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Patent Ductus Arteriosus: Transcatheter vs. Surgical Closure in 2022

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Disclosure Slide

• I have no pertinent financial relationships to disclose
Outline

• Anatomy and Physiology
• Clinical symptoms
• Indications for closure
• Transcatheter versus surgical closure
• Case example
Patent Ductus Arteriosus

- Occurs in 2-8 per 1000 live births.
- More common in premature infants
  - 45% of infants < 1750 grams
  - 80% of infants < 1200 grams
- 30 times more common in those living at high altitude (> 4500m)
Spontaneous closure

- Functional closure (24-72 hours)
  - Loss of PGE from placenta
  - Higher oxygen levels
- Anatomic closure (2-3 weeks)
  - Smooth muscle contraction leads to cell destruction and fibrosis
  - Ligamentum arteriosum
Left to Right Shunt Physiology

- Communication between systemic and pulmonary circulations
  - Intracardiac (ASD, VSD)
  - Extracardiac (PDA, AP window)
- Increased pulmonary blood flow
- Volume loaded heart
- Normal oxygen saturations
  - Pass CCHD screen
Clinical Symptoms in Neonates

• Heart murmur
• Heart failure symptoms
  • Tachypnea, tachycardia, pulmonary congestion, poor feeding, diaphoresis with feeds, poor weight gain
• Compromised systemic perfusion
  • IVH, NEC, renal dysfunction
• Hypoxia
  • Pulmonary edema
  • Pulmonary hypertension with right-to-left shunt
Indications for Closure

• Audible murmur
• Heart failure symptoms
• Left heart dilation
• Elevated RV and PA pressures without right-to-left shunting
PDA Closure in Premature Infants

• Balance of disease risk versus procedural risk
  • How much morbidity is attributable to PDA
• Timing
  • Prophylactic, early before symptoms, or late after symptoms
• Type of closure
  • Medical, transcatheter, or surgical
PDA Closure in Premature Infants

- Universal Prophylactic
- Selective or Case-by-case
- Rarely, if ever, Intervene
CMH Typical Treatment Algorithm

- Is a moderate (or larger) PDA present?
- Is the PDA causing symptoms?
- Are the symptoms medically manageable?
- Contraindications to medical therapy?
- Contraindications to interventional therapy?
- Which intervention do you want?
Transcatheter versus Surgical Closure

• Surgical Ligation
  • Post PDA ligation syndrome
  • Vocal cord paralysis
  • Scoliosis
  • LPA ligation

• Transcatheter device closure
  • Not a great option on HFOV
  • Risk of aortic and LPA obstruction
  • Case reports of vocal cord paralysis
  • Requires transport to cardiac catheterization lab (most centers)
Transcatheter versus Surgical Closure

Original Research

Trend and Outcomes for Surgical Versus Transcatheter Patent Ductus Arteriosus Closure in Neonates and Infants at US Children’s Hospitals

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Background: Pharmacologic therapy for patent ductus arteriosus closure is not consistently successful. Surgical ligation (SL) or transcatheter closure (TC) may be needed. Large multicenter analyses comparing outcomes and resource use between SL and TC are lacking. We hypothesized that patients undergoing TC have improved outcomes compared with SL, including mortality, hospital and intensive care unit length of stay, and mechanical ventilation.

Methods and Results: Using the 2016 to 2020 Pediatric Health Information System database, characteristics, outcomes, and charges of patients aged ≤1 year who underwent TC or SL were analyzed. A total of 679 infants undergoing TC (n=503) or SL (n=176) were identified. Surgical patients were younger (0.1 versus 0.6 years; P<0.001) and more premature (39% versus 20.1%; P<0.001). Surgical patients had higher mortality (1.7% versus 0%; P=0.002). Using inverse probability of treatment weighting by the propensity score, multivariable-adjusted analyses demonstrated favorable outcomes in TC: intensive care unit admission rates (adjusted odds ratio [OR], 0.52; 95% CI, 0.31–0.86; P=0.01); mechanical ventilation rates (adjusted OR, 0.3; 95% CI, 0.19–0.56; P=0.001); and shorter hospital (adjusted coefficient, 2 days shorter; 95% CI, 1.3–7.7; P=0.001) and postoperative (adjusted coefficient, 1.2 days shorter; 95% CI, 0.14–5.2; P=0.038) stays. Overall charges and readmission rates were similar. Among premature neonates and infants, hospital (adjusted difference in medians, 4 days; 95% CI, 1.7–6.3 days; P<0.001) and postoperative stays (adjusted difference in medians, 3 days; 95% CI, 1.1–4.6 days; P=0.002) were longer for SL.

Conclusions: TC is associated with lower mortality and reduced length of stay compared with SL. Rates of TC continue to increase compared with SL.

Keywords: cardiac catheterization • cardiovascular surgical procedure • cost • outcomes • patent ductus arteriosus

Preterm Percutaneous Closure of PDA in Preterm Infants: Procedural Charges and Outcomes

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Abstract

Background: Studies comparing percutaneous closure of patent ductus arteriosus (PDA) with surgical ligation tend to exclude preterm infants and have not assessed procedural charges. We compared our contemporary outcomes and charges of device closure to surgical ligation of PDA in preterm infants.

Methods and results: Preterm infants who underwent initial PDA closure during their newborn hospitalization January 2014 to September 2017 were grouped based on intention to treat surgery versus device closure. Patient demographics, procedural details, and immediate postprocedural outcomes were compared. Procedural charges for device closure versus surgical ligation were compared.

Results: Compared with the device group (n=30), patients undergoing surgical ligation (n=38) were younger, smaller, and required more perinatal support (P<0.005). The procedure time was shorter for surgical ligation (P<0.001). Although there was no procedural mortality in either group, the complication rate was higher for device closure than surgical ligation (3.3% versus 0%; P=0.28). The proportion of patients returning to per-procedural respiratory support by 48 h after procedure was similar; there was a higher proportion of surgical patients who required no postoperative support in the first 24 h after procedure (P=0.15). The procedural charges for transcatheter device closure were twice as expensive as those for surgical ligation.

Conclusions: In our study experience with percutaneous PDA closure, we found a percutaneous approach in preterm infants feasible and well tolerated. Both surgical ligation and device closure were associated with perinatal or postoperative complications. Procedural charges were higher for percutaneous closure, driven by device charge and catheterization costs utilized. Further investigation is needed to establish guidelines for follow-up therapy for PDA closure in preterm infants, including cost-benefit analysis.
Surgical PDA Ligation

• First successful ligation by Gross in 1939
• Left posterolateral thoracotomy
• Left lung must be down for some length of time
• Locate PDA and place surgical clip on PDA
Transcatheter PDA Device Closure

- Portsman first to close PDA via cardiac catheterization in 1967
- Significant amount of R&D over the next several decades developing coils and devices
- AMPLATZER duct occluder FDA approved in 2003
  - Still currently in use
  - Off-label in patients < 6 months old
Trascatheter Device Closure in Premature Infants

A Novel Technique for Transcatheter Patent Ductus Arteriosus Closure in Extremely Preterm Infants Using Commercially Available Technology

Evan M. Zahn, MD, PhD; Philip N. Piovano, MD; Charles Simmons, MD; and Ruchira Garg, MD

Objectives: To describe a new technique for transcatheter patent ductus arteriosus (PDA) closure in extremely preterm infants using commercially available technology. Background: PDA in premature neonates continues to be a significant clinical problem contributing importantly to both mortality and morbidity. Surgical ligation and medical therapy both have their drawbacks. Material and Methods: Hospital records and catheterization reports of all premature neonates (<32 weeks gestation) who underwent transcatheter PDA closure between March 2013 and February 2016 were reviewed. Particular attention was paid to procedural details, complications, and short and mid-term outcomes. Results: Six premature infants born at gestational ages ranging between 29 and 31 weeks (median, 29 weeks) underwent attempted transcatheter PDA closure using the Amplatzer Vascular Plug II (AVP II). Median age and weight were 21.3 days (10.7–31 days) and 1.1 kg (0.6–2.0 kg), respectively. Fluoroscopy and echocardiography were used to guide device. Device placement was achieved in all patients with no major complications. Conclusion: This preliminary experience demonstrates the feasibility of transcatheter PDA closure in extremely premature infants using currently available technology with a high success rate and minimal complications. This report also describes a novel technique combining a combination of echocardiography and fluoroscopy to avoid air embolism in this fragile patient population.

Key words: patent ductus arteriosus; vascular occlusion

PDA closure in 6 preterm infants (median weight 1.1 kg) with Amplatzer Vascular Plug II

Initial Clinical Experience with the Medtronic Microvascular Plug™ in Transcatheter Occlusion of PDAs in Extremely Premature Infants

Shyam Sathuramad, MD; Henri Justino, MD; B. Rush Walder, III, MD; Wolfgang Radlko, MD; and Athar M. Qureshi, MD

Objectives: To describe the early multicenter, clinical experience with the Medtronic Microvascular Plug™ (MVP) for the occlusion of patent ductus arteriosus (PDA) in premature infants. Background: The MVP is a large diameter plug that can be delivered through a microcatheter for occlusion of abnormal blood vessels. Methods: A retrospective review of patient characteristics and clinical outcomes performed in two centers using the MVP was performed. Results: Fifteen premature infants underwent attempted PDA occlusion using the MVP. The median age and birth weight were 26.5 ± 3.3 weeks and 735 ± 251 g, respectively. The median age and weight at the time of the procedure were 1,216 g (700–3,500 g) and 4.6 weeks (1–12 weeks), respectively. Median procedure and fluoroscopic times were 45 and 6.3 minutes, respectively. The median radiation and contrast doses were 19.7 mGy and 2.4 mL/kg, respectively. Antegrade occlusion was successfully achieved in 15 patients <2 kg with only hemor rash, no access aided by echo guidance. The two patients >2 kg had arterial access and attempted retrograde occlusion; one of which was unsuccessful due to the PDA being short and wide. Complete closure was achieved in 13 of 14 successful procedures (93%), with one patient having a small residual shunt that was not seen on follow-up. There were no complications related to the procedure or noted during follow-up (Medson 11 months). Conclusions: The MVP is a new, large-diameter vascular occlusion device that may be useful for the occlusion of PDA in extremely premature infants.

Key words: patent ductus arteriosus; Microvascular Plug™; premature

PDA closure in 15 preterm infants (median weight 1.2 kg) with Medtronic Microvascular Plug
Amplatzer Piccolo™ Occluder Device Trial

- Non-randomized prospective trial at 9 US centers in premature infants ≥700 grams
- Primary endpoint-PDA closure at 6 months
- Secondary endpoints-LPA and aortic obstruction
- PDA ≤ 4 mm in diameter, ≥ 3 mm length
- Placed through a 4 French delivery system
Amplatzer Piccolo™ Occluder Device Trial

Received FDA approval in January 2019
Case Example

- 29 weeks EGA, birth weight 1.45 kg
- Poor respiratory effort, sats in the 50’s on NIV
- Intubated at 4 min of life
- Surfactant x3
- HFOV for 14 days then switched to CMV
- Tylenol x 2 without significant change in large PDA
- Taken to cath lab on DOL 18
Case Outcome

- Extubated in 5 days
- Discharged home in 2 months on ¼ L O₂
- PO ad lib 22 kcal/oz
- Follow-up ECHOs
  - No residual PDA
  - No LPA obstruction
  - No arch obstruction
Summary

• There are multiple options (medical, transcatheter, and surgical) to treat PDAs in premature infants

• The Piccolo is an FDA approved device designed for PDA closure in ELBW premature infants with extremely favorable outcomes
  • Not good for infants on HFOV, active infections, unstable infants who can’t be transferred to a center performing this procedure, and infants with LPA stenosis/aortic coarctation

• Working with industry is not bad—there are companies committed to improving CHD treatment
Special Thank You

- Dr. Toby Rockefeller
  - Starting our Piccolo PDA closure program in ELBW premature infants
  - Assisting with the preparation of this presentation
Questions?