Ductus Arteriosus: Dilemmas of Treatment vs. No Treatment in the Premature Neonate

Time allotted: 30 Minutes.       No Disclosures.

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Professor Emeritus, Stanford University
Where is the Ductus
The ductus arteriosus in the preterm infant: Histologic and clinical observations

Adriana C. Gittenberger-de Groot, M.D.,* Ingrid van Ertbruggen, M.D., Andr~ J.M.G. Moulaert, M.D., and Eric Harinck, M.D.,

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In reality prematurity is a multisystem disorder of every organ and the consequences of immaturity in one organ may have consequences for many other organs.

The premature infant with a patent ductus arteriosus has problems due to immaturity of most physiological processes—respiration, absorption and nutrition, central nervous system, circulation, renal function, electrolyte balance, and metabolism—all of which occur even in the absence of a patent ductus arteriosus.

As a result, it is difficult to know what contribution the patent ductus arteriosus is making to the infant’s problems, and therefore difficult to decide if the ductus should be closed and if closure has made a difference to the child’s course. Early experience after closure of the ductus in premature infants has shown that expectations of normality after closure of the patent ductus arteriosus are unrealistic.

PDA may remain asymptomatic in the face of respiratory disease. Is the big ductus shunt affecting the infant? This is the hardest question to answer, because none of the findings listed above can tell us how well the left ventricle is compensating. Failure to distinguish between a large but well compensated shunt and a shunt that is causing problems is at least part of the reason why closing the ductus may not appear to be useful therapy.
In a nutshell we can say that there has been a general shift in the management of PDA in preterm neonates from the “aggressive approach” to a more “conservative approach.”

On the basis of available evidences, rationalization and individual emphasis on precise identification of a hemodynamically significant duct seem to be the way forward.
Among infants <27 weeks of gestation, with a PDA at the time of hospital discharge, 75% of the infants spontaneously close the duct by the end of the first year.

Incidence of PDA in Preemies

- 1/100- Live births
- In Preemies 8/1000
- In healthy preterm neonates >30 weeks gestation, PDA closes by day 4 in 90% and by day 7 in 98%
- <24 weeks gestation babies stand at a dismal 8% and 13% by day 4 and day 7, respectively
- In 50–70% of preterm infants with birth weight <1,500 g. the ductus remains patent
- Among infants less than 1500 g who still have a PDA at the time of hospital discharge, it will spontaneously close by the end of the first year in 86% of the infants
- Among infants <27 weeks of gestation, with a PDA at the time of hospital discharge, 75% of the infants spontaneously close the duct by the end of the first year.
Five decades after the recognition of delayed closure of the ductus in preterm infants, management remains heterogeneous and controversial. Routine early treatment to close the ductus does not appear to be beneficial, but selective later treatment may still prove valuable. The timing, criteria, objectives and methods for such treatments remain to be established. Potential strategies for minimizing the adverse effects of PDA while awaiting spontaneous closure or achievement of treatment criteria need careful evaluation in clinical trials.

Elimination of ductal shunting and its consequences by surgical ligation or by induction of ductal constriction with cyclo-oxygenase (C0X) inhibition promised to ameliorate the adverse outcomes associated with ductal patency. However, neither individual randomized controlled trials nor meta-analyses of those trials have confirmed this hypothesis.
Treatment of the PDA in infants >1000 g BW is rarely warranted, as nearly all (94%) will spontaneously close and the rate of complications in this population are low. However, among infants <1000 g BW, the PDA is far less likely to close spontaneously.
The Issue of a PDA

Living with the Patent Ductus Arteriosus: Management Trends and Neonatal Outcomes
Veena Goel MD., Jonathan Palma MD. MS., William E. Benitz MD.
Lucile Packard Children’s Hospital at Stanford, Palo Alto, CA

Background

The persistently patent ductus arteriosus (PDA) in preterm infants has been associated with, and thought to cause, multiple morbidities and even death. Standard of practice has been to aggressively identify and close the PDA with non-steroidal anti-inflammatory medications (NSAIDs) and/or surgical ligation. In January 2009 at Pediatric Grand Rounds at Lucile Packard Children’s Hospital (LPCH), Dr. W. Benitz presented his meta-analysis suggesting no benefit with traditional PDA management in preterm infants. We compare PDA management and neonatal outcomes at LPCH before and after the practice of aggressive closure was called into question.

Methods

Retrospective study approved by institutional review board;

Data collection:
Very low birth weight (VLBW) infants with PDA at LPCH were identified from 2006-2012 using data submitted to the California Perinatal Quality Care Collaborative (CPQCC) electronic database. Era 1 = January 2006 through December 2008
Era 2 = January 2009 through December 2011

Infant characteristic data were extracted from CPQCC (see Table 1)

- Age at the time of intervention (NSAID or ligation) was determined via manual chart review.

Neonatal outcome data were extracted from CPQCC (see Table 2).

Data analysis:
Chi-squared or Fisher’s exact tests were used for comparison of categorical variables.
Wilcoxon Rank Sum (Mann-Whitney) tests were used for continuous variables.

Results & Discussion

Table 1 Infant Characteristics

<table>
<thead>
<tr>
<th>Era 1</th>
<th>Era 2</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of VLBW infants</td>
<td>350</td>
<td>254</td>
</tr>
<tr>
<td>Number with PDA (%)</td>
<td>126 (41%)</td>
<td>95 (32%)</td>
</tr>
<tr>
<td>Estimated gestational age (weeks)*</td>
<td>27.7</td>
<td>27.3</td>
</tr>
<tr>
<td>Birth weight (grams)</td>
<td>998.7</td>
<td>962.2</td>
</tr>
<tr>
<td>Number of VLBW infants without NSAID use or ligation</td>
<td>186 (64%)</td>
<td>229 (80%)</td>
</tr>
<tr>
<td>NSAID use* (%)</td>
<td>99 (79%)</td>
<td>40 (42%)</td>
</tr>
<tr>
<td>Age in days at NSAI (mean/median)</td>
<td>4/3</td>
<td>6/4</td>
</tr>
<tr>
<td>Surgical ligation*</td>
<td>35 (23%)</td>
<td>28 (23%)</td>
</tr>
</tbody>
</table>

We believe that the patients diagnosed with PDA were a sicker subset of VLBW patients in Era 2 because PDA was less likely to be diagnosed if it was not going to be treated.

- NSAID use:
  - Decreased rate of Indomethacin/ibuprofen use
  - Older age at first dose of Indomethacin

- Surgical ligation:
  - No change in rate of ligation.
  - Older age at time of ligation.

Conclusions

- After January 2009, a less aggressive approach has been used for ductal closure in pre-term VLBW infants with PDA at LPCH.

  - We believe that the patients diagnosed with PDA were a sicker subset of VLBW patients in Era 2 because PDA was less likely to be diagnosed if it was not going to be treated.

- Proportion of infants with confirmed PDA who developed CLD was higher in Era 2. It is unclear whether this is due to an association between conservative PDA management and CLD, or due to an association between CLD and patients confirmed to have PDA.

  - Single-center observational study by Kaempf et al.2 also suggested an upward trend in CLD.

  - These changes in management are not the result of standard unit practice. Instead, management preference varied from attending to attending.

References

1. Benitz WE. Treatment of persistent patent ductus
2. Kaempf et al.
In 50–70% of preterm infants with birth weight <1,500 g, the ductus remains patent.

An open ductus may contribute to the development of BPD by shunting blood into the lungs, resulting in pulmonary edema and the persistent need for ventilatory support. This population of preterm infants with a PDA would benefit from strategies to reduce complications and optimize outcomes.

615 preterm infants with birth weight <1,500 g admitted to the Neonatal Intensive Care Unit, of whom 209 (34%) were found to have a PDA by ECHO. Twenty-two patients were excluded and 187 remaining subjects had their PDA either treated (75%) or conservatively managed.

The mean gestational age of the 187 subjects was 27.6 ± 2 wk and the mean age at PDA treatment was 4 ± 4 d among those treated. Mean ductal diameter at the time of treatment was 1.7 ± 0.6 mm.

Only lower gestational age and not PDA treatment or ECHO score was associated with the adverse outcome of death or BPD. Further investigation of PDA management strategies and effects on adverse outcomes of prematurity is needed.
Table 1. Comparison of Echocardiographic Markers of HSDA where LVO = left ventricular output, SVC = superior vena cava, LVSTI = left ventricular stroke volume index, IVRT = isovolumic relaxation time, PWD = pulse wave Doppler, CWD = continuous wave Doppler, PA = pulmonary artery. (empty boxes implies data not available)

<table>
<thead>
<tr>
<th>Feature quantified</th>
<th>Modality / Position of sample gate</th>
<th>No PDA</th>
<th>Small</th>
<th>Moderate</th>
<th>Large</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transductal diameter (mm)</td>
<td>Two-dimensional, short axis view</td>
<td>0</td>
<td>&lt; 1.5</td>
<td>1.5-3</td>
<td>&gt; 3</td>
</tr>
<tr>
<td>Left atrial: aortic ratio</td>
<td>M-mode, long axis view</td>
<td>1.13 ± 0.23</td>
<td>&lt; 1.4:1</td>
<td>1.4 - 1.6:1</td>
<td>&gt; 1.6:1</td>
</tr>
<tr>
<td>Left ventricular: aortic ratio</td>
<td>M-mode, long axis view</td>
<td>1.86 ± 0.29</td>
<td>-</td>
<td>2.15 ± 0.39</td>
<td>2.27 ± 0.37</td>
</tr>
<tr>
<td>Ductal velocity $V_{\text{max}}$ (cm/s)</td>
<td>PWD at pulmonary end of duct</td>
<td>0</td>
<td>&gt; 2</td>
<td>1.5-2</td>
<td>&lt; 1.5</td>
</tr>
<tr>
<td>Antegrade PA diastolic flow (cm/s)</td>
<td>PWD within main pulmonary artery</td>
<td>0</td>
<td>0-20</td>
<td>&gt; 20</td>
<td>-</td>
</tr>
<tr>
<td>Antegrade PA diastolic flow (cm/s)</td>
<td>PWD within left pulmonary artery</td>
<td>0</td>
<td>&gt; 30</td>
<td>30-50</td>
<td>&gt; 50</td>
</tr>
<tr>
<td>Retrograde diastolic flow (cm/s)</td>
<td>CWD within descending Ao (% of forward flow)</td>
<td>10</td>
<td>&lt; 30</td>
<td>30-50</td>
<td>&gt; 50</td>
</tr>
<tr>
<td>Aortic stroke volume (ml/kg)</td>
<td>PWD of LV outflow tract</td>
<td>≤ 2.25</td>
<td>-</td>
<td>-</td>
<td>≥ 2.34</td>
</tr>
<tr>
<td>Left ventricular output (ml/kg/min)</td>
<td>PWD of LV outflow tract</td>
<td>190-310</td>
<td>-</td>
<td>-</td>
<td>&gt; 314</td>
</tr>
<tr>
<td>LVO / SVC flow ratio</td>
<td>PWD of flow in superior vena cava</td>
<td>2.4 ± 0.3</td>
<td>-</td>
<td>-</td>
<td>4.5 ± 0.6</td>
</tr>
<tr>
<td>LVSTI ratio</td>
<td>M-mode of aortic valve</td>
<td>0.34 ± 0.09</td>
<td>-</td>
<td>0.26 ± 0.03</td>
<td>0.24 ± 0.07</td>
</tr>
<tr>
<td>E wave / A wave ratio</td>
<td>Transmitral Doppler</td>
<td>&lt; 1</td>
<td>&lt; 1</td>
<td>1-1.5</td>
<td>&gt; 1.5</td>
</tr>
<tr>
<td>IVRT (ms)</td>
<td>Between mitral &amp; aortic valves</td>
<td>&gt; 55</td>
<td>46-54</td>
<td>36-45</td>
<td>&lt; 35</td>
</tr>
</tbody>
</table>
Jet Physics

Vena contracta: Smallest area of flow in or downstream from a restrictive orifice.
Jet physics is important and the value of Doppler color flow signals in determining the size of the duct. As with a garden hose stream, the size of the jet diminishes to a point called the *vena contracta*. This narrowest point in a jet is a little smaller than the actual size of the tube (the duct) through which it is traveling, but provides a reasonable estimate of its true size. 

The PISA stands for Proximal Isovelocity Surface Acceleration.
The Other PISA
Quantitation of Patent Ductus Size.

- Documentation of size of ductus by imaging, color & Vena Contracta

- Ductus diameter as a % of the of the left pulmonary artery:
  - >1 indicated a large PDA, <1 but >0.5 moderate and <0.5 a small duct

- LA/Ao Ratio (>1.3:1) and Left Ventricular hyperdynamic contractions

- Retrograde abdominal aortic flow
  - If Prograde Flow --> Mild; If Retrograde flow --> large
  - (VTI of Reverse vs. Forward Flow)

- Ductus Doppler --> Restrictive if velocity is >2 msec and continuous Non-restrictive, if goes to baseline

- PISA
  - Small-- small shunt
  - Pisa Moderate- moderate sized shunt
  - No Pisa Large Shunt

Apgar-like score
## Echocardiographic Scoring System for Patent Ductus Arteriosus

Start with 10 points

<table>
<thead>
<tr>
<th>Parameter</th>
<th>0</th>
<th>-1</th>
<th>-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>LA:Ao ratio</td>
<td>&lt;1</td>
<td>1-1.3</td>
<td>&gt;1.3</td>
</tr>
<tr>
<td>Retrograde aortic flow (reverse:forward flow)</td>
<td>None</td>
<td>0-0.4</td>
<td>&gt;0.4</td>
</tr>
<tr>
<td>PISA</td>
<td>No ductus</td>
<td>Some</td>
<td>None when ductus present</td>
</tr>
<tr>
<td>Ductus:LPA ratio</td>
<td>&lt;0.25</td>
<td>0.25-0.5</td>
<td>&gt;0.5</td>
</tr>
<tr>
<td>Doppler of PDA</td>
<td>Continuous flow</td>
<td>Left-right and stops at baseline</td>
<td>Bidirectional</td>
</tr>
</tbody>
</table>

Hemodynamically significant ductus if score <5
**Strength:** This is a simple measurement made by the technologist usually fairly accurate. Can be made of Two-dimensional Echo as well.

**Weakness:** This technique was a surrogate for measuring left atrial size. Now Z scores are available. Confounding associations on the cardiac basis.

Premature infants have a PFO.
The LA:AO Ratio ( > 1.3:1)
Flow Dynamics in the Juxtaductus Aorta.

Ao Prox to Duct  Ductus Flow

Ao Disatal to Duct
Ductus Size

**Horizontal Ductus (Transposition)**

**Strength:** This is a measurement that is linear and easy to make. It certainly parallels whether the duct is large, moderate or small.

**Weakness:** Minor differences of the type that relate to pixels differences can make large differences in the amount of flow. The question of where the narrowest portion of the ductus might be makes it be difficult sometimes to see the exact point of narrowing.

**Vertical Ductus  
(Pulmonary Under-circulation)**
Large Patent Ductus Arteriosus

The Ducuts Cut

PA

D

LA

DAO
Ductus Cut and Flow Dynamics

- MPA
- LPA
- Duct
- Arch
- D Ao
- Isthmus
Large PDA

Subcostal Sagittal Image

Suprasternal Sagittal Image
Ductus Size
Ductus Size

Pulm Htn
Ductus Size: Doppler Velocities.

Tiny

Small

Moderate

Large
Ductus Size: Doppler Velocities.

**Strength:** This is a simple measurement. A pressure difference > 1 m/s means the duct must be constricted. When there is a large ducts and/or when there is PHT

**Weakness** Angle of insonation has to be low. Gradation of the degree of ductus constriction related to variations in low systemic pressures.
Patent Ductus Size Assessment by Color

\[ Q = \frac{2\pi r^2 \cdot NL \cdot 0.60}{1000} \]
\[ = \frac{2.22}{7} (0.04\text{cm})^2 \cdot 55 \text{ (= NL)} \]
\[ = 6.29 \times 0.0016 \times 0.55 \]
\[ = 0.5532 \text{ ml/sec} \quad \text{x60 secs/min} \]
\[ = 33.211 \text{ ml/min} \quad \text{÷ BSA 0.18} \]
\[ = 185 \text{ ml/min/m}^2 \text{ BSA} \quad \text{÷ 1000} \]
\[ = 0.185 \text{ l/min/m}^2 \text{ BSA} \]
Large PDA: PISA

The Ductus Cut
Small Ducts: Pisa & Vena Contracta

Parasternal Ducuts Cut

Subcostal The Ducuts Cut
Smaller PISA
Color Techniques

**Strength:** Doppler color flow is often more sensitive than imaging in defining flow, defining blood flow better than imaging, particularly with smaller ducts also more 3-dimensional in character as the slice thickness is as limited in the regular image.

**Weakness:** With all Color Doppler modalities the techniques is sensitive to machine type, gain, filtering, and changes in the Nyquist limit. So we can have a variety of possibilities, which make assessment somewhat artifactual.

(i) The PISA Method.

**Strength:** This technique has been validated in laboratory situations permitting fairly accurate assessment for flow on the proximal side of a jet. This is the only Doppler technique which allows for the assessment of flow within a jet system.

**Weakness:** Unfortunately, it requires two circumstances to be accurate. The first is the orifice through which the flow occurs has to be round and the second is that the jet should not be interfered with by the lateral confines of the duct. Not being a free jet and some of it may be confined and altered by the shape of the duct. There are many confounding problems in assessing flow across the duct by this means because there is no free jet in this situation. What we have observed is that when there is a large ductus with large amount of flow, there is no PISA because there is no constriction, when there is a moderate sized ductus with a moderate amount of flow, there is a large PISA and when there is when there is a small ductus with small amount of flow, there is a small PISA.
(ii) Vena Contracta and Color Doppler Jet Width Measurement.

**Strength:** The same as for the previous sections on Doppler color flow.

**Weakness:** The same as for the previous sections on Doppler color flow.
Strength: Surrogate for blood pressure measurement, it really looks for runoff of a large shunt and for retrograde flow. Lesser degrees of flow are found to occur with lesser shunts.

Weakness: Technologists often don't get axial enough to evaluate flow adequately and in that circumstance the low velocity of the retrograde flow can be lost. Wall Filter issues: If the wall filter - if too high, obfuscates the low flow velocity in diastole.
The Ductus and Pressure Assessment

- **V** = -3.51 m/s
  - **PG** = 49.2 mmHg

**CW Duct**
- **V** = 4.47 m/s
  - **PG** = 79.9 mmHg
- **V** = 3.29 m/s
  - **PG** = 43.3 mmHg

**PFO**

**Duct pressure assessment**
There are many critical issues in measurement of ductus size. We need to get better at measurements.

What we need to concentrate on is which ductus is critical in terms of defining outcomes.

Perhaps we need to concentrate only on the large PDA in terms of outcomes.

Clearly prospective trials are necessary.

We have been examining too many ductuses by Echo in preemies!
Based on current evidence, prophylactic indomethacin is not recommended for the treatment of PDA in preterm infants.

There are well-established side effects of indomethacin, such as significant reduction in cerebral, mesenteric, and renal blood flow velocities as measured by Doppler ultrasonography, as well as possible adverse effects on platelet function, have raised serious questions on the prophylactic use of this drug.

With growing concerns over the side effects of indomethacin, a safer alternative was requested. Ibuprofen has been shown to be less nephrotoxic than indomethacin.

It has been found that 85.2% of PDAs closed if the first dose of indomethacin was administered within 24 hours of birth. However, this rate decreased to 48.1% when treatment was started 72 hours or later after birth. It has been shown that although early indomethacin treatment improved PDA closure rates, it was associated with increased renal side effects and offered no respiratory advantage over late indomethacin administration in ventilated surfactant-treated infants.

What about Cox inhibitors?
What about Surgical Ligation?

They found that even though infants were exposed to larger PDA shunts for longer durations in the conservative treatment period, the rates of BPD, sepsis, retinopathy of prematurity (ROP) neurological injury, and death did not change. However, their overall rate of was significantly lower.

It has also been shown in experimental models that early surgical ligation of the duct impedes lung growth in preterm baboons.

The lack of any respiratory or neurological benefit shown by these studies, recent research also indicates that surgical ligation of the duct may in fact cause more harm than good. It has been shown that secondary surgical closure was associated with increased odds for neurodevelopmental impairment and increased adjusted odds for BPD but decreased adjusted odds for death.
What About Interventional Catheterization?

Trans-catheter Closure of Patent Ductus Arteriosus (PDA) in Extremely Low Birth Weight (ELBW) Premature Infants: A New Treatment Option for an At-Risk Population

By Evan M. Zahn, MD; Ruchira Garg, MD; Alistair Phillips, MD

June 2014; Volume 12; Issue 6

Table 1. Demographic Data

<table>
<thead>
<tr>
<th>Patient</th>
<th>Birth Weight (gm)</th>
<th>Gestational age (weeks+days)</th>
<th>Sex</th>
<th>Procedure Weight (gm)</th>
<th>Procedure Age (days)</th>
<th>Ventilator Dependence</th>
<th>Inotrope Dependence</th>
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<tbody>
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<td>1</td>
<td>2480</td>
<td>31+6</td>
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<td>2240</td>
<td>18</td>
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</tr>
</tbody>
</table>
There is no generally accepted understanding of the echocardiographic markers of hemodynamic significance and their importance for treatment or prognosis. Echocardiography could be looked upon as the best representation of the circulatory state, but a fundamental problem is the lack of gold standard for the physiologic effects of a ductal shunt related to the echocardiographic findings. The relative importance of pulmonary over circulation, vascular resistances, and systemic hypoperfusion also remain to be clarified.
Misuse and overuse of medical interventions that do not directly improve a patient’s health contribute significantly to the unsustainable growth of healthcare spending. ACP’s goal is to determine whether diagnostic tests and treatments for various diseases provide good value, i.e. medical benefits that are commensurate with their costs and outweigh any harm. We do this by analyzing their benefits, harms, and costs based on the best available evidence.

Approximately 30% of healthcare costs (more than $750 billion annually) are spent on wasted care.

ACP has developed clinical recommendations, physician resources, curriculum and public policy recommendations around this initiative.

http://hvc.acponline.org/index.html
Comparison of Data Points on Stanford Study

- Left atrial size by M-mode normalized to the aorta as LA:Ao ratio
- Also Left atrial by 2 D area as a reflection of LA Size
- Ventricular Function. Fractional Sortening index as a surrogate for ejection fraction
- Mitral regurgitation and atrial left to right shunt which might compromise estimate of LA size
- Retrograde diastolic flow by Doppler ultrasound in the abd. aorta as a surrogate for systolic: diastolic and pulse pressure.
- Ductus size measurement by 2 D or and by Doppler color flow at the vena contracta, measured by Doppler or Doppler color flow
- Pulmonary artery size as a reflection of the size for the Ductus. A ratio between the Duct: LPA > 1 suggests a large duct.
- Proximal Isovelocy Surface acceleration as a reflection ductus left to right shunt.
- Aortopulmonary pressure differences across the arterial duct measured by Doppler or Doppler color flow.
Impressions

♥ The data on the original study used patient data unrelated to the temporal time of the decision making process.

♥ It seemed that the neonatologists neither read the reports or consulted with cardiology about ductus closure. I reread the reports to see if I disagreed with anyone in the Echo lab who read a report and found near 100% concordance.

♥ Looking at the data it seemed that once the ductus was constricted there was very little chance that patient was going to reopen the duct. I have encountered only one patient in the series.

♥ Following on this point it seems that there was a large number of patients who got unnecessary Echoes @ $4,600.00

♥ 8/10 patients sampled for the surgically closed ductus cohort of 70 patients had no hemodynamic reason for having their ductus ligated!

♥ Compliance between the two observers was much better than in the original study.
Lessons

♥ Check and re-check your data.

♥ Remember garbage in + garbage out!

♥ If you want to do good research you have to do it your self! or at least have a close supervision of the plan, measurements and results.
Plan

♥ Will we be able to make inferences from our retrospective study?

♥ What can we do going forward?

♥ We must do a better job talking to each other and pay as a team for the benefit of our patients

♥ We need a prospective study.

♥ This is a neonatology study, involving cardiology.