PG27(A) Guideline for major extracorporeal perfusion 2015

Short title: Extracorporeal perfusion

1. Introduction

Major extracorporeal perfusion (ECP) involves the diversion of patient blood through an artificial circuit incorporating a pumping device for the purpose of assisting the circulation, and usually providing gas exchange for oxygen and carbon dioxide. It is most commonly indicated for the purpose of facilitating cardiac surgery or surgery involving the great vessels but may involve circulatory support in other contexts.

These guidelines seek to ensure the safe conduct of major extracorporeal perfusion and address the following aspects:

1.1 Organisation of the major ECP service.

1.2 Training and continuing professional development of fellows of ANZCA and other medical practitioners who undertake independent responsibility for ECP.

1.3 Heart-lung machines for major ECP.

1.4 Clinical management of major ECP.

2. Organisation of the major ECP service

Major ECP perfusion should be provided within an organised hospital-based service that is staffed with an appropriate number of trained and qualified personnel. These guidelines are the recommended requirements for services and facilities for ECP.

2.1 Head of service

2.1.1 A major ECP service must have a designated head of service, who should be responsible for the administration and delivery of the service.

2.1.2 ECP requires the prescription and administration of a number of potent drugs and complex medication-containing solutions, the assessment of patients, and the development of evidence based policies for the use of these drugs and solutions in a manner that recognises the variability between patients. It follows that it is ideal for the head of the major ECP service to be a registered medical practitioner. Alternatively, the head of the major ECP service must have an explicit line of accountability to a registered medical practitioner (usually a cardiac anaesthetist or a cardiac surgeon) who should contribute to the development of all policies and take medical responsibility for signing off these policies once agreed.

2.2 Staffing

The head of the service should ensure that the ECP service has appropriate staffing, facilities and equipment, that there are appropriately trained staff to cover in hours and out-of-hours requirements, including emergencies, and that members of the service are designated to:

2.2.1 Maintain and regularly review an inventory of all hardware equipment, including records of maintenance and repairs and preventative maintenance. All equipment must meet current standards in electrical safety for cardiac protection.

2.2.2 Maintain an inventory of orders, receipts and supplies of all disposable equipment.

2.2.3 Provide ongoing assessment of the efficacy and cost-benefit of currently used and potentially available equipment.

2.2.4 In liaison with the departments of cardiac anaesthesia and cardiac surgery, maintain and review all protocols for ECP.

2.2.5 Ideally, conduct research into relevant aspects of ECP.

2.3 Physical facilities

The major ECP service requires adequate dedicated space in close proximity and with easy access to the operating theatre and postoperative recovery/intensive care unit for:

2.3.1 Storage of hardware items.

2.3.2 Storage of adequate supplies of disposable equipment in appropriate areas, with respect to lighting and protection from humidity, moisture and temperature extremes.

2.3.3 A clean area, in accordance with standards applicable and relevant to assembly of circuits, for use during ECP.

2.3.4 Storage of patient perfusion records and other data used for quality assurance, research and other activities, including the performance data of all devices used during the conduct of ECP.

2.3.5 Offices and secretarial assistance for the head of the service and other members of the service.

3. Training and continuing professional development

These guidelines are the recommended requirements for the training and continued professional development of fellows of ANZCA and other medical practitioners who undertake independent responsibility for perfusion.

3.1 Perfusion training objectives

3.1.1 Training should result in a detailed knowledge of all medical aspects of patients undergoing major ECP and the ability to manage these aspects effectively. This includes managing the anaesthetized patient on cardiopulmonary bypass, and assuming medical responsibility for administration of all medications given via the heart-lung machine during this period. Essential areas of physiological and pathophysiological management include optimisations of cardiovascular parameters, gas exchange, acid base homeostasis, glucose and electrolyte balance, coagulation and blood conservation requirements and the administration of blood and blood products.

3.1.2 Trainees must understand the principles of operation and design of perfusion equipment and become fully capable of assembling and operating it throughout the surgical procedure. They must also understand the principles of operation and design of other circulatory support equipment and be able to assemble and operate it as needed. This includes cell salvage equipment, haemofilters, intra-aortic counter-pulsation devices,

and extracorporeal membrane oxygenation devices. An understanding of the principles of operation of specialised equipment such as ventricular assist devices is required.

3.2 Perfusion training requirements

Medical practitioners should complete a structured training program or fellowship in perfusion that includes the following components:

3.2.1 Before commencement of specific training as medical perfusionists, medical practitioners should hold specialist qualifications which include the necessary background in physiology and pharmacology, such as fellowship of ANZCA. Advanced trainees in their last year of training may commence training in medical perfusion, provided they have completed the physiology and pharmacology components of their training.

3.2.2 The training period should be of at least 12 months duration but not longer than 24 months. During this training period a log book must be kept, to include relevant activities such as circuit assemblies, perfusion services, simulated perfusions and other perfusion related training experiences.

3.2.3 During training at least 75 perfusions should be performed with full operation of the heart-lung machine by the trainee from commencement to cessation of bypass. At least the first 50 cases should be performed under the close supervision of a fully trained medical perfusionist and include assembly of the equipment to be used. The remainder of the cases may be performed by the trainee independently, but with a fully trained medical perfusionist being immediately available to assist if necessary. If the trainee is to practise in a paediatric environment alone then the above requirements apply to paediatric cases specifically.

3.2.4 Training must include simulation of the following critical scenarios: main pump head failure, gas in the patient circuit, oxygenator changeout. They must demonstrate to a supervisor, a fully trained medical perfusionist, that they are competent to manage these situations.

3.2.5 The above training requirements apply in full to all medical perfusionists who complete their training after the date of promulgation of this document. Medical perfusionists who trained before the date of this document must have attained the capability detailed in section 3.1 and the experience detailed in item 3.2.3, and must be in current practice meeting the requirements of section 3.3. Such individuals must have their capacity as medical perfusionists supported by current hospital accreditation for management of perfusion in their scope of practice.

3.3 Continuing professional development

Fellows who are practising medical perfusion are required to maintain relevant continuing professional development (CPD), consistent with ANZCA's CPD policy and standards, as in all other aspects of their practice. For practitioners seeking further guidance, the following is a recommended minimum:

3.3.1 Managing whole body perfusion, from commencement to cessation of bypass, at least 40 times per year. In at least 20 of these cases, the medical perfusionist should operate the heart-lung machine. A record of these cases should be kept and be easily retrievable

3.3.2 A continuing education and quality assurance program that includes regular review of current knowledge related to ECP and periodic simulation of the following critical scenarios: main pump head failure, gas in the patient circuit, oxygenator changeout.

3.3.3 Auditing and data collection on all patients, with periodic review of data and all incidents occurring during or associated with major ECP.

4. Heart-lung machines for major ECP

The heart-lung machine consists of a mobile console, which incorporates the hardware necessary for ECP and enables the application of accessories and disposable equipment.

These guidelines describe the requirements for a heart-lung machine and associated equipment for the safe provision of ECP.

4.1 Standards, compliance and maintenance

All electrically powered components of the heart-lung machine should meet current Australian and/or New Zealand electromedical specifications for electrical safety for cardiac protected procedures and other relevant standards. The heart-lung machine should also comply with requirements listed further in this section and must meet applicable standards.

All components of the heart-lung machine should undergo routine biomedical engineering inspection and maintenance at regular intervals, and full documentation of these events should be recorded. A biomedical engineering repair service should be readily available whenever faults are detected in the components, and full documentation of these events should also be recorded.

4.2 Components of the heart-lung machine

The mobile heart-lung machine console should generally include the following items, although in certain clinical circumstances not all items will necessarily be appropriate:

4.2.1 Pump heads

4.2.1.1 There should be three or more pump heads capable of providing appropriate fluid flow for cardiopulmonary bypass.

4.2.1.2 Arterial pump heads must have alarms and servo-control mechanisms where appropriate, with manual override capability, for:

4.2.1.2.1 Blood reservoir low level detection.

4.2.1.2.2 Arterial line over-pressure detection

4.2.1.2.3 Bubble detection.

4.2.1.3 All pump heads must have electronic circuitry incorporating "runaway" control protection.

4.2.1.4 All pump heads must provide an option for displaying pump flow in either litres per minute or revolutions per minute, and must be capable of easy calibration.

4.2.1.5 All pump heads which provide controls for flow operation in either direction should be controlled by a lockable device, such that initiation of reversal of flow requires two actions.

4.2.1.6 All roller-pump heads must incorporate a transparent removable cover and an adjustable occlusion mechanism.

4.2.1.7 All pump heads must be capable of manual operation for emergency use. A cranking system must be immediately accessible.

4.2.2 Gas supply system

4.2.2.1 The heart-lung machine must be connectable to an indexed piped medical oxygen and air supply consistent with applicable standards, including alarm systems.

4.2.2.2 The heart-lung machine must be connectable to a readily available emergency supply of oxygen in the event of piped gas failure.

4.2.2.3 The heart-lung machine must be equipped with gas flow meters and gas blenders consistent with applicable standards.

4.2.2.4 An oxygen analyser consistent with applicable standards must be used before and during cardiopulmonary bypass either in the gas supply line to the oxygenator, or on the effluent gas from the oxygenator.

4.2.2.5 If volatile agents are used during cardiopulmonary bypass, the heart-lung machine must be connected to a device for scavenging waste gases from the oxygenator.

4.2.3 Heat exchange source

4.2.3.1 Heat exchange sources provide reticulated water at controllable temperatures through a heat exchange circuit within the oxygenator and/or blood reservoir.

4.2.3.2 Heat exchangers utilise hot and cold water supplies from an external piped system OR a self-contained electronic heater/cooler and pump. Sources must supply water at temperatures controllable between 4° C and 42° C.

4.2.3.3 Heat exchangers must supply water flow between 10 and 25 litres per minute at a pressure not exceeding 600 mm Hg.

4.2.3.4 Heat exchangers must incorporate monitors, alarms and alarm override facilities for water temperature, and indicate water pump failure and low water level.

4.2.3.5 There must be a second heat exchanger available in case of failure of the primary device.

4.2.4 Low level detection monitor

4.2.4.1 Low level detection monitors are safety devices secured to the oxygenator and/or reservoir in the extracorporeal circuit which monitor for a predetermined minimum blood level in these devices.

4.2.4.2 A low level detection device must be used during the conduct of every ECP procedure.

4.2.4.3 The low level detection device must incorporate both audible and visual alarms, and servo-control systems to the primary blood flow pump, with an override facility.

4.2.5 Arterial line pressure monitoring devices

4.2.5.1 Arterial line pressure monitoring devices continuously measure and display outgoing blood perfusion pressure to the patient from the extracorporeal circuit.

4.2.5.2 An arterial line pressure monitoring device must be inserted at an appropriate point in the line providing perfusion to the patient. When a membrane oxygenator is included in the circuit, line pressure must be measured both pre- and post- membrane if possible, so that the transmembrane gradient can be monitored.

4.2.5.3 Arterial line pressure monitoring devices must incorporate both audible and visual alarms that are activated when adjustable preset pressures are exceeded, and must incorporate servo-control systems to the primary blood flow pump, with an override facility.

4.2.6 Gas-emboli detector

4.2.6.1 Gas-emboli detectors monitor the passage of gas bubbles in the arterial line and should be inserted in the line providing perfusion to the patient.

4.2.6.2 A gas-emboli detector to detect macro-gas emboli must be used during the conduct of every ECP.

4.2.6.3 The gas-emboli detector must incorporate both audible and visual alarms, and servo-control systems to the primary blood flow pump, with an override facility.

4.2.7 Venous haemoglobin oxygen saturation monitor

4.2.7.1 Venous blood haemoglobin oxygen saturation monitors are used to detect the oxygen saturation of blood returning from the patient to the ECP circuit.

4.2.7.2 A venous blood haemoglobin oxygen saturation monitor must be used during the conduct of every procedure requiring cardiopulmonary bypass.

4.2.7.3 The sensor must be placed in the venous line at a point most distal from the patient, in order to minimize inaccuracies due to streaming of blood.

4.2.7.4 The monitor must be calibrated when applicable.

4.2.8 Other equipment

4.2.8.1 An electrical power source, including emergency supplies, consistent with standards applicable to all electrical supplies in operating suites.

4.2.8.2 Devices for appropriate incorporation of disposable equipment, particularly a blood reservoir, oxygenator and plastic tubing and filters.

4.2.8.3 An integrated light source assisting monitoring of blood reservoir levels.

4.2.8.4 Temperature monitoring devices for arterial and venous blood, with both audible and visual alarms, which have adjustable limits.

4.2.8.5 During cardiopulmonary bypass, the effluent gas should be continuously monitored for oxygen and carbon dioxide; if a vapouriser is fitted to the heart-lung machine, volatile anaesthetic should also be monitored.

4.2.8.6 Appropriate equipment for delivery of cardioplegia, including pumps, temperature control devices, a bubble trap and pressure monitoring as necessary.

4.2.8.7 A patient monitor must be clearly visible to the perfusionist, displaying electrocardiography trace, intravascular pressures, core temperature and other relevant parameters.

4.3 Perfusion machines and equipment for other applications of ECP

4.3.1 Perfusion machines and equipment for applications other than CPB for cardiac and related surgery (for example, cardiopulmonary bypass support in acute cardiovascular and/or respiratory failure; perfusion for transplantation surgery; isolated limb or organ perfusion) must be tailored to the particular perfusion needs of the application.

4.3.2 The relevant components of perfusion machines in these other applications should generally comply with the standards listed for the heart-lung machine in section 4.2.

4.4 Disposable equipment for ECP

4.4.1 All disposable equipment must be manufactured and assembled in accordance with established quality assurance specifications, processes and procedures, as required by relevant standards.

4.4.2 All disposable equipment must be inspected for records of quality control, defects and breaches in packaging and sterility.

4.4.3 All disposable equipment must be used only after familiarisation with the manufacturers' specifications and instructions for use.

4.4.4 All disposable equipment should be stored in areas with appropriate environmental conditions as required by relevant standards.

5. Clinical management of major ECP

Major ECP must only be managed by those with expertise in all aspects of the perfusion services, including the expertise to operate the heart-lung machine. If a medical perfusionist is managing the perfusion, the medical perfusionist must either operate the heart-lung machine or directly supervise its operation.

ECP requires the administration of drugs, complex medication-containing solutions, fluids and sometimes blood or blood products. The prescription of these drugs and fluids is a medical responsibility. Unless the perfusionist has prescribing rights, there must be an explicit line of accountability to a registered medical practitioner for all drugs administered during ECP.

These guidelines are the recommended requirements for the clinical management.

5.1 Pre-operative patient assessment

5.1.1 All patients undergoing major ECP should be assessed preoperatively in relation to the specific requirements of ECP, and assessed for possible additional risks or issues that may affect the patient or the management of the ECP. The planned perfusion and

perfusion-related services must be discussed with the patient except when precluded by an emergency situation.

5.2 Clinical management of major ECP

5.2.1 Major ECP circuit assembly and priming

5.2.1.1 Prior to application, the major ECP circuit must be assembled, checked and primed according to written protocols developed by each institution. These protocols must encompass standards for handling sterile equipment, be consistent with manufacturers' recommendations, and include appropriate selection of priming solutions and a procedure for checking the circuit.

5.2.1.2 An electronic or written pre-bypass checklist for the assembled and primed circuit and all components of the major ECP machine must be completed, signed and kept on record.

5.2.1.3 Drugs added to the major ECP circuit must be checked and signed for according to protocols.

5.2.2 Initiation of major ECP

5.2.2.1 The perfusionist should be immediately and exclusively available for the care of the patient, and involved in the management of the perfusion, at all times from the commencement of anaesthesia, until, in the case of cardiac surgery, closure of the chest.

5.2.2.2 The anticoagulation status of the patient must be assessed in relation to the planned procedure, and noted on the perfusion record.

5.2.3 Maintenance of major ECP

5.2.3.1 During maintenance of major ECP, continuous and vigilant assessment and management is required of all monitored physiological parameters, coagulation status and monitored machine parameters. A clear display of monitored parameters is essential.

5.2.3.2 Determination of appropriate cardiovascular flows and perfusion pressures, and of acid base homeostasis and gas exchange, should be evidence based wherever possible and comply with institutional protocols.

5.2.3.3 Consideration of co-morbid medical conditions, including diabetes, renal or hepatic impairment, cerebrovascular disease or anaemia is essential.

5.2.3.4 Clear and frequent communication between the perfusionist, the surgeon and the anaesthetist is essential during perfusion.

5.2.4 Cessation of major ECP

5.2.4.1 Weaning from major ECP and resumption of adequate cardiac and pulmonary function requires particular care and skill as difficulties may occur at this time. Close co-operation and communication between the perfusionist, anaesthetist and surgeon is essential.

5.2.4.2 The major ECP circuit must be kept in a functional state until it is agreed by the surgeon, and the anaesthetist, and the perfusionist responsible for the case that it is no longer required.

5.3 Protocols for management of major ECP

5.3.1 Basic clinical management protocols for ECP and anticoagulation should be evidence based and established in consultation with perfusion, anaesthesia, and surgical staff and be regularly reviewed.

5.3.2 Protocols for management of critical events should be distributed and regularly practised by all perfusion staff.

5.3.3 Such protocols must cover gas leaks or failure in the supply of gas, blood circuit leaks or rupture, massive air embolism, pump failure, oxygenator, filter or heat exchanger malfunction and the detection of clots in the circuit.

5.4 Patient records of major ECP

A contemporaneous electronic or written record of the conduct of ECP must be made in a form appropriate for retention in the medical records of the patient. The record should include:

5.4.1 Patient details, operative procedure and relevant pre-operative clinical information.

5.4.2 Names of perfusion, anaesthetic and surgical staff.

5.4.3 Equipment and circuit details, including serial numbers of major disposable items.

5.4.4 A completed and signed pre-bypass check list.

5.4.5 Monitored machine parameters.

5.4.6 Monitored physiological parameters.

5.4.7 All fluids and drugs administered to the patient, including prime constituents, and drugs and fluids administered subsequently.

5.4.8 Notation of administration of cardioplegia, including type, volume and route of administration.

5.4.9 Fluid outputs.

5.4.10 Notations of relevant events during ECP.

This document is accompanied by a background paper (PG27(A)BP) which provides more detailed information regarding the rationale and interpretation of the Guideline.

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