardiac Risk Evaluation (EuroSCORE); or the Society of Thoracic Surgeons Predicted Risk Of Mortality (STS-PROM) more than 10%.

Results: Successful implantation was achieved in all patients with satisfactory postoperative gradients. In-hospital mortality was 18%. Stroke was not observed in any patient.

Conclusions: Transcatheter aortic valve implantation provides a privileged and direct approach to the aortic valve and allows antegrade manipulation of the instruments. There are no limits on the size of introducing system and it is not affected by peripheral vessel tortuosity or disease.

Key words: Aortic valve replacement, Calcific aortic valve stenosis, Transcatheter aortic valve implantation, Transapical

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Introduction

Aortic Stenosis (AS) is the most common valvular pathology in western countries[1] with a prevalence that is expected to markedly increase as the population ages. The onset of symptoms heralds a mortality rate of about 25% per year and the mortality rate at 5 and 10 years is 68% and 82% respectively.[2] Aortic Valve Replacement (AVR) is indicated in severe symptomatic AS.[3] Conventional surgical AVR performed under cardiopulmonary bypass and aortic cross-clamping is the reference treatment and has shown to improve outcome and survival. When performed as an isolated procedure, it carries an average 30 day mortality of 3.8±1.5%.[4] However, certain factors are known to increase the operative risk. A large multivariate study, showed that the 5 most important predictors of mortality after AVR were age≥80 years, New York Heart Association (NYHA) class ≥III, Ejection Fraction (EF)≤30% associated with previous MI, emergent

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AVR and concomitant Coronary Artery Bypass Grafting (CABG) surgery.[4] Patients with severe AS can thus be refused surgery in the presence of severe comorbidities; this was the case in 31.8% of patients in the Euro Heart Survey on Valvular Heart Disease[1] and 62% of patients in a similar study from the USA.[2] With the aging population, the proportion of patients with contraindications for surgery is also expected to increase.

In addition to comorbidities, patients may present with *technical difficulties* and complexities which make AVR challenging to perform. This is particularly true in patients undergoing redo surgery with patent coronary artery bypass grafts, those with previous mediastinal radiotherapy or in the presence of a heavily calcified and atheromatous ascending aorta (porcelain aorta).[5]

Transcatheter Aortic Valve Implantation (TAVI) techniques have been developed to provide alternative approaches to patients who fall into these categories and for whom conventional AVR is associated with very high risk. These techniques do not require cardiopulmonary bypass or aortic cross clamping and can be performed under general or locoregional anesthesia, with fluoroscopic and echocardiographic guidance.[6] These techniques have been performed via two different approaches, the Transfemoral (TF) and Transapical (TA) routes with established feasibility.[7]

In this study, we describe the results of transcatheter aortic valve implantation in high-risk patients with aortic stenosis using the transapical approach.

Methods

From September 2006 to March 2010, with mean follow up of 2 years, 45 patients with severe symptomatic AS requiring AVR, with mean pressure gradient of 50±12 mmHg, Aortic Valve Area (AVA) of 0.72±0.17 2cm, and Left Ventricular Ejection Fraction (LVEF) of 49±13%, in whom conventional surgery was considered high risk or contraindicated by a multidisciplinary team or for whom the TF route could not be performed, which were mainly unsuitable femoroiliac accesses and severely calcified aortic arch and descending aorta, were referred for TAVI via the transapical approach and included in a prospective registry. Demographic and patients' characteristics are described in Table I. Ethical committee approval was obtained and all patients gave informed consent and underwent complete evaluation using Transthoracic Echocardiography (TTE), coronary angiography, aortic and femoroiliac angiography. The procedure was performed under general anaesthesia, the patient heparinised (75 IU/kg b.w., IV). Heparin was reversed at the end of the procedure. In all patients, the implanted valve was the Edwards SAPIEN Transcatheter Heart Valve (Edwards Lifesciences Inc., CA, USA). TAVI was performed through a left antero-lateral mini-thoracotomy. The site of the incision was determined by localisation of the apex by TEE prior to prepping the patient. The pericardium was opened and attached to the chest wall. The left ventricular apex was then punctured through 2 purse-string sutures. A sheath (initially 33 French, then 26 French) was introduced in the left ventricle and the prosthesis implanted using the antegrade route via the Ascendra™ system under rapid ventricular pacing.[8]

Implantation success was defined by valve implantation in the correct position. Outcomes were described according to the guidelines for reporting mortality and morbidity after cardiac interventions.[9] Procedural success is defined as valve implantation in the correct position, with good immediate hemodynamic result and no major complications.

Results

Procedural success for TAVI was 100%. There was no intraoperative mortality. In all, the aortic valve area and mean trans-prosthetic gradient were satisfactory. There were no prosthesis malpositioning or conversion to on-pump surgical AVR. Paravalvular leaks were frequent immediately after implantation, but were mild or moderate in 14/45 patients (31%). In one patient, immediate post-implantation severe aortic regurgitation was managed by implantation of a second prosthesis into the first one *("valve after valve")* with satisfactory results as shown in (Table II).

Vascular complications occurred in 6/45 patients (12%). One patient had delayed rupture (after one week) of the femoral arterial access site, and one patient with severe peripheral artery disease had thrombosis of the common iliac artery in the context of septic shock, leading to leg ischemia and contributing to her eventual demise, the other 4 patients had deterioration of their already existing peripheral vascular disease. There were no strokes; this was probably related to the antegrade positioning and manipulation of the delivery system

Table I. Demographics and patients' characteristics

	n=45 (%)
Age (years, mean±SD)	81±10
Female gender	17(45)
Diabetes	14(45)
Renal failure (creatinine>2 mg/dl)	8(45)
Severe COPD (FEV1 <70% predicted and FEV1 / VC ratio <60%)	15(45)
NYHA class	
II	4
III	34
IV	7
Coronary artery disease	31
Previous MI	13
Previous PCI	11
Previous CABG	13
Peripheral artery disease	19
Stroke	5
Cancer	12
Porcelain aorta	17
Other severe comorbidities	14
≥ 2 comorbidities	26
Logistic EuroSCORE (%)	
-Mean±SD	16±12
-Range	11-57
STS-PROM (%)	
-Mean±SD	11±7
-Range	7-41
Aortic valve area	
-cm²	0.72±0.17
-cm²/m²	0.46±0.09
Mean gradient (mmHg)	50±12
Systolic pulmonary artery pressure ≥ 60 mmHg	9
LVEF (%)	49±13

Values are expressed as n (%) or mean±SD, unless otherwise stated.

Table II. Immediate post-implantation results

	Transapical TAVI (n=45)
Aortic valve area	
-cm²	1.71±0.54
-cm²/m²	0.71±0.30
Mean gradient (mmHg)	
-mean±SD	7±4
-range	2-10
Paravalvular aortic regurgitation	
-Grade 0-I	14
-Grade II	0
-Grade III	1
Valve after valve	1

Values are expressed as n (%) or mean ±SD, unless otherwise stated.

and valve. In 2 patients, a pace-maker was implanted to treat atrioventricular blocks. Three tamponades occurred, one; 4 hours after the procedure, with satisfactory recovery after surgical drainage, and other two patients; 2 days postoperatively, due to the rupture of the left ventricular apex, requiring emergent reintervention. This was followed by multiorgan failure and death at day 39. In-hospital mortality was 18% (8 patients), cause of in-hospital mortality were intractable arrhythmias and Left Ventricle (LV) failure in 2, septic shock in 2, and 4 patients died because of multiorgan failure. Mean follow-up was 8.6±5.6 (4–22) months. Six patients died after discharge (13%), cause of postdischarge mortality were pulmonary infection in 2 patients and LV failure in the other 4 patients. Late complications included pericardial effusion one month after TA-TAVI treated with surgical drainage. A false aneurysm of the apex of the left ventricle occurred 2 months after a transapical TAVI, and was treated by surgical closure with uneventful recovery.[9] There was no reintervention, hemolysis, or permanent valve-related impairment.

Discussion

The most frequent indication for aortic valve replacement is age-related degenerative calcific AS.[10] The operative mortality of AVR in elderly is higher than in the general population and is approximately 7-10%.[11] Scores predicting operative risk have been employed to provide an objective assessment of potential mortality and morbidity for patients, with variable accuracy. The preoperative

work up of this study group predicted high surgical risk or technical challenges to conventional AVR. Thus Transcatheter aortic valve implantation techniques were considered as an alternative therapeutic solution. Patient selecting for TAVI followed a multidisciplinary evaluation and included patients with predicted mortality rate by EuroSCORE >20% and by STS PROM>10%. The original cohort was treated with the transfemoral approach as the first option, while the transapical approach was reserved for patients refused both conventional surgery and the transfemoral approach. The overall observed hospital mortality of compares favourably with these predicted mortality rates. The fact that the transapical approach is a more direct approach allowing surgical control of the site of puncture and introduction of the necessary instruments may explain procedural safety. The high post-procedure in-hospital death in the transapical group correlates with the high risk in these patients who had severe peripheral artery disease, frequent coronary artery disease, previous coronary artery surgery and myocardial infarction, renal failure, and extra cardiac comorbidities, all known to negatively affect survival.[9,15] The selection process reserving the transapical approach to patients contraindicated for the transfemoral approach can explain the high post procedural mortality rate.[12]

Complications of TAVI included access complications related to femoral puncture which in the transapical group was performed to allow per procedure angiography and provided immediate access to launch cardiopulmonary bypass in case of conversion.[13] This was associated with significant complications and contributed to death in one patient. No stroke occurred after TAVI in this study which seems a consistent advantage of this approach.[14-16] Again, the more direct approach and less manipulation with the aorta is a logical explanation for a lower risk of stroke. Complete atrioventricular blocks requiring pace-maker implantation concerned 4% of patients, and have been described in similar ranges with the Edwards-SAPIEN prosthesis.[4,6,9] There was no myocardial infarction, nor coronary obstruction, nor induced mitral valve dysfunction, which confirmed the anatomical adequacy of the prosthesis to the left ventricular outflow tract and the environing structures. Adequate pre-procedure annulus sizing and continuous TEE monitoring during TAVI may have contributed to this result.

Generally, initial procedural success rate is high (93%).[17] The SOURCE registry provided the results of the Edwards SAPIEN™ valve of 32 centers with 1038 patients. The implantation success rate of the transapical procedure was above 90%. TA patients had a 30 day mortality of 10.3%. The stroke rate was 2.4% and pacemaker implantation rate was 6.7%. Vascular complication rate was less than 3%.[18]

Complications

	Transapical TAVI (n=45)
Major vascular complications	6
Stroke	0
Tamponade	3
Heart block requiring pace-maker implantation	2
In-hospital death	8(18%)
Cause:	
Intractable arrythmias & LV* failure	2
Septic shock	2
Multiorgan failure	4
Postdischarge Mortality	6(13%)
Causes	
LV failure	4
Pulmonary infection	2
Duration of hospital stay	17±10

Values are expressed as n (%) or mean ± SD, unless otherwise stated
* LV: Left ventricle

Limitation of the Study

Further analytical studies using larger numbers of patients and longer time period are needed, i.e the 5-years overall survival mortality using Kaplan-Meier method are needed.

Conclusions

Transcatheter aortic valve implantation expands the scope of the treatment of aortic stenosis in high-risk patients. While 2 different approaches have been advocated for valve implantation, their results are influenced by the selection strategy. The TA route provides a direct approach to the aortic valve and allows antegrade manipulation of the instruments. There are no limits on the size of introducing system and it is not affected by peripheral vessel tortuosity or disease. The results at 2 years in high risk patients are encouraging.

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