

Screening For Retinopathy of Prematurity Based on National Health Mission- Rashtriya Bal Swasthya Karyakram (NHM-RBSK) Guidelines: A Clinical Study

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Received: 01-04-2026 / Revised: 15-05-2026 / Accepted: 21-06-2026

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Conflict of interest: Nil

Abstract

Background: ROP is a vasoproliferative disease of retina that affects premature infants. In India, the guidelines given by the National neonatology forum were followed for ROP screening previously. In February 2013, RBSK was launched under the National Health Mission, which focussed on improving the quality of life of children from the time of birth to 18 years through timely screening for various defects, including eye and vision related problems.

Aim: To evaluate the incidence of Retinopathy of Prematurity (ROP) and analyse the risk factors in premature infants based on National Health Mission-Rashtriya Bal Swasthya Karyakram (NHM-RBSK) guidelines.

Methodology: The present study was a cross sectional study based on NHM-RBSK guidelines for ROP screening in a tertiary care hospital. All included babies were subjected to indirect ophthalmoscopy and the presence or absence of ROP was noted. Prior to that a detailed history from the parents and case records was collected regarding various pre, intra and postnatal risk factors. The data was analyzed statistically using appropriate tests.

Results: The incidence of ROP was found to be 14.7%. Gestational age(GA) < 27 weeks, Birth weight (BW) <1700 grams, Oxygen therapy for > 5 days and multiple gestation were statistically significant risk factors on univariate analysis and multiple gestation and PDA were the significant risk factors on multiple logistic regression analysis.

Keywords: Retinopathy of Prematurity, Incidence, Risk factors.

DOI: 10.25258/ijcpr.18.7.199

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Introduction

ROP is a vasoproliferative disease of retina that affects premature infants. The World Health Organization (WHO) vision 2020 programme has identified ROP as an important cause of blindness in both high and middle income countries. ROP is estimated to affect more than 50000 infants annually worldwide. In India every year 500 children are estimated to become blind from ROP. While ROP may cause severe visual impairment, the condition fortunately carries a good prognosis, given early screening and management. [1]

In India, the guidelines given by the National neonatology forum were followed for ROP screening previously [2]. In February 2013, RBSK was launched under the National Health Mission, which focused on improving the quality of life of children from the time of birth to 18 years through timely screening for various defects, including eye

and vision related problems. Under this programme guidelines were formulated for universal eye screening in newborns including ROP [3]. The present study aims to assess the incidence and risk factors of ROP in premature infants based on NHM-RBSK guidelines.

Methodology

The present study was a hospital based, observational study performed on babies included in the study for ROP screening as per NHM-RBSK guidelines. The babies were referred from Special Newborn Care Unit (SNCU) and Neonatal Intensive Care Unit (NICU) of Government General Hospital, Tirupati to the Department of Ophthalmology for ROP screening. Babies with hazy ocular media which would prevent fundus examination and critically ill babies were excluded

from the study. A written informed consent was taken from the parents/ guardians of children who accompanied the babies. A detailed history regarding the pre, intra and postnatal risk factors was collected from the parent/guardian/ medical records whichever was possible. After examining the anterior segment to exclude neovascularisation of iris and pupillary rigidity, pupillary dilatation was done and Indirect ophthalmoscopy was performed with a 20 Diopter lens.

Documentation was done in a standardized proforma, which included the zone of vascularization, the stage of ROP, the extent of ROP in clock hours, the presence of plus or pre plus disease, the presence of Aggressive posterior ROP (APROP), whether treatment was indicated and when follow up was indicated. In ROP positive eyes the severity was graded and the staging was done according to International Classification of ROP (4).

Statistical Analysis: The data was tabulated and compared between ROP positive and negative groups. Qualitative variables such as the presence or absence of a risk factor were tested by the Chi-square test to find an association. Quantitative data such as gestational age and birth weight were expressed in the form of mean and analyzed using an unpaired t-test. Significant variables on univariate analysis were further tested using multivariate analysis. The study has got institutional scientific and ethics committee approval.

Results

263 premature infants referred from NICU, SNCU of the Department of Paediatrics Government

General Hospital, Tirupathi between August 2019 and July 2020 to the Department of Ophthalmology, for ROP screening were included in the study. Two babies were excluded from the study because of hazy media one with mucopolysaccharidosis and the other with congenital cataract.

The overall incidence of ROP was found to be 14.7%. On univariate analysis Gestational age < 27wks (p value 0.010), Birth weight < 1700gms (p value 0.035), Oxygen therapy for > 5 days (p value 0.031) and multiple gestation (p value 0.004) were the risk factors found to be statistically significantly associated with ROP. Multiple gestation (p value 0.045) and PDA (p value 0.015) were the predictor variables with statistical significance on multivariate analysis. The odds of developing ROP was found to be 11.83 times more in babies with PDA than in those without PDA where as it was 2.33 times more in babies delivered in multiple births when compared to those born of singleton pregnancies.

Discussion

Retinopathy of Prematurity is one of the important causes of preventable blindness in children in India and worldwide. Studies on ROP done in various parts of India over a period of time have shown variable incidence (Table 1) and a huge variation in associated risk factors (Table 2). The present study conducted in the Department of Ophthalmology, GG Hospital, Tirupati, a tertiary care hospital, was designed to assess the incidence and analyse the risk factors of ROP.

Table 1: Incidence OF ROP

Study	Year	Incidence	Inclusion criteria	
			Birth Weight in grams	GA in weeks
Present study	2020	14.17%	<2000	≤34
Charan et al(14)	1995	47%	≤1700	
Gopal et al(15)	1995	38%	<2000	
Crystal et al(1)	2016	2.3%	<1750	<34
Kumar N et al(16)	2017	16%	<1500	<35
Snehal Thakre et al(17)	2017	27.73%	≤1750	≤34
Dhaivat vasavada et al(18)	2017	19.28%	<7000	<34
Anoop mantri et al(19)	2017	13.6%	-	<34
Anamika Dwivedi et al(20)	2018	30%	<2000 at 4wks of age	<37
Kanagulla Anudeep et al(13)	2019	37%	<1700	<34
Ahuja AA et al(21)	2021	32.6%	<1900	<36
INTERNATIONAL STUDIES				
Bas AY et al(22)	2018	27%	≤1500	≤32
Chang JW et al(23)	2019	48.55	≤1500	≤32
Gaber et al(24)	2021	34.1%	≤2000	≤34

India is a big country with huge population and a vast difference in the cultural, social, educational,

healthcare practices and available health care facilities, all of which can influence the incidence

of prematurity and low birth weight, which in turn can affect the incidence of ROP and its associated risk factors. Some states have adopted screening with a portable Retcam (Karnataka Internet Assisted Diagnosis of Retinopathy of Prematurity Programme (KIDROP), whereas some institutes are utilizing the services of trained paramedical personnel for ROP screening in remote areas which can increase the detection of ROP cases.

Some multicentric studies have shown that the incidence of ROP varied between the cohorts of

babies enrolled from different NICUs because of differences in protocols for neonatal care. NICUs in different states and places may differ in available equipment, interventions done and treatment protocols, for example, target oxygen saturation, which in turn can influence the occurrence and severity of ROP.

The difference in data collection can be one important confounding factor.

Table 2: Risk Factors Associated With Rop

Indian Studies		
Study	Year	Risk factors
Present study	2020	low gestational age, low birth weight, oxygen therapy multiple births, PDA
Rekha S et al [25]	1996	Anemia, duration of oxygen therapy
Agarwal R et al [26]	2002	apnoea, clinical sepsis, male gender
Crystal et al [1]	2016	multiple gestation, Oxygen therapy, RDS, sepsis
Kumar N et al [16]	2017	RDS, Oxygen therapy, septicemia, exchange transfusion
Snehal Thakre et al [17]	2017	Birth weight, ventilation, blood transfusion, RDS, sepsis
Dhaivat vasavada et al [18]	2017	Oxygen therapy
Anamika Dwivedi et al [20]	2018	low gestational age, RDS, late presentation for screening
Kanagulla Anudeep et al [13]	2019	low gestational age, Oxygen therapy, RDS
Ahuja A A et al [21]	2021	Oxygen therapy, RDS, low birth weight
International Studies		
Bas AY et al [22]	2018	low birth weight, small GA, total days on Oxygen, relative weight gain, frequency of red blood cell transfusion
Chang JW et al [23]	2019	prenatal steroid use, GA, the duration of mechanical ventilation and RDS
Gabber et al [24]	2021	low GA, low birth weight, apnoea, supplementary oxygen administration, thrombocytopenia, phototherapy for jaundice

The incidence of ROP in the present study is 14.7% which is slightly lower than the previous studies. In the studies shown in the Table 1 there was not much difference in the inclusion criteria. In spite of the relatively same upper limit of birth weight and similar gestational age as inclusion criteria in the above studies, incidence varied between 2.3% and 47%. In Crystal et al study (1) the incidence of ROP was only 2.3%. The reason proposed for this low incidence was that the NICU from which the babies were enrolled into the study abides by strict Oxygen therapy and ROP screening guidelines. Because of the above reason many infants born at this facility presented with fewer perinatal risk factors and subsequently lower overall incidence of

ROP. Improved prenatal and perinatal care and management of neonates may be the reason for the relatively low incidence of ROP in the present study. Etiopathogenesis of ROP is complex in the sense that it has multiple maternal, infantile and environmental risk factors (Table 2), each one of which acts as a confounding factor while studying the effect of others. Le A Owen et al (6) in their research article "Retinopathy of Prematurity: A comprehensive risk analysis for prediction and prevention of disease", performed univariate, stepwise regression and statistical interaction analyses of 57 proposed ROP risk variables which were significantly associated with each outcome measure.

Table 3: Univariate Analysis of Risk Factors

Risk factors		Present (%)	n	Absent (%)	n	Total n (%)	χ^2 value	p-value
Birth weight(grams)	<1.700	31(17.2)		149(90.7)		180(100.0)	4.423	0.035;S
	>1.700	6(7.4)		75(92.6)		81(100.0)		
Gestational age(weeks)	≤27	12(29.3)		29(70.7)		41(100.0)	9.134	0.01; S
	28-31	17(11.6)		129(88.4)		146(100.0)		
	≥32	8(10.8)		66(89.2)		74(100.0)		
Gender	Male	20(14.1)		122(85.9)		142(100.0)	0.002	0.963; NS
	Female	17(14.3)		102(85.7)		119(100.0)		
Oxygen support	>5 days	19(20.4)		74(79.6)		93(100.0)	4.645	0.031; S
	<5 days	18(10.7)		150(89.3)		168(100.0)		
Sepsis	Present	13(15.9)		69(84.1)		82(100.0)	0.277	0.599;NS
	Absent	24 (13.4)		154(85.6)		180(100)		
RDS	Present	26(14.4)		154(85.6)		180(100.0)	0.034	0.853;NS
	Absent	11(13.6)		70(86.4)		81(100.0)		
Multiple births	Present	12(28.6)		30(71.4)		42(100.0)	8.525	0.004; S
	Absent	25(11.4)		194(88.6)		219(100.0)		
Apnea	Present	10(18.2)		45(81.8)		55(100.0)	0.919	0.338;NS
	Absent	27(13.1)		179(86.9)		206(100.0)		
PDA	Present	2(40.0)		3(60.0)		5(100.0)	2.794	0.095;NS
	Absent	35(13.7)		221(86.3)		256(100.0)		
CVS defects other than PDA	Present	0(0.0)		2(100.0)		2(100.0)	0.322	0.750;NS
	Absent	36(13.9)		223(86.1)		259(100.0)		
Anemia	Present	9(17.3)		43(82.7)		52(100.0)	0.523	0.469;NS
	Absent	28(13.4)		181(86.6)		209(100.0)		
Thrombocytopenia	Present	7(19.4)		29(80.6)		36(100.0)	0.953	0.329;NS
	Absent	30(13.3)		195(86.7)		225(100.0)NS		
PIH	Present	10(18.9)		43(81.1)		53(100.0)	1.203	0.273;NS
	Absent	27(13.0)		181(87.0)		208(100.0)		
Maternal anaemia	Present	16(16.8)		79(83.2)		95(100.0)	0.872	0.350;NS
	Absent	21(12.7)		145(87.3)		166(100.0)		

Table 4: Multi Variate Analysis

Predictor variable	B Value	Std Error	P-Value	OR	95% Confidence Interval	
					Lower	Upper
Birth weight	0.878	0.541	0.104:NS	2.407	0.834	6.949
Gestational Age	0.381	0.450	0.398:NS	1.464	0.605	3.539
Oxygen support > 5 Days	0.351	0.429	0.413:NS	1.421	0.613	3.294
Multiple births	0.849	0.424	0.045:S	2.337	1.018	5.362
PDA	2.471	1.017	0.015:S	11.386	1.612	86.89

In the present study RDS was the most prevalent risk factor among ROP positive babies 26 (70.27%), followed by Oxygen exposure for >5 days 19 (51%), sepsis 13 (35.31%), multiple births 12 (32.4%), anemia and blood transfusion 9 (24.32%), thrombocytopenia 7 (18.91%), PDA 2 (5.4%). Maternal risk factors found among ROP positive babies in the study were anemia 16 (43.2%) and PIH 10 (27.2%).

Among the above risk factors on univariate logistic regression analysis, birth weight <1700gms, GA<27wks, oxygen therapy >5 days, multiple pregnancies and Patent Ductus Arteriosus (PDA) were found to be dependent risk factors. On multivariate regression analysis, PDA and multiple

pregnancies were found to be independent risk factors with statistical significance.

In a study conducted by Gonzalez Viejo et al [7], "Is PDA a risk factor for Retinopathy of Prematurity", they evaluated a total of 131 premature infants, 79 with PDA and 52 without PDA. A statistically significant association was found between PDA and the occurrence of ROP. But on applying a multiple logistic regression model, the significance was lost. They concluded that PDA does not increase the risk of development of ROP. A study by E-John et al [8] reported that infants with PDA required ventilator support for a prolonged period. They also observed that all but one of more severe grades of ROP occurred among infants with PDA.

Infants born out of multiple gestation are prone to be premature and to have low BW, both of which are potential risk factors for ROP. "The relationship between multiple pregnancy and incidence of ROP" a study by M Motta et al [9] concluded that incidence of ROP was significantly higher in twins than in singletons. Riazi-Esfahani M et al [10], in their study "ROP: single versus multiple birth pregnancies", concluded that there was no statistically significant difference in the frequency and severity of ROP when compared between infants born of multiple gestation and singleton pregnancies. The Cryotherapy for ROP study [11] showed that the likelihood of developing threshold ROP disease to be 36% greater in multiple births. Multiple gestation was taken as an independent risk factor for ROP by Sood et al (12). A study by Kanugella Anudeep et al [13] found multiple gestation was not a statistically significant risk factor for the development of ROP. A study conducted at a tertiary care centre in Telangana by Crystal et al [1] found that the most prevalent prenatal risk factor was multiple gestation.

The incidence of multiple pregnancies is increasing all over the world because of assisted reproductive technology. According to some fertility experts, India is now witnessing a tenfold rise in twinning rates for the past two decades because of assisted reproductive technology, ovulation inducing drugs, increasing maternal age, with women delaying motherhood until they meet their educational and career goals.

In view of the above situation and also because of conflicting results from previous studies regarding the relation between multiple gestation and incidence of ROP further such studies are strongly recommended to arrive at an authentic conclusion.

Conclusion

Improved antenatal, perinatal and neonatal care, strict implementation of Oxygen therapy guidelines with proper monitoring, training programmes to improve ROP awareness among medical and paramedical personnel in NICUs and SNCUs, following updated screening criteria and protocols for ROP screening can all go hand in hand a long way in decreasing the incidence, early identification and effective management of ROP thereby leading to a decline in childhood blindness.

Strengths of the study: All babies were screened by a single trained ophthalmologist

Limitations:

- Critically ill babies and babies with poor chances of survival were not included in the study
- Lack of photo documentation
- Lack of long term follow up

Future Recommendations:

1. The present study is a unit based study. A comprehensive country based survey on ROP is recommended to determine any regional differences in disease prevalence.
2. The use of telemedicine systems with trained personnel may be the future for ROP screening
3. Universal newborn eye screening at delivery points and at SNCUs must be established to identify and manage ROP at an early stage.

Ethical considerations: The study has got Institutional Ethics and Scientific committee approval

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