First experience with the Edwards SAPIEN transcatheter aortic valve implantation (TAVI)

Data from the Western Cape, South Africa

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ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) is an exciting new technology that was launched in South Africa in October 2009 for the treatment of aortic stenosis in patients at high risk for conventional surgery. We report our initial experience with TAVI in the Western Cape, South Africa.

Methods: 70 patients with severe symptomatic aortic stenosis underwent TAVI with the Edwards SAPIEN device (26 via transapical approach and 44 via transfemoral) at Panorama and Vergelegen Mediclinic hospitals in the Western Cape. All implants were performed by a team consisting of 2 cardiothoracic anaesthesiologists, 2 cardiothoracic surgeons, 2 cardiologists and an echo expert.

Results: Patients were at high risk with a mean age of 80 years and a mean logistic EuroSCORE of 26. The acute procedural success rate was 97% with two acute deaths. At 30 days, there were a total of 5 deaths. Major vascular complications were seen in 6 cases (9%). Only one stroke was seen during the follow-up period.

Conclusions: With a multidisciplinary team approach and careful patient selection, TAVI can be performed by a high volume centre in South Africa with results comparable to international published outcomes. SAHeart 2012; 9:6-13

INTRODUCTION

It is well established that the treatment of choice for severe symptomatic aortic valve stenosis is valve replacement. Since the first surgical implantation in 1960,[1] this procedure has gained a multitude of evidence to support its use with an estimated one million implants to date. In high volume centres, 30-day mortality rates as low as 4% have been reported.[2-4] Despite this, up to a third of patients are not even referred for valve replacement due to perceived high risk.[5] This has lead to a search for less invasive alternatives. Alain Cribier did the first transcatheter aortic valve implantation in 2002[6] and this was followed by huge interest in the field. The Cribier-Edwards™ (Edwards Lifesciences™, Irvine, California) valve received CE-mark accreditation in 2007 and to date an estimated 18 000 of these valves (and subsequently the improved Edwards SAPIEN™ and SAPIEN XT™ valves) have been implanted.

The first transcatheter aortic valve implants (TAVI) in South Africa were implanted in October 2009 by 3 teams, one each in Johannesburg, Cape Town and Durban. We report on the experience of the Cape Town team from October 2009 until July 2011.

METHODS

The heart team

Our team consists of 2 cardiologists, 2 surgeons, 2 anaesthesiologists and an echocardiography expert. Patients are screened by the cardiologists as well as the surgeons. After assessment they are discussed and approved by the team as a whole. A significant percentage of our cases are referred by cardiothoracic surgeons outside of the team, who have declared the patients inoperable or very high risk candidates for open valve replacement. All members of the team are present during all implants.

Patients

Patients were accepted for the procedure only if they fulfilled the indications for which the Edwards device received CE-mark

accreditation: They had to have a clear indication for aortic valve replacement (symptomatic severe aortic stenosis with a valve area of less than 0.8cm^2 and a mean gradient of greater than 40mmHg) but deemed too high risk for operative aortic valve replacement (log EuroSCORE >20 or STS score >10) or a contra-indication for open valve replacement (e.g. porcelain aorta). All patients provided written informed consent. Contra-indications include: dominant aortic regurgitation; bicuspid aortic valve; aortic annulus size unsuitable; unprotected left coronary obstruction likely; and excessive frailty.

Screening

Screening was performed by at least a cardiologist and a surgeon. The reasons for turning patients down for TAVI included poor general health (opinion of more than one team member); insufficient symptoms; conventional surgery was a realistic possibility; the aortic annulus measured <18 or >26mm (as delineated by TEE); and refusal by medical aid to fund the procedure.

Patients underwent transthoracic echocardiography (TTE) to assess severity of disease as well as annulus size measurement and suitability of the landing zone of the prosthesis. Recent coronary angiogram was required, but no coronary intervention or infarction was allowed within the month preceding the TAVI. Coronary revascularisation was performed only if deemed to be clinically relevant (generally, this implied the presence of regular angina). The ileo-femoral arteries were assessed by conventional angiography or CT scan. Transfemoral implantation was the preferred route, unless ileo-femoral anatomy was unfavourable due to tortuosity, inadequate calibre and extensive calcification.

CT scan of the aortic root was performed in some of the patients to assess the annulus size. This modality tends to oversize the annulus, requires extra contrast and local expertise is limited. We therefore performed it only in a limited number of cases.

The final decision on the valve size was made with an annulus measurement using transoesophageal echocardiography (TEE).

The procedures

Although the techniques for transfemoral and transapical aortic valve implantation have been described previously,[7] certain detail is retained in this report as it is required to put the complications and outcomes in perspective.

All procedures were performed in the cardiac catheterisation laboratory, with equipment for cardiopulmonary bypass and sternotomy/thoracotomy on standby. Patients were preloaded with aspirin (325mg) and after arterial access was obtained, loaded with 5 000 IU of heparin. Aspirin (75-150mg) was continued indefinitely. We implanted the Edwards SAPIEN™ bovine valve using the RetroFlex-II™ delivery system (Edwards Lifesciences™, Irvine, California) for transfemoral procedures and the Ascendra™ transapical catheter (Edwards Lifesciences™, Irvine, California) for transapical procedures. From November 2010 (case number 38) onwards cases were performed using the Edwards SAPIEN XT™ device and the Novaflex™ (Edwards Lifesciences™, Irvine, California) delivery system.

All cases were done under general anaesthesia to facilitate continuous TEE monitoring. Due to the large calibre catheters (24 French for the 26mm and 22 French for the 23mm Edwards SAPIEN valve and 19 and 18 French respectively for the 26mm and 23mm SAPIEN XT valve), we opted to do surgical arterial cut down in the groin. An Amplatzer extra-stiff guide wire was passed over the aortic valve. A 20-22mm balloon was used to pre-dilate the aortic valve under rapid ventricular pacing.

The Edwards SAPIEN device was then positioned fluoroscopically and deployed with balloon inflation under rapid ventricular pacing. Immediate success was assessed with supra aortic contrast injection as well as with TEE. The puncture site in the groin was closed surgically and the result of this closure was assessed with a contrast injection through the pigtail catheter in the contralateral groin.

The technique for the SAPIEN XT™ implantation is similar except that the valve is mounted on the delivery catheter, behind the balloon. Once exited from the insertion sheath into the abdominal aorta, the balloon is pulled back into the crimped valve and clicks into place. The mounted valve is then advanced further up the aorta.

For the transapical approach, a left mini-thoracotomy was made with liberal infiltration with long acting local anaesthetic. The left ventricular apex was exposed and pre-closed with plegetted purse string sutures. After puncture of the left ventricular apex, the rest of the procedure is largely the same as for transfemoral approach, except that the valve is mounted in the opposite orientation on the balloon catheter.

Data collection

An echocardiogram was performed prior to discharge and patients were then seen at 30 days and where applicable, 6 months and 1 year. We will report only the 30 day data.

Transthoracic echocardiography was performed before hospital discharge and then at 30 days and 1 year at the implantation centre. Aortic valve area was calculated with the continuity equation (via the velocity-time integral method) from data derived before and after device implantation.

Measurement of the left ventricular outflow tract for calculations of aortic valve area was performed with 2-dimensional imaging in a zoomed-up parasternal long-axis view. For patients located geographically far from Cape Town and unable to return to the implantation centre for further studies, these measurements were undertaken by an experienced local service.

Aortic incompetence was classified as para-valvular or valvular and graded as none, trivial, moderate and severe.

Study end-points

We assessed each patient for any complication but focussed on the following outcomes: complications (including stroke, major vascular complications requiring acute intervention or blood transfusion; conduction abnormalities requiring permanent pacing; renal failure requiring dialysis) procedural success rate; 30-day mortality; and New York Heart Association functional status after the procedure. For vascular access complications, stroke and bleeding, we used VARC-definitions.[8]

Statistical analysis

P-values for differences in outcomes were calculated using the Mann-Whitney U equation (unless stated otherwise) and a value of ≤0.05 was considered significant.

RESULTS

Baseline characteristics

Seventy patients were included in the study cohort. This represented approximately a third of the total number screened. Unfortunately accurate screening statistics were not recorded by all the practices involved, preventing us from analysing the outcome in patients not accepted for TAVI.

Of the 70 patients undergoing TAVI, 26 received a transapical valve and 44 transfemoral. The rate of transfemoral usage increased significantly after the introduction of the lower profile SAPIEN XT valve (from 50% transfemoral with the larger device to 72% with the SAPIEN XT device).

TABLE 1: Patient baseline characteristics

Patient baseline characteristics	Total (n=70)	Transapical (n=26)	Transfemoral (n=44)	P-value (comparing TA to TF)
Age (range)	80 (63-92)	77	82	0.01
Male sex, n (%)	31 (46)	19 (73*)	12 (27*)	0.5
History of CABG, n (%)	28 (40)	15 (55*)	13 (30*)	0.2
History of chest radiation, n (%)	1 (1.4)	0	1 (2*)	0.4
History of peripheral vascular disease, n (%)	15 (22)	12 (46*)	3 (7*)	0.0005
History of COPD, n (%)	31 (41)	8 (31*)	23 (52*)	0.6
History of previous cancer, n (%)	10 (14)	2 (8*)	8 (18*)	0.6
Prior permanent pacemaker, n (%)	15 (22)	6 (23*)	9 (20*)	
Porcelain aorta, n (%)	7 (10)	7 (10*)	0	0.003
Logistic EuroSCORE (range)	26.4 (9-55)	26.5 (15-39)	26.3 (9-55)	0.72
NYHA functional class:				
I	0	0	0	
II	11	2	9	
III	40	16	24	
IV	19	11	8	

**Expressed as a percentage of the total number of cases for this particular approach (transapical or transfemoral). TA: transapical, TF: transfemoral.*

TABLE 2: Procedural details and immediate outcomes

	Total (n=70), n (%)	Transapical (n=26), n (%*)	Transfemoral (n=44), n (%*)	P-value (comparing TF to TA)
Implanted valve size				
23mm	38 (54)	14 (54)	24 (55)	
26mm	32 (46)	12 (46)	20 (45)	
Valve-in-valve	0	0	0	
Conversion to open AVR	0	0	0	
Average procedure time, min (range)	84.7 (45-200)	83 (60-200)	65 (45-140)	0.61
Contrast use, average (range)	112ml (40-325)	95 (60-189)	119 (40-325)	0.21
Acute procedural success, n(%)	68 (97)	25 (96)	43 (98)	
Post-implant AR> grade 1, n (%)	9 (13)	1 (4)	8 (18)	0.3
Post-implant AR> grade 2	0	0	0	
Mean MR grade				
pre-TAVI	1.5	1.6	1.4	
post-TAVI	1	1	1	0.014#
Hospital stay (days)				
Intensive care	3.4	3.8	2.9	0.07
High care unit	4.2	5	3.5	0.02
Ward	2	2.7	1.5	0.02
Time to extubation (hrs)	6.2	13.2	1.3	<0.01

**Expressed as a percentage of the total number of cases for this approach (transapical or transfemoral). #Compared to MR grade pre-TAVI. TA: transapical, TF: transfemoral.*

Coronary revascularisation was not required in any patient after referral to our team although 3 patients had PCI procedures done in the last 6 months prior to referral to us.

Patients were old (mean age was 80) and had high predicted mortality (average logistic EuroSCORE was 26.6) (see Table 1). Of the 12 patients with a EuroSCORE below 20, all had either a STS score >10 and or had absolute contra-indications to surgery.

A few of these deserve special mention:

- Patient 16 had a CT scan that showed extensive circumferential calcification of the thoracic aorta which excluded cross clamping;
- Patient 25 had a previous attempt at aortic valve replacement but at operation, cross clamping of the aorta was impossible due to calcification;
- Patient 31 was on long term immune suppressants for rheumatoid arthritis and was turned down for surgery by an independent surgeon due to frailty and fear of poor wound healing;
- Patient 29 had a EuroSCORE over 20, but deemed an operative candidate at another institution. She had received previous radiation to her thorax for breast cancer. An open aortic valve replacement was attempted but abandoned after a lengthy effort due to hostile thorax.

Procedural outcomes

Procedural success was achieved in all but 2 patients (97%). Both patients died acutely (see under Complications below). Valves were placed successfully in all patients who survived the initial procedure. See Table 2 for detail. 30-day mortality was 7.1% in a cohort with a predicted 30-day mortality of 26% (according to log EuroSCORE). In an effort to delineate a potential learning curve, we compared procedural parameters for the first half of our experience (cases 1-35) with the second half (cases 36-70). This is delineated in Table 3.

Complications

Several complications occurred, underlining how frail these patients are. They include ileus with aspiration; Stevens-Johnson syndrome

due to antibiotics; retropharyngeal haematoma from central venous cannulation (with inadvertent puncture of the carotid artery); and lower respiratory tract infection. Major complications are listed in Table 4. Vascular access related complications were frequent (occurred in 15% of cases) but were not associated with any acute fatality.

We experienced 5 fatalities within 30 days of the procedure:

1. Patient 20 was an 88-year-old female with a log EuroSCORE of 34. Her peripheral vessels were diseased but of adequate calibre for the 24 French delivery system. Her implant went without problems but 7 days after the implant, she developed acute arterial occlusion of the contralateral femoral artery. This culminated in an ischaemic leg and acute renal failure.

2. Patient 37 was a 92-year-old lady who was still working full time. She received a successful implant, but a few hours after the procedure, she sat up to have lunch. This was promptly followed by haemodynamic collapse due to the 6 French temporary pacing wire used perforating her right ventricle. She died despite immediate diagnosis and treatment of this complication. We have since then adopted the use of 5 French pacing wires only.

3. Patient 48 was transferred from another institution with diabetes, obstructive jaundice, pre-renal failure, previous pulmonary embolism and critical AS. He was deemed too ill for TAVI and received a balloon aortic valvuloplasty. Despite the successful valvuloplasty, his condition did not improve dramatically and a successful TAVI was performed a week later. He however remained unwell and died 21 days later of multi-organ failure.

4. Patient 57 had a previous history of alcohol abuse and poor wound healing (with sternal dehiscence after bypass surgery 10 years prior). He was done via a transapical approach because of a horizontal ascending aorta. After needle puncture of his left ventricular apex, the ventricle developed a tear that could not be contained. This lead to eventual institution of peripheral extra corporeal circulation but the tearing could not be contained despite prolonged surgical intervention.

5. Patient 58 was an 80-year-old lady who had a device inserted from a femoral approach. After balloon valvuloplasty, the device was placed in the left ventricle but on TEE, extensive oscillating tissue attached to the device was seen. The activated clotting time at this stage was >300 and we deployed the valve. The patient developed extensive embolisation down her

TABLE 3: Learning curve

Column 1	1st 35 cases	2nd 35 cases
Procedure time (min)	93.42	68.83
Screening time (min)	16.59	13.79
Time to extubation (hrs)	10.09	1.28
ICU stay (days)	3.97	2.78
Procedural success*. n (%)	34 (97%)	31 (86%)

**Denotes patients discharged from hospital with a functional valve.*

TABLE 4: Major complications at 30 days

Major complications at 30 days	Total (n=65), n (%)	Transapical (n=26), n (%*)	Transfemoral (n=44), n (%*)	P-value (comparing TA to TF)
Death	4 (6)	1 (4)	3 (6.8)	0.05
Stroke	1 (1.4)	1 (4)	0	0.33
Permanent pacemaker	2 (3)	0	2 (5)	0.17
Renal failure requiring dialysis	0	0	0	
Vascular access complications				
Major (VARC definition)	6 (9)	3 (11.5)	3 (6.8)	0.8
Minor (VARC definition)	4 (6)	0	4 (9)	0.09
Major bleeding (VARC definition)	4 (6)	3 (11.5)	1 (2.5)	0.6

**Expressed as a percentages of the total number of cases for this particular approach (transapical or transfemoral). P-values calculated with the Fisher-exact formula.*
VARC: Valve Academic Research Consortium,[8] TA: transapical, TF: transfemoral.

coronaries. This was aspirated, she was thrombolysed and the left main was stented. After initial recovery, she deteriorated again and we could not resuscitate her successfully. A medico-legal autopsy was performed but the result was not at our disposal.

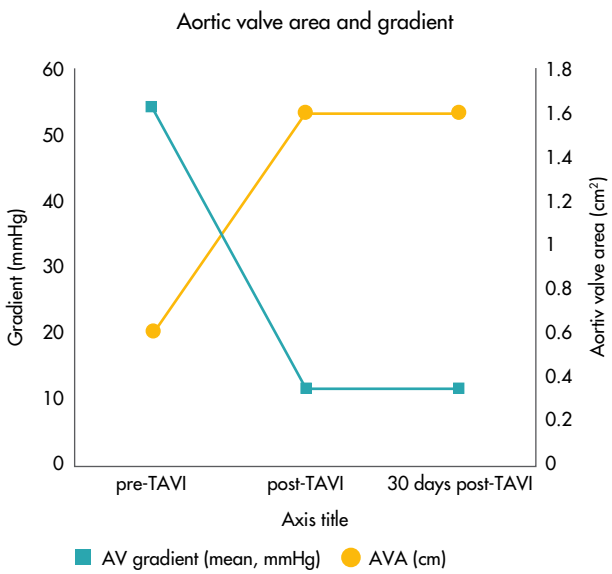

FIGURE 1: Change in mean gradient across the aortic valve (AV gradient) and aortic valve area calculated by echocardiography (AVA) prior to TAVI, immediately after TAVI and 30 days post-TAVI.

Renal failure requiring dialysis was not seen, despite a mean contrast usage of 112ml. This was likely due to good renal function prior to the procedure with a mean serum creatinine level of 110umol/l (range 60-254).

Echocardiographic assessment revealed that the mean gradient across the aortic valve fell from 54 to 11.6mmHg (see Figure 1). The mean AR grade remained low at 1 post op and 13% of cases had grade 1 or 2 AR but no cases with >grade 2 AR.

Most patients experienced significant symptomatic relief as depicted in Figure 2.

The purpose of this study is to describe the short term outcome of the procedures but we do have access to 1-year mortality follow up data on 29 patients: 4 of them (14%) have died. Of these, only one was procedural. The others occurred more than 30 days post-procedure. These patients had an average log EuroSCORE of 35% and an average age of 85 which puts them at the higher risk end of the cohort as a whole.

DISCUSSION

Transcatheter aortic valve implantation has grown rapidly since the first implants by Cribier. The Edwards SAPIEN bioprostheses has now been approved for clinical use in the European Union and preliminary guidance for its use has been published by the National

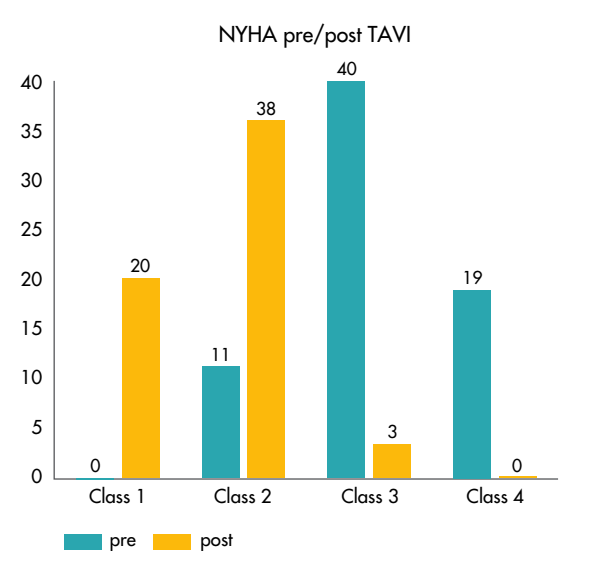

FIGURE 2: Most patients experienced significant improvement in symptoms of dyspnoea. The blue bars denote New York Heart Association functional class pre-TAVI and yellow post-TAVI.

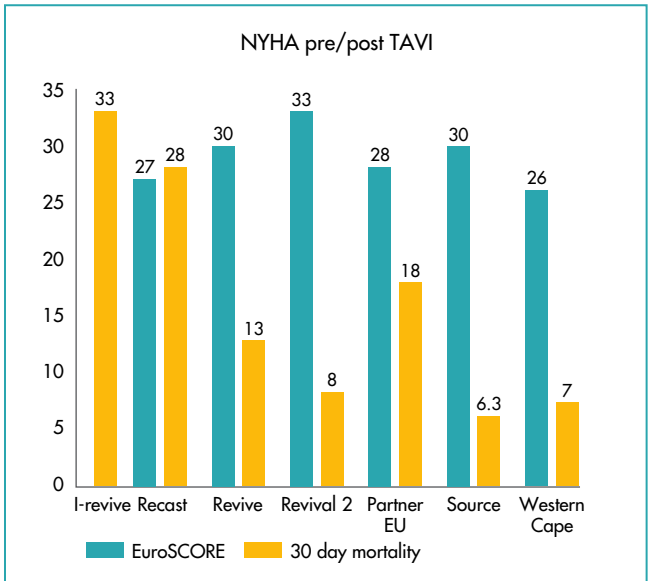

FIGURE 3: Predicted 30 mortality (log EuroSCORE in blue) compared to actual 30 day mortality (%, in yellow) across different TAVI studies, including the current study (Western Cape).[10,11,18,19]

Institute of Clinical Excellence, the European Association of Cardio-Thoracic Surgery, and the European Society of Cardiology.

This emphasises that these procedures should only be offered to patients at high risk for conventional surgery as conventional surgery has more data to support its use and safety. Patient selection remains a problem and the currently used EuroSCORE tend to overestimate the risk, while the Society of Thoracic Surgeons' score system underestimates it. Although we could not demonstrate it with formal risk assessment scores, it is our opinion that patients on the extremely high risk end of the spectrum are also not ideal candidates for TAVI. A multidisciplinary team assessment of the patient and individualisation of the selection process is currently the best way to select suitable candidates in our opinion.

We had a high implantation success rate of 97% which compares well with more recently published figures of 90-96%.[9-11] Thirty-day mortality was also low at 7.1% which also compares well with published data of other groups, summarised in Figure 3.

Of the 2 procedural deaths we had, both were due to factors we could not predict and, in retrospect, the team's opinion was that these complications were not predictable and we would not alter our management if given another chance. The patient who died due to thrombus on the valve (patient 58 discussed under Results) most likely had a vascular injury in the aorta with aortic tissue stuck on the device which then stimulated the thrombus formation. One year follow up was only available for the first 29 cases and here our figure of 14% mortality compares well to both cohorts of the PARTNER trial (24 and 30% mortality). Patient populations are likely to have differed significantly between these studies and direct comparisons are probably not accurate. One explanation for our good results may be that, because of the financial constraints, we were stricter with our selection of cases although this is not reflected in the log EuroSCORE risk prediction (26% in our cohort as compared to 29% in cohort A and 26% in cohort B of the PARTNER trial).[9,12]

Another major cause for morbidity and mortality is major vascular complications. We had a significant number of these but most were in the first half of our experience and since the introduction of the smaller calibre SAPIEN XT device, we only experienced one major vascular complication. Comparing our results to other groups is not easy, as the VARC definitions[8] were not available and therefore not used in most of these studies. Our figure of 9% major complications compares well to the 30% reported by the PARTNER trial.[9]

Post-procedural MR was significantly lower when considering the group as a whole, however in individual cases, the degree of MR may have worsened or improved and predicting this change was not possible. This is similar to the observations of others.[13] Although functional MR (as opposed to MR due to structural disease of the valve) could improve in theory, this has not been validated in studies.[14]

TAVI can be performed via the transfemoral route in patients who are awake. This makes the use of constant TEE monitoring virtually impossible. We feel that the benefit of having immediate access to an accurate diagnostic tool in case of a complication outweighs the risk of general anaesthesia. Furthermore, using a closure device for the femoral access site, adds to the cost of this procedure and we therefore continue to do surgical cut down in most transfemoral cases.

Technically, TAVI represents new challenges to both interventionists used to performing coronary interventions (with much smaller calibre devices) and surgeons not used to dealing with catheters and guide wires. A significant learning curve is therefore observed and despite our experience to date, this learning curve continues. Demonstrating a learning curve from the data is not simple as the numbers are small and outliers skew the data significantly. We could however show that most of the procedure-related parameters improved with experience (Table 3) but despite this, most of the patients who did not survive the hospitalisation, came from the second half of our experience. This illustrates how fragile these patients are and how unpredictable major complications can be. A learning curve was also demonstrated by numerous other groups with Webb demonstrating a fall in procedural mortality from 12 to 3% in the transfemoral group.[15] This learning curve can only be maintained if the team performs adequate numbers of the procedure, something that will be very difficult in South Africa with its relatively small number of patients who can afford this costly procedure and resistance from some of the health care funders to support this new technology. Justifying such an expensive procedure in a country with a large proportion of poor people is diffucult and necessitates great care in patient selection to ensure that only deserving candidates are offered this procedure. One can only hope that the devices become more affordable in future and that it will be suitable for rheumatic heart disease.

Shortcomings of the study

Although we turned a significant number of patients down for the procedure, this data was not collected prospectively and outcomes of these patients cannot be reported. A further study on the reasons for patients being turned may provide valuable information. Furthermore, our very low stroke rate may be explained by the fact that we did not follow all the patients up ourselves and there may have been under reporting. It has been shown repeatedly that most patients undergoing TAVI will have MRI visible micro-emboli to the brain, although clinically significant stroke is much rarer.[16,17] Finally, this is only a report on short term data, reflecting our implantation success. Longer follow up is needed to further delineate these results.

CONCLUSIONS

With a multidisciplinary team approach and careful patient selection, TAVI can be performed by a high volume centre in South Africa with results comparable to international published outcomes. Mortality is better than predicted by EuroSCORE, underscoring the shortcomings of this scoring system. Patient selection remains difficult and further studies are needed to improve on this.

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