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Prevalence, Risk Factors And Outcome Of Retinopathy Of Prematurity In A Tertiary Care Neonatal Intensive Care Unit.

Kanchankumar Bhagyawant*, Ravinder Reddy Lotkal, and Varadharajan Venkatramani.

[1]Associate Professor, Department of Paediatrics, Zydus Medical College & Hospital, Dahod, Gujrat, India.
[2]Resident, Department of Paediatrics, Ruby Hall Clinic, Pune, Maharashtra, India.
[3]Senior Consultant Paediatrician, Department of Paediatrics, Ruby Hall clinic, Pune, Maharashtra, India.

ABSTRACT

Retinopathy of prematurity (ROP) is a vision threatening disease associated with abnormal retinal vascular development in neonates with risk factors like prematurity, low birth weight and exposure to large amount of oxygen. We studied the prevalence, risk factors, and outcomes of newborns admitted to the Neonatal Intensive Care Unit (NICU) over a 21-month period in this study and tried to discuss preventive measures. We studied 70 preterm babies who were at risk of developing ROP. Prevalence of ROP in this study was 52.9% which was more compared to previous studies. Gestational age and birth weight were found to be the most significant risk factors for developing ROP and oxygen therapy, RDS, sepsis and blood transfusion were other independent risk factors. Regarding the treatment, out of 37 ROP cases, 11 cases required treatment, 9 (24.3%) cases required laser treatment, 1 (2.7%) case required Bevacizumab and 1 (2.7%) case required both laser and Bevacizumab and 26 cases regressed on their own.

Keywords: Retinopathy of prematurity, prematurity, low birth weight, risk factors, respiratory distress syndrome

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Corresponding author

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INTRODUCTION

Retinopathy of prematurity (ROP) is a vision threatening disease associated with abnormal retinal vascular development in neonates with risk factors like prematurity, low birth weight and exposure to large amount of oxygen [1,2] Breastfeeding has been suggested to have a protective effect against a number of risk factors, including apnoea, intraventricular haemorrhage, respiratory disorders, sepsis, vitamin E deficiency, heart disease, hypercarbia, increased O2 consumption, decreased PH, decreased blood O2, bradycardia, blood transfusion, amount of oxygen received, prolonged ventilation, postnatal weight gain, and hyperglycaemia [3,4].

Preterm babies' retinas are either avascular or partially vascular at birth because the development of the embryonic retinal arteries begins in the third month of pregnancy and continues until birth, resulting in abnormal stages of the development of the eye in preterm babies. ROP development can take up to 4–5 weeks after birth, during which we can do retinal examinations and interventions to prevent irreversible damage because of retinal detachment and to enhance visual outcomes [5]. The fact that ROP can progress rapidly and that treatment must be started as soon as possible to maximise chances of success, timing is one of the most critical components of treatment success. These days, the disease is under control owing to better maternity and newborn care, ROP screening recommendations, early detection, and timely intervention [6].

Laser photo ablation of the non-vascularized, immature retina is currently the standard of care for ROP [7]. The treatment options for ROP include cerclage, laser photocoagulation, parsplana vitrectomy, cryotherapy, and the use of drugs that block vascular endothelial growth factor (VEGF) and vitamin E supplementation as a preventive measure, according to CRYO-ROP and Etrops research. Even after ROP screening, it's crucial to monitor premature children since they may develop amblyopia, reactive abnormalities, myopia, glaucoma, retinal detachment, and a higher chance of strabismus [8]. We studied the prevalence, risk factors, and outcomes of newborns admitted to the Neonatal Intensive Care Unit (NICU) over a 21-month period in this study and tried to discuss preventive measures.

MATERIALS AND METHODS

Study Design

Prospective observational study.

Study Period

This study was conducted from 1st August 2018 to 30th April, 2020 in a tertiary care centre.

Study Sample

This study being time bound for 21 months only, 70 new born admitted at tertiary level neonatal intensive care unit that were screened for ROP were included in the study.

Inclusion Criteria

- Babies admitted with gestational age ≤34weeks or babies with birth weight ≤1750grams.
- Babies between 1750-2000grams or gestational age 34-36weeks, who are at higher risk of developing ROP like respiratory distress syndrome, sepsis, multiple blood transfusions, multiple births apnoeic episodes and intraventricular haemorrhage.

Exclusion Criteria

- Babies with suspected chromosomal anomalies.
- Babies who died before full vascularisation of the retina.

Details of the antenatal history, perinatal risk factors and the predisposing risk factors for the ROP were noted in the predefined proforma along with detailed treatment history.
Local eye examination: (done by single specialized retinal surgeon)

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The first screening was carried out in NICU not later than 4 weeks of age or 28 days postnatal under all aseptic precautions and following as per the guidelines of National Neonatology Forum of India [9]. Infants <28 weeks or <1200 grams birth weight was screened early at 2-3 weeks of age to enable early identification of Aggressive posterior ROP (AP-ROP). Subsequent examinations were done at 2-3 weeks interval or even earlier, if necessary, till retina is fully vascularised. Classification of ROP was done according to the International classification (ICROP). The entire data analysed using statistical methods.

RESULTS

Table 1: Distribution of sex of neonates studied

Of 70 cases studied, 37(52.9%) were male and 33(47.1%) were female.

Table 1: Distribution of sex of neonates studied

Sex	Number of cases	Percentage of cases (%)
Male	37	52.9
Female	33	47.1
Total	**70**	**100.0**

Table 2: Distribution of birth weight of neonates studied

Of 70 cases studied 1 (1.4%) was birth weight less than 1000 gm (ELBW category), 13 (18.6%) birth weight between 1000 – 1499 gm (VLBW category), 54 (77.1%) birth weight between 1500 – 2499 gm (LBW category) and 2 (2.9%) were birth weight more than 2500 gm (Normal birth weight category).

Table 2: Distribution of birth weight of neonates studied

Birth weight(gm)	Number of cases	Percentage of cases (%)
<1000(ELBW) 1000–1499(VLBW) 1500–2499(LBW) ≥2500(Normal)	1 13 54 2	1.4 18.6 77.1 2.9
Total	**70**	**100.0**
Mean ± SD [Birth weight (gm)]	**1718.0± 365.6**	
Min–Max [Birth weight (gm)]	**860.0– 2700.0**	

Table 3: Distribution of gestational age in the study group.

Of 70 cases studied, 5 (7.1%) had gestational age below 30 weeks, 44 (62.9%) had gestational age between 30 – 34 weeks and 21 (30.0%) had gestational age between 34 – 36 weeks. The distribution of mean ± SD of gestational age was 32.7 ± 1.7 weeks and the minimum –maximum range was 27.7 – 35.4 weeks.

Table 3: Distribution of gestational age in the study group

Gestational age(weeks)	Number of cases	Percentage of cases (%)
≤30.00 30.00– 34.00 34.00– 36.00	5 44 21	7.1 62.9 30.0
Total	**70**	**100.0**
Means [Gestational age (weeks)]	**32.7±1.7**	
Min–Max [Gestational age (weeks)]	**27.7–35.4**	

Table 4: Distribution of duration of O2 therapy given in the study group.

Out 47 patients who required O2 therapy, 16 (34.0%) had duration less than 1 week and 31 (66.0%) had duration more than 1 week.

Table 4: Distribution of duration of O2 therapy given in the study group

DurationofO2therapy required	Number of cases	Percentage of cases (%)
<1week	16	34.0
≥1week	31	66.0
Total	**47**	**100.0**

Table 5: Distribution of maternal risk factors in the study group.

Of 70 cases studied, 54 (77.1%) did not have and risk factor, 7 (10.0%) had PIH, 8 (11.4%) had GDM and 1 (1.4%) had PIH as well as GDM.

Table 5: Distribution of maternal risk factors in the study group

Maternal risk factors	Number of cases	Percentage of cases (%)
Nil	54	77.1
PIH	7	10.0
GDM	8	11.4
PIH+ GDM	1	1.4
Total	**70**	**100.0**

Distribution of mode of delivery: Of 70 cases studied, 3 (4.3%) had normal mode of delivery and 67 (95.7%) had LSCS mode of delivery.

Table 6: Distribution of neonatal risk factors in the study group.

Of 70 neonates studied, 18 (25.7%) had apnoea, 10 (14.3%) had sepsis, 1 (1.4%) had birth asphyxia, 39 (55.7%) had respiratory distress syndrome, 4 (5.7%) had intraventricular haemorrhage, 47 (67.1%) required O2 therapy, 6 (8.6%) required blood transfusion and 3 (4.3%) required exchange transfusion. Out of 47 neonates who required O2 therapy, 31 (64.0%) had duration of O2 therapy more than 1-week.

Table 6: Distribution of neonatal risk factors in the study group

Neonatal risk factors	Number of cases	Percentage of cases (%)
Apnea	18	25.7
Sepsis	10	14.3
Birth asphyxia	1	1.4
Respiratory distress syndrome	39	55.7
Intraventricular hemorrhage	4	5.7
O2therapy required	47	67.1
Duration of O2 therapy (≥1week)	31	66.0
Blood transfusion required	6	8.6
Exchange transfusion required	3	4.3

Table 7: Distribution of prevalence of ROP in the study group

37(52.9%) patients had the ROP.

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Table 7: Distribution of prevalence of ROP in the study group

ROP	Number of cases	Percentage of cases (%)
Absent	33	47.1
Present	37	52.9
Total	**70**	**100.0**

Table 8: Distribution of prevalence of stage of ROP in the study group.

Out of 37 cases with ROP, 2 (5.4%) had stage 2, 21 (56.8%) had stage 2 and 14 (37.8%) had stage 3 ROP.

Table 8: Distribution of prevalence of stage of ROP in the study group

Stage of ROP	Number of cases	Percentage of cases (%)
Stage 1	2	5.4
Stage 2	21	56.8
Stage 3	14	37.8
Total	**37**	**100.0**

Table 9: Distribution of prevalence of zone of ROP in the study group.

Out of 37 cases studied, 1 (2.7%) had zone 1 involvement, 31 (83.8%) had zone 2 involvement and 5(13.5%) had zone 3 involvement in the study group. One (2.7%) had aggressive posterior ROP (APROP) in the study group.

Table 9: Distribution of prevalence of zone of ROP in the study group.

Zone of ROP	Number of cases	Percentage of cases (%)
Zone 1	1	2.7
Zone 2	31	83.8
Zone 3	5	13.5
Total	**37**	**100.0**

Table 10: Univariate analysis of general risk factors of ROP.

Distribution of prevalence of ROP differs significantly across various gestational age groups in the study group (P-value<0.001).Significantly higher proportion of cases with gestational age less than 34weeks had higher prevalence of ROP compared to group of cases with gestational age between 34–36 weeks (P-value<0.01).

Table 10: Univariate analysis of general risk factors of ROP

		No ROP(n=33)		ROP(n=37)		Total(n=70)		
Risk factors		**n**	**%**	**n**	**%**	**n**	**%**	**P-value**
Gestational age(weeks)	≤30.00	0	0.0	5	100.0	5	100.0	0.002**
	30.00– 34.00	17	38.6	27	61.4	44	100.0	
	34.00– 36.00	16	76.2	5	23.8	21	100.0	
Maternal risk factors	Nil	29	53.7	25	46.3	54	100.0	0.161NS
	PIH	1	14.3	6	85.7	7	100.0	
	GDM	3	37.5	5	62.5	8	100.0	
	PIH+ GDM	0	0.0	1	100.0	1	100.0	
Mode of delivery	Normal	1	33.3	2	66.7	3	100.0	0.999NS
	LSCS	32	47.8	35	52.2	67	100.0	
P-value by Chi-Square test. P-value<0.05 is considered to be statistically significant.***P-Value<0.001, NS–Statistically non-significant.								

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Distribution of prevalence of ROP did not differ significantly across various maternal risk groups in the study group (P-value>0.05).

Distribution of prevalence of ROP did not differ significantly between group of women with normal delivery and group of women with LSCS mode of delivery in the study group (P-value>0.05).

Table 11 A and B: Univariate analysis of neonatal risk factors of ROP.

Table 11 A: Univariate analysis of neonatal risk factors of ROP

		No ROP(n=33)		ROP(n=37)		Total(n=70)		
Neonatal Risk Factors		**N**	**%**	**n**	**%**	**n**	**%**	**P-value**
Birth weight(gm)	<1000(ELBW)	0	0.0	1	100.0	1	100.0	0.025*
	1000–1499(VLBW)	2	15.4	11	84.6	13	100.0	
	1500–2499(LBW)	29	53.7	25	46.3	54	100.0	
	≥2500(Normal)	2	100.0	0	0.0	2	100.0	
Sex	Male	16	43.2	21	56.8	37	100.0	0.489NS
	Female	17	51.5	16	48.5	33	100.0	
Apnea	Yes	10	55.6	8	44.4	18	100.0	0.407NS
	No	23	44.2	29	55.8	52	100.0	
Sepsis	Yes	0	0.0	10	100.0	10	100.0	0.001***
	No	33	55.0	27	45.0	60	100.0	
Birth asphyxia	Yes	0	0.0	1	100.0	1	100.0	0.999NS
	No	33	47.8	36	52.2	69	100.0	

Table 11 B: Univariate analysis of neonatal risk factors of ROP

		No ROP(n=33)		ROP(n=37)		Total(n=70)		
Neonatal Risk Factors		**N**	**%**	**n**	**%**	**n**	**%**	**P-value**
Respiratory distress Syndrome	Yes	7	17.9	32	82.1	39	100.0	0.001***
	No	26	83.9	5	16.1	31	100.0	
Intraventricular Hemorrhage	Yes	1	25.0	3	75.0	4	100.0	0.616NS
	No	32	48.5	34	51.5	66	100.0	
O2therapy required	Yes	13	27.7	34	72.3	47	100.0	0.001***
	No	20	87.0	3	13.0	23	100.0	
Duration of O2 therapy	<1week	11	68.8	5	31.3	16	100.0	0.001***
	≥1week	2	6.5	29	93.5	31	100.0	
Blood transfusion Required	Yes	0	0.0	6	100.0	6	100.0	0.026*
	No	33	51.6	31	48.4	64	100.0	
Exchange transfusion required	Yes	0	0.0	3	100.0	3	100.0	0.242NS
	No	33	49.3	34	50.7	67	100.0	

P-value by Chi-Square test. P-value<0.05 is considered to be statistically significant.*P-value<0.05,***P-Value<0.001, NS–Statistically Non-significant.

Distribution of prevalence of ROP differs significantly across various birth weight groups in the study group (P-value<0.05). Significantly higher proportion of cases with birth weight in ELBW and VLBW category had higher prevalence of ROP compared to group of cases with birth weight in LBW and normal category (P-value<0.05).

Distribution of prevalence of ROP did not differ significantly between group of male and group of female neonates in the study group (P-value>0.05).

Distribution of prevalence of ROP did not differ significantly between group of neonates with apnea and between the neonates who did not have apnea in the study group (P-value>0.05).

Distribution of prevalence of ROP differs significantly between group of neonates with and without sepsis in the study group (P-value<0.05). Significantly higher proportion of neonates with sepsis had higher prevalence of ROP compared to group of neonates who did not have sepsis (P-value<0.05).

Distribution of prevalence of ROP differs significantly between group of neonates with or without birth asphyxia in the study group (P-value>0.05).

Distribution of prevalence of ROP differs significantly between group of neonates with and without RDS in the study group (P-value<0.05). Significantly higher proportion of neonates with RDS had higher prevalence of ROP compared to group of neonates who did not have RDS (P-value<0.05).

Distribution of prevalence of ROP did not differ significantly between group of neonates with and or without IVH in the study group (P-value>0.05).

Distribution of prevalence of ROP differs significantly between group of neonates with and without requirement of O2 therapy in the study group (P-value<0.05). Significantly higher proportion of neonates who required O2 therapy had higher prevalence of ROP compared to group of neonates who did not require O2 therapy (P-value<0.05).

Distribution of prevalence of ROP differs significantly between group of neonates with different durations of O2 therapy required in the study group (P-value<0.05). Significantly higher proportion of neonates who required blood transfusion had higher prevalence of ROP compared to group of neonates who did not require blood transfusion (P-value<0.05).

Distribution of prevalence of ROP did not differ significantly between group of neonates with and without requirement of exchange transfusion in the study group (P-value>0.05). Higher proportion of neonates who required O2 therapy for more than 1 week had higher prevalence of ROP compared to group of neonates required O2 therapy for less than 1 week(P-value<0.05).

Distribution of prevalence of ROP differs significantly between group of neonates with and without requirement of blood transfusion in the study group (P-value<0.05). Significantly higher proportion of neonates who required blood transfusion had higher prevalence of ROP compared to group of neonates who did not require blood transfusion (P-value<0.05).

Table12: Distribution of type of treatment given for ROP.

Of 37 cases with ROP, 26 (70.3%) did not require treatment, 9 (24.3%) were given laser treatment, 1 (2.7%) was given Bevacizumab and 1 (2.7%) was given both Laser +Bevacizumab as a treatment on ROP.

Table12: Distribution of type of treatment given for ROP.

Treatment	Number of cases	%of cases
Nil	26	70.3
Laser	9	24.3
Bevacizumab	1	2.7
Laser+Bevacizumab	1	2.7
Total	**37**	**100.0**

Table 13: Multivariate logistic regression analysis to obtain the independent determinants of ROP.

Table 13: Multivariate logistic regression analysis to obtain the independent determinants of ROP

Risk factors (Variables included in the model)		Odds Ratio(OR)	95%CI for Odds Ratio	P-value
Gestational age(weeks)	<34.00	4.29	2.96–6.99	0.001***
	34.00–36.00	1.00[Reference]	--	--
Birth weight(gm)	<1499	2.84	1.11–4.67	0.036*
	≥1500	1.00[Reference]	--	--
Sepsis	Yes	3.15	1.37–5.44	0.007**
	No	1.00[Reference]	--	--
RDS	Yes	2.94	1.23–4.86	0.019*
	No	1.00[Reference]	--	--
O2therapy required	Yes	1.76	1.05–2.59	0.024*
	No	1.00[Reference]	--	--
Blood transfusion required	Yes	1.89	0.93–3.03	0.089NS
	No	1.00[Reference]	--	--

[Odds Ratio=1: Reference Category]. Dependent variable: ROP. *P-value<0.05, **P-value<0.01, ***P-value<0.001, NS: Statistically Non-Significant.

Multivariate logistic regression with dependent variable ROP and independent variables such as gestational age, birth weight, and neonatal complications such as sepsis, RDS, O2 therapy and blood transfusion required was performed to obtain the statistically significant and independent determinants of prevalence of ROP. The independent variables included in the model were statistically significant on univariate analysis. On multivariate logistic regression analysis, gestational age, birth weight, sepsis, RDS and O2 therapy requirement are the independent and significant determinants of prevalence of ROP in the study group p-value <0.05 for all).

DISCUSSION

In India, low birth weight infants have a 38% to 51.9% incidence of ROP. Since retinal detachment, which can happen in the most extreme cases, is the secondary cause of vision loss [5]. ROP is currently the leading cause of infant blindness in both industrialised and developing nations. Amblyopia, strabismus, and myopia are also common conditions [10].

In the present study, a total 70 babies screened as per the guidelines of NNF of India, 37 (52.9%) were Males and 33 (47.1%) were females. 37 babies who developed ROP, 21 (56.8%) were males and 16 (43.2%). R. Nikhil et al found that the prevalence of ROP in his study is 19.2%, which was very low when compared to present study which was 52.9%. The higher prevalence in present study is because of selection of patients and probably high- risk group for developing ROP [5]. Dwivedi A et al., found that Prevalence of severe ROP was 14.2% (109) of which 60 (55.5%) were classic and 30 (27.7%) were APROP and Hungi B, et al have reported 13.2% of ROP cases were APROP which stands very high when compared to our study 2.7% out of 37 cases of ROP [11,12].

Birth weight usually correlates with maturity of the new-born. Hence in most of the previous studies, incidence of ROP was highest in babies weighing <1500grams. Whereas recent studies show a slightly different pattern. Vinekar et al. study, the scenario in developing countries is quite different [13]. Larger and gestationally 'older' infants are more likely to develop ROP compared to their counterparts in Western countries. Jalali et al study, the application of Western screening guidelines in developing countries has been questioned [14].

In present study, occurrence of ROP with mean birth weight (1718.0 ± 365.6) was higher than mean birth weight of other studies like 1555 grams in Hungi B et al, 1355 grams in Gopal L et al, 1285

grams in Charan R et al, 1282 grams in Aggarwal R et al., 1113 grams in Kumar P et al., and 1315 grams in Padhi TR et al [12,15-19].

Prematurity is single most important risk factor for ROP. Both the incidence and severity of ROP are inversely related to gestational age. Mean gestational age (32.7 ± 1.7 weeks) in present study was higher than mean gestational age of other studies like, 30.3 weeks in Aggarwal R et al., 29 weeks in Kumar P et al., 32 weeks Hungi B et al., 30.7 weeks in Padhi TR et al., and 31.6 weeks in Maini B et al [12,17-19,21].

In present study, stage 2 was more common out of all stages. Similar results like in present study were seen in Charan R et al and Goyal a et al [22,16]. While stage 1 was more common in Rekha S et al, Chaudhari S et al and Le c et al. Stage 4 and 5 were absent in present study as well as in recent studies. Previously, these babies were not timely diagnosed and presented late with stage 4 and 5 ROP but now with timely screening correct diagnosis could have been made [11].

Over the years, the link between ROP and supplemental oxygen has been proved by various controlled trials and clinical studies. However, a safe level of oxygen usage has not been found. At the level of intensive care management complete elimination or restriction of oxygen is not feasible [25]. So screening of all new-borns to be done who are exposed to oxygen administration. In present study results show that out of 70 babies screened 47 were given oxygen, 34(72.3%) developed ROP. In the present study there is very high significant correlation between oxygen supplementation and ROP. The duration of oxygen therapy for more than 7 days was a significant risk factor for development of ROP. In present study, we found it as a significant risk factor ($p<0.001$).

In present study, Sepsis was found to be a highly significant risk factor ($p<0.001$). It was also found by linear regression that septicaemia alone was an independent risk factor in the development of ROP. Maheshwari R et al, Aggarwal R et al, Gupta VP et al and Chaudhari S et al also found septicaemia a significant risk factor in multivariate analysis [26,17,27,23]. Measures to prevent and adequately treat sepsis would go a long way in lowering the incidence of ROP.

In present study, blood transfusion was found to be highly significant risk factors ($p<0.001$) for the development of ROP. Even though exact role of blood transfusion in ROP is unclear as per Indian and western literature, there was an apparent trend of more ROP with the association of blood transfusion. Hence the nurseries all over the world are now using blood transfusion in a restricted manner [25].

In present study there is very highly significant correlation between RDS and ROP (p value 0.001).

In the present study, gestational age, birth weight, sepsis, respiratory distress syndrome, oxygen therapy showed significant correlation on univariate and multivariate analysis on development of ROP whereas blood transfusion showed significant correlation on univariate analysis and apnoea, birth asphyxia, IVH, exchange transfusion, mode of delivery, sex and maternal factors like PIH, GDM are found to insignificant correlation with the development of ROP.

Out of 37 ROP cases, 11 cases required treatment. 9(24.3%) cases required laser treatment, 1(2.7%) case required Bevacizumab and 1(2.7%) case required both laser and Bevacizumab and 26(70.3%) cases regressed on their own.

CONCLUSION

We conclude that

- Total 70 neonates were screened for ROP during the period 1st August 2018 to 30th April 2020.
- Amongst these 70 neonates, 37 had ROP which accounts for the prevalence of 52.9% in our tertiary level NICU.
- ccording to stages of ROP, 5 (5.4%) cases are stage 1, 21 (56.8%) cases are stage 2 and 14 (37.8%) cases are stage 3 ROP. According to Zones of ROP, 1 (2.7%) had zone 1 involvement, 31 (83.8%) had zone 2 involvement and 5 (13.5%) had zone 3 involvement.
- APROP was found in 1 (2, 7%) case.

- According to our study, the neonates who had ROP of gestational age ≤30.0 weeks 5(100%), 30 – 34 weeks gestational age 27(61.4%) and 34 – 36 weeks gestational age 5(23.8%) and the neonates who developed ROP with birth weight <1000gm was 1(100%), birth weight 1000 – 1499gm are 11(84.6%), birth weight 1500 – 2499gm are 25(46.3%). Neonates with birth weight greater than 2500gm developed no ROP.
- Gestational age and birth weight are the most significant risk factors for developing ROP. The other independent risk factors for ROP are oxygen therapy, RDS, sepsis and blood transfusion.
- Out of 37 ROP cases, 11 cases required treatment. 9 (24.3%) cases required laser treatment, 1 (2.7%) case required Bevacizumab and 1 (2.7%) case required both laser and Bevacizumab and 26 cases that do not require treatment regressed on their own.
- Neonates receiving oxygen should be used cautiously to maintain saturation of 90-95% with pulse oximeters and blended oxygen, that are used in delivery rooms and neonatal units to guide oxygen therapy.
- Use of restrictive blood transfusion policy.
- As the roles of the obstetrician, neonatologist and ophthalmologist are vital; they should work in close co-operation to reduce the prevalence and morbidity associated with ROP.

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