

Anesthesia protocols for “bedside” preterm patent ductus arteriosus ligation: A single-institutional experience

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ABSTRACT

- Background** : Hemodynamically significant patent ductus arteriosus (PDA) is frequently encountered in preterm infants sometimes requiring surgical attention. Although PDA ligation is regularly performed in the operating room, conducting it at the bedside in a neonatal intensive care unit (NICU) and its anesthetic management remains challenging.
- Aim** : We aim to discuss the anesthetic considerations in patients undergoing bedside PDA ligation and describe our experience highlighting the feasibility and safety of this procedure.
- Setting and Design** : The study was conducted in the NICU in a tertiary care hospital; This was a retrospective, observational study.
- Methods** : Preterm infants scheduled for bedside PDA ligation using a predefined anesthesia protocol between August 2005 and October 2020 were included.
- Statistical Analysis Used** : Quantitative data were presented as median with interquartile range and categorical data were presented as numbers and percentage thereof.
- Results** : Sixty-six premature infants underwent bedside PDA ligation. Thirty-day mortality was 4.5% (3 infants), but there were no procedural deaths. One (1.5%) patient had intraoperative endotracheal tube dislodgement. Three (4.5%) infants had postoperative pneumothorax requiring an additional chest tube insertion. Twenty-one (32%) patients required initiation of postoperative inotrope/vasodilator therapy within 6 h. Three postligation cardiac syndromes (\geq Grade-III mitral regurgitation with left ventricular dysfunction and hypotension) occurred.
- Conclusions** : Although anesthesia for preterm neonates undergoing bedside PDA ligation poses unique challenges, it can be safely conducted by following a predetermined standardized anesthesia protocol. Its successful conduct requires utmost vigilance and pristine understanding of the principles of neonatal and cardiac care.
- Keywords** : Anesthesia for preterm patent ductus arteriosus, bedside patent ductus arteriosus ligation, ductal ligation in neonatal intensive care unit, postligation cardiac syndrome

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INTRODUCTION

Management strategies for hemodynamically significant patent ductus arteriosus (PDA) in a premature newborn vary among different institutes. These involve medical treatment (fluid restriction, diuretics, and supportive care), nonsteroidal anti-inflammatory drug (NSAID) therapy, closure (ligation/device), and conservative watchfulness. When indicated, surgical ligation of the preterm PDA must be offered, which can be undertaken either in the operating room (OR) or in the neonatal intensive care unit (NICU). Although routinely done, transporting a sick neonate from NICU to OR is a demanding job requiring utmost vigilance. Inherent risks during transportation are cardiorespiratory instability, thermo-dysregulation, accidental endotracheal tube (ETT) dislodgement, displacement of invasive lines, infusion pump dysfunction leading to discontinuation or purge of inotropes, and incubator malfunction. Keeping these issues in mind, procedures such as emergency balloon atrial septostomies,^[1] delayed sternal closure, adjustable pulmonary artery banding, and diaphragmatic plication have been performed in the cardiac intensive care units successfully. Noncardiac procedures (emergency laparotomy, gastrostomy, peritoneal drainage, and ventricular drain insertion for hydrocephalus) have also been safely conducted in NICU. Abundant literature exists for anesthesia pertaining to PDA ligation in the OR,^[2-5] but publications addressing anesthesia for bedside ligation in preterm infants are lacking.^[6] In this article, we would like to highlight important peri-operative issues and concerns, which will help in safe conduct of PDA ligation for preterm babies in the NICU.

METHODS

Medical records of preterm infants undergoing PDA ligation in NICU between August 2005 and October 2020 were reviewed. Patients included had either an isolated PDA or associated cardiac lesion that did not need concurrent attention. Patients with “suspected” coarctation, failed device attempts with or without a migrated device, airway insufficiency necessitating ductal “division,” and “pexy” procedures were managed in the OR. Hemodynamically significant PDA was diagnosed by transthoracic echocardiography (TTE) on basis of left atria to aorta ratio >1.4 , PDA diameter >1.5 mm/kg, and diastolic flow reversal in descending thoracic aorta (DTA). Ligation was considered if there was a failure to wean from respiratory support, contraindication or refractoriness to NSAIDs, and unresponsiveness to decongestion. Complete blood counts, blood culture and endotracheal culture (if intubated), levels and trends of inflammatory markers (C-reactive protein, procalcitonin), and a

chest X-ray (CXR) were obtained. Packed red blood cells (15 ml/kg) were arranged for all patients. Platelets were transfused 2 h prior to surgery if thrombocyte counts $<80,000$ /dl. After obtaining informed parental consent, surgery was scheduled. A standard anesthesia protocol, as described below, was used for all patients. The surgery involved left lateral, muscle-sparing thoracotomy via the 3rd intercostal space, placement of either a size 300 (medium-large) or 400 (large) titanium clip with minimal dissection, and routine thoracotomy closure over a 12 Fr drain.

Anesthetic Considerations – Success of bedside ligation starts with strong communication and coordination between “parent” neonatology and “visiting” anesthesia teams. A preoperative checklist [Box 1] ensures safety and smooth conduct. Two peripheral intravenous (I/V) access are ensured in patients in whom central lines are not *in situ*. I/V maintenance fluid and/or parenteral nutrition (PN) is continued during the procedure. Heart rate (HR), pulse oximetry (SpO₂), and end-tidal carbon dioxide (EtCO₂) were monitored carefully. Since 2015, cerebral and somatic near-infrared spectrometry has been added to this armamentarium. Noninvasive blood pressure (BP) is set to cycle every 3 min unless an invasive arterial pressure line is in place. An arterial line is not necessarily inserted preoperatively. Most patients are already intubated and ventilated, while others are on noninvasive ventilatory support or supplemental oxygen, where the intubation is performed by the anesthesiologists. We prefer opioid induction (fentanyl-2 mcg/kg) with a nondepolarising muscle relaxant (pancuronium-0.1 mg/kg) and opt to titrate anesthetics as and when required, not exceeding a total of 5 mcg/kg of fentanyl. Peak inspiratory pressure is set to achieve tidal volumes of 5 ml/kg with ventilatory rates targeting an EtCO₂ of 45–50 mmHg and fractional inspired oxygen concentration (FiO₂) to achieve SpO₂ of 94%–95%. Vigilance is maintained to prevent dislodgement of the ETT and displacement of lines during positioning. Intraoperatively, lung retraction may not be tolerated leading to hypercarbia and/or hypoxic crisis, which is managed by manual hyperventilation using higher FiO₂ and communicating with the surgeon to intermittently release retraction. Just prior to ligation, a small dose of nitroglycerine (1–2 mcg/kg) is supplemented to curtail acute BP surge. Successful ligation is detected by a rise in diastolic pressures, drop-in HR, and variable and transient rise in systolic BP. Intercostal block with 0.25% bupivacaine (1 ml/kg) is administered for adjuvant analgesia. Lungs are inflated, manually or by inspiratory hold on the ventilator, prior to rib approximation. The baby is placed back in the supine position. Either morphine (20 mcg/kg/h) or fentanyl (1 mcg/kg/h) infusion is chosen for postoperative analgesia. Our protocol is to perform

Box 1: Preoperative checklist

Bedside PDA ligation checklist

- Order NPO of 6 h prior to surgery (4 h if breast-milk fed)
- With fasting initiate 4 ml/kg/h of 10% dextrose with half normal saline/PN as per neonatology
- Set NICU ambient temperature at 28°C
- Check open-care system, switch the overhead lights on, and fix radiant warmer to manual mode at 35°C. Keep the side rails off
- Three-lead continuous ECG
- Core (rectal) and peripheral (skin of the dorsum of foot) temperature probes
- Right hand (preductal) and lower limb (postductal) SpO₂ probes
- Appropriately sized BP cuffs placed if invasive arterial line is not already *in situ*
- Check CXR for ETT position and bilateral lung fields
- Check for in-line EtCO₂
- Record optimal ventilatory settings (robust communication with the NICU team)
- Set humidifier at 37°C
- Jackson Rees circuit should be kept ready at bed side
- Two patent I/V line accesses assured
- NTG (1 mcg/kg/ml) prepared
- Baseline electrolytes, arterial blood gas, and blood sugar levels should be checked and corrected before induction
- Cross-matched PRBC (15 ml/kg) checked and available in NICU
- Transfuse 10 ml/kg RDP if platelet count is 50,000-80,000/dl or SDP if <50,000/dl, 2 h before surgery

PDA: Patent ductus arteriosus, PN: Parenteral nutrition, NICU: Neonatal intensive care unit, ECG: Electrocardiogram, SpO₂: Pulse oximetry, BP: Blood pressure, ETT: Endotracheal tube, EtCO₂: End-tidal carbon dioxide, I/V: Intravenous, NTG: Nitroglycerine, RDP: Random donor platelets, SDP: Single donor platelets, PRBC: Packed red blood cells, CXR: Chest X-ray, NPO: Nil per oral

TTE immediately and 6-h post ligation. Clinical and echocardiographic assessment guides inotrope use. For isolated diastolic hypertension (high afterload) with preserved left ventricular (LV) function, sodium nitroprusside (SNP) is used with titration of BP according to perinatology guidelines,^[7] necessitating insertion of arterial line. If mitral regurgitation (MR) ≥ Grade-III develops or worsens from its preoperative grade, we choose dobutamine (preserved LV function) or levosimendan (LV dysfunction). If LV dysfunction is associated with hypotension, epinephrine is added. CXR is done to check ETT position, lungs expansion, and pneumothorax. A detail handover to the neonatology team is mandatory.

Statistics

Quantitative data were presented as median with interquartile range (IQR) and categorical data were presented as numbers and percentage thereof.

RESULTS

Sixty-six patients underwent PDA closure in NICU. The demographic details are tabulated in Table 1. Twenty-five (38%) extracardiac [Table 2] and ten (15%) cardiac anomalies were documented. One patient each had surgery for eventration of diaphragm, bilateral choanal atresia, and creation of an ileostomy and mucous fistula at 22 days, 45 days, and 19 days, respectively prior to PDA surgery. Fifteen (23%) had contraindication to NSAIDs (necrotizing enterocolitis, intraventricular hemorrhage (IVH) >Grade-II, acute kidney injury, and sepsis-induced severe thrombocytopenia). Twenty (30%) patients who had culture-positive sepsis had received at least 48 h of sensitive antibiotics. Four of these were on various combinations of dopamine, adrenaline, or

noradrenaline with a median inotropic score of 8 at the time of surgery.

There were no procedural deaths but there were three (4.5%) in-hospital (30 days) mortalities, the details of which are provided in Table 3. One patient had accidental extubation intraoperatively after lung retraction, which was managed by prompt recognition, immediate application of sterile dressing over the open wound, and turning the patient to supine position and re-intubation. Three (4.5%) patients required insertion of an additional anterior thoracostomy tube for draining residual postoperative pneumothorax. None developed chylothorax or hemothorax. Postprocedure CXR revealed pulmonary collapse most frequently involving the right upper lobe followed by the left lung. These were managed with tracheal suctioning, physiotherapy, and lung recruitment strategies. Twenty-one (32%) patients required initiation of postoperative inotrope/vasodilator therapy within 6 h of ligation. Six required SNP infusion for isolated diastolic hypertension, 12 needed dobutamine for > Grade-III MR with preserved LV function, and 3 patients received a combination of epinephrine and levosimendan for ≥ Grade-III MR with LV dysfunction and hypotension. Three patients demonstrated severe pulmonary dysfunction necessitating shifting to high-frequency oscillator support transiently. No patient developed hypothermia, but transient hyperthermia (core temperature >37.5°C) occurred in three (4.5%). Transfusion needs were limited to 12 (18%) patients who required platelet administration preoperatively. No patient required blood product administration intraoperatively or within 6 h post procedure. The median stay in the NICU prior to PDA ligation was 30 (IQR: 19–52) days and that postligation was 22 (IQR: 5–37) days.

DISCUSSION

Anesthetic management of PDA ligation in the NICU should not only consider the challenges involved in performing a surgical intervention outside the OR but should also discuss the problems inherent to sick preterm newborns who pose a significant risk for anesthesia. Issues such as edematous lungs, congestive heart failure, and pulmonary hypertension accompany hemodynamically significant PDA. Preterm infants also suffer from fragile, immature lungs with surfactant deficiency, and reduced lung compliance. Chronic mechanical ventilation makes them susceptible to atelectasis, ventilator-associated pneumonia, and bronchopulmonary dysplasia. Anesthesiologists must be cognizant of the fact that intravascular depletion

due to chronic fluid restriction and/or diuretics leads to poor tolerance to anesthetics^[2] and therefore may need replacement despite appearing edematous.

Kumar Sinha and Neogi^[8] emphasized that if provision to perform surgeries in the NICU was kept in mind while setting up the infrastructure, various surgeries could be safely performed. In addition, it offers economic advantages by optimal resource utilization, saving OR charges, and better management of OR time allocation.^[9] Importantly, continuity of care by the neonatology team is maintained and families are minimally disrupted.^[10]

Contrarily, it has certain limitations too. Inadequate overhead lights, inadjustable beds, and limited space put a strain on the surgical team.^[11] It disrupts the serenity of NICU. In an emergency (torrential bleed), it is impossible to transport the patient safely to the OR.

Table 1: Demographic details

Variable	Distribution
Age (days), median (IQR)	30 (19-52)
Gender (male/female)	39/27
Body weight (kg), median (IQR)	1.4 (0.97-2)
Gestational age (weeks), median (IQR)	31 (28-33)
NSAID therapy	
Three cycles	39
Two cycles	12
Contraindicated	15
Culture-positive sepsis	20
NEC	13
IVH	7
Ventilation dependence	
Invasive	32
Noninvasive	25
Oxygen by nasal cannula/mask	9

IQR: Interquartile range, NSAID: Nonsteroidal anti-inflammatory drug, NEC: Necrotizing enterocolitis, IVH: Intraventricular hemorrhage

Table 2: Noncardiac anomalies

Extracardiac anomalies	n
Tracheobronchomalacia	4
Hydrocephalus	4
Inguinal hernia	3
Spina bifida occulta	2
Congenital talipes equinovarus	2
Preauricular tag	2
VII cranial nerve palsy	1
Diaphragmatic eventration	1
Tracheoesophageal atresia	1
Meconium ileus	1
Choanal atresia	1
Pierre robin syndrome	1
Congenital adrenal hyperplasia	1
Congenital rubella syndrome	1

Table 3: Mortality

Patient serial number	Gestational age (weeks)	Age at surgery (days)	Weight (kg)	Postoperative day	Cause of death
11	32	14	0.885	6	Sepsis, congenital rubella syndrome, pancytopenia
23	31	33	1.055	5	NEC
47	28	26	1.200	3	Pulmonary hemorrhage

NEC: Necrotizing enterocolitis

Perioperative concerns for bedside patent ductus arteriosus ligation

1. Temperature – Premature infants exhibit weak homeothermic response making them susceptible to hypothermia-induced acidosis and bradycardic arrest. Hyperthermia is equally devastating and when beyond the infant’s ability to dissipate heat, it can cause tachycardia, seizures, and catabolism.^[12] In our series, surgeries were performed on infants placed on neonatal open-care systems under servo-controlled radiant warmers (Babytherm-8004, Draeger, Lübeck Germany). Babies under drapes can get overheated from failure of controls or dislodgement of sensor probes. Therefore, rectal temperature should be monitored and radiant warmer set on manual mode fixed at 35°C. We also recommend nonwoven, lightweight disposable drapes to avoid thermal dysregulation and prevent the heavy drapes interfering with ventilation of preterm infants
2. Vascular access – Patency of both peripheral I/V lines should be checked and not presumed. One line is dedicated for inotropes if required and the other for bolus medications, fluids, or blood. Low prime-volume extension lines help maintaining access away from the surgical field. This is important during events requiring rapid fluid replacement such as bleeding, as once under the drapes it is impossible to access or secure I/V lines
3. Airway and ventilation issues – Anesthesiologists are often concerned about working with the NICU

ventilator instead of the familiar OR anesthesia station. This is rather counterintuitive as most anesthesia machines are incapable of delivering the low tidal volumes reliably vis-à-vis a typical neonatal ventilator. Before starting the procedure, it is prudent to ensure adequate ETT size or if already *in situ* to check for tube leaks, fixation, and to confirm appropriate placement by both auscultation and CXR. CXR must be analyzed for the right lung's adequacy as a gas exchange unit. Ventilation-perfusion mismatch in a thoracotomy decubitus compromises the respiratory mechanics of congested baby lungs which can lead to intermittent desaturation and bradycardia which is further accentuated by lung retraction during dissection. A detailed plan must be in place for effective manual ventilation and accidental ETT dislodgement

4. Anesthetic agents – Perioperative pain control in preterm and newborns undergoing bedside PDA ligation is not only an anesthesiologist's ethical responsibility but is also a well-recognized issue for neurodevelopment, altered pain sensitivity, and neuroanatomical and behavioral abnormalities noted as late as in the adolescence. Fentanyl, among the newer generation synthetic opioids, is the most frequently used analgesic.^[13,14] Currently, there is no consensus on the ideal anesthetic regime applied for bedside surgical ductus ligation on preterms. In NICU, unavailability of inhalational agents reduces the options for the anesthetist. Anand *et al.*^[15] concluded that the stress and hormonal response to surgery as well as protein lysis can be mitigated by fentanyl. Janvier *et al.* suggested that a minimum dose of 10.5 mcg/kg of fentanyl or equivalent provides respiratory stability in preterm infants undergoing PDA ligation. In the same study, 38% of the premature infants received <10 mcg/kg of fentanyl and they hypothesized that more unstable and immature patients would receive less analgesia as larger doses would lead to hemodynamic instability.^[2] Incidence of chest wall rigidity and laryngospasm have been reported even after low dose of fentanyl (3–5 mcg/kg) in preterms.^[16] In our study, we used a low-dose fentanyl regime as most of our patients were sick and already on morphine infusion. Striking a balance for the optimal dose of opioids, where low-dose regimes are assumed to provide inadequate analgesia while being safer and high-dose strategies which obtund stress response but cause hypotension, is a rather fine art. In his review, Wolf^[17] raised a pertinent question, whether anesthetic management strategies really matter while performing short procedures like PDA ligation? The author suggested that anesthetists being perioperative physicians should be mindful that results must be assessed not only in short-term

- goals such as survival, wean ability from respiratory support, and hospital discharge but also in long-term outcomes such as optimal and holistic development
5. Infection concerns – Contrary to the belief that there may be an increased incidence of infections (systemic or surgical site) in patients operated in the NICU, there are no reports justifying this assumption. Gavilanes *et al.*^[18] did not report any local or systemic infection within 72 h of the procedure, thus concluding that NICU is a safe place to conduct surgical procedures. In agreement to the above findings, no new systemic sepsis or surgical site infection was documented in our cohort of patients
6. Postligation hemodynamics [Box 2 for detection and management]
 - BP control – Ligation of PDA may cause an acute surge in BP which can lead to IVH.^[3] Tight BP control also facilitates safe and atraumatic ligation
 - Postligation cardiac syndrome leading to cardiovascular collapse and pulmonary dysfunction occurs in 28%–45% of cases appearing 6–12 h after ligation and is attributed to both an acute increase in LV afterload and systolic LV dysfunction.^[20–22] The former is due to the sudden closure of the low resistance pulmonary circuit and leads to diastolic hypertension, while the latter is attributed to an acute decrease in preload that is particularly aggravated in intravascularly volume-depleted patients secondary to preoperative fluid restriction and aggressive diuresis. This preload-dependent systolic dysfunction manifests as hypotension and is poorly tolerated^[23,24]
 - Iatrogenic coarctation due to clipping of DTA is a known complication after ligation^[25,26]
 - Inadvertent ligation of the left pulmonary artery is a very rare complication with an estimated incidence of 0.001%.^[27]

Both the above conditions must be detected promptly and managed urgently.

Although this study was not primarily designed to compare OR versus NICU ligations, some points can be inferred by comparing our outcomes with results of a few studies including OR ligation procedures. Although the 30-day mortality and perioperative (procedure related) hemodynamic instability were comparable between PDA ligation in OR (5% and 38.2% respectively) as reported by Lee *et al.*^[28] and those in our series (4.5% and 32% respectively), transport-related problems such as hemodynamic instability during shifting to (5.6%) and from (12.4%) the OR and hypothermia (<36°C) in the intraoperative (26.3%) or postoperative (12%) period were noted in patients with OR ligations. Wang *et al.*^[9] too noted hypothermia in 39.3% of the patients with the

Box 2: Postligation hemodynamic concerns: Detection and management

Blood pressure control

Acute hypertension can lead to IVH and traumatic ligation
NTG (1-2 mcg/kg) bolus with supplemental opioid and relaxants just before clipping

Post ligation cardiac syndrome

Cardiovascular collapse and pulmonary dysfunction

Typically presenting 6-12 h postoperative

Diagnosed by

Worsening ventilatory parameters, high EtCO₂, and low SpO₂

Diastolic hypertension due to acute increase in LV afterload

Hypotension due to systolic LV dysfunction

TTE to ascertain systolic as well as diastolic LV function

Management

Manage pulmonary dysfunction by ventilatory optimization/high frequency oscillator

Acute rise in afterload is best managed by initiating vasodilator/inodilator therapy

Preload dependent systolic dysfunction is managed by volume resuscitation

Volume unresponsive hypotension mandates inotropes

Iatrogenic coarctation

Disappearance of pulsatility in arterial waveform or loss of SpO₂ trace in lower limb along with brachiocephalic hypertension just after ligation

NIRS (cerebral - somatic difference) also of assistance

Should be confirmed by TTE and addressed urgently in the OR using appropriate repair techniques

Inadvertent ligation of left pulmonary artery

Intraoperative detection: Decrease in SpO₂ and a decrease followed by an increase in EtCO₂^[19]

Postoperative detection: Persistent ductal murmur, no improvement in ventilatory parameters or oligemic left lung on CXR

Confirmed by TTE and must prompt urgent unclipping or repair in the OR

IVH: Intraventricular hemorrhage, NTG: Nitro-glycerine, NIRS: Near infrared spectrometry, OR: Operating room, EtCO₂: End-tidal carbon dioxide, SpO₂: Pulse oximetry, CXR: Chest X-ray, LV: Left ventricular, TTE: Transthoracic echocardiography

lowest body temperature of 35.2°C in OR ligations. In our series, no patient experienced hypothermia; on the contrary, transient hyperthermia >37.5°C was observed in 4.5% of the cohort.

Encouraged by the above results, we developed a “mobile bedside PDA ligation team” comprising two surgeons, one anesthesiologist, 1 pediatric cardiologist, 1 anesthesia technician, and two pediatric cardiac OR nursing staff, equipped with instruments and consumables. This team offers bedside PDA ligation at peripheral centers lacking pediatric cardiac surgical facilities but proficient in tertiary-level NICU care, thus eliminating the integral risk of transferring sick patients from one NICU to another.

Anesthetic guidelines pertaining to PDA ligation in constrained environments like NICU do not exist. We believe the strength of this article is its attempt to fill this void by addressing perioperative issues for bedside PDA ligation. Such protocols will encourage, guide, and persuade other teams in developing countries to establish and smoothly run such programs. Unfortunately, we recognize certain limitations in our study as it was not designed to compare PDA ligation performed in the NICU with those done in the OR. It also lacks neurodevelopmental and behavioral long-term follow-up of these children which may be addressed by future studies.

CONCLUSIONS

Operating on a sick preterm in the NICU not only requires knowledge, thorough understanding of the subject, and competency but also requires

impeccable communication and rapid response time to unanticipated crises. It must be recognized that bedside PDA ligation in the NICU can be accomplished without jeopardizing safety by utilizing meticulous planning by anesthesiologists and close collaboration with the neonatology team.

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Conflicts of interest

There are no conflicts of interest.

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