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Incidence and risk factors for any retinopathy of prematurity (ROP) and type 1 ROP in a neonatal care unit (NICU) in North Karnataka

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Abstract: *Purpose:* To report the incidence and risk factors for any ROP and type 1 ROP and treatment outcomes of type 1 ROP. *Methods and Material:* Infants born in our hospital with gestational age (GA) of < 34weeks or birth weight (BW) < 2000g were screened for ROP and treated if type 1 ROP developed. Incidence of any ROP and type 1 ROP were calculated. Several variables were evaluated by univariate and multivariate analyses to find their significance for any ROP and type 1 ROP. Results of treatment for type 1 ROP are reported. *Results:* Out of 263 infants screened, 64 (24.3%) developed any ROP and 15(5.7%) type 1 ROP. All the eyes with type 1 ROP showed complete regression after treatment. Multivariate analysis showed that; infants with GA of 31-34 weeks had significantly less any ROP (P=0.002) and type 1 ROP (p= 0.020) versus infants of GA ≤30w. Infants with BW≥1501g had less any ROP (P=0.025) and less type 1 ROP (P=0.018) versus infants with BW ≤1250g. Infants with BW 1251g to 1500g had less type 1 ROP versus infants with BW≤1250g. (P=0.042) and females had significantly less type 1 ROP (P= 0.012) versus male infants. *Conclusions:* The incidence of any ROP and type 1 ROP were relatively low in our study. Type 1 ROP regressed completely in all eyes after treatment. GA, BW and gender were significant factors for any ROP and type 1 ROP.

Keywords: Retinopathy of Prematurity, Type 1 ROP, Incidence, Risk Factors, Treatment Outcomes.

Introduction

Retinopathy of Prematurity (ROP) is a vaso-proliferative disorder of the developing retina in premature infants and is the leading cause of preventable blindness in children [1-2]. The middle-income countries including India are experiencing the third epidemic of ROP due to the increased survival of premature babies because of expanding neonatal services in the country [3]. Hence, 10% of the worldwide estimate of visual impairment and blindness due to ROP was contributed by India in the year 2010 [4]. A robust screening program to detect ROP and treat if severe ROP is detected will reduce the blindness due to ROP. Presently severe ROP is defined as type 1 ROP described in the early treatment of ROP study (ETROP) [5]. Several studies from different parts of the world have reported results of screening for ROP, with incidences of any ROP and type I ROP of, 13.7 to 43.1% and 1.8 to 24.4% respectively [6-15]. The varying incidences of type 1 ROP in different countries of the world have been attributed to the economic development, characteristics of premature babies screened and the level of neonatal care [2].

In India, the screening criteria for ROP as advised by the Government of India under Rashtriya Bal Swasthya Karyakram (RBSK) are, infants born with gestational age(GA) <34 weeks or birth weight (BW)<2000g and those infants born outside these parameters if they have specified risk factors [16]. Earlier guidelines for screening for ROP were issued by an expert committee and included infants born with GA<34 -35 weeks and BW<1700g

[17]. The data regarding the incidence of any ROP and severe ROP from district places in India are few [8,11,14,18]. Vinekar et al reported results of internet-based screening in Karnataka state that included six districts of Karnataka state [14].

In this study, we aim to report the incidence of any ROP and type 1 ROP and the results of its treatment in our hospital which serves mainly rural population in Belagavi district. There are no published reports about ROP from our district in the literature. We also, aim to study the risk factors for the development of any ROP and Type 1 ROP among our study population.

Material and Methods

In a prospective, observational, interventional single-centre study, we screened all infants admitted to the neonatal intensive care units (NICU) of KLES Dr. Prabhakar Kore Hospital during the calendar year 2019. Approval was obtained from the Institutional Ethics Committee for the study. Efforts were made to remain true to the guidelines of the Declaration of Helsinki. Informed consent was taken from the parents for regular screening. We followed the screening guidelines of RBSK which were, infants of GA ≤ 34 weeks or BW ≤ 2000g [16]. We also included infants with BW > 2000 g or GA 34-36 weeks if other comorbidities were present as per the guidelines [16]. The sample size was limited by the number of infants meeting the criteria of ROP screening and those admitted in the department of neonatology in our hospital during the calendar year of 2019.

The first ROP examination was at 4 weeks of chronological age in all except those with GA<28 weeks or BW<1200g, in whom, the first ROP examination was at 2-3 weeks of chronological age to detect aggressive posterior ROP (APROP). Dilatation of pupils was achieved with tropicamide 0.4% eye drops instilled 3 times at an interval of 15 minutes. All the examinations were conducted in the NICU for admitted infants and in the Ophthalmology clinic for discharged infants. The examination was conducted using sterile Alphonso lid speculum and scleral depressors for each examination. Fundus examination was done by indirect ophthalmoscope using a 20 or 28 D lens. The findings were recorded in a data collection sheet for both eyes at each examination. If any ROP was present, it was classified according to the International Classification of ROP (ICROP) and entered in the chart [19]. Follow up examinations were performed every 1 -2 weeks according to the presence of ROP and its stage as per the guidelines [16].

The parents of infants who developed type 1 ROP were counseled, and informed consent was taken after explaining the need for treatment and the risks involved. Treatment for type 1 ROP in all the cases was carried out by Vivek Wani. Those who developed Type 1 ROP in Zone I or APROP were treated by intravitreal injection (IVI) of anti-vascular endothelial growth factor (VEGF) and those with type 1 ROP in Zone II or zone III were treated with laser photocoagulation.

Both intravitreal injection and indirect ophthalmoscope laser treatments were carried out in the operation theatre in the presence of a neonatologist to monitor the infant. For indirect laser photocoagulation, confluent and moderately intense white burns were applied to the avascular retina from the edge of the vascular retina to the ora-serrata under topical anaesthesia. We used a green laser (532 nm Nd: YAG double frequency- PUREPOINT Laser, Alcon, Texas, USA) for indirect ophthalmoscope delivery of laser.

The IVI of anti-VEGF was carried out under all aseptic precautions using topical anaesthesia after pupillary dilatation under a microscope in the operating theatre. The dose of intravitreal Bevacizumab (Avastin®, Genentech Inc., South San Francisco, CA,USA) was 0.625 mg in 0.025 ml and of Ranibizumab (Accentrix®, Novartis Inc. India) was 0.25 mg in 0.025 ml. Topical proparacaine hydrochloride 0.5% eye drops and 5% povidone-iodine were instilled in the eye three times before the injection.

The injection was given at a distance of 1.5mm from the limbus through pars-plicata. Moxifloxacin 0.5 % eye drops were used 4 times a day post-injection for a week. Retreatment by laser of skipped areas was carried out if persistence of active ROP with plus disease was present. If eyes that received

anti-VEGF showed re-activation of ROP and appearance of plus disease during follow up, they were subjected to laser photocoagulation of the entire avascular retina.

Data were collected for all the infants regarding the date of birth, gender, GA at birth, BW and single or multiple pregnancies. We recorded maternal morbidities, neonatal events and interventions. The stage and zone of ROP along with the presence or absence of plus disease, the postmenstrual age (PMA), the highest stage of ROP in each infant were noted. For type 1 ROP, PMA at its appearance, zone, stage and plus disease were noted. The treatment given for Type 1 ROP, and the results of treatment were noted.

Statistical analysis: All the above data were entered in a spreadsheet and analysis was done on SPSS software version 20.0 (IBM, SPSS, USA). We carried out univariate and multivariate logistic regression analyses comparing different maternal, neonatal and post-natal independent variables of infants who developed any ROP and type 1 ROP with those who did not develop any ROP and type 1 ROP. All the variables were entered as categorical data for these analyses. Odds ratios and 95% confidence intervals (CI) were calculated wherever applicable. P-value of <0.05 was taken as significant for all the statistical analyses

Results

A total of 263 infants were screened of which 155 were males (58.93%). The average BW and GA of 263 infants were, 1598.8g ± 440.1 (range: 716-3100g) and 33 weeks ± 2.8 (range: 24-40) respectively. The distribution of infants according to the category of their GA and BW and the presence or absence of any ROP and type 1 ROP are shown in table 1 with statistical significance by univariate analysis.

The frequency of maternal variables were singleton pregnancy in 192 infants (72.7%), delivery by caesarian section in 197 (74.9%), gestational diabetes in 24 mothers (9.1%), maternal hypertension in 98 (37.3%), antenatal steroid treatment in 64(24.3%) and premature rupture of amniotic membranes (PPROM) in 43 (16.4%).None of the maternal variables, except maternal hypertension, were associated with any ROP or type 1 ROP by univariate analysis. Out of 98 infants whose mothers had hypertension during pregnancy, 32(32.6%) developed any ROP and 10(10.2%) developed type 1 ROP against 32(19.4%) and 5(3%) out of 165 infants without maternal hypertension developing any ROP and type 1ROP respectively. The difference was significant by univariate analysis for both any ROP and type 1ROP.

Table-1: Gestational age (GA) and birth weight (BW) of infants with and without any ROP and type 1 ROP

For any ROP	**Category**	**Any ROP Absent Number (%)**	**Any ROP Present Number (%)**	**P-value**
Gestational age (GA) in weeks	GA ≤ 30	18 (9.05)	35 (54.69)	<0.0001
	GA -31 to 34	111 (55.78)	25(39.06)	
	GA ≥35	70 (35.18)	4(6.25)	
Birth weight(BW)	BW ≤1250g	25 (12.56)	36 (56.25)	<0.0001
	BW 1251 to 1500g	47 (23.62)	15 (23.44)	
	≥1501g	127 (63.82)	13 (20.31)	
For type 1 ROP		**Type 1 ROP Absent - N (%)**	**Type 1 ROP Present -N (%)**	**P-value**
Gestational age (GA) In weeks	GA ≤ 30 weeks	42 (16.94)	11 (73.33)	<0.0001
	GA -31 to 34 weeks	132 (53.23)	4 (26.67)	
	GA ≥35 weeks	74 (29.84)	0 (0.00)	
Birth weight(BW)	BW ≤1250g	48 (19.35)	13(86.67)	<0.0001
	BW 1251 to 1500g	61 (24.60)	1 (6.67)	
	BW ≥1501g	139 (56.05)	1 (6.67)	

Neonatal morbidities which were significant for the development of any ROP and type 1 ROP by univariate analysis are shown in tables 2 and 3 respectively, with their frequencies.

Table-2: Factors found to be significant for any ROP by univariate analysis

Factors	Category	Any ROP absent Number (%)	Any ROP present Number (%)	P-value
Respiratory distress Syndrome (RDS)	Absent	116(58.29)	21(32.81)	<0.0001
	Present	83(41.71)	43(67.19)	
Apnea of prematurity	Absent	173 (86.93)	34(53.13)	<0.0001
	Present	26 (13.07)	30(46.88)	
Persistent ductus arteriosus (PDA)	Absent	180 (90.45)	45(70.31)	<0.0001
	Present	19 (9.55)	19 (29.69)	
Sepsis	Absent	129(64.82)	20(31.25)	<0.0001
	Present	70(35.18)	44(68.75)	
Anemia	Absent	185(92.96)	47 (73.44)	<0.0001
	Present	14(7.04)	17 (26.56)	
Ventilated	No	162 (81.41)	26(40.63)	<0.0001
	Yes	37 (18.59)	38 (59.38)	
Oxygen supplementation	Not given	108 (54.27)	11(17.19)	<0.0001
	Given for 1-7d	76 (38.19)	34 (53.13)	
	Given ≥8days	15(7.54)	19 (29.69)	
Blood transfusion	Not given	154 (77.39)	25(39.06)	<0.0001
	Given	45 (22.61)	39 (60.94)	
Platelets transfusion	Not given	159 (79.90)	28 (43.75)	<0.0001
	Given	40(20.10)	36 (56.25)	

Table-3: Factors found to be significant for type 1 ROP by univariate analysis

Factors	Category	Type I ROP absent %	Type I ROP present %	p-value
Apnea of prematurely	Absent	201 (81.05)	6 (40.00)	<0.0001
	Present	47 (18.95)	9 (60.00)	
Peristent Ductus Arteriosus (PDA)	Absent	215 (86.69)	10 (66.67)	0.0320
	Present	33 (13.31)	5 (33.33)	
Sepsis	Absent	146 (58.87)	3 (20.00)	0.0030
	Present	102 (41.13)	12 (80.00)	
Ventilation	Not ventilated	181 (72.98)	7 (46.67)	0.0280
	Ventilated	67 (27.02)	8 (53.33)	
Oxygen supplementation	No oxygen given	117 (47.18)	2 (13.33)	0.0020
	Given for 1-7 days	103 (41.53)	7 (46.67)	
	Given for ≥8 days	28 (11.29)	6 (40.00)	
Blood transfusion	Not given	175 (70.56)	4 (26.67)	0.0001
	Given	73 (29.44)	11 (73.33)	
Platelets	Not given	182 (73.39)	5 (33.33)	0.0010
	Given	66 (26.61)	10 (66.67)	

Any ROP was seen in 119 eyes of 64(24.3%) infants, out of whom 28 eyes of 15 (5.7%) infants had type 1 ROP. Any ROP developed at a mean postmenstrual age (PMA) of 35.4 weeks (±3.58; range 27-47). There were 19(7.2%) infants with BW>2000g and GA>34 weeks who were screened for the presence of risk factors like sepsis, oxygen administration or stormy neonatal course. Out of these 19 infants, only one developed stage 1ROP in zone III.

Out of the 15 infants who developed type 1 ROP, 13 had bilateral and two unilateral disease. Two infants had bilateral APROP. The type 1 ROP in the other 24 eyes consisted of -bilateral stage 2+ in zone I in one infant, bilateral stage 3+ in zone II in seven infants, stage 2+ in Zone II in five eyes of three infants and stage 3+ in Zone III in three eyes of two infants. Type I ROP was diagnosed at a mean PMA of 34.6 weeks (1.85; range 31-38**).** No infant with GA>33 weeks and BW>1670g developed type 1 ROP in our study.

One infant with APROP was treated with bilateral IVI ranibizumab and another infant with bilateral IVI bevacizumab. The infant treated with IVI ranibizumab showed re-appearance of stage 3+ ROP in both eyes after six weeks of IVI for which laser photocoagulation of avascular retina was done resulting in complete regression in both eyes. The infant treated with bevacizumab showed complete regression of the disease with vascularization of the retina up to the ora in both eyes. The other 24 eyes of 13 infants with type 1 ROP received laser treatment of the avascular retina.

All the 24 eyes showed complete regression of ROP except three eyes, which had persistence of stage3+ for which, they underwent laser treatment of skipped areas. These three retreated eyes showed complete regression of ROP.

Multivariate logistic regression analysis showed that higher gestational age and birth weight were protective against the development of any ROP as well as type 1 ROP. Additionally, female subjects were found to be less prone to develop type 1 ROP by multivariate analysis. These variables, odds ratio, 95% CI and P values are shown in table 4. All other variables were not found to be significant by multivariate analysis for any ROP or type 1 ROP.

Table-4: Factors found significant by multivariate logistic regression analysis for any ROP and type 1 ROP

Variable	Category	Odds ratio	95% Confidence interval	P value
For any ROP				
Gestational age(weeks)	≤30	Reference		
	31-34	0.21	0.08-0.55	0.0020
	≥35	0.07	0.01-0.33	0.0010
Birth weight(g)	≤1250	Reference		
	1251 to 1500	0.47	.16-1.43	0.180
	≥1501 g	0.28	0.09-0.86	0.0250
For Type I ROP				
Gestational age	≤30	Reference		
	31-34	0.16	0.03-0.75	0.020
	≥35	0.00	0.00-	0.970
Birth weight	≤1250	Reference		
	1251 to 1500	0.07	.01-0.91	0.0420
	≥1501 g	0.06	0.03-0.65	0.0180
Gender	Male	Ref		
	Female	0.15	0.03-0.065	0.0120

Discussion

In this study of 263 infants, the incidence of any ROP and type 1 ROP were 24.3% and 5.7% respectively. All the eyes with type 1 ROP showed complete regression after treatment, with none of the treated eyes having unfavourable outcomes as defined in the ETROP study [5]. In India, screening guidelines for ROP are BW <2000g and GA<34 weeks [16].

Vinekar et al in a landmark study used the same criteria in a telemedicine-based screening of 4167 infants from six districts of rural Karnataka and reported any ROP in 24.33% [14]. Hungi et al following the same guidelines of screening reported a higher incidence of any ROP of 41.5% in118 infants [18]. This higher incidence of any ROP could be due to the small sample size of the study.

Other studies from India have used different guidelines for screening, with GA of <32 to < 37 weeks and BW of <1500g to <1900g and reported incidence of any ROP of 19% to 33% which are comparable to the incidence of 24.3% in our study [8-9,11,15,20]. While using the same guidelines of screening, some authors from other countries have reported a low incidence of 13.7% and others very high incidence of 56-71% of any ROP. [7, 21-22].

Whenever the screening guidelines for ROP are lower BW and GA than used in our study, then the reported incidence of any ROP is higher and ranges from 33.9 to 68%.[6,13,23] In the present study, the incidence of any ROP in a subgroup of infants with BW<1251g was 56.3%. It is still much lower than 68% and 74.4%% reported in studies that investigated ROP in infants with BW<1251g [23-24].

Type 1 ROP: The incidence of type 1 ROP in our study was 5.7% which is comparable to studies from India and elsewhere which have reported incidence of < 10%. [7,10,12,14-15]. Other studies from India have reported a higher incidence of type 1 ROP ≥ 10%. [8,11,18,20]. Acevedo-Castellon et al screened 132 infants with BW<1700g and GA ≤34 weeks and reported type 1 ROP in 27.3% which is higher probably due to the inclusion of referred infants from other NICUs [21].

In our study, all the 15 infants with type 1 ROP had BW<1700 g and 13 of the 15 infants had BW<1251g. There were three infants with type 1 ROP with GA of ≥31 weeks but all had BW < 1500g. There was one infant with a BW of 1670g but the GA was 30 weeks. Had we used the screening guidelines of the American Academy of Pediatrics (AAP) for ROP, which are GA≤30 weeks or BW<1500g, then also we could have detected type 1 ROP in all the 15 infants [25]. However, others have observed that if the screening guidelines of AAP were used in their subjects they would have missed some cases of type 1 ROP [9,10,20,26]. In infants with BW<1251g the incidence of type I ROP in our study was 21.3% compared to 24% in a study by Wani et al and 21.3% in ETROP study [23-24].

The mean GA and BW of infants with type 1 ROP in a subgroup of infants with BW<1251g were, 29.5 weeks and 1055g respectively in our study versus 25.6 weeks and 745 g reported in the ETROP study. [23]. This supports observation by Gilbert et al that, more mature infants develop severe ROP in countries with low/moderate levels of development compared to highly developed countries. This has been attributed to lack of advanced neonatal care and timely screening for ROP [2]. Hence the present guidelines in India are to be followed to select infants for ROP screening. Table 5 shows a comparison of screening guidelines, average GA and BW, the incidence of any ROP and type 1 ROP of some studies with our present study.

Risk factors for any ROP: Though many variables were found to be significant for association with any ROP by univariate analysis (table 3), multivariate analysis showed that only GA and BW were the significant risk factors for both any ROP and type 1 ROP (Table 4). Both GA and BW are indicators of prematurity and hence the higher risk of any ROP. Many studies have reported the association of lower GA with any ROP [8,11,13,15,20,22]. The significance of lower BW for any ROP has also been recognized in many studies [7,11-13, 15, 22]. Other studies have observed that supplemental oxygen, sepsis, pulmonary disease, IVH and vaginal delivery to be significant factors associated

with any ROP [7,8,11-12,22]. Oxygen administration, sepsis and RDS were significant for their association with any ROP by univariate analysis in our study too but not in multivariate analysis.

Table-5: Comparison of studies for incidence of any ROP and type I ROP

Study and place of study	Number of infants	Inclusion criteria GA* and BW†	Mean GA± SD in weeks and BW± SD in grams	Any ROP% Type 1 ROP%
Quinn et al [6] USA	7483	GA≤30 BW<1500g	28 ± 3 1099± 259	43.1 6.9
Braimah et al [7] Ghana	401	GA<37 BW<2000	32.2± 2.4 1600± 400	13.7 1.8
Bas et al [10] Turkey	6115	GA<32 W BW <1500G	1457±479 28.9±6.3	27 6.7
Ahuja et al [11] India	325	GA≤36 W BW ≤1900G	1420±300 30.68±2.84	32.6 13.2
Vinekar et al [14] India	4167	GA<34 BW<2000G	1592.7 31.7	24.33 4.4
Castellon et al [21] Mexico	132	GA≤34 BW <1700g	1594±96 32±3	56.1 28.8
ETROP study [23] USA	6998	BW <1251g	907 27.4	68 36.9
Present study	263	GA<34 BW<2000G	1598.8 ±440.1 33± 2.8	24.3 5.7

*GA-gestational age, † BW-birth weight

Risk factors for type 1 ROP: Several variables were found to be significant for type 1 ROP by univariate analysis as shown in table 4. Other studies have found anaemia, RDS, sepsis, blood transfusion, relatively less gain of weight at 28 days, ventilated days, pulmonary diseases, PDA and IVH to be significant risk factors for type 1 ROP [9,10,12,15,24, 26].

Some of the above factors were significant only by univariate analysis in our study as shown in table 4. In our study, multivariate analysis showed that GA, BW and male gender were the three significant factors for type 1 ROP. The role of lower GA and BW in type 1 ROP has been reported by several studies.[8,10,12,24] In our study female gender was found to be negatively associated with type 1 ROP by multivariate analysis. A study from the US also observed that male infants were 1.5 times more likely to develop type 1 ROP compared to female infants [27].

Oxygen was the first factor to be implicated in the development of ROP [28]. In our study oxygen supplementation was a significant factor only in univariate analysis. Other studies have found oxygen requirement to be a significant factor in the development of type 1 ROP [8-10].

Our study had a small number of type 1 ROP and only two out of 15(13.3%) had APROP. However, Goyal et al and Dwivedi et al reported APROP in 20.7% and 27.5% of type 1 ROP cases respectively. [9,20]. As our study was limited to infants from our hospital, timely screening was possible with no cases with advanced ROP at presentation. However when a screening program includes infants from other NICUs, then a referral may be delayed and one may see advanced cases of ROP at presentation as was reported by Dwivedi et al [20]. Hence the education of NICU staff is very important to avoid this late referral [20].

In our study, all the 28 eyes with type 1 ROP showed regression of disease after treatment, with none having unfavourable outcomes as defined in the ETROP study [5]. Pradeep Kumar et al and Rao et al also reported no unfavourable outcome in the treated eyes [15, 26]. Goyal et al reported unfavourable outcomes in 2.4% of treated eyes and Vinekar et al in 7.8% of treated cases [9, 14]. However our study is relatively small compared to the studies mentioned above. [9,14].

Conclusions

This is the first study of the incidence of any ROP and type 1 ROP from our district. In our study of 263 infants, the incidence of any ROP and type 1 ROP are comparable to other district-level studies of India. All the treated infants showed full regression of the disease. The study shows that infants with GA≤30 weeks or BW≤1500 g need to be carefully observed for the development of any ROP and type 1 ROP. Our screening guidelines of GA<34 weeks and BW<2000g are adequate to detect all infants with any ROP and type 1 ROP. Multivariate analysis of risk factors in our study showed that lower BW and lower GA were significant risk factors for the development of both any ROP and type I ROP and male gender was significant factor for the development of type I ROP.

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