INTRODUCTION

Since the original British Paediatric Cardiac Association (BPCA) guidelines published over 11 years ago², therapeutic catheterisation in congenital heart disease has changed beyond recognition. Diagnostic cardiac catheterisation is now a relatively uncommon investigation due to the availability of modern imaging techniques. These have largely superseded catheterisation but the acquisition of haemodynamic data remains an important part of the assessment of some children. As a result, the vast majority of catheter procedures undertaken in children with congenital heart disease in the UK are performed with a view to therapeutic intervention. Since the previous guidelines there have been significant improvements in the equipment available to the catheterising paediatric cardiologist. New balloons, stents and particularly occlusion devices have allowed cardiologists to reliably tackle lesions that were previously the domain of the cardiac surgeon. In addition, over the last few years the interventional paediatric cardiologist has started to work with cardiac surgical colleagues to deliver combined surgical and transcatheter treatment in the operating theatre and newly designed theatre/laboratories (so called “hybrid laboratories”).

Evidence based recommendations in paediatric cardiac catheterisation

Although studies looking at the safety and efficacy of catheter-based procedures in children are published, the relatively small numbers of patients, lack of homogeneity in the underlying cardiac diseases affecting this age group and the difficulty constructing and executing studies viewed in other areas of medicine as the “gold standard” mean that evolution in this area has largely been developmental. As such the available evidence base on which to make recommendations for treatment is limited. In the construction of this document the working group have attempted to organise the available data into a classification of recommendations but perhaps as importantly, have also provided a narrative summarising the current expert opinion in a UK context. Therefore it is important to recognise that this document, like other similar publications from other organisations³ makes recommendations based on a consensus about best practice but should not be considered definitive.
UK outcome and activity data - the congenital cardiac audit database (CCAD): www.ccad.org.uk

In the original BPCA guidelines much emphasis was placed on the need to collect comprehensive data on catheterisation procedures in patients with congenital heart disease. Over the last decade the UK central cardiac audit database (CCAD) project has collected national outcome data on therapeutic catheterisation from all UK congenital heart disease centres. This data is independently validated and contains information on approximately 20000 catheterisation procedures in patients with congenital heart disease. Currently only mortality and re-intervention after the index procedure are recorded, so the data outputs are relatively unsophisticated but the information gives an insight into the numbers and nature of procedures performed yearly in the UK.

It should be noted that in many centres a combination of paediatric and adult congenital cardiac cases are performed in the paediatric catheterisation laboratory. The view of the working group is that this is entirely appropriate and probably in the best interests of the patients given that the disease processes are essentially the same. All cases of any age with congenital heart disease treated in the catheterisation laboratory should count towards individual clinicians case load (see below) for the purposes of clinical governance and revalidation.

Requirements for paediatric cardiac catheterisation

Facilities, equipment and radiation protection

There are a number of standards published for the structure and contents of a modern catheterisation laboratory. Although practical arrangements for shared use with other specialties are sometimes necessary a paediatric cardiac catheterisation laboratory should be specifically designed for paediatric cardiac use and should be available 24/7, within a reasonable time frame for emergency cases.

Clearly the physical requirements in a cardiac catheter laboratory depend on the portfolio of catheterisation procedures to be performed. Although it is possible to perform limited studies with a mobile fluoroscopy arm outside a formal laboratory environment this should not be used as the basis for a catheterisation programme. At the other extreme, there are currently available complex “hybrid” catheter/operating suites facilitating catheterisation, surgery or both within a single space. The physical requirements for a laboratory of this nature are greater than for an ordinary catheter laboratory and require consideration of the physical and equipment needs of both a paediatric cardiac operating theatre and a catheter laboratory and as such have not been specifically considered in this document.

The ideal facilities for a non-hybrid catheterisation laboratory include:

1) Adequate floor space: For a biplane laboratory, ideally about 30x24 feet to reasonably accommodate the necessary staff and equipment. The basic catheterisation equipment and monitors need to be situated so there is enough space and access to the patient for both anaesthetic equipment and additional imaging such as trans-oesophageal echocardiography (TOE). The catheter laboratory needs to be designed so the lateral fluoroscopic tube can easily be removed prior to and at the end of the procedure in order to facilitate easy and safe access to the patient.

2) High quality biplane fluoroscopic equipment with compound angulation, and intrinsic field size capabilities to cope with patients of all sizes with congenital heart disease (infant to adult).

3) Adequate numbers of high quality, real-time monitors to display biplane images and haemodynamic data (ideally with additional monitoring to directly show TOE imaging and previous CT/MRI data on the main monitor rack at the same time). Monitors should be installed on rails that allow them to be moved easily and angulated so that operators can easily see them.
4) Sterile operative environment: Although not strictly necessary for a number of catheterisation procedures it is important that a modern catheter laboratory, intended for increasing complex interventional procedures in congenital and structural heart disease should have clean air filtration systems ideally on a par with a modern operating theatre. This is particularly important for programmes intending to perform trans-catheter valve replacements or “open” hybrid interventions.

5) Anaesthetic equipment: As well as the necessary space for general anaesthesia, there should be piped anaesthetic gas supply, suction and in-built scavenging systems to remove escaped anaesthetic gases.

6) Lighting: Adequate “house” lighting, with the ability to variably dim lights. An additional movable, powerful and widely adjustable light should be available to illuminate vascular access sites, ideally on a ceiling mounted boom to minimise the use of floor space.

7) Digital storage of angiographic data, so that it is immediately archived and available for immediate review and on-line/off-line analysis.

8) Auxiliary space: A separate room with appropriate recording facilities for haemodynamic information along with a microphone system to allow communication between the catheterising physician and the technician.

Disposable equipment

Catheterisation of patients with congenital heart disease requires a large inventory of consumables. Available equipment including sheaths, needles, wires, catheters, occlusion devices and balloons should all be specifically designed for paediatric use. Modification of equipment designed for use in adult patients should only be used where there is no good alternative.

It is absolutely essential that the laboratory has an efficient system for restocking disposables and ensuring that adequate stock levels are maintained. Systems should be in place to ensure that the correct equipment is available before commencing a case.

Radiation protection

Rules relating to the measurement of radiation dosage, the reduction of radiation and maximum radiation protection for the patients as well as the staff in the catheterisation theatres must be strictly enforced. These include protection of the pelvic areas of the patients and protection of the thyroid gland and the eyes of the operators. Fluoroscopy times and radiation doses for the laboratory personnel must be measured, recorded and audited. All operators within the catheter laboratory must have up to date radiation protection training.

General anaesthesia and recovery of patients after procedures

Not every paediatric case requires general anaesthesia but it should be immediately available within the same building in the event of an emergency and should be provided by anaesthetic staff fully trained and competent in the management of paediatric cardiac cases.

Further information on standards for general anaesthesia in children have been published by the Royal college of Anaesthetics and these should be implemented for all paediatric cardiac invasive services.

Recovery of paediatric patients from cardiac catheterisation procedures, either under local or general anaesthetic should be in a separate area from adult patients under the supervision of trained staff with access to piped oxygen, full patient monitoring (ECG, Saturation, blood pressure). The recovery area should to be close to the cardiac catheter laboratory such that the cardiologist and anaesthetist can be accessed quickly in the event of a problem.
Surgical cover

Paediatric cardiac surgical cover should be available for all interventional procedures, including immediate access to cardiopulmonary bypass either in the catheter laboratory or a nearby cardiac operating theatre. It is not usually necessary to have a paediatric cardiac surgeon on standby within the cardiac catheter laboratory, though this can be considered for interventions with a high risk of serious complications. When there is a perceived risk of the need for surgery or haemorrhagic complications occurring, consideration should be given to cross-matching of blood prior to the interventional procedure. As far as possible interventional catheter procedures should take place during normal working hours.

The working group does not feel there is currently evidence to suggest that diagnostic catheterisation requires on-site paediatric cardiac surgical cover and as such these procedures can be carried out in centres equipped to deal with the requirements for general anaesthesia and recovery of these cases along with appropriately skilled paediatric cardiologists and supporting staff without the need for on-site paediatric cardiac surgery. It is essential that diagnostic cardiac catheterisation is not performed in lieu of more appropriate non-invasive investigations.

It is the view of the working group that although there are currently centres who may be able to support diagnostic catheterisation even if surgical cover were removed, it is hard to see how the small (and diminishing) numbers of diagnostic cases required outside of tertiary centres could support the requirements for a long-term paediatric diagnostic catheterisation programme in these centres.

Co-location of other clinical services

Patients undergoing interventional congenital cardiac catheterisation may have multi-system problems. As such there should be co-location of the same clinical services required for paediatric cardiac surgery.

Given the increasing complexity of modern congenital cardiac intervention, not least the frequent use of large bore vascular equipment, the co-location or immediate availability of vascular surgical and radiology services for centres undertaking is extremely important.

Multi-disciplinary clinical meeting

Interventional activity in the catheter lab and decisions on selection of patients is the remit of the department’s MDT meetings. Whilst discussion of each case that is going to be taken to the laboratory may not be necessary, catheter laboratory activity and case mix should be reviewed regularly in an MDT/morbidity/ mortality meeting. However complex, controversial and rare cases should be considered at the MDT with contributions from congenital cardiac surgeon(s), non-invasive congenital cardiologists and experts in congenital cardiac intervention. Strong differences of opinion must be resolved before an elective case is listed, including involvement of the lead for clinical risk at the institution if necessary (or whatever mechanism is appropriate to that centre). Strong differences of opinion in the laboratory at the time of the procedure would be expected to result in a default decision not to intervene, with the case being discussed or re-discussed electively at a later date.

New procedures and implantable devices

New interventional catheter procedures and devices become available over time and tertiary units providing care for these patients are be expected to remain up-to date with developments with the lead interventionalist is taking a central guiding role. Each network providing care for congenital heart disease patients should have clearly defined governance strategies for the evaluation of new procedures. All units where new congenital cardiac catheterisation procedures are to take place should have in place mechanisms to ensure good clinical governance and patient safety. In particular there should be evidence of a robust strategy relating to data recording for procedures and implantable devices that are new to that unit/network.
Personnel

Catheter laboratory staff

In addition to the primary operator and a skilled assistant the following staff are necessary to safely perform congenital cardiac catheterisation:

1) Dedicated and appropriately trained cardiac physiologists responsible for pressure monitoring, saturation and haemodynamic calculations, the maintenance and monitoring of continuous electrocardiogram (ECG) and the maintenance and application of the defibrillator system including remote pads where appropriate.
2) Radiographer; to actively minimise radiation exposure, ensure accurate calibration and angiographic measurements as well as the mandatory calculation of radiation exposure (a requirement of the UK mandatory central cardiac audit database-CCAD).
3) A “running” member of staff, without other duties and with specific knowledge of the location of equipment required in congenital cardiac catheterisation.
4) A nurse with experience of cardiac catheterisation in children.

Medical staff

Training

In the past training programmes for UK specialist registrars in paediatric cardiology included significant exposure to invasive cardiac procedures. Over recent years the UK paediatric cardiology community has actively supported the development of special interest training along a number of different routes after acquisition of training in paediatric cardiology. Those trainees wishing to develop a special interest in paediatric cardiac catheterisation currently require 2 years additional training in an approved post following successful completion of the basic competencies acquired during the 3 years of core training.15 Training requirements may change during the life-span of this document and up-to-date information should be sought on the JCPTB website.15

Whereas in the past most paediatric cardiac units relied on “general” paediatric cardiologists to contribute to the invasive workload and in particular out of hours cover the inevitable consequence of current training is that many newly qualified specialists in paediatric cardiology do not have sufficiently developed invasive skills to contribute to invasive work. This has major implications for the provision of services.

Mentoring and development

Invasive paediatric cardiology is a complex and demanding sub-speciality and as such it is unrealistic for a newly qualified invasive consultant to be fully competent in all aspects of cardiac catheterisation. Therefore a newly qualified consultant (and the department employing them) should expect to be mentored and should work within an invasive team under the direction of a lead interventionalist (see below) whilst additional experience is gained. Ideally, newly qualified consultants would initially share catheter lists with more experienced colleagues gradually performing procedures alone as competencies are obtained and demonstrated. For many interventions it is desirable to have 2 experienced consultants operating together regardless of the experience of the individual operators to maximise patient safety.

Consultants and staffing of invasive services

1) There is mandatory requirement for 24/7 invasive cover of paediatric cardiac patients within a tertiary level (surgical) service. Therefore as a result the minimum number of catheterising paediatric cardiologists to support an invasive programme is 4.
2) Each unit should have a clearly identified lead cardiologist for invasive services. This individual should perform at least 100 cardiac catheterisation procedures per annum on patients with congenital heart disease. This individual should be responsible for the overall
direction of the programme, clinical governance relating to invasive services, and should ensure that all involved with invasive cardiology remain up-to-date as well as overseeing that training requirements for junior cardiology are met.

3) Each other invasive paediatric cardiologist, other than the lead should perform at least 50 audited cardiac catheterisation procedures per annum.

4) It is acceptable for procedures performed jointly to count towards both operators numbers.

Implications for working practices

Current training and working practices will have a significant effect on the provision of invasive paediatric cardiac services in the future. Supporting the minimum numbers of invasive cardiologists required to provide appropriate programmes in the UK will require a significant change to working practices in some units and will require commissioning support. It is possible that rationalisation of paediatric cardiac services may create an environment in which increased case-loads support larger groups of invasive cardiologists within each unit. However the joint working of consultants, not only as a way of ensuring the best results for individual patients but as a mechanism for maximising clinical exposure for specialists should be actively supported both by individual hospital services and their commissioners. Many UK invasive paediatric cardiac services remain viable as a result of procedures performed in adult patients with congenital heart disease. These patients should be treated where they can receive the best possible care and commissioners need to take into account the potential effects on their paediatric cardiac services when commissioning new services from new providers.

Electro-physiology and pacing

Although specifics of practice in this area are beyond the remit of this document, the review group have considered the specific issue of where these procedures in the paediatric age range should be undertaken. It is the view of the BCCA working group that paediatric electrophysiology and pacing procedures like all other invasive cardiac procedures should take place in an environment appropriate for the care of children with congenital heart disease. As such the standards for care (in particular those relating to child appropriate staffing, accommodation, general anaesthesia and recovery) should be the same as for other catheterisation procedures as detailed above.
References

1. Adult congenital heart disease interventions: Recommendations from a joint working group of the British Congenital Cardiac Association (BCCA), British Cardiovascular Intervention Society (BCIS) and the British Cardiovascular Society (BCS).

2. Recommendations of the British Paediatric Cardiac Association for therapeutic catheterisation in congenital heart disease.


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