ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

Original Research Article

"A STUDY OF INCIDENCE AND RISK FACTORS OF RETINOPATHY OF PREMATURITY IN A TERTIARY CARE MODERN GOVERNMENT MATERNITY HOSPITAL"

Dr. Talishetty Swathy[1], Dr. Swetha C[2], *Dr. CH Archana[3], Dr. Anita Sethi[4], Dr. Mudavath Pradeepraj Chowhan[5]

1. 2. 3. Assistant Professor, Department of Pediatrics, Osmania Medical College, Hyderabad.

4. Professor, Department of Pediatrics, Osmania Medical College, Hyderabad.

5. Post Graduate, Department of Pediatrics, Osmania Medical College, Hyderabad.

***Corresponding Author: Dr. CH Archana, Assistant Professor, Department of Pediatrics, Osmania Medical College, Hyderabad.**

ABSTRACT:

Background: Retinopathy of prematurity (ROP) is a significant cause of preventable blindness across both the developed and developing countries. Recent advancements in neonatal care have led to an increase in the survival of low birth weight infants, resulting in a rise of ROP incidence. Globally, ROP is estimated to affect more than 50,000 infants annually. In India, every year, 500 children are estimated to become blind from ROP.

AIM: To study the incidence of RETINOPATHY OF PREMATURITY and its risk factors in infants admitted at SNCU of a tertiary care maternity hospital.

MATERIAL & METHODS: Study Design: Prospective hospital based descriptional study. **Study area:** Special New-born Care Unit (SNCU) of Modern Government Maternity hospital. **Study Period:** Jan. 2020 - Dec. 2020. **Study population:** Preterm babies less than or equal to 34 weeks of gestational age, babies with weight less than or equal to 2 kgs and babies of any gestational age or weight with significant risk factors admitted in SNCU. **Sample size:** study consisted a total of 365 cases. **Sampling method:** Simple Random sampling method. **Study tools and Data collection procedure:** Babies admitted in SNCU with birth weight equal or less than 2 kg and preterm babies less than 34 weeks of gestational age, satisfying the inclusion criteria were enrolled into the study and admitted after getting informed consent from the parents/guardians. A detailed history and clinical examination were done for the study population and all the points were noted. The study population was evaluated further.

Results: Among the study population, babies who developed ROP were exposed to oxygen for longer duration. The association between the duration of exposure to oxygen and development of retinopathy was statistically significant with P value of 0.00001. The association between ROP and gestational age at birth was statistically significant.

CONCLUSION: The present study reflects the incidence of ROP and its risk factors in a SNCU. The incidence of ROP in the present study was 4.93%. Among the ROP cases, birth weight ranges between 1.42± 0.25 and it was significantly associated with development of ROP. Among the study population, babies born prematurely i.e., at lowest mean gestational age at birth had developed retinopathy.

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

Keywords: Retinopathy of prematurity**,** preventable blindness**,** exposure to oxygen

INTRODUCTION:

Retinopathy of prematurity (ROP) is a significant cause of preventable blindness across both the developed and developing countries. Recent advancements in neonatal care have led to an increase in the survival of low birth weight infants, resulting in a rise of ROP incidence. Globally, ROP is estimated to affect more than 50,000 infants annually. In India, every year, 500 children are estimated to become blind from ROP.[1]

While ROP may cause severe visual impairments, the condition fortunately carries a good prognosis, given early screening and management. Thus, an effective screening protocol is essential for timely detection and treatment of this avoidable disease.[2]

Moreover, there is a disparity between the profiles of ROP infants in developing countries versus developed countries, and no unified screening guidelines exist for ROP across the world. If current American and British screening guidelines for ROP infants were applied in India, a large proportion of Indian infants would be missed because heavier infants (>1500 g) are also at a risk for developing ROP.[3] The National Neonatology Forum recommends screening of all babies with birth weight < 2000g or gestational age < 34 weeks or infants 34 – 36 weeks of gestational age with risk factors at 4weeks of birth and for smaller babies with gestation less than 28 weeks or birth weight less than 1200g, at 2-3weeks of age. [4-5]

Early identification of retinal damage and the institution of appropriate treatment prevent blindness and offer child better overall development. [6] ROP is characterized by abnormal neovascular development in the retina of premature infants. These abnormal blood vessels are fragile and can leak or bleed, scarring the retina and pulling it out of position. This causes a tractional retinal detachment, which is the main cause of visual impairment and blindness in ROP. [7]

The stages of ROP describe the ophthalmoscopic findings at the junction between the vascularized and avascular retina; stage 1 is a faint demarcation line, stage 2 is an elevated ridge, stage 3 is an extraretinal fibrovascular tissue, stage 4 is a subtotal retinal detachment, while stage 5 is a total retinal detachment. In addition, plus disease, which indicates significant vascular dilation and tortuosity observed at the posterior retinal vessels, may be present at any stage and reflects the increased blood flow through the retina. [8]

Blindness due to ROP has an inherent economic burden on any country's GDP, the cost of screening and managing is much lower than the cost of productivity loss on the state exchequer. Hence the present study was undertaken to study the incidence, risk factors of ROP in preterm babies admitted to SNCU, tertiary care hospital.

AIM: To study the incidence of RETINOPATHY OF PREMATURITY and its risk factors in infants admitted at SNCU of a tertiary care maternity hospital

OBJECTIVES:

1. Estimate the incidence of ROP in preterm infants in the SNCU.
2. Identify the risk factors which predispose to ROP.

MATERIAL & METHODS:

Study Design: Prospective hospital based descriptional study.

Study area: Special New-born Care Unit (SNCU) of Modern Government Maternity hospital.

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

Study Period: Jan. 2020 - Dec. 2020.

Study population: Preterm babies less than or equal to 34 weeks of gestational age, babies with weight less than or equal to 2 kgs and babies of any gestational age or weight with significant risk factors admitted in SNCU.

Sample size: study consisted a total of 365 cases.

Sampling method: Simple Random sampling method.

Inclusion criteria:

● ≤34 weeks of gestation,

● ≤2000 g of birthweight

● Any Gestational age 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) Apneas, k) Poor postnatal weight gain

Exclusion criteria:

• Infants who died before sufficient number of eye examinations could be done to diagnose ROP.

• Infants who were lost to follow up before sufficient number of eye examinations could be done to either rule out ROP or see the progression/regression of established ROP.

• Congenital cataract, hazy cornea, abnormal anterior chamber.

• Parents or guardians who are not willing to give informed consent.

Ethical consideration: Institutional Ethical committee permission was taken prior to the commencement of the study.

Study tools and Data collection procedure: Babies admitted in SNCU with birth weight equal or less than 2 kg and preterm babies less than 34 weeks of gestational age, satisfying the inclusion criteria were enrolled into the study and admitted after getting informed consent from the parents/guardians. A detailed history and clinical examination were done for the study population and all the points were noted. The study population was evaluated further. They were evaluated for ROP. The following investigations were done:

 Complete blood count and all the baseline investigations

 Fundus evaluation by indirect ophthalmoscopy

The treatment and investigations were documented.

Statistical analysis:

The data was entered in Microsoft Excel 2010 version. Data was analyzed using Microsoft Excel 2010 and Epi Info 7.2.0. Descriptive and inferential statistical analysis were used in the present study. Results on continuous measurements were presented on Mean ± SD [Min-Max] and results on categorical measurements were presented in Number [%]. Significance was assessed at a 5% level of significance. Student t-test is used to compare inter-group variation for continuous variables.

OBSERVATIONS & RESULTS:

Among the study population, 63.56% had their birth weights between 1.51-2.0 kilograms, 35.89% had their birth weights between 1-1.5kilograms and 0.54% had their birth weight <1kilogram. Among the study population, males and females contributed an almost equal

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

share. Among the study population, 53.9% were LSCS, 46.02% were normal vaginal deliveries.

Table 1: showing apnea of prematurity

Apnea of Prematurity	Frequency	Percentage
No	317	86.84
Yes	48	13.15
Grand Total	365	100

Among the study population, 13.1% had history of apnea of prematurity.

Table 2: showing the presence of sepsis among study population

Sepsis	Frequency	Percentage
No	161	36.99
Yes	204	55.89
Grand Total	365	100.00

Among the study population, 55.89% had sepsis.

Table 3: showing the incidence of retinopathy:

ROP present	Frequency	Percentage
Couldn’t follow up	37	10.14
ROP present	18	4.93
Normal	310	84.93
Grand Total	365	100.00

Among the study population, 4.93% of them had developed ROP.

Table 4: showing the duration of exposure to oxygen

Oxygen	Frequency	Percentage
Not required	89	24.38
1	81	22.19
2	95	26.03
3	53	14.52
4	29	7.95

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

5	11	3.01
6	4	1.10
7	2	0.55
8	1	0.27
Grand Total	365	100.00

Table 5: showing the characteristic features/ risk factors of ROP babies:

Risk factor		Frequency	Percentage
Maternal factors (n=17)			
GA at delivery	<36+6 weeks	14	82.35
	37 weeks and above	3	17.65
Birth order	< or equal to 2	11	64.70
	>2	6	35.29
Mode of delivery	LSCS	7	41.17
	NVD	10	58.82
PIH	Present	4	23.2
	Absent	13	76.47
GDM	Present	0	0
Anemia	Present	12	70.58
	Absent	5	29.41
Multiple gestation	Present	7	41.17
	Absent	10	58.82
Fetal characteristics (n=18)			
Gender	Male	8	47.45
	Female	10	58.82

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

Antenatal steroid	Given	9	50.00
	Not given	9	50.00
Respiratory distress syndrome	Present	11	64.70
	Absent	7	41.17
TTNB	Present	3	17.64
	Absent	15	88.23
Apnea	Present	5	29.41
	Absent	13	76.47
Sepsis	Present	10	58.82
	Absent	8	47.45

Table 6: The association between oxygen duration and ROP

ROP	Frequency	Mean ± SD	T test P value
Normal	310	1.94±1.41	0.00001
Present	18	3.45± 1.54	

Among the study population, babies who developed ROP were exposed to oxygen for longer duration. The association between the duration of exposure to oxygen and development of retinopathy was statistically significant with P value of 0.00001.

Table 7: showing the association between birth weight and ROP

ROP	Frequency	Mean ± SD	ANOVA P value
Couldn't follow up	37	1.51 ± 0.33	<0.000001
Normal	310	1.69±0.24	
Present	18	1.42± 0.25	

Among the study population, babies with lowest mean birth weight had developed retinopathy. The association between ROP and birth weight was statistically significant.
Maternal risk factors like gestational diabetes mellitus and pre-eclampsia are not significantly associated with development of ROP. Anemia is significantly associated with development of ROP with P value of 0.02, 0.01 respectively.

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

Neonatal factors like RDS and sepsis were significantly associated with development of ROP with P value of 0.04.

DISCUSSION:

Significance of ROP screening lies in the fact that ROP is the most common cause of childhood blindness which is preventable. The primary prevention of ROP can be done by limiting the exposure to antenatal, natal and postnatal risk factors which are proposed to contribute to the increased incidence as well as severity of ROP. Secondary prevention of ROP is done by timely screening and early treatment to prevent blindness that can occur in severe ROP who miss the screening and are not treated. So, the secondary prevention of ROP is given utmost importance in the WHO VISION 2020 programme. [9]

In this era of improving standards of neonatal care, ROP is becoming a significant problem in developing countries like India. Though there are data from the different urban and rural areas of India, reports from large randomised multicentric trials are lacking from our country. So, there is a scarcity of data on the epidemiology of ROP from the Indian sub-continent. [10]

The incidence of ROP in the present study is 4.93% Various studies have shown that about 9.4%-25.4% of babies with gestational age 32 week or less develop some degree of ROP. The findings of the present study can be compared with the following studies:

Author	Incidence
Present study	4.93% of them had developed ROP.
Priyadarshini et al [11]	19.58 %.
Dwivedi A et al [12]	30%
Akher Ali et al [13]	16.36%
Kumar N et al [14].,,	16 %
Balakrishnan U [15].,,	18.45 %
Chaudhari S et al [16]	22.3%
Gupta VP et al [17].,,	21.7%
Patil J et al [18].,,	17.5%

Studies in the literature usually use a cut-off point of a BW of 1,250gm or 1,500gm or 1,750gm, a GA of 28wk or 32 wks., or both. Using a BW of 2000gms or less, a GA of 34 weeks or less, or both as criteria for inclusion in this study explains the similar incidence of ROP when compared to other Indian studies. The overall incidence of ROP in the present study is 4.93%.

Patil [18] et al reported the overall incidence of ROP as 17.5%. They studied 40 babies with <32wk or < 1250gm. Gupta et al [119] in 2003 reported overall incidence as 21.7%. They studied 60 babies with ≤ 35wk or ≤1500gm.

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

However, in most instances it is not possible to compare studies, as the inclusion criteria are different. The incidence of ROP in our study would have increased if the screening was done only in babies weighing <1300gm or in babies <32wk of GA at birth. Screening of babies with a GA of <34wk and/or 2000gm BW in this study have made the incidence of ROP comparable to other Indian studies.

In the present study, among the study population, the mean gestational age was 34.5 weeks with standard deviation of 2.39 weeks, ranging from 28 weeks to 40 weeks. Priyadarshini et al [11] found that the gestational age of infants studied had a range from 26 – 36 weeks. The mean of the gestational age was 31.89 weeks with a standard deviation of 2.46 weeks. Among the 97 infants studied, 29 (29.9 %) were ≤ 30 weeks, 54 (55.67 %) were between 30 – 34 weeks and 14 (14.43 %) were > 34 weeks. Dwivedi A et al [12] found that mean gestational age was 31.05±0.11. (Range 26-38 wks.) Compared to other studies gestational age in this study is more i.e., 34.5±2.39, as in this SNCU the babies with birth weight <1kg and babies who require ventilatory support will be shifted to paediatric tertiary care centre.

In the present study, Among the study population, 63.56% had their birth weights between 1.51-2.0 kilograms, 35.89% had their birth weights between 1-1.5kilograms and 0.54% had their birth weight <1kilogram. Priyadarshini et al [11] found that weight of infants studied ranged from 850 – 1980 gms with a mean weight of 1430.93 gms with a SD of ± 270.26 gms. Among the 97 infants enrolled 9 (9.3 %) were ≤ 1000 gms, 73 (75.25 %) were between 1000 – 1750 gms and 15 (15.46 %) were > 1750 gms.

The duration of oxygen administered was an independent risk factor for development of ROP. Preliminary work has suggested that continuous oxygen monitoring may reduce the incidence of ROP. In present study oxygen administration is a significant risk factor for development of ROP (p=0.0001). RDS is a significant risk factor in the present study. Gupta et al and associates reported ROP in 33.3% of babies with RDS. In our study, 42% of babies among cases had RDS, which is almost comparable to the other studies mentioned. Clinical Sepsis is an independent risk factor for ROP in the present study and corroborates with findings of other studies. Gupta et al in his study reported 52% sepsis among babies with ROP. [17] In the present study clinical sepsis was a risk factor 55.89% of the cases had clinical sepsis, but it was not an independent risk factor. Its prevention and early treatment may reduce the incidence of ROP.

In the present study, the factors significantly associated with development of ROP were low birth weight, low gestational age at birth, multiple gestations, exposure to oxygen and phototherapy for longer duration, RDS and sepsis and Maternal factors like anemia. Other maternal factors like pre-eclampsia, GDM and antenatal steroids are not significantly associated with ROP.

CONCLUSION:

The present study reflects the incidence of ROP and its risk factors in a SNCU. The incidence of ROP in the present study was 4.93%. Among the ROP cases, birth weight ranges between 1.42± 0.25 and it was significantly associated with development of ROP. Among the study population, babies born prematurely i.e., at lowest mean gestational age at birth had developed retinopathy. The association between ROP and gestational age at birth was statistically significant. RDS, Sepsis, and antenatal anemia were found to be significant risk factors. The treatment related risk factors associated with ROP are Oxygen therapy,

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

Phototherapy. Regular screening programme with a criteria of Gestational age <34 weeks and birth weight <2000gms and or both Gestational age>34 weeks and babies more than 2000gms with other risk factors should be screened at the discretion of the neonatologist and ophthalmologist.

REFERENCES:

1. Gilbert C. Retinopathy of prematurity: A global perspective of the epidemics, population of babies at risk and implications for control. Early Hum Dev 2008; 84:77-82.
2. Patwardhan SD, Azad R, Gogia V, Chandra P, Gupta S. Prevailing clinical practices regarding screening for retinopathy of prematurity among pediatricians in India: A pilot survey. Indian J Ophthalmol 2011; 59:427-30.
3. Vinekar A, Dogra MR, Sangtam T, Narang A, Gupta A. Retinopathy of prematurity in Asian Indian babies weighing greater than 1250 grams at birth: Ten-year data from a tertiary care center in a developing country. Indian J Ophthalmol 2007; 55:331-6.
4. National Neonatology Forum, India. Evidence-based Clinical Practice Guidelines. Available from: http:// www.nnfi.org/images/pdf/nnf_cpg_consolidated_file january102011. pdf. Accessed September 26, 2014.
5. Rashtriya Bal Swasthya Karyakram. Guidelines for Universal Eye Screening in Newborns Including Retinopathy of Prematurity 2017 Ministry of Health and Family Welfare, Government of India. [Last accessed on 2019 Sep 25]. Available from: https://wwwnhmgovin/images/pdf/programmes/RBSK/Resource_Documents/Revised_ROP_ Guidelines-Web_Optimizedpdf.
6. Fanaroff AA, Martin RJ, editors. Neonatal perinatal medicine. 7 th ed. Louis: Mosby; 2002. p. 676-745.
7. Azad R, Chandra P. Retinopathy of prematurity. J Indian Med Assoc 2005; 103:370-2.
8. International Committee for the Classification of Retinopathy of Prematurity. The International Classification of Retinopathy of Prematurity revisited. Arch Ophthalmol 2005; 123:991-9.
9. Gilbert C, Foster A. Childhood blindness in the context of vision 2020- the right to sight. WHO Bulletin 2001; 79:227-32.
10. Agarwal R, Ashok K, Deorari R, Azad V, Kumar H, Talwar, D, et al. Changing profile of retinopathy of prematurity. J Tropical Pediatrics 2002; 48:239-42.
11. Priyadarshini D, Devi S, Panda P. Prospective study on prevalence of retinopathy of prematurity in Ganjam District. J Evid Based Med Healthc 2021;8(03):120-125.
12. Dwivedi A, Dwivedi D, Lakhtakia S, Chalisgaonkar C, Jain S. Prevalence, risk factors and pattern of severe retinopathy of prematurity in eastern Madhya Pradesh. Indian J Ophthalmol 2019; 67:819-23.
13. Akher Ali. Retinopathy of Prematurity: Incidence and Risk Factor: A Hospital Based Study. ǁ IOSR Journal of Dental and Medical Sciences (IOSR-JDMS),2019; 18(7); 05-12
14. Kumar N, Kaushik SL, Grover N, Sharma RL. Retinopathy of prematurity: incidence and risk factors: a hospital based study from Shimla, Himachal Pradesh, India. International Journal of Research in Medical Sciences. 2016 Dec 19;5(1):56-61.
15. Balakrishnan U, Shaik SJ, Manian N, Muthukumar M, Thomas M, Amboiram P, Ninan B, Chandrasekaran A, Ramaswamy S. Screening based on incidence of severe retinopathy of

ISSN: 0975-3583, 0976-2833 VOL13, ISSUE 07, 2022

prematurity in a tertiary care center in India: are Indian infants different? International Journal of Contemporary Pediatrics. 2016 Dec 21;3(3):847-53.
16. Chaudhari S, Patwardhan V, Vaidya U, Kadam S, Kamat A. Retinopathy of prematurity in a tertiary care center--incidence, risk factors and outcome. Indian pediatrics. 2009 Mar 1;46(3).
17. Gupta VP, Dhaliwal U, Sharma R, Gupta P, Rohatgi J. Retinopathy of prematurity—risk factors. The Indian Journal of Pediatrics. 2004 Oct 1;71(10):887-92.
18. Patil J, Deodhar J, Wagh S, Pandit AN. High risk factors for development of Retinopathy of Prematurity. Indian Pediatrics 1997; 34:1024-7.