



The Cardiac Society of Australia and New Zealand

Position Statement

Performance of and Support Facilities for a Primary Percutaneous Coronary Intervention (PCI) Service

This Position Statement was originally developed by a Working Group chaired by Dr Nigel Jepson. The Statement was reviewed by members of the Interventional Council Executive, chaired by Dr Jim Stewart. None of the reviewers have a Conflict of Interest to disclose.

The Statement was reviewed by the Continuing Education and Recertification Committee and ratified at the CSANZ Board meeting held on Friday 1st August 2014.

Primary PCI is indicated in patients with STEMI or MI with new LBBB presenting < 12 hours from symptom onset. The benefits are dependent upon the delivery of prompt and expert therapy by an established and effective primary PCI program. This Position Statement outlines the requirements to develop a dedicated acute infarct angioplasty service capable of delivering every day, 24 hour therapy.

For the purpose of this document, primary PCI for STEMI incorporates patients undergoing rescue intervention for failed reperfusion after thrombolysis with evidence of either haemodynamic or electrical instability or ongoing ischaemia.

Elective PCI and primary PCI for STEMI are different although obviously related disciplines. Experience in elective PCI only partially translates to experience with primary PCI for STEMI. The volume-outcome relationship exists for both elective procedures and primary PCI but has important differences. Available data indicate that the best results are obtained by operators who are highly experienced both in elective PCI and in primary PCI who work in institutions that have established an active program for primary PCI. Operator experience in elective PCI is not sufficient to confer expertise in primary PCI as there are aspects and conduct unique to the urgent procedure.

It is recommended that primary PCI for STEMI be performed by appropriately trained higher volume operators experienced in both elective and primary PCI. All operators and centres should meet the minimum requirements set in the Cardiac Society's "Position Statement for Competency in Percutaneous Coronary Intervention." Ongoing activity levels expected for maintenance of competence:

Individual	75+ elective PCI procedures per year 11+ primary PCI cases per year
Centre	36+ primary PCI procedures for STEMI per year 200+ overall PCI cases per year

Personnel and facility requirements for an effective primary PCI program (irrespective of whether cardiac surgery is available onsite) -

- Full support and commitment from hospital administration, fulfilling institutional requirements including support services.
- A comprehensive system of care to shorten time between symptom onset and primary PCI should be in place. Ideally this should include an 'in-field activation' program established in conjunction with local ambulance services to minimize treatment delays. Furthermore a system facilitating early recognition in the Emergency Department with prompt contact with the Cardiology team should be established. Pathways of communication and a clearly defined mechanism of primary PCI activation needs to be implemented prospectively. Real-time data feedback with Emergency Department and catheterisation laboratory staff should be undertaken.
- Experienced nursing and technical catheterisation staff with training in interventional laboratories. Personnel must be experienced in managing acutely unwell patients with haemodynamic and electrical instability.
- Laboratory staff must be skilled in all aspects of interventional equipment and must participate in an on call schedule permitting laboratory operation 24 hours-per-day, 365-days-per-year.
- A well equipped and maintained catheterisation laboratory with high-resolution digital imaging capacity and an appropriately diverse inventory of interventional equipment including intra-aortic balloon pump capability and resuscitative equipment.
- Coronary care unit staff must be adept in haemodynamic monitoring, temporary pacemaker operation and IABP management.
- Primary PCI must be performed routinely as the treatment of first choice for STEMI around the clock to ensure streamlined care paths and increased case volumes. Door to balloon times should not exceed 90 minutes.
- Primary PCI may be reasonably considered by a high volume operator (experience > 1000 PCI cases, including undertaking 11+ primary PCI per year) in an established unit with experience in elective PCI although without a dedicated 24 hours-per-day, 365-days-per-year program. This is particularly relevant to a non-metropolitan centre with adequate facilities and infrastructure and when the operator felt primary PCI was the preferred treatment strategy. Audit of clinical outcomes in these patients would need to be closely monitored.
- On-site rigorous data collection, ongoing program of outcomes review, benchmarking, quality improvement and formalized periodic case analysis. Door to balloon times should be frequently reviewed as a component of quality assessment with a view to implementing strategies permitting optimal reperfusion within 90 minutes of presentation.

The Society believes that a policy of routine primary PCI should only be performed after an elective PCI program has been established and shown to perform with acceptable morbidity and mortality. Hospital administration must fully support the program and enable provision of institutional requirements. Institutions should participate in 3-6 month period of implementation, during which time development of a formalized primary PCI program is instituted that includes establishment of standards, training of staff, logistic development and creation of a quality-assessment and error management system.

A policy of 24/7 primary PCI however should not be offered until in view of the laboratory director, there is:

- Sufficient infrastructure (workforce and clinical services) to ensure that procedures can be performed safely outside routine working hours
- Appropriately trained interventional cardiologists, willing to participate in such a program which should ideally include more than 2 interventional cardiologists.

Primary PCI service without surgical back-up -

- Operator and institutional experience as defined above
- Proven plan for rapid transport to a cardiac surgical centre
- Performed in a timely fashion (< 90 mins)
- Case selection must be rigorous

Caution: Discretion should be exercised when assessing haemodynamically stable patients with complex infarct related lesions that have TIMI 3 flow.

Urgent transfer to institution with cardiac surgery of patients with:

High-grade residual left main or multi-vessel disease and clinical or haemodynamic instability after culprit vessel primary PCI, preferably with IABP support

The Society believes that careful and complete record keeping and peer-review auditing of individual and procedural results is mandatory and an intrinsic part of quality assurance related to primary PCI procedures (whether undertaken with or without surgical backup). The lack of prompt availability of these details would constitute a major breach of this policy.