Transcatheter Closure of the Patent Ductus Arteriosus Compared to Surgical Ligation:

Comparison of Respiratory Outcomes in the Extremely Preterm Infant

NICHD

NEONATAL RESEARCH NETWORK

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Catheter closure | Surgical ligation | p-value

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RESULTS

INTRODUCTION

Cardiac transcatheter closure of the patent ductus arteriosus (PDA) in preterm infants is an increasingly treatment option. Characterization of the preterm population undergoing transcatheter PDA closure and assessment of respiratory outcomes are critical to understanding the effects of secular approaches to PDA management and design of future trials.

OBJECTIVE

To determine if preterm infants <29 weeks' gestation or with birth weight <1000 g with a PDA treated with transcatheter closure compared to surgical ligation had improved respiratory outcomes

METHODS

Study population: NICHD Neonatal Research Network (NRN) Generic Database from 1/1/2016 until 12/31/2020

Study design: Retrospective comparative evaluation of infants with a diagnosis of PDA managed with transcatheter closure compared to surgical ligation

Outcomes:

- Primary outcome total days of mechanical ventilation
- Additional respiratory outcomes bronchopulmonary dysplasia (BPD), days on positive pressure, need for home oxygen, diuretics at discharge

Statistical analysis: Linear and logistic regression analyses adjusted for center, birth year, gestational age, and age at PDA intervention

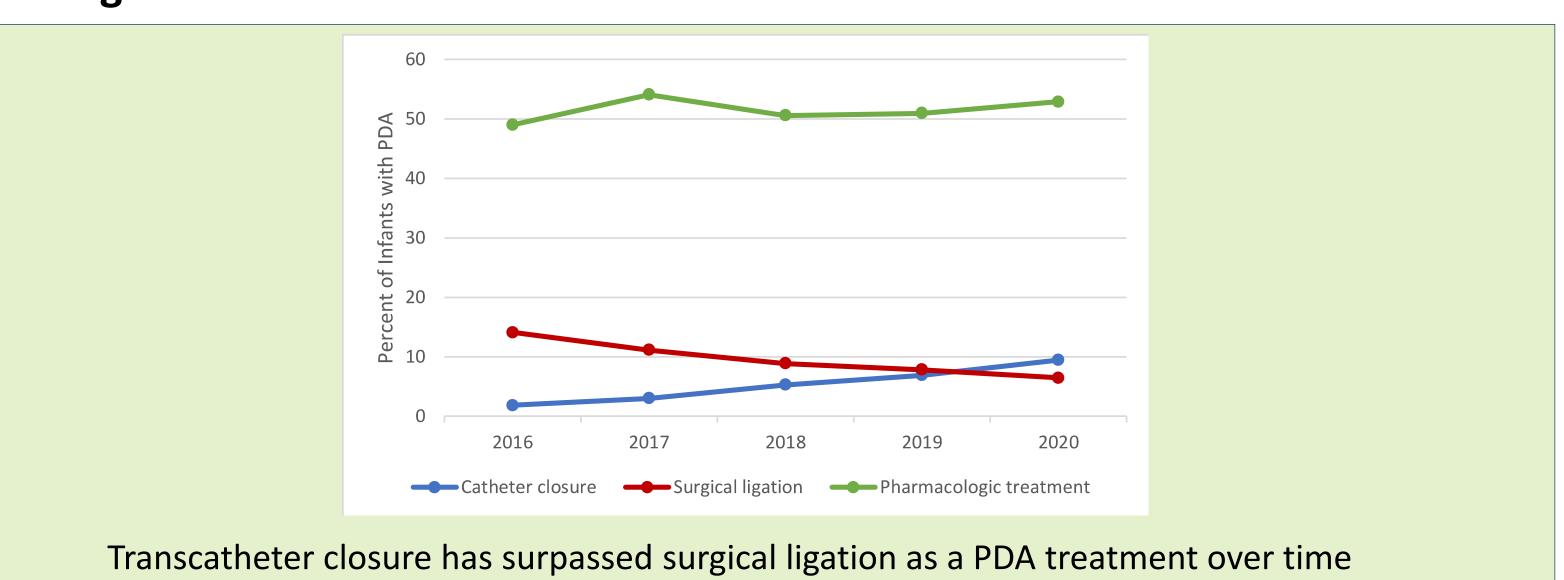
Table 1. Neonatal and Patent Ductus Arteriosus Treatment Characteristics

Characteristics

	(n=202)	(n=362)	
Gestational age (weeks), median (IQR)	25.4 (24.1, 27.1)	24.9 (24.0, 25.9)	<0.01
Birth weight (g), median (IQR)	740 (610, 880)	685 (585, 810)	<0.01
Male	88 (44)	173 (48)	0.33
Age at intervention (days) ^a	59 (28)	34 (17)	<0.01
Postmenstrual age at intervention (weeks) ^a	34 (5)	30 (3)	<0.01
Previous pharmacologic therapies to treat PDA			
Indomethacin	59 (29)	145 (40)	<0.01
Ibuprofen	62 (31)	128 (35)	0.26
Acetaminophen	46 (23)	119 (33)	0.01
At least one pharmacologic treatment	139 (69)	288 (80)	<0.01
More than one pharmacologic treatment	35 (17)	150 (41)	<0.01
Prophylactic indomethacin ^b	15 (7)	94 (26)	<0.01
Other morbidities			
Necrotizing enterocolitis (NEC)	32 (16)	33 (9)	0.02
Surgical NEC	14 (7)	16 (4)	0.21
NEC before PDA closure ^c	27 (87)	12 (41)	<0.01
Spontaneous gastrointestinal perforation	12 (6)	33 (9)	0.18
Severe IVH (grade 3 or 4)	48 (24)	70 (19)	0.22
Culture positive sepsis	54 (27)	125 (35)	0.06
Pulmonary characteristics			
Pneumothorax	10 (5)	10 (5) 40 (11)	
Pulmonary interstitial emphysema	33 (16)	77 (21)	0.16
Pulmonary hemorrhage	16 (8)	39 (11)	0.27
Use of inhaled nitric oxide	43 (21)	59 (16)	0.14
Received surfactant	189 (94)	344 (95)	0.46
Steroid use for BPD ^c	89 (44)	172 (49)	0.28

Compared to surgical ligation, infants with transcatheter PDA closure demonstrated no difference in respiratory outcomes including total days of mechanical ventilation, positive pressure support, BPD, home oxygen use, or diuretics at discharge.

Figure 1. PDA Treatment in the Neonatal Research Network 2016-2020



Continuous Outcomes in Survivors		Adjusted		
	Catheter Closure (n=202)		Surgical Ligation (n=362)	p-value
Days on mechanical ventilation	50 (45-55)		50 (47-54)	0.91
Days on positive pressure support	81 (77-86)		84 (81-87)	0.41
Days in hospital	148 (136-159)		159 (151-168)	0.13
Categorical outcomes	Catheter Closure	Surgical Ligation	Adjusted Odds Ratio (95% CI)	Adjusted p-value
Bronchopulmonary dysplasia (BPD)*				
Supplemental oxygen at 36 weeks	165 (82)	290 (83)	1.16 (0.58, 2.33)	0.67
BPD grade 1, 2, or 3	187 (93)	321 (92)	0.71 (0.24, 2.07)	0.53
BPD grade 2 or 3	150 (75)	221 (64)	1.02 (0.57, 1.84)	0.94
Death prior to discharge	6 (3)	22 (6)	0.42 (0.12, 1.47)	0.18
Death prior to discharge or supplemental oxygen at 36 weeks	166 (82)	301 (83)	1.10 (0.55, 2.20)	0.79
Death prior to discharge or BPD grade 1, 2, or 3	188 (93)	332 (92)	0.66 (0.22, 1.93)	0.44
Home oxygen at discharge	99 (55)	188 (61)	0.68 (0.38, 1.24)	0.21
Diuretics at discharge	50 (28)	120 (39)	0.90 (0.49, 1.65)	0.73

DISCUSSION

- In a multicenter neonatal database, respiratory outcomes did not differ for infants treated with PDA transcatheter closure compared to surgical ligation. However, innate differences between groups exist.
- The confounding effects of lower rate of medical treatment, higher rate of preintervention NEC, and older age at definitive PDA closure by the transcatheter route requires prospective evaluation.
- Study limitations include absence of a standardized definition of PDA hemodynamic significance and lack of comprehensive respiratory data reflecting days of mechanical ventilation after treatment.

CONCLUSIONS

Transcatheter PDA closure was not associated with improved respiratory outcomes for extremely preterm infants with a PDA when compared to surgical ligation. The effect of earlier intervention and shorter duration of PDA exposure on respiratory outcomes remains a knowledge gap.









Transcatheter closure has surpa	ssed surgical	ligation as a l	PDA treatment over time	
Table 2. Respiratory Outcome Compared to Surgical Ligation		nscathete	r PDA Closure as	
Continuous Outcomes in Survivors	Adjusted Mean (95% CI)			
	Catheter Closure (n=202)		Surgical Ligation (n=362)	
Days on mechanical ventilation	50 (45-55)		50 (47-54)	
Days on positive pressure support	81 (77-86)		84 (81-87)	
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BPD grade 2 or 3	150 (75)	221 (64)	1.02 (0.57, 1.84)	
Peath prior to discharge	6 (3)	22 (6)	0.42 (0.12, 1.47)	
Death prior to discharge or upplemental oxygen at 36 weeks	166 (82)	301 (83)	1.10 (0.55, 2.20)	
Death prior to discharge or BPD grade 1, 2, or 3	188 (93)	332 (92)	0.66 (0.22, 1.93)	

NEC in ligation group; dn=201 for catheter closure group and 351 for ligation group.