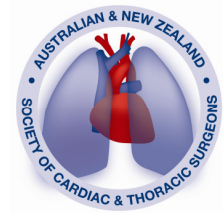




The Cardiac Society of
Australia and New Zealand



Position Statement for the Operator and Institutional Requirements for a Transcatheter Aortic Valve Implantation (TAVI) program

This Position Statement was developed by a Working Group comprising Darren Walters*, Mark Webster, Sanjeevan Pasupati, Antony Walton**, David Muller, Jim Stewart, Michael Williams, Andrew MacIsaac, Greg Scalia, Michael Wilson, Adam El Gamel, Andrew Clarke, Jayme Bennetts and Paul Bannon. Unless stated, the authors have no Conflict of Interest to disclose.

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Background

Transcatheter Aortic Valve Implantation (TAVI) has been developed as a therapy for the treatment of aortic stenosis(1). This condition is the most common acquired form of valvular heart disease in western countries such as Australia and New Zealand(2-4). Its prevalence increases with age and it is projected to increase in prevalence over time as the population ages. Around 30-50% of patients are rejected for surgery predominantly due to their age or significant co-morbidities(5-7).

In Australia and New Zealand, a number of transcatheter valves, including the Medtronic CoreValve and the Edwards SAPIEN transcatheter valve have been used as part of commercial availability, clinical registries and under special access schemes since 2008(8-10). Others, such as the Lotus and Portico valves, have become available more recently.

The technology is currently under consideration for approval by the Therapeutic Goods Administration (TGA) in Australia. The first generation (24Fr) Edwards SAPIEN valve has received TGA approval for use in Australia but will not be commercialised. Both Edwards Sapien and Medtronic CoreValve have European CE mark, and recent FDA approval for selected patient groups. Transcatheter valve implantation is approved and can be performed for specific indications in New Zealand. The Cardiac Society of Australia and New Zealand (CSANZ) and the Australia and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) has joined together to provide recommendations for institutions and individual operators to assess their ability to initiate and maintain a transcatheter valve program in their health care environment.

It is acknowledged that multi-society consensus statements have been produced in the USA and Europe(11, 12). These statements have been reviewed as part of the development of these guidelines. The technology is new and information regarding the required training, resources and operator competencies is still emerging(13). The current recommendations have been established with the aim of ensuring patient safety, as well as ensuring that individual operators and hospitals are committed to high quality outcomes(14-17).

Conflict of Interest disclosure:

*Darren Walters - Research: Boston Scientific (Lotus), Medtronic (CoreValve), Edwards (Solace and Source), St Jude (Portico). Proctor and consultant to Edwards. Research and advisory for Siemens (valve guide)

**Antony Walton – Research: Medtronic / Edwards. Medtronic: Medical Advisory Board, proctor – RDN, TAVI

Heart Team Approach

The development of transcatheter aortic valve replacement techniques as an alternative to traditional surgical replacement of the aortic valve, has mainly been targeted to high risk populations(18-22). The technical aspects of the procedure require a combination of skills in percutaneous vascular and cardiac interventions and surgery. Decision making in relation to the patients most likely to benefit from this new technology is complex, as is the appropriate allocation of resources for what is currently an expensive prosthesis. Fundamental to the establishment of a successful transcatheter valve program is the development of a multi-disciplinary “Heart Team”(23, 24).

A Heart Team is defined as a multi-disciplinary team of professionals who are charged with the governance of, and accountability for, the decision making and outcomes of the TAVI program within an institution. It consists of a formal multi-disciplinary collaboration between a broad range of health care professionals with expertise in the assessment and management of patients with valvular heart disease, including during the peri-procedural period. The core members of a Heart team are an interventional cardiologist and a cardiac surgeon supported by a TAVI nurse case manager / co-ordinator. The Heart Team should include a broad range of health professionals providing all the necessary skills and expertise to fully assess patients who are potential TAVI candidates, provide balanced judgment about the most appropriate procedure in patients deemed appropriate for an aortic valve intervention, guide and perform a TAVI if indicated and support the patient peri-procedurally. Typically a Heart Team could include, but is not limited to, the following:

- Interventional Cardiologist(s)
- Cardiothoracic Surgeon(s)
- Imaging Cardiologist (CT, TTE, TOE) / Radiologist
- TAVI Nurse Case Manager / Co-ordinator
- General Cardiologist(s)
- Cardiac Anaesthetist
- Intensive Care Physician
- Geriatrician / General Physician
- Vascular Surgeon

The use of this type of multi-disciplinary team has been shown to improve outcomes in complex procedures such as TAVI (11,15,23,24). One of the principle roles of the team is to ensure that patients are adequately evaluated (worked up) and selected for the procedure. This is to ensure all the co-morbidities and risks for the patient are evaluated fully and the best treatment option for the patient (medical therapy, traditional surgery or transcatheter valve therapy) is considered. Such decisions should be considered in a formal case conference involving the members of the Heart Team.

Pro-formas are useful to ensure all information is presented succinctly; minutes of the meeting, including a synopsis of the discussion and the eventual decision, should be recorded.

The group can give advice on the best type of device, consider the preferred route, correct sizing of the device, the mode of anaesthesia and the post-operative care. A decision about an emergency plan, should the procedure become complicated, must be undertaken at some point in advance of the operation/procedure. Prior to the operative date a pre-operative briefing is beneficial for the preparation of the team on the day.

Interventional Cardiologist

The interventional cardiologist should be trained in accordance with CSANZ guidelines(25). The current generation of devices requires two operators; a primary and a secondary operator(13). These recommendations apply to both. A background in structural intervention is considered an important pre requisite for competency in TAVI(11, 14, 16). While expertise in all of the following is not essential, useful clinical experience for the TAVI interventionist should include:

- Coronary diagnostic procedures, including left heart catheterization and the invasive assessment of aortic stenosis
- Coronary interventions
- Peripheral vascular diagnostic procedures
- Peripheral vascular interventions
- Balloon aortic, mitral, and pulmonic valve dilatation
- Intra-aortic balloon pump (IABP), other cardiac support
- Large vessel access and closure

For interventionists who have never performed TAVI, the following pre requisites are suggested (11, 14): 100 structural procedures lifetime or *20 left sided structural per year of which at least 10 should be balloon aortic valvuloplasty.*

The interventionist should have been trained and proctored on the devices being used. For an operator who has never implanted a transcatheter valve, a minimum of 10 proctored cases, in which the primary and secondary operators are working as a team, is recommended(26-28). Additional cases may be required depending on the assessment of the proctor.

Cardiac Surgeon

Surgeons involved in TAVI procedures should be experienced in operating on high-risk surgical AVR patients(11, 12, 29, 30). They should have experience in obtaining access via trans-apical and less invasive routes such as hemi-sternotomy or thoracotomy. Experience with open exposure and access to the ilio-femoral arteries is desirable.

The following experience and training is recommended:

- 100 surgical AVR career, at least 10 of which are ‘‘high-risk’’ (STS score ≥ 6) or
- 25 AVR per year or
- 50 AVR in 2 years and
- at least 20 AVR in last year prior to TAVI initiation
- Experience with, and management of, peripherally inserted cardiopulmonary bypass
- Experience with open retroperitoneal exposure of, and surgical intervention on, the iliac arteries

The surgeon should also have been trained and proctored on the devices being used. For a surgeon who has never implanted a transcatheter valve, a minimum of 10 proctored cases, in which the primary and secondary operators are working as a team, is recommended(11, 12, 17). Additional cases may be required depending on the assessment of the proctor.

Institutional Requirements

TAVI programs should be established in high volume cardiac surgical centres where on site valve surgery is performed.

The following activity levels for institutions undertaking TAVI programs are suggested(11, 12, 17):

- Institutional interventional program
 - 1000 catheter studies/400 PCI per year
- Institutional surgical program
 - 50 Total AVR per year of which at least 10 aortic valve replacement (AVR) should be high-risk (STS score ≥ 6)
 - Minimum of 2 institutionally-based cardiac surgeons in program

The facilities should include but are not limited to:

1. Cardiac catheterisation laboratory or hybrid operating room (OR) equipped with a fixed radiographic imaging system with high resolution fluoroscopy and facility for cineangiography and haemodynamic monitoring.
2. Non-invasive imaging
 - a. Echocardiographic laboratory with transthoracic and transoesophageal echocardiographic capabilities. Sonographers and echocardiographers experienced in valvular heart disease.
 - b. Access to a vascular laboratory (noninvasive) with vascular specialists capable of performing and interpreting vascular studies.
 - c. Access to a CT angiography laboratory with CT technologists and specialists who can acquire and interpret cardiac CT studies.
3. A sterile environment that meets, at minimum, OR standards or standards necessary for pacemaker/ICD implantation.
4. Sufficient space to accommodate the necessary equipment for implantations, including space for anaesthesia, echocardiography, and cardiopulmonary bypass equipment and personnel.
 - Appropriate equipment for the procedure and for dealing with possible complications including complete heart block, large vessel rupture, pericardial tamponade, and haemodynamic collapse.
 - A post procedure intensive care facility, HDU, or CCU experienced in managing complex cardiac patients, including patients following conventional cardiac surgery.

The following are desirable, but may not be available in most current interventional cardiology suites:

1. Circulating heating, ventilation, and air conditioning laminar flow diffusers
2. High-output surgical lighting.
3. Facilities for running cardiopulmonary bypass or extracorporeal membrane oxygenators (ECMO).

Volume and Outcome Monitoring Requirements

The following minimum volume and outcomes requirements are recommended for approved TAVI programs(11, 12, 17, 27-31):

- Program volume of 20 TAVI per year or 40 per 2 years
- 30-day all-cause mortality < 10%
- 30-day all-cause neurologic events including transient ischemic attack (TIAs) < 10%
- Major vascular complication rate < 10%
- >90% institutional follow-up
- 80% 1-year survival rate for patients after the program has been running for 2 years (2-year average)
- All cases should be submitted to a prospective national database registry

The development of a national database and registry of outcomes will be undertaken between the CSANZ and ANZSCTS. Appropriate resources should be allocated for data entry and follow-up.

These guidelines provide a framework for the establishment and maintenance of a successful TAVI program. They are designed to ensure optimal patient outcomes. They also are intended to provide guidance to individual operators and prospective institutions considering the establishment of a TAVI program.

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