



GUIDELINE

Cardiac: Management of Balloon Atrial Septostomy (BAS)

Scope (Staff):	Nursing and Medical Staff
Scope (Area):	NICU KEMH, NICU PCH, NETS WA

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this [disclaimer](#)

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Aim

To describe the procedure, roles and responsibilities of the neonatology and cardiology teams when performing a balloon atrial septostomy (BAS) procedure in neonates with congenital heart defects on 3B NICU, PCH.

Risk

Failure to follow this guideline may lead to adverse outcomes for the infant.

Background

- BAS is a procedure that is used to enlarge the foramen ovale to facilitate mixing at the atrial level until definitive surgery can be performed. A catheter is passed through either the umbilical or femoral vein, into the right atrium and through the foramen ovale into the left atrium, using simultaneous echocardiographic control to guide the operator.
- In BAS, a balloon at the end of the catheter is inflated and pulled back into the right atrium, so enlarging the foramen ovale. When this procedure is unsuccessful or contraindicated it may be necessary to transfer the infant to the cardiac catheterisation suite for further intervention to create or enlarge the opening in the atrial septum.
- The main indication for a BAS is for transposition of the great arteries (TGA), the congenital cardiac anomaly in which the aorta arises from the right ventricle and the pulmonary trunk arises from the left ventricle.
- Less commonly, BAS is carried out in children with other cyanotic congenital abnormalities (e.g. some infants with pulmonary atresia, tricuspid atresia).
- The Paediatric Cardiology team at Perth Children's Hospital will assess the infant and determine the need for a BAS. A cardiology consultant or cardiology fellow (under guidance of consultant) will perform the procedure.

Neonatology Team Responsibilities

1. The Consultant Neonatologist on call will be informed and will be in attendance for the BAS. Adequate neonatal staff (medical and nursing) shall be available to manage ventilation and drug administration as well as to open equipment / disposables for the operator.
2. Blood to be sent urgently for: blood gas, full blood count, coagulation profile, urea and electrolytes as well as a cross match to blood bank for 1Unit of PRBC. Please call transfusion to arrange urgent blood to be sent up to the unit.
3. The PRBC need to be available on the NICU prior to the commencement of the BAS. The pack can be kept in the satellite fridge next to PCC.
4. The infant will be kept nil by mouth where possible (non-emergent situation) >3 hours (breast milk) or >4 hours (formula).
5. Two intravenous access sites are required, usually peripheral intravenous cannulae. Avoid the umbilical vessels/ femoral vein as the umbilical and/or femoral vein will be required for the BAS procedure. One site dedicated for the prostaglandin infusion and the other for fluids and other medications.
6. Nurse on an open warmer. Where possible, the procedure should take place in procedure room 11 or 16.
7. Babies will be intubated, ventilated and sedated for BAS procedure. Intravenous sedation / muscle relaxation medication boluses should be available and prepared.

8. Ensure continuous monitoring of the infant, including ECG, pre- and post- ductal saturations, ETCO₂ and BP cuff set to cycle every 2 minutes (preferably on R arm, but not R leg).

Cardiology Team Responsibilities

1. Confirm the diagnosis and the requirement for a BAS. Appropriate discussion and review with a second cardiologist as well as the neonatologist on call. The cardiac surgeon needs to be informed that a BAS is going to be performed and timing discussed re: possible surgical cover if required. Document said discussion in patient notes.
2. The setting for the procedure shall be decided by the cardiologist as follows:
 - a) Bedside procedure if presumed to be straightforward.
 - b) Cath lab for fluoroscopically guided procedure (cardiac anaesthetist present) if complicated procedure predicted: very floppy/redundant inter-atrial septum, unsuccessful bedside procedure, very thick atrial septum.
3. Cardiologist to obtain written, informed consent from the parents / legal guardian and documentation of the consent process must be entered into the patient's medical record.
4. A description of the procedure, indications for the procedure as well as a detailed description of the possible risks shall be outlined.
 - a) The main safety concerns relate to death, failure of the procedure, transient arrhythmias, bleeding from access site(s), vessel trauma with compromise of perfusion to leg(s), embolism (clot and balloon fragments) – including cerebrovascular events, cardiac injury, tamponade.
 - b) Among the identified studies, mortality from the procedure ranged from 2% (2/104, 3/149 to 3% (3/108).
 - c) One study reported a minor complication rate of 10% (26/248) and a lethal complication rate of 1% (3/248).
5. A pre-packed bag of required disposables is available in the cardiology office area on 2C.
6. For details of stock kept in the bag please refer to [appendix 1](#)
 - a) Please keep all packaging to facilitate re-stocking of the disposables used.
 - b) Please ensure re-stocking of disposables used as soon as possible – and no later than the next working day.
 - o Cath lab staff in theatre 7 will assist with this – leave all packaging of disposables used in BAS Procedure.

BAS Procedure

This is a surgical [aseptic technique](#) procedure. Scrub as per [CAHS Scrubbing, Gowning and Gloving Protocol](#). A sterile field should be prepared and draped (Non-iodine containing prep).

Intravenous Access

- If umbilical route to be used – secure the base of the umbilical stump with umbilical tape.
- If femoral access to be used
 - Ultrasound guidance is advisable
 - Adequate local anaesthesia instilled into groin (1% *Lignocaine* 0.1ml/kg 0.2 % *Ropivacaine* 0.5ml/kg).
- BAS Catheters. Balloons are inflated with 0.9% Saline if echo-guided procedure and with dilute contrast (1:5) if fluoroscopic guided procedure performed. At PCH there are two catheter options:
 1. Edwards Lifesciences Fogarty® dilatation catheter
 - 6 Fr sheath with a balloon volume of 1.8ml
 - Has an introducer which should be removed prior to introduction into the patient.
 - Has a “lumen lock” which is engaged following balloon inflation and prior to pull-back and opened for balloon deflation.
 2. Medtronic Rashkind Septostomy catheter®
 - 6 Fr sheath with a balloon volume of 2ml.
 - No “lumen lock” – a 3-way tap will be required to keep balloon inflated during pull-back.

Note: Integrity of balloon must be checked and balloon de-aired before introducing into patient. Check expiry date on packaging.

Step-by-step Technique

1. De-aired balloon catheter passed into IVC, into RA and through PFO into the LA under guidance of the echocardiogram.
2. Inflate the balloon carefully with the appropriate volume of saline (see above) with balloon clearly visible on the echocardiogram.
3. Take special care to avoid the Atrio-ventricular valve, pulmonary veins and the atrial appendages (must be confirmed by echo image prior to the pull-back)
4. Pull the balloon back gently onto the atrial septum (feeling slight resistance as well as clear visualisation on the echo).
5. With a rapid controlled jerk of the balloon the membranous margin of the PFO is torn.
6. Take special care not to pull the balloon into the IVC.
7. If the colour flow on the echocardiogram is deemed inadequate a repeat of the procedure can be performed as above.

Postoperative Care

- Cardiology will reassess the size of the interatrial communication on echocardiogram.
- Ensure continuous monitoring is maintained and observations recorded. Keep saturations within acceptable limits (as set by cardiology team).

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- Perform neurovascular observations of lower limbs. Inform cardiology of discolouration coolness and / or decreased pulses.
- If femoral venous access was used, elevate the leg slightly. The leg may appear suffused and mildly oedematous for 24-48 hours after the procedure. Please discuss with cardiologist if concerned.
- Observe for signs of bleeding from the access site (umbilical or femoral). Apply pressure as required and inform Cardiology of any excessive bleeding.
- Aim to discontinue sedation and if infant was intubated for the procedure extubate when clinically appropriate. **NOTE**: The infant should not be in pain once the catheter is removed so ongoing analgesia/ sedation is not required unless for other purposes. Discuss with the on-call neonatologist.
- Review the need for continued prostaglandin (PGE1) infusion with the cardiology team.


Related CAHS internal policies, procedures and guidelines

CAHS Perioperative Protocol - [Surgical Hand Antisepsis \(scrubbing\)](#), [Gowning and Gloving](#)

References and related external legislation, policies, and guidelines

1. Allen HD, Beekman III RH, Garson A, Hijazi ZM, Mullins C, O’Laughlin MP, Taubert KA. Pediatric Therapeutic Cardiac Catheterization: A Statement for Healthcare Professionals From the Council on Cardiovascular Disease in the Young, American Heart Association. *Circulation*. 1998; 97:609-625.
2. Pihkala J, Nykanen D, Freedom RM, Benson LN. Interventional Cardiac Catheterization. *Pediatric Clinics of North America*. Apr 1999; 46(2): 441-464.
3. Lock JE, Keane JF, Perry SB editors. *Diagnostic and Interventional Catheterization in Congenital Heart Disease*. Kluwer Academic Publishers. c. 2000. Pg 245-248.
4. Rudolph AM. *Congenital Diseases of the Heart: Clinical-Physiological Considerations*. Futura Publishing Company Inc. c. 2001. Pg 728-729.
5. McQuillen PS, Hamrick SE, Perez MJ, Barkovich AJ, Gliddent DV, Karl TR, Teitel D, Miller SP. Balloon atrial septostomy is associated with preoperative stroke in neonates with transposition of the great arteries. *Circulation* 2006 Jan 17;113(2):280-5

This document can be made available in alternative formats on request.

Document Owner:	Neonatology		
Reviewer / Team:	Neonatology and Cardiology		
Date First Issued:	Oct 2019	Last Reviewed:	May 2024
Amendment Dates:	Ownership and endorsement of this guideline changed from Cardiology to NCG. Title changed from Management of Balloon Atrial Septostomy for Congenital Heart Defects in the Neonatal Intensive Care Unit.	Next Review Date:	28 th May 2027
Approved by:	Neonatology Coordinating Group	Date:	28 th May 2024
Endorsed by:	Neonatology Coordinating Group		
Standards Applicable:	NSQHS Standards:  Child Safe Standards: 1,10		

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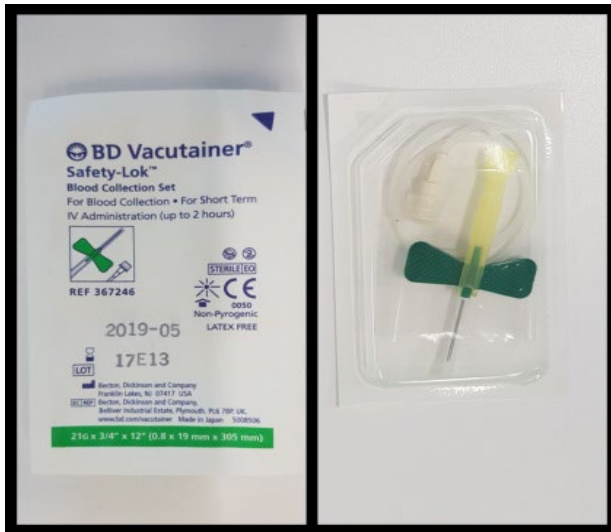
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Appendix 1: Equipment and Location

Disposables are kept in Office 2C for after-hours use:



21 G “butterfly” needle -X2

- 0,018” wire required if using for vascular access



Vygon ® arterial leadercath-X2

- Includes 0.018” wire as well as 20 G access needle



7F Radiofocus ® Introducer sheath- X2

- Set includes Sheath and dilator, 0.025” Terumo® wire and 20G cannula
- Sheath to be flushed and 2 way tap closed prior to commencing vascular access



6F Radiofocus ® Introducer sheath- X2

- Set includes Sheath and dilator, 0.025” Terumo® wire and 20G cannula
- Sheath to be flushed and 2 way tap closed prior to commencing vascular access

Edwards Lifesciences 5F (1.67mm) Atrioseptostomy catheter – X2

- Requires 6F introducer sheath
- Remove introducer prior to inserting catheter into patient
- Maximum volume of saline – 1.8ml



Medtronic 6F Rashkind Balloon Septostomy Catheter X2

- Requires 6F introducer sheath (may be a tight fit, easily passes through 7F introducer sheath)
- Requires 3-way tap to keep balloon inflated on pull-back
- Maximum volume of saline into balloon - 2ml

