

# BALLOON ATRIAL SEPTOSTOMY PERFORMED IN GCNC - CHW

## PRACTICE GUIDELINE<sup>®</sup>

### DOCUMENT SUMMARY/KEY POINTS

- Neonates with Transposition of the Great Arteries (TGA) may require an emergency balloon atrial septostomy (BAS) at the bedside under echocardiographic (ECHO) guidance.
- The need for a BAS will be decided by the on-call cardiology team and may occasionally include neonates with other complex cardiac conditions.
- All equipment to be prepared and ready by nursing staff when requested.
- The Blue Balloon Septostomy Trolley is restocked after each procedure and left ready in the storeroom.

### CHANGE SUMMARY

- The catheter equipment table and stock checklist have been changed to reflect current stock and processes.
- 23/02/24: Minor review
  - Updated unapproved drug names to align with international harmonisation of medication names (lidocaine and sodium chloride)
  - Removal of error-prone abbreviations

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

<b>Approved by:</b>	SCHN Policy, Procedure and Guideline Committee	
<b>Date Effective:</b>	1 <sup>st</sup> January 2024	<b>Review Period:</b> 3 years
<b>Team Leader:</b>	CNE	<b>Area/Dept:</b> GCNC

## READ ACKNOWLEDGEMENT

- All clinicians working in Grace Centre for Newborn Intensive Care are required to read a hard copy of the guideline which will be available in the unit and sign in order to verify reading guideline.
- Notification of the revised policy will be communicated to staff via the units Clinical Practice review Forum.

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## Introduction

D-transposition of the Great Arteries (d-TGA) is one of the most commonly diagnosed cyanotic congenital heart disease in the neonatal period<sup>1,2</sup>. d-TGA is a congenital heart defect where the aorta and the pulmonary arteries are transposed. This results in two separate parallel circulations, one pulmonary and one systemic which after birth rely on a degree of mixing either at the atrial level via patent foramen ovale (PFO) or atrial septal defect (ASD) and/or at the ventricular level via a ventricular septal defect (VSD) in order to provide oxygenated blood to the systemic circulation<sup>6</sup>.

Following birth with known d-TGA or a postnatal diagnosis, fetal circulation can be maintained using a prostaglandin E1 (Alprostadil) infusion<sup>2</sup> typically commenced at 5-10 nanogram/kg/min to maintain ductal patency and facilitate mixing at the atrial level. Despite excellent corrective surgical outcomes, there continues to be significant preoperative morbidity and potential mortality due to cardiovascular compromise<sup>1</sup>, primarily due to restriction in oxygenated blood flow.

After birth, the foramen ovale reduces in size which further decreases the oxygenated blood available for systemic circulation. This may not be responsive to prostaglandin-enhanced left atrial filling, and therefore, the infant becomes more hypoxic, requiring a balloon atrial septostomy (BAS).

BAS is an endovascular or catheter technique for enlarging the foramen ovale communication between the left and right atrium<sup>3</sup>. It is primarily used for preliminary improvement or stabilisation of oxygenation primarily in infants with d-TGA pending corrective surgery, usually within one week of birth. However, the procedure can be beneficial for selected patients with other defects where atrial septal mixing optimises oxygenation or circulation (e.g. hypoplastic left heart syndrome).

The aim of this procedure is to create an adequate communication between the right and left side of the heart to facilitate mixing of blood to provide oxygen delivery systemically<sup>5-7</sup>. This procedure is usually performed as an emergency procedure at the bedside with ultrasound guidance but can also be performed in the cardiac catheter laboratory.

**For some infants, a BAS may be an emergency procedure performed immediately when the infant arrives on the unit. In situations with marked hypoxaemia, it is a life-saving procedure that may be required prior to obtaining parental consent.**

## Balloon Atrial Septostomy

A BAS in the newborn may be performed either within the catheter laboratory under angiographic guidance or within the neonatal intensive care using echocardiogram guidance, with the latter being more frequent<sup>8</sup>. The procedure is now performed most commonly via the femoral vein, however, the Cardiology team should be consulted prior to umbilical catheters being inserted to confirm that the umbilical route is not being utilised for BAS.

### Admission to Ward

- A senior medical officer at Westmead Hospital will notify the on-call consultant cardiologist when delivery of an infant with TGA is imminent or planned. The Grace Centre for Newborn Intensive Care will be notified via the standard group paging system and via a phone call to the on-duty Nursing Unit Manager (NUM) in Grace. The high-risk obstetric admission algorithm for infants with congenital heart disease is utilised, including an individualised Neonatal Care Plan.
- If there is significant hypoxaemia at Westmead Hospital (oxygen saturations persistently <70% after stabilisation in the delivery room), the on-call consultant Neonatologist in Grace and the on-call cardiologist should ideally be notified by a phone call from a senior medical officer from Westmead Hospital, in addition to notification of the Grace duty NUM by the Westmead NICU Team Leader or NUM.
- The consultant neonatologist and cardiology team should be notified immediately when the infant arrives in GCNIC.
- Prepare a bed space that is fully accessible and if possible, has vacant bed spaces on either side of the allocated bed space to allow room for the procedure.
- See policy: [Admission and Discharge Criteria to the Grace Centre for Newborn Care - CHW](#)
- Ensure BAS trolley and emergency trolley is fully stocked and ready for use prior to patient's arrival.

### Preparation for procedure

#### **Parental Consent**

Written consent is obtained prior to the procedure from a parent or legal carer by the cardiology team (preferably the cardiologist performing the procedure). In the case of an emergency, phone consent should be obtained wherever possible.

#### **Pre-procedural observations**

Baseline observations of heart rate, respiratory rate, oxygen saturations, blood pressure, blood sugar levels, urine output, and pain assessment are documented prior to the procedure.

**Pre-procedural tests and interventions**

- Echocardiogram
- Blood gas – on admission or within 1-2 hours prior to procedure
- Full blood count, group and hold including a maternal blood sample – results not required prior to BAS but generally performed on admission for all newborns with congenital cardiac disease
- IV cannula in place for procedure
- Infant is typically intubated and mechanically ventilated for analgesia, muscle relaxation and to facilitate the procedure, particularly where the procedure is performed via the femoral vein
- Sedation with intravenous morphine is commenced and the infant should be muscle-relaxed immediately prior to the procedure if requested by the cardiologist.

**Procedure**

- BAS is organised in consultation with the neonatologist and cardiologist. The family is informed when the time has been confirmed. Where possible, the procedure is performed within business hours to reduce complication rates<sup>9</sup>.
- The procedure is performed by a paediatric cardiologist and/or fellow.
- The Neonatologist, Neonatal Fellow or Nurse Practitioner assists with management of mechanical ventilation.
- The assigned nurse must be at the neonate's bedside during the procedure, assessing signs of the infant's pain and level of sedation, and assisting with positioning and mechanical ventilation as required.
- Ongoing assessment of vital signs is required.
- A second nurse must be available to assist the cardiologist in a scout role.
- After obtaining vascular access via the available route with an appropriately sized catheter, a balloon catheter is advanced into the right atrium through the inferior vena cava.
- From the right atrium, the catheter enters the left atrium through a restrictive communication. The balloon is inflated to manufacturer specifications and following correct position confirmation (using fluoroscopy or echocardiography guidance), with a short and quick movement the inflated balloon is passed into the right atrium (where it is immediately deflated)<sup>8</sup>. This may be repeated several times if required. This is designed to create an atrial communication in TGA that will enhance bidirectional mixing of pulmonary and systemic venous blood, hence improving oxygen saturation<sup>10-11</sup> and cerebral perfusion<sup>12</sup>.
- An echocardiography outcome is verified by an assessment of the measurement of the intra-atrial communication, including Doppler flow characteristics.

**Equipment**

1. Echocardiography machine (arranged by cardiology)
2. Dressing trolley and clear sterile drape
3. Zoll Defibrillator, checked for use and on standby. Ensure correct size defibrillator pads, in date.  
See policy: [Cardiopulmonary Resuscitation and Equipment](#)
4. BAS Trolley common equipment required (refer to equipment table for more information):
  - i. Sterile gowns and gloves, cap, and mask (for each proceduralist)
  - ii. Balloon septostomy venous catheter tray
  - iii. Intravenous (IV) cut-down tray + Lidocaine 1% ampoule (for femoral access)
  - iv. Umbilical tie, scalpel/blade, suture material (for umbilical access)
  - v. Numed Z-6 Atrioseptostomy Catheters – sizes 4F/9.5mm & 5F/13.5mm (located in Catheter Lab)
  - vi. Arterial Sheaths – Terumo 5F / 6F / 7F sheaths & Cordis 8F sheaths
  - vii. Selection of guide wires (refer to stock list)
  - viii. 12cm Safeguard Pressure Assist Device
  - ix. Sterile ultrasound probe transducer covers – 1 'hockey stick' probe cover for vascular access and another ultrasound probe cover for the echo transducer
  - x. Dressing pack
  - xi. Large and small green drapes
  - xii. Syringes 2mL, 5mL, 10mL
  - xiii. Blunt needles
  - xiv. Aqueous chlorhexidine 0.1%
  - xv. Sodium chloride 0.9% ampoules
  - xvi. Heparinised saline 50 International Units /5mL
  - xvii. UAC, UVC lines and 5F NGT may be used
5. A full surgical thoracotomy set is available from PICU if required.

*Individual cardiologists may request equipment in addition to the list above.*

**Pain relief**

- All infants are given 50-100microgram/kg of IV morphine prior to the procedure. A continuous morphine infusion is administered and titrated as appropriate.
- If the neonate is muscle relaxed, the heart rate and blood pressure are monitored to assess pain. Have 2 doses of muscle relaxation drawn up in case an additional dose is required during the procedure.
- See policy: [Pain Management in Newborn Infants - CHW](#)

**Privacy**

Visitors and other parents located near the infant are asked to leave the immediate area for the duration of the procedure. A privacy screen should be placed around the bed space.

**Post-Procedure**

A successful BAS should result in increased intra-atrial mixing of blood resulting in an increased PaO<sub>2</sub> and an increase in oxygen saturations. Intravenous prostaglandin may be reduced or discontinued following the procedure on the advice of the cardiologist and neonatologist. If clinically appropriate, intravenous sedation is weaned and extubation is performed pending timing of an arterial switch procedure and any associated comorbidity.

It is not uncommon, however, for the oxygen saturation to fall over subsequent days. The target saturation level for the infant is prescribed by the cardiologist to identify when there is a need for cardiology consultation and possible adjustments in treatment including recommencing prostaglandin. These levels are documented in the electronic medical record (eMR) and at the bedside.

**Observations**

- Arterial blood gas – attend immediately post-procedure then as guided clinically or requested by neonatologist.
- Complete physical assessment.
- Continuous cardio-respiratory and oxygen saturation monitoring.
- Blood pressure – usually continuous via invasive line. If invasive monitoring is not available, non-invasive blood pressure assessment should at least be documented hourly for four hours and then every four hours ongoing
- Monitor the axillary temperature every four hours and continuously monitor skin temperature.
- Neurovascular observations on lower limbs (for umbilical access) and affected limb (for femoral access). Every fifteen minutes for one hour, then every 30 minutes for two hours, hourly for a further two hours, and four hourly for at least the next 24 hours<sup>13</sup>.
- Assess site for bleeding and formation of a haematoma. For femoral access, the dressing should remain intact for at least 24 hours or on specific advice from the interventional cardiologist.

- Urine output – target >1mL/kg/hour, although this will be impacted by postnatal evolution of renal function (especially if BAS is performed at less than 24 hours old)
- Observe for signs of abdominal distension or tenderness that could suggest internal bleeding/extravasation.
- Undertake pain assessment four hourly (or more if clinically indicated) using the M-PAT and document scores in the eMR.

### ***Restocking after BAS procedure***

The nurse caring for the infant is responsible to ensure the BAS trolley is restocked at the completion of the procedure including:

- Dirty instruments are returned to CSSD or steel recycling (where appropriate) and a replacement pack is obtained
- Instructions on where to obtain additional stock can be located on the BAS checklist
- Do not add more items to the draw than what is listed on the trolley checklist
- The cardiology team records the procedure on PedCath and notifies the cardiac physiologist of the septostomy catheter used for the procedure
- The responsibilities of restocking is highlight in the BAS checklist below

### ***Checking BAS Trolley***

- The BAS trolley is checked each week by nursing staff
- The task is allocated via the NUM or Team Leader in the allocation book a signature in the allocation book is required to demonstrate the trolley has been checked
- If the trolley has a secure tag in place that is not broken the contents are considered complete. Document in the allocation book the serial number of the tag and sign that the check has been completed.
- If there is not a tag in place the trolley contents are required to be checked and a new tag applied to the trolley. Document the new tag number and sign to indicate the check has been completed in the allocation book.
- In the event stock is required that is not stored in GCNIC contact: cardiac physiologist for catheter items
- The stock items highlighted in RED are checked each week by a physiologist from Cardiology and replenished as necessary
- In the event stock is required that is not stored in GCNC contact cardiac physiologists for catheter items



## Safety Considerations




Placement of umbilical venous catheters in infants with unrepaired TGA should be considered with caution due to the risk of intracranial bleeding.



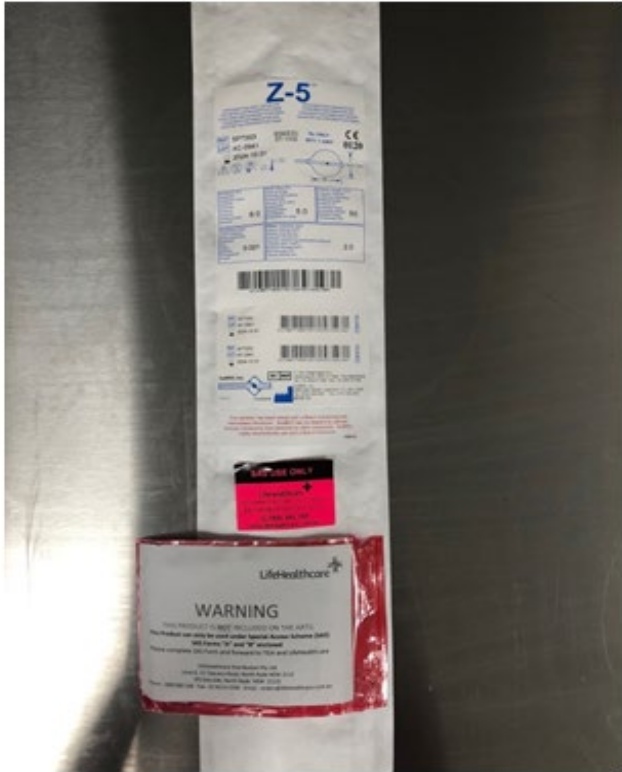
### Complications

Complication	Signs	Action
<b>Bleeding/haematoma</b>	<ul style="list-style-type: none"> <li>Oozing from site</li> <li>Haematoma</li> <li>Hypertension</li> </ul>	<ul style="list-style-type: none"> <li>Place pressure over site</li> <li>Alert medical staff</li> </ul>
<b>Thrombosis</b>	<ul style="list-style-type: none"> <li>Poor perfusion</li> <li>Cool peripheries</li> <li>Absent pedal pulse/s</li> <li>Pale lower limbs</li> <li>Limb puffiness/congestion</li> </ul>	<ul style="list-style-type: none"> <li>Alert medical staff</li> <li>Consider heparin infusion</li> </ul>
<b>Arrhythmias</b>	<ul style="list-style-type: none"> <li>Sinus bradycardia</li> <li>Ventricular tachycardia</li> <li>Ventricular fibrillation</li> </ul>	<ul style="list-style-type: none"> <li>Alert medical staff</li> <li>Defibrillation</li> </ul>
<b>Cardiac Tamponade</b>	<ul style="list-style-type: none"> <li>Hypotension</li> <li>Tachycardia</li> <li>Tachypnoea</li> <li>Cool and sweaty</li> <li>Decreased oxygen saturation</li> <li>Cardiac arrest</li> </ul>	<ul style="list-style-type: none"> <li>Medical emergency</li> <li>Pericardial drainage</li> </ul>
<b>Cerebral Vascular Accident<sup>4</sup></b>	<ul style="list-style-type: none"> <li>Decreased level of consciousness</li> <li>Balloon catheter not intact</li> </ul>	<ul style="list-style-type: none"> <li>Alert medical staff</li> </ul>
<b>Increased length of hospital stay<sup>4</sup></b>	<ul style="list-style-type: none"> <li>Up to two-fold length of stay</li> </ul>	

## Equipment Utilised During Balloon Atrial Septostomy

It is important for nurses and to become familiar with equipment used in BAS procedures some of the items are listed below:

Item	Image	Location
<p>Coronary Guide Wires</p>		<p>Drawer 3</p>
<p>Terumo Angled Glidewire</p> <p>Cook Std Guide Wire</p> <p>Arrow Short Guide Wire</p>		<p>Drawer 3</p>
<p>Terumo Arterial Sheath</p> <p>6F (also 5F 7F &amp; 8F)</p>		<p>Drawer 4</p>

<p>Cordis Arterial Sheath</p> <p>8F</p>	 <p>The image shows two items: a clear plastic tray containing a blue Cordis arterial sheath and its associated components, and a white sterile packaging bag for the sheath. The bag is labeled '11 cm 0.037" 8F' and 'Cordis'.</p>	<p>Drawer 4</p>
<p>Ultrasound Transducer Probe Cover (2 styles)</p>	 <p>The image shows two items: a white sterile packaging bag for a 'CIVICO Easy-Shear™ Transducer Cover' and a blue probe cover inside a clear plastic bag.</p>	<p>Drawer 6</p>
<p>Numed Z-5 Septostomy Catheter</p> <p>4F/9.5mm &amp; 5F/13.5mm</p>	 <p>The image shows a white sterile packaging bag for a 'Z-5' catheter. A red and white warning label is attached to the bottom of the bag, with the text 'WARNING' and 'LIFEHEALTHCARE'.</p>	<p>Supplied by Interventional Cardiology Service</p> <p>Located in glass cupboard within Cardiac Catheter Lab</p>

**BAS Trolley Checklist**

<b>Drawer</b>	<b>Contents</b>	<b>Number</b>
<b>1 Syringes and injectables</b>	3mL luer lock syringes	4
	5mL non- luer lock syringes	4
	18G needles	4
	19G needles	4
	21G needles	4
	25G needles	4
	3-way taps	2
	Heparinised saline 5mL	4
	0.9% sodium chloride 10mL	4
	Xylocaine 1% ampoules	2
	Red caps	4
	Filters	2
	Chooks foot	2
	Blunt needles	2
	Alcohol wipes	5
	Water for injection	4
<b>2 Dressing equipment</b>	Small tegaderm dressing	4
	Steri strips	4
	Gauze squares	10
	Umbilical tapes ½" (2); ¼" (2); 2/30" (1)	2
	Cotton balls	10
	Small leucoplast	1
	Large leucoplast	1
	Cord clamp cutter	2
	Suture material (3-0 & 4-0)	2
	Disposable scalpel	4
	Stitch cutter	4
	Aqueous chlorhexidine	4
	Iodine	1
	12cm SafeGuard Pressure Device	2
<b>3 Cardiac Catheter preparation</b>	<i>Insite 20G cannula</i>	4
	<i>Insite 22G cannula</i>	4
	<i>Insite(medicut) 18</i>	4
	<i>0.018 Cook Std guide wire</i>	2
	<i>0.021 Cook Std guide wire</i>	2 (1 x 50cm & 1 x 145cm)
	<i>0.025 Cook Std guide wire</i>	2
	<i>0.035 Cook Std guide wire</i>	2
	<i>0.018 Arrow guide wire</i>	5
	<i>0.018 Terumo Angled wire</i>	2
	<i>0.025 Terumo Angled wire</i>	2
	<i>0.035 Terumo Angled wire</i>	2
	<i>0.018 Platinum Plus wire</i>	2
	<i>0.014 Asahi Sion Blue wire</i>	2
	<i>0.014 Hi Torque BMW wire</i>	2
<i>NG tubes (Green)</i>	Unable to be restocked	

<b>4</b> <b>Cardiac catheterisation</b>	<i>Terumo 5Fr sheath</i>	2
	<i>Terumo 6Fr sheath</i>	3
	<i>Terumo 7Fr sheath</i>	3
	<i>Cordis 8Fr Sheath</i>	3
<b>5</b> <b>Surgical/ procedural equipment</b>	Umbilical cut down tray	2
	Septostomy tray	2
	Leg stabiliser	1
<b>6</b> <b>Sterile preparation</b>	Sterile gowns	3
	Clear sterile sheet	2
	<i>Surgiboot Probe cover</i>	4
	<i>Small Probe cover</i>	2
	Fenestrated drape	3
	Minor procedure drape	3
	Sterile gloves; size 6-8	2 of each size
	Face masks	3
	Hats	3
Dressing pack	4	

Items highlighted in *red* require re-stocking from the cardiac catheter laboratory.

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