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Prevalence, risk factors and severity of retinopathy of prematurity in preterm infants in a tertiary care hospital in rural Karnataka

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ABSTRACT

Introduction: Retinopathy of prematurity (ROP) is a condition which is one of the major causes of preventable childhood blindness. ROP may develop in premature new-borns due to avascular or incompletely vascularized retina at birth which are prone to damage. The purpose of this study is to investigate the prevalence of retinopathy of prematurity (ROP), as well as its risk factors and severity, among newborns who were admitted to and screened at a tertiary care facility that serves a rural community.
Materials and Methods: A cross-sectional study was conducted for a period of 1 year. All infants born prematurely who were admitted to the hospital and had a birth weight of less than or equal to 1500 g and/or less than 32 weeks of gestation were included in the study. Additionally, babies born between 1501-2500 grams and/or 33-35 weeks who were at a higher risk were also included. Under aseptic conditions all preterms were screened with RetCam in NICU of a tertiary hospital situated in rural area in Karnataka.
Results: 224 preterm babies were screened for ROP. No ROP was noted in 185 babies (82.59%), 9 babies had stage 1 (4.02%), 21 babies stage 2 (9.38%), 9 babies had stage 3 ROP (4.02). No infant developed stage 4 and stage 5 ROP. Prevalence of ROP is 17.41% in our study. Low birth weight (LBW), Very low birth weight (VLBW), Respiratory Distress Syndrome and sepsis are found to be clinically significant in this study.
Conclusion: In this study, the prevalence of ROP is 17.41%. LBW, VLBW, Respiratory Distress Syndrome and sepsis are found to significant risk factors. Early screening and timely appropriate treatment of ROP can prevent from causing childhood blindness.

1. Introduction

Across the globe, childhood blindness is a major health concern. Estimates of childhood blindness globally is around 1.42 million. Children suffering from moderate to severe visual impairment is 17.52 million.[1] ROP is an abbreviation for retinopathy of prematurity, which is a vaso-proliferative disease that damages the developing retina of premature infants who were born with a low birth weight.[2] The incidence of ROP in India ranges from 38 to 47%.[3] ROP may develop in premature new-borns during the course of four to five weeks following delivery and is marked by an avascular or incompletely vascularized retina at birth.[2] The course and presentation of ROP are determined by multiple risk factors which are interlinked with the pathogenesis of the development of the different stages of ROP.[4]

Prematurely born infants are the ones who are at risk of developing ROP. Other factors like, low birth weight (LBW), problems with oxygenation, Respiratory distress syndrome (RDS), multiple blood transfusions, Neonatal hyperbiluribinemia (NNHB), sepsis, multiple gestation and maternal factors like maternal anemia, pregnancy induced hypertension (PIH), gestational diabetes mellitus (GDM) have also been implicated in the causation of ROP.[5]

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It is imperative that improved care for mothers and newborns, screening recommendations for ROP that are suitable for countries with middle-income levels, and broad prompt treatment be implemented immediately in order to contain this pandemic.[6] The purpose of this study is to determine the prevalence of retinopathy of prematurity (ROP), as well as its risk factors and severity, among newborns who are going to be hospitalised and screened in a tertiary care institute that serves a rural population.

2. Materials and Methods

2.1. Study design

After obtaining institutional ethical clearance for start of study, a Cross-sectional observational study was conducted for a period of one year between June 2021 to May 2022 at R L Jalappa Hospital and Research Hospital attached to Sri Devaraj Urs Medical College, located in Tamaka, Kolar, a rural part of Karnataka. Sample size was estimated based on study by Dwivedi A et al., using open epi software version 3, with 6% error and 95% confidence interval.[7]

All preterm infants admitted to the hospital with a birth weight of less than 1500 g and/or less than 32 weeks of gestation were included in the study after informed consent was obtained. Babies with birth weights between 1500 and 2500 g and/or 33 to 35 weeks of gestation who were at a higher risk of developing ROP due to factors such as respiratory distress syndrome, sepsis, multiple blood transfusions, or multiple births were also included.

Babies born prematurely who were admitted to the NICU for critical illness and were already receiving treatment for ROP in another facility were not included in the study.

At either 32 weeks of gestation or 4 weeks of age, whichever came first, a first screening examination was performed. For this reason, the gestational age was determined using the date of the woman's most recent menstrual period, or with the assistance of first-trimester sonography in cases where the date of the woman's most recent menstrual period was unknown. In the case of neonates born exceedingly prematurely, the babies are often checked at an earlier age than usual.

The patient's demographic history as well as risk factors such as respiratory distress syndrome, multiple blood transfusions, sepsis, multiple deliveries, apneic episodes, and hyperoxygenation were taken into account.

The anterior segment of the eye was examined, and then the pupils were dilated using a mixture of phenylephrine 2.5% and tropicamide 0.5%. This solution was instilled topically into the eye three times, with a 10-minute break in between each instillation, approximately an hour before the scheduled inspection. As a precaution, any surplus eye drops were removed with sterile cotton, and the mother was warned not to feed the baby right before the examination for fear that the infant would throw up or aspirate any liquid that was consumed. An ophthalmologist utilising RetCam carried out the assessment in the NICU while taking all appropriate hygienic procedures. The RetCam procedure was carried out with extreme caution in order to avoid exerting an excessive amount of force on the globe. If the initial examination did not reveal any signs of ROP, the children were re-examined once every two weeks up until the point where vascularization was fully developed. If ROP was found, retinal examinations were carried out on a weekly basis for stage 1 and stage 2 of the disease, and on a more frequent basis for stage 3 of the disease, and this continued until the condition began to resolve itself or reached the threshold stage. Pre-plus, plus disease was not considered ROP group. Comparison is done based on stages of ROP. Babies who were making progress toward the threshold stage were given the necessary treatment, and those who appeared to be regressing were monitored until the vascularization process was finished. As the ophthalmologist had recommended, the newly discharged infants were contacted for a follow-up appointment.

Birth weight of preterm babies are classified as LBW - Low birth weight (<2500g), VLBW-Very low birth weight (<1500g) and ELBW- extremely low birth weight (<1000g).

Staging of ROP based on ICROP (International classification of retinopathy of prematurity).[8]

1. Stage 1: Demarcation Line
2. Stage 2: Ridge
3. Stage 3: Extraretinal Fibrovascular Proliferation
4. Stage 4: Partial Retinal Detachment
5. Stage 5: Total Retinal Detachment.

2.2. Statistical analysis

Descriptive analysis was depicted by mean and standard deviation for quantitative variables. Frequency and proportion for categorical variables was used.

For normally distributed quantitative parameters the mean values were compared between study groups using independent sample t- test (2 groups) / ANOVA test (> 2 groups). By using Cross tabulation and comparing the percentages, the association between explanatory variables and categorical outcomes was assessed. Statistical significance was tested by using Chi-square test. Univariate Binary logistic regression analysis was performed to test the association between the explanatory variables and outcome variables. With 95% Confidence interval, unadjusted Odds ratio is presented. Variables with statistical significance in univariate analysis were used to compute multivariate regression analysis. Adjusted odds ratio along with their 95% CI is presented.

P value < 0.05 was considered statistically significant. Data was analysed by using coGuide software, V.1.01(BDSS Corp. Released 2020. coGuide Statistics software, Version 1.0, India: BDSS corp).

Fig. 1: ROP screening

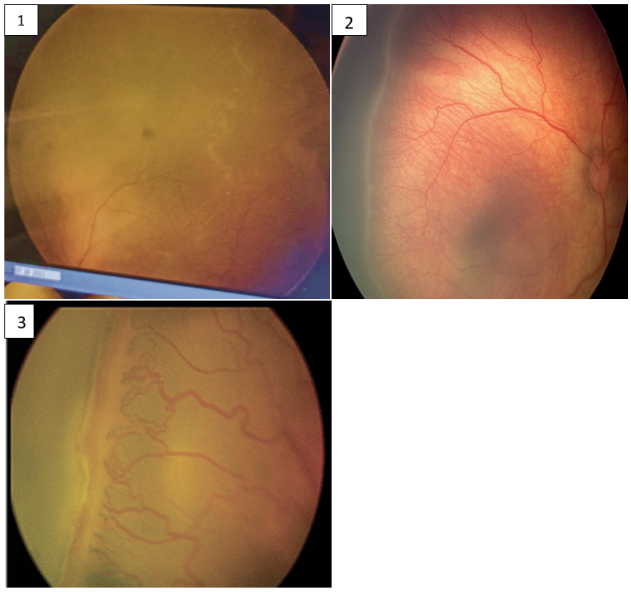


Fig. 2: Showing 1. Stage 1 ROP, 2. Stage 2 ROP, Stage 3 ROP

3. Result

In the end, there were a total of 224 participants included in the analysis.

Table 1: Descriptive analysis of parameters in the study population

Parameter	Frequency (n=224)	Percentage %
Birth weight (kg)	1.59 ± 0.36 (ranged 0.88, 3.20)	
Gestational age(weeks)	32.44 ± 2.00	
Gender		
Male	116	51.79
Female	108	48.21
LBW	131	58.48
VLBW	82	36.61
ELBW	4	1.79
RDS	147	65.63
Sepsis	83	37.05
NNHB	36	16.07
CHD	14	6.25
Blood transfusion	36	16.07
TWIN	47	20.98
Maternal anaemia	112	50
PIH	60	26.79
GDM	11	4.91
Hypothyroid	10	4.46
Diagnosed ROP		
Stage 1	9	4.02
Stage 2	21	9.38
Stage 3	9	4.02
No ROP	185	82.59

The mean birth weight was 1.59 ± 0.36, ranged between 0.88 to 3.20 in the study population. The mean gestational age was 32.44 ± 2, ranged between 24 to 41 in the study population. The majority of babies (51.79%) were male. Among the study population 65.63% babies had respiratory distress syndrome (RDS), 58.48% LBW, 50% maternal anaemia, 37.05% sepsis and 36.61% had VLBW. Only 39 (17.41%) babies were diagnosed with ROP. (Table 1)

For each unit increase in birth weight, the odds of occurrence of ROP were 0.17 times (0.05 to 0.57). There was a statistically significant link between the two factors (P value less than 0.05).

For each unit increase in gestational age, the odds of occurrence of ROP were 0.65 times (0.53 to 0.79). There was a statistically significant link between the two factors (P value less than 0.05).

Compared to no LBW, the odds of occurrence of ROP were 0.3 times (0.14 to 0.62). There was a statistically significant link between the two factors (P value less than 0.05).

Compared to no VLBW, the odds of occurrence of ROP were 2.88 times (1.41 to 5.89) and There was a statistically

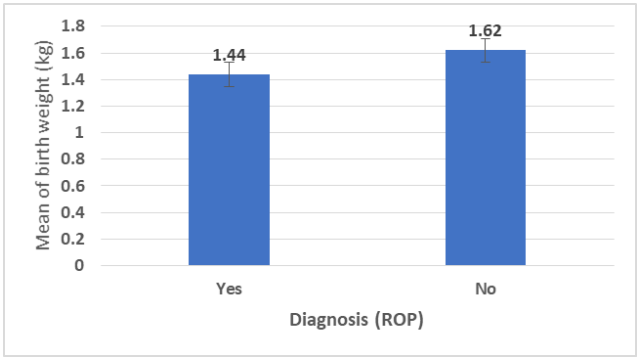
Table 2: Comparison of diagnosis (ROP) with parameters in the study population (N=224)

Parameter	Diagnosis (ROP)		Odds ratio (95% CI)	P Value
	Yes	No		
Birth weight (kg)	1.44 ± 0.39	1.62 ± 0.35	0.17 (0.05-0.57)	0.004
Gestational age (weeks)	31.05 ± 2.51	32.72 ± 1.76	0.65 (0.53-0.79)	<0.001
Gender				
Male (N = 116)	18 (15.52%)	98 (84.48%)	0.808(0.40-1.62)	0.550
Female (N = 108)	20 (18.52%)	88 (81.48%)	Baseline	
LBW				
Yes (N = 131)	13 (9.92%)	118 (90.08%)	0.3 (0.14-0.62)	0.001
No (N = 93)	25 (26.88%)	68 (73.12%)	Baseline	
VLBW				
Yes (N = 82)	22 (26.83%)	60 (73.17%)	2.88 (1.41-5.89)	0.004
No (N = 142)	16 (11.27%)	126 (88.73%)	Baseline	
ELBW				
Yes (N = 4)	2 (50.00%)	2 (50.00%)	5.11 (0.69-37.47)	0.108
No (N = 220)	36 (16.36%)	184 (83.64%)	Baseline	
RDS				
Yes (N = 147)	34 (23.13%)	113 (76.87%)	5.49 (1.87-16.12)	0.002
No (N = 77)	4 (5.19%)	73 (94.81%)	Baseline	
Sepsis				
Yes (N = 83)	23 (27.71%)	60 (72.29%)	3.22 (1.56-6.61)	0.001
No (N = 141)	15 (10.64%)	126 (89.36%)	Baseline	
NNHB				
Yes (N = 36)	7 (19.44%)	29 (80.56%)	1.22 (0.49-3.04)	0.666
No (N = 188)	31 (16.49%)	157 (83.51%)	Baseline	
CHD				
Yes (N = 14)	3 (21.43%)	11 (78.57%)	1.36 (0.36-5.14)	0.647
No (N = 210)	35 (16.67%)	175 (83.33%)	Baseline	
Blood transfusion				
Yes (N = 36)	10 (27.78%)	26 (72.22%)	2.19 (0.95-5.05)	0.064
No (N = 188)	28 (14.89%)	160 (85.11%)	Baseline	
TWIN				
Yes (N = 47)	11 (23.40%)	36 (76.60%)	1.69 (0.77-3.74)	0.189
No (N = 177)	27 (15.25%)	150 (84.75%)	Baseline	
Maternal anaemia				
Yes (N = 112)	21 (18.75%)	91 (81.25%)	1.29 (0.64-2.6)	0.477
No (N = 112)	17 (15.18%)	95 (84.82%)	Baseline	
PIH				
Yes (N = 60)	11 (18.33%)	49 (81.67%)	1.13 (0.52-2.46)	0.741
No (N = 164)	27 (16.46%)	137 (83.54%)	Baseline	
GDM				
Yes (N = 11)	3 (27.27%)	8 (72.73%)	1.91 (0.48-7.54)	0.358
No (N = 213)	35 (16.43%)	178 (83.57%)	Baseline	
Hypothyroid				
Yes (N = 10)	3 (30.00%)	7 (70.00%)	2.19 (0.54-8.89)	0.272
No (N = 214)	35 (16.36%)	179 (83.64%)	Baseline	

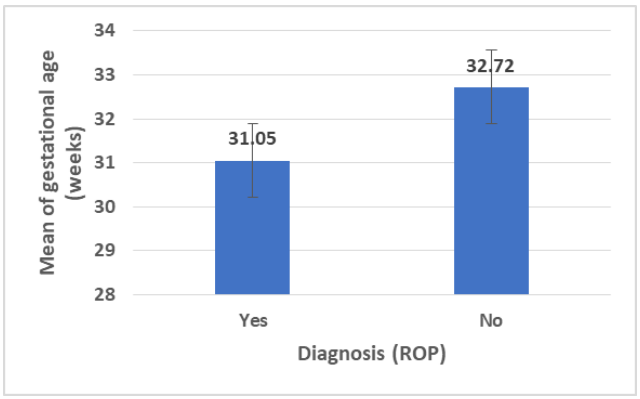
significant link between the two factors (P value less than 0.05).

Compared to no RDS, the odds of occurrence of ROP were 5.49 times (1.87 to 16.12) and There was a statistically significant link between the two factors (P value less than 0.05).

Compared to no Sepsis, the odds of occurrence of ROP were 3.22 times (1.56 to 6.61) and There was a statistically significant link between the two factors (P value less than 0.05). (Table 2)



Graph 1: Error bar chart of comparison of Birth weight (kg) between diagnosis (ROP) in the study population (N=224)



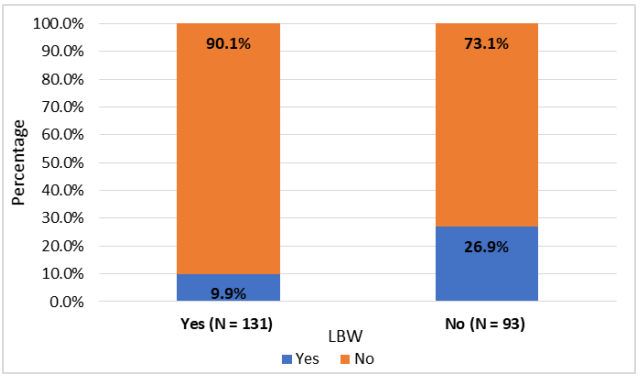
Graph 2: Error bar chart of comparison of Gestational age (weeks) between diagnosis (ROP) in the study population (N=224)

The mean difference of birth weight (kg) and gestational age (weeks) across the diagnosis was found statistically significant (P value < 0.05). (Table 4)

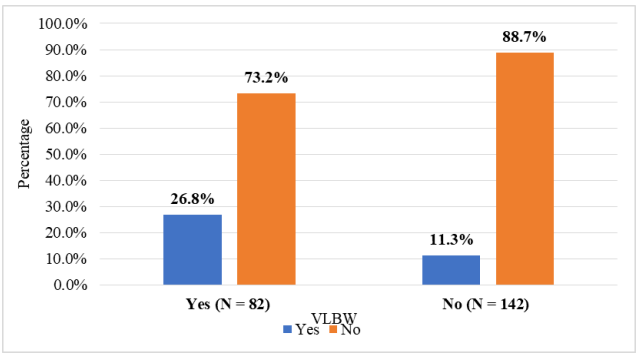
Parameters LBW, VLBW, RDS, and Sepsis are statistically significant with development of ROP but there was no correlation with stages of ROP.

ELBW though found statistically insignificant 25% had stage 2 and 25% had stage 3 ROP.

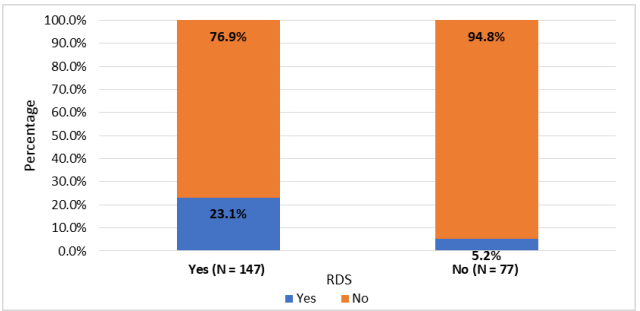
NNHB is more associated with stage 2 and stage 3. No cases in stage 1 had NNHB.



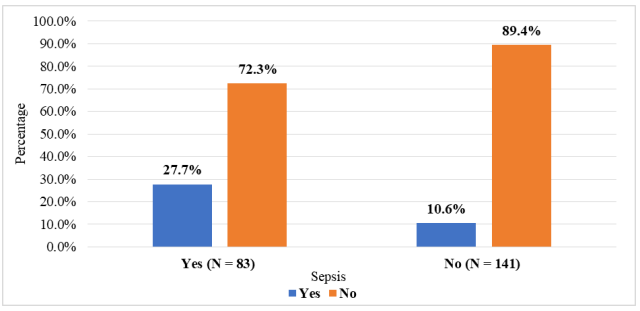
Graph 3: Stacked bar chart of comparison of LBW between diagnosis (ROP) in the study population (N=224)



Graph 4: Cluster bar chart of comparison of VLBW between diagnosis (ROP) in the study population (N=224)



Graph 5: Stacked bar chart of comparison of RDS between diagnosis (ROP) in the study population (N=224)



Graph 6: Cluster bar chart of comparison of Sepsis between diagnosis (ROP) in the study population (N=224)

Table 3: Comparison of diagnosis (ROP) with parameters in the study population (n=224)

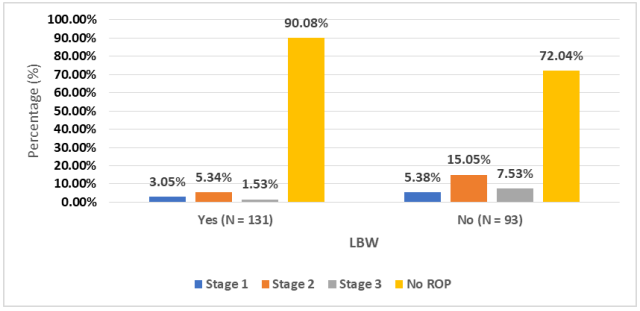
Parameter	Adjusted odds ratio	95% CI (Lower-Upper)	P Value
Birth weight (kg)	0.449	(0.122 - 1.655)	0.229
Gestational age (weeks)	0.692	(0.561 - 0.854)	0.001
LBW	0.359	(0.079 – 1.624)	0.183
VLBW	1.258	(0.284 – 5.58)	0.762
RDS	5.129	(1.696 – 15.506)	0.004
Sepsis	2.833	(1.324 – 6.059)	0.007

Table 4: Comparison of parameter with stages of ROP in the study population (N=224)

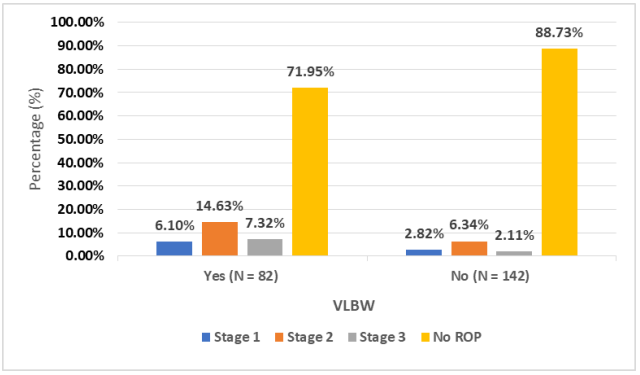
	Diagnosis				
Parameter	Stage 1 (N=9) Mean ± SD	Stage 2 (N=21) Mean ± SD	Stage 3 (N=9) Mean ± SD	No ROP (N=185) Mean ± SD	**ANOVA P Value**
Birth weight (kg)	1.47 ± 0.36	1.46 ± 0.42	1.29 ± 0.34	1.63 ± 0.35	0.0092
Gestational age (weeks)	31.11 ± 2.32	31.05 ± 2.29	31.00 ± 3.28	32.73 ± 1.76	<0.001

The difference in the proportion of diagnosis between parameters (CHD, Blood transfusion, TWIN, Maternal anaemia, PIH and GDM) was statistically not significant (P value > 0.05).

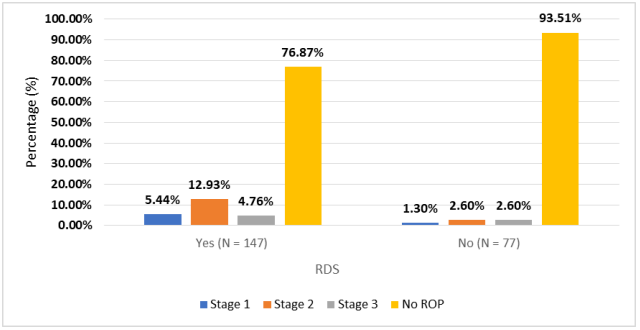
Maternal risk factors like maternal anaemia, PIH were found to be more in stage 2 and 3 compared to stage 1. There is no difference seen in between stage 1, 2, 3 of ROP (Table 5).



Graph 7: Cluster bar chart of comparison of LBW between diagnosis in the study population (N=224)



Graph 8: Cluster bar chart of comparison of VLBW between diagnosis in the study population (N=224)



Graph 9: Cluster bar chart of comparison of RDS between diagnosis in the study population (N=224)

4. Discussion

The prevalence of ROP in our study was 17.41%. Among which stage 1 accounts for 4.02%, stage 2 accounts for 9.38% and stage 3 accounts for 4.02%. In the past, newborns did not go through routine screenings and were diagnosed with stages IV and V of ROP at a later age. Nowadays, however, newborns go through screenings on time, are diagnosed early, and receive treatment on time, therefore we have not identified any babies with stages IV and V of ROP.

Kumar et al., has reported the incidence of any stage of ROP was 11.9%.[5] Vinekar A, et al., reported the incidence of any stage ROP was 22.39%.[9] The prevalence of ROP was found to be 17.68% in Rizvi SA et al.[10] 51.72% of those diagnosed with ROP had stage 1, 31.03% had stage 2, 10.35% had stage 3, and 6.90% of infants had APROP. No infants developed ROP to the stage 4 or 5 level during this study. According to the research done by Nikhil R et al.[6] the prevalence of ROP is 19.2%. Among ROP newborns, 40% were in stage 1, 40% were in stage 2 & 20% were in stage 3. There was no much difference in incidence of ROP among

Table 5: Comparison of risk factors with diagnosis in the study population (n=224)

Risk factors	Diagnosis (%)				Chi square value	P value
	Stage 1	Stage 2	Stage 3	No ROP		
LBW						
Yes (n = 131)	3.05	5.3	1.53	90.08	13.22	0.0042
No (n = 93)	5.4	15.05	7.5	72.04		
VLBW						
Yes (n=82)	6.1	14.6	7.3	71.9	10.49	0.0149
No (N = 142)	2.8	6.3	2.1	88.7		
ELBW						
Yes (n = 4)	0	25	25	50	*	*
No (n= 220)	4.09	9.09	3.6	83.1		
RDS						
Yes (n= 147)	5.4	12.9	4.8	76.9	10.19	0.0170
No (n = 77)	1.3	2.6	2.6	93.5		
Sepsis						
Yes (n = 83)	7.2	15.7	6.02	71.08	12.38	0.0062
No (n= 141)	2.1	5.7	2.8	89.4		
NNHB						
Yes (n = 36)	0	11.1	8.3	80.6	*	*
No (n= 188)	4.8	9.04	3.2	82.9		
CHD						
Yes (n = 14)	7.1	14.3	7.14	71.4	1.34	0.7208
No (n= 210)	3.8	9.05	3.8	83.3		
Blood transfusion						
Yes (N = 36)	8.3	19.4	2.8	69.4	7.69	0.0529
No (N = 188)	3.2	7.5	4.3	85.1		
TWIN						
Yes (n = 47)	8.5	10.6	4.3	76.6	3.36	0.3399
No (n = 177)	2.8	9.04	3.9	84.2		
Maternal anaemia						
Yes (n = 112)	3.6	10.7	5.4	80.4	1.67	0.6425
No (n = 112)	4.5	8.04	2.7	84.8		
PIH						
Yes (n = 60)	3.3	8.3	6.7	81.7	1.63	0.6526
No (n = 164)	4.3	9.8	3.05	82.9		
GDM						
Yes (n = 11)	9.09	9.09	9.09	72.7	1.62	0.6550
No (n = 213)	3.7	9.4	3.8	83.1		
Hypothyroid						
Yes (n = 10)	0	30	0	70	*	*
No (n = 214)	4.2	8.4	4.21	83.2		

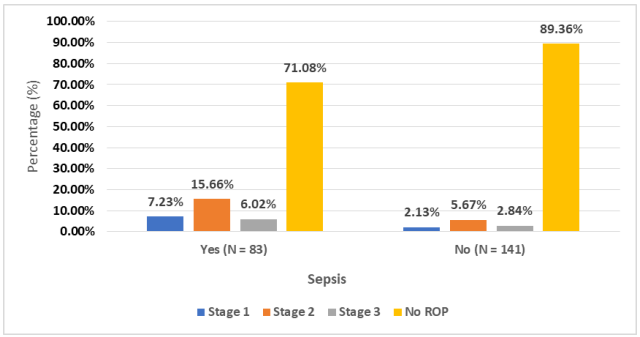
*No statistical test was applied- due to 0 subjects in the cells

male and female babies in our study which is similar in other studies.[10–12]

The mean gestational age was 32.44 ± 2 weeks in this study and mean birth weight was 1.59 ± 0.36kg which co-related with the study by Dwivedi A et al reported Mean gestational age (GA) of 33.28 ± 0.105 and mean birth weight (BW) was 1.63 ± 0.015.[7] And a study by Kumar et al. which showed mean birth weight and gestation of the infants screened for ROP as1335±351 g and 31±2.2 wks, respectively.[6] The study conducted by Rizvi SA et al. found that the average gestational age of the newborns who participated was 32.43 weeks (2.18 weeks), and their average birth weight was 1.55 kg (0.39 kg).[10] According to the statistics, the occurrence of ROP rose when both BW and GA decreased.[13]

According to research done by Rizvi SA et al., having a low birth weight is an additional important risk factor for the development of ROP.[10] The CRYO ROP study, which was a multicenter trial using cryotherapy, came to the conclusion that a higher risk of developing ROP was associated with a lower birth weight.[14]

According to the research carried out by Nikhil R et al., a lower birth weight was strongly associated with an increased incidence of ROP.[6] Extremely low birth weight newborns,



Graph 10: Cluster bar chart of comparison of Sepsis between diagnosis in the study population (N=224)

defined as those weighing less than 1000 grams at birth, had an incidence of ROP that was 48.0%, whereas very low birth weight babies, defined as those weighing between 1001 and 1500 grams at birth, had a 6.97% incidence. The chance of having ROP increases in proportion to the earlier in gestation the baby is born.

ROP is a condition that can be caused by a number of different reasons. In a study, researchers speculated that factors such as short gestational age, LBW, sepsis, oxygen therapy, RDS, and blood transfusion might play a role in the development of ROP.[15] According to the findings of a number of studies, the most significant risk factors for the development of ROP were a low birth weight and a low gestational age at the time of delivery.[16–18]

In Azami M et al., study, ROP risk factors include the prevalence of blood transfusion, septicemia, weight < 1000 g, weight < 1500 g, frequency of phototherapy, respiratory distress syndrome (RDS), low gestational age, however, preeclampsia significantly decreases the prevalence of ROP.[12]

The research conducted by Rizvi SA et al. found that there was a strong relationship between the development of ROP and gestational age, LBW, multiple gestation, a history of blood transfusion, respiratory distress syndrome, and infection.[10] However, we found that there is no significant association between ROP and sex, neonatal jaundice.

Respiratory disorders such as respiratory distress syndrome (RDS) in neonates, if left untreated, can lead to advanced stages of ROP. RDS if present along with low gestational age, it is associated with aggressive posterior ROP. The infants may require oxygen therapy and mechanical ventilation in RDS, both of which are risk factors for developing ROP.[4] In the present study, compared to no RDS, the odds of occurrence of ROP were 5.49 times (1.87 to 16.12) and There was a statistically significant link between the two factors (P value less than 0.05).

On univariate analysis, the researchers Rizvi SA et al. observed that multiple gestation was statistically significant.[10] According to the research conducted by Nikhil R et al. out of 78 newborns, 44 were singletons and 34 were twins. ROP was found in 8 of the singletons (out of a total of 44). Only seven of the 34 twins were diagnosed with ROP.[6] In studies that were similar to ours, the researchers did not find a significant association between many pregnancies and ROP.

According to the findings of Hakeem AH et al., there was a statistically significant connection between the occurrence of ROP and gestational age, the presence of infection, and the number of times blood transfusions were received. On the other hand, there was not a significant association between the occurrence of ROP and the sex of the child, the manner of delivery, the birth weight, RDS, congenital heart problems, or phototherapy.[19] In our study, we found that there is statistically significant for sepsis. In our study, the difference in the proportion of diagnosis between factors like (CHD, Blood transfusion, Maternal anaemia, PIH and GDM) was statistically not significant as observed in many other studies.

5. Conclusion

In this study the prevalence of Retinopathy of prematurity is 17.41%. The risk factors such as LBW, VLBW, RDS, Sepsis are found to be clinically significant. Few risk factors which are insignificant in our study, are seen as significant risk factors in other studies. So each and every risk factor should be carefully evaluated and managed. Severity is seen correlating with independent riskfactors such as LBW, VLBW, RDS, Sepsis. Hence, multidisciplinary approach of treating prematurely born child would decrease the burden of childhood blindness globally.

6. Source of Funding

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7. Conflict of Interest

None.

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