Retinopathy of prematurity in a reference maternity hospital in Northeastern Brazil: incidence, associated factors, and outcomes

Retinopatia da prematuridade em uma maternidade de referência do Nordeste Brasileiro: incidência, fatores associados e desfechos

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ABSTRACT

Objective: To evaluate the incidence of retinopathy of prematurity and of its outcomes in a reference maternity hospital in northeastern Brazil and to identify associated factors.

Methods: A cross-sectional, retrospective study was conducted using secondary data from newborns screened between August 2020 and November 2022.

Results: The statistical analysis included 166 infants. The disease incidence was 40% (66 cases). Stage 2 was the most incident (46 cases), followed by stage 1 (15 cases) and stage 3 (5 cases). No neonates were diagnosed with zone 1. Zone 2 was the most incident (61 cases), and cases in zone 3 (4 cases) were rare. Among the 42 infants assessed for plus, a few presented pre-plus (12%) or plus (7.1%). Among those with retinopathy of prematurity, 17% (11 cases) required treatment (laser photocoagulation). Birth weight, gestational age at birth, 1st minute Apgar score, resuscitation in the delivery room, use of surfactant, use of conventional ventilation, use of nasal continuous positive airway pressure and apnea were statistically associated ($p \leq 0,05$) with the disease diagnosis and its outcomes.

Conclusion: The epidemiological profile found was compatible with results reported from several other countries.

RESUMO

Objetivo: Avaliar a incidência de retinopatia da prematuridade e de seus desfechos em uma maternidade de referência do nordeste brasileiro e identificar fatores associados.

Métodos: Realizou-se estudo transversal e retrospectivo com dados secundários de recém-nascidos triados entre agosto de 2020 e novembro de 2022.

Resultados: A análise estatística incluiu 166 lactentes. A incidência da doença foi de 40% (66 casos). O estágio 2 foi mais incidente (46 casos), seguido do estágio 1 (15 casos) e do estágio 3 (5 casos). Nenhum neonato foi diagnosticado com zona 1. A zona 2 foi mais incidente (61 casos), e casos na zona 3 (4 casos) foram raros. Entre os 42 lactentes avaliados para *plus*, poucos apresentaram pré-*plus* (12%) ou *plus* (7,1%). Entre aqueles com retinopatia, 17% (11 casos) necessitaram de tratamento (fotocoagulação a *laser*). Peso ao nascer, idade gestacional ao nascer, índice de Apgar do 1° minuto, reanimação na sala de parto, uso de surfactante, uso de ventilação convencional, uso de pressão positiva contínua nasal nas vias aéreas e apneia associaram-se estatisticamente ($p \leq 0,05$) ao diagnóstico da doença e aos seus desfechos.

Conclusão: O perfil epidemiológico encontrado foi compatível com resultados reportados em vários outros países.

INTRODUCTION

Retinal vascularization begins with the projection of the central hyaloid artery, which regresses around the 16th week of pregnancy.[1] Concomitantly, definitive vascular plexuses form from the optic nerve towards the periphery, controlled by a well-orchestrated gradient of angiogenic factors released by astrocytes in response to fetal physiological hypoxia, and vascularization is completed at the 40th week of pregnancy.[1] In preterm babies, extrauterine high oxygen tension, which can be exacerbated by supplemental oxygenation, downregulates angiogenic factors when the vascularization has not yet been completed, interrupting it (vaso-obliterative phase).[1] As the baby matures, the metabolic demands of the retina grow, leading to a now hypoxic state, which can be intensified by the withdrawal of supplemental oxygenation, and this ultimately triggers a burst of angiogenic factors lacking regulated temporal and spatial gradients, generating pathological neovascularization (vaso-proliferative phase).[1] These events characterize retinopathy of prematurity (ROP), currently one of the main causes of childhood blindness in the world.[2] This disease is internationally classified according to three indicators: zones (I to III), stages (1, 2, 3, 4a, 4b and 5) and plus (present or absent).[2]

Given the large premature population in Brazil, which corresponded to 9.95% of live births in 2019,[3] an epidemiological assessment of ROP in the country's health services is necessary. Thus, the present study aimed to evaluate the incidence of ROP and of its outcomes in a reference maternity hospital in northeastern Brazil and to identify associated factors.

METHODS

Study design

A cross-sectional and retrospective study of secondary data was conducted at the *Maternidade Escola Assis Chateaubriand* (MEAC), a tertiary care maternity hospital in the city of Fortaleza (Ceará, Brazil), which is subordinated to the *Universidade Federal do Ceará* (UFC). The study protocol was registered at *Plataforma Brasil* and approved by the MEAC Research Ethics Committee (CAAE: 68793623.8.0000.5050; protocol: 6.028.805).

Collected data

The data were obtained from standard screening forms referring to newborns undergoing screening for ROP at MEAC, born between August 2020 and November 2022, following the guidelines from the *Sociedade Brasileira de Pediatria* (SBP), the *Conselho Brasileiro de Oftalmologia* (CBO) and the *Sociedade Brasileira de Oftalmologia Pediátrica* (SBOP).[4] The screening included newborns presenting with birth weight ≤ 1,500 g; or gestational age at birth ≤ 32 weeks; or any of the following risk factors, if ROP screening is deemed necessary according to the pediatrician's evaluation: respiratory distress syndrome; sepsis; blood transfusions; multiple gestation; intraventricular hemorrhage.

The first screening was carried out between the 4th and 6th week of life,[4] except when other health conditions made it impossible to meet this deadline. Babies with a completely vascularized retina were discharged, while those with incomplete vascularization or with ROP were kept under follow-up, with each subsequent consultation recorded on the same standard screening form. All assessments were carried out by a single observer, according to the International Classification of Retinopathy of Prematurity Revisited (ICROP revisited) published in 2005.[5] In 2021, the third edition of the International Classification of Retinopathy of Prematurity (ICROP3) was published;[6] however, it could not be adopted in the present study, given its retrospective nature. Still according to the SBP, CBO, and SBOP guidelines,[4] treatment (laser photocoagulation or intravitreal injection of anti-vascular endothelial growth factor [anti-VEGF]) was given to babies presenting with: zone I ROP at any stage with plus disease; zone I, stage 3 ROP; zone II, stage 2 or 3 ROP with plus.

Standard screening forms were designed to contain the following information:

- Maternal variables: maternal age, prenatal care, type of delivery, multiple pregnancy.
- Neonatal variables: gestational age at birth, birth weight, sex, gestational adequacy, 1st minute Apgar score, 5th minute Apgar score, resuscitation in the delivery room, respiratory distress syndrome, use of surfactant, use of oxygen, use of conventional ventilation, use of nasal continuous positive airway pressure (CPAP), sepsis, periventricular hemorrhage and its degree, anemia, blood transfusion, and apnea.
- Evolution variables: equivalent gestational age at consultation; retinal status at the time of evaluation (incomplete vascularization, ROP or vascularized); when ROP occurred, stage (1, 2, 3, 4a, 4b, 5), zone (1 to 3) and occurrence of plus (pre-plus, plus, no plus) at the time of evaluation; use of oxygen therapy; use of treatment and type of treatment (laser photocoagulation or intravitreal injection of anti-VEGF).
- The gestational age of the newborn was calculated by the date of the last menstrual period. Obstetric

ultrasound was used when the first method was not possible. The birth weight obtained in the delivery room was considered. Gestational adequacy was divided into appropriate for gestational age (AGA) (between the 10th and 90th percentiles), small for gestational age (SGA) (below the 10th percentile) and large for gestational age (LGA) (above the 90th percentile). The degree of periventricular hemorrhage was assessed using transfontanellar ultrasound. Retinal status, as well as the parameters for ROP (stage, zone and plus) were evaluated by fundoscopy performed by an ophthalmologist.

Data treatment

Based on the information registered at the standard screening forms, each neonate was assigned an outcome, which could be: spontaneous vascularization without ROP; spontaneous regression after ROP; post-ROP treatment regression; death; hospital transfer; incomplete outcome: said of those who did not undergo any examination during the follow-up period for reasons other than death or hospital transfer, had a recommendation to return, but did not attend follow-up anymore, nor did they previously present with vascularized retinal status, were not assigned a final retinal status due to a lack of sufficient information on the standard screening form.

Patients assigned with outcomes such as death, hospital transfer and incomplete outcome were excluded from the statistical analysis. Records that showed inconsistency between registered retinal statuses (e.g., a ROP retinal status followed by an incomplete vascularization retinal status in a subsequent visit), indicating possible form filling mistakes, were also excluded from the statistical analysis.

Since ROP is a progressive condition, some babies received different stage, zone and plus classifications over the entire follow-up period (e.g., a baby with ROP stage 1 in the first consultation could evolve with ROP stage 3 in the next consultation). Therefore, a record of the most severe diagnosis of ROP were kept for each ROP patient.

Statistical analysis

Variables were presented as mean and standard deviation, and as median, percentiles, frequency, and prevalence rate. In analyzing the characteristics of the participants, the Mann-Whitney U and Kruskall-Wallis tests were used, since the data did not adhere to the Gaussian distribution. To investigate the association between categorical variables, Pearson's chi-square test, and Fisher's exact test were used. A significance level of 5% was adopted. Statistical analyses were performed using the statistical program R and Microsoft Excel 2016.

RESULTS

In total, 421 standard forms of newborns screened for ROP at MEAC, born between August 2020 and November 2022, were analyzed. Of these, 255 were considered invalid and excluded from the statistical analysis, due to: outcome death (32 forms), outcome hospital transfer (119 forms), incomplete outcome (92 forms) or inconsistency between registered retinal statuses (12 forms).

Table 1 shows the results regarding maternal and neonatal variables, obtained from the 166 valid forms. The following variables were excluded from the analysis due to a lack of sufficient data: occurrence of periventricular hemorrhage (95% of valid forms not completed) and degree of periventricular hemorrhage (98% of valid forms not completed).

Table 2 shows the profile of ROP diagnoses among screened newborns, indicating the stage, zone, and plus classification obtained in the most severe ROP diagnosis during the monitoring period. The incidence of the disease was 40%. No newborn was diagnosed with ROP stage greater than 3. Stage 2 was the most common (70%), followed by stage 1 (23%) and stage 3 (7.6%). No neonate was diagnosed with zone 1 for ROP. Zone 2 was the most incident (94%), with few cases of zone 3 (6.2%). A small portion presented pre-plus (12%) or plus (7.1%). Note that the number of forms with any indication regarding stage (66 forms), zone (65 forms) and plus (42 forms) differed. The mean equivalent gestational age at the time of the most severe ROP diagnosis was 36.39 ± 2.53 weeks. Among those with ROP, 83% had spontaneous regression and 17% had regression after treatment. Among those treated for ROP, all underwent laser photocoagulation.

Table 3 presents the results from the correlation analysis between maternal and neonatal variables with ROP diagnosis and the stage, zone and plus of ROP in the most severe diagnosis. Maternal age ($p = 0.046$), birth weight ($p < 0.001$), gestational age at birth ($p < 0.001$), 1st minute Apgar score ($p = 0.004$), resuscitation in the delivery room ($p = 0.004$), use of surfactant ($p < 0.001$), use of conventional ventilation ($p < 0.001$), use of nasal CPAP ($p = 0.029$), sepsis ($p = 0.049$), anemia ($p = 0.027$), blood transfusion ($p = 0.028$) and apnea ($p = 0.008$) showed statistically significant associations with ROP diagnosis. Birth weight ($p = 0.004$) and gestational age at birth ($p = 0.010$) were associated with the ROP stage at the most

Table 1. Maternal and neonatal variables

Maternal variables	
Use of conventional ventilation	
No	56 (37)
Yes	94 (63)
Maternal age, years	29 ± 7 (30)
Prenatal care	
No	12 (7.5)
Yes	149 (92.5)
Type of delivery	
Cesarean section	125 (76)
Vaginal birth	40 (24)
Multiple pregnancy	
No	131 (79)
Yes	34 (21)
Neonatal variables	
Sex	
Female	88 (53)
Male	76 (46)
Indeterminate	1 (0.6)
Birth weight, g	1,255 ± 393 (1,223)
Gestational age at birth, weeks	29.73 ± 2.56 (30.14)
Gestational adequacy	
AGA	110 (71)
LGA	6 (3.9)
SGA	38 (25)
1st minute Apgar score	6.17 ± 2.28 (7.00)
5th minute Apgar score	8.02 ± 1.30 (8.00)
Resuscitation in the delivery room	
No	73 (45)
Yes	88 (55)
Respiratory distress syndrome	
No	3 (1.9)
Yes	158 (98)
Use of surfactant	
No	55 (37)
Yes	92 (63)
Use of oxygen	
No	4 (2.5)
Yes	156 (98)
Use of nasal CPAP	
No	43 (29)
Yes	106 (71)
Sepsis	
No	10 (31)
Yes	22 (69)
Anemia	
No	126 (88)
Yes	18 (13)
Blood transfusion	
No	128 (89)
Yes	16 (11)
Apnea	
No	122 (88)
Yes	17 (12)

There were 19 forms with maternal age not informed, 5 forms with prenatal care not informed, 1 form with type of delivery not informed, 1 form with multiple births not informed, 1 form with sex not informed, 12 forms with gestational adequacy not informed, 4 forms with 1st minute Apgar score not informed, 4 forms with 5th minute Apgar score not informed, 5 forms with resuscitation in the delivery room not informed, 5 forms with respiratory distress syndrome not informed, 19 forms with use of surfactant not informed, 6 forms with use of oxygen not informed, 16 forms with use of conventional ventilation not informed, 17 forms with use of nasal CPAP not informed, 134 forms with sepsis not informed, 22 forms with anemia not informed, 22 forms with blood transfusion not informed and 27 forms with apnea not informed.
Results expressed as mean ± standard deviation (median) or n (%).
AGA: appropriate for gestational age; LGA: large for gestational age; SGA: small for gestational age; CPAP: continuous positive airway pressure.

Table 2. Retinopathy of prematurity diagnosis

ROP diagnosis					
No			100 (60)		
Yes			66 (40)		
Treatment incidence among ROP cases			11 (17)		
Most severe ROP diagnosis during monitoring					
Stage 1	15 (23)	Zone 1	0	Pre-plus	5 (12)
Stage 2	46 (70)	Zone 2	61 (94)	Plus	3 (7.1)
Stage 3	5 (7.6)	Zone 3	4 (6.2)	No plus	34 (81)
Stage 4 (a,b)	0				
Stage 5	0				
Equivalent gestational age at the time of the most severe ROP diagnosis (weeks)			36.39 ± 2.53 (36.14)		
Outcome					
Spontaneous vascularization without ROP				100 (60)	
Spontaneous regression after ROP				55 (33)	
Post-ROP treatment regression				11 (6.6)	

One newborn was diagnosed with ROP but did not have a reported zone; 24 newborns were diagnosed with ROP but did not have a reported plus.
Results expressed as n (%) or mean ± standard deviation (median).
ROP: retinopathy of prematurity.

severe diagnosis. Birth weight (p = 0.034), gestational age at birth (p = 0.020), and apnea (p = 0.047) were associated with the ROP zone in the most severe diagnosis. Birth weight (p = 0.008) and use of nasal CPAP (p = 0.012) were associated with ROP plus classification in the most severe diagnosis.

Table 4 presents the results from the correlation analysis between the outcome and maternal and neonatal variables. Birth weight (p < 0.001), gestational age at birth (p < 0.001), 1st minute Apgar score (p = 0.004), resuscitation in the delivery room (p < 0.001), use of surfactant (p < 0.001), use conventional ventilation (p < 0.001), use of nasal CPAP (p = 0.003) and apnea (p = 0.026) were statistically significantly associated with the outcome.

DISCUSSION

Table 5 shows ROP epidemiological profiles previously reported.[7-31] Among the 25 studies analyzed, the average incidence of ROP was 30% with a standard deviation of 11%. Among the 21 studies that reported the percentage of babies with ROP who were recommended treatment, the average was 26% with a standard deviation of 16%. In comparison, the present study found an incidence of ROP of 40%, with an incidence of treatment of 17% among those affected. Both values coincide with the scientific literature average within a variation range of one standard deviation.

The slightly higher-than-average incidence of ROP observed may be attributed to the fact that the sample was drawn from a tertiary public maternity hospital, where most women are admitted due to high-risk pregnancies. It is reasonable to assume that neonates in this setting, unlike premature infants born of average-risk pregnancies, accumulate more risk factors, resulting in a higher incidence of ROP. Similarly, the slightly lower-than-expected

Table 3. Correlation between maternal and neonatal variables with retinopathy of prematurity diagnosis and with retinopathy of prematurity stage, zone, and plus in the most severe diagnosis

Maternal and neonatal variables	ROP diagnosis				ROP stage in the most severe diagnosis					ROP zone in the most severe diagnosis				ROP plus in the most severe diagnosis				
	n	No	Yes	p-value*	n	1	2	3	p-value*	n	2	3	p-value*	n	Plus	Pre-plus	No plus	p-value*
Maternal age, years	147	30 ± 7 (31)	28 ± 6 (28)	0.046	57	29 ± 8 (29)	28 ± 6 (28)	26 ± 5 (24)	0.618	56	28 ± 6 (28)	32 ± 9 (35)	0.202	36	27 ± 5 (24)	27 ± 6 (26)	27 ± 6 (28)	0.987
Prenatal care	161			0.544	64				0.190	63			> 0.999	40				> 0.999
No		6 (6.2)	6 (9.4)			0	5 (11)	1 (20)			5 (8.5)	0			0	0	4 (12)	
Yes		91 (94)	58 (91)			15 (100)	39 (89)	4 (80)			54 (92)	4 (100)			3 (100)	4 (100)	29 (88)	
Type of delivery	165			0.115	65				0.202	64			0.300	41				> 0.999
Cesarean section		80 (80)	45 (69)			8 (53)	34 (76)	3 (60)			40 (67)	4 (100)			2 (67)	3 (75)	24 (71)	
Vaginal birth		20 (20)	20 (31)			7 (47)	11 (24)	2 (40)			20 (33)	0			1 (33)	1 (25)	10 (29)	
Multiple pregnancy	165			0.346	65				0.874	64			0.539	41				0.119
No		23 (23)	11 (17)			3 (20)	7 (16)	1 (20)			10 (17)	1 (25)			2 (67)	0	5 (15)	
Yes		77 (77)	54 (83)			12 (80)	38 (84)	4 (80)			50 (83)	3 (75)						
Sex	164			0.895	66				0.717	65			0.341	42				0.864
Female		53 (54)	35 (53)			9 (60)	24 (52)	2 (40)			33 (54)	1 (25)			1 (33)	3 (60)	16 (47)	
Male		45 (45)	31 (47)			6 (40)	22 (48)	3 (60)			28 (46)	3 (75)			2 (67)	2 (40)	18 (53)	
Birth weight, g	166	1,405 ± 337 (1,388)	1,027 ± 363 (908)	< 0.001	66	1,287 ± 377 (1,160)	926 ± 301 (883)	1,181 ± 475 (1,140)	0.004	65	995 ± 346 (900)	1,349 ± 353 (1,260)	0.034	42	857 ± 246 (730)	587 ± 150 (560)	960 ± 275 (890)	0.008
Gestational age at birth, weeks	166	30.92 ± 2.01 (31.14)	27.94 ± 2.24 (27.71)	< 0.001	66	29.31 ± 1.58 (29.29)	27.62 ± 2.20 (27.14)	26.69 ± 2.79 (25.29)	0.010	65	27.81 ± 2.16 (27.57)	30.57 ± 1.60 (30.71)	0.020	42	26.29 ± 1.61 (25.43)	25.94 ± 1.53 (27.00)	27.55 ± 2.20 (27.07)	0.285
Gestational adequacy	154			0.951	59				0.115	58			> 0.999	37				0.406
AGA		67 (71)	43 (73)			11 (92)	28 (67)	4 (80)			41 (75)	2 (67)			3 (100)	2 (50)	22 (73)	
LGA		4 (4)	2 (3)			0	1 (2.4)	1 (20)			1 (2)	0			0	0	0	
SGA		24 (25)	14 (24)			1 (8.3)	13 (31)	0			13 (24)	1 (33)			0	2 (50)	8 (27)	
1st minute Apgar score	162	6.58 ± 2.15 (7.00)	5.55 ± 2.35 (6.00)	0.004	64	6.00 ± 2.29 (6.50)	5.58 ± 2.42 (6.00)	4.00 ± 1.41 (3.00)	0.183	63	5.51 ± 2.40 (6.00)	6.75 ± 0.96 (6.50)	0.400	41	4.00 ± 1.73 (3.00)	6.00 ± 1.00 (6.00)	5.27 ± 2.61 (6.00)	0.470
5th minute Apgar score	162	8.18 ± 1.11 (8.50)	7.77 ± 1.53 (8.00)	0.126	64	8.29 ± 0.73 (8.00)	7.67 ± 1.71 (8.00)	7.20 ± 1.30 (7.00)	0.325	63	7.76 ± 1.56 (8.00)	8.25 ± 0.96 (8.50)	0.666	41	7.67 ± 1.53 (8.00)	8.00 ± 1.00 (8.00)	7.33 ± 1.85 (8.00)	0.859
Resuscitation in the delivery room	161			0.004	64				0.102	63			0.090	41				0.806
No		53 (55)	20 (31)			7 (50)	13 (29)	0			17 (29)	3 (75)			0	1 (25)	9 (26)	
Yes		44 (45)	44 (69)			7 (50)	32 (71)	5 (100)			42 (71)	1 (25)			3 (100)	3 (75)	25 (74)	
Respiratory distress syndrome	161			0.277	64					63				41				-

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Continuation.

Maternal and neonatal variables	ROP diagnosis				ROP stage in the most severe diagnosis					ROP zone in the most severe diagnosis				ROP plus in the most severe diagnosis			
	n	No	Yes	p-value*	n	1	2	3	p-value*	n	2	3	p-value*	n	Plus	Pre-plus	No plus	p-value*
No		3 (3)	0			0	0	0			0	0			0	0	0	
Yes		94 (97)	64 (100)			14 (100)	45 (100)	5 (100)			59 (100)	4 (100)			3 (100)	4 (100)	34 (100)	-
Use of surfactant	147			< 0.001	60				0.738	59			> 0.999	38				0.733
No		45 (52)	10 (17)			3 (23)	7 (17)	0			10 (18)	0			0	1 (25)	5 (16)	
Yes		42 (48)	50 (83)			10 (77)	35 (83)	5 (100)			46 (82)	3 (100)			3 (100)	3 (75)	26 (84)	
Use of oxygen	160			> 0.999	63				> 0.999	62			> 0.999	39				> 0.999
No		3 (3)	1 (2)			0	1 (2)	0			1 (2)	0			0	0	1 (3)	
Yes		94 (97)	62 (98)			15 (100)	42 (98)	5 (100)			57 (98)	4 (100)			3 (100)	4 (100)	31 (97)	
Use of conventional ventilation	150			< 0.001	56				0.171	55			> 0.999	34				> 0.999
No		46 (49)	10 (18)			5 (36)	5 (13)	0			10 (19)	0			0	0	4 (14)	
Yes		48 (51)	46 (82)			9 (64)	34 (87)	3 (100)			42 (81)	3 (100)			2 (100)	3 (100)	25 (86)	
Use of nasal CPAP	149			0.029	56				0.365	55			> 0.999	36				0.012
No		21 (23)	22 (39)			6 (43)	13 (34)	3 (75)			21 (40)	1 (50)			3 (100)	2 (100)	11 (35)	
Yes		72 (77)	34 (61)			8 (57)	25 (66)	1 (25)			32 (60)	1 (50)			0	0	20 (65)	
Sepsis	32			0.049	19				> 0.999	19			> 0.999	12				> 0.999
No		7 (54)	3 (16)			0	3 (20)	0			3 (17)	0			0	0 (NA)	2 (18)	
Yes		6 (46)	16 (84)			3 (100)	12 (80)	1 (100)			15 (83)	1 (100)			1 (100)	0 (NA)	9 (82)	
Anemia	144			0.027	54				0.444	53			> 0.999	34				> 0.999
No		83 (92)	43 (80)			12 (92)	27 (75)	4 (80)			40 (78)	2 (100)			2 (67)	3 (75)	19 (70)	
Yes		7 (8)	11 (20)			1 (8)	9 (25)	1 (20)			11 (22)	0			1 (33)	1 (25)	8 (30)	
Blood transfusion	144			0.028	54				0.549	53			> 0.999	34				> 0.999
No		84 (93)	44 (81)			12 (92)	28 (78)	4 (80)			41 (80)	2 (100)			2 (67)	3 (75)	20 (74)	
Yes		6 (7)	10 (19)			1 (8)	8 (22)	1 (20)			10 (20)	0			1 (33)	1 (25)	7 (26)	
Apnea	139			0.008	50				0.761	49			0.047	31				> 0.999
No		83 (93)	39 (78)			9 (69)	26 (81)	4 (80)			38 (81)	0			2 (100)	3 (75)	19 (76)	
Yes		6 (7)	11 (22)			4 (31)	6 (19)	1 (20)			9 (19)	2 (100)			0	1 (25)	6 (24)	

The analysis did not consider indeterminate sex; no newborns were diagnosed with retinopathy of prematurity stage greater than 3 or retinopathy of prematurity zone 1

Results expressed as mean ± standard deviation (median) or n (%).

* Fisher's exact test; Mann-Whitney test; Chi-squared test of independence; Kruskal-Wallis test.

ROP: retinopathy of prematurity; AGA: appropriate for gestational age; LGA: large for gestational age; SGA: small for gestational age; CPAP: continuous positive airway pressure.

Table 4. Correlation between outcome and maternal and neonatal variables

Maternal and neonatal variables	n	Outcome			p-value*
		Spontaneous regression after ROP	Spontaneous vascularization without ROP	Post-ROP treatment regression	
Maternal age (years)	147	28 ± 7 (28)	30 ± 7 (31)	27 ± 6 (26)	0.119
Prenatal care	161				0.523
No		5 (9.3)	6 (6.2)	1 (10)	
Yes		49 (91)	91 (94)	9 (90)	
Type of delivery	165				0.078
Cesarean section		40 (73)	80 (80)	5 (50)	
Vaginal birth		15 (27)	20 (20)	5 (50)	
Multiple pregnancy	165				0.596
No		9 (16)	23 (23)	2 (20)	
Yes		46 (84)	77 (77)	8 (80)	
Sex	164				0.851
Female		30 (55)	53 (54)	5 (45)	
Male		25 (45)	45 (46)	6 (55)	
Birth weight, g	166	1,056 ± 345 (960)	1,405 ± 337 (1,388)	883 ± 430 (710)	< 0.001
Gestational age at birth, weeks	166	28.31 ± 2.10 (28.00)	30.92 ± 2.01 (31.14)	26.05 ± 2.03 (25.29)	< 0.001
Gestational adequacy	154				0.566
AGA		35 (71)	67 (71)	8 (80)	
LGA		1 (2.0)	4 (4.2)	1 (10)	
SGA		13 (27)	24 (25)	1 (10)	
1st minute Apgar score	162	5.75 ± 2.34 (6.00)	6.58 ± 2.15 (7.00)	4.55 ± 2.21 (4.00)	0.004
5th minute Apgar score	162	7.87 ± 1.52 (8.00)	8.18 ± 1.11 (8.50)	7.27 ± 1.56 (8.00)	0.111
Resuscitation in the delivery room	161				< 0.001
No		20 (36)	53 (55)	0 (0)	
Yes		34 (63)	44 (45)	10 (100)	
Respiratory distress syndrome	161				0.632
No		0 (0)	3 (3.1)	0 (0)	
Yes		54 (100)	94 (97)	10 (100)	
Use of surfactant	147				< 0.001
No		10 (20)	45 (52)	0 (0)	
Yes		40 (80)	42 (48)	10 (100)	
Use of oxygen	160				> 0.999
No		1 (1.9)	3 (3.1)	0 (0)	
Yes		52 (98)	94 (97)	10 (100)	
Use of conventional ventilation	150				< 0.001
No		10 (21)	46 (49)	0 (0)	
Yes		38 (79)	48 (51)	8 (100)	
Use of nasal CPAP	149				0.003
No		15 (32)	21 (23)	7 (78)	
Yes		32 (68)	72 (77)	2 (22)	
Sepsis	32				0.082
No		3 (18)	7 (54)	0 (0)	
Yes		14 (82)	6 (46)	2 (100)	
Anemia	144				0.071
No		35 (80)	83 (92)	8 (80)	
Yes		9 (20)	7 (7.8)	2 (20)	
Blood transfusion	144				0.066
No		36 (82)	84 (93)	8 (80)	
Yes		8 (18)	6 (6.7)	2 (20)	
Apnea	139				0.026
No		32 (78)	83 (93)	7 (78)	
Yes		9 (22)	6 (6.7)	2 (22)	

The analysis did not consider indeterminate sex.
Results expressed as mean ± standard deviation (median) or n (%).
* Fisher's exact test; Kruskal-Wallis test; Chi-squared test of independence.
ROP: retinopathy of prematurity; AGA: appropriate for gestational age; LGA: large for gestational age; SGA: small for gestational age; CPAP: continuous positive airway pressure.

incidence of ROP treatment could also be explained by sample selection: in a specialized hospital for high-risk pregnancies, the premature death of infants with multiple risk factors is likely more common, preventing them from reaching the stage where more severe cases of ROP would be diagnosed and recommended for treatment. In fact, 32 babies were excluded from the analysis due to death, 22 of whom were never stable enough to undergo ophthalmologic evaluation.

Table 6 shows ROP stage profiles previously reported.[7-10,13,15-19,25] Among the 11 studies analyzed, each stage average incidence and standard deviation was: 37

Table 5. Retinopathy of prematurity epidemiological profiles previously reported

Authors	Country	Sample n	GA* (weeks)	BW* (g)	Sex		ROP cases n (%)*	Treatment performed or recommended n (%)†
					Female n (%)*	Male n (%)*		
de Las Rivas Ramírez et al.[7]	Spain	452	29.38 ± 2.53	1,187.1 ± 322.27	224 (49.6)	228 (50.4)	202 (44.7)	66 (32.7)
Al-Qahtani et al.[8]	Saudi Arabia	593 (only 581 were screened for ROP)	28.8 ± 2.8‡	1118 ± 276.6‡	321 (54.1)	272 (45.9)	224 (38.6)	15 (6.7)
Port et al.[9]	United States	1,354	-	-	657 (48.5)	697 (51.5)	526 (38.8)	80 (15.2)
Carranza-Mendizabal et al.[10]	Peru	216	> 32 weeks in 59.7 of the infants	> 1,500 in 6 of the infants	94 (43.5)	122 (56.5)	72 (33.3)	-
Almeida et al.[11]	Portugal	475	30 (range: 23-36)	1229 (range: 408 - 2,620)	221 (46.5)	254 (53.5)	113 (23.8)	29 (25.7)
Ndyabawe et al.[12]	Uganda	331	30.4 ± 2.7	1,597 ± 509	173 (52.3)	158 (47.7)	19 (5.7)	13 (68.4)
Kumar et al.[13]	India	340	-	-	-	185 (54.4)	63 (18.5)	8 (12.7)
Yucel et al.[14]	Turkey	2,186	31 (range: 22-38)	1500 (range: 540-3450)	1,075(49.2)	1,111 (50.8)	952 (43.5)	175 (18.4)
Abbas et al.[15]	Iraq	134	30.4 ± 2.5	1532.3 ± 507.7	58 (43.3)	76 (56.7)	45 (33.6)	15 (33.3)
Prasad et al.[16]	India	410	-	-	175 (42.7)	235 (57.3)	110 (26.8)	-
Acevedo-Castellón et al.[17]	Mexico	132	32w3d ± 3d	1,594 ± 96	-	-	74 (56)	38 (51)
Hwang et al.[18]	South Korea	2,009	26.5 ± 2.2	913 ± 252	-	-	686 (34.1)	231 (33.7)
Albalawi et al.[19]	Saudi Arabia	108	≤ 32 weeks in 91.7 of the infants	1,000-1,500g in 72.2 of the infants	47 (43.5)	62 (56.5)	36 (33.3)	3 (8.3)
Bas et al.[21]	Turkey	6,115	28.9 ± 6.3	1,457 ± 479	3,163 (51.7)	2,952 (48.3)	1,695 (27)	414 (24.4)
Alizadeh et al.[20]	Iran	716	31.4 ± 2.8	1629 ± 502	-	-	164 (22.9)	22 (13.4)
Bhatnagar et al.[22]	United States	1 881 098	-	-	884 979 (47.0)	995 012 (52.9)	125 212 (6.7)	-
Caruggi et al.[23]	Italy	475	30.4 (range: 22.1 - 33.8)	1,300 (range: 410-2840)	236 (49.7)	239 (50.3)	119 (25)	28 (23.5)
Chow et al.[24]	Hong Kong / China	754	29w 6d ± 2w 3d	1,250 ± 330	362 (48)	392 (52)	234 (31.0)	-
Isaacs et al.[25]	Australia	8,823 (post- 2,015)	28w 4d ± 16d	1144.6 ± 335.30	4114 (46.6)	4709 (53.4)	2926 (33.2)	346 (11.8)
Khan et al.[26]	United States	31 606	-	-	-	-	8,384 (26.5)	489 (5.8)
Li et al.[27]	China	4,069	32.3 ± 2.6	1751.9 ± 509.4	-	2163 (53.2)	728 (17.9)	78 (10.7)
Modrzejewska et al.[28]	Poland	7,401 (period: nov 2020 - nov 2021)	-	-	-	-	1,500 (20)	329 (22)
Tekchandani et al.[29]	India	2,595	31.3 ± 2.8	1,451 ± 405	-	-	839 (32.3)	329 (39.21)
Vasavada et al.[30]	India	280	30.6 ± 1.97	1,639 ± 414	65 (23.2)	215 (76.8)	54 (19.3)	26 (48.1)
Noor et al.[31]	Egypt	159	31.87 ± 1.81	1,784.71 ± 560.30	71 (44.7)	88 (55.3)	41 (25.8)	10 (24.4)

Variables presented as mean ± standard deviation or n (%).
* Percentage relative to the sample; †percentage relative to total ROP cases; ‡ value relative to the total sample (593) and not the sample screened for ROP (581); the data presented are from other studies.[7-31]
ROP: retinopathy of prematurity; GA: gestational age at birth; BW: birth weight.

Table 6. Retinopathy of prematurity classification profiles previously reported

Authors	Country	ROP cases n	Stage						Zone			Plus		
			1	2	3	4a	4b	5	1	2	3	Pre-plus	Plus	No plus
de Las Rivas Ramírez et al.[7]	Spain	202	45 (22.3)	120 (59.4)	33 (16.3)	4 (2)		0	24 (11.9)	169 (83.7)	9 (4.5)			
Al-Qahtani et al.[8]	Saudi Arabia	224 (only 212 were staged)	125/212 (59.0)	65/212(30.7)	22 /212 (10.4)	0	0	0						
Port et al.[9]	United States	526	209 (39.7)	174 (33.1)	140 (26.6)	3 (0.6)		0						
Carranza-Mendizabal et al.[10]	Peru	72	32 (44.4)	23 (32.9)	17 (23.6)	0	0	0	0	11 (15.3)	61 (84.7)			
Kumar et al.[13]	India	63	19 (30.2)	40 (63.5)	4 (6.3)	0	0	0	3 (4.5)	32 (50.8)	28 (44.4)			
Yucel et al.[14]	Turkey	952										-	150 (15.8)	802 (84.2)
Abbas et al.[15]	Iraq	45	6 (13.3)	28 (62.2)	8 (17.2)	0	0	3 (6.7)	9 (20.0)	22 (48.9)	14 (31.1)	-	5 (3.7)	129 (96.3)
Prasad et al.[16]	India	110	37 (33.6)	18 (16.4)	50 (45.5)	4 (3.6)		1 (0.9)						
Acevedo-Castellón et al.[17]	Mexico	74	19 (26)	31 (42)	22 (30)	1 (1)	1 (1)	0	7 (9.5)	60 (81)	7 (9.5)			
Hwang et al.[18]	South Korea	686	235 (34,3)	218 (31.8)	229 (33.4)	4 (0.5)		0						
Albalawi et al.[19]	Saudi Arabia	36	24 (66.7)	10 (27.8)	2 (5.6)	0	0	0)	1 (2.7)	10 (27.8)	25 (69.4)	-	1 (2.7)	35 (97.2)
Isaacs et al.[25]	Australia	2926	1204 (41.1)	1139 (38.9)	569 (19.4)	14(0.5)		0						
Tekchandani et al.[29]	India	1,678 eyes (only 1,416 eyes were classified according to the zone)							102 eyes (7.2)	1304 eyes (92.1)	10 eyes (0.7)			
Noor et al.[31]	Egypt	41										9 (22.0)	11 (26.8)	21 (51.2)

The data presented are from other studies.[7-10,13-19,25,29,31]
Results expressed as n (%).

± 16% for stage 1, 40 ± 15% for stage 2, 21 ± 12% for stage 3, 1 ± 1 % for stage 4 and 1 ± 2% for stage 5. In comparison, in the present study, stage 2 corresponded to 70% of ROP cases, an incidence considerably higher than the reported average.

Table 6 also displays ROP zone profiles previously reported.[7,10,13,15,17,19,29] Among the 7 studies analyzed, each zone average incidence and standard deviation was: 8 ± 7% for zone 1, 58 ± 32% for zone 2 and 35 ± 33% for zone 3. In comparison, in the present study, zone 2 corresponded to 94% of ROP cases assessed for zone, an incidence higher than the reported average. This result may be explained by sample selection: in a tertiary public maternity hospital specializing in high-risk pregnancies, babies with multiple risk factors are likely to be in such critical condition that they either die before developing zone I ROP or experience significant delays in ophthalmologic evaluation. In the latter, by the time they become stable enough for examination, the disease may have already advanced from zone I to zone II, resulting in a lower number of zone I cases being registered.

Table 6 also shows ROP plus previously reported profiles.[14,15,19,31] Among the 4 studies analyzed, plus was absent in 82% of ROP cases with a standard deviation of 22%. In comparison, in the present study, plus was absent in 81% of the ROP cases assessed for plus, a percentage compatible with the reported average. Only one study considered pre-plus category, reporting an incidence of 22% (Table 6). In comparison, the present study showed a lower incidence of pre-plus, corresponding to 12% of ROP cases assessed for plus.

Unlike other selected articles,[7,8] maternal age has been identified as a factor associated with ROP. However, the difference between the average age found in mothers of newborns with ROP (28 ± 6 years) was only slightly lower than that of mothers of newborns without ROP (30 ± 7 years).

The association observed between lower birth weight and ROP diagnosis is widely confirmed by other studies.[7-15,31] Likewise, the correlation found between a lower gestational age at birth and ROP diagnosis is also well described in the scientific literature.[7-15,31].

The relationship between lower 1st minute Apgar score and ROP development is confirmed by data reported by other authors.[7,8] Regarding the positive relationship between resuscitation in the delivery room and ROP, there is also a report corroborating these findings.[7]

Regarding the positive association between use of surfactant and ROP, contrary to the present study, a higher incidence of surfactant use among those without ROP (27%) when compared to those with ROP (14.1%), with a statistical difference (p = 0.01) between groups, has been reported.[13] Furthermore, the present study found that the use of conventional ventilation was positively associated with ROP diagnosis, while the use of nasal CPAP was negatively associated. Such apparent contradictions could be explained by the dual role of oxygenation in the disease pathophysiology. While post-partum hyperoxia is the main driver of the vaso-obliterative phase of the disease, hypoxia directs the subsequent vaso-proliferative phase.[1] Hence, theoretically, the phase of the disease in which surfactant use or supplemental oxygenation is initiated, as well as its duration and, in the case of oxygen supplementation, its intensity, should affect the outcome regarding ROP. In fact, although oxygen supplementation has been largely considered a risk factor for ROP,[9,10,31] a recent review[2] gathered findings that suggest that lower oxygen saturation ranges during the vaso-obliterative phase, followed by more liberal oxygen saturations (96%) in the vaso-proliferative phase of ROP pathogenesis, could be a strategy that may reduce the severity of the disease.

Regarding the higher incidence of sepsis among newborns with ROP (Table 3), similar results were previously reported.[9-11,13,14,16] The positive association between anemia, apnea, and blood transfusion to a ROP diagnosis (Table 3) is also corroborated by other authors.[7,10,12,31]

The association between lower birth weight and lower gestational age at birth with a worse ROP zone is expected, since both gestational age at birth less than 30 weeks and birth weight less than 1250 g have been identified as independent risk factors for severe ROP.[13] The association between more advanced ROP stages with lower gestational ages is also consistent with another report.[13] However, although birth weight was correlated with ROP stage and ROP plus, the direction of these associations was unexpected, with a lower average birth weight found across intermediate stages and plus classification, respectively stage 2 and pre-plus.

A correlation between apnea and ROP zone was observed, with a higher incidence of apnea across the less severe ROP zones. However, other investigations have demonstrated a higher incidence of apnea (53% *versus* 36%) among those with ROP progression when compared to those without ROP progression (p = 0.021).[7]

Furthermore, the use of nasal CPAP was associated with the plus classification, with a higher incidence among the non-plus babies. This result reinforces the negative association between the use of nasal CPAP and ROP diagnosis.

Regarding Table 4, the association between lower birth weight and progressively worse outcomes, namely

ROP development and a need for treatment, is confirmed by other research. A study found that newborns with ROP requiring treatment were born with statistically lower weights than those who did not require treatment (1,707 ± 597 *versus* 1,316 ± 346 g; p < 0.0001).[17] Similar results were reported elsewhere.[9,18]

Regarding the correlation between a lower gestational age at birth and a progressively worse outcome, higher gestational ages among newborns who did not require treatment have already been reported (33w 2d ± 3w *versus* 30w 4d ± 2w 3d; p = 0.0002).[17] Accordingly, an association between lower gestational age at birth and ROP progression or severity has already been reported.[7,13] Gestational age at birth has also been identified as an independent risk factor for treatment-requiring ROP.[9]

Regarding the association between lower 1st minute Apgar score and a worse outcome, statistically lower 1st minute Apgar scores (p = 0.05) have been reported when comparing babies with ROP stage ≥ 3 (3.6 ± 1.7) and babies with ROP stage ≤ 2 (4.2 ± 1.9), as well as when comparing the latter to babies without ROP (5.1 ± 1.9).[18]

Regarding resuscitation in the delivery room, use of surfactant, use of conventional ventilation and apnea, all of them presented higher incidences associated with worse outcomes. However, an association was also observed between higher incidences of nasal CPAP use and a progressively better outcome. These findings might also be explained by the different roles that oxygenation plays during the vaso-obliterative and vaso-proliferative phases of ROP progression. Similarly, another study reported statistically higher incidences of cardiopulmonary resuscitation (64.7% *versus* 81.8%), use of surfactant (54.4% *versus* 78.8%), mechanical ventilation (52.9% *versus* 80.3%) and apnea (36% *versus* 53%) among infants with ROP progression when compared to those without progression (p < 0.05), while no significant association was found between CPAP use and ROP progression [7].

CONCLUSION

In general, the epidemiological profile found for retinopathy of prematurity and its associated factors in a maternity hospital in northeastern Brazil was compatible with the results found in the literature for several other locations around the world.

AUTHORS' CONTRIBUTION

Clara de Amorim de Carvalho: conceptualization, data curation, methodology, formal analysis; Mila Almeida Vasconcelos: conceptualization, data curation, methodology, formal analysis; Daniel Pessoa Ferreia Marinho: conceptualization, data curation, methodology, formal analysis; Erick Sampaio Andrade: conceptualization, data curation, methodology; Daniel Ribeiro Alves: conceptualization, data curation, methodology; Adriana Araujo Oliveira: data curation, methodology, formal analysis; Francisco Xavier de Aquino Junior: conceptualization, data curation, methodology; Igor Carvalho Brasil: data curation; Antonio Levi Alves Silva: data curation; Natália Ponte Nogueira Marques: conceptualization, data curation, methodology, formal analysis, supervision, project administration.

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