<table>
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<tr>
<th><strong>Title:</strong></th>
<th>Guideline for the management of Patent Ductus Arteriosus (PDA).</th>
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<tbody>
<tr>
<td><strong>Reference Number</strong></td>
<td>GL-ODN-09</td>
</tr>
<tr>
<td><strong>Main Author (s)</strong></td>
<td>North West, North Wales &amp; Isle of Man Children’s Heart Network with comments from all NW neonatal clinical leads</td>
</tr>
<tr>
<td><strong>Target Audience</strong></td>
<td>NWNODN clinicians</td>
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<td><strong>Ratified by:</strong></td>
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<td><strong>Date Ratified:</strong></td>
<td>31st July 2020</td>
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<td>Ratified</td>
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<th>Author</th>
<th>Notes</th>
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<td>2019</td>
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</table>
Management of Patent Ductus Arteriosus

Background

The ductus arteriosus closes spontaneously in many preterm infants but prolonged ductal patency is a complication of extreme preterm birth [1]. A persistently patent ductus with a large ductal shunt (a 'haemodynamically significant', hsPDA) is associated with pulmonary hyper-perfusion, systemic hypo-perfusion and adverse clinical outcomes including pulmonary haemorrhage, NEC, CLD and mortality [2].

Which babies should undergo echocardiography?

An echocardiogram should be performed in any preterm baby in whom the clinical signs and/or radiological features suggest the presence of a hsPDA. These include murmur, tachycardia, full pulses, an active praecordium, hypotension, cardiomegaly, worsening respiratory status and dependence on respiratory support.

Diagnosis of hsPDA

Diagnosis of PDA can only be made using 2D and Doppler echocardiography; clinical signs are unreliable and should not be used in isolation to make the diagnosis. Early echocardiographic ‘screening’ for PDA is not routinely performed. Diagnostic echocardiography should include an initial assessment to exclude structural heart disease and, specifically, duct-dependent cardiac defects.

Assessment of hsPDA should include measures of ductal size and the magnitude and impact of the ductal shunt. The following echocardiographic indices and thresholds should be used to define a hsPDA [3]:

1. PDA diameter > 2.0 mm (either using 2D or colour Doppler)
2. Ductal flow pattern ('growing' pattern or pulsatile with Vmax < 2 m/s and Vmax/Vmin > 2)
3. Retrograde post ductal aortic/coeliac/SMA diastolic flow
4. La/Ao ≥ 2
5. LVO > 300 ml/kg/min
6. Mitral valve E/A ratio > 1

The diagnosis of hsPDA should be made in the presence of supportive clinical signs and at least 3 of the above echo indices.
Management of babies with PDA

a. **Babies with PDA and a small ductal shunt** (i.e. not haemodynamically significant) should be managed expectantly. A repeat echo should be performed if the baby has a cardiorespiratory deterioration or if a murmur is still present prior to discharge home. Refer to cardiology if PDA is still present at discharge.

b. **Asymptomatic babies with echocardiographic criteria of hsPDA** should also be managed expectantly, but with a low threshold for repeating the echo if the baby develops any symptoms of hsPDA. Subsequently, management should follow (a) or (c), as appropriate.

c. **Symptomatic babies* with a hsPDA** may be treated with diuretics, ibuprofen and/or paracetamol (see below).

*Clinical features include persistent hypotension, pulmonary haemorrhage, prolonged dependence (or increase in) invasive or non-invasive respiratory support, feed intolerance.

Management strategies/therapeutic interventions (see appendix 1)

**Expectant management**
This approach is used when uncomplicated spontaneous closure of the ductus arteriosus is anticipated. Management is the same as in a baby in whom the PDA is closed.

**Non-pharmacological intervention**
Although there is no clear evidence of clinical efficacy, various approaches including fluid restriction, increasing PEEP, permissive hypercapnia, maintaining a high haematocrit and higher target SpO2 (89-94%) have all been used as part of a ‘conservative’ approach to managing a hsPDA [4].

**Action:**
- Follow current unit guidelines for fluid, blood transfusion and oxygen and respiratory support;
- Give information leaflet on PDA to parents.

**Diuretic therapy**
There is some evidence that furosemide stimulates renal synthesis of prostaglandin E2 (a dilator of the ductus arteriosus) and delays ductal closure. The risk of PDA is greater with furosemide compared with chlorothiazide. Furosemide is associated with nephro- and ototoxicity.

**Action:**
- Use chlorothiazide (and not furosemide) for management of PDA-associated left heart volume overload and pulmonary oedema.
Pharmacological closure

Although pharmacological closure of the DA is associated with decreased severe IVH and pulmonary haemorrhage, there is no convincing evidence of longer-term benefit from randomised controlled trials [5]. A conservative management approach might also be superior to early routine treatment in babies dependent on respiratory support [6].

a. Ibuprofen

Ibuprofen is effective in achieving ductal closure in around 70-80% of cases [7, 8]. There is some evidence that oral therapy and higher dosage regimens are associated with higher closure rates [7-9].

<table>
<thead>
<tr>
<th>Action:</th>
</tr>
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<tbody>
<tr>
<td>- Use standard dose ibuprofen (3 doses of 10, 5, 5 mg/kg at 24 hourly intervals) as routine first-line pharmacological treatment of hsPDA in babies &lt; 21 days of age;</td>
</tr>
<tr>
<td>- Use oral (rather than IV) ibuprofen if baby is receiving full enteral feeds;</td>
</tr>
<tr>
<td>- Re-assess the ductus arteriosus and ductal shunt after 3 days;</td>
</tr>
<tr>
<td>- A second course of high dose ibuprofen (3 doses of 20, 10, 10 mg/kg at 24 hourly intervals) can be considered if baby is still under 21 days of age.</td>
</tr>
</tbody>
</table>

b. Paracetamol (acetaminophen) (see appendix 3 for sample drug information sheet)

Paracetamol has comparable efficacy to ibuprofen in ductal closure but there is limited information on long-term safety [10]. There is some evidence to support the use of paracetamol in late treatment of PDA after failure of previous NSAID therapy, although the efficacy in achieving ductal closure was only 15% [11].

<table>
<thead>
<tr>
<th>Action:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Consider using paracetamol to treat hsPDA in babies ≥ 21 days of age, or in babies &lt; 21 days in whom there are contraindications to using ibuprofen (refer to drug information folder);</td>
</tr>
<tr>
<td>- Reassess the ductus arteriosus and ductal shunt after 3 days.</td>
</tr>
</tbody>
</table>

Surgical closure

Surgical closure should be considered in babies with hsPDA despite pharmacological therapy (or in whom pharmacological therapy is contraindicated) who remain dependent on high levels of respiratory support (ventilation, CPAP or HFNC). Duct ligation carries significant risks associated with transfer, surgery and post-operative complications (such as post-ligation cardiac syndrome) [12]. Catheter closure might be appropriate in selected larger babies (≥ 6 kg) at the discretion of the cardiologists.

<table>
<thead>
<tr>
<th>Action:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Consider duct ligation in babies with hsPDA who are dependent on high levels of respiratory support (ventilation, CPAP or HFNC) .</td>
</tr>
<tr>
<td>- A consultant-to-consultant referral should be made to the cardiology team verbally and using the cardiac surgery proforma (appendix 2);</td>
</tr>
<tr>
<td>- A pre-op echo should be performed within 3 days of transfer to confirm that a hsPDA is still present.</td>
</tr>
</tbody>
</table>
Appendix 1

Signs suggestive of PDA

Echo to exclude structural cardiac defect and assess ductal patency and haemodynamic significance

Duct closed

Small PDA (not haemodynamically significant)

Expectant management

Re-echo if cardiorespiratory deterioration or at discharge (if murmur present)

Refer to cardiology if PDA still present at discharge

Haemodynamically significant PDA (hsPDA)

Asymptomatic

Symptomatic*

< 21 days

≥ 21 days

Contraindication to ibuprofen?

No

Ibuprofen (max. two courses)

Re-echo after 3 days

hsPDA still present and baby symptomatic?

Yes

Paracetamol (max. two courses)

Paracetamol (one course only)

Refer for surgical closure

* Consider diuretics in babies with echo evidence of left heart volume overload
Appendix 2: Cardiac Surgery Referral Form for PDA ligation

**Please fax this form back to Alder Hey Hospital, Cardiac Surgical Department on: 0151 252 5643**

---

### Cardiac Surgery Referral Form

**ALDER HEY CHILDREN’S NHS FOUNDATION TRUST**

**Cardiac Directorate - PDA Transfer Form**

<table>
<thead>
<tr>
<th>FAX TRANSMISSION FOR THE URGENT ATTENTION OF:</th>
<th>TELEPHONE NUMBER:</th>
<th><strong>FAX NUMBER: DATE:</strong></th>
</tr>
</thead>
</table>

**Please complete accordingly and fax back to 0151 252 5643 at least 12 hours prior to transfer of patient**

<table>
<thead>
<tr>
<th>Name:</th>
<th>DoB: ........../........./....... Sex:</th>
<th>NHS Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>Ward: ..................................</td>
<td>Referring Hospital:</td>
</tr>
<tr>
<td>................................................</td>
<td>Gestation Age: ..........</td>
<td>Referring Consultant:</td>
</tr>
<tr>
<td>................................................</td>
<td>Birth Weight: ................</td>
<td>Registrar:</td>
</tr>
<tr>
<td>Postcode: .................................</td>
<td>Current Weight: ..................</td>
<td>Named Nurse: ...............</td>
</tr>
</tbody>
</table>

---

### INDICATIONS FOR PDA LIGATION

[Details of indications will be filled in later]

---

**Referring Hospital must give latest results (24-48 hours old)**

**DATE DONE:**

---

### FULL BLOOD COUNT

<table>
<thead>
<tr>
<th>Hb:</th>
<th>CREAT:</th>
</tr>
</thead>
</table>

**RENAL PROFILE**

<table>
<thead>
<tr>
<th>Wcc:</th>
<th>Urea:</th>
</tr>
</thead>
</table>

**CLOTTING**

<table>
<thead>
<tr>
<th>Platelets:</th>
<th>Na:</th>
<th>K:</th>
</tr>
</thead>
</table>

**CRP:**

<table>
<thead>
<tr>
<th>PT:</th>
<th>BLOOD GROUP:</th>
</tr>
</thead>
</table>

**OTHER:**

**INR:**

**Fibrinogen:**

---

- Infection Concerns (please state): .......................................................... CONFIRMED: YES / NO
- Does the patient have a known Blood Group? If YES please fax the report to Alder Hey Transfusion Department ensuring that four patient identifiers (i.e. NHS No, Name, DOB) are included on the fax. CONFIRMED: YES / NO
- **THERE IS NO LONGER ANY NEED TO TRANSFER ANY BLOOD PRODUCTS WITH THE PATIENT**
- The child’s parent(s) must accompany the child to Alder Hey to sign Consent Form, arriving no later than 8am. CONFIRMED: YES / NO
- If parents arrive later than 8am this may result in surgery being delayed or cancelled
- Is the child going back to the referring hospital on the same day (i.e. round trip)?
- Is the referring hospital hospital mised with Liverpool Women’s Hospital to ensure they are able to take the child post-operatively. The LWH will collect the child from Alder Hey. CONFIRMED: YES / NO

### PRE-OPERATIVE CHEST X-RAYS MUST BE NO GREATER THAN 24 HOURS OLD ON THE DAY OR SURGERY

- Please upload the most recent chest X-Ray to the Alder Hey PACS System for viewing prior to surgery. Please mark these as ‘Pre Cardiac Surgery’ at the time of upload: CONFIRMED: YES / NO

### NOTE TO THE REFERRING HOSPITAL:

**PLEASE ENSURE YOU TELEPHONE THE INTENSIVE CARE UNIT ON THE MORNING OF TRANSFER & PRIOR TO DEPARTURE TO CONFIRM BED AVAILABILITY / OPERATION. DIRECT LINE: 0151 252 5242/ 5241**

### OTHER INFORMATION

---

### FOR AH USE ONLY:

- Inform ITU of patient. Spoke to ........................................... CONFIRMED: YES / NO
- Inform Consultant on-call for day of admission for echo. Dr .................................. CONFIRMED: YES / NO
- Transfusion Department informed.
- Alder Hey Unit number & casenotes made up (AH ........................................ ) CONFIRMED: YES / NO

Date of referral: ........................................ Date of transfer: ................................ Proposed Date of Surgery: ........................................
Appendix 3: Sample Ibuprofen Drug Information Summary (LWH, May 2020)

**IBUPROFEN**

<table>
<thead>
<tr>
<th>INDICATION:</th>
<th>Treatment of haemodynamically significant patent ductus arteriosus (PDA) confirmed by ECG examination in neonates &lt;34 weeks gestational age.</th>
</tr>
</thead>
</table>

**BACKGROUND**

Ibuprofen is a non-steroidal anti-inflammatory drug with anti-pyretic and analgesic effects. It interferes with prostaglandin synthesis through cyclo-oxygenase inhibition. Ibuprofen has less of an effect on organ perfusion as compared to indomethacin. Ibuprofen may inhibit platelet aggregation and increase bleeding time.

**PRESENTATION**

2mL ampoule containing 10mg Ibuprofen Pedea® (5mg/mL)

pH 7.8 – 8.2

**DOSE:**

Initial (loading) dose of **10 mg/Kg** by IV infusion over 15 minutes followed at 24 hourly intervals by two further (maintenance) doses of **5 mg/Kg** by IV infusion over 15 minutes.

A second course of high dose ibuprofen may be given if the PDA remains haemodynamically significant 48 hours after the end of the first course:

Initial (loading) dose of **20 mg/Kg** by IV infusion over 15 minutes followed at 24 hourly intervals by two further (maintenance) doses of **10 mg/Kg** by IV infusion over 15 minutes.

**ADMINISTRATION:**

Preferably administer undiluted. However, may be diluted to a suitable volume with sodium chloride 0.9% or glucose 5% to adjust the volume to enable practical administration.

Select IBUFROFEN on GUARDRAILS system

**LOADING DOSE:** Infuse intravenously at a rate of 40mg/Kg/hour for 15mins to deliver a dose of 10mg/Kg **OR** 80mg/Kg/hour for 15mins to deliver a dose of 20mg/Kg

**MAINTENANCE DOSE:** Infuse intravenously at a rate of 20mg/Kg/hour for 15mins to deliver a dose of 5mg/Kg **OR** 40mg/Kg/hour for 15mins to deliver a dose of 10mg/Kg

**DILUENTS**

Sodium chloride 0.9% or Glucose 5%
ROUTE OF ADMINISTRATION
Administer by INTRAVENOUS INFUSION over 15 minutes.

In order to avoid ibuprofen being in contact with any acidic solution, the infusion line should be rinsed over 15 minutes before and after administration, with 1.5-2mL sodium chloride 0.9% or glucose 5%

FLUSH
Sodium chloride 0.9% or Glucose 5%

CAUTION
Monitor for bleeding problems including upper gastrointestinal bleeding. May mask signs of infection. Avoid in severe liver disease. Avoid in moderate/severe renal impairment. If anuria or oliguria occurs after the first or second dose, the next dose should be withheld until urine output returns to normal levels.

COMPATIBILITY
Do not infuse with any other medicines.

KNOWN INCOMPATIBILITIES
Do not use chlorhexidine to disinfect ampoules as it is incompatible with ibuprofen (Pedea®) solution. For asepsis use ethanol 60% or isopropyl alcohol 70%. Ensure external surface of ampoules is dry before opening.

SIDE EFFECTS
Thrombocytopenia, neutropenia, intraventricular haemorrhage, periventricular leukomalacia, bronchopulmonary dysplasia, pulmonary haemorrhage, hypoxemia, necrotising enterocolitis, intestinal perforation, gastrointestinal haemorrhage, oliguria, acute renal failure, fluid retention, haematuria

MONITORING
Weight, urine output, urea, electrolytes, platelet function and severe hyperbilirubinaemia. Blood creatinine increase and blood sodium decrease may occur.

INTERACTIONS
Ibuprofen may decrease the clearance of aminoglycosides such as gentamicin and strict surveillance of antibiotic levels is important during co-administration with ibuprofen. Ibuprofen may reduce the effect of diuretics. It may increase the risk of gastrointestinal haemorrhage when used in combination with corticosteroids.

STORAGE
Store at room temperature in original packaging to protect from light. After first opening of an ampoule, any unused
portions must be discarded.

OTHER INFORMATION
1. Licensed for closure of ductus arteriosis (premature neonate <34 weeks)
2. Excipients include: trometamol.
3. Not used for analgesia in this neonatal unit.
4. Contraindicated with duct-dependent congenital heart disease; life-threatening infections; active bleeding especially intracranial or gastrointestinal; thrombocytopenia or coagulopathy; marked unconjugated hyperbilirubinaemia; known or suspected NEC, pulmonary hypertension.

REFERENCES
High dose Ibuprofen: Dani et al. High-dose ibuprofen for patent ductus arteriosus in extremely preterm infants: a randomized controlled study. **Clin Pharmacol Ther.** 2012 Apr;91(4):590-6
Appendix 4: Sample Paracetamol Drug Information Summary (LWH, 2019)

PARACETAMOL

INDICATION:
- For analgesia and pyrexia in babies ≥ 28 weeks post-menstrual age (PMA) (See pain and sedation guideline)

BACKGROUND
Paracetamol is a non-opioid analgesic with antipyretic properties. It does not cause respiratory depression and causes less irritation to the stomach than NSAIDs such as ibuprofen. Paracetamol causes ductal constriction and is used as an alternative to Ibuprofen in the management of babies with a PDA. Paracetamol can cause severe life-threatening hepatic damage in overdosage. It can be given orally, rectally and intravenously. There are limited safety data on the use of paracetamol in preterm infants. Optimum pain relief occurs approximately one hour after peak serum concentration has been reached. Peak concentrations are reached almost immediately after IV administration and in 30-60 minutes following oral administration (longer with rectal administration). The reported elimination half-life varies from a median of 4 hours in term infants to 8 hours in infants <32 weeks.

PRESENTATION
100mL vial containing 1000mg Paracetamol (10mg/mL)
Already in solution
Paracetamol oral suspension 120mg/5mL
pH 5 – 7

FOR ANALGESIA AND PYREXIA
- Can be prescribed regularly or when required (PRN)
- Review prescription regularly and stop if no longer required.

<table>
<thead>
<tr>
<th>INTRAVENOUS Dose</th>
<th>≥ 28 weeks PMA</th>
<th>20mg/Kg Loading Dose followed 6 hours later by Maintenance Dose of 10mg/Kg every SIX hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORAL/ENTERAL Dose</td>
<td>28 – 32 weeks PMA</td>
<td>20mg/Kg Loading Dose followed 12 hours later by Maintenance Dose of 10mg/Kg every TWELVE hours</td>
</tr>
<tr>
<td></td>
<td>&gt; 32 weeks PMA</td>
<td>20mg/Kg Loading Dose followed 6 hours later by Maintenance Dose of 10mg/Kg every SIX hours</td>
</tr>
</tbody>
</table>

FOR PDA CLOSURE
- Use IV route if available
- Use for 3 days initially then review clinically and by ECHO. A further 3-day course may be prescribed, if indicated (Consultant decision)
<table>
<thead>
<tr>
<th>INTRAVENOUS Dose</th>
<th>All babies</th>
<th>20mg/Kg Loading Dose followed 6 hours later by Maintenance Dose of 10mg/Kg every SIX hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORAL/ENTERAL Dose</td>
<td>All babies</td>
<td>15mg/Kg every SIX hours (no loading dose required)</td>
</tr>
</tbody>
</table>

**ADMINISTRATION**

**INTRAVENOUS:**
1. Calculate volume needed for required dose.
2. Withdraw the required volume from the vial into a syringe (plus extra volume to prime the administration line). Can be administered without further dilution.
3. Administer dose by INTRAVENOUS INFUSION over 15 minutes using GUARDRAILS.

<table>
<thead>
<tr>
<th>Loading dose (select Paracetamol LOADING)</th>
<th>20 mg/kg over 15 minutes is equivalent to 80 mg/kg/hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance dose (select Paracetamol MAINT)</td>
<td>10 mg/kg over 15 minutes is equivalent to 40 mg/kg/hour</td>
</tr>
</tbody>
</table>

* In smaller infants an excess will have to be drawn up and VTBI set on the pump to allow administration of small volumes or IV preparation may be diluted to a suitable volume to enable practical administration. (Diluted solution has an expiry of one hour including infusion time)

**ORAL/ENTERAL:**
Shake bottle before use. Measure required dose and administer orally or via enteral feeding tube.

**DILUENTS**
Sodium Chloride 0.9%, Glucose 5%

**ROUTE OF ADMINISTRATION**
Administer by IV infusion over 15 minutes via peripheral or central access using GUARDRIALS.

**FLUSH**
Sodium Chloride 0.9% or Glucose 5%

**CAUTION**
Reduce intravenous dose by 50% in patients with hepatic impairment or neonates with unconjugated hyperbilirubinaemia. Drug clearance is slower in jaundiced babies. Risk of liver toxicity with overdosage. Clinical signs and symptoms of liver damage are not usually seen until 2-6 days after administration.

**COMPATIBILITY**
Glucose 5%, glucose 10%, sodium chloride 0.9%

**KNOWN**
Do infuse with other medicines or infusions.
INCOMPATABILITIES

SIDE EFFECTS
Hypotension, hypersensitivity reactions, flushing, tachycardia, injection site reactions. Rarely thrombocytopenia, leucopenia, neutropenia.

MONITORING
Monitor pain score (NPASS), temperature, oxygenation, hepatic function, renal function and ECHO (if treating PDA)

INTERACTIONS
Increased risk of hepatotoxicity with carbamazepine, clavulanic acid, flucloxacinil, fluconazole, valproate. Decreased efficacy with phenobarbitone, phenytoin and rifampicin

STORAGE
Vials: Store at room temperature and protect from light. Each vial is single use, discard any remaining solution after use. Oral Suspension: Store at room temperature. Do NOT refrigerate or freeze paracetamol.

OTHER INFORMATION
1. Paracetamol is not licensed for use in children under 2 months of age.
2. Paracetamol solution for injection is isotonic.
3. Paracetamol suppositories for rectal administration are not stocked at LWH. Rectal absorption in the neonate is unpredictable and this route is rarely used.
4. Paracetamol toxicity is treated with acetylcysteine as it reduces the hepatotoxic effects of paracetamol overdose by replenishing glutathione stores, thereby enhancing production of the non-toxic metabolites.

Acetylcysteine dose and administration instructions (as per BNFc)
- 150 mg/Kg IV during the first hour and then 50 mg/Kg over the next 4 hours followed by 100 mg/Kg over 16 hours as described below:
- Initial infusion: Take one 10mL vial of acetylcysteine and dilute with 30mL of Glucose 5% to give a 50mg/mL solution. Infuse at a rate of 3mL/Kg/hour for one hour only.
- Subsequent infusion: Take one 10mL vial of acetylcysteine and dilute with 310mL of Glucose 5% to give a 6.25mg/mL solution. When the initial infusion has finished, infuse this solution at a rate of 2mL/Kg/hour for 4 hours and then at a rate of 1mL/Kg/hour for 16 hours.

REFERENCES
BNF for Children (ONLINE), Neonatal Formulary 7th Edition, Medusa injectable medicines guide (ONLINE), Trissel Handbook on Injectable Drugs (ONLINE), SPC: Paracetamol 10mg/ml solution for infusion; Paracetamol 120mg/5ml oral suspension (ONLINE). Online resources accessed 28/05/2019

General References


