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POSITION STATEMENT

Operator and Institutional Requirements for Transcatheter Mitral Valve Therapies in Australia: a CSANZ and ANZSCTS Position Statement

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The expert Position Statement is a description of the requirements for Accreditation for transcatheter mitral valve therapy (TMVT) in Australia. The requirements include the need for a multidisciplinary Heart Team review of individual cases, mandatory reporting of outcome data to a national TMVT Registry, and accreditation of individuals and institutions by the Conjoint Accreditation Committee, the assigned accreditation authority.

Keywords Mitral regurgitation • Heart failure • Transcatheter mitral valve therapy

Background

Severe mitral valve regurgitation (MR) is responsible for considerable morbidity, mortality and expense to the health care system [1–3]. Its prevalence increases with age, affecting more than 7% of individuals >65 years old [3]. Guidelines are well established for the surgical management of MR [4,5] and yet, the majority of patients with severe, symptomatic MR do not undergo surgery [6–8], typically because of advanced age or comorbidities. The high prevalence of MR in surgically ineligible patients, and the uncertain results of surgery for functional or secondary MR [9–11], have led to the development of less invasive approaches including transcatheter mitral valve repair (TMVr) [12,13] and transcatheter mitral valve replacement (TMVR) [14]. In the most recent US guidelines for the management of valvular heart

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disease, TMVr by edge-to-edge repair [12,13] is considered reasonable in patients with severe, symptomatic primary MR (Class of Recommendation: 2a, Level of Evidence: B-NR), and in selected patients with severe secondary MR (Class of Recommendation: 2a, Level of Evidence: B-R), who are considered to be at high or prohibitive risk for surgery [5].

In April 2020, the Medical Services Advisory Committee (MSAC), Department of Health and Ageing, Government of Australia supported the public funding of TMVr by edge-to-edge repair/tissue approximation using the MitraClip™ system (Abbott Structural, Santa Clara, CA, USA) in patients with moderate-severe or severe symptomatic degenerative (or primary) MR and left ventricular ejection fraction (LVEF) ≥20% who are determined by a Heart Team to be ineligible for surgical intervention. Support for patients with moderate–severe or severe symptomatic functional (or secondary) MR was restricted to those who are surgically ineligible with left ventricular ejection fraction (LVEF) 20–50%, and LV end-systolic diameter <70 mm, in whom symptoms persist despite maximally tolerated guideline-directed medical therapy [15]. As was required for transcatheter aortic valve implantation (TAVI) [16], MSAC recommended that operators and institutions performing transcatheter mitral valve interventions be formally recognised by an Accreditation Committee, that patient eligibility for these procedures be determined by a Heart Team, and that a national Registry be established to allow evaluation and review of procedural volumes and outcomes [15]. Accordingly, a Writing Group of individuals with expertise in transcatheter valve interventions, surgical valve therapies and advanced cardiac imaging was formed to develop this Position Statement with representation from the Cardiac Society of Australia and New Zealand (CSANZ) and the Australia and New Zealand Society of Cardiac and Thoracic Surgery (ANZSCTS). The Statement is not an evidence-based treatment guideline but rather a description of the requirements for Accreditation for transcatheter mitral valve therapy (TMVT) based on expert consensus.

Current Status in Australia

Transcatheter Mitral Valve Repair

Since the first MitraClip was implanted in 2003, more than 100,000 interventions have been performed globally. The device received *Conformité Européenne* (CE) Mark approval in Europe in March 2008, and Therapeutic Goods Administration (TGA) approval in Australia in April 2011. MSAC support for public funding of the procedure was given on the basis that the procedure is effective and safe, and cost-effective (depending on the negotiated price of the prosthesis). To date, unfunded procedures have been performed in both public hospital and private hospital settings, with a 30–40% yearly increase in national annual volume over the past 3 years. It is estimated that in Australia, 65% of treated patients have primary MR and the remaining 35% have secondary MR (data on file, Abbott Australia, Macquarie Park, NSW, Australia).

In addition to the MitraClip system, several other devices are available in Australia for transcatheter mitral valve repair. PASCAL (Edwards Lifesciences, Irvine, CA, USA), a leaflet repair device not unlike MitraClip, recently received Australian TGA approval and is available commercially [17]. Indirect annuloplasty using the Carillon Mitral Contour System (Cardiac Dimensions, Kirkland, WA, USA) [18] has also recently received TGA approval.

Transcatheter Mitral Valve Replacement (TMVR)

Although no TMVR device is commercially available in Australia, several devices have been evaluated in early feasibility studies. These include the Tendyne Mitral Valve System (Abbott Structural) [19,20], the Intrepid valve (Medtronic Cardiovascular, Santa Rosa, CA, USA) [21], and the Edwards M3 valve (Edwards Lifesciences). It is anticipated that once TGA approval for these devices is obtained, approval for prosthesis listing and public funding will be contingent on the same conditions as outlined for MitraClip [15].

Accreditation Requirements

Following approval of funding for TAVI [16], at the recommendation of MSAC and the Department of Health, a Conjoint Committee for Accreditation of TAVI programs was established in 2017 under the auspices of the Cardiac Society of Australia and New Zealand (CSANZ) and the Australian and New Zealand Society of Cardiac and Thoracic Surgery (ANZSCTS). This committee was charged with providing a framework for accreditation of institutions and individual operators wishing to perform TAVI in Australia, for benchmarked evaluation of outcomes, and for providing feedback to sites and individuals using data from the National TAVI Registry. These outcome measures will form the basis for reaccreditation of TAVI programs, which will occur every 3 years. The recommendations of MSAC for the implementation of public funding for TMVT [15] include the same requirements as were outlined for TAVI. Specifically, these include the need for a multidisciplinary Heart Team review of individual cases, mandatory reporting of outcome data to a national TMVT Registry, and accreditation of individuals and institutions by the Conjoint Accreditation Committee, the assigned accreditation authority [15].

Heart Team

The concept of a collaborative, multidisciplinary Heart Team (MDT) to facilitate decision making and to optimise patient outcomes is now well established and is widely endorsed in all international guidelines for the management of valve disease [4,5,22,23]. The MSAC decision and Commonwealth Medicare Benefits Schedule (CMBS) procedural item descriptors for transcatheter mitral valve repair mandate the involvement of a cohesive MDT consisting of a broad range

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of health professionals who meet regularly and maintain an auditable record of individual patient management plans. This is particularly important for patients with mitral valve disease and heart failure for whom management options may include guideline-directed medical therapy, transcatheter valve repair or replacement, minimally invasive valve surgery, or open valve surgery. Anatomical factors that must be considered include valve morphology, LV myocardial geometry and performance, pulmonary vascular haemodynamics, right ventricular function, and severity of concomitant tricuspid valve disease. In addition, patient comorbidities, frailty, cognitive function and social circumstances are fundamentally important considerations. Although specific technical decisions may be left to the procedural team, the MDT should consider all aspects of the procedure including the management of peri-procedural complications, and appropriateness of emergency surgery. This should include incorporation of the patient's wishes as part of a shared decision-making process [22]. These decisions should be reviewed by the procedural team at the preoperative briefing/"team huddle" immediately prior to the intervention.

The minimum personnel requirements for a Heart Team are as follows:

i) Core personnel:
   - Cardiothoracic Surgeon experienced in surgical mitral valve repair
   - Interventional Cardiologist experienced in TMVT
   - Specialist or Consultant Physician who does not perform transcatheter mitral valve procedures, preferably one with expertise in advanced cardiac imaging

ii) Other personnel may include:
   - Cardiothoracic Surgeon
   - Interventional Cardiologist
   - Cardiologist with heart failure expertise
   - Nurse Co-ordinator
   - Geriatrician
   - General Medicine Physician
   - Intensive Care Physician
   - Anaesthetist
   - Vascular Surgeon
   - Radiologist

Institutional Requirements

In line with other guidelines [22], this Position Statement recognises the important relationship between procedural volume and outcomes of valve interventions [24–27]. This is particularly true for TMVT. For example, the 2019 Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry report on transcatheter mitral valve repair [27] showed increasing procedural success, reduced procedural time and reduced procedural complications with increasing procedural experience. An inflection point for improved outcomes was apparent after the first 50 institutional cases, with continued improvements up to and perhaps beyond the first 200 cases [27]. Although some of this improvement might be related to better patient selection rather than improved technical proficiency [28], the principle of better clinical outcomes in high procedural volume centres remains valid. Likewise, surgical data from the New York State database showed higher mitral valve repair rates for primary MR, and improved 1-year survival in centres performing >25 mitral operations per year [25]. Based on these observations, and established recommendations in other jurisdictions, the preferred model for accreditation of TMVT programs in Australia specifies minimum volume requirements for both institutions and operators, and encourages the development of Comprehensive Heart Valve Centres [29].

Requirements for institutional accreditation of a TMVT program are summarised in Table 1 and include the following:

- An established interventional cardiology and structural heart program (>2 years of operation) as evidenced by:
  - ≥100 structural heart procedures per year (of which ≥50 are TAVI procedures) and
  - ≥1,000 diagnostic cardiac catheterisations per year and
  - ≥300 percutaneous coronary intervention procedures per year.
- An established cardiothoracic surgical program (≥2 years of operation) with at least two cardiac surgeon operators with annual cardiac surgical volumes ≥150 major cardiac surgical cases per year, including ≥30 mitral valve surgeries per year.
- At least one cardiac surgeon who has performed ≥40 MV surgeries over the past 2 years.
- Anticipated transcatheter mitral valve procedural volume ≥20 cases per year.
- Multidisciplinary heart team that meets regularly (ideally weekly).
- An established and accredited TAVI program is highly desirable, as it implies the presence of a functioning MDT, on-site surgical support, a nurse co-ordinator and database management.

The minimum institutional facilities should include:

- Cardiac catheterisation laboratory or hybrid operating room with fixed radiographic imaging equipment, high resolution fluoroscopy and cineangiography, haemodynamic monitoring, and sufficient space to provide room for echocardiography and anaesthesia staff and equipment.
- Appropriate equipment for managing complications including, but not limited to:
  - cardiac arrhythmias (defibrillator, resuscitation equipment, temporary pacing)
  - major vascular complications and bleeding (balloon catheters, covered stents)
  - pericardial tamponade (pericardiocentesis tray)
  - haemodynamic collapse (intra-aortic balloon pump, extracorporeal membrane oxygenator [ECMO])

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Table 1 Key individual, institutional, and program requirements for TMVT accreditation of new operators and TMVT hospitals.

Operator	Institution	Program
≥300 career PCIs	≥1,000 caths/year and ≥300 PCIs/year	Multidisciplinary heart team with auditable meeting minutes
≥50 structural heart disease interventions AND ≥20 transseptal procedures	≥50 open heart surgical procedures/year including ≥30 mitral valve operations/year	TMVT co-ordinator and database manager
≥20 TMVT procedures during past 2 yrs	At least 2 on-site cardiac surgeons and appropriate operating room staff	TMVT database with facility to export data to TMVT National Registry
CT Surgeon: ≥20 MV surgeries/yr (50% repairs)	On-site vascular surgery with ≥30 endovascular procedures/year	
≥10 proctored device-specific TMVT cases	Anticipated annual TMVT volume ≥20 cases	
Anticipated annual TMVT volume ≥20 cases	Cath lab/hybrid lab with appropriate resources for TMVT	
	Expertise in TMVT imaging including TTE, TOE and cardiac CT imaging	
	Cardiac anaesthesia support	
	Postoperative ICU/HDU/CCU support	
	Electrophysiology/pacing support	

Abbreviations: CCU, coronary care unit; HDU, high dependency unit; ICU, intensive care unit; MV, mitral valve; PCI, percutaneous coronary intervention; TMVT, transcatheter mitral valve therapies; TOE, transoesophageal echocardiogram; TTE, transthoracic echocardiogram.

  - persistent inter-atrial shunting (atrial septal defect [ASD] closure devices)
  - device embolisation (retrieval snares).
- Advanced echocardiography support including three dimensional (3D) transoesophageal imaging, and a cardiologist or anaesthetist with expertise in cardiac imaging who has guided ≥50 structural heart procedures via transoesophageal echocardiography (TOE). For an imaging specialist new to guiding TMVT procedures (ie, <50 cases), proctoring by an imaging specialist experienced in TMVT (ie, career >50 cases) is required for at least 10 cases.
- Access to a vascular laboratory (non-invasive) with vascular specialists capable of performing and interpreting vascular studies.
- Access to a computed tomography (CT) laboratory with CT technologists and specialists who can acquire and interpret cardiac CT studies.
- Operating theatre, staff and equipment available to provide urgent cardiac surgical back-up.
- On-site vascular surgical support including an active vascular surgical program (≥30 arterial endovascular procedures/year).
- On-site intensive care and coronary care units experienced in managing cardiac surgical patients.
- Infrastructure and personnel for maintenance of a transcatheter mitral valve therapy (TMVT) database, and data submission to the TMVT National Registry.

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

- Circulating heating, ventilation, and air conditioning laminar flow diffusers.
- High-output lighting for surgical intervention.
- Capability of running cardiopulmonary bypass/ECMO in addition to anaesthesia gas and power supplies (ie, dual outlets).

Operator Requirements

Requirements for accreditation of individual operators are as follows (Table 1):

- Completion of training in Interventional Cardiology as per CSANZ requirements [30] (Interventional Cardiologist operator) OR completion of training in Cardiothoracic Surgery as per ANZSCTS requirements (Cardiac Surgical operator).
- Interventional Cardiology operators should have a broad procedural experience that includes complex coronary interventions, transseptal puncture, placement of large calibre arterial and venous sheaths, balloon dilatation of the aortic and/or mitral valve, transcatheter valve implantation and pericardiocentesis.
- Involvement as primary or secondary operator in ≥100 transcatheter structural heart procedures (*not* including pericardiocentesis, endomyocardial biopsy, device closure

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for patent foramen ovale/atrial septal defect/patent ductus arteriosus (PFO/ASD/PDA).

Specific requirements for transseptal (TS) TMVT:

- For established TMVT operators:
  - ≥40 TS-TMVT cases (TS-TMVr or TS-TMVR) during the past 5 years as primary or secondary operator in Australia with 30-day stroke, mortality, open surgical conversion, major vascular complication, and death rates <5%.
- For less experienced operators:
  - Involvement as primary or secondary operator in ≥50 structural heart procedures including first operator experience of ≥20 transseptal procedures.
  - Involvement as primary or secondary operator in ≥20 TS-TMVT cases (TS-TMVr or TS-TMVR) in the last 2 years, including a minimum of 10 cases in Australia under proctor supervision. Proctoring should be performed on-site by an accredited TMVT operator. Supervised cases must be certified by the physician-proctor and co-signed by an industry representative. It is expected that industry supervision will continue well beyond the initial period of physician proctoring.
  - Anticipated annual TMVT procedural volume ≥20 cases.

Maintenance of Competency and Accreditation

In order to maintain individual and institutional program accreditation, annual procedural volume and clinical outcomes will be reviewed periodically by the TMVT Accreditation Committee using data from the TMVT National Registry. Sites failing to meet volume, quality of care and reporting requirements will be advised of their need to institute quality control measures to maintain their accreditation. A formal reaccreditation process will occur every 3 years. The following are the minimum annual procedural volumes and outcome measures required for reaccreditation of approved programs:

- Institutional volume of ≥20 TMVT cases (TS-TMVr or TS-TMVR) per year or ≥40 per 2 years. This volume may be performed by multiple individual proceduralists. Where public and private hospital programs are co-located and function as a single program, volumes can be combined if the same team (including medical and nursing staff) perform the procedures at both sites.
- Individual procedural volume of ≥20 TMVT cases (TS-TMVr or TS-TMVR) per year or 40 per 2 years. This individual volume may be accumulated at more than one institution.
- The following key performance outcome measures will be evaluated:
  - 30-day all-cause mortality
  - 1-year all-cause mortality
  - 30-day all-cause neurologic events including transient ischaemic attack (TIAs)
  - Major vascular complications.
- Institutions and individuals will be expected to achieve outcomes that are consistently within two standard deviations of the average outcomes of peer institutions in the TMVT Registry as determined by funnel plot quality reviews.
- >90% submission of complete data, including 1-year follow-up, to the National TMVT Registry.

New Procedures

This Position Statement primarily addresses the requirements for implementation of transcatheter mitral valve repair or replacement for severe, symptomatic MR. However, the requirements outlined can also be applied to programs wishing to perform other related interventions including balloon mitral valvuloplasty for rheumatic mitral valve stenosis, transcatheter valve implantation for degenerative mitral valve prostheses or severe mitral annular calcification, and closure of mitral paravalvular leaks. The TMVT National Registry will include modules to collect data for these interventions. Likewise, the Registry will be configured to accept data relating to interventions for tricuspid valve disease, which have been initiated in Australia during the past few months. Although no device is currently TGA-approved for the treatment of severe tricuspid regurgitation, several have received CE Mark approval and should soon be available in this country [31]. While approval for public funding for these interventions will take some years, the requirements established in this Position Statement for transcatheter mitral interventions, will provide a framework for adding transcatheter tricuspid interventions to established Structural Heart Disease interventional programs.

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