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Clinical Profile and Immediate Outcomes of Patent Ductus Arteriosus in Preterm Neonates Admitted in the NICU of a Tertiary Care Hospital in Central India

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Abstract

Background: Patency of the ductus arteriosus is vital for the survival of the foetus. The ductus often fails to close in premature infants called patent ductus arteriosus (PDA). We aim to study the clinical profile and assess the immediate outcomes of preterm neonates diagnosed with clinically significant PDA.

Objectives: To evaluate the clinical profile and immediate outcomes of Patent Ductus Arteriosus in Preterm Neonates admitted in the NICU of a Tertiary care hospital in central India. Methods: This prospective observational descriptive study was conducted in the Department of Paediatrics at a Tertiary Care Centre over a period of 24 months, from August 2022 to June 2024. All preterm neonates admitted to the NICU with a gestational age of less than 37 weeks and a birth weight of less than 2.5 kg, or with clinically apparent Patent Ductus Arteriosus (PDA), were included in the study. Institutional Ethical Committee (IEC) approval and written informed consent from parents were obtained before enrolment of study participants. Detailed clinical history, examination findings and investigations were recorded, and all data were entered into a Microsoft Excel spreadsheet. Statistical analysis was performed, and results were presented as frequencies and percentages. Results: A total of 250 preterm neonates who fulfilled the inclusion and exclusion criteria were enrolled in the study. During the study period, a total of 961 suspected neonates were screened; of them, 250 were diagnosed with PDA, representing an incidence rate of 26.01%. Most of the mothers 107 (42.8%) were between 21 and 25 years, with a mean maternal age of 24.78 ± 3.15 years. Most of the mothers were primigravida, 165 (66.0%). In 179 (71.6%) of cases, patent ductus arteriosus (PDA) was classified as idiopathic. 77 (30.8%) had gestational age between 32 and 33 weeks. The mean gestational age was 32.12 ± 1.41 weeks. Most of the neonates, 103 (41.2%) with PDA, had birth weight between 1500 and 2499 grams. The commonest clinical finding was a systolic murmur detected in 179 (71.6%) of neonates. Moderate-sized patent ductus arteriosus (PDA), in 117 (46.8%) neonates, was the commonest 2D ECHO finding in the first 24 hours of life. The majority of the neonates, 169 (67.6%), were managed medically. The commonest complication observed was heart failure in 34 (13.6%) of neonates. 102 (40.8%) of the neonates with PDA experienced spontaneous closure. 229(91.6%) of the neonates being discharged alive, Mortality observed was 21 (8.4%).

Conclusion: The present study provides important insights into the incidence of PDA, its aetiology, diagnosis, management, and outcomes. The incidence of PDA was found to be 26.01%. Most cases were idiopathic. Echocardiography emerged as a vital tool in the early diagnosis of PDA. Most neonates were managed medically, while a significant portion experienced spontaneous closure of the ductus arteriosus. Complications such as heart failure were common among neonates with PDA. Thus, early diagnosis and individualised management strategies, including both medical treatment and conservative observation, play a critical role in improving outcomes for neonates with PDA.

Keywords:
Prematurity; Morbidity; Mortality; Congenital heart disease; Echocardiography

Abbreviations:
NICU: Neonatal Intensive Care Unit; PDA: Patent Ductus Arteriosus; LSCS: Lower Segment Caesarean Section; ECHO: Echocardiography; NSAID: Non-steroidal Anti-Inflammatory Drug

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Introduction

Patent Ductus Arteriosus (PDA) is the most common Congenital Heart Disease (CHD) in the Preterm and one of the commonest CHD seen in the neonatal ICU [1]. The ductus arteriosus is a blood vessel that exists during foetal development. It connects the main pulmonary artery to the aorta and, together with the foramen ovale, serves to allow blood to bypass the pulmonary circulation [2]. In healthy, full-term infants, the ductus arteriosus usually closes within 48-72 hours of birth, but in preterm infants it frequently remains open beyond the first days of life [3]. PDA comprises 5%-10% of all congenital heart diseases, excluding premature neonates. It is more common in females than in males. Clinical evidence of PDA appears in 45% of neonates with a birth weight of <1750 g and in about 80% of neonates with a birth weight of <1200 g. Significant PDA occurs in 15% of premature infants with a birth weight of <1750 g and in 40%-50% of those with a birth weight of <1500 g [4]. Studies have shown that the incidence of PDA ranges from 20% to 60% in infants born before 28 weeks of gestation [5]. Based on the size of the PDA, it is classified as large when the diameter is >3mm, moderate when the diameter is between 1.5 mm and 3 mm, and small when the diameter is <1.5 mm [6]. Risk factors for PDA include prematurity, respiratory distress syndrome, high volume of intravenous fluids in 1st week, sepsis, prolonged rupture of membranes, use of furosemide, male sex, and aminoglycoside antibiotics [7]. The clinical manifestations of PDA vary depending on the size of the ductus and the degree of left-to-right shunting. Common signs include a characteristic heart murmur, tachypnoea, poor feeding, and failure to thrive. In severe cases, PDA can lead to congestive heart failure, pulmonary haemorrhage, and increased risk of intraventricular haemorrhage. The early identification and management of PDA are, therefore, crucial to prevent these complications and improve neonatal outcomes [3,8]. Echocardiography has emerged as a promising modality to screen newborns at risk of adverse effects of ductal shunting. This helps in identifying PDAs that require treatment to ultimately prevent unnecessary therapy or delay of necessary therapy [9]. The complications associated with PDA can be profound and multifaceted. Left untreated, PDA can lead to prolonged respiratory support, chronic lung disease, necrotising enterocolitis, and increased mortality. Moreover, the condition is associated with significant long-term morbidity, including neurodevelopmental impairment due to the associated hemodynamic instability and hypoperfusion of vital organs [10]. The management of PDA involves a combination of medical and surgical approaches. Pharmacological treatment with NSAIDs aims to induce ductal closure by inhibiting the production of PGE2. However, not all infants respond to medical treatment, and some may require surgical intervention. Recent advancements in minimally invasive techniques have improved the safety profile of surgical intervention [11].

This study aims to fill the gap in regional data on PDA by providing comprehensive insights into its incidence, aetiology, clinical presentation, diagnostic approaches, and outcomes of preterm neonates admitted to a tertiary care hospital in central India.

Materials & Methods

Study participants & sample size

It was a duration-based study. All the neonates admitted in the NICU of <37 weeks of gestation and birth weight <2.5 kg or having clinically apparent patent ductus arteriosus were included in the study, as per the inclusion criteria.

Statistical analysis

The quantitative data were represented as their mean ± SD. Categorical and nominal data were expressed as percentages. The significance threshold of p-value was set at <0.05. All analyses were carried out using SPSS software version 21.

Ethical consideration

Institutional Ethical Committee (IEC) approval was taken. After satisfying both inclusion and exclusion criteria, neonates were enrolled following the acquisition of written informed consent from the guardians or parents.

Data collection

This prospective observational descriptive study was conducted on 250 neonates admitted to the NICU with gestational age <37 weeks and birth weight <2.5 kg, or with clinically apparent patent ductus arteriosus, during a 24-month study period from August 2022 to June 2024. Neonates <37 weeks of gestation admitted to the NICU with one or more symptoms of clinically apparent patent ductus arteriosus were assessed.

Clinically apparent PDA was defined as the presence of any one of the following signs:

- Hyperactive precordium (visible precordial pulsation in >2 rib spaces),
- Systolic murmur (usually an ejection systolic murmur of grade ≥ III at the 1/2 left ICS, or a continuous machinery murmur),
- Bounding peripheral pulses (easily palpable dorsalis pedis).

Echocardiographic approach

All enrolled newborns underwent their first echocardiographic scan within 24 hours of birth, with subsequent scans at 48 and 72 hours of age. These scans were performed on a Toshiba 580 A ultrasound system using a 7 MHz phased array probe for real-time scanning and pulsed/continuous wave/colour. Standard acoustic windows and scanning planes were used to obtain a complete 2D picture of cardiac anatomy, with M-mode measurements of chambers and Doppler evaluation of intracardiac blood flow. These scans were performed by a single examiner trained in comprehensive ECHO. All recordings were measured in triplicate and averaged to remove intra-observer variation. Images were interpreted by a single paediatric cardiologist who was masked to patient and clinical data. The data were collected, coded and stored until final analysis. These babies were monitored clinically for signs of PDA up to two weeks of age or discharge, whichever was later. Those who became clinically apparent during this period underwent a confirmatory echo scan on the same day; the rest, who remained free of signs, underwent their last scan at either the 14th day of life or at discharge, whichever was later, to ascertain the closure or persistence of the asymptomatic duct. Neonates with clinically apparent PDA received medical and surgical interventions for ductal closure as per unit protocol.

Results

During the study period, a total of 250 neonates who fulfilled the inclusion and exclusion criteria were included in the study.

Incidence	Frequency	Percentage (%)
Total neonates screened	961	100
Neonates with PDA	250	26.01

Table 1: Incidence of PDA in preterm neonates admitted to the NICU.

Table 1 depicts that, During the study period, a total of 961 suspected preterm neonates were screened, of those 250 were diagnosed with PDA, representing an incidence rate of 26.01%.

Demographic characteristics	Frequency (N=250)	Percentage (%)
Age of mother in years		
<20	22	8.8
21 to 25	107	42.8
26 to 30	92	36.8
>30	29	11.6
Gravida(G)		
G1	165	66
G2	70	28
G ≥ 3	15	6
Mode of delivery		
Normal Vaginal Delivery (NVD)	118	47.2
Lower Segment Caesarean Section (LSCS)	132	52.8
Gestational age (In weeks)		
Extremely preterm (<28 weeks)	37	14.8
Verypreterm (28-31 weeks)	73	29.2
Moderately preterm (32-33 weeks)	77	30.8
Late preterm (34-36 weeks)	63	25.2

Birth weight (in grams)		
<1000	49	19.6
1000 to 1499	981	39.2
1500 to 2499	103	41.2

Table 2: Demographic profile of Mothers and Preterm Neonates.

From the Table 2, it was observed that most of the mothers were from the age group of 21 to 25 years 107 (42.8%). The mean age of mother was 24.78 ± 3.15 years, ranged from 17 to 40 years. Most of the mothers 165 (66.0%) were belonging to gravida1. Maximum neonates 77 (30.8%) had gestational age between 32 to 33 weeks. The mean gestational age was 32.12 ± 1.41 weeks. In the present study, out of the total 250 neonates diagnosed with Patent Ductus Arteriosus (PDA), 52.8% (132 neonates) were delivered by caesarean section, while 47.2% (118 neonates) were delivered *via* vaginal delivery. 103 (41.2%) babies born with birth weight between 1500 to 2499 gram. The mean birth weight was 1538.95 ± 499.51 gram.

Aetiology of PDA	**Frequency (N-250)**	**Percentage (%)**
Idiopathic	179	71.6
Maternal Infections	31	12.4
Maternal Diabetes Mellitus	22	8.8
Other Causes (Prematurity, Hypoxia)	18	7.2

Table 3: Etiological classifications of PDA in neonates.

Table 3 depicts, Etiological classifications of PDA in Neonates. Most cases 179 (71.6%) were classified as idiopathic, where no specific cause could be determined. Maternal infections contributed to 31(12.4%) of the cases, while 22(8.8%) were associated with maternal diabetes mellitus. The remaining 18(7.2%) of cases were categorized under "Other Causes," which included factors such as prematurity and hypoxia, both of which are known risk factors for the persistence of the ductus arteriosus after birth.

Clinical Signs	**Frequency (N=250)**	**Percentage (%)**
Hyperactive Precordium	151	60.4
Systolic Murmur	179	71.6
Bounding Peripheral Pulses	130	52

Table 4: Clinical signs of PDA in preterm neonates.

Table 4, showing the Clinical Signs of PDA in Preterm Neonates. Commonest was systolic murmur, often a characteristic sign of PDA, detected in 179 (71.6%) of the neonates. Hyperactive precordium was noted in 151 (60.4%) and Bounding peripheral pulses, were observed in 130 (52.0%) of the neonates.

Echocardiographic timing	**Echocardiographic Findings**	**Frequency**	**Percentage**
1st Scan (Within 24 hours) (N=250)	Small PDA	81	32.4
	Moderate PDA	117	46.8
	Large PDA	52	20.8
2nd Scan (At 48 hours), (N=198)	Persistent PDA	167	84.34
	Spontaneous Closure	31	15.65
3rd Scan (At 72 hours), (N=150)	Persistent PDA	107	71.33
	Spontaneous Closure	43	28.66

Table 5: Echocardiographic Findings of the preterm neonates.

Table5 showed, During the first scan performed within 24 hours of life, 117 (46.8%) of neonates were found to have a moderate PDA, while 81(32.4%) had a small PDA and 52 (20.8%) had a large PDA. The second scan, conducted at 48 hours, 167 (84.34%) of neonates still had a persistent PDA, while 31(15.65%) showed spontaneous closure of the ductus arteriosus. By the third scan at 72 hours, the percentage of persistent PDA cases had decreased to 107 (71.33%), with 43 (28.66%) of neonates showing spontaneous closure. These findings highlight the natural course of PDA closure in some neonate's while underscoring the need for continued monitoring in others.

Management	Frequency (N=250)	Percentage (%)
Medical Management (NSAIDs)	169	67.6
Conservative (Observation)	81	32.4

Table 6: Management of preterm neonates with PDA.

Most of the neonates 169 (67.6%) were managed medically, primarily using Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) to encourage closure of the ductus arteriosus. 81(32.4%) of the neonates were managed conservatively with observation, reflecting cases where spontaneous closure was anticipated or where the PDA was small and asymptomatic. Neonatal were followed up in consequent scans who did not have spontaneous closure were referred to higher centre for patch/Device closure.

Complications	Frequency (N=250)	Percentage (%)
Heart Failure	34	13.6
Pulmonary Haemorrhage	20	8
Bronchopulmonary Dysplasia (BPD)	49	19.6

Table 7: Complications of PDA in preterm neonates.

In Table 7, Among the preterm neonates, the most frequent complication was Bronchopulmonary Dysplasia (BPD), affecting 49 (19.6%) of the neonates. 34(13.6%) developed heart failure, while Pulmonary hemorrhage, a serious condition, was seen in 20 (8.0%) of the patients.

Outcomes	Frequency (N=250)	Percentage (%)
Spontaneous Closure	102	40.8
Mortality	21	8.4
Discharged	229	91.6

Table 8: Clinical Outcomes of preterm neonates with PDA.

Out of total 250 neonates, 102 (40.8%) experienced spontaneous closure of the PDA at the end of the study. The overall survival rate was high, with 229(91.6%) of neonates were survived and discharged. However, there was a mortality rate of 21(8.4%), reflecting the severe complications that can arise from PDA and associated conditions in this vulnerable population (Table 8).

Discussion

In the present study, of 961 neonates screened for PDA, 250 were diagnosed, yielding an incidence of 26.01%. A similar study by Van Overmeire, et al reported an incidence of 20-30% of PDA in preterm neonates [12]. In the present study, most mothers, 107 (42.8%), were aged 21 to 25 years. Isayama, T et al., found that most mothers of neonates with PDA were aged between 20 and 30 years [13]. In the present study, most mothers, 165 (66%), were primigravida (gravida 1), followed by 28% who were gravida 2, and 3% who had been pregnant three or more times (gravida ≥ 3). Similar findings were observed in the study conducted by Kumar, et al [14], who reported that 68.5% of mothers of neonates diagnosed with PDA were primigravida. Similarly, the study by McNamara, et al. [15] observed that PDA is more common in preterm infants, with a significant proportion (32%) of affected neonates born between 32 and 34 weeks of gestation. In the present study, 52.8% of neonates with patent ductus arteriosus were delivered *via* caesarean section (C-section), while 47.2% were delivered vaginally. A study by Schmidt, et al reported that around 55%of preterm infants with PDA were born *via* C-section [16]. This is slightly higher than findings from the study by Fowlie and Davis [17], which reported that around 40% of neonates with PDA were delivered vaginally. In the study by Shilpa, et al [18], of the 37 neonates with primary closure, 8 (21.6%) had a birth weight <1000 g, 6 (16.2%) weighed 1000 to 1500 g, 14 (37.8%) weighed 1500 to 2500 g, and 9 (24.3%) weighed <2500 g. Of the 17 neonates with secondary closure, 7 (41.2%) weighed <1000 g, 3 (17.6%) weighed 1000 to 1500 g, 5 (29.4%) weighed 1500-2500 g, and 2 (11.7%) weighed >2500

g. Two neonates with non-closure of PDA weighed >2500 g. In the present study, most cases (71.6%) of Patent Ductus Arteriosus (PDA) were classified as idiopathic, with no specific cause identified. Maternal infections were responsible for 12.4% of cases, 8.8% were associated with maternal diabetes mellitus, and the remaining 7.2% fell under "Other Causes," which included factors such as prematurity and hypoxia. Dinakara, P et al [19] also identified idiopathic PDA in 69.5% of their cases, closely relating to the findings of the current study. They further reported a similar contribution of maternal diabetes mellitus (9.5%), which aligns with the 8.8% found in this research. In contrast, Singh, VA et al [20] found a slightly lower proportion of idiopathic cases (64.2%), with a higher contribution from maternal infections (18%). Shahnaz Pourarian, et al [21] similarly identified prematurity and hypoxia as major contributors to PDA, reporting rates of 6.8% for maternal diabetes and 13.2% for maternal infections. In the present study, systolic murmurs were the most common finding, present in 71.6%, followed by hyperactive precordium in 60.4% and bounding peripheral pulses in 52% of preterm neonates. These findings are comparable with the study by Shilpa, et al, who observed a similar prevalence of systolic murmurs in 70% of their cohort, hyperactive precordium in 58% of cases, and bounding pulses in 50%. This consistency suggests that these clinical signs are reliable indicators of PDA across different populations. A study conducted by Shilpa, et al, who reported that 95% of their cohort received an initial echocardiographic scan within the first 24 hours, with follow-up scans at 48 and 72 hours in 85% and 70% of cases, respectively. Bhardwaj A, et al noted that 100% of patients underwent an initial echocardiographic evaluation within 24 hours. Their follow-up rates were 80% at 48 hours and 62% at 72 hours, which closely match the findings of this study. Ramos FG, et al [22] examined PDA progression in premature neonates using initial and follow-up scans. The results showed 48% with moderate PDA, 30% with small PDA, and 22% with large PDA at initial scans. At 48 hours, 82% had persistent PDA, with 18% showing closure, and at 72 hours, 72% persisted with PDA and 28% showed closure, consistent with the findings in the present study. The management strategy aligns with established practices and reflects the variability in PDA presentations and responses to treatment. Nemerofsky, et al [23] reported a closure rate of 71% in VLBW newborns. In another study by Koch, et al [24], 35% of extremely low birth weight infants showed spontaneous ductal closure within the first 10 days of life. The mortality rate of 8.4% in our study reflects the serious complications that can arise from PDA and associated conditions.

Limitations

This was a single-centre study with limited follow-up. The study primarily focused on outcomes in the neonatal period, with limited long-term follow-up of neonates after discharge, specifically examining echocardiographic variability. The study mainly focused on medical management with NSAIDs and conservative observation. Other potential treatment options, such as surgical or interventional procedures for PDA closure, were not explored in detail, limiting the study's scope in assessing the full range of therapeutic approaches.

Conclusion

The present study provides important insights into the incidence, aetiology, diagnosis, management, and outcomes of PDA. The incidence of PDA was 26.01%. Most cases were idiopathic. Echocardiography was a vital tool for early diagnosis of PDA. Most neonates were managed medically, and a significant proportion experienced spontaneous closure of the ductus arteriosus. Complications, including heart failure, were common among neonates with PDA. Thus, early diagnosis and individualised management strategies, including both medical treatment and conservative observation, play a critical role in improving outcomes for neonates with PDA.

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