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Introduction of an interdisciplinary heart team-based transcatheter aortic valve implantation programme: short and mid-term outcomes

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Key words
transcatheter aortic valve implantation, aortic valve stenosis, heart valve prosthesis, high-risk patient, aortic valve replacement.

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Abstract

Background: Transcatheter aortic valve implantation (TAVI) has been developed to treat symptomatic aortic stenosis in patients deemed too high risk for open-heart surgery. To address this complex population, an interdisciplinary heart team approach was proposed.

Aim: Present the short- and mid-term outcomes of the first 100 patients in the Royal Prince Alfred Hospital multidisciplinary TAVI programme.

Methods: Single-centre registry. Baseline and procedural data were prospectively recorded. Outcomes were recorded according to Valve Academic Research Consortium – version 2 guidelines.

Results: All patients underwent a comprehensive interdisciplinary pre-procedural evaluation. Sixty-eight transfemoral and 32 transapical implantations were performed. Mean age was 82 (±8.9) years old with an average logistic EuroSCORE of 33. Although 13 procedures had major complications, there was no intraprocedural mortality. During the first month, 9% of patients were re-admitted due to heart failure and 13% had a permanent pacemaker implanted. A 3% 30-day and 8% follow-up (mean 17 months) mortalities were recorded. While no significant differences in the rate of complications were found between the first and second half of the experience, all cases of mortality within 30 days ($n = 3$) occurred in the initial half. Sustained haemodynamic results were obtained with TAVI (immediate mean aortic valve gradient reduction from 47 to 9 mmHg; 1-year echocardiographic gradient 9.9 mmHg, with no moderate or severe aortic regurgitation).

Conclusion: Excellent results can be achieved with TAVI in very high-risk patients at an Australian institution. A comprehensive evaluation based on a heart team can overcome most of the difficulties imposed by this challenging population.

Introduction

Transcatheter aortic valve implantation (TAVI) has been developed to treat severe symptomatic aortic stenosis in patients deemed high risk for open-heart surgery.[1,2] Since its clinical introduction in 2002, an appreciable amount of experience has been gained, leading to progressive improvements in safety and procedural efficacy. However, as with any new intervention, there exists a great variability between different centres in terms of patient selection and the results achieved by the procedure.[3] Whereas a single high-volume Israeli centre reported a 30-day mortality as low as 2.3%,[4] the multicentre European experience has reported a much higher 15% 30-day mortality,[5] although both studies recruited patients with similar levels of risk. Likewise, the Ibero-American registry reported 1220 patients with an average EuroSCORE of 17.8%,[6] markedly lower than the 27.8% in the Australia-New Zealand registry.[7]

A significant learning curve has been reported for TAVI[8] with considerable reduction in adverse clinical events, including mortality, with increasing procedural experience. As more sites seek to initiate TAVI programmes, there is concern that the learning curve associated with the procedure may predispose to suboptimal clinical outcomes. Moreover, in order to improve clinical decision making and procedural outcomes of these challenging patients, interdisciplinary heart teams have been recommended.[9]

The aim of this study was to present the short and mid-term outcomes of the first 100 patients in the Royal Prince Alfred Hospital (RPAH) TAVI programme, with a special emphasis on the value of a multidisciplinary approach.

Methods

Patient selection

Between the beginning of our TAVI programme in June 2009 and July 2013, 100 consecutive implantations were performed and formed the study cohort. Data regarding baseline patient characteristics (age, gender, comorbidities, symptomatic status, previous medical history), cardiac and pulmonary function, basic laboratory tests, intraoperative outcomes, echocardiography results and clinical follow up were prospectively recorded. Local ethics committee approval was obtained.

Procedural aspects

TAVI were performed either by the transfemoral (TF) or transapical (TA) approaches using one of the two currently available devices: the Edwards SAPIEN transcatheter heart valve (Edwards Lifesciences, Irvine, CA, USA) and the Medtronic CoreValve Revalving system (Medtronic, Minneapolis, MN, USA). A combined team comprised of interventional cardiologists and cardiothoracic surgeons performed all implantations. Additionally, the patients were prepared as per open-heart surgery, with general anaesthesia, full haemodynamic monitoring (arterial line, central venous access with pulmonary artery catheter) and trans-oesophageal echocardiography. When deemed necessary, vascular surgeons were also included in the procedure and a primed extracorporeal membrane oxygenation (ECMO) circuit was available for use if needed.

The procedure was performed following the current technical recommendations, explained in detail elsewhere.[10,11]

End-points definitions

Events were prospectively recorded as per Valve Academic Research Consortium version 2 (VARC2) criteria.[12] Echocardiographic follow up was made according to the treating physician preference and all patients had at least one exam prior to discharge, one during the first 6 months and one echocardiogram yearly thereafter. Clinical follow up was made by the treating physician as well as at least one member of the TAVI team. Composite end-points were also defined by VARC2 and included device success and early safety (at 30 days postoperation).

Statistical analysis

Continuous variables were reported as mean ± standard deviation (SD) and categorical variables as number (percentage). In order to determine if there was an early phase of poorer performance, the cohort was divided into an early group (n = 50) and late group (n = 50). Differences in the means of continuous variables (e.g. age) were tested through the use of an independent samples t-test or nonparametric test for non-normally distributed data, while proportional differences in categorical variables (e.g. patient did or did not have a life-threatening bleed) were tested through the use of Fisher's exact test. Statistical analysis was performed with SPSS 22 software (IBM, Armonk, NY, USA).

Results

TAVI multidisciplinary team

As described previously,[13] our TAVI team is comprised of two interventional cardiologists, a non-invasive cardiologist, two cardiothoracic surgeons, a clinical nurse

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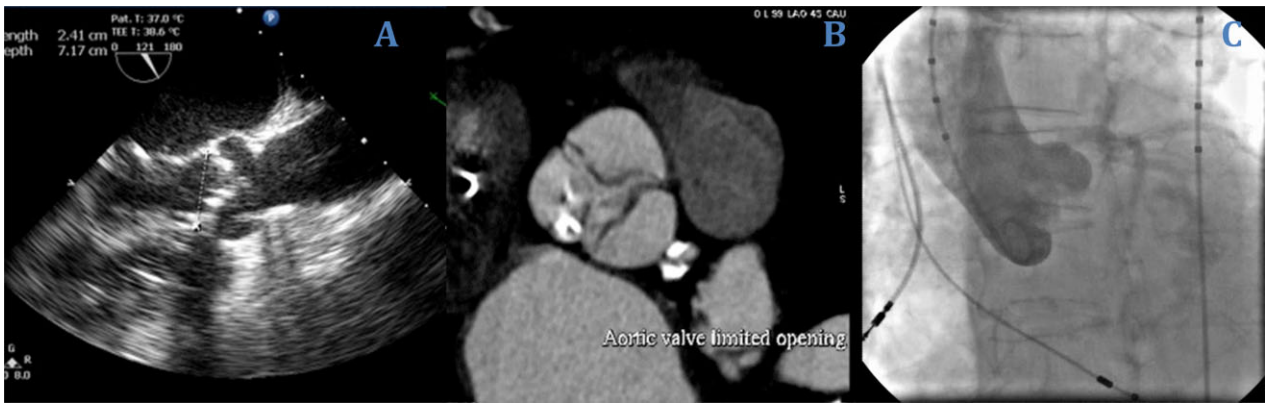

Figure 1 Multimodality assessment of the aortic root with (A) trans-oesophageal echocardiography, (B) CT scan and (C) calibrated aortography. Comprehensive evaluation of the aortic anatomy allows for proper device selection and procedural planning. A similar method was used to evaluate the ilio-femoral vessels.

consultant, a respiratory physician, a cardiac radiologist, a cardiac anaesthetist and a geriatrician. Criteria for inclusion into the TAVI programme included interdisciplinary consensus that a patient is high risk for surgical aortic valve replacement, defined as a logistic EuroSCORE > 15% and/or the presence of other complicating factors not represented in classical risk scores, such as frailty, porcelain aorta, liver disease or hostile chest. Pre-procedural evaluation includes at least a comprehensive echocardiographic analysis, a coronary, aortic and ilio-femoral angiography, a cardiac and aortic computed tomography (CT) scan, spirometry, carotid ultrasonography and any other required evaluation depending on the patient's comorbidities. Multimodality imaging of aortic valve anatomy, incorporating echocardiography, calibrated aortography and three-dimensional (3D) CT aortography (in the second half of our experience), was used to determine anatomic suitability for TAVI and for procedural planning (Fig. 1). Peripheral vascular anatomy was routinely assessed by a combination of calibrated angiography and 3D CT angiography, principally to determine suitability for TF arterial access. Once the patient is considered suitable for TAVI, the case is presented again at the meeting and all the procedural aspects of that individual implantation are discussed in order to foresee any possible complications and plan suitable bailout strategies.

Patient characteristics

A total of 100 patients underwent TAVI at RPAH during the period from June 2009 to June 2013. Of these, 68 were TF and 32 TA implantations. Regardless of the mode of vascular access, all TAVI were performed by at least one interventional cardiologist and one cardiothoracic surgeon. Mean age was 82 (±8.9) years old and 37% of patients were female. Patients included in our TAVI programme were all very high risk for open surgery, as demonstrated by a mean logistic EuroSCORE of 33. When the cohort was divided and analysed into the first and second 50 patients, there were no major differences in the baseline patient characteristics and the logistic EuroSCOREs were comparable between groups (31.4 vs 34.8, $P = 0.45$). Table 1 shows the baseline patient characteristics for the total population and for TF and TA groups.

Table 1 TAVI baseline patient characteristics

	All patients *n* = 100	Transfemoral *n* = 68	Transapical *n* = 32
Age (years)	82.6 ± 8.9	83.1 ± 10.0	81.6 ± 5.8
Male	63 (63)	42 (62)	21 (66)
Body mass index (mean ± SD)	26.2 ± 5.0	26.8 ± 5.0	25.3 ± 5.0
NYHA class III and IV	87 (87)	57 (84)	30 (94)
Moderate-severe lung disease	12 (12)	5 (7)	7 (22)
Previous myocardial infarction	31 (31)	16 (24)	15 (47)
Previous CABG	39 (39)	28 (41)	11 (34)
Previous PCI	29 (29)	21 (31)	8 (25)
Previous valve surgery	2 (2)	2 (3)	0 (0)
Previous balloon aortic valvuloplasty	48 (48)	34 (50)	14 (44)
Previous permanent pacemaker	15 (15)	11 (16)	4 (13)
Cerebrovascular disease	28 (28)	14 (21)	14 (44)
Peripheral vascular disease	30 (30)	15 (22)	15 (47)
Renal insufficiency†	44 (44)	29 (43)	15 (47)
Patients on dialysis	5 (5)	1 (1)	4 (13)
Atrial fibrillation	34 (34)	25 (37)	9 (28)
Logistic EuroSCORE	33.1 ± 22.6	27.9 ± 17.7	44.3 ± 27.6

Figures presented as *n* (%), mean ± standard deviation, and median (range) as appropriate. †Defined as creatinine > 110 μmol/L. CABG, coronary artery bypass graft; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; TAVI, transcatheter aortic valve implantation.

Table 2 TAVI intraprocedural details and outcomes

	All patients *n* = 100	Transfemoral *n* = 68	Transapical *n* = 32	Early cohort *n* = 50	Late cohort *n* = 50	Early versus late *P*-value
Prosthesis details						
ES	20 (20)	11 (16)	9 (28)	20 (40)	0 (0)	<0.01
ES-XT	78 (78)	55 (81)	23 (72)	30 (60)	48 (96)	<0.01
Medtronic CoreValve	2 (2)	2 (3)	0 (0)	0 (0)	2 (4)	0.50
23 mm ES prosthesis	37 (37)	21 (31)	16 (50)	25 (50)	12 (24)	0.02
26 mm ES prosthesis	48 (48)	38 (56)	10 (31)	24 (48)	24 (48)	1.0
29 mm ES prosthesis	13 (13)	8 (12)	5 (16)	1 (2)	12 (24)	<0.01
Intraoperative outcomes						
Complicated procedure	13 (13)	7 (10)	6 (19)	7 (14)	6 (12)	0.54
Elective ECMO support	8 (8)	3 (4)	5 (16)	3 (6)	5 (10)	0.62
Emergent ECMO	3 (3)	1 (2)	2 (6)	2 (4)	1 (3)	0.72
Valve malpositioning	4 (4)	4 (6)	0 (0)	1 (2)	3 (6)	0.64
Cardiac tamponade	3 (3)	2 (3)	1 (3)	2 (4)	1 (2)	0.46
Aortic root rupture	2 (2)	2 (4)	0 (0)	1 (2)	1 (2)	1.0
VT/VF post-pacing	6 (6)	2 (3)	4 (13)	3 (6)	3 (6)	1.0
Device success†	94 (94)	62 (91)	32 (100)	47 (94)	47 (94)	1.0

Figures presented as *n* (%). †Defined according to VARC2 criteria. Complicated procedure, valve malpositioning, cardiac tamponade, aortic/annulus rupture, coronary obstruction, cardiac arrest, structural damage, major vascular complications or life-threatening bleeding; ECMO, extracorporeal membrane oxygenation; ES, Edwards SAPIEN; TAVI, transcatheter aortic valve implantation; VF, ventricular fibrillation; VT, ventricular tachycardia.

Procedural outcomes

All but two TAVI were performed using balloon-expandable Edwards SAPIEN transcatheter heart valves. The Medtronic CoreValve was used in the other two cases, one due to anatomic characteristics (valve-in-valve implantation into a small diameter bioprosthetic valve) that favoured the self-expanding CoreValve system. The Edwards SAPIEN XT transcatheter heart valve on a Novoflex delivery system was introduced from the case number 21 onwards. The main advantage is its lower profile resulting in a smaller minimum ilio-femoral vessel diameter requirement, thereby favouring the TF approach. Nine out of 20 cases performed with the former SAPIEN system were TA (45%), whereas only 23 of the following 78 cases performed with the XT system were TA implantations (29%).

Elective haemodynamic support using ECMO was used in eight cases. Moreover, in three additional patients ECMO was emergently instituted as a rescue for life-threatening complications. There was no intraprocedural mortality in our series. Table 2 reports the main procedural aspects and intraoperative outcomes of the TAVI patients for the whole cohort, TF and TA procedures, and the first and second half of the experience. Device success (as defined by VARC2 criteria) was achieved in 94% of cases. Thirteen procedures had major complications. There were four cases of valve malpositioning, three patients with cardiac tamponade and two cases of aortic annular rupture. There were no significant differences in the rate of complications between the first and second half of our experience. Immediately after valve implantation, paravalvular aortic regurgitation (AR) was assessed by a combination of trans-oesophageal echocardiography, angiography and invasive haemodynamics. In case moderate or severe aortic AR was found – depending on the mechanism – balloon post-dilation (for valve malapposition) or valve-in-valve deployment (for valve malpositioning) were performed. This allowed for only 6% moderate AR and 0% severe AR after TAVI. The mean aortic valve gradient was significantly reduced after the implantation, from an average of 47 mmHg to 9 mmHg 1 month after the procedure (Fig. 2).

30-day outcomes

There were three mortalities during the first 30 days after the procedure: two due to cardiac causes and one due to acute adrenal insufficiency after inadvertent suspension of chronic steroidal therapy when admitted to another hospital. They all occurred within the first 50 cases of our experience. The most common events during the first month were re-admission due to heart failure and the need for a permanent pacemaker after the procedure (9% and 13% respectively). On the other hand, the incidence of new myocardial infarction (MI) or stroke was low (2% each). Table 3 reports the short-term results after the implantation. Early safety outcome (as per VARC2 criteria) is a measure of a 30-day uncomplicated course after TAVI and was achieved by 86% of patients. Hospital length of stay (HLOS) was 6.1 (±8.3) days for the whole cohort and 4.7 (±8.4) days for the TF patients.

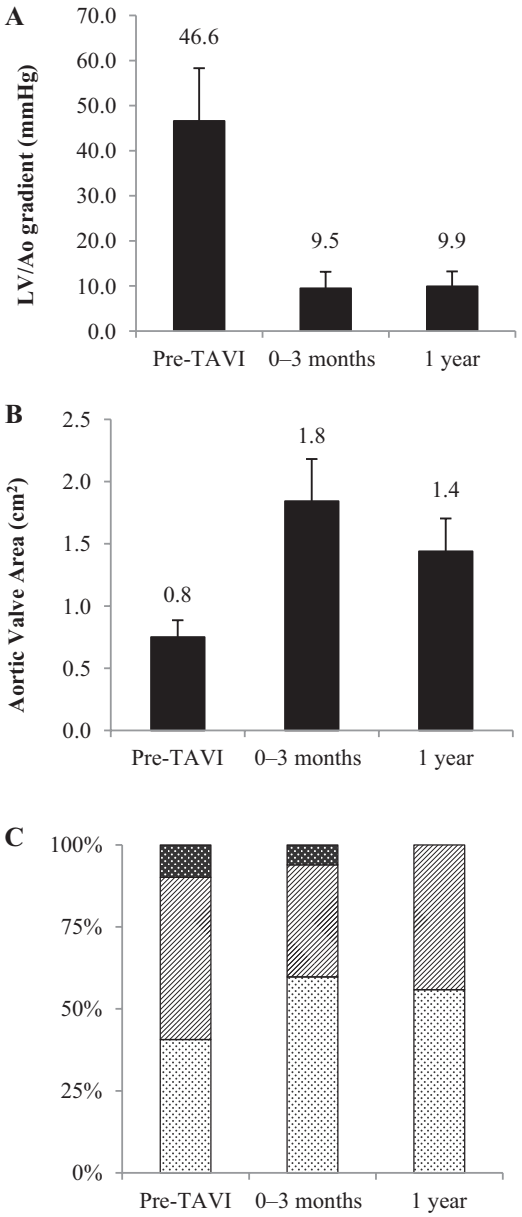

Figure 2 TAVI (transfemoral and transapical combined) echocardiographic data pre-TAVI, 0–3 months post-TAVI, and 1 year post-TAVI. (A) Mean aortic gradient. (B) Aortic valve area. (C) Paravalvular regurgitation. (■), Severe; (▩), moderate; (▨), mild; (⊡), none/trace.

Late follow-up outcomes

The cumulative mortality of our series during an average follow up of 17.1 (SD 10.5) months was 8%. The estimated 1-year mortality was 7%. The five additional deaths after the first month were due to cardiac causes in three and non-cardiac in two (died after surgery for oesophageal cancer and for peripheral vascular disease). Two of the cardiac deaths were sudden death in patients with previous TA access. After the first 30 days, there were two patients with new strokes, two with MI and three patients with newly diagnosed cancer. The prosthetic valve gradient and degree of AR up to 1 year after the procedure are shown in Figure 2. No episodes of valve thrombosis or endocarditis were recorded.

Discussion

This single-hospital series of our first 100 cases undergoing TAVI demonstrates that high rates of procedural success and low complication rates are achievable in a high-risk elderly patient cohort when using a multidisciplinary approach. Although this was an extremely high-risk population, with a mean logistic EuroSCORE of 33%, the clinical and technical success were comparable with most current series.[14,15]

Patient selection and pre-procedural management

During interdisciplinary evaluation, patients were offered TAVI if they fit within the eligibility 'sweet spot' of (i) meeting high-risk criteria for surgical aortic valve replacement; (ii) fulfilling anatomical suitability criteria for TAVI and (iii) were deemed highly likely to derive significant functional and prognostic benefit from the procedure. Using this heart team approach, the patients selected had similar scores to other current registries such as SOURCE ANZ.[7] However, in contrast to some programmes (e.g. partner cohorts), patients with comorbidities (e.g. oxygen-dependent chronic airways limitation, metastatic malignancy, etc.) that would preclude significant functional or prognostic improvement from TAVI were not offered the procedure.

In addition, an essential part of this heart team approach is to re-assess and optimise management of the patient's comorbidities and treatments. As shown here, almost one third of patients had a history of MI and 39% of previous bypass surgery. Previous series have shown that up to 75% of patients have documented coronary artery disease.[16] We treated with angioplasty all significant stenoses prior to TAVI, frequently using a fractional flow reserve-guided approach that has been shown to recognise accurately haemodynamically significant stenoses and reduce future events.[17] By the similar means, clinically indicated carotid and peripheral stenoses were addressed before TAVI. This may have contributed to the low rates of strokes and MI showed in our series. Pre-TAVI coronary artery intervention is, however, still a matter of debate, and ongoing studies will seek to clarify further the role of pre-TAVI coronary intervention (ACTIVATION trial, ISRCTN registry number 75836930). Balloon aortic valvuloplasty (BAV) as a bridge to TAVI

Table 3 TAVI 30-day postoperative outcomes

	All patients *n* = 100	Transfemoral *n* = 68	Transapical *n* = 32	Early cohort *n* = 50	Late cohort *n* = 50	Early versus late *P*-value
Mortality						
All-cause	3 (3.0)	3 (4.4)	0 (0.0)	3 (6.0)	0 (0.0)	0.24
Cardiovascular	2 (2.0)	2 (2.9)	0 (0.0)	2 (4.0)	0 (0.0)	0.49
Myocardial infarction						
Peri-procedural (<72 h)	2 (2.0)	1 (1.5)	1 (3.1)	0 (0.0)	2 (4.0)	0.49
Neurological injury						
Disabling	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	–
Non-disabling	2 (2.0)	1 (1.5)	1 (3.1)	1 (2.0)	1 (2.0)	1.0
Ischaemic stroke	2 (2.0)	1 (1.5)	1 (3.1)	1 (2.0)	1 (2.0)	1.0
Acute kidney injury						
Acute renal failure‡	11 (11.0)	4 (5.9)	7 (21.9)	6 (12.0)	5 (10.0)	0.86
New renal replacement therapy	5 (5.0)	1 (1.5)	4 (12.5)	3 (6.0)	2 (4.0)	1.0
Vascular complications						
Major	6 (6.0)	5 (7.4)	1 (3.1)	3 (6.0)	3 (6.0)	1.0
Minor	11 (11.0)	11 (16.2)	0 (0.0)	4 (8.0)	7 (14.0)	0.35
Bleeding						
Life-threatening	5 (5.0)	3 (4.4)	2 (6.3)	3 (6.0)	2 (4.0)	1.0
Major	11 (11.0)	6 (8.8)	5 (15.6)	7 (14.0)	4 (8.0)	0.53
Minor	14 (14.0)	7 (10.3)	7 (21.9)	7 (14.0)	7 (14.0)	1.0
Other						
Need for PPM	13 (13.0)	9 (12.5)	4 (12.5)	4 (8.0)	9 (18.0)	0.23
HLOS (days)	6.1 ± 8.3	4.7 ± 8.4	9.0 ± 7.2	6.7 ± 9.1	5.5 ± 7.4	0.47
Early safety†	86 (86)	60 (88)	26 (81)	42 (84)	44 (88)	0.77

Figures presented as *n* (%) and mean ± standard deviation as appropriate. †Defined according to VARC2 criteria. ‡VARC2 acute kidney injury stages 2–3. AF, atrial fibrillation; HLOS, hospital length of stay; PPM, permanent pacemaker; TAVI, transcatheter aortic valve implantation; VARC2, Valve Academic Research Consortium version 2.

was also commonly performed (48%). Recent experience has shown that BAV is associated with low complications in this setting (1% mortality in stable patients without severely depressed ejection fraction), is useful to categorise patients without a clear-cut indication for TAVI (e.g. symptoms not solely due to aortic stenosis) and is associated with a significant clinical improvement prior to the decision for TAVI being made.[18]

Intraprocedural and acute management

Although 13% of procedures had a major complication, some of them with more than one simultaneously, none of the patients died during the implantation procedure. Serious complications such as aortic annulus rupture and acute pericardial tamponade were managed by the combined efforts of the procedural heart team. In Germany, a detailed experience of 412 patients showed a 1% incidence of aortic annulus rupture, 5.6% of valve malpositioning, 2.5% of tamponade and 10% of major vascular complications.[19] These numbers are very similar to our series, underscoring the complexity of the procedure and the importance of being prepared to deal promptly with these untoward events. In the German experience,[19] 1.2% of patients received emergency cardiopulmonary bypass. Femoral veno-arterial ECMO was used more frequently in our experience (11% of patients), the difference mainly due to an 8% use of elective ECMO (and only 3% of emergent use). Reasons to provide this support during the TAVI were biventricular heart failure that did not respond sufficiently to inotropes, unrevascularisable coronary artery disease or refractory pulmonary hypertension with poor right ventricular function.

The excellent haemodynamic results obtained with this technology are well-recognised.[20] As expected, we found a marked reduction in the aortic valve gradient after the procedure. Importantly, this was accompanied by a very low percentage of significant paravalvular AR, which has been shown to impact the late prognosis negatively.[21] Proper sizing of the valve, with multimodal assessment of the aortic root and ascending aorta with CT scan, echocardiography and aortography is a critical step to minimise prosthesis mismatch and residual AR.[22] In case of moderate or severe AR due to valve malapposition, balloon post-dilatation, weighing the benefits of reducing AR and the greater risk of stroke,[23] is a useful tool to improve the immediate result.

Although 11% of patients had VARC2 criteria stage 2 or 3 renal dysfunction after the procedure, this did not impact the short-term mortality and no patient requiring temporary renal support required long-term haemodialysis. In contrast, this follow up might have translated into a rate of pacemaker implantation after the TAVI (13%) higher than the 6.5% previously reported for the Edwards SAPIEN valve.[24] The short HLOS is encouraging as these fragile patients might benefit from an early discharge. In a previously published experience of surgical aortic valve replacement in elderly patients at RPAH, the HLOS was 12.5 days,[25] markedly longer than the TAVI experience.

The role of experience

Although the importance of experience has been demonstrated by Webb *et al.*,[8] there were no significant differences neither in intraprocedural outcomes nor in acute complications between the first and the second 50 patients of our series. However, three patients died within the 30-day period in the first half compared with zero in the second half of the experience, and there was a nonsignificant trend to more permanent pacemaker implantations in the second 50 patients. We believe this highlights how a new TAVI programme can be successfully initiated on the experience of existing high-volume centres, learning from their achievements and complications in order to avoid a long learning curve. Furthermore, the systematic implementation of a comprehensive training programme that incorporates electronic learning resources, simulators, didactic teaching, case observation and case proctoring with proceduralists from high-volume centres can overcome the initial lack of experience of a given group and allow for the implementation of a successful and safe programme for patients.

Late outcomes

Contemporary patients treated by TAVI represent a frail elderly patient group, often with significant comorbidities. Close follow up by different members of the heart team is often needed and dedicated cardiac rehabilitation programmes are recommended.[26] In our series, 30% actively participated in rehabilitation, although it was offered to every patient before discharge.

The 8% mortality achieved by our series is markedly lower than initial experiences, such as PARTNER cohort A.[27] In a contemporary experience, the US SAPIEN XT registry presented a 30-day mortality of 7.6%,[28] whereas SOURCE ANZ showed a 1-year mortality of 13% for TF and 23% for TA TAVI.[7] However, it is worth noting that up to half of the deaths after TAVI are noncardiac in nature, underscoring the frailty of these patients.[14] Even when compared with patients from our same institution, the results are favourable. In the surgical aortic valve replacement in elderly patients experience at RPAH, the 1-year mortality was 12%, although the median EuroSCORE was much lower (10.9%).[25]

Limitations

There are several limitations to our study. First, it represents the initial experience of a single centre, with a limited number of patients; therefore, our results are no generalisable to all TAVI procedures. Second, its observational nature does not allow making any conclusions regarding superiority over surgical valve replacement. Last, the follow up is still limited to know long-term valve outcomes and clinical results.

Conclusion

Excellent clinical results can be achieved with the introduction of a TAVI programme for high-risk patients with severe symptomatic aortic stenosis at an Australian institution. A comprehensive patient evaluation and a multidisciplinary approach based on a heart team can overcome most of the difficulties imposed by this challenging population.

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