Transcatheter aortic valve implantation for severe aortic stenosis—a new paradigm for multidisciplinary intervention: A prospective cohort study

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Background Transcatheter aortic valve implantation (TAVI) is an alternative treatment option for patients with aortic stenosis deemed high risk or unsuitable for aortic valve replacement. The aim of this study was to assess the feasibility of TAVI in elderly patients, the delivery of this technology with a multidisciplinary approach, and the use of traditional surgical scoring systems.

Methods One hundred fifty-one consecutive patients (mean age 82.6 ± 7.3 years) with severe aortic stenosis underwent TAVI with the Edwards Lifesciences (Irvine, CA) Sapien bioprosthesis using the transapical (n = 84; 56%) or transfemoral (n = 67; 44%) approach from August 2007 to September 2009 at King's Health Partners, London, United Kingdom. We analyzed procedural outcome, complications, functional status, and midterm outcome of patients.

Results The multidisciplinary team comprised interventional cardiologists, cardiothoracic surgeons, imaging specialists, cardiac anesthetists, and specialist nurses. Seventy percent of patients were in New York Heart Association class III/IV, and logistic EuroSCORE was 21.6 ± 11.9. Procedural success was achieved in 98%. Postoperative complications included stroke (6%), complete atrioventricular block (5.3%), renal failure requiring hemofiltration (9.3%), and vascular injury (8.6%). Overall 30-day mortality was 9.9% (n = 15). The logistic EuroSCORE was a predictor of short-term mortality (logistic regression model, $P < .05$). Thirty-day mortality post-TAVI for patients with logistic EuroSCORE <20, 20 to 40, and >40 was 5.4%, 13.2%, and 22.2%, respectively.

Conclusions Transcatheter aortic valve implantation is a feasible treatment option in this patient group with promising short/medium-term results. Renal failure is the commonest short-term complication, and the incidence of vascular complications remains high. Risk prediction/case selection remains challenging, and a multidisciplinary team approach appears to be helpful in appropriate patient selection. (Am Heart J 2010;160:237-43.)

Aortic stenosis (AS) is the most common form of valvular heart disease. It predominantly affects the elderly and is usually caused by a degenerative, age-related process of valve calcification and destruction.[1,2] In our aging population, AS is becoming an increasingly prevalent condition, well known to have a poor prognosis and, moreover, associated with significant morbidity, multiple/prolonged hospital admissions, and a significant reduction in quality of life. Once AS becomes symptomatic, life expectancy decreases dramatically.[3] Until recently, the only definitive treatment of severe AS has been surgical aortic valve replacement, which remains the "gold standard" therapy. Medical management alone has a high mortality; and balloon valvuloplasty, although providing transient symptomatic relief, does not favorably impact on survival.[4] Transcatheter aortic valve implantation (TAVI) is a novel technique that is performed without the need for cardiopulmonary bypass or sternotomy and may therefore carry significantly lower procedural risk.

Elderly patients requiring aortic valve replacement often remain untreated because of multiple medical and

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social problems. Successful implementation of TAVI in this population requires a multidisciplinary team (MDT) approach from the early stages of patient selection. The purpose of this study was to evaluate our outcomes and to assess the feasibility of TAVI in elderly patients, with the delivery of this technology using a multidisciplinary approach. In addition, we aimed to analyze the usefulness of the logistic EuroSCORE in selecting patients for TAVI.

Methods

Patient population

The study is based on a registry prospectively including all patients undergoing TAVI at King's Health Partners from August 2007 to September 2009. Transcatheter aortic valve implantation has been approved for use in patients with symptomatic severe AS who are deemed unfit for conventional, surgical aortic valve replacement (logistic EuroSCORE >20 or Society of Thoracic Surgeons (STS) score >10% or turned down by 2 separate cardiothoracic surgeons). The United Kingdom National Institutes for Clinical Excellence have published a preliminary appraisal.[5]

Potential TAVI candidates underwent a systematic workup that included evaluation by the MDT, echocardiography (2- and 3-dimensional, transthoracic, and transesophageal), coronary angiography, right heart catheterization, aorto/ileofemoral angiography, and computed tomography (the latter to assess the extent/degree of arterial calcification). Patients were approved for the procedure at a multidisciplinary meeting that was minuted. The results of the multidisciplinary meeting were sent to the referring physician, the general practitioner, and the patient.

The procedure was performed transfemorally (TF) or transapically (TA) using the Edwards-Sapien (Edwards Lifesciences, Inc, CA, USA) valve. The mode of access was determined by the caliber, tortuosity, and calcification of the femoral/iliac arteries and aorta.

The *transfemoral procedure* was first described by Cribier et al[6] and Webb et al.[7] After arterial puncture or surgical exposure, the femoral artery is dilated to accommodate the delivery sheath. Balloon aortic valvuloplasty (BAV) is performed under conditions of rapid pacing (~200 beat/min) to minimize cardiac output and therefore minimize balloon movement on inflation. The Edwards-Sapien valve prosthesis is balloon mounted and is also deployed with rapid pacing (within the dilated native valve) to facilitate accurate placement.

The *transapical procedure* was first described by Walther et al.[8] Access to the left ventricular (LV) apex is gained through a left anterolateral minithoracotomy. Under fluoroscopic guidance, the apex is punctured and the native valve is crossed anterogradely. After BAV, the valve prosthesis is implanted using a similar technique to the transfemoral approach. The LV apex is closed with a purse-string suture. There was no need for access using the subclavian artery because, in patients with difficult access because of the size or quality of the femoral arteries, the transapical approach was used.

The TAVI program MDT consisted of at least 2 interventional cardiologists, 2 cardiothoracic surgeons, a cardiac imaging specialist, 2 cardiac anesthetists, a TAVI research fellow, and a specialist nurse. In addition, we now involve Care of the Elderly physicians, social workers, and physiotherapists (Figure 1). In the first instance, the suitability of the potential candidate for conventional AVR was assessed. If conventional surgery was deemed too high risk, TAVI was considered. Logistic EuroScore, comorbidities, fragility, and mobility were taken into account. The decision about the access site was based on heart/valve anatomy and vasculature. In total, 386 patients were referred to the MDT, from whom 151 patients eventually underwent TAVI. The reasons for declining TAVI were as follows: aortic valve annulus too large (n = 10) or too small (n = 1), patient declined workup investigations (n = 11), patient declined after workup investigations (n = 12), and only moderate AS (n = 27). Forty-eight patients were referred for conventional surgery, 1 patient was referred for CoreValve, 49 patients had medical therapy only, and 44 patients had BAV and then medical therapy. Eighteen patients died before scheduled TAVI, and 5 patients died before entering workup phase. The reasons for declining TAVI and referring for medical treatment only were short life expectancy (cancer), general fragility, immobilization, nonfavorable cardiac anatomy (grossly hypertrophied "sigmoid" septum, annulus size), and comorbidities (eg, severe airways disease).

Aims of the study

The aim of this study was to analyze the TAVI experience in an elderly population at King's Health Partners. In addition, we sought to evaluate the importance of a multidisciplinary approach on patient selection, the procedure itself, and short/midterm outcome and complications.

Study end points

We focused on outcome measures and analyzed the following: procedural success rate, 30-day mortality, complications (including stroke, major vascular complications, myocardial infarction, conduction abnormalities requiring permanent pacing, renal failure), and functional status after the procedure.

Statistical analysis

Continuous variables are presented as mean ± SD or SEM. Categorical variables are presented as percentages and frequencies. For comparison of continuous variables between groups, the 1-way Student t test was used. Categorical variables were compared by the χ^2 test. Paired t test was used for comparison of continuous variables before and after intervention. A logistic regression model was used to analyze the impact of multiple variables on short-term outcome. $P < .05$ was considered statistically significant.

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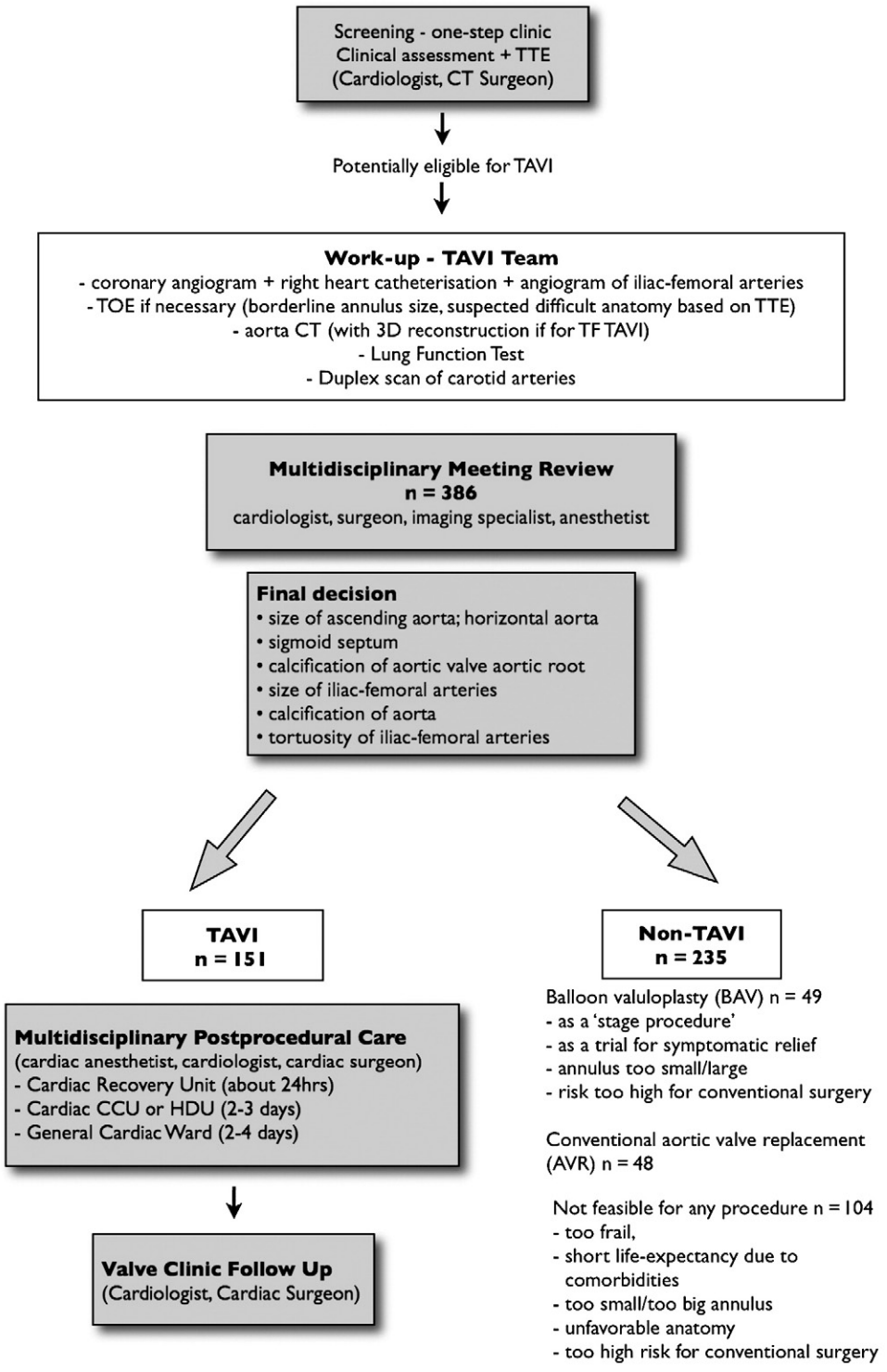
Results

The baseline clinical characteristics are shown in Table I. Most patients were >75 years old (87.4%, mean age 82.6 years). Echocardiographic features are consistent with severe AS in all cases: mean peak pressure

Figure 1



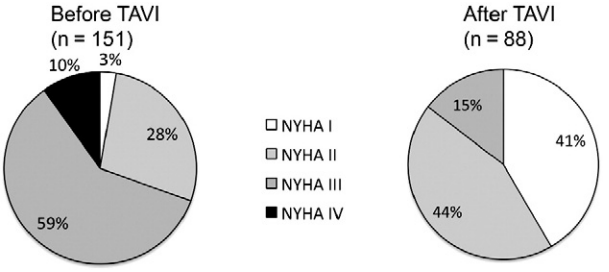
The TAVI service at King's Health Partners. The TAVI team is involved at the early stage of patient selection.

Table I. Baseline clinical characteristics

	TA (n = 84)	TF (n = 67)	*P*	All
Age (y ± SE)	82.2 ± 0.8	83 ± 0.8	.48	82.5 ± 7.4
Female gender (n/%)	45 (54)	24 (36)	<.05	69 (46)
BMI (mean ± SE)	25.6 ± 0.5	27.4 ± 0.8	.07	26.4 ± 5.7
Logistic EuroSCORE (mean ± SE)	23.4 ± 1.5	19.4 ± 1.1	<.05	21.6 ± 11.9
Cardiac rhythm SR (%)	60 (71.4)	48 (71.6)	.56	108 (71.5)
AF (%)	18 (21.4)	18 (26.9)	.28	36 (23.8)
PPM (%)	7 (8.4)	4 (6)	.41	11 (7.3)
Mitral regurgitation ≥moderate (%)	16 (19)	8 (12.1)	.18	24 (16)
Aortic regurgitation ≥moderate (%)	12 (14.3)	4 (6.1)	.09	16 (10.6)
Previous cerebral ischemic event (%)	17 (20.2)	11 (16.4)	.35	28 (18.5)
Diabetes (%)	17 (20.2)	18 (26.9)	.22	35 (23.2)
Hypertension (%)	54 (64.3)	42 (62.7)	.49	96 (63.4)
Severe lung disease (%)	26 (31)	15 (22.4)	.16	41 (27.2)
Carotid artery stenosis >50% (%)	20 (23.8)	9 (13.4)	.08	29 (19.2)
Porcelain aorta (%)	11 (13.1)	9 (13.4)	.56	20 (13.2)
CRF (>stage 3) (%)	52 (61.9)	28 (41.8)	<.05	80 (53)
Creatinine (μmol/L)	112.8 ± 5.9	109.7 ± 7.6	.74	111.4 ± 57.6
eGFR (mean ± SE)	56.3 ± 2.5	62 ± 2.4	.09	58.8 ± 21.4
Peripheral vascular disease (%)	30 (35.7)	7 (10.4)	<.05	37 (24.5)
Coronary artery disease >50% (%)	40 (47.6)	26 (38.8)	.18	66 (43.7)
Prior coronary angioplasty	12 (14.3)	7 (10.4)	.32	19 (12.6)
Prior CABG (%)	24 (28.6)	12 (17.9)	.09	36 (23.8)

CABG, Coronary artery bypass graft; *BMI*, body mass index; *SR*, sinus rhythm; *AF*, atrial fibrillation; *PPM*, permanent pacemaker; *CRF*, chronic renal failure; *eGFR*, estimated glomerular filtration rate.

Figure 2



Functional status before and after TAVI by NYHA class (NYHA class at follow-up at 30 days was available for 88 patients [65%]).

Table II. Outcome and complications at 30 days (number/percentage)

	TA (n = 84)	TF (n = 67)	*P*	All (N = 151)
Procedural success	83 (99)	65 (97)	.84	148 (98)
Femoral-femoral cardiopulmonary bypass	3 (3.6)	2 (2.9)	.84	5 (3.3)
Q wave myocardial infarction	0 (0)	0 (0)	1	0 (0)
Stroke	4 (4.8)	5 (7.5)	.72	9 (6)
Conduction abnormalities requiring PPM	5 (6)	3 (4.5)	.97	8 (5.3)
Major vascular complications	2 (2.3)	11(16.4)	<.05	13 (8.6)
CVVH	10 (11.9)	4 (6)	.33	14 (9.3)
Acute on chronic renal failure	35 (44.9)	15 (22.7)	<.05	50 (34.7)
Death, 0-7 d	5 (6)	2 (3)	.63	7 (4.6)
Death, 30 d	11 (13.1)	4 (6)	.24	15 (9.9)

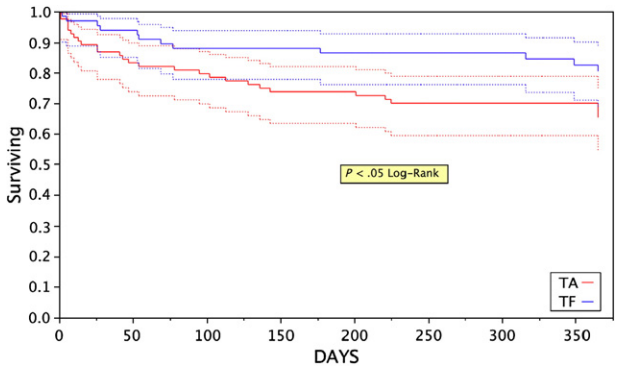
Acute-on-chronic renal failure is defined as a >25% increase in serum creatinine at 72 to 96 hours postprocedure. *CVVH*, Continuous venovenous hemofiltration.

gradient of 79.2 ± 25.5 mm Hg, mean gradient of 49.7% ± 11.5%, and mean aortic valve orifice area of 0.62 ± 0.16 cm^2. The majority had isolated AS with concomitant mitral regurgitation (≥moderate) and aortic regurgitation (≥moderate) in only 16% and 10.6%, respectively. Most patients were very symptomatic with 70% in New York Heart Association (NYHA) class III or IV (Figure 2). Eleven (7.3%) patients with chest pain and significant proximal coronary artery disease that could produce ischemia during rapid pacing underwent percutaneous coronary intervention as a staged procedure before TAVI.

Transcatheter aortic valve implantation procedural success was achieved in 98%. The Edwards-Sapien 23-mm valve was used in 42%; and the 26-mm valve, in 58%. Clinical outcome at 30 days is summarized in Table II.

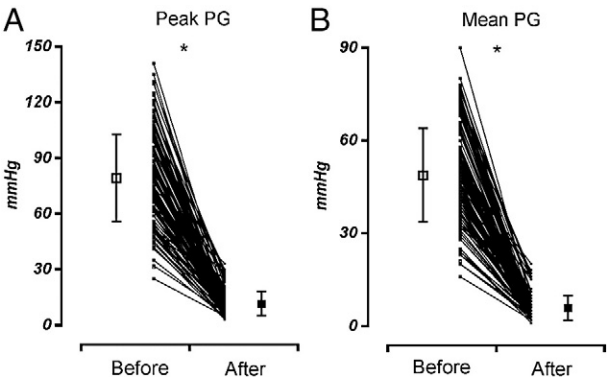
The logistic EuroSCORE predicted operative mortality of 21.6% ± 11.9% compared with actual outcomes of 9.9% 30-day mortality post-TAVI. The logistic EuroSCORE was a good gross predictor of short-term mortality (logistic regression model, $P < .05$). Thirty-day mortality post-TAVI for patients with logistic EuroSCORE <20, 20 to 40, and >40 was 5.4%, 13.2%, and 22.2%, respectively. Twelve-month survival rate in the TA group was 70.2% compared with 83.6% in the TF group with median follow-up of 375 and 416 days, respectively. Figure 3 shows 12-month survival rate after

Figure 3



Twelve-month survival after TAVI (Kaplan-Meier curves for transapical and transfemoral approach).

Figure 4



Echocardiographic characteristics before the TAVI and valve function postprocedure (**A**—peak pressure gradient; **B**—mean pressure gradient; *$P < .005$, paired samples *t* test; echocardiographic data postprocedure from 131 patients).

transfemoral and transapical TAVI. The Kaplan-Meier curves in the TF and TA group continued to separate during 12 months of follow-up. The reasons for 30-day mortality were as follows: multiorgan failure (n = 7), cerebrovascular accident, CVA and its complications (n = 3), dissection of ascending aorta (n = 1), respiratory failure (n = 1), ruptured left ventricular apex (n = 1), pancreatitis (n = 1), and sepsis (n = 1).

The major vascular complication rate (defined as vascular damage requiring emergency intervention or blood transfusion) was 8.6% but was not associated with increased mortality. Six percent of patients had a CVA after TAVI. This complication was associated with increased 30-day mortality (44.4% in CVA group). Fifty-three of patients had stage 3/4 chronic renal failure preprocedure, defined as glomerular filtration rate <60 mL/min. Thirty-five percent of all patients had a >25% increase in creatinine at 72 to 96 hours postprocedure. The duration of in-hospital stay was significantly longer after transapical TAVI compared with the transfemoral procedure (19 ± 2 vs 11 ± 1 days, $P < .05$, Student *t* test).

At discharge, the echocardiographic mean transaortic gradient had fallen from 48.8 ± 1.4 to 5.8 ± 0.4 mm Hg ($P < .005$); and peak gradient, from 79.2 ± 2 to 11.4 ± 0.6 mm Hg ($P < .005$) (Figure 4). Remarkably, only 1 patient (0.7%) had severe AR, 5 patients (3.6%) had moderate AR, and 22 (15.7%) had mild AR.

Discussion

Percutaneous catheter-based approaches to the treatment of valve disease have been studied in animal models for several years, but it was Bonhoeffer et al[9] who performed the first human percutaneous valve implantation (in the pulmonary position) in 2000. Aortic valve implantation was achieved shortly after this in 2002 by Alan Cribier.[10] The Edwards-Sapien bioprosthesis has now been approved for clinical use in the European Union and preliminary guidance for its use has been published by the National Institute of Clinical Excellence, the European Association of Cardio-Thoracic Surgery, and the European Society of Cardiology.[5,11]

Transcatheter aortic valve implantation is still reserved for high-risk elderly patients with symptomatic severe AS. These patients are often frail, with limited mobility and a poor long-term prognosis if untreated. However, it is worth noting that life expectancy in the general population of octogenarians was 9 years in 2009 (Office of National Statistics, United Kingdom); and the trend of increasing life expectancy will continue in the coming decades. As a result, the prevalence of AS will increase in these higher-risk patients.

In the general population, the risk of conventional aortic valve surgery is low (about 3%); and even when valve replacement is performed with concurrent coronary artery bypass grafting, the operative risk in all-comers does not exceed 5%.[2] However, the risk of aortic valve surgery is significantly higher in the elderly; and perhaps as a consequence, about one third of patients with symptomatic severe AS are not referred for surgery or are turned down for surgical treatment.[12] A number of scoring systems have been designed for the assessment of operative risk precardiac surgery (eg, EuroSCORE, Society of Thoracic Surgeons score); but these are often criticized, mainly because their predictive ability is reduced in high-risk and elderly patients. Moreover, their applicability to this novel technique has been questioned. No TAVI-specific scoring system exists so risk stratification is based mainly on nonquantifiable parameters such as patients' mobility, frailty, general condition, and the physician/surgeon's “gut feeling.” It

has been shown recently that logistic EuroSCORE overestimates mortality in TAVI patients.[13] A specific TAVI risk score would help, but the key to appropriate case selection is a multidisciplinary approach.

Early experience of TAVI in humans was acquired in the Initial Registry of EndoVascular Implantation of Valves in Europe trial, which was followed by the Registry of Endovascular Critical Aortic Stenosis Treatment trial.[6] Anatomical and functional success was obtained in >90% of patients. Importantly, the improvement in aortic valve area and mean aortic gradient was maintained at 24 months; and in addition, an improvement in LV ejection fraction was observed, mainly in patients with depressed systolic function at baseline. John Webb's group[7] reported a similar experience with the initial transfemoral cohort—valve implantation was successful in 86%, with the 30-day mortality at about 12% (compared with an expected mortality of 28%). These initial results were influenced by a marked learning curve: the procedural success increased from 76% (first 25 patients) to 96% in the following patients, with a significant decrease in 30-day mortality.

In our series, procedural success rate was achieved in 98% of all cases, with a 30-day mortality of 9.9%. We did not have any procedural mortality, and the outcome was significantly better than predicted. There was a remarkably low rate of aortic regurgitation with only 6 (3.9%) of 138 patients left with >grade 2 regurgitation. The most frequent complication in our series was acute-on-chronic renal failure; and those with preexisting renal impairment had a high risk of developing renal failure postprocedure, probably because of contrast exposure and hypotension during rapid pacing. Impaired renal function was a poor prognostic marker, and those patients who developed significant renal impairment tended to fare poorly.

Although the frequency of vascular complications in our series was 16.4% in the transfemoral group, it did not contribute to postprocedural mortality. Preprocedural screening, patient selection, improved delivery systems, and vascular management appear to be relevant.[14] The decision about suitability for the transfemoral approach was made on a case-by-case basis. It is based not only on vessel size, but on severity and localization of vascular calcification as well as vessel tortuosity, in the knowledge that the TA approach is always an alternative that is not affected by peripheral vascular disease. Our surgeons do not believe a thoracic aortic valve conduit can bring any benefit given the alternative treatment option of TAVI. In addition, it does not avoid a major thoracotomy and often needs support using cardiopulmonary bypass.

It is important to emphasize that there is a significant difference in baseline clinical characteristics between the TA and TF group. By definition, the TA group is higher risk because patients in this group are selected on the basis of peripheral vascular disease. This is likely to account for the higher mortality in TA group. The logistic EuroSCORE was higher in the TA groups (Table I) (19.4% TF vs 23.4% TA, $P < .05$). In addition, there was a significantly higher incidence of peripheral vascular disease, chronic renal failure, and female patients in the TA group. All those factors are known predictors for postoperative mortality and morbidity after conventional aortic valve replacement. In the SOURCE registry (with >1,000 patients included), the TA (n = 575) versus TF (n = 463) logistic EuroSCORE was 29.1 versus 25.7 ($P < .001$) (manuscript in press).

The MDT is central to our TAVI program and initially consisted of 2 interventional cardiologists, 2 cardiothoracic surgeons, a cardiac imaging specialist, and 2 cardiac anesthetists. As our program expanded, a specialist nurse and a dedicated interventional fellow were appointed. We have established a "one-stop" valve clinic, where potential candidates and post-TAVI patients are assessed clinically and echocardiographically. We are now working closely with Care of the Elderly physicians and community nurses.

This new technique has the potential to revolutionize the treatment of AS, but randomized clinical trial data are needed with careful evaluation of longer-term results. The PARTNER-IDE study is a randomized controlled trial comparing standard surgical aortic valve replacement with TAVI (using the Edwards-Sapien valve) and also optimal medical treatment to TAVI in patients deemed inoperable. The study is currently ongoing in the United States and Canada, and 1-year results are expected to be presented in September 2010.

Summary

These data confirm the feasibility of this novel technique and show promising short- and midterm results in an elderly population. Our data represent one of the largest European single-center experiences; and they emphasize the importance of a multidisciplinary approach, which appears key for appropriate patient selection and successful implementation of this very promising technique. Logistic EuroSCORE can be helpful in identifying high-risk patients, but clinical judgment remains essential. Perhaps, the TAVI experience will change the way we introduce new interventional cardiac techniques in the future.

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All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

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