

Retinopathy of Prematurity: Incidence and Risk Factor: A Hospital Based Study

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Abstract: Background: Retinopathy of prematurity (ROP), which was previously called as Retrolental Fibroplasia (RFL), is a vaso-proliferative disorder of the retina. Preterm low birth weight infants are more prone for this disease those are exposed to large amount of Oxygen.

Objectives: To study the incidence of ROP in preterm infants with a gestational age of ≤ 32 weeks or a birth weight of less than 1500 grams admitted to NICU for a period of 1 year. To identify the risk factor which could influence the development of ROP.

Methods: This was a prospective observational study, conducted at NICU, Gauhati Medical College, Guwahati, from 1st July 2017 to 30th June 2018.

Result: Out of 347 admission to NICU, 122 satisfied inclusion criteria. 20 babies developed any stage of ROP and 102 babies who did not develop ROP were termed as NON ROP. The mean birth weight among ROP was calculated 1178.70 ± 309.513 gm and NON ROP was 1288.69 ± 148.447 gm. Overall incidence of ROP in this study was 16.39%. Statistical analysis showed Birth weight ($p < 0.001$), Gestational age ($p < 0.016$), Oxygen supplementation ($p = 0.000$), Apnea ($p < 0.001$), Sepsis ($p = 0.009$), Anemia needing blood transfusion ($p = 0.0329$), CPAP ($P = 0.000$) were found risk factor for developing ROP. However Surfactant therapy, Mechanical Ventilation and Phototherapy were found insignificant.

Conclusion: The timely retinal screening in high-risk preterm infants is important to prevent the development of ROP and its complications.

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I. Introduction

Retinopathy of prematurity (ROP) is a vasoproliferative disorder of the retina among premature babies. ROP begins to develop between 32 and 34 weeks after conception, regardless of gestational age at delivery and has two distinct phases. During the acute first phase, the normal vasculogenesis of the retina is disturbed by the relative hyperoxia of the extrauterine environment. This causes vaso-obliteration and non-vascularization of some areas of the anterior retina. The subsequent hypoxia causes a second chronic phase, characterized by the proliferation of vascular and glial cells, arteriovenous shunt formation, occasionally leading to involution or permanent cicatricial changes and visual impairment. It is the major cause of preventable blindness in infants. Spectrum of ROP is broad and ranges from a spontaneously recovering stage to a vision threatening sequelae. In infants with birth weight less than 1000 grams, the risk of ROP is 82%, and 9.3% of them are potentially under the risk of blindness.¹

The pathogenic process involved in causation of ROP is multifactorial. It is attributed to many possible risk factors like prematurity, hyperoxia, sepsis, necrotizing enterocolitis, intraventricular hemorrhage (IVH), low birth weight (LBW), prolonged exposure to Oxygen, severity of neonatal illnesses, severe respiratory distress requiring mechanical ventilation, shock, hypoxia, prolonged ventilatory support, need for blood transfusion, acidosis, anemia, high ambient light and vitamin E deficiency.

Screening programs in India are inadequate because of lack of trained manpower, infrastructure, non-referral from paediatricians and lack of awareness about the disease in general.

The present study was conducted in Gauhati Medical College, Neonatal Intensive Care Unit (NICU) with the following aims and objectives:

1. To study the incidence of ROP in preterm infants with a gestational age of ≤ 32 weeks or a birth weight of less than 1500 grams admitted to the Neonatal Intensive Care Unit (NICU), Gauhati Medical College and hospital for a period of 1 year.
2. To identify the risk factor which could influence the development of ROP.

II. Material And Methods

Study Design: A prospective observational study.

Place of Study: The study was conducted at Neonatal Intensive Care Unit (NICU) under the Department of Paediatrics Gauhati Medical College and Hospital.

Duration of Study: Study was carried out for a period of one year from 1st of July 2017 to 30th June 2018.

Study Population: All babies admitted in NICU, Gauhati Medical College and Hospital who were ≤ 32 weeks gestation or with birth weight < 1500 grams during study period were screened.

Consent and Ethical Clearance: Informed consent of parents was taken after explaining in detail about procedure involved in the present study. Ethical clearance was obtained.

Inclusion Criteria:

- Babies with birth weight < 1500 gm
- Babies born at ≤ 32 weeks of gestation
- Selected preterm infants with a birth weight between 1500 and 2000g or gestational age of more than 32 weeks with sickness like-
 - ❖ need of cardiorespiratory support
 - ❖ prolonged oxygen therapy
 - ❖ apnea of prematurity
 - ❖ anemia needing blood transfusion and neonatal sepsis or believed by their attending pediatrician or neonatologist to be at high risk.

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.
- Consent not given

Preparation and Precautions:

During examination, all the precautions were taken as per the AAP 2013 guidelines.² Babies were fed at least one hour before examination to avoid vomiting and aspiration. Hand washing was done and asepsis maintained before examination. Trained person in neonatology was available throughout the procedure in anticipation of any complications.

Dilatation of the Pupil: Pupils were dilated with Phenylephrine 2.5% and Tropicamide 0.5%. One drop of Tropicamide was instilled every 10-15 minutes for 4 times starting 1 hour before the scheduled time for examination. This was followed by Phenylephrine, one drop just before examination.

Instruments used: Indirect ophthalmoscope with 20D lens, pediatric wire speculum, scleral indenter.

First Examination and follow up:

The first indirect ophthalmoscopic examination was performed in NICU at 3-4 weeks of chronological age or 32 weeks post conceptional age whichever was later by ophthalmologist. If no ROP was detected at initial examination the infants were re-evaluated every 2 weeks until complete vascularization of retina.

Procedure:

The Screening of ROP involves indirect ophthalmoscopy using 20D or 28/30D lens by an experienced ophthalmologist. After instilling a topical anesthetic drop like Proparacaine, a wire speculum is inserted to keep the eye-lids apart. First the anterior segment of the eye is examined to look for tunica vasculosa lentis, pupillary dilation, and lens / media clarity; followed by the posterior pole to look for plus disease; followed by sequential examination of all clock hours of the peripheral retina. A sclera depressor is often used to indent the eye externally to examine areas of interest, rotate and stabilize the eye. Ophthalmological notes should be made after each ROP examination, detailing zone, stage and extent in terms of clock hours of any ROP and the presence of any pre-plus or plus disease. These notes should include a recommendation for the timing of the next examination (if needed) and be kept with the baby's record. Details of ROP were recorded in the proforma as per International Classification of ROP (ICROP) as shown in figure below-

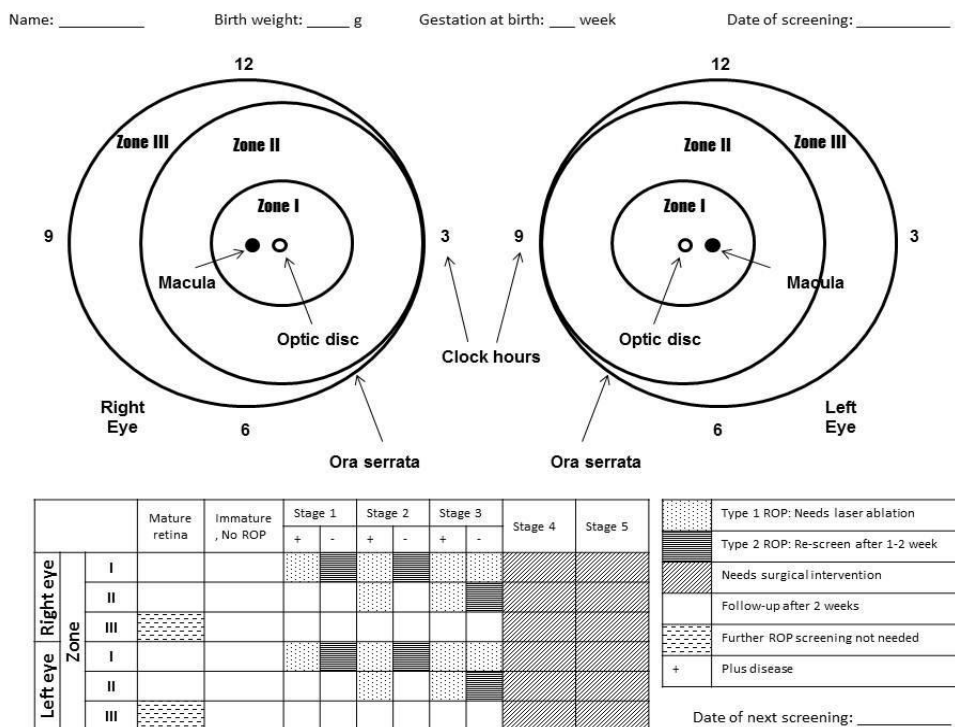


FIGURE 1: Retinopathy of Prematurity Screening record

Statistical Methods: A prospective analysis was done on the data available to identified risk factors associated with ROP and Non ROP infants. The Excel, INSTAT.EXE, SSPS software (Version 21.0) were used for data entry and analysis. P value <0.05 is statistically significant.

III. Results And Observations

The present study was conducted at the NEONATAL INTENSIVE CARE UNIT (NICU) of GAUHATI MEDICAL COLLEGE AND HOSPITAL, Guwahati, Assam from 1st July 2017 to 30th June 2018. Of the total 347 admission to NICU, 122 babies (35.15%) satisfied the inclusion criteria and were enrolled in present study. Neonates who developed any stage of ROP were considered as ROP and the neonates without ROP were considered as NON ROP.

Table 1: Incidence of ROP among Study Subjects (N = 122)

In the present study, the overall incidence of ROP was 16.36% (20 babies). Among these 15 babies(75.00%) had stage 1 ROP, 1 baby(5.00%) had stage 2, 1 baby(5.00%) had stage 3, 1 baby(5.00%) had stage 1+, 1 baby(5.00%) had stage 2+, 1 baby(5.00%) had stage 3+ respectively.

	Number	Percentage
Non ROP	102	83.60%
ROP	20	16.39%
Stage 1	15	75.00%
Stage 2	1	5.00%
Stage 3	1	5.00%
Stage 1+	1	5.00%
Stage 2+	1	5.00%
Stage3+	1	5.00%

Table 2: Analysis of Neonatal Risk Factors And ROP

PARAMETER	RESPONSE	ROP	NON ROP	P VALUE
BIRTH WEIGHT IN GRAMS	MEAN	1178.70	1288.69	<0.001(SIGNIFICANT)
	STANDARD DEVIATION	309.513	148.447	
GESTATIONAL AGE (IN WEEKS)	MEAN	29.25	30.73	<0.016(SIGNIFICANT)
	STANDARD DEVIATION	1.618	1.260	
OXYGEN SUPPLEMENTATION IN DAYS	YES	19	45	0.000(SIGNIFICANT)
	NO	1	57	
APNEA	YES	13	19	<0.001(SIGNIFICANT)

	NO	7	83	
SEPSIS	YES	7	12	0.009(SIGNIFICANT)
	NO	13	90	
ANEMIA NEEDING BLOOD TRANSFUSION	YES	5	6	0.0329 (SIGNIFICANT)
	NO	15	96	
CPAP	YES	13	21	0.000(SIGNIFICANT)
	NO	7	81	
MECHANICAL VENTILATION	YES	2	3	0.145(NOT SIGNIFICANT)
	NO	18	99	
SURFACTANT THERAPY	YES	5	19	0.512 (NOT SIGNIFICANT)
	NO	15	83	
PHOTOTHERAPY	YES	4	22	0.876 (NOT SIGNIFICANT)
	NO	16	80	

IV. Discussion:

Incidence ROP: The overall incidence of ROP in the present study was 16.39%. The overall incidence of ROP found in various Indian studies and from various international studies were 17.5% to 51.9% and 10.0% to 45.4% respectively.^{3, 4, 5, 6}

Table 3: Incidence of ROP In Various Indian Studies.

AUTHOR / YEAR	GESTATIONAL AGE(IN WEEKS)	BIRTH WEIGHT(IN GRAMS)	INCIDENCE OF ROP
Maheshwari R/1996 ³	<35	<1500	20%
Patil J / 1997 ⁷	<32	<1250	21.7%
Gupta VP/2004 ⁸	<32	≤1700	21.7%
Chaudhari S/2009 ⁹	<32	<1500	22.3%
Balakrishnan U/ 2016 ¹⁰	<34	≤1750	18.45
Kumar N /2017 ¹¹	<35	<1500	16.00%
Present study	<32	<1500	16.39%

Table4: Showing Incidence of ROP in Various International Studies.

INTERNATIONAL STUDIES	GESTATIONAL AGE(IN WEEKS)	BIRTH WEIGHT(IN GRAMS)	INCIDENCE
	≤32	≤1500	25.4%
Nair P /2003 ¹²			
Fortes Filho JB/2009 ¹³	<32	<1500	24.2%
Lomuto CC/2010 ¹⁴	<32	<1500	26.2%
Mitsiakos G/2016 ¹⁵	<32	<1500	15.06%
Yau GS/2016 ¹⁶	<32	<1500	18.5%

Significant Risk Factors of Various Studies: Following risk factors were discussed with other studies as follows-

1. Birth Weight and Gestation:

Table 5:

Author/year	Parameter	NON ROP		ROP		P value
		n	%	n	%	
Rao KA/2013 ¹⁷	Birth weight(in grams)	≤999	14		14	<0.001
		1000-1249	49		23	0.001
		1000-1500	85		17	0.12
		>1500	73		7	-
	Gestational age (weeks)	≤30	38		21	<0.001
		31-32	78		29	0.001
>32		105		11	-	
Shivaprasad B /2014 ¹⁸	Birth weight(in grams)	<1000	5	5.7%	5	38.5%
		1001-1500	42	48.3%	6	46.2%
		1501-1750	40	46.0%	2	15.4%
	Gestational age(weeks)	24-28	1	1.1%	4	30.8%
		28-33	47	54.0%	8	61.5%
		33-35	39	44.8%	1	7.7%
Vijayalaxmi Gagandeep/2016 ¹⁹	Birth weight(in grams)	<1000(3)	1		2	0.002
		1000-1500(149)	119		30	
		>1500(42)	41		1	
	Gestational	≤32	100		28	0.01

Present Study	age(weeks)	>32	61		5		
	Birth weight(in grams)	<1000	2	1.96%	6	30%	<0.001
		1000-1499	89	87.25%	12	60%	
		1500-2000	11	10.78%	2	10%	
	Gestational age(weeks)	27	0		2		0.030
		28	4		6		0.0041
		29	15		4		0.7422
		30	20		4		1.000
		31	32		2		0.165
32		25		1		0.125	
	33	6		1		1.000	

2. Other Risk Factors are Discussed with Various Studies as Follows-

(A) Oxygen Therapy:

Table 6(A):

Author/Year	Oxygen Therapy				
	ROP		NON ROP		P Value
	N	%	N	%	
Rekha S/1996 ⁴	46		54		0.005
Chaudhuri S/2009 ⁹		64.5%		39.7%	0.031
Shivaprasad. B/2014 ¹⁸	10	76.9%	35	40.2%	0.013
Kumar N/2017 ¹¹	8		25		0.027
Vasavada D/2017 ²⁰	45	83%	140	63%	0.004
Ahuja AA/ 2018 ²¹	40		12		0.01
Present Study	19		45		0.000

(B) Duration Of Oxygen Therapy:

Table 6(B):

Author/year	Mean duration of Oxygen(in days)		P value
	ROP	NON ROP	
Shah VA /2005 ²²	55.8±75.6	10.4±22.1	0.0001
Freitas AM /2018 ²³	27	6	<0.001
Bas AY/2018 ²⁴	65±53	10±23	<0.001
Present study	7.74±2.725	1.50±2.062	<0.001

(C) Mean Of Maximum SpO₂:

Table 6(C):

Author/year	ROP		NON ROP		P value
	Mean of Maximum SPO ₂ (%)	Standard Deviation	Mean of Maximum SPO ₂ (%)	Standard Deviation	
Shetty SP/2015 ²⁵	97.429	3.780	99.212	1.152	0.01
Present Study	95.26%	1.195	93.56%	2.062	0.001

(D) Apnea:

Table 7:

Author/year	Apnea				P value
	ROP		NON ROP		
	n	%	n	%	
Rekha S/1996 ⁴					0.001
Chaudhuri S/2009 ⁹		38.4%		10.7%	0.0001
Rao KA/2013 ¹⁷	10		16		0.03
Shivaprasad B/2014 ¹⁸	6	46.2%	7	8.0%	<0.001
Sneha R/2014 ²⁶	7	19.4%	4	7.4%	0.108
Kumar N/2017 ¹¹	1		4		0.797
Present Study	13		19		<0.001

(E) Sepsis

Table 8:

Author /year	Sepsis				P value
	ROP		NON ROP		
	n	%	n	%	
Rekha S/1996 ⁴					0.04
VAShah/2005 ²²	42	25.5%	32	8%	0.0001
Chaudhuri S/2009 ⁹		22.0%		11.4%	0.001

Rao KA/2013 ¹⁷	7		19		0.03
Kapoor R/2014 ²⁷	13	35.1%	24	64.9%	0.0001
Sneha R/2014 ²⁶	17	31.4%	18	50%	0.122
Shivaprasad B/2014 ¹⁸	6	46.2%	8	9.2%	<0.001
Kumar N/2017 ¹¹	6		26		0.68
Freitas AM/2018 ²³	165	83.5%	285	71.6%	0.001
Present Study	7	35%	12	11.76%	0.009

(F) Anemia Needing Blood Transfusion:

Table 9:

Author/year	Blood transfusion				
	ROP		NON ROP		P value
	n	%	n	%	
Al-Essa M/1999 ²⁸	55	93%	56	79%	0.025
Chaudhuri S/2009 ⁹		23.6%		14.2%	0.125
Rao KA/2013 ¹⁷	13		17		0.002
Present Study	5	25%	6	5.88%	0.0329

(G) Cpap

Table 10:

Author/year	CPAP				P value
	ROP		NON ROP		
	n	%	n	%	
Chaudhuri S/2009 ⁹		68.9%		67.4%	0.578
Shivaprasad B/2014 ¹⁸	3	23.1%	15	17.2%	0.000
Present Study	13	65%	21	20.59%	<0.001

(H) Mechanical Ventilation(Mv):

Table 11:

Author/year	Mechanical Ventilation				P value
	ROP		NON ROP		
	n	%	n	%	
ChaudhuriS/2009 ⁹		41.7%		24.8%	0.031
Chen M/2011 ²⁹	48		20		0.0106
Vijayalaxmi Gagandeep/2016 ¹⁹		5	16		0.365
Present Study	2	10.0%	3	2.94	0.145

(I) Surfactant Administration

Table 12:

Author/year	Surfactant therapy				P value
	ROP		NON ROP		
	n	%	n	%	
VA Shah/2005 ²²	41	24.9%	59	14.8%	0.037
Vander Merwe SK/2013 ³⁰	7	50%	110	33.5%	0.2035
Kumar N/2017 ¹¹	1		7		0.768
Dhillon SP /2017 ³¹	1		2		0.447
Present Study	5		19		0.512

(J) Phototherapy:

Table 13:

Author/year	Phototherapy				P value
	ROP		NON ROP		
	n	%	n	%	
Al-Essa M/1999 ²⁷	56	95%	60	84.5%	0.08
Sneha R/2014 ²⁶	22	61.1%	24	44.4	0.137
Vijayalaxmi Gagandeep/2016 ¹⁹	12		59		1
Dhillon SP/2017 ³¹	3		19		0.598
Present Study	4		22		0.876

The present study was discussed with various other studies as mentioned in above tables. The present study correlates well with other studies.

Mechanical Ventilation, Surfactant therapy and phototherapy were not found statistically significant risk factors of ROP in present study.

V. Conclusion:

The incidence of ROP in present study was 16.39%. A treatment was performed in 20% of ROP cases. ROP remains a major complication in pre-mature newborns despite all the advances that have been made in recent years. The excellence in neonatal care, screening and early treatment of ROP are keys to prevent vision loss induced by this disease. It is mandatory to do ophthalmological check up of those newborns who have satisfied the criteria.

In present study the most significant risk factors to development of ROP were low birth weight, low gestational age, need for oxygen therapy, neonatal sepsis, apnea of prematurity, need of cardiopulmonary support (CPAP), and anemia needing blood transfusion. However, phototherapy, use of surfactant, MV were not seen significantly associated with ROP in present study.

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