Decentralisation of Transcatheter Aortic Valve Implantation- a review of outcomes and experiences in developing a service in Remote Australia

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Abstract

The introduction of Transcatheter Aortic Valve Implantation (TAVI) has transformed interventional cardiology and minimally invasive cardiac surgery. TAVI is a relatively new technique that is rapidly expanding in its indications and technology as well as places of practice. De-centralisation of this previous supra-specialised procedure can be done safely and efficaciously, to improve the health inequalities across regional and remote Australia. The purpose of this study is to detail the introduction of the TAVI program at a geographically isolated tertiary hospital in regional Australia. Illustrating the safe introduction of TAVI in this location may guide other isolated hospitals on the introduction of the service.

Title: Decentralisation of Transcatheter Aortic Valve Implantation- a review of outcomes and experiences in developing a service in Remote Australia

Short Title : Introduction of Transcatheter Aortic Valve Implantation to Rural and Remote Australia

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Abstract :

The introduction of Transcatheter Aortic Valve Implantation (TAVI) has transformed interventional cardiology and minimally invasive cardiac surgery. TAVI is a relatively new technique that is rapidly expanding in its indications and technology as well as places of practice. De-centralisation of this previous supra-specialised procedure can be done safely and efficaciously, to improve the health inequalities across regional and remote Australia. The purpose of this study is to detail the introduction of the TAVI program at a geographically isolated tertiary hospital in regional Australia. Illustrating the safe introduction of TAVI in this location may guide other isolated hospitals on the introduction of the service.

Introduction

TAVI was first described in 2002, as a salvage procedure in the context of cardiogenic shock secondary to severe Aortic Stenosis (AS).(1) Following it successful utilisation the procedure developed further to become a routine method for management of aortic valve disease. The technology surrounding TAVI and the indications for the procedure are rapidly developing. Originally the procedure was reserved for Supra-specialised tertiary and quaternary centres, but with demonstration of efficacy and safety the technology is moving outward to less specialised peripheral centres.

TAVI is often compared against surgical Aortic Valve Replacement (sAVR). This competitive approach to analysis is inherently biased. The technical procedure of a TAVI is vastly different to that of a sAVR, as such it has different risk to reward ratio. The two procedures should be thought of as complementary interventions on the increasing spectrum of management options for aortic valve disease.

The Placement of Aortic Transcatheter Valve (PARTNER) Trials were the corner stone of understanding the strengths and weaknesses of TAVI in clinical practice. The PARTNER trail was a multi-centred, randomized control trial that examined the safety and efficacy of TAVI vs sAVR in High-risk surgical patients.(2) The PARTNER Trial demonstrated that in high-risk patients, TAVI had lower rates of acute all-cause mortality in 30 days than sAVR (3.4% vs 6.5%). TAVI however was consistently associated with more stroke, major vascular complications, heart-block, pacemaker dependence and para-valulvar leak. Importantly at one-year, mortality between sAVR and TAVI was equivocal. sAVR expectedly demonstrated higher rates of bleeding and atrial fibrillation (AF). (3, 4) Understanding the risk profile of these procedures is fundamental assessing the most appropriate intervention in practice for a given patient.

Service Provisions:

For context, our centre serves as a tertiary cardiac centre for 1.3 million people, over 1.26 Km^2. Between 6-64% of this population identify as Aboriginal or Torre Strait Islander (ATSI), depending on regional variation. Consequently 20% of cardiac surgery preformed in our centre, is performed on ATSI people.(5) Hence, introduction of a TAVI service in our centre compared to more metropolitan centres must adapt to accommodate the geographic and demographic challenges of remote Australia.

At our centre TAVI is offered only to those deemed to be surgically high-risk or prohibitively high-risk. Objectively quantified by the Society of Thoracic Surgeons Risk Score (STS Score), where patients scoring equal to or greater than ten percent were deemed high risk. Patients may also be offered based on the individual case assessment by treating surgeon or cardiologist.

Also unique to our service model; the TAVI program is jointly run by Cardiothoracic Surgery (CTS) and Cardiology, were all cases are managed under a shared care pathway and all procedures are performed with dual proceduralist from each respective specialty.

Below is a synopsis of the current peri-operative assessment for all TAVI Candidates used in our centre:

Clinical Assessments by: (through local, outreach and telehealth clinics)

- TAVI proceduralists (Cardiac Surgeon or Cardiologist)
- Geriatrician
- Cardiac Anaesthetist

Investigations/Diagnostic Imaging:

- Basic Biochemistry
- Extended Geriatric screening
- Transthoracic Echocardiography (TTE)
- Carotid Doppler Ultrasonography
- Coronary Angiogram
- TAVI protocol Computed Tomography (CT)
- Electrocardiogram (ECG)
- Respiratory Function Testing (RFTs)

On completion of the above the patients are then presented in the High-Risk Valve Multi-disciplinary team (MDT) meeting. This team consists of a cardiothoracic surgeon, interventional cardiologist, diagnostic imaging cardiologist, general physician/geriatrician and Cardiac Anaesthetist. This meeting formally reviews all the aforementioned investigations, discusses the suitability for sAVR, TAVI or medical management and defines ceilings of care intra and perioperatively.

Procedural access is also decided within the MDT meeting, using a 3D reconstruction of the vascular and aortic anatomy using *3mensio*(PIE medical Imaging). The involvement of CTS in the TAVI program implies that in addition to transfemoral and subclavian access, direct aortic access TAVI may be utilised via hemi-stermotomy or thoracotomy.

High-risk Valve MDT meetings are held on a monthly cycle and occur one week prior to the TAVI procedural list. An intensive care physician may be involved in the MDT meeting and peri-operative assessment if the case necessitates Intensive Care Unit (ICU) admission.

Following the TAVI, patients will be admitted to either the Coronary Care Unity (CCU) or ICU.

Day one post-procedurally, all subjects undergo an echocardiogram to define their valvular gradients and Paravalvular leak. This is repeated in the outpatient department at six weeks, and one-year.

All the peri-operative data is recorded in a local database and uploaded to the Australasian Cardiac Outcome Registry (ACOR). The unit and both its cardiac surgeon and cardiologist proceduralists have been accredited with ACOR and the TAVI Committee for independent practice since April 2020.

Materials/Method

Retrospective analysis of patients undergoing TAVI at our Centre between the 20$^{\text{th}}$ of November 2018 to the 16$^{\text{th}}$ of January of 2020. Examining the rates of; 30 day mortality, 30 Cerebrovascular Accident/Transient ischaemic Attack (CVA/TAI), Major Vascular Complication, Acute Kidney Injury (AKI), Arrhythmia, Major Bleeding as defined by the Valve Academic Research Consortium-2 Consensus (VARC-2) metrics and definitions. (7) Additionally the pre and post procedural cardiac and valvular functions will be compared, as will length of stay post procedurally and ICU admission.

Simple descriptive statistical analysis has been performed.

Ethics Approval : Human Research Ethics Committee, Townsville University Hospital

Approval Number: HREC/QTHS/62863

Results

Table 1.

Intra-Procedural Complications

There was one arrest noted during the procedure, fortunately this did not result in death.

One patient developed a noted AV block during the valve deployment but did not require pacing. No patients had a pacemaker inserted within 30 days of the procedure. However, post procedurally five (26%) patients developed a new Left Bundle Branch Block (LBBB). Additionally, only one patient developed new AF following the procedure.

Table 2.

The average post-operative decrease in haemoglobin(Hb) was 1.5g/dL. Two patients had a decreases in haemoglobin $>$ 3.5 g/dL post procedurally, requiring transfusions. The source however was not clinically apparent, there may have been an element of haemodilution.

As defined by the VARC-2 definition there were no significant AKIs noted in the cohort within the first 48 hours. Two however did require emergent dialysis post procedurally, fortunately they did not become dialysis dependent.

Post Procedural Echocardiography

At six weeks three patients showed a significant improvement in the LVEF, compared to the pre-TAVI echo, two patients had a 10% improvement in their LVEF, and one patient showed a 20% improvement in EF. At six weeks no patients had a sustained reduction in their EF of more than 7%. Unfortunately, three of 19 TTEs were not available for analysis at six weeks.

Severity and change in time of paravalvular leak is demonstrated in Table 3.

Table 3.

Table 4.

Morbidity and Mortality

No major vascular events or CVA/TIA were documented in the first 30 days post-procedurally. There were no deaths within 30 days of the procedure. There were no emergent surgical interventions, and no explanations required with 30 days.

Discussion

The purpose of the paper is to guide the introduction of TAVI in regional centres by demonstrating the safe introduction at our centre. The results above and analysis below is an early indication of good efficacy and safe practice.

The PARTNER Trials demonstrated rates of Major vascular complication around 11% and 3.8% risk of stroke in TAVI patients. For accreditation a centre must demonstrate Major vascular complications less than or equal to 5 % and CVA/TIA rate less than or equal to 8%. One would expect based on these numbers to observe between one to two patients suffering a Major Vascular Complications and one episode of CVA/TIA in a cohort of 19 patients. All-cause mortality at 30 days for the comparable cohort in the in the PARTNER Trial was 6.5%, which would equate to one patient in a 19-patient cohort. The absence of these adverse outcomes in this study is likely due to the small sample size as well as careful patient selection. Given this is a pilot program it is subject to its own form of patient selection bias, in the respect that a developing program and newly accredited practitioners understandably would be more discerning and cautious in their patient selection compared. Small sample size and selection bias aside, these rates observed in this early program are reassuring that the procedure is being performed safely and comparably to other centres nationally and internationally.

Similarly the echocardiographic outcome data presented in tables 3 and 4, show promising efficacy in restoring physiological valvular gradients and function. The PARTNER trial showed rates of 12.2% for moderate to severe paravalvular leak at 30 days, while in our cohort on 10% of patients developed moderate paravalvular leak, and there were 0 cases of severe leak. (3)

If these trends continue, the department will meet ongoing ACOR accreditation requirements. Unfortunately, due to Corona Virus Disease -19 (COVID-19) the program was interrupted, hence the small sample size recorded in this paper. To-date with the re-instated program post COVID-19 precautions the department has performed 45 TAVIs, with trends noted as with the first 19 patients.

As the institution has developed, there has been a change in the care provided to patients as the program becomes more streamlined. At initiation all patients were admitted to ICU following the procedure, as the familiarity with the procedure increased, particularly towards the end of 2019 patients were increasingly admitted to CCU. All transfemoral, subclavian and anterior thoracotomy TAVIs are routinely admitted to CCU. Those who receive a hemi-sternotomy are admitted to ICU routinely. Overtime the post-procedural length of stay has been shortening. At initiation post operative stay varied considerably between 2-12 days, now patients are routinely staying between one to two days post TAVI. Soon, TAVI may become a day procedure at our centre.

The average number of procedures performed in a single session is also increasing with time. At initiation the team were only able to facilitate two patients per session, but now are routinely performing three in a single session. As patient referrals increase with the developing service this number is also set to increase with time.

Despite the unique demographics of the region, only one patient identified as Aboriginal in this cohort, which is a drastic under-representation. It is postulated to be the result of two factors, the average age of the cohort was approximately 80 years, while the Average life expectancy of ASTI people in regional Australia is between 65-75 years. Additionally, in regional and rural Australia, there is considerable epidemiological difference in the valvular pathology encountered in the ASTI and non-ASTI population, were it is common for ASTI people to present younger with other valve pathology such as infective endocarditis or rheumatic heart disease.(8) This speaks to the health inequality across Australia and particularly between the Indigenous and non-Indigenous Australians. Exemplifying why decentralisation of TAVI and introduction of a program to regional/remote Australia is an important step forward in cardiac and public health.

While the program is running well at the present time, the drive for improvement into the future is strong. The department moving forward are trailing new delivery systems for more ergonomic and effective deployment. This may further improve rates of paravalvular leak. Drafts of a standardized anti-coagulant and anti-platelet guideline post TAVI are being written with the recent publishing of the POPULAR Trial.(9) The department are actively upskilling other practitioners to increase the number of TAVI competent proceduralist. Concurrently the existing proceduralists are seeking training and accreditation with a different valve prosthesis to cater to a wider spectrum of patients, as valve sizing does limit the current scope of practice. A referral pathway is being developed and disseminated to the wider referral basin. Ideally, in the future the development of a Streamlined TAVI clinic may also occur.

Conclusion

Introduction of TAVI in regional and remote centres can be performed safely and efficaciously. Decentralisation of this procedure will help to bridge the health inequalities noted between metropolitan and rural areas. As the service grows rural Australia hopefully will also aid closing the gap in Health discrepancies between Indigenous and Non-indigenous populations in Australia.

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Table 1. Base Line Characteristics

Characteristic	**Characteristic**	**Number (% in v**
Average Age	Average Age	79.6 yrs
Male Gender	Male Gender	11 (58 %)
Indigenous	Indigenous	1 (5%)
BMI- Average	**BMI- Average**	29.4
Underweight BMI	< 18.5	1 (5%)
Normal	18.5-24.9	5 (26%)
Overweight	25-29.9	5 (26%)
Obese BMI (> 40)	Obese BMI (> 40)	8 (42%)
Obese I	30-34.9	4 (21%)
Obese II	35-39.9	2 (10%)
Obese III	>40	2 (10%)
Chronic Kidney Disease	**Chronic Kidney Disease**	
	Stage 1	3 (15%)
	Stage 2	10 (52%)
	Stage 3	6 (31%)
	Stage 4	0
	Stage 5	0
	Dialysis Dependent	0
Heart Failure Reduced Ejection Fraction (HFrEF)	Heart Failure Reduced Ejection Fraction (HFrEF)	6 (31%)
COPD	COPD	5 (26%)
Previous Cardiac Surgery	Previous Cardiac Surgery	10 (52%)
Diabetes Mellitus	Diabetes Mellitus	6 (31%)
Carotid Disease (>70%)	Carotid Disease (>70%)	3 (15%)
Aortic Stenosis	**Aortic Stenosis**	**18 (94%)**
	Mild	0
	Moderate	1 (5%)
	Severe	17 (89%)
Aortic Regurgitation Total	**Aortic Regurgitation Total**	10 (53%)

Characteristic	Characteristic	Number (% in v
	Mild	9 (47%)
	Severe	1 (5%)#
Average AV Gradient (mmHg)	**Average AV Gradient (mmHg)**	
	Mean	46.68 (+/- 15.1)
	Peak	75.89 (+/-24.5)
AVA	AVA	0.8 +/- 0.2
Tricuspid Valve	Tricuspid Valve	17 (89%)
Bicuspid	Bicuspid	1 (5%)
Previous Aortic Valve Prosthesis	Previous Aortic Valve Prosthesis	1 (5%)
Cardiovascular Conductive Disease	**Cardiovascular Conductive Disease**	
Atrial Fibrillation	Atrial Fibrillation	4 (21%)
PPM	PPM	2 (10%)
Native Bundle Branch Blocks	Native Bundle Branch Blocks	0
Existing Heart block	Existing Heart block	1 (Type 1) (5%)

+rounded to whole figures

previous surgical prosthetic valve degeneration

Table 2: Access and Valve Size

Procedural Access	**Number** (%)
Femoral	17 (89.5%)
Hemi-sternotomy	1 (5.2%)
Thoracotomy	1 (5.2%)
Valve Size	
23 mm	1 (5.2%)
25 mm	4 (21%)
27 mm	7 (36.8%)
29mm	7 (36.8%)

Table 3. Valve Gradients

	Pre-procedural	Post-Procedural Average	Change in Gradient
Average Peak Gradient	75.8 mmHg	17.41 mmHg	- 53.39 mmHg
Average Mean Gradient	46.6 mmHg	8.91 mmHg	- 37.69 mmHg

Table 4. Echocardiographic Parameters Comparison; Pre and Post TAVI

Case	**Pre TAVI EF (%)**	**D1 Post EF (%)**	**6 Week Post TAVI EF (%)**	**D1 Post TAVI AR**	**6Wk Post A**
1	37	39	40	Trivial	Nil
2	47	45	55	Trivial	Nil
3	55	60	55	Nil	Nil
4	57	55	50	Nil	Nil
5	55	55	55	Nil	Nil
6	55	60	60	Nil	Nil
7	35	45	45	Trivial	Nil

Case	Pre TAVI EF (%)	D1 Post EF (%)	6 Week Post TAVI EF (%)	D1 Post TAVI AR	6Wk Post A
8	35	40	55	Nil	Nil
9	55	50	50	Nil	Nil
10	48	55	50	Nil	Nil
11	70	60	64	Mild	Nil
12	60	55	53	Nil	Trivial
13	55	60	-	Mild	-
14	55	60	65	Mild	Nil
15	54	55	55	Nil	Nil
16	60	55	60	Nil	Nil
17	65	60	-	Nil	-
18	55	50	60	Nil	Trivial
19	55	55	0	Nil	-