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# PDA Update: *Clarity or Confusion?*

Robert DiGeronimo, MD

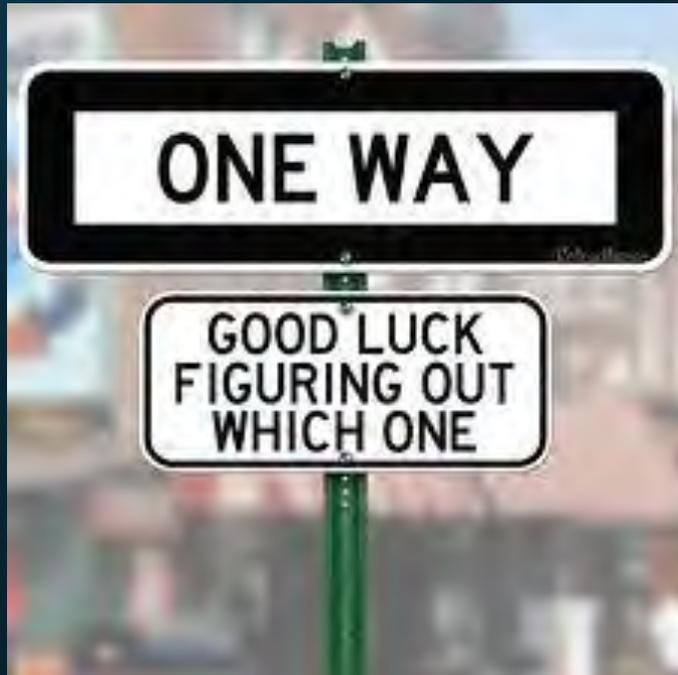




No  
Disclosures/Conflicts  
of Interest



# PDA Treatment Guidelines





What is Your  
Practice?

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Do you  
perform  
screening  
echos for PDA  
in an ELBW  
infant?

Within 24-48 hours of birth

Within 7 days of birth

Within 10-14 days of birth

Only if I hear a murmur

I never routinely screen for PDA

DOL 20, 25wk  
infant w/ a  
large hsPDA  
remains on  
vent, would  
you treat and  
if so, how?

indomethacin

ibuprofen

acetaminophen

PDA coil closure

Conservative (expectant) management

If previous patient's PDA fails to close with medical treatment, would you consider coil closure in cath lab?

Yes

No

Do you worry  
about adverse  
consequences  
from a  
persistent large  
 $L > R$  shunt from  
a hsPDA?

Yes

No

# The PDA...

- One of most studied topics in neonatology
- PubMed literature search April 2025 cited **14558** articles, **230** systemic reviews and **332 RCTs (58 in the past 5 years alone)**

PubMed®

MY CUSTOM FILTERS 

**All (14,558)**

Diagnosis/Narrow (201)

Etiology/Narrow (1,122)

Prognosis/Narrow (1,068)

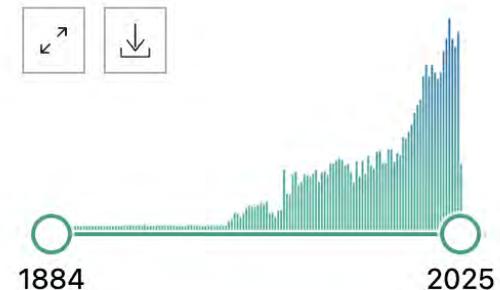
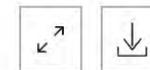
Review (1,320)

Systematic Reviews (230)

Therapy/Narrow (395)

– show fewer

RESULTS BY YEAR

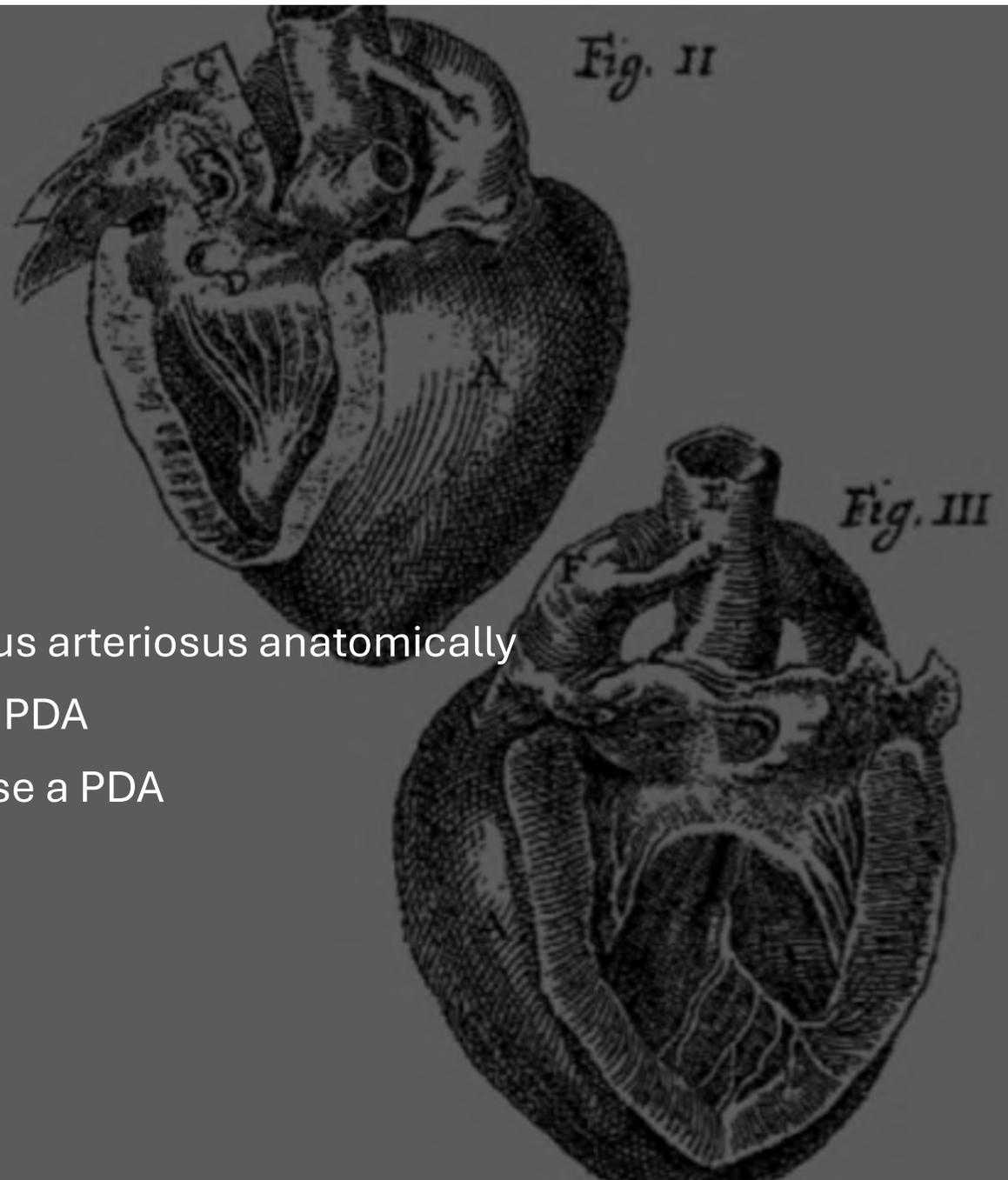


# History

**Galen** (2nd century AD): First described the ductus arteriosus anatomically

**Morgagni** (18th century): Described pathological PDA

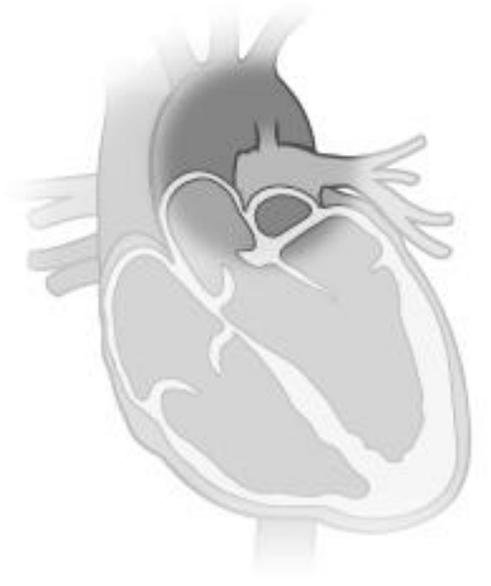
**Dr. Robert E. Gross** (1938): First to surgically close a PDA



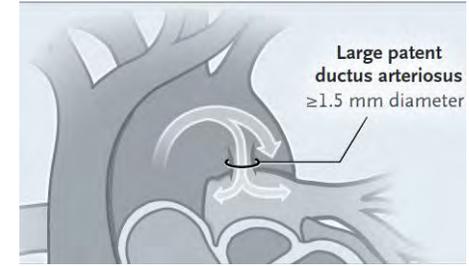
# PDA Physiology

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- Functionally closes in most term newborns in 3-4 days
- Common delay in closing for premature infants, *risk increases with lower GA and BW*
- **Acute** concerns related to “ductal steal”, *diverting blood flow from systemic circulation altering end-organ perfusion*
- **Chronic** concerns related to “long-term exposure” to an *ongoing systemic to pulmonary shunt*



# PDA Significance



- Historically the presence of a PDA has been associated with numerous morbidities including BPD, NEC, IVH, PVL, ND impairment/death *and these associations often lead many clinicians to treat a PDA*
- **Multiple RCTs of early PDA treatment, however, have failed to demonstrate significant reductions in clinically important outcomes**

# *Why have studies failed to provide a definitive answer?*

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- Many Confounders
- Unable to reach sample size in several large RCTs
- Open label treatment in almost all trials coupled with high rate of treatment failure
  - >> *true difference between arms likely only 25-50%*
- Poor definition of a “hemodynamically significant” PDA
- Unsure when to treat and what treatment should be

## STATE-OF-THE-ART

# Treatment of persistent patent ductus arteriosus in preterm infants: time to accept the null hypothesis?

**WE Benitz**

*Division of Neonatal and Developmental Medicine, Department of Pediatrics, Stanford University School of Medicine, Palo Alto, CA, USA*

CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care

American Academy  
of Pediatrics



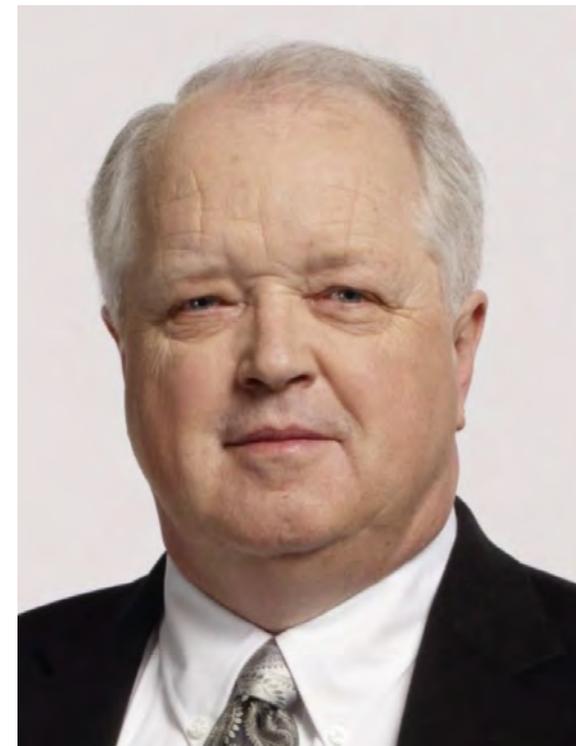
DEDICATED TO THE HEALTH OF ALL CHILDREN®

## Patent Ductus Arteriosus in Preterm Infants

William E. Benitz, MD, FAAP, COMMITTEE ON FETUS AND NEWBORN

Despite a large body of basic science and clinical research and clinical experience with thousands of infants over nearly 6 decades,<sup>1</sup> there is still uncertainty and controversy about the significance, evaluation, and management of patent ductus arteriosus in preterm infants, resulting in substantial heterogeneity in clinical practice. The purpose of this clinical report is to summarize the evidence available to guide evaluation and treatment of preterm infants with prolonged ductal patency in the first few weeks after birth.

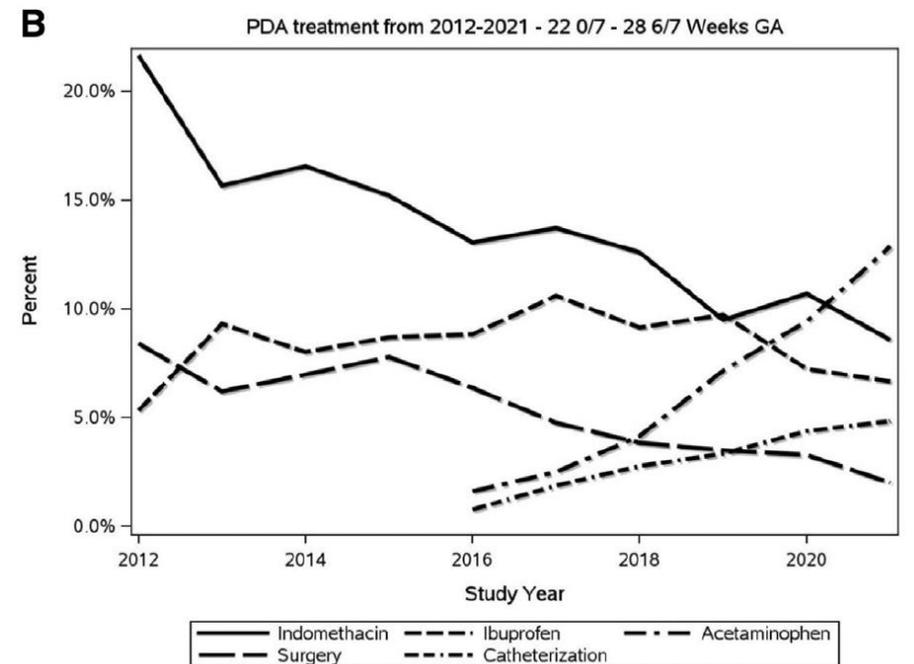
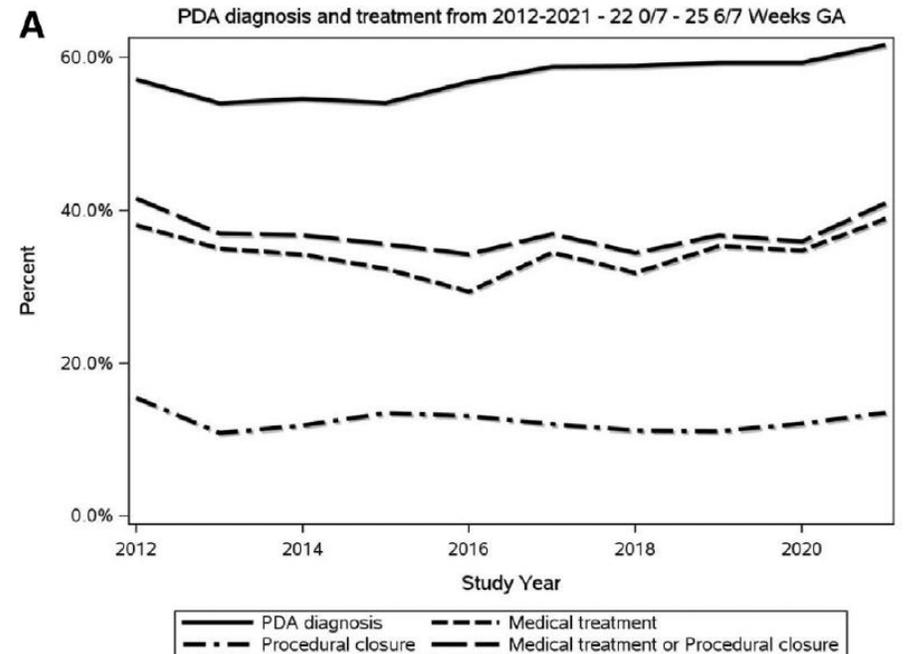
abstract



## Secular Trends in Patent Ductus Arteriosus Management in Infants Born Preterm in the National Institute of Child Health and Human Development Neonatal Research Network

Dinushan C. Kaluarachchi, MBBS<sup>1</sup>, Matthew A. Rysavy, MD, PhD<sup>2</sup>, Benjamin A. Carper, MS<sup>3</sup>, Valerie Y. Chock, MD, Ms Epi<sup>4</sup>, Matthew M. Laughon, MD, MPH<sup>5</sup>, Carl H. Backes, MD<sup>6</sup>, Tarah T. Colaizy, MD, MPH<sup>7</sup>, Edward F. Bell, MD<sup>7</sup>, and Patrick J. McNamara, MB BCh, BAO, MSc<sup>7</sup>

We evaluated changes in patent ductus arteriosus (PDA) diagnosis and treatment from 2012 through 2021 in a network of US academic hospitals. PDA treatment decreased among infants born at 26-28 weeks but not among infants born at 22-25 weeks. Rates of indomethacin use and PDA ligation decreased while acetaminophen use and transcatheter PDA closure increased. (*J Pediatr* 2024;266:113877).





CLINICAL REPORT Guidance for the Clinician in Rendering Pediatric Care



American Academy  
of Pediatrics



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# Patent Ductus Arteriosus in Preterm Infants

Namasivayam Ambalavanan, MD,<sup>1</sup> Susan W. Aucott, MD,<sup>2</sup> Arash Salavitarbar, MD,<sup>3</sup> Victor Y. Levy, MD,<sup>4</sup> and the  
Committee on Fetus and Newborn and Section on Cardiology and Cardiac Surgery

*PEDIATRICS* Volume 155, Issue 5, May 2025:e2025071425

# AAP Statement Recommendations



- *Prophylactic medical interventions (not guided by knowledge of PDA status) are not recommended*
- **Very early (<72 hours) or early (<7 to 14 days) treatment** (regardless of hemodynamic significance) does not improve outcomes and is not recommended
- **Conservative management** may let infants avoid medical therapy or procedural exposure, allowing spontaneous delayed closure without risk of increased adverse outcomes



Cochrane Database of Systematic Reviews

**Interventions for patent ductus arteriosus (PDA) in preterm infants:  
an overview of Cochrane Systematic Reviews (Review)**

Mitra S, de Boode WP, Weisz DE, Shah PS

- 16 Cochrane Reviews, corresponding to 138 randomized clinical trials (RCT)
- 11,856 preterm infants
- 9 specific for symptomatic treatment to medical and surgical interventions

# Mitra S, Cochrane Database of Systematic Reviews 2023

- **All meds effective in closing PDA vs. no treatment**

- Indomethacin: RR 0.30, 95% CI 0.23 to 0.38; high-certainty evidence
- Ibuprofen: RR 0.62, 95% CI 0.44 to 0.86; moderate-certainty evidence
  - ✓ Oral more effective vs. IV (RR 0.38, 95% CI 0.26 to 0.56)
  - ✓ High-dose more effective vs. standard-dose (RR 0.37, 95% CI 0.22 to 0.61)
- Acetaminophen: RR 0.35, 95% CI 0.23 to 0.53; low-certainty evidence

- **No evidence on the effect of treatment on composite outcome of death, neurodevelopmental disability OR CLD**

# PDA Tolerate Trial

200 babies, < 28 weeks (*mean, 25.8 +/- 1.1 weeks*)

- *Stratified by 23-25 weeks, 26-28 weeks and by center*

Randomized between DOL 6 thru 14, 50% intubated

## Outcomes

- **Primary: need for PDA ligation**
- **Secondary: multiple including BPD, NEC and Death**

Moderate to large PDA shunts > specific defined criteria

Rx per center with indomethacin, ibuprofen or acetaminophen

## Findings:

- **No difference in outcomes**
- *Lots of "rescue treatment"*
- *Secondary analysis found those babies vent > 10 days had less severe BPD*

# BeneDuctus Trial- *Expectant management or Early Ibuprofen for PDA*

Multicenter, noninferiority trial

263 babies, < 28 weeks

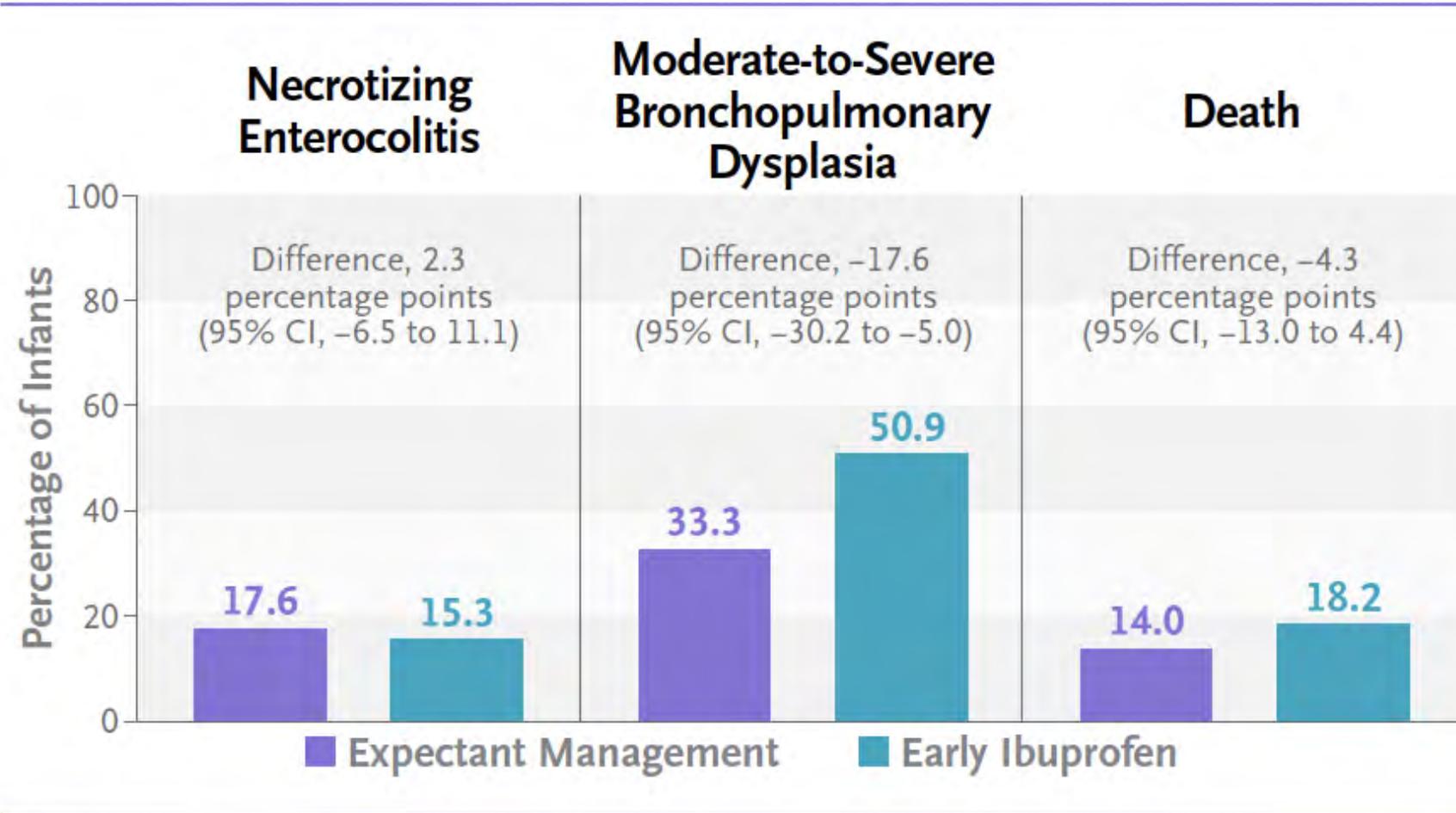
*median GA 26 weeks, BW 845 g*

*hsPDA (diameter, >1.5 mm, with left-to-right shunting)*

Treatment between 24 and 72 hours

Low dose ibuprofen vs expectant mgt

**Outcome: composite primary outcome included NEC, moderate to severe BPD, or death at 36 weeks PMA**



# Baby OSCAR- *Trial early treatment with ibuprofen*

Similar to BeneDuctus  
trial

Double-blind placebo  
RCT in UK

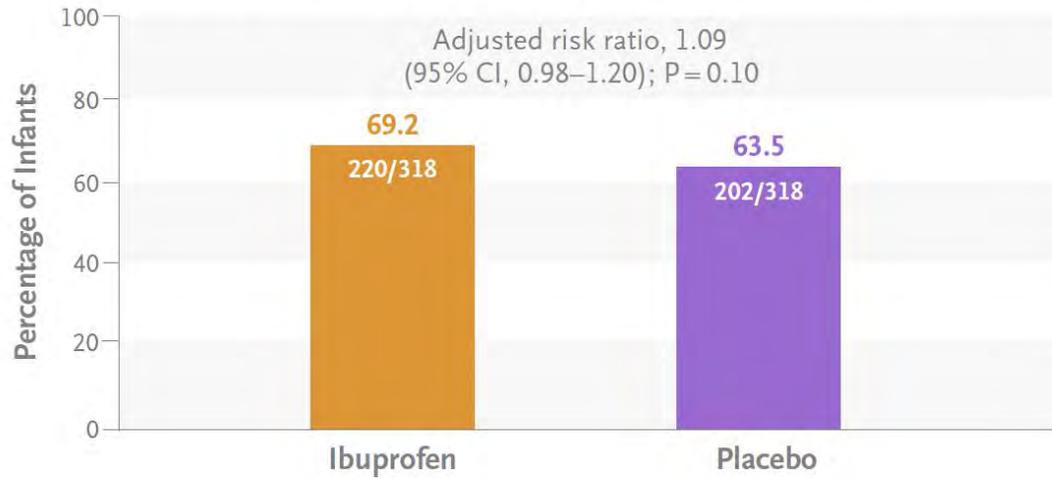
600+ babies, 23-29  
weeks

hsPDA = *diameter of*  
 *$\geq 1.5$  mm with pulsatile*  
*flow*

Early treatment w/  
ibuprofen (low dose),  
<72 hours

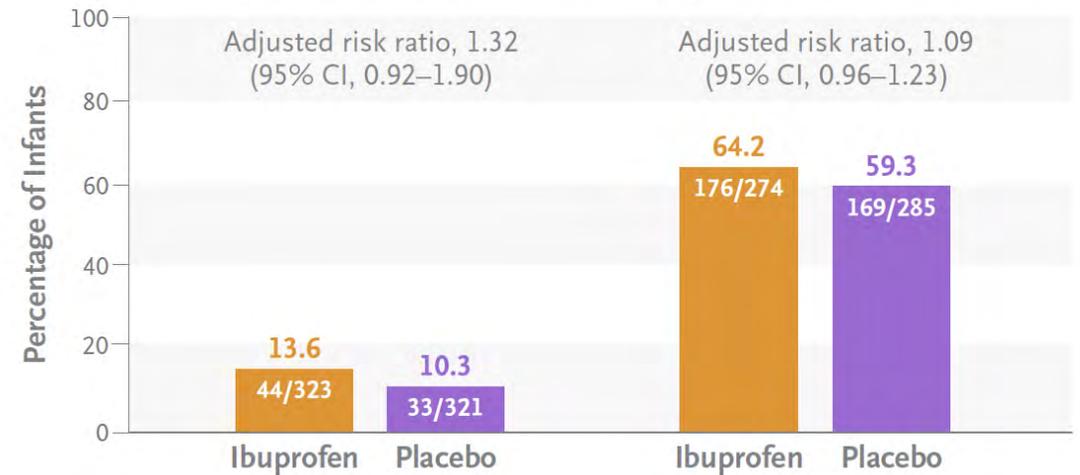
**Outcome: composite  
of death or moderate  
or severe BPD at 36  
weeks PMA**

### Death or Moderate or Severe BPD at 36 Wk Postmenstrual Age



### Death by 36 Wk Postmenstrual Age

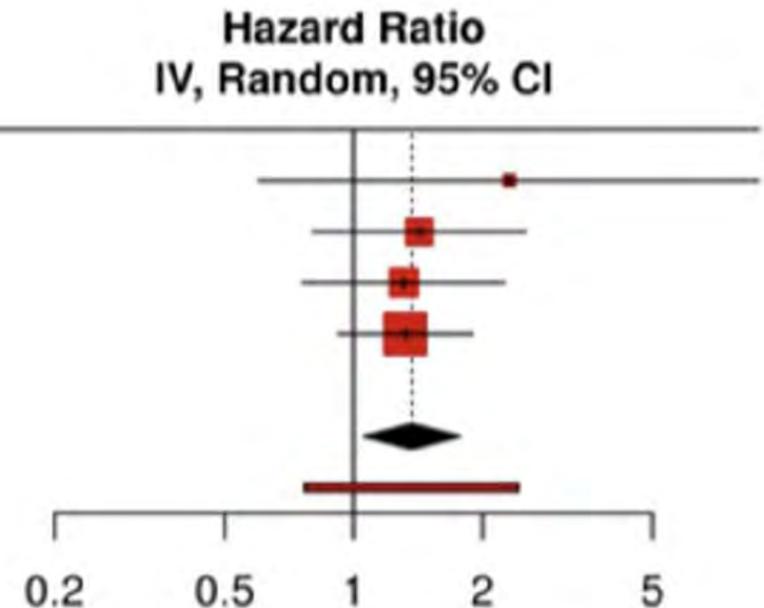
### Moderate or Severe BPD at 36 Wk Postmenstrual Age



# Meta-analysis: Early Targeted Treatment of PDA with Ibuprofen Death by 36 weeks

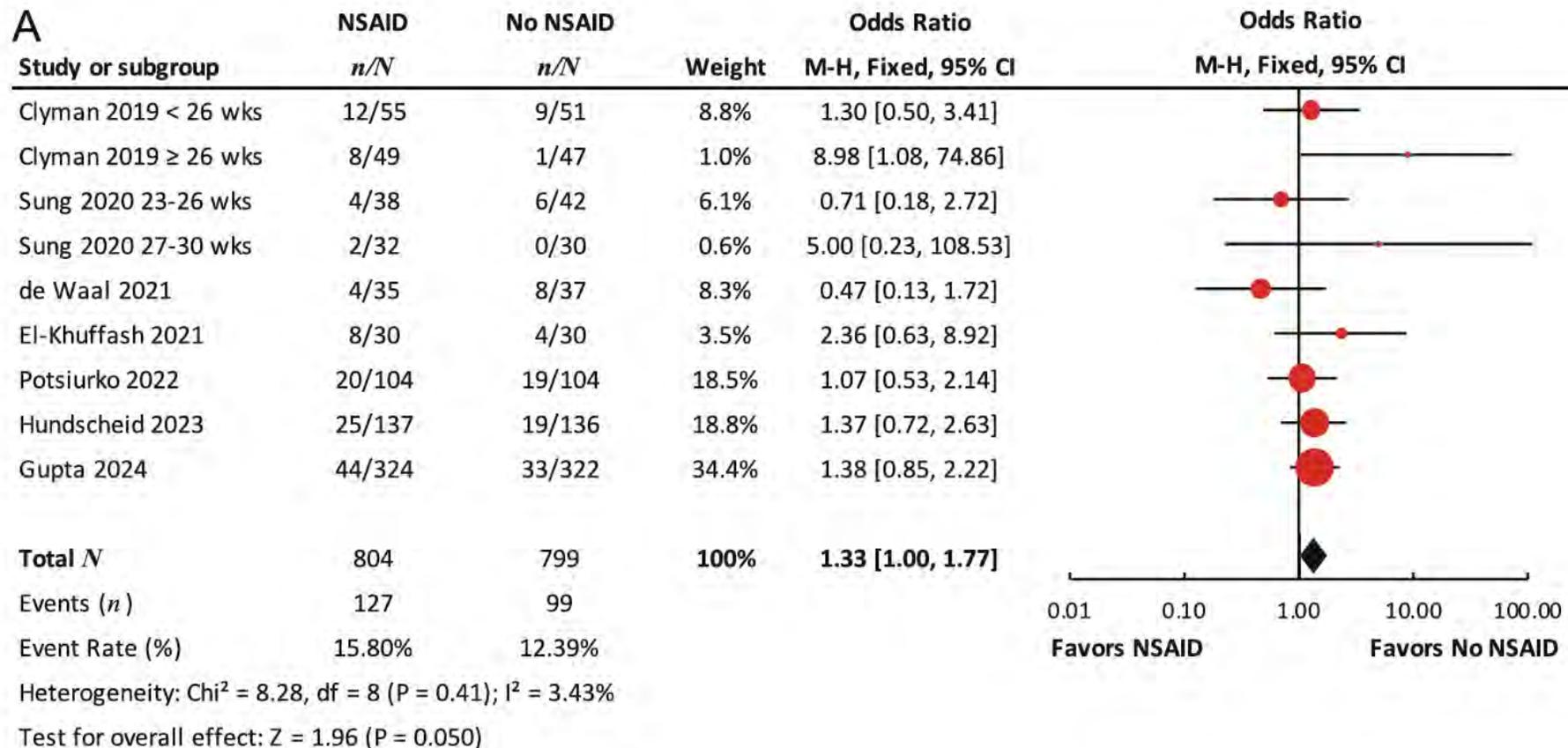
Gupta S and Donn S, Sem in Fetal and Neonatal Medicine 29 (2024)

Study	logHR	SE	Weight	Hazard Ratio IV, Random, 95% CI
PDA RCT 2020	0.8376	0.6880	3.8%	2.31 [0.60; 8.90]
TRIOCAPI 2021	0.3525	0.2937	20.8%	1.42 [0.80; 2.53]
BeNeDuctus 2022	0.2705	0.2780	23.2%	1.31 [0.76; 2.26]
Baby-OSCAR 2024	0.2792	0.1850	52.3%	1.32 [0.92; 1.90]
<b>Total (95% CI)</b>			<b>100.0%</b>	<b>1.37 [1.05; 1.78]</b>
<b>Prediction interval</b>				<b>[0.77; 2.43]</b>
Heterogeneity: $\text{Tau}^2 = 0$ ; $\text{Chi}^2 = 0.66$ , $\text{df} = 3$ ( $P = 0.88$ ); $I^2 = 0\%$				
Test for overall effect: $Z = 2.34$ ( $P = 0.02$ )				



Gupta S (Unpublished data)

# Mortality with Early Treatment NSAIDs



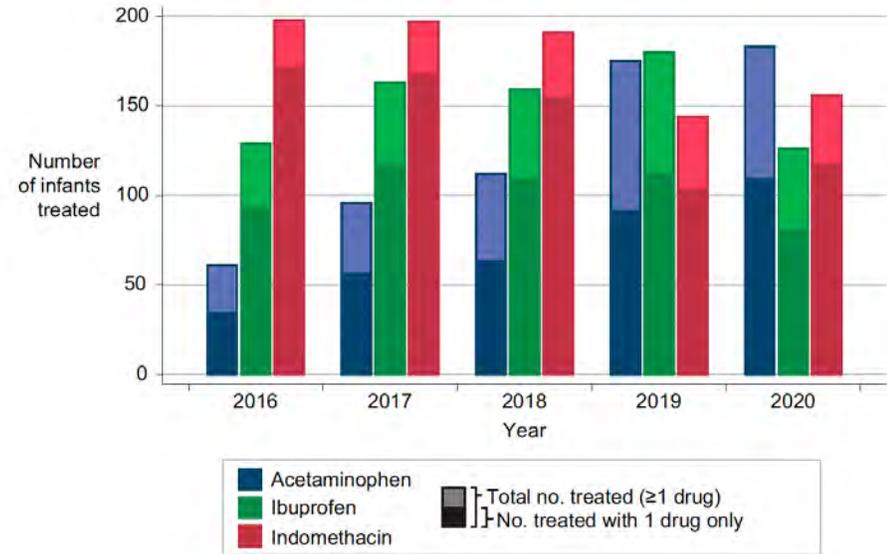
# Benitz W- J Perinatology 2024

*“Given the evidence that early (at or before 14 days of age) treatment with indomethacin or ibuprofen may result in increased mortality and possibly other long-term adverse outcomes, **provision of early treatment as a component of standard neonatal care can no longer be recommended** except under exceptional circumstances”*

*“Consideration of this information regarding adverse effects of NSAIDs may lead health care providers and parents to prefer **alternative novel regimens (e.g., acetaminophen, transcatheter occlusion)** for which evidence of adverse impacts is (so far) lacking”*

# Acetaminophen for Patent Ductus Arteriosus and Risk of Mortality and Pulmonary Morbidity

Erik A. Jensen, MD, MSCE,<sup>a</sup> Sara B. DeMauro, MD, MSCE,<sup>a</sup> Matthew A. Rysavy, MD, PhD,<sup>b</sup> Ravi M. Patel, MD, MSc,<sup>c</sup> Matthew M. Laughon, MD, MPH,<sup>d</sup> Eric C. Eichenwald, MD,<sup>a</sup> Barbara T. Do, PhD,<sup>e</sup> Abhik Das, PhD,<sup>e</sup> Clyde J. Wright, MD<sup>f</sup> for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Neonatal Research Network\*



*E Jensen, PEDIATRICS 154:2, August 2024*

- **NRN Network: 2016-2020**
- 22 to 28 weeks' gestation, 401 to 1000 g
- 1921 infants, 627 (32.6%) received acetaminophen
- Primary Outcome Death or Grade 2 or 3 BPD at 36 weeks PMA

- *Acetaminophen associated w/ increased risk of pre-discharge mortality (13.3% vs 10.0%) when adjusting for perinatal and early postnatal factors (aRR 1.42, 95% CI 1.02–1.93), but not seen in exploratory analyses that included later postnatal factors (aRR 1.28, 95% CI 0.91–1.82)*

# Summary Prophylactic/Early PDA Treatment

Increased closure of PDA and reduced risk for PDA ligation

No differences in long-term outcomes

**Ibuprofen trend toward increased BPD and increased mortality**

Efficacy and safety of Acetaminophen needs to be further studied

Insufficient data on 22-24 weeks

*What about  
PDA  
treatment  
after >7-14  
days?*



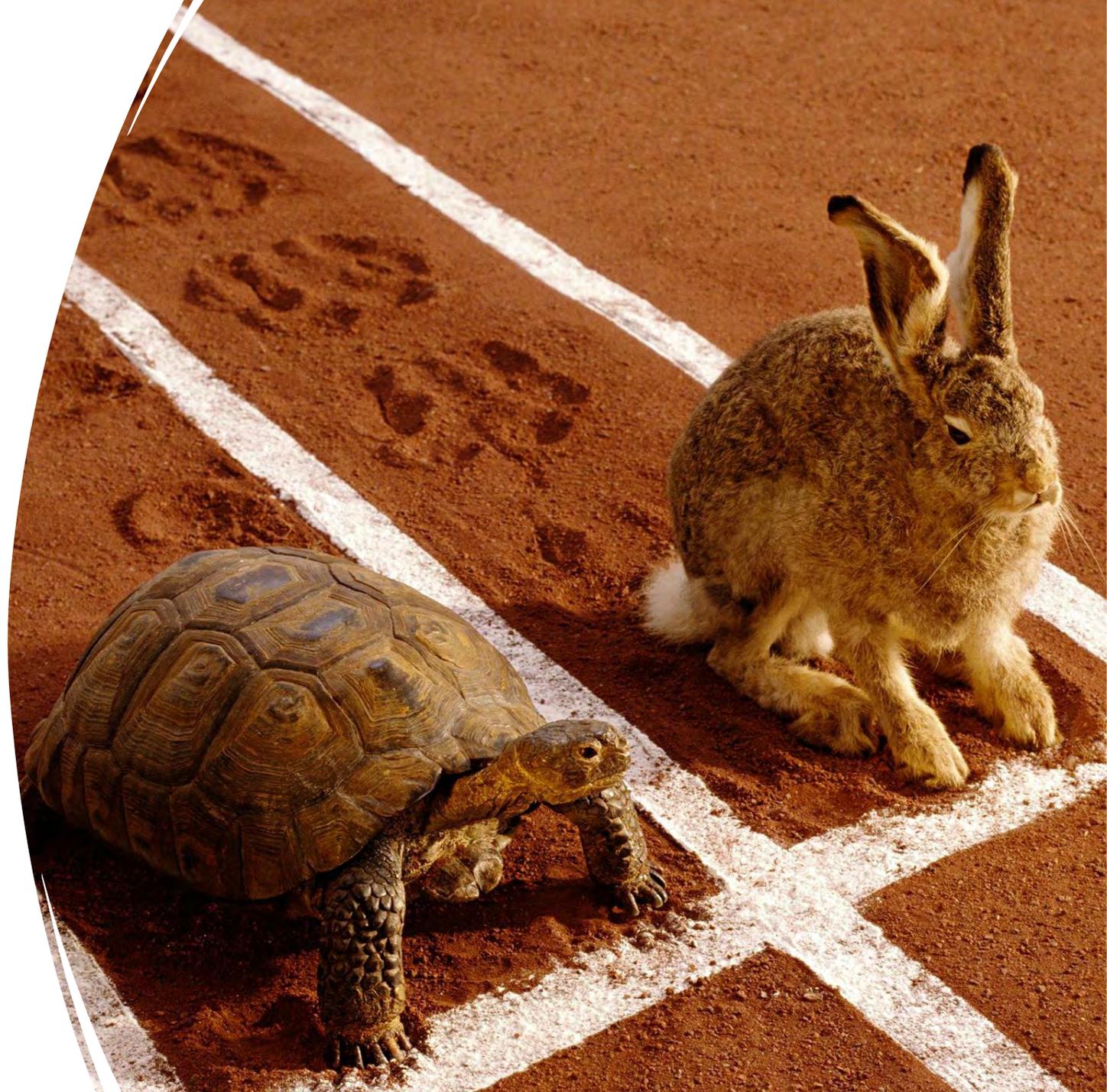
# AAP Statement Recommendations



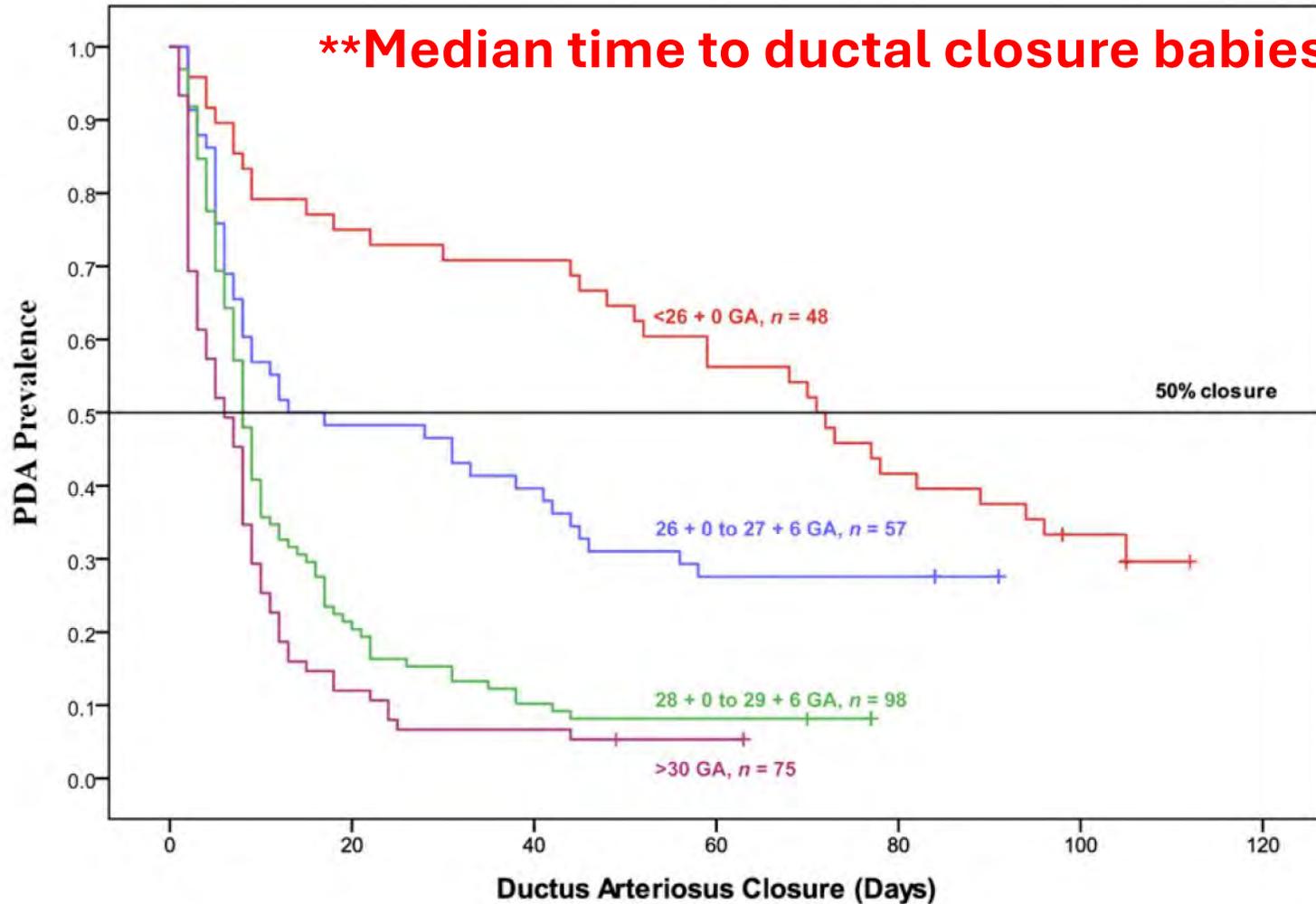
- **There is insufficient data for recommendations on management of hsPDA beyond 2 weeks of age**
  - *Benefits/risks of watchful expectancy with close monitoring, medical or transcatheter closure, or surgical ligation have not been adequately defined*
  - ***If hsPDA persists beyond 2 weeks of age despite pharmacologic therapy of up to 2 courses (or if medical therapy is contraindicated), such infants may be considered for either transcatheter closure or surgical ligation***

*What About  
Expectant  
Management?*

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# Semberova J. *PEDIATRICS* Volume 140, number 2, 2017



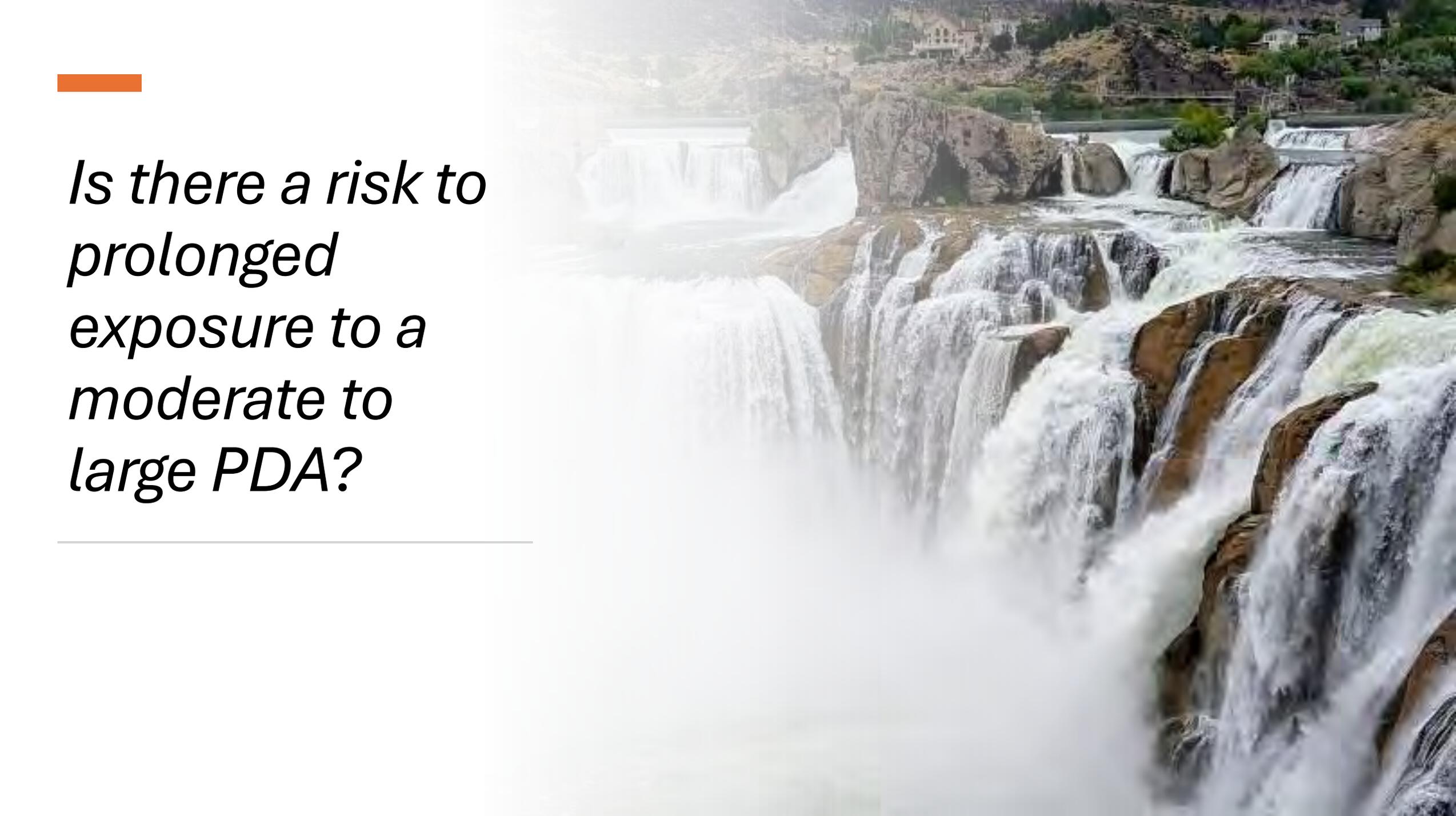
- *Retrospective cohort study conducted in 2 European level-3 NICUs*
- *368 eligible >> 280 received no treatment and truly conservative mgt*
- *85% closed prior to hospital discharge*

# Unanswered Questions with No Treatment

Several studies over the past decade suggest this approach is safe, but all retrospective data often with confounding factors

Concern for prolonged exposure to moderate-large L>R shunt adversely affecting lung function, heart remodeling, pulmonary hypertension and ND impairment

Literature doesn't address question of which infants may benefit from a selective strategy only treating those with a true hsPDA



*Is there a risk to prolonged exposure to a moderate to large PDA?*

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## ORIGINAL ARTICLE

### What happens when the patent ductus arteriosus is treated less aggressively in very low birth weight infants?

JW Kaempf, YX Wu, AJ Kaempf, AM Kaempf, L Wang and G Grunkemeier

Providence St Vincent Medical Center, Women and Children's Program, Neonatal Intensive Care Unit, Portland, OR, USA

- *Observational study single center infants born 501 to 1500 g in two distinct epochs.*
- *Era 1 (January 2005 to Dec 2007)*
- *Era 2 (January 2008 to June 2009)*
- ***Conservative mgt reasonable strategy but increased CLD or mortality after 7d***

**Table 3** Clinical outcomes Era 1 vs. Era 2

	<i>Era 1</i>	<i>Era 2</i>	<i>P-value</i>
Number of infants ( <i>N</i> )	139	72	
Mortality after day 7	8%	13%	0.28
Chronic lung disease	32%	43%	0.10
Mortality after day 7 or chronic lung disease	40%	54%	0.04
Pulmonary hemorrhage	2.2%	5.6%	0.23
Grade 3–4 intraventricular hemorrhage	5.8%	5.6%	0.95
Periventricular leukomalacia	3.0%	1.4%	0.49
Necrotizing enterocolitis	7.2%	5.6%	0.65
Spontaneous intestinal perforation	5.0%	2.8%	0.44
Late onset sepsis	11%	13%	0.71
<i>Retinopathy of prematurity</i>			0.78
None	54%	55%	
Stage 1–2	35%	37%	
Stage 3–4	11%	7.7%	
Growth velocity (mean ± s.d.; g kg <sup>-1</sup> day <sup>-1</sup> )	13 ± 5	13 ± 5	0.77



## Association between Hemodynamically Significant Patent Ductus Arteriosus and Bronchopulmonary Dysplasia

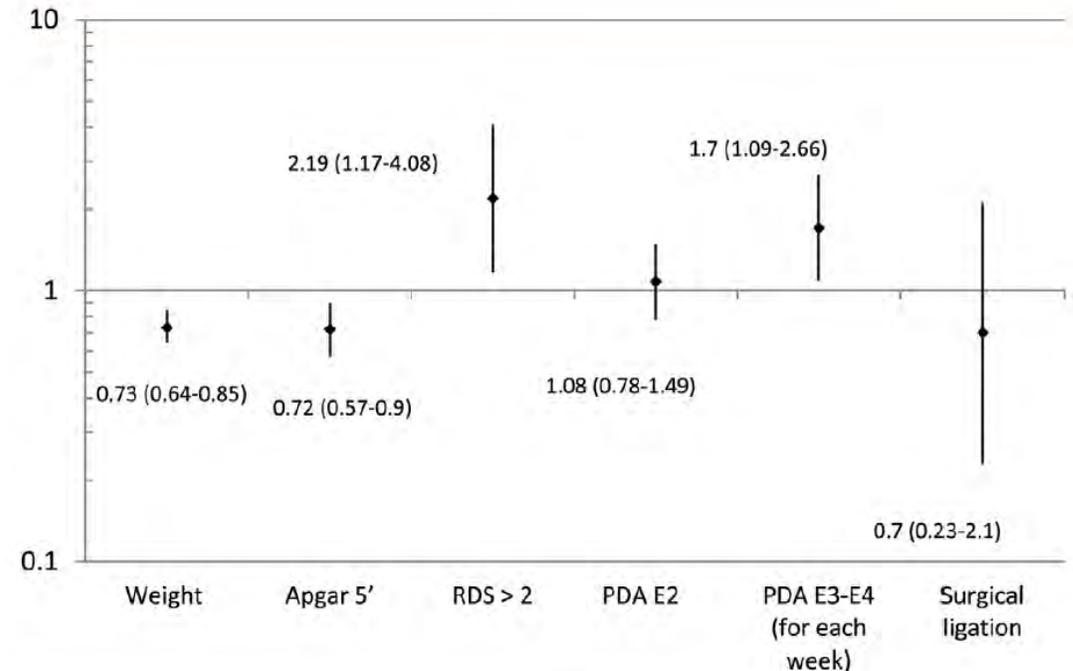
Federico Schena, MD, Gaia Francescato, MD, PhD, Alessia Cappelleri, MD, Irene Piccioli, MD, Alessandra Mayer, MD, Fabio Mosca, MD, and Monica Fumagalli, MD

**Objective** To assess whether the duration and magnitude of the shunt with patent ductus arteriosus (PDA) are related to a higher incidence of bronchopulmonary dysplasia (BPD) or death.

**Study design** A total of 242 infants  $\leq 28$  weeks gestational age were evaluated retrospectively between 2007 and 2012; 105 (43.3%) developed BPD or died (group 1) and 137 (56.6%) did not (group 2). A review of all echocardiographic evaluations performed from birth up to 36 weeks of postconceptional age or final ductal closure was carried out, to detect the presence of PDA, and estimate the severity of ductal shunt through the "PDA staging system" proposed by McNamara and Sehgal.

**Results** Group 1 presented with a hemodynamically significant ductus arteriosus (DA) (E3 and/or E4-PDA) for a longer period of time vs group 2: 4.8 vs 2.3 days, respectively ( $P < .001$ ). Persistence of a nonsignificant DA (E2) was not associated with development of BPD ( $P = .16$ ). Each week of a hemodynamically significant DA represented an added risk for BPD (OR 1.7), and the duration of a small, nonsignificant DA (E2) did not. Surgical ligation of PDA itself was not found to be an independent risk factor for BPD. In the subgroup of patients who received ligation, a later ligation (33 vs 23 days) and a prolonged PDA were the only factors associated to BPD or death.

**Conclusions** A shared scoring system of the severity of ductal shunt is helpful to correctly evaluate the association between PDA morbidities, to compare scientific studies, and to guide treatment. (*J Pediatr* 2015;166:1488-92).

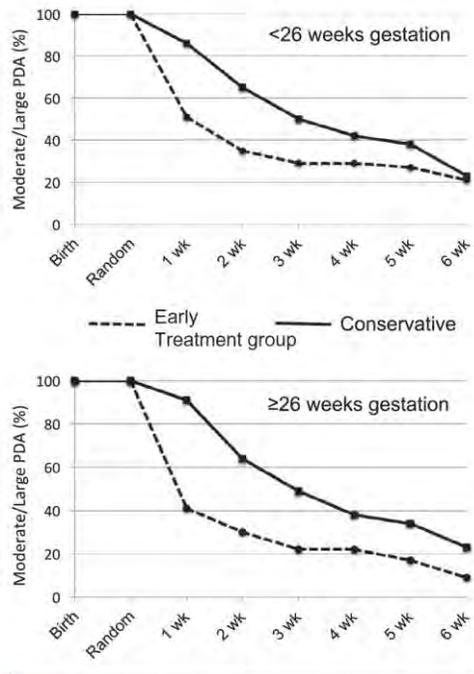


**Figure.** Multivariate analysis, OR for the BPD, or death group.

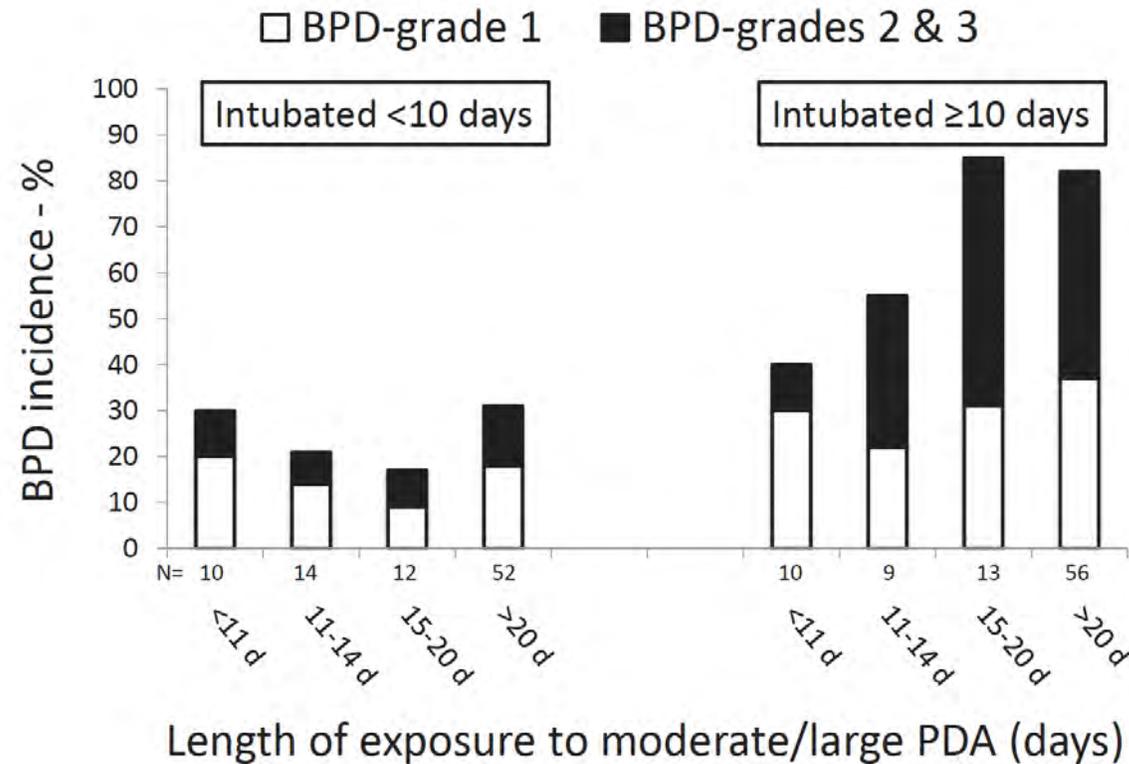
**More targeted approach to defining hsPDA may be more predictive**

# Secondary Analysis: PDA-TOLERATE: *J Peds* 2021;229:283-88

- Prolonged PDA exposure ( $\geq 11$  days) associated with an increased risk of BPD when intubated  $>10$  days**



**Figure 5.** Weekly incidence of moderate-to-large PDA shunts in the CT and ERT groups after randomization. Infants were delivered between 23<sup>07</sup> and 25<sup>07</sup> weeks (ie, <26 weeks) and between 26<sup>07</sup> and 27<sup>07</sup> weeks (ie, ≥26 weeks) gestation.



## Relationship between Duration of Infant Exposure to a Moderate-to-Large Patent Ductus Arteriosus Shunt and the Risk of Developing Bronchopulmonary Dysplasia or Death Before 36 Weeks

Ronald I. Clyman, MD<sup>1,2</sup> Nancy K. Hills, PhD<sup>3</sup> Melissa Liebowitz, MD<sup>1</sup> Sandy Johng, MD<sup>1</sup>

<sup>1</sup> Department of Pediatrics, University of California San Francisco, San Francisco, California

<sup>2</sup> Cardiovascular Research Institute, University of California San Francisco, San Francisco, California

<sup>3</sup> Department of Neurology, University of California San Francisco, San Francisco, California

[Address for correspondence](#) Ronald I. Clyman, MD, University of California San Francisco, 550 16th Street, UCSF Box 0734, San Francisco, CA 94158-0734 (e-mail: clymanr@peds.ucsf.edu).

Am J Perinatol 2020;37:216–223.

Birth: infants <28 weeks ( $n = 485$ )  
(January 1, 2005 – December 31, 2018)

Survived <7 days ( $n = 62$ ):  
37 Intracranial hemorrhage  
10 Respiratory failure  
8 Pulmonary hemorrhage  
5 Bacteremia  
2 Necrotizing enterocolitis

Study population – Survived  $\geq 7$  days ( $n = 423$ )

	Ductus closed	Ductus small	Ductus moderate-to-large: Duration of exposure				
			<7 d	7-13 d	14-27 d	28-48 d	>49 d
$n =$	197	34	19	56	41	45	31
BPD/Death	28 %	24 %	16 %	45 %	46 %	47 %	58 %
BPD	23 %	21 %	16 %	33 %	41 %	45 %	58 %

# Triocapi Trial

CLINICAL RESEARCH ARTICLE OPEN

## Patent ductus arteriosus, tracheal ventilation, and the risk of bronchopulmonary dysplasia

Ronald I. Clyman<sup>1</sup>, Nancy K. Hills<sup>2</sup>, Gilles Cambonie<sup>3</sup>, Thierry Debillon<sup>4</sup>, Isabelle Ligi<sup>5</sup>, Geraldine Gascoin<sup>6</sup>, Juliana Patkai<sup>7</sup>, Alain Beuchee<sup>8</sup>, Geraldine Favrais<sup>9</sup>, Xavier Durrmeyer<sup>10,11</sup>, Cyril Flamant<sup>12,13</sup> and Jean Christophe Roze<sup>12,13</sup>

**BACKGROUND:** An increased risk for bronchopulmonary dysplasia (BPD) exists when moderate-to-large patent ductus arteriosus shunts (hsPDA) persist beyond 14 days.

**GOAL:** To examine the interaction between prolonged exposures to tracheal ventilation ( $\geq 10$  days) and hsPDA on the incidence of BPD in infants  $< 28$  weeks gestation.

**STUDY DESIGN:** Predefined definitions of prolonged ventilation ( $\geq 10$  days), hsPDA ( $\geq 14$  days), and BPD (room air challenge test at 36 weeks) were used to analyze deidentified data from the multicenter TRIOCAPI RCT in a secondary analysis of the trial.

**RESULTS:** Among 307 infants who survived  $> 14$  days, 41 died before 36 weeks. Among survivors, 93/266 had BPD. The association between BPD and hsPDA depended on the length of intubation. In multivariable analyses, prolonged hsPDA shunts were associated with increased BPD (odds ratio (OR) (95% confidence interval (CI)) = 3.00 (1.58–5.71)) when infants required intubation for  $\geq 10$  days. In contrast, there was no significant association between hsPDA exposure and BPD when infants were intubated  $< 10$  days (OR (95% CI) = 1.49 (0.98–2.26)). A similar relationship between prolonged hsPDA and length of intubation was found for BPD/death ( $n = 307$ ): infants intubated  $\geq 10$  days: OR (95% CI) = 2.41 (1.47–3.95); infants intubated  $< 10$  days: OR (95% CI) = 1.37 (0.86–2.19)).

**CONCLUSIONS:** Moderate-to-large PDAs were associated with increased risks of BPD and BPD/death—but only when infants required intubation  $\geq 10$  days.

*Pediatric Research* (2022) 91:652–658; <https://doi.org/10.1038/s41390-021-01475-w>

**Table 3.** Stratified generalized estimating equation models examining the relationship between PDA exposure and BPD or BPD/death before 36 weeks in two subpopulations of infants: those intubated for  $< 10$  days and those intubated for  $\geq 10$  days.

### PDA duration among infants intubated $< 10$ days

Characteristic	BPD <sup>a</sup> (N = 161)			BPD/death before 36 weeks <sup>b</sup> (N = 181)		
	OR	95% CI	P value	OR	95% CI	P value
PDA duration						
<14 days	Ref.			Ref.		
$\geq 14$ days	1.34	(0.87, 2.08)	0.180	1.32	(0.75, 2.29)	0.324

### PDA duration among infants intubated $\geq 10$ days

Characteristic	BPD <sup>a</sup> (N = 105)			BPD/death before 36 weeks <sup>b</sup> (N = 126)		
	OR	95% CI	P value	OR	95% CI	P value
PDA duration						
<14 days	Ref.			Ref.		
$\geq 14$ days	2.80	(1.31, 5.97)	0.008	2.17	(1.17, 4.02)	0.014

The Final models for BPD and BPD/death were adjusted for the demographic variables from Table 1 that were considered to be “important demographic variables” (see “Methods”).

<sup>a</sup>Adjusted for PDA duration, gestational age, infant still intubated at 24 h, and PDA ligation.

<sup>b</sup>Adjusted for PDA duration, gestational age, infant still intubated at 24 h, PDA ligation, and intracranial hemorrhage (grades 3 or 4).



## Changes in Patent Ductus Arteriosus Management and Outcomes in Infants Born at 26-28 Weeks' Gestation

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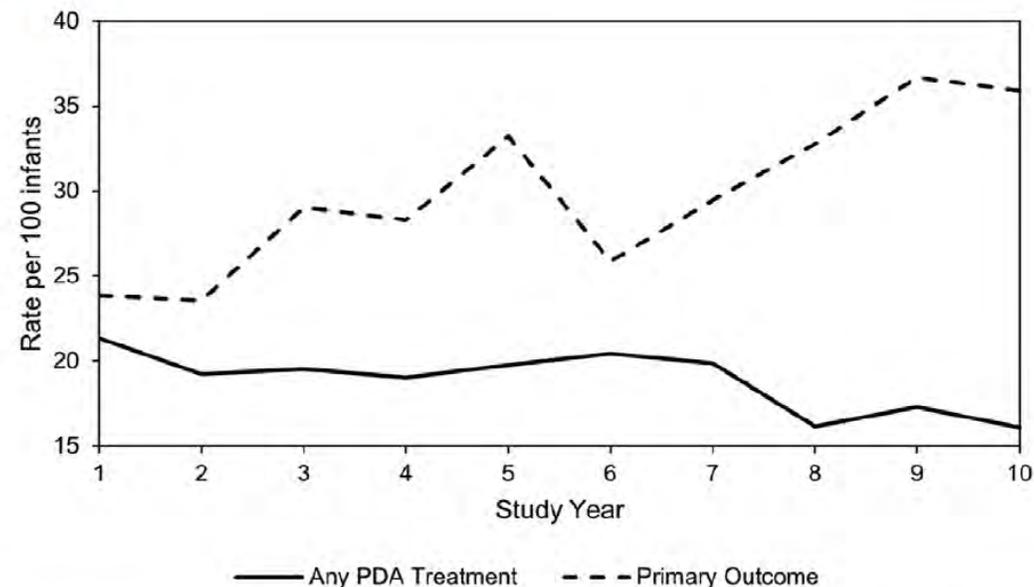
**Objective** To investigate the association between the secular decrease in treatment of patent ductus arteriosus (PDA) and trends in neonatal mortality and morbidity in infants born at 26 0/7-28 6/7 weeks' gestation.

**Study design** A retrospective cohort study including infants born between 2012 and 2021 in continually participating hospitals in the National Institute of Child Health and Human Development Neonatal Research Network. The primary composite outcome was defined as surgical necrotizing enterocolitis, grade 2-3 bronchopulmonary dysplasia (BPD), severe intraventricular hemorrhage, or death. Relationships of temporal trends in PDA treatment with the primary composite outcome and its components were analyzed using a multilevel model accounting for patient-level factors. A separate analysis assessed these relationships stratified by hospital changes in PDA treatment.

**Results** The study included 7864 infants. There was a decrease in any PDA treatment from 21% to 16% ( $P < .01$ ) and an increase in the primary composite outcome from 24% to 36% ( $P < .01$ ). Change in the primary outcome was driven by increased grade 2-3 BPD (13%-26%,  $P < .01$ ), with grade 2 BPD accounting for most of this increase (10%-22%,  $P < .01$ ). Temporal decreases in PDA treatment were associated with increases in the primary outcome and grade 2-3 BPD after adjusting for patient-level factors ( $P < .01$ ). However, stratified analyses showed that grade 2-3 BPD increased in all hospital groups, regardless of changes in PDA management.

**Conclusions** From 2012 to 2021, temporal decreases in PDA treatment for infants 26-28 weeks were associated with an increase in grade 2-3 BPD. However, caution is warranted in determining causality. Reasons for increased grade 2-3 BPD during the past decade warrant investigation. (*J Pediatr* 2025;279:114456).

**Trial registration** Generic Database: NCT00063063.



**Figure 1.** Rates of PDA, treatment, and outcomes (2012-2021).

**\*\* From 2012 to 2021, temporal decreases in PDA treatment for infants 26-28 weeks were associated with an increase in grade 2-3 BPD**



## Hemodynamic and clinical consequences of early versus delayed closure of patent ductus arteriosus in extremely low birth weight infants

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### Abstract

**Objectives** To describe changes in hemodynamics, respiratory support, and growth associated with transcatheter PDA closure (TCPC) in ELBW infants, stratified by postnatal age at treatment.

**Study design** This is an observational study of ELBW infants who underwent TCPC at ≤4 weeks (Group-1;  $n = 34$ ), 4–8 weeks (Group-2;  $n = 33$ ), and >8 weeks of age (Group-3;  $n = 33$ ). Hemodynamic assessment was performed during TCPC. Multivariate Cox-proportionate-hazard modeling was used to identify factors associated with respiratory severity score (RSS) >2 for >30 days following TCPC.

**Results** In comparison with Group-1, Group-3 infants had higher pulmonary vascular resistance ( $PVRi = 3.3$  vs.  $1.6$   $WU \cdot m^2$ ;  $P = 0.01$ ), less weight gain between 4 and 8 weeks of age (16 vs. 25 g/day) and took longer to achieve  $RSS < 2$  (median 81 vs. 20 days;  $P = 0.001$ ).  $RSS > 2$  for >30 days was associated with TCPC >8 weeks (OR = 3.2, 95% CI: 1.75–5.8;  $p = 0.03$ ) and  $PVRi \geq 3$  (OR = 4.5, 95% CI: 2.7–8.9;  $p < 0.01$ ).

**Conclusion** ELBW infants may benefit from PDA closure within the first 4 weeks of life in order to prevent early onset pulmonary vascular disease, promote faster growth, and for quicker weaning of ventilator and oxygen support.

**Table 2** Baseline hemodynamics.

Variable	Group-1 ( $n = 34$ )	Group-2 ( $n = 33$ )	Group-3 ( $n = 33$ )	<i>P</i> value
Baseline Qp:Qs PA vs. aorta systolic BP (%)	2.5 (1.6–4)	2 (1.3–3.1)	1.8 (0.8–4.2)	0.438 <sup>a</sup>
Baseline PVRi ( $WU \cdot m^2$ )	1.6 (1–2.3)	2 (1–4.8)	3.3 (2.4–7.6)	<0.001 <sup>b</sup>

Qp:Qs pulmonary to systemic flow ratio, PA pulmonary artery, BP blood pressure, PVRi pulmonary vascular resistance indexed.

<sup>a</sup>Overall *P* value comparing all three groups.



Original Investigation | Pediatrics

# Patent Ductus Arteriosus and Bronchopulmonary Dysplasia–Associated Pulmonary Hypertension A Bayesian Meta-Analysis

Eduardo Villamor, MD, PhD; Elke van Westering-Kroon, MD; Gema E. Gonzalez-Luis, MD, PhD; František Bartoš, MSc; Steven H. Abman, MD; Maurice J. Huizing, MSc

## ORIGINAL ARTICLE

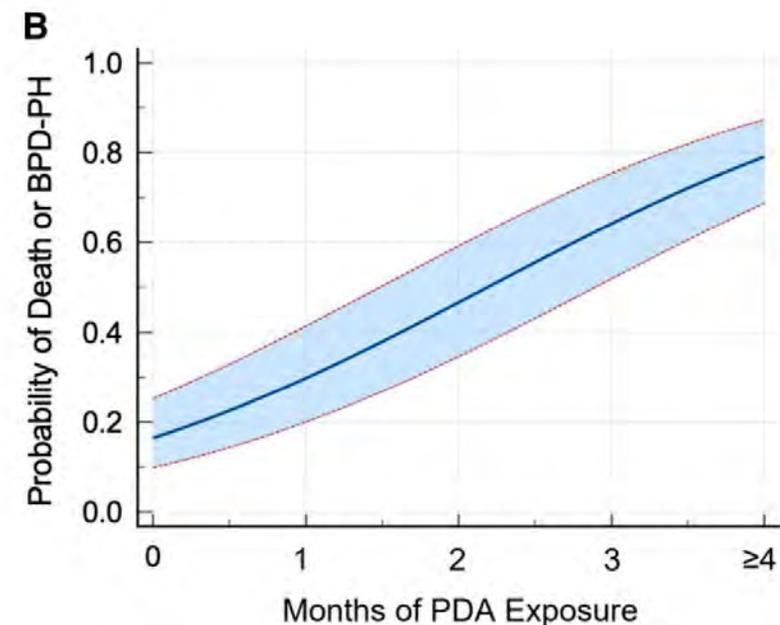
### Patent Ductus Arteriosus and Development of Bronchopulmonary Dysplasia–associated Pulmonary Hypertension

Samuel J. Gentle<sup>1</sup>, Colm P. Travers<sup>1</sup>, Matthew Clark<sup>2</sup>, Waldemar A. Carlo<sup>1</sup>, and Namasivayam Ambalavanan<sup>1</sup>

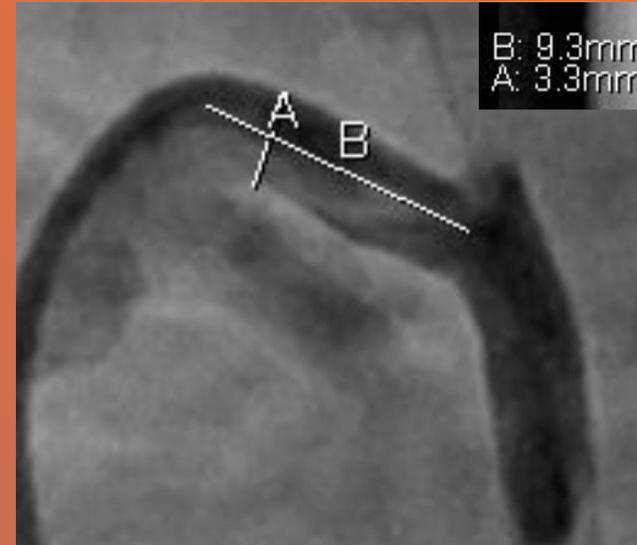
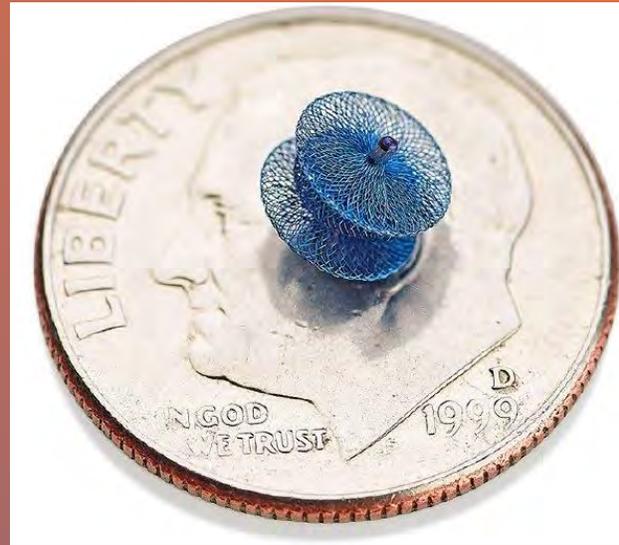
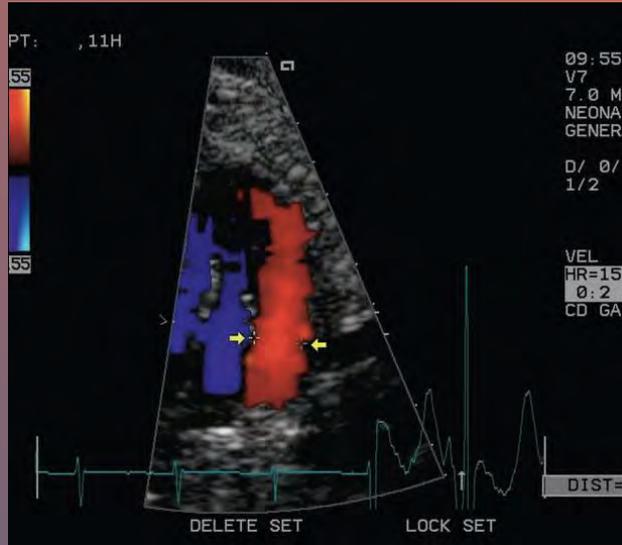
<sup>1</sup>Division of Neonatology, Department of Pediatrics, and <sup>2</sup>Division of Cardiology, Department of Pediatrics, The University of Alabama at Birmingham, Birmingham, Alabama

*American J of Respiratory and Critical Care: 207 No. 7 | 2023*

- 22-28 wks GA, 2017-2020, retrospective case-control study
- PDA (aOR, 4.29; 95% CI, 1.89–9.77) and moderate to large PDA (aOR, 4.15; 95% CI, 1.78–9.64) significantly related to BPD-PH at discharge



\* BPD-PH at discharge or death with coefficients of 0.40 (p < 0.001) and 0.45 (p < 0.001), respectively



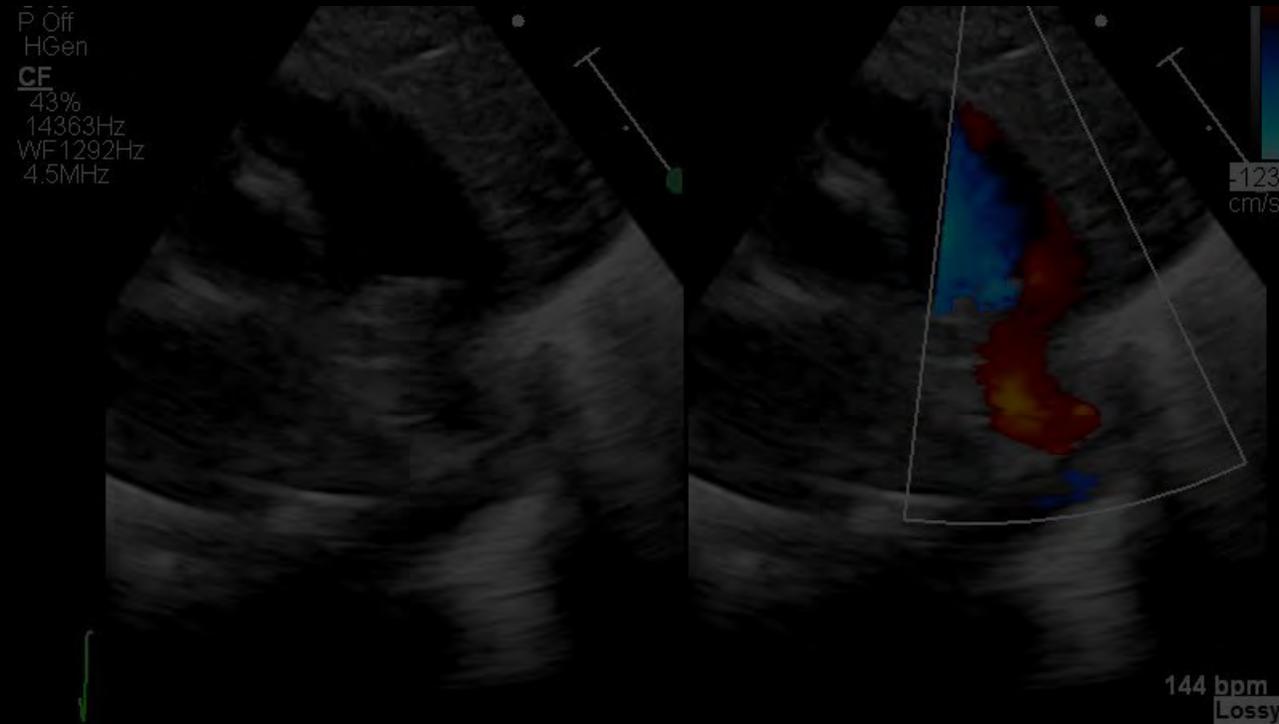
# Existing Knowledge Gaps

+

o

# Defining the hsPDA...

- A hsPDA infrequent  $\geq 28$  weeks (especially without RDS)
- **In babies  $\leq 26-28$  weeks:**
  - **20-30%** of PDA's close by 2-3 weeks of age
  - **40-50%** remain open (and maybe significant on echocardiogram, but are clinically irrelevant)
  - **<5-10%** may cause long-term issues
- Increased risk of neonatal morbidities is only associated w/ moderate-to-large high-volume shunt (not with small, low volume shunt)



# Defining a hemodynamically significant PDA?

<b>Echocardiographic</b>		<b>Clinical features</b>
<i>Category</i>	<i>Measures</i>	
<b>Ductus arteriosus</b>	Size, flow patterns, gradient (High vs. low volume)	
<b>Pulmonary overcirculation</b>	LA/AO, LVO, PV Doppler, LPA diastolic flow	Degree of respiratory support + compromise
<b>Systemic hypoperfusion</b>	RVO, Descending aorta celiac, MCA flow	End-organ perfusion (AKI, NEC, IVH)
<b>Myocardial performance</b>	Systolic & Diastolic function (MV E/A, IVRT)	Additional: Sepsis ?

# PDA Scoring Systems

ORIGINAL  
ARTICLES

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## A Patent Ductus Arteriosus Severity Score Predicts Chronic Lung Disease or Death before Discharge

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**Objectives** To test the hypothesis that a patent ductus arteriosus (PDA) severity score (PDA<sub>sc</sub>) incorporating markers of pulmonary overcirculation and left ventricular (LV) diastolic function can predict chronic lung disease or death before discharge (CLD/death).

**Study design** A multicenter prospective observational study was conducted for infants <29 weeks gestation. An echocardiogram was carried out on day 2 to measure PDA diameter and maximum flow velocity, LV output, diastolic flow in the descending aorta and celiac trunk, and variables of LV function using tissue Doppler imaging. Predictors of CLD/death were identified using logistic regression methods. A PDA<sub>sc</sub> was created and a receiver operating characteristic curve was constructed to assess its ability to predict CLD/death.

**Results** We studied 141 infants at a mean (SD) gestation and birthweight of 26 (1.4) weeks and 952 (235) g, respectively. Five variables were identified that were independently associated with CLD/death (gestation at birth, PDA diameter, maximum flow velocity, LV output, and LV a' wave). The PDA<sub>sc</sub> had a range from 0 (low risk) to 13 (high risk). Infants who developed CLD/death had a higher score than those who did not (7.3 [1.8] vs 3.8 [2.0],  $P < .001$ ). PDA<sub>sc</sub> had an area under the curve of 0.92 (95% CI 0.86-0.97,  $P < .001$ ) for the ability to predict CLD/death. A PDA<sub>sc</sub> cut-off of 5 has sensitivity and specificity of 92% and 87%, and positive and negative predictive values of 92% and 82%, respectively.

**Conclusions** A PDA<sub>sc</sub> on day 2 can predict the later occurrence of CLD/death further highlighting the association between PDA significance and morbidity. (*J Pediatr* 2015;167:1354-61).

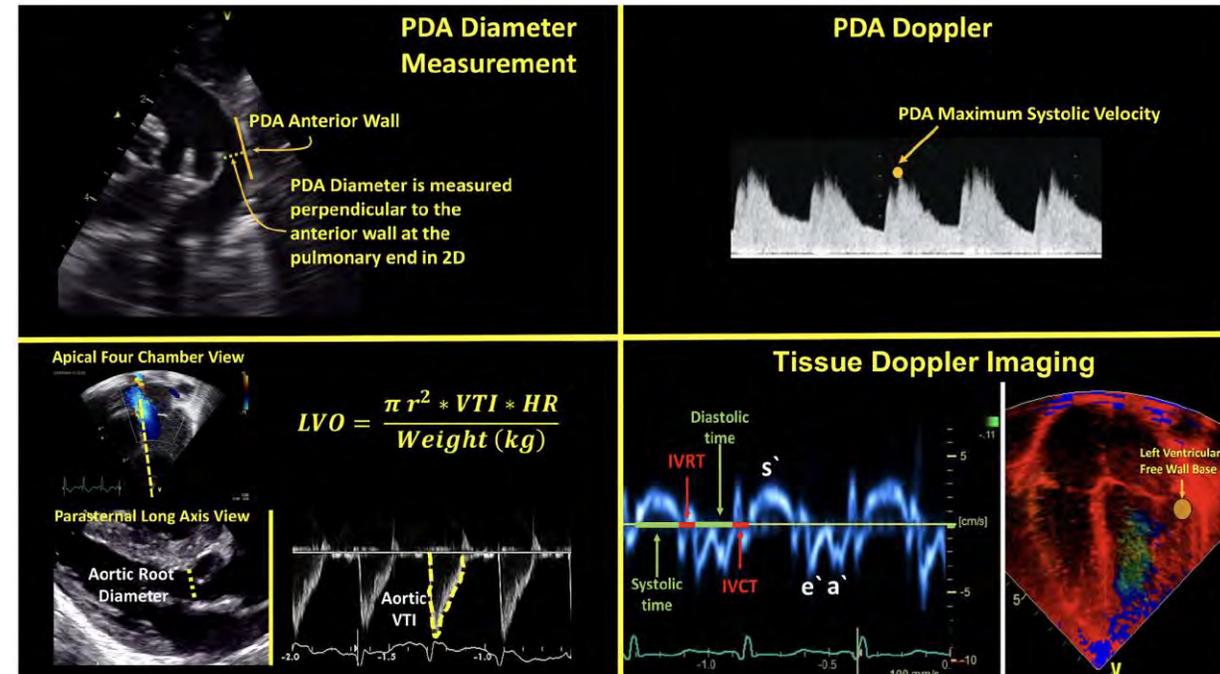
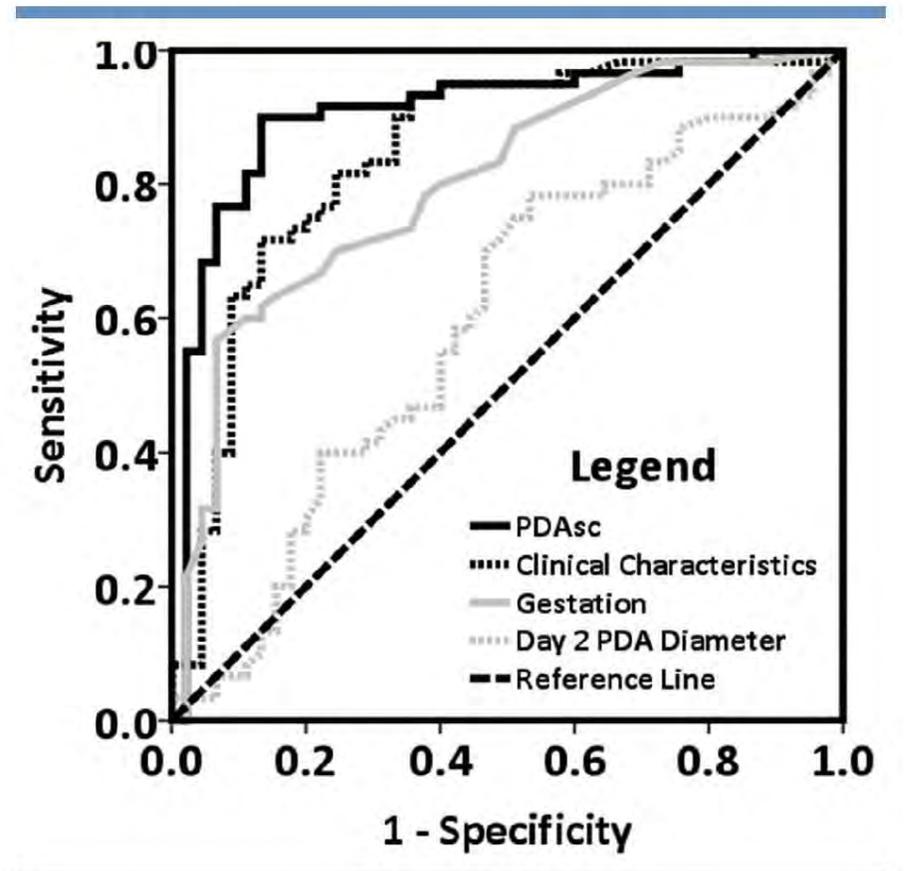
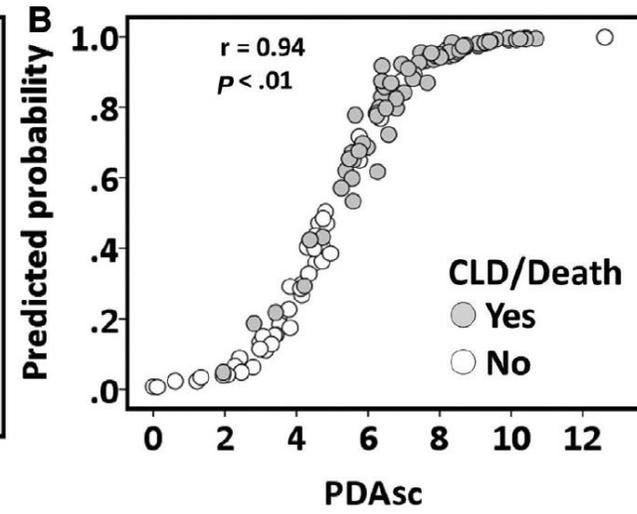
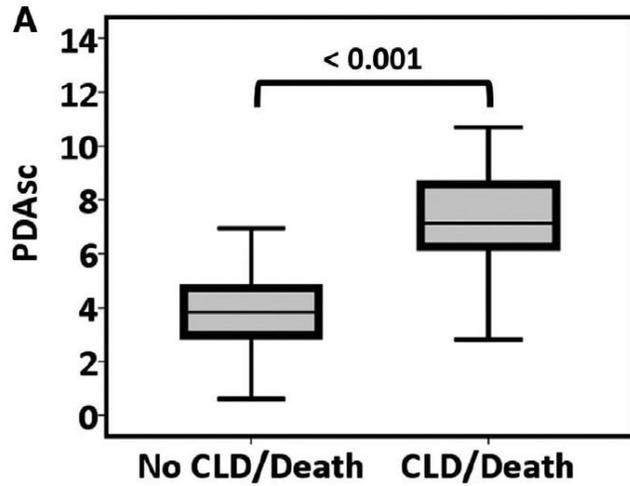


Fig. 1. Echocardiography components of the PDA Severity Score.

*EL-Khuffash A J Pediatr 2015;167:1354-61*



- *AUC 0.92 (95% CI 0.86-0.97,  $p < .001$ )*
- *PDA score cut-off of 5: sensitivity and specificity of 92% and 87%, PPV and NPV of 92% and 82%, respectively*

# Iowa Approach

## Impact of Early Hemodynamic Screening on Extremely Preterm Outcomes in a High-Performance Center

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<sup>1</sup>Department of Pediatrics, <sup>2</sup>Carver College of Medicine, <sup>3</sup>Institute for Clinical and Translational Science, and <sup>4</sup>Department of Internal Medicine, University of Iowa, Iowa City, Iowa; and <sup>5</sup>Department of Pediatrics, University of Oklahoma, Oklahoma City, Oklahoma

### Abstract

**Rationale:** Increasing survival of extremely preterm infants with a stable rate of severe intraventricular hemorrhage represents a growing health risk for neonates.

**Objectives:** To evaluate the role of early hemodynamic screening (HS) on the risk of death or severe intraventricular hemorrhage.

**Methods:** All eligible patients 22–26<sup>+</sup> weeks' gestation born and/or admitted <24 hours postnatal age were included. As compared with standard neonatal care for control subjects (January 2008–December 2017), patients admitted in the second epoch (October 2018–April 2022) were exposed to HS using targeted neonatal echocardiography at 12–18 hours.

**Measurements and Main Results:** A primary composite outcome of death or severe intraventricular hemorrhage was decided *a priori* using a 10% reduction in baseline rate to calculate sample size. A total of 423 control subjects and 191 screening patients were

recruited with a mean gestation and birth weight of 24.7 ± 1.5 weeks and 699 ± 191 g, respectively. Infants born at 22–23 weeks represented 41% (n = 78) of the HS epoch versus 32% (n = 137) of the control subjects (P = 0.004). An increase in perinatal optimization (e.g., antepartum steroids) but with a decline in maternal health (e.g., increased obesity) was seen in the HS versus control epoch. A reduction in the primary outcome and each of severe intraventricular hemorrhage, death, death in the first postnatal week, necrotizing enterocolitis, and severe bronchopulmonary dysplasia was seen in the screening era. After adjustment for perinatal confounders and time, screening was independently associated with survival free of severe intraventricular hemorrhage (OR 2.09, 95% CI [1.19, 3.66]).

**Conclusions:** Early HS and physiology-guided care may be an avenue to further improve neonatal outcomes; further evaluation is warranted.

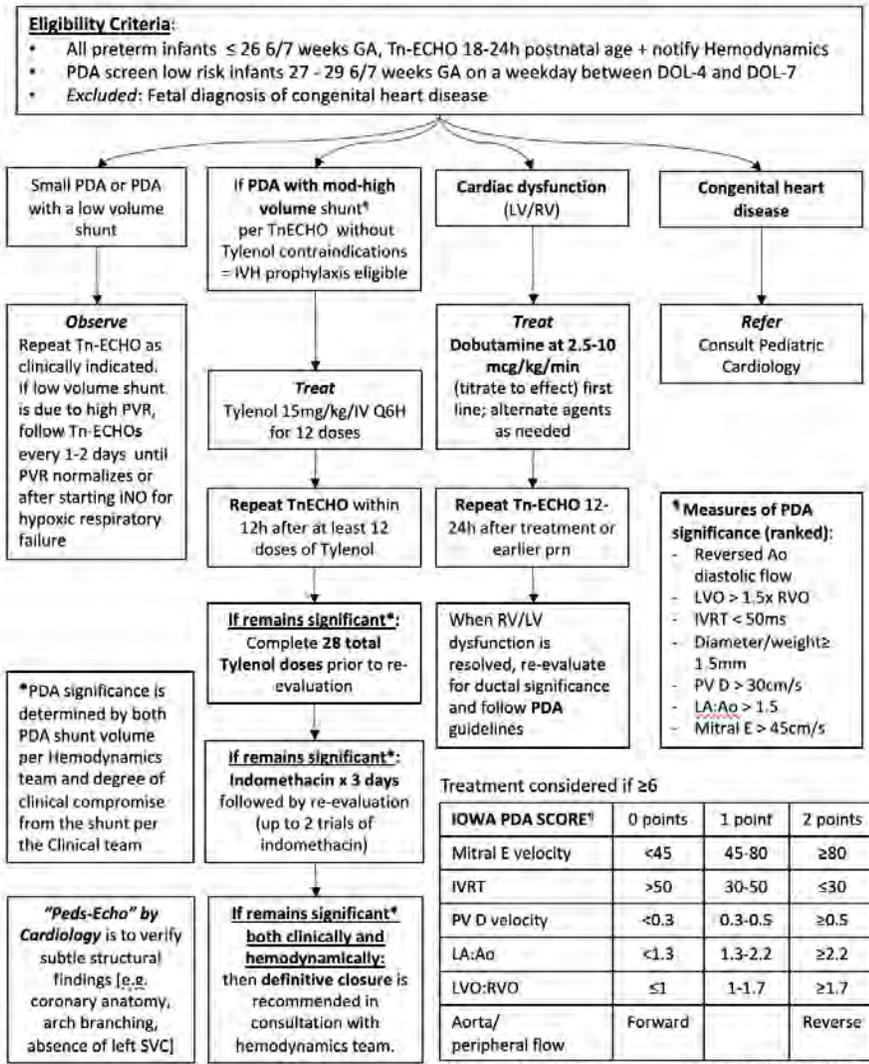
**Keywords:** targeted neonatal echocardiography; extremely preterm infant; intraventricular hemorrhage; necrotizing enterocolitis; bronchopulmonary dysplasia

**Supplemental Table 2** Echocardiographic markers evaluated to determine Iowa PDA score

Marker	0 points	1 point	2 points
Mitral valve E-wave velocity, cm/sec	<45	45–80	>80
IVRT, msec	>50	30–50	<30
PV D-wave velocity, cm/sec	<30	30–50	>50
Left atrium/aorta ratio	<1.3	1.3–2.2	>2.2
LVO, mL/min/kg	<250	250–430	>430
Diastolic flow in descending aorta and/or celiac/middle cerebral artery	Forward		Reversed



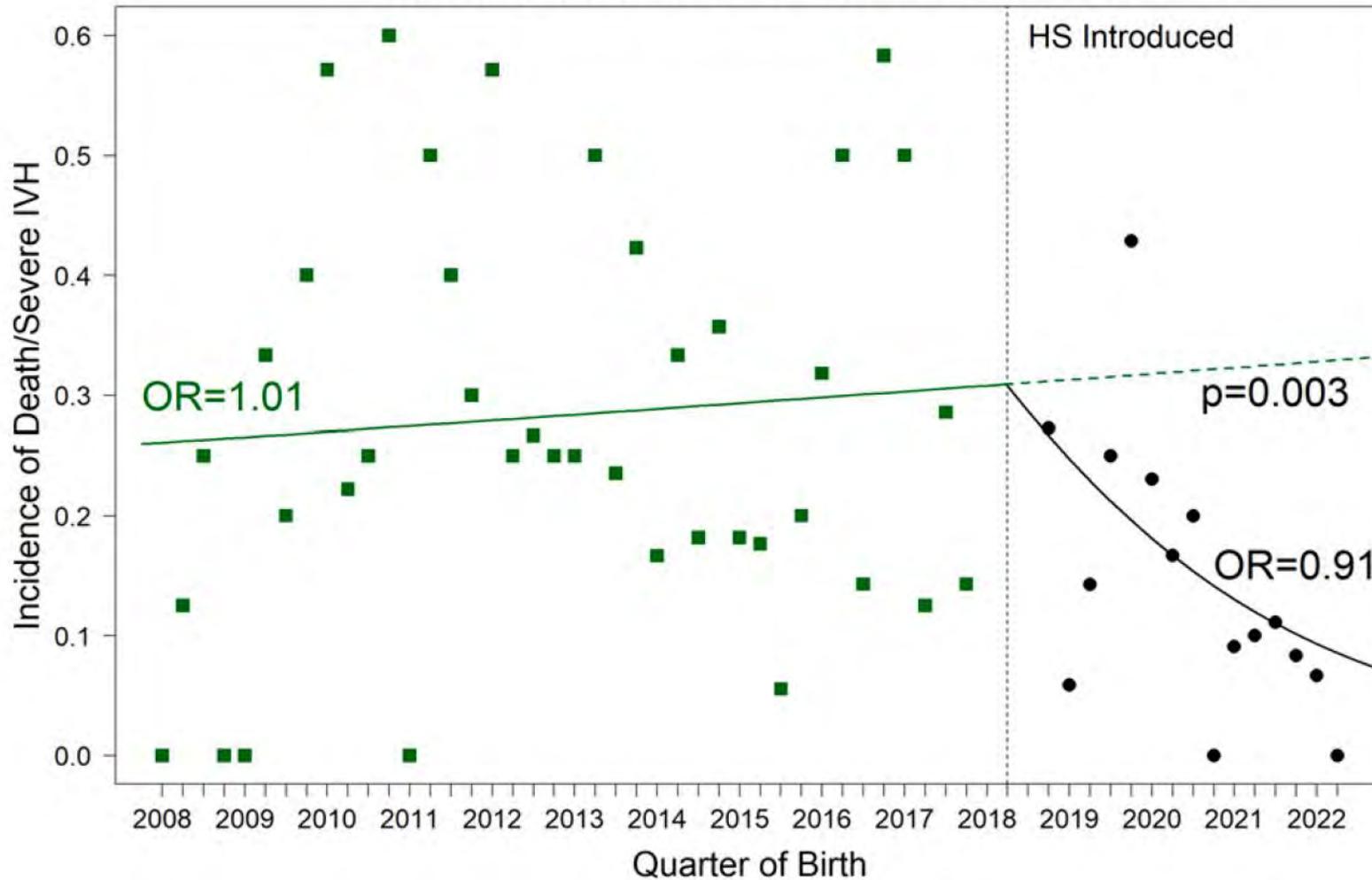
## Guidelines for PDA Screening and Management in Extremely Preterm Neonates



November 5, 2020; R. Giesinger, P. McNamara, J. Klein

IVRT = isovolumetric relaxation time, PV = pulmonary vein  
Score = sum of points + [PDA diameter/weight]

## Quarterly Incidence of Death/Severe IVH



## Secondary Outcomes:

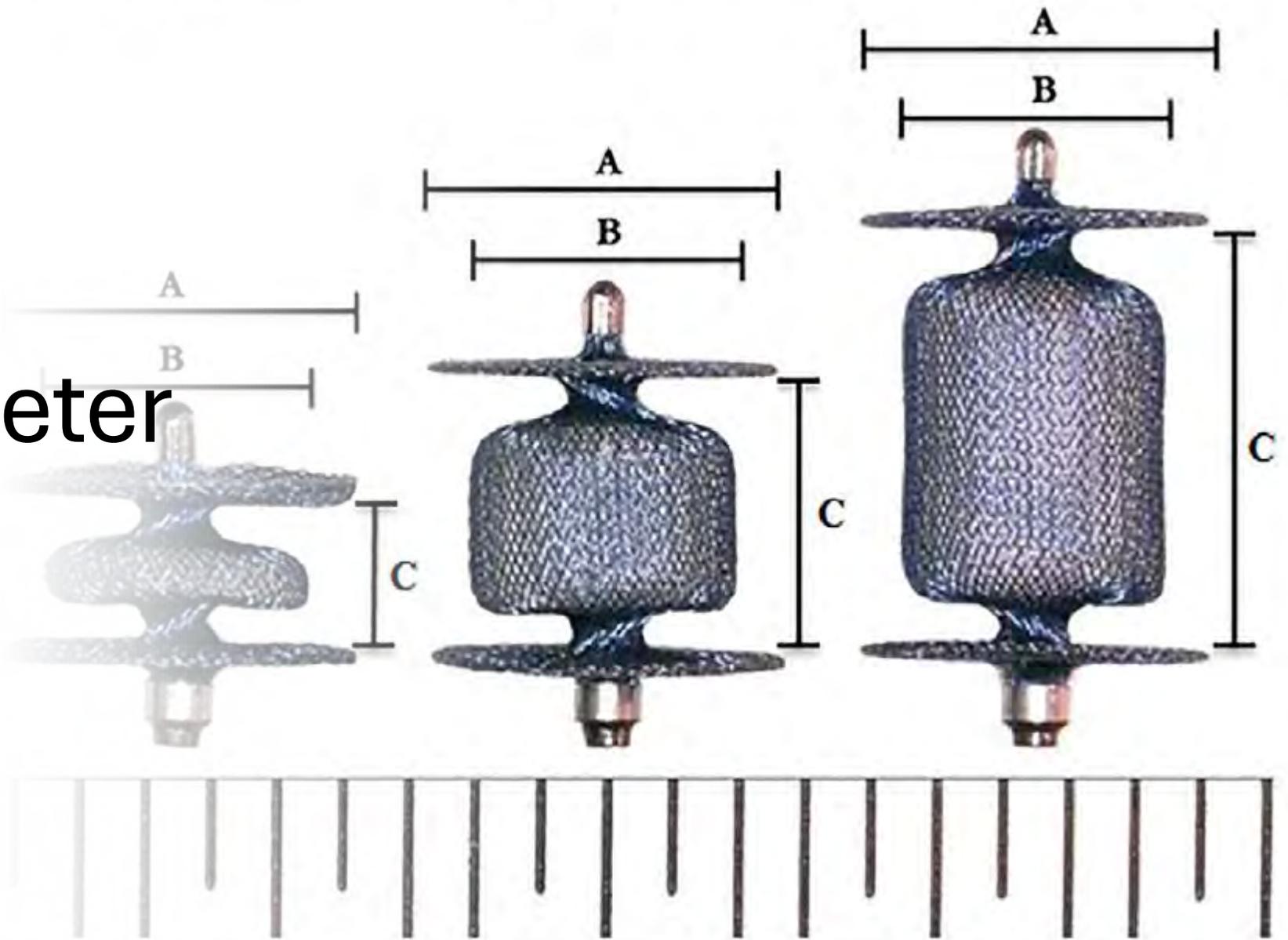
- **Less severe Grade 3 BPD ( $p < .02$ )**
- **Less NEC ( $p < .001$ )**
- **More overall survival free of severe morbidity ( $p < .001$ )**



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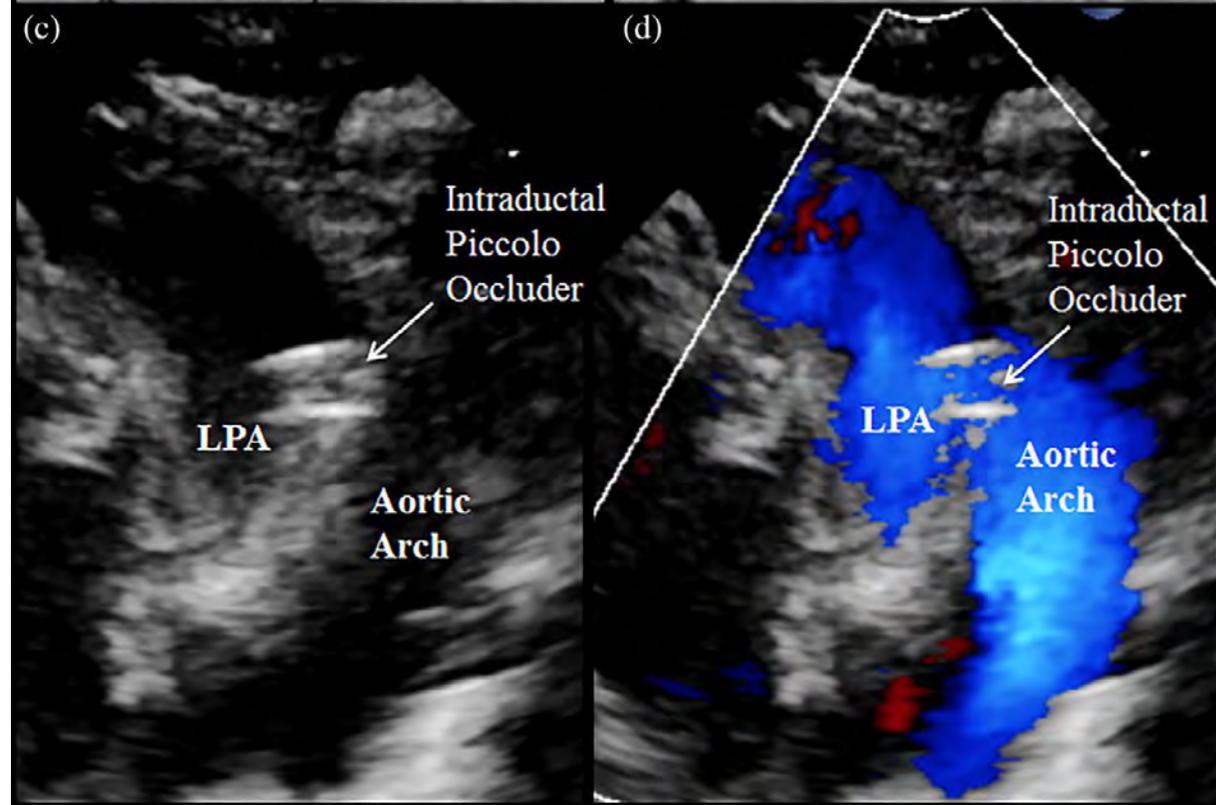
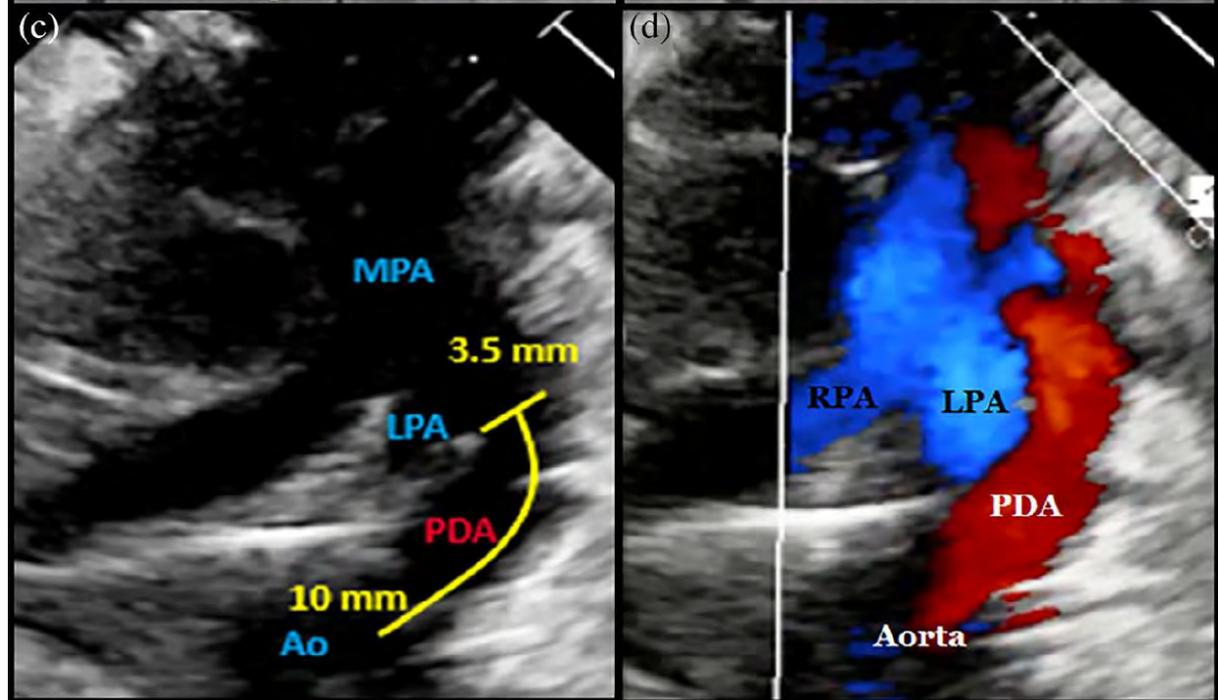
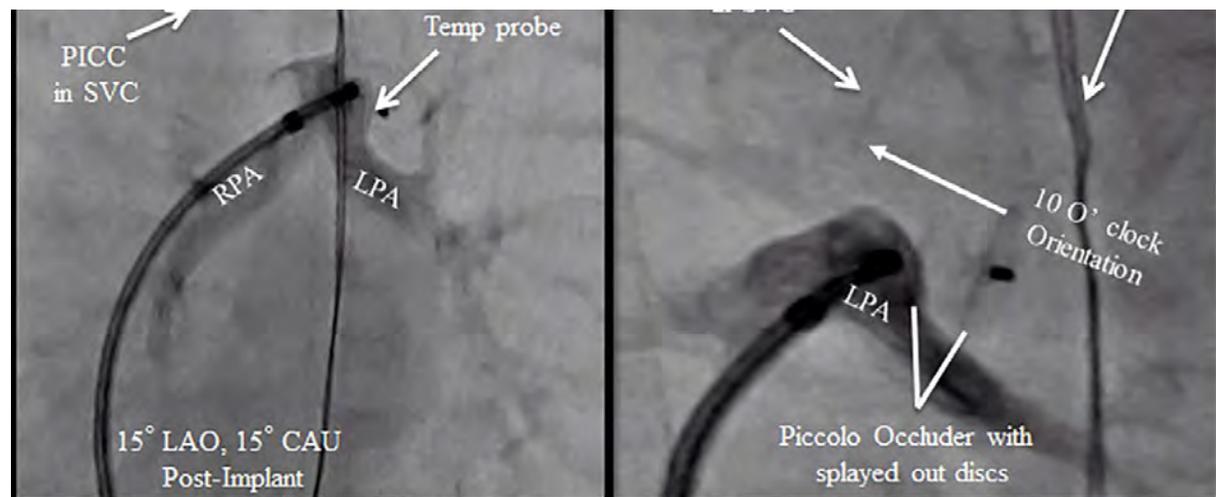
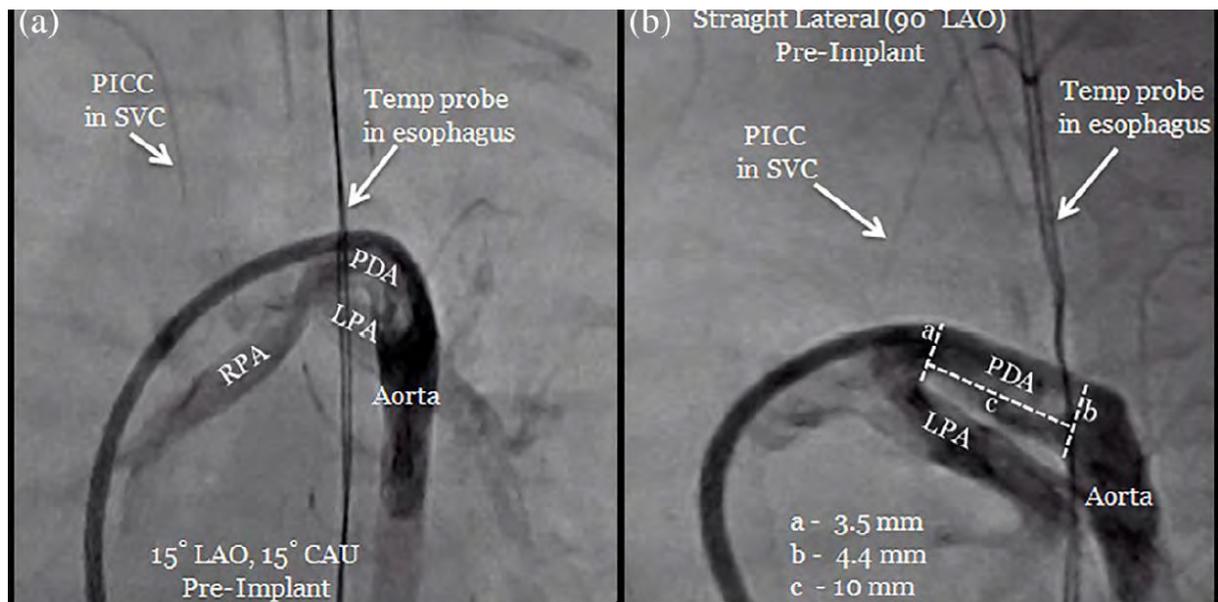
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# Transcatheter Closure



## Effectiveness of repeated pharmacological courses for patent ductus arteriosus in preterm infants

Carlo Dani<sup>a,b,\*</sup>, Giovanni Sassudelli<sup>a</sup>, Carlotta Milocchi<sup>a</sup>, Venturella Vangi<sup>a</sup>, Simone Pratesi<sup>a</sup>, Chiara Poggi<sup>a</sup>, Iuri Corsini<sup>a</sup>

Dani et al Archives 2025

- N=107 preterm infants with a hsPDA treated with pharmacotherapy
- **Closure rates:**
  - **1<sup>st</sup> course: 62%** (< 26: 54% and ≥ 26: 69%)
  - **2<sup>nd</sup> course: 25%** (< 26: 28% and ≥ 26: 22%)
  - **3<sup>rd</sup> course: 8%.** (< 26: 0% and ≥ 26: 8%)
- **High rate of failure with 2<sup>nd</sup> and 3<sup>rd</sup> course of pharmacotherapy**
- Effectiveness in infants < 26 weeks is significantly reduced.

	Infants born at 22–25 wks (n = 32)	Infants born at 26–28 wks (n = 75)
<b>First course:</b>		
Ibuprofen	30 (94)	65 (87)
Paracetamol	2 (6)	10 (13)
Failure of the 1st course	18/32 (56)	23/75 (31)
Ibuprofen	17/30 (57)	19/65 (25)
Paracetamol	1/2 (50)	4/10 (40)
<b>Infants treated with a second course (N = 41)</b>		
<b>Second course:</b>		
Ibuprofen	18	23
Ibuprofen plus paracetamol	11 (61)	19 (83)
Paracetamol	3 (17)	0
Failure of the 2nd course	4 (22)	4 (17)
Ibuprofen	13/18 (72)	18/23 (78)
Ibuprofen plus paracetamol	8/11 (73)	15/19 (79)
Paracetamol	2/3 (66)	0
Failure of the 3rd course	3/4 (75)	3/4 (75)
<b>Infants treated with a third course (N = 26)</b>		
<b>Third course:</b>		
Ibuprofen	1	25
Ibuprofen plus paracetamol	1 (100)	9 (36)
Paracetamol	0	5 (20)
Failure of the 3rd course	0	11 (44)
Ibuprofen	1/1 (100)	23/25 (92)
Ibuprofen plus paracetamol	1 (100)	7/9 (78)
Paracetamol	0	5/5 (100)
Surgical ligation	0	11/11 (100)
Mortality	7/32 (22)	8/75 (11)
	9/32 (28)	3/75 (4)

# Is Device Closure Feasible and Safe in Extremely Preterm Infants?

## Amplatzer Piccolo Occluder clinical trial for percutaneous closure of the patent ductus arteriosus in patients $\geq 700$ grams

Shyam K. Sathanandam MD<sup>1</sup> | Dan Gutfinger MD, PhD<sup>2</sup> | Laura O'Brien PhD<sup>2</sup> |  
 Thomas J. Forbes MD<sup>3</sup> | Matthew J. Gillespie MD<sup>4</sup> | Darren P. Berman MD<sup>5</sup> |  
 Aimee K. Armstrong MD<sup>5</sup> | Shabana Shahanavaz MD<sup>6</sup> | Thomas K. Jones MD<sup>7</sup> |  
 Brian H. Morray MD<sup>7</sup> | Toby A. Rockefeller MD<sup>6</sup> | Henri Justino MD<sup>8</sup> |  
 David G. Nykanen MD<sup>9</sup> | Evan M. Zahn MD<sup>10</sup>

Catheter Cardiovasc Interv. 2020

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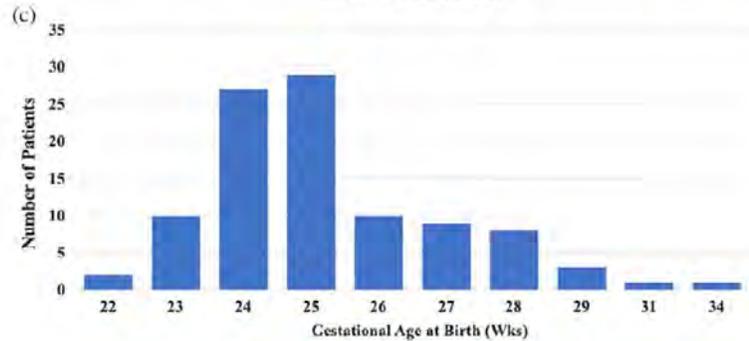
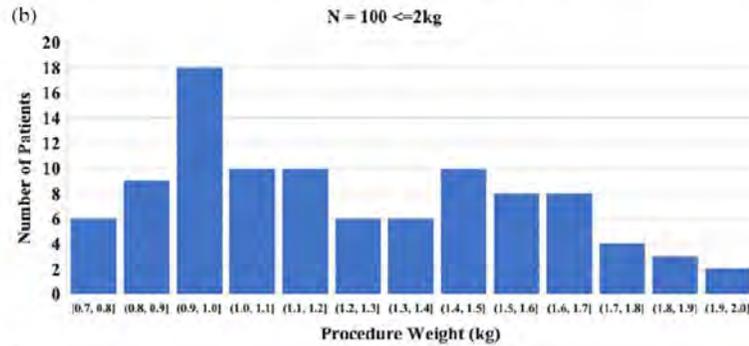
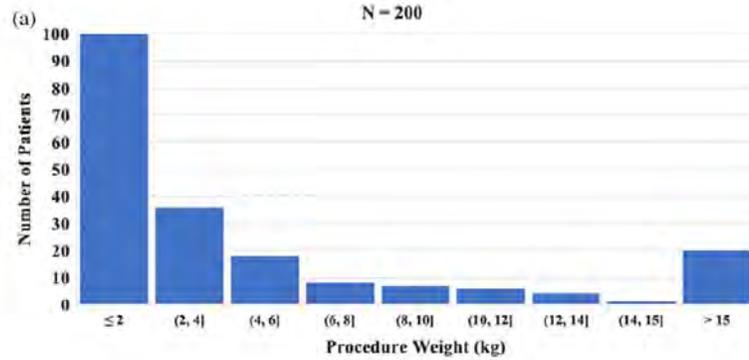


N=100 < 2 kg (200 total)	Median	Range
Gestational age birth (weeks)	25.0	22-34
Weight at birth (grams)	720	430-1,495
Age implant (days)	36.5	10-97
Weight at implant (grams)	1,200	700-2,000

Successful Implant (feasibility)	99/100 (99%)
Intra-Procedural Embolization*	2/100 (2%)
Post-Procedural Migration**	1/100 (1%)

- **No major complication** (Death, life-threatening, open surgical ligation)
- **No residual shunt** at 6 months
- **No LPA stenosis** / 1 aortic narrowing

**\*\*TC closure offers minimally invasive option for closing hsPDA but long-term benefits unproven to date**



**TABLE 4** Outcomes

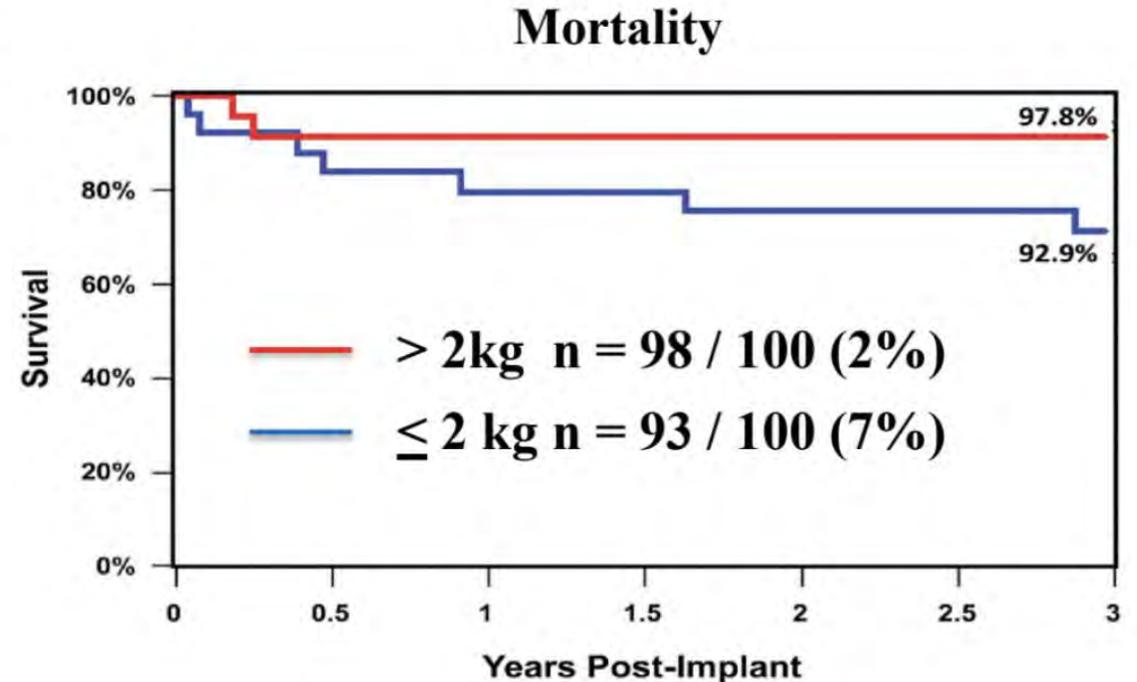
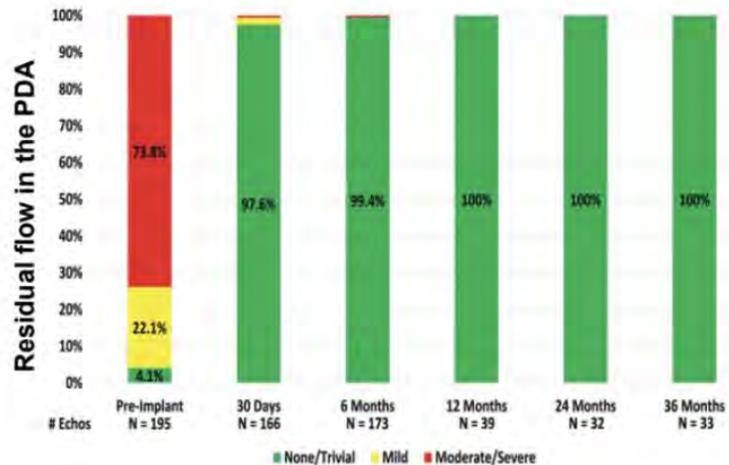
	≤2 kg (N = 100)	>2 kg (N = 100)	Total (N = 200)
Implant success (%)	99 (99.0%)	92 (92.0%)	191 (95.5%)
Intra-procedural device embolization rate (%)	2 (2.0%)	3 (3.0%)	5 (2.5%)
Post-procedure device migration rate (%) <sup>a</sup>	1/99 (1.01%)	1/92 (1.09%)	2/191 (1.05%)
Rate of effective closure at 6 months (%) <sup>b</sup>	89/89 (100.0%)	83/84 (98.8%)	172/173 (99.4%)
Rate of major complications through 180 days (%)	4/96 (4.2%)	0/98 (0%)	4/194 (2.1%)
Rate of clinically significant obstruction of the LPA or aorta through 6-months (%) <sup>a</sup>	2/99 (2.02%)	0/92 (0.0%)	2/191 (1.05%)
Rate of tricuspid valve regurgitation (%)	5 (5.0%)	0 (0.0%)	5 (2.5%)

# 3-year Follow Up

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Journal of Perinatology 2023

3-year follow-up of a prospective, multicenter study of the Amplatzer Piccolo™ Occluder for transcatheter patent ductus arteriosus closure in children  $\geq 700$  grams

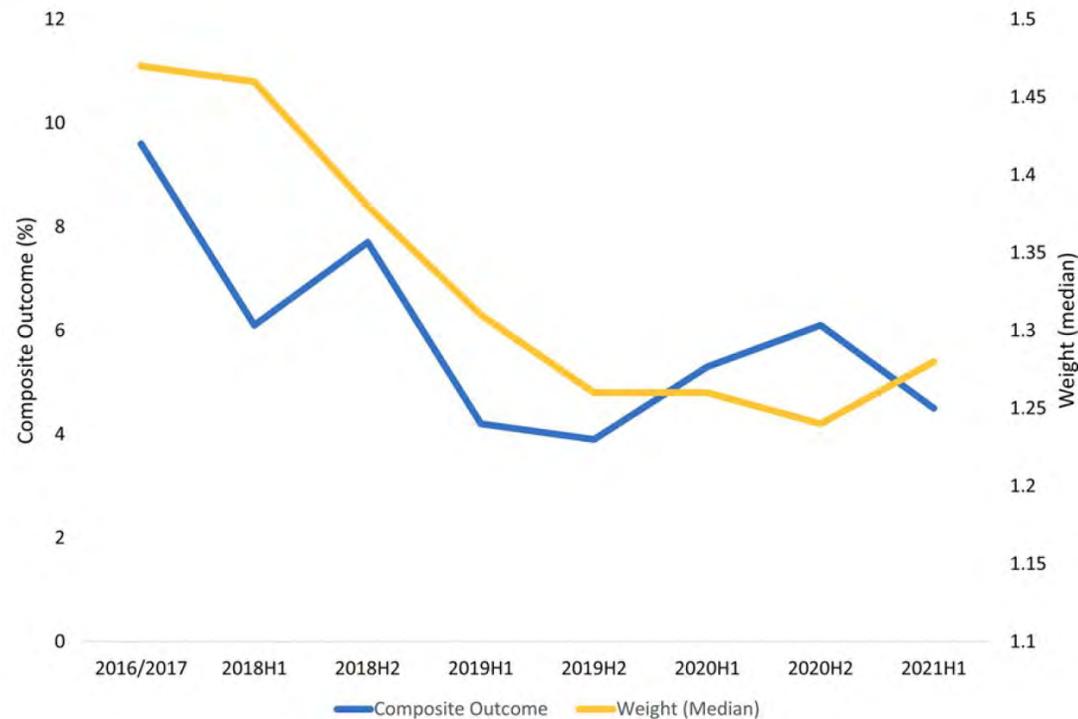


**Conclusion: High rates of PDA closure, low complication rate and survival >95% 3-years**

# Percutaneous Closure of the Patent Ductus Arteriosus in Infants $\leq 2$ kg: IMPACT Registry Insights

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	Odds Ratio (95% Confidence Interval)	P
Age $\geq 30$ d and weight $\geq 1$ kg: Reference		
Versus age $< 30$ d and weight $< 1$ kg	1.36 (0.72–2.57)	.344
Versus age $< 30$ d and weight $\geq 1$ kg	0.69 (0.35–1.35)	.282
Versus age $\geq 30$ d and weight $< 1$ kg	0.9 (0.35–2.32)	.829
Others		
Higher volume hospitals performing patent ductus arteriosus closure in patients $\leq 2$ kg (more than median annual volume)	0.45 (0.27–0.74)	.001
Any arterial versus exclusively venous access	4.49 (2.11–9.54)	$< .001$



**\*\*Institutional experience critical to success**



## Current Trends in Invasive Closure of Patent Ductus Arteriosus in Very Low Birth Weight Infants in United States Children's Hospitals, 2016-2021

Kuan-Chi Lai, MD, MPH<sup>1</sup>, Troy Richardson, PhD<sup>2</sup>, Darren Berman, MD<sup>3</sup>, Sara B. DeMauro, MD, MSCE<sup>4</sup>, Brian C. King, MD<sup>5</sup>, Joanne Lagatta, MD<sup>6</sup>, Henry C. Lee, MD<sup>7</sup>, Tamorah Lewis, MD, PhD<sup>8</sup>, Shahab Noori, MD, MS CBTI<sup>1</sup>, Michael L. O'Byrne, MD, MSCE<sup>9</sup>, Ravi M. Patel, MD, MSc<sup>10</sup>, Jonathan L. Slaughter, MD, MPH<sup>11</sup>, and Ashwini Lakshmanan, MD, MS, MPH<sup>1,12</sup>

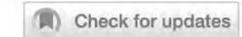
- *PHIS Database 42 Children's Hospitals*
- *2418 VLBW infants (1182 surgical ligation; 1236 transcatheter occlusion)*
- ***The proportion of infants receiving transcatheter occlusion increased from 17% in 2016 to 84% in 2021 ( $p < .001$ ).***

# PDA Coil

Journal of Perinatology

[www.nature.com/jp](http://www.nature.com/jp)

## REVIEW ARTICLE

 Check for updates

# Procedural closure of the patent ductus arteriosus in preterm infants: a clinical practice guideline

Souvik Mitra<sup>1,5</sup>, Adrienne R. Bischoff <sup>2,5</sup>, Shyam Sathanandam <sup>3</sup>, Satyan Lakshminrusimha <sup>4</sup> and Patrick J. McNamara <sup>2</sup>✉

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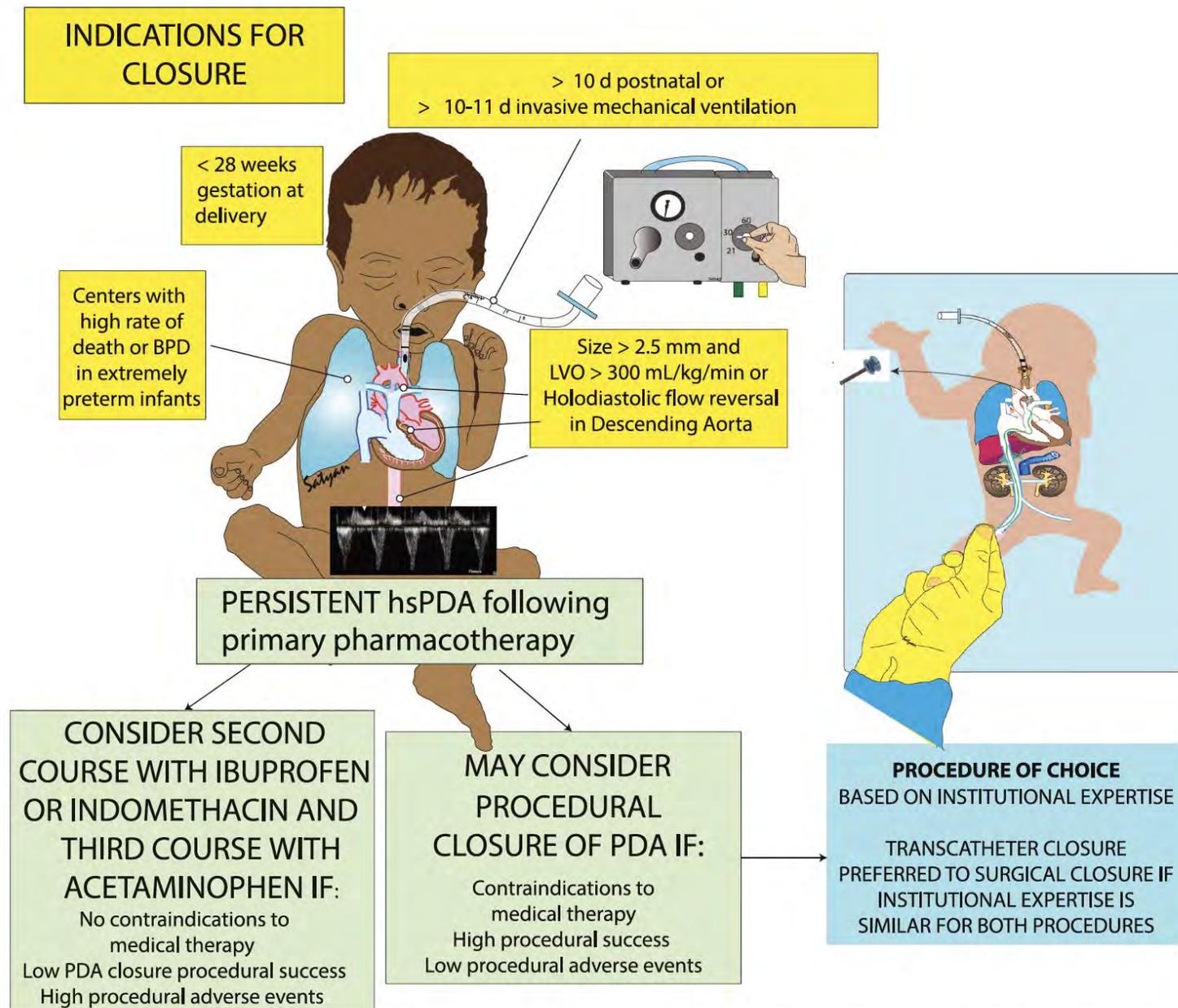
**IMPORTANCE:** Transcatheter closure of the patent ductus arteriosus (PDA) is being increasingly adopted as an alternative to surgical PDA closure in preterm infants.

**OBJECTIVE:** To develop rigorous clinical practice guideline recommendations on procedural PDA closure in preterm infants.

**METHODS:** The principles of the GRADE (Grading of Recommendations Assessment, Development and Evaluation) Evidence-to-Decision (EtD) framework were used to develop the guideline recommendations. An e-Delphi survey of 45 experts was conducted and recommendations that reached  $\geq 75\%$  agreement were accepted as consensus.

**MAIN RECOMMENDATIONS:** Procedural PDA closure may be considered in extremely preterm infants (<28 weeks gestational age) requiring invasive mechanical ventilation >10 postnatal days and confirmed to have a large hemodynamically significant PDA, at centers with high local rates of death and/or bronchopulmonary dysplasia (*conditional recommendation*). If sufficient institutional expertise is available and patient characteristics are suitable, transcatheter PDA closure may be considered as the preferred approach over PDA ligation (*conditional recommendation*).

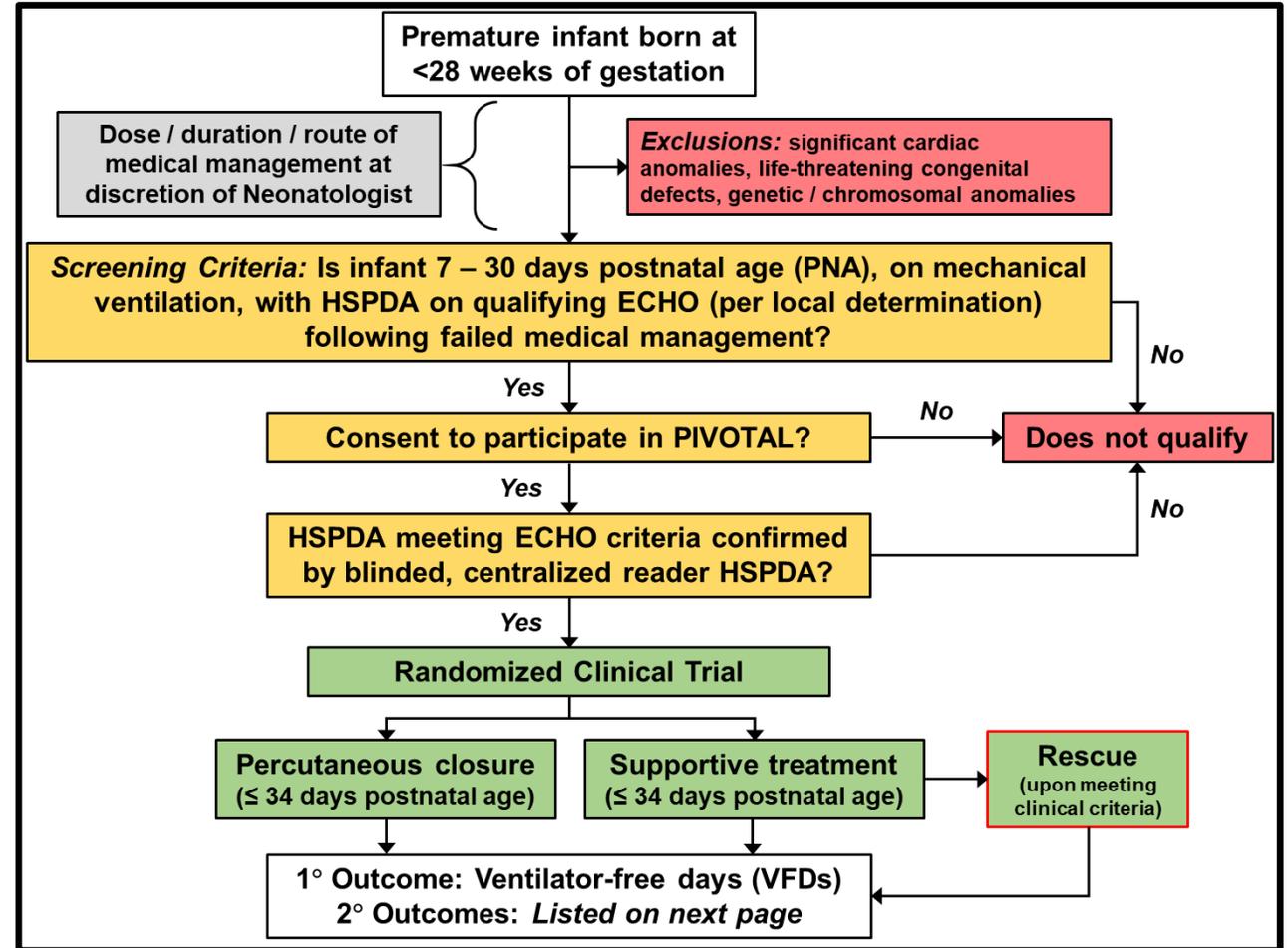
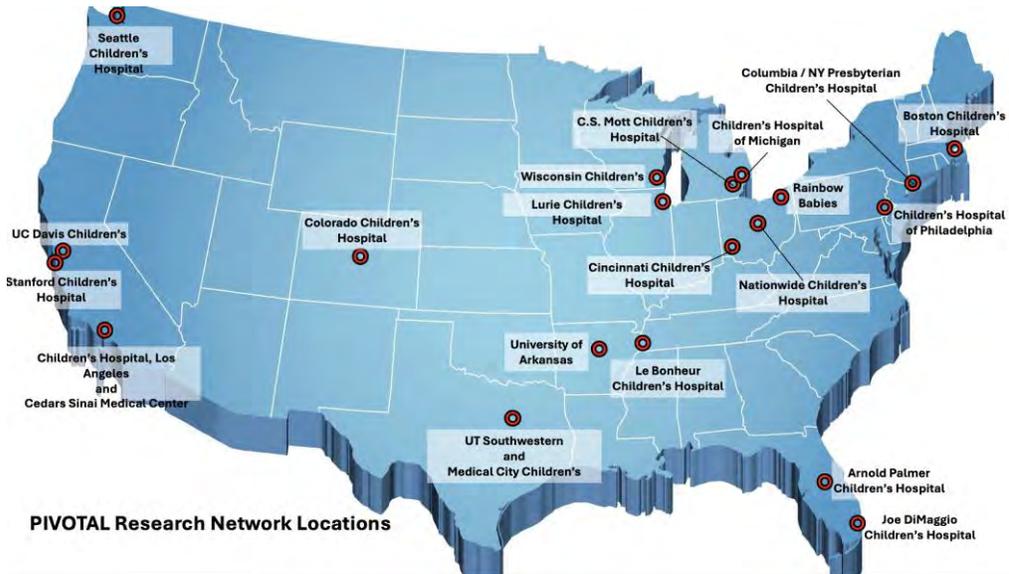
*Journal of Perinatology*; <https://doi.org/10.1038/s41372-024-02052-9>



**Fig. 1 Summary of recommendations.** BPD bronchopulmonary dysplasia, LVO left ventricular output, hsPDA hemodynamically significant patent ductus arteriosus.

# PIVOTAL

## Percutaneous Intervention Versus Observational Trial of Arterial ductus in Low-weight infants



# Summary

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- Current evidence does not support early treatment of PDA (<7 days)
- Future research should focus *on defining* the neonatal population, including PDA characteristics, that would benefit most from elimination of a “hemodynamically” significant shunt
- *NEED* to define the safest and most effective treatment strategies that leads to meaningful improvement in clinical outcomes
- Interventions with high success rates such as interventional PDA coil closure, especially long-term outcomes, urgently need further study
- *AND* need to include the smallest, greatest at-risk patients in future studies



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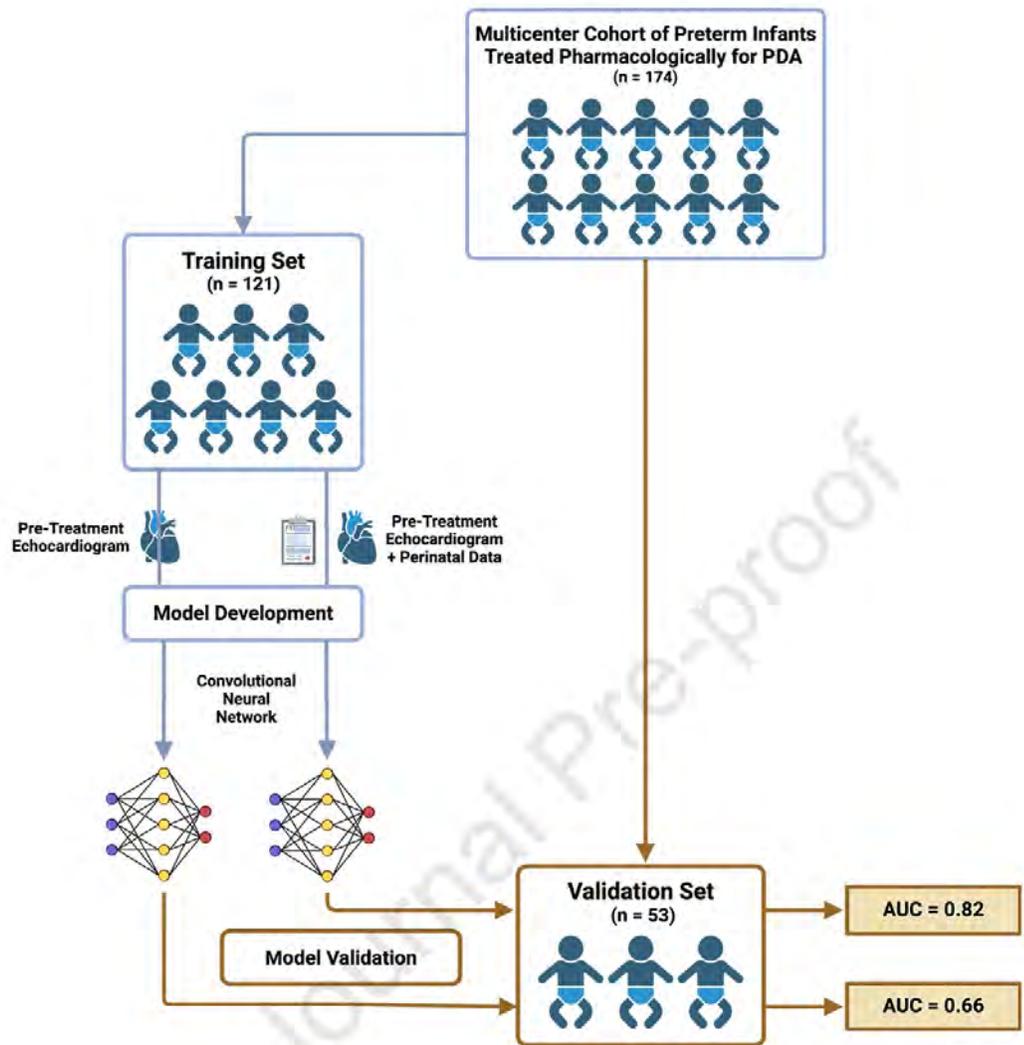
In Press, Journal Pre-proof [? What's this?](#)



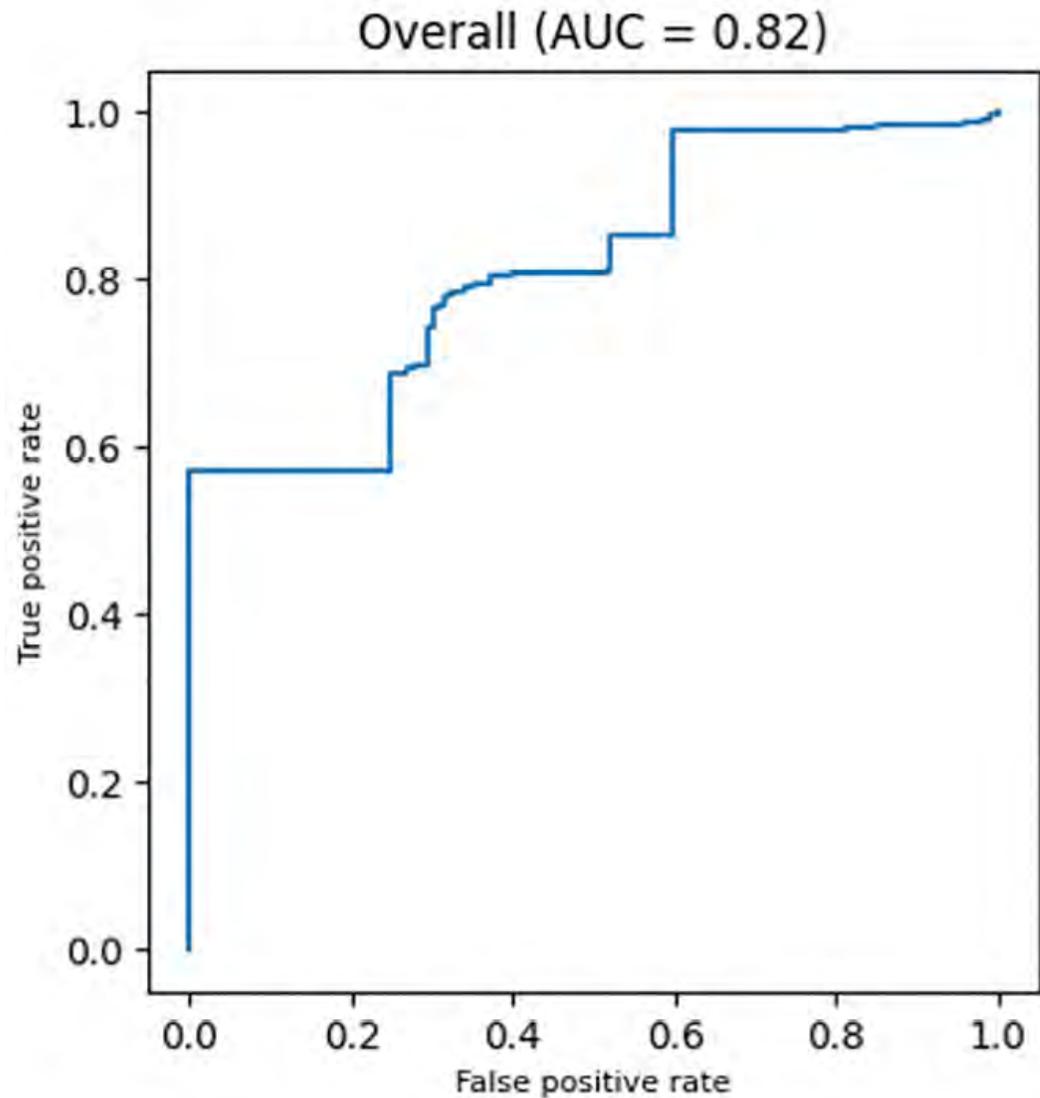
Clinical Investigations

## Development and Validation of a Novel Deep Learning Model to Predict Pharmacologic Closure of Patent Ductus Arteriosus in Premature Infants

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Sharma: J Am Soc Echocardiogr 2025



# PDA THINK TANK

Questions?



"Yes, they're all fools, gentlemen . . . But the question remains, 'What KIND of fools are they?'"