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Assessment Of Incidence And Risk Factors In The Development Of Retinopathy Of Prematurity In A Tertiary Care Hospital: A Prospective Study.

H G Anitha[1], Bhuvanesh B T[2], Preeti Dharmatti [3]* Vijay Kumar Murteli[4].
[1]Assistant professor, East point college of medical sciences and Research centre.
[2]specialist in pediatrics,CHC DODDAKUNCHE, HOLENARASIPUR.
[3]consultant pediatrician at Aski Hospital,Bagalkot
[4]Professor, department of pediatrics,BIMS, BELAGAVI.

Correspondence:
Dr. Preeti Dharmatti.
Consultant Pediatrician At Aski Hospital, Bagalkot.

Email:
preetidharmatti6@gmail.com

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Abstract
Background: Retinopathy of Prematurity (ROP) is a multifactorial vasculo-proliferative retinal disorder. Approximately 65% of infants with a birth weight <1250g and 80% of those with a birth weight <1000 g will develop some degree of ROP. ***Objective.*** To Study the incidence of ROP in preterm infants admitted to NICU. To Study the risk factors and Clinical Profile of babies with ROP. ***Methods:*** This Prospective observational Study study was carried out in Belagavi Institute Of Medical Sciences(BIMS) Hospital, Belagavi.. All premature babies satisfying any one of the inclusion criteria admitted to Neonatal Intensive Care Unit(NICU) from March 2021 to February 2022 were subjects of the study. ***Result:*** Lower birth weight is a risk factor for ROP in this study (p <0.001). The mean gestational age of the babies with ROP was (31weeks) and in those without ROP (33weeks),lower gestational age is risk factor for ROP in our study(p <0.001). Incidence of ROP is inversely related to Birth weight and gestational age. In our study longer duration of oxygen administration and need for oxygen supplementation in babies with ROP (p <0.001) was statically significant. Respiratory distress in the babies (P <0.01) ,PIH in the mother (p <0.05) had positive correlation with development of ROP . longer duration of hospital stay (p=0.004) is statically significant and is independent risk for development of ROP in our study. ***Conclusion:*** Risk factors predisposing to ROP were gestational age and birth weight. Various other risk factors like, Respiratorydistress syndrome, longer duration of oxygen therapy, longer duration of hospital stay, low hemoglobin and platelet count and phototherapy.

Keywords: ROP, Risk factors, Incidence.

INTRODUCTION
In India, approximately, 1 in 1000 children is blind, and the incidence of ROP is reported between 24% and 47%.1. Clinical observations suggest that the onset of ROP consists of two stages. 2 The primary stage involves an initial insult, such as hyperoxia, at critical point in retinal vascularization that results in vasoconstriction and subsequent arrest in vascular development.2

During the second stage, neovascularization occurs and this aberrant retinal vessel growth is thought to be driven by excess angiogenic (vasculo-proliferative) factors. New vessels grow through the retina into vitreous and extensive fibrovascular proliferation can lead to retinal detachment.2

India has the highest number of preterm deliveries in the world and hence, a huge burden of ROP. Staging the disease correctly, following the international treatment guidelines and timely screening could help in reducing this burden. ROP blindness is incurable and only way to avoid this is by detailed dilated retinal examination of all premature at risk babies definitely by 30 days of birth.3

ROP is one of the most common disorders affecting the eyes of the premature infants ,in the absence of treatment ,it can result in retinal detachment and permanent loss of vision .Advances in neonatal care have resulted in increase in survival rates of very premature infants and consequent increase in incidence of ROP.4

Risk factors predisposing to ROP were gestational age and birth weight alone and along with the various risk factors like birth asphyxia, sepsis, multiple blood transfusion, respiratory distress syndrome, multiple birth, antenatal steroid use and phototherapy.5

The occurrence of ROP is trending towards a rise including newborns with higher birth weight and gestational age in developing countries; hence necessitating the need of comprehensive Screening of Newborns with risk factors in these developing countries.5.

MATERIALS AND METHODS

This Prospective observational study was carried out in Belagavi Institute Of Medical Sciences (BIMS) Hospital, Belagavi. All premature babies satisfying any one of the inclusion criteria admitted to Neonatal Intensive Care Unit (NICU) from March 2021 to February 2022 were subjects of the study. All the babies admitted to NICU during the study period, who satisfied the criteria, were analyzed and were followed up till retina is fully vascularized.

INCLUSION CRITERIA

- Babies less than or equal to 34 weeks of gestational age.
- Babies with birth weight less than or equal to 2kgs.
- Gestational age between 34 to 36 weeks but with risk factors such as

a) Cardio –respiratory support,
b) Prolonged oxygen therapy,
c) Respiratory distress syndrome,
d) Chronic lung disease,
e) Fetal hemorrhage ,
f) Blood transfusion,
g) Neonatal sepsis
h) Exchange transfusion ,
i) Intraventricular hemorrhage
j) Apnea

EXCLUSION CRITERIA

- Babies with congenital anomalies
- Babies who did not complete follow - up were excluded from analysis.

SAMPLE SIZE: 82

Sample size calculated as follows ,with incidence of 19.3% from the article by Chaudhari S, Patwardhan et al.6

- n=Z2pq/d2

n =1.962*19.3*80.7/81
n =74
With 10% loss to follow up sample size is
n,=n/1-10%=74/0.9=82

PROCEDURE:

- Detailed history and profile of the patient was noted as for the Proforma.
- Gestational age was assessed by New Ballard score.
- First ROP screening was done between 3rd week and 4th weeks afterbirth .
- If any baby is delivered earlier than 28 weeks of gestation or birth weight less than 1200 gm ROP screening was done at 2-3 weeks after birth.
- Babies were examined by the Trained ophthalmologist each time.
- All aseptic precautions was taken.
- Pupils were dilated using combination of 2.5% phenylephrine and 0.4% Tropicamide eye drops instilled two times in each eye at intervals of 15mins.7
- Each baby underwent wide field digital imaging with Ret-camshuttle (Clarity Medical Systems , Inc.) ,images stored and compared using software of the machine at each visit by the ophthalmologist .
- If no ROP is detected at initial examination, infants were examined every 2 weeks until their vessels have grown out to the Ora serrata and the retina is considered mature.
- If ROP is diagnosed, the frequency of follow up examination was decided by ophthalmologist depending on the stage of ROP.

Statistical Analysis:

- As the data was not normal, nonparametric test (Mann Whitney 'U' test) was applied to see the median difference between cases and controls.
- SPSS Version 23 was applied.
- Standard error of proportion was applied to see the difference between 2 proportions..

RESULTS

Among the Babies admitted to NICU 82 babies satisfying the inclusion criteria were enrolled in the study and studied.

Table 1: Evaluation of maternal risk factors with development of ROP

Parameter	With ROP (n=7)	Without ROP(n=75)	P value	Significance
Pregnancy Induced Hypertension				
Yes	4(57.14%)	14(18.67%)	<0.05	significant
No	3(42.86%)	61(81.3%)		
Ante Partum Haemorrhage				
Yes	0	0	>0.05	Not significant
No	7	75		
Maternal Steroid administration (Dexamethasone)				
Yes	1(14.28%)	15(20%)	>0.05	Not significant
No	6(85.72%)	60(80%)		
Meconium stained amniotic fluid				
Yes	0	5(6.67%)	< 0.05	significant
No	7	70(93.33%)		

- Among the mothers 4/7 in ROP group and 14/75 in the non ROP group had PIH in mother. It is statistically significant in our study ($p < 0.05$).
- None of the mothers In both the groups had antepartum haemorrhage in our study ($p > 0.05$).
- Out of the 16/82 babies whose mothers received antenatal steroids 1 developed ROP and 15 did not develop ROP and it is not statistically significant in our study.
- None of the babies had exposure to meconium stained liquor in the babies who developed ROP, only 5/75 babies in the Non-ROP group had meconium stained liquor and it is not statically significant ($P< 0.05$). The mothers age with ROP (25.17 +/-3.37)and without ROP(25.0 +/-4.1)are not significant statically (0.789) and are comparable.

Table 2: Incidence of ROP among study subject and their distribution into inborn and out-born

	CASES WITH ROP(PERCENTAGE) (n=7)	**CASES WITHOUT ROP(PERCENTAGE) (n =75)**	**PVALUE**	**INFERENCE**
INBORN	3(42.8%)	59(78.6%)		
OUTBORN	4(57.2%)	16(21.4%)	**0.035**	**Significant**
TOTAL	7(8.5%)	75(91.5%)		

Here 3/7 in ROP group and 59/75 in the non-ROP group are In-born, and 4/7 in ROP group and 16/75 in non ROP group are out-born**.** 1/7 in ROP group and 33/75 in non- ROP group are born through vaginal route , 6/7 in ROP group and 42/75 in non ROP group are born through LSCS. The mode delivery among the cases is comparable in our study and is not statically significant. In ROP group 1/7(14.29%) and in non ROP group 35/75(46.67%) are male. 6/7 (85.71%) in ROP group and 40/75 (53.33%) are female.

Gender based distribution of babies in relation to development of ROP is not significant statically (P= 0.107) and they are comparable in our study. The mean birth order in babies with ROP (1.83+/-0.75) and in non ROP group is (1.73+/-0.9) p value is 0.863 .Birth order among babies is comparable and is not significant(p=0.863) statically in our study . Only 5/75 babies In non –ROP group required resuscitation at birth and none (0/7) In the ROP group, it is not statically significant in our study.

Table 3: Correlation Between Mean Apgar Score At 1min And 5 Min Among Cases To Development Of ROP

APGAR SCORE	Mean +/-SD	P-Value	Inference
APGAR @ 1min with ROP(n=7)	7.25+/-0.76	0.127	Not significant
APGAR @ 1min without ROP(n=75)	8.5+/-0.55		
APGAR @ 5 min with ROP(n=7)	8.5+/-0.55	0.821	Not significant
APGAR @ 5 min without ROP(n=75)	8.36+/-0.58		

Mean APGAR score at 1 min in ROP group is (7.25+/-0.76) and in non ROP group is (8.5+/-0.55) ,the mean APGAR score at 5min in ROP group (8.5+/-0.55) and in non ROP group (8.36+/-0.58). Out of 82 babies ,7 with ROP and 75 without ROP. Maximum of the babies 2/7 (28.57%) in ROP group and 40/75 (53.3%)in non ROP lies between 1500 to 1999 grams birth weight group. Mean birth weight among cases with ROP is (1.275kg) and those without ROP is (1.7kg) , low birth weight is a significant risk factor in development of ROP in our study ($p < 0.001$).

Mean Length Babies in ROP group is (45.0+/-1.79) and in without ROP group is (46.71+/-1.8),p value (0.011).
Mean Head circumference in ROP group is (30.5+/-0.89) and in without ROP group is (31.54+/-1.5) ,p value (0.015). lower length and head circumference are statically significant in our study. Among the 7 babies with ROP ,majority of the babies 5/7 (71.6 %) fall in the gestational group of (31-32) weeks group .

Among the 75 babies without ROP ,majority of the babies lie in the 33-34weeks (29.3%) and 34-35 weeks (30.67%) gestational group. Mean gestational age among cases with ROP is 31 weeks and those without ROP is 33 weeks is statistically significant ($p<0.001$).So lower gestational age as positive correlation in development of ROP . Mean HR in Babies with ROP is (132.33+/-5.43) and in without ROP is (137.49+/-11.31), p value (0.346).

Mean RR in babies with ROP (68.67+/-3.27) and in without ROP (55.81+/-9.28) ,p value (<0.001).Babies with Respiratory distress are likely to develop ROP, it is statically significant in our study . Out of the 82 babies studied, 45(54.8%) received oxygen, among them 7 (8.5%) were in the ROP group ,whereas 38(46.3%) were in the non ROP group. All the babies in the ROP group has exposure to Oxygen in our study making it statistically significant for development of ROP.

Distribution Among the mode of oxygen delivery among babies with ROP oxygen by hood (1/7) ,CPAP (6/7) and mechanical ventilation (0/7) when compared to cases without ROP is oxygen by hood (31/75) ,CPAP (6/75) and mechanical ventilation (1/7). 6/7 babies in ROP group and 17/75 babies in the non-ROP group received oxygen for more than 72 hours it was statically significant. Mean duration of oxygen requirement in babies with ROP is 140.5 hours and in the non- ROP group is 42.24 hours , statistically it is significant. Its seen in our study that longer duration of oxygen exposure is associated with development of ROP.

Table 4: Incidence of ROP among the babies studied

	NUMBER	PERCENTAGE
WITH ROP(n=7)	7	8.5%
WITHOUT ROP(n=75)	75	91.5%
Total	82	100%

Incidence of ROP among the 82 babies studied is 7 (8.5%).

DISCUSSION

Its seen that PIH in mother is a risk factor for Development of ROP in our study, and as also seen in other studies. Out of the 16/82 babies whose mothers received antenatal steroids 1 developed ROP and 15 did not develop ROP and it is not statistically significant in our study.

In a study by Manish Tandon et al[8] in 105 babies, 49 with ROP, with incidence being 46.7% the correlation of reduction of ROP in mothers exposed to ANS was not statically significant. In our study the mean maternal age in babies with ROP was (25.17 +/-3.37years) and in the non-ROP group was (25.0 +/-4.1) they are comparable.Whereas in study done by Uchida et al in 182 babies ,84 with ROP the mean age of mothers in ROP group is 31 years and in non-ROP group is 33 years ,here the incidence in babies born to lower maternal age was higher ,so lower maternal had positive correlation with ROP development.The mode delivery among the cases is comparable in our study and is not statically significant in our study. In our study gender of the babies in ROP and non ROP group are comparable (p= 0.107). Correlating with a study done by Flavius Beca at al[9], where they studied 7299 babies found that gender distribution among the babies was comparable.

Here even though babies with ROP had lower APGAR score at 1 min compared to the non-ROP group, but the APGAR score of the both groups was comparable at 5min . Also in the study by Alajbe-jovic[10] in 80 babies , APGAR at 5 min in ROP group (5.52 ± 1.0) and in Non ROP group (7.01 ± 0.76) also tells that lower APGAR scores at 5 min is associated with development of ROP. In our study low birth weight was statistically associated with development of ROP(p<0.001). Also in Study by Sujith Patel et al[11] in 286 babies ,69 babies had ROP found that Low birth weight was significant risk factor for ROP (p<0.01).Prematurity is single most important risk factor for ROP ,and Gestational age (33.23 ± 3.38 weeks) with p <0.05 and birthweight (1622.38 ± 612.89) were inversely proportional to the incidence of ROP in a study by Sujit Patel et al[11] in 286 babies with 69 babies with ROP .

It correlates in the present study also mean birth weight In Babies with ROP being (1275grams) and mean gestational age being (31 weeks) as compared to the mean birth weight without ROP being (1700grams) and mean gestational age without ROP (33weeks). It also correlates in studies done by with relationship between lower gestational age and development of ROP Ebrahim et al(p =0.0001) and Krishna et al(p=0.02) as described above. In the present study we can see that all the cases with ROP required oxygen administration (7/7) , it seen in the study that mean duration of oxygen requirement in those with ROP (140.5 HOURS) those without ROP (42.24hrs) is statistically significant (p<0.001) . Rekha et al[12] ,studied 100 babies ,found that oxygen was one of the significant risk factor ,also showed the duration of oxygen exposure those with and without ROP was significant(p<0.001),mean duration of oxygen in ROP group (1.8±2.9 days) and in non-ROP group being (0.5±0.92 days). In a study done by Chaudhari et al[6] in 552 babies ,123 with ROP ,oxygen exposure was a risk factor for development of ROP (P=0.031).

In a study done by Soumya Agrawal et al[13] in 51 babies ,9 with ROP oxygen exposure was a risk factor for development of ROP in their study (p=0.042). In our present study Respiratory distress syndrome (RDS) (p<0.01) was statically significant as a positive correlation for development of ROP. Study by Sujit Patel et al[11] in 286 babies ,69 babies had ROP found that RDS was significant risk factor for ROP (p<0.01). Study by Anuja sathar[14] et al in 812 preterm babies ,found that 203 cases with ROP and a significant correlation with RDS (p =0.03). In our study it is found that anemia in babies with ROP was not statically significant with development of ROP (>0.05) **.**

- In study by Manish Tandon et al[8] in 105 babies ,49 babies with ROP among them 38 had amenia found that it was risk factor for development of ROP .(P=0.027).
- In a study done by Lundgren et al[15] ,in 227 babies less than 28weeks,25 babies with ROP all of them has anemia , found that anemia had positive association with ROP development (p<0.001) and warranted treatment.

Apnea was not a risk factor for ROP in a study done in 59 babies,49 babies with ROP by Manish Tandon et al[8] (p=0.708). In a study by Chaudhari et al[6] in 552 babies ,123 babies with ROP, 47 had apneic episode and was found to be a risk factor for development of ROP.

Table 5 : Comparison of incidence ROP of present study with other studies

STUDY	Number of babies studied	Number of babies with ROP	GESTATIONAL AGE(WEEKS)	BIRTH WEIGHT (GRAMS)	INCIDENCE
Swarna Rekha et al[12] (1996)	100	46	<34	< 1500	46%
Crystal et al (2021)[16]	2910	66	<34	<1750	2.3%
Sujit S Patel et al(2019)[11]	286	69	<34	<2000	24.1%
Ashish Athale et al (2020)[7]	104	27	<34	<1700	25.96%
Present study	82	7	< 34	<2000	8.5%

- The incidence of ROP in our study id 8.5% ,out of 82 babies studied < 34 weeks and <2000 grams .
- Where as in other studies study by Swarna Rekha et al[12] had incidence of 46% ,they had studied 100 babies with < 34 weeks or < 1500 grams.
- The incidence of ROP in study by Sujith Patel et al[11] done in 286 babies < 34 weeks or <2000grams was 24.1%.
- In study by Ashish Athale et al[7] in 104 babies in <34 weeks or <1700fram babies the incidence was 25.96%

In the present study it is seen that the longer duration of hospitalization as positive correlation with development of ROP . Also in a study by Alaa A Nugud et al[17] in 163 babies ,44 had ROP it was found that babies with ROP had longer duration of hospital stay 106 days compared to non ROP group 49 days.

CONCLUSION

Lower birth weight is a risk factor for ROP in this study (p <0.001). The mean gestational age of the babies with ROP was (31weeks) and in those without ROP (33weeks),lower gestational age is risk factor for ROP in our study(p <0.001). Incidence of ROP is inversely related to Birth weight and gestational age. In our study longer duration of oxygen administration and need for oxygen supplementation in babies with ROP (p <0.001) was statically significant. Respiratory distress in the babies (P <0.01) ,PIH in the mother (p <0.05) had positive correlation with development of ROP . longer duration of hospital stay (p=0.004) is statically significant and is independent risk for development of ROP in our study.

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