Original Article

Report from a Trained Specialist Dependent ROP Screening Program in Two State Government Managed Special Newborn Care Units (SNCUs) of North Bengal

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Context : Retinopathy of Prematurity (ROP) is emerging as the leading cause of childhood blindness in India. Due to lack of specialists trained in ROP, many SNCUs in remote areas do not have a regular ROP screening program.

Aim : We organized a monthly, ROP screening program in two State Government managed SNCUs of North Bengal, to find the incidence of ROP and feasibility of running such a program.

Materials and Methods : A retrospective analysis of babies weighing ≤2000 g or ≤34 weeks of gestation screened from November 2017 till May 2020.

Results : Of the 508 babies screened 69 (13.6%) had ROP. 16 (3.2%) babies developed vision threatening ROP requiring Laser. The risk of any ROP increased with decreasing birth weight (Extended Mantel Haenszel Chi Square for linear trend: 15.4; p value: 0.00009). Of the pre-fixed 31 screening camps, only 19 (61.3%) could be conducted. Due to irregular screening, 180 (35.4%) of the babies underwent "Delayed screening" (first screening beyond 30 days of life). For these babies the odds of developing any ROP was 2.08 times (OR: 2.08; 95% CI: 1.25-3.48; p value: 0.002)higher and vision threatening ROP requiring Laser, 3.9 times (OR: 3.9; 95% CI: 1.1-13.7; p value: 0.015)higher, compared to those screened on time.

Conclusions : This is a first of its kind report from any SNCU located in North Bengal. It highlights the importance of regular ROP screening and also exposes the limitations of a screening program dependent on physical screening by a trained specialist.

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***Key words* : Retinopathy of Prematurity, Retina, Childhood Blindness, Special Newborn Care Units, North Bengal.**

Nearly 2% of total live births in India are infants with birth weight ≤2000 grams and gestational age ≤34 weeks[1]. All these babies are at risk of developing Retinopathy of Prematurity. Although the exact prevalence of ROP in India is not known, the incidence reported is between 22-52%[2,3]. In 20% of these babies have severe ROP and can go completely blind, if not diagnosed and treated at the right time[4]. With improved survival rate of premature babies across the country the number of infants who need ROP screening is bound to increase[5].

A premature child is not born with ROP[6]. Usually the disease develops over time. Hence, by proactively screening for ROP, one can detect the disease early and intervene[7]. Timely intervention with Laser can reduce the risk of progression of ROP to retinal detachment[8]. The National Guidelines for ROP screening mandates that all babies weighing ≤2000 g or ≤34 weeks of gestation need to be screened[9]. The guidelines also mandate that at least one screening should be completed within 30 days of life.

Ophthalmologists need to undergo special training to screen for and treat ROP. In a country like India with over 20,000 ophthalmologists, less than 150 actively practice ROP management[10]. The distribution of these specialists is also uneven. Though there are over 700 "Special Neonatal Care Units (SNCUs)" in India with one in nearly all district headquarters, most

Editor's Comment :

- This first of its kind study based on data from regular ROP screening program in government SNCUs of a district in North Bengal, highlights the urgent need to address the threat of blindness from ROP.
- Development of SNCU facilties have improved survival rates of premature babies. However, due to lack of ophthalmologists trained to do ROP screening in the periphery, many of those at risk are not being screened.
- To overcome this obstacle government needs to consider Retinal camera based tele-screening programs.

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of these units do not have regular ongoing ROP screening programme[11].

Though there are functional SNCUs under State government Health Services, in all the district towns in Northern part of Bengal, to the best of our knowledge none of them have an ongoing regular ROP screening programme. The Two-Government run SNCUs in (blinded) district have been an exception. Since 2017, regular ROP screening programme is being conducted at the SNCUs of (blinded) district hospital and (blinded) State General Hospital, jointly by a specialized private Retina institute in (blinded), licensed under the West Bengal Clinical Establishments (Registration, Regulation & Transparency) Rules, 2017 and the District Health & Family Welfare Samiti (DH & FWS), (blinded). We analysed the data from that screening program to assess incidence of ROP in the district and requirements for establishing such an operational screening programme in all the SNCUs of North Bengal.

Material and Method

This is a retrospective analysis of data from the monthly ROP screening programme carried out at SNCUs of (blinded) District Hospital and (blinded) State General Hospital, in (blinded) district.

One of the authors examined all eligible infants subsequent to detailed history, including birth weight, gestational age at birth and adverse events during stay in the SNCUs, using a binocular indirect ophthalmoscope and +20 D lens under topical anaesthesia using 2% proparacaine eye drops. The eyelids of the babies were separated with an infant wire speculum and a wire vectis was used as a scleral depressor. The pupils were dilated using 0.4% tropicamide +2.5% phenylephrine eye drops three times till full dilatation occurred. Any ROP if present was graded into stages and zones as per the International Classification of Retinopathy of Prematurity (ICROP)[12]. Repeated examinations were scheduled separately, for babies with any stage of ROP till the ROP completely regressed or reached high risk pre-threshold or threshold ROP; at which stage immediate laser treatment was conducted under topical anaesthesia, under anaesthetist supervision, using doubled-frequency Nd: YAG laser and Laser Indirect ophthalmoscope.

We abstracted data of all babies weighing $\leq$2000 g or $\leq$34 weeks gestation screened between November, 2017 and May, 2020, from the hospital records.

As Postconceptional age at birth could not be assessed reliably in all cases, we further analyzed the data based on the birth weight of the babies. The babies were accordingly grouped based on birth weight into three groups as Group A with birth Weight of $\leq$1000 g, Group B with birth weight of >1000g but <1500g and Group C with birth weight of $\geq$1500g to 2000g and assigned to those groups as number of babies with any ROP and number of babies with vision threatening ROP (Table 1).

We calculated the Chi square for linear trend for examining the linear trend in incidence of ROP in babies with reducing birth weight. We also calculated the Chi square for linear trend for examining the incidence of vision threatening ROP in babies with ROP with reducing birth weight. We used EpiInfo version 2007 for the data analysis.

We also calculated proportions and measured the association in terms of Odds Ratio (OR) for estimating the higher risk of ROP among those eligible babies, who underwent "Delayed screening" of beyond 30 days after birth as against those screenedtimely i.e. within 30 days of birth.

Results

We conducted 19 (61.3%) ROP screening against a planned and pre-fixed schedule for 31 camps during the study period (November'17 to May'20). Of the 12 missed camps, 10 (83.3%) were due to unavailability of the retina specialist and 2 (16.7%) due to the national lockdown consequent to the COVID-19 pandemic.

We screened 508 babies for ROP during the study period and detected ROP in 69 (13.6%) babies. Out of 508 babies screened, 328 (64.6%) babies were screened within 30 days of birth while 180 (35.4%) babies were beyond 30 days of birth. ROP was detected in 34 and 35 cases in among babies screened within 30 days of birth and beyond 30 days of birth, respectively.

Of the 69 babies with ROP, 53 (76.8%) babies had spontaneous regression of ROP, while 16 (23.1%) babies developed vision threatening ROP requiring laser treatment. All the babies treated with laser recovered. No one needed surgery or anti-VEGF injections.

We detected 8 (66.7%) cases of ROP in Group A, 25 (16.3%) in Group B and 36 (10.5%) in Group C. We also detected 6 (50%),13 (2.6%) and 6 (1.7%) vision threatening ROP in Groups A, B and C respectively (Table 1).

We estimated an Odds Ratio of 2.08 (95% Confidence Interval: 1.25-3.48; p value: 0.002) risk of ROP among the babies with delayed ROP screening compared to those with screening within 30 days of birth (Table 2).

We also estimated an Odds Ratio of 3.9 (95% Confidence Interval: 1.1-13.7; p value: 0.015) risk of developing vision threatening ROP requiring Laser among the babies with delayed ROP screening compared to those with screening within 30 days of birth (Table 3).

We estimated the Chi Square for linear trend (Extended Mantel Haenszel) of 15.4 (p value: 0.00009) with respect to increasing trend of incidence of ROP in high risk babies with reduced birth weight (Table 4).

We also estimated the Chi Square for linear trend (Extended Mantel Haenszel) of 9 (p value: 0.0026) with respect to an increase in incidence of vision threatening ROP requiring laser with decreased birth weight (Table 5).

Discussion

Of the 508 babies screened during the study period, we detected ROP in 69 cases with an incidence of 13.6%. This incidence is lower than the incidence of ROP (22-52%) reported in other studies from India[2,3]. Based on ROP screening conducted in the SNCU of a Tertiary Care Hospital located in Southern India, Le *et al* have also reported a low incidence of ROP (2.3%) ascribing it to the proportion of "large babies" (33% had a birth weight of ≥1500g), in their study sample[13]. In our study too, 67.5% of the babies had birth weight between ≥1500g to 2000g, which may explain the lower incidence of ROP of in our series.

The incidence of ROP was not uniform among the three age groups in which we had divided the babies. Rather the incidence of ROP was found to be relatively higher with decrease in birth weights. Further, the risk of ROP cases developing vision threatening ROP requiring Laser therapy was also found to be higher with decrease in birth weights. Analysis for linear trend among high risk babies using Chi Square for trend showed statistically significant rise in incidence of ROP with reduction in birth weight, as well as, rise in vision threatening ROP among ROP cases with reduction in birth weight. Dhingra et al have earlier reported that the mean birth weight and gestational age of the infants who developed ROP were significantly lower than those who did not develop ROP[14]. The authors found that, compared to the birth weight category >1500 gms (which was the reference category), birth weight categories of ≤1000 gms and 1001-1250 gms independently had

Table 1 — *Overview of the babies screened for Retinopathy of Prematurity (ROP), any ROP babies and babies with visioning threatening ROP grouped birth weight wise, A## district, West Bengal, India, 2017 – 2020 (May)*

Weight at birth (gms)	# ROP screening within 30 days	# ROP screening beyond 30 days	# babies with ROP	# of babies with vision threatening ROP
< 1000	6 (1.2%)	6 (1.2%)	8 (66,7%)	6 (50%)
>1000-<1500	80 (15.7%)	73 (14.4%)	25 (16.8%)	4 (2.6%)
≥1500	242 (47.6%)	101 (19.9%)	36 (10.5%)	6 (1.7%)
TOTAL	328 (64.6)	180 (35.4%	69 (13.6%)	16 (3.2%)

Table 2 — *Measure of Association (Odds Ratio) between detection of ROP among babies with delayed screening > 30 days after birth, A##, West Bengal, India, 2017 – 2020 (May)*

Exposure	Outcome	ROP	NO ROP	TOTAL
	# Babies screened for ROP > 30 days after birth	35	145	187
	# Babies screened for ROP < 30 days of birth	34	294	328
Total		69	439	508

Odds Ratio: 2.08
95% Confidence Interval (CI): 1.7 – 3.8, p value : 0.0000538

Table 3 — *Measure of Association (Odds Ratio) between detection of vision threatening ROP among babies with delayed screening > 30 days after birth, A##, West Bengal, India, 2017 – 2020 (May)*

Exposure	Outcome	# Vision threatening ROP	# Any ROP	Total
	# Babies with ROP screened >30 days after birth	12	23	35
	# Babies with ROP screened < 30 days of birth	04	30	34
Total		16	53	69

Odds Ratio: 3.9
95% Confidence Interval (CI): 1.1 – 13.7, p value: 0.015

Table 4 — *Analysis of linear trend in babies of RDP with reducing birth weight, A##, West Bengal, India, 2017-2020 (May)*

Weight at birth (gms)	# High Risk Babies	RDP	No RDP	Odds Ratio
<1000	12	08	04	1
>1000-<1500	153	25	128	0.098
>1500	343	36	307	0.059

Chi Square for trend (Extended Mantel Haenszel) : 15.4
p value: 0.00009

Table 5 — *Analysis of linear trend in babies with any ROP of vision threatening ROP with reducing birth weight, A##, West Bengal, India, 2017 – 2020 (May)*

Weight at birth (gms)	ROP	Vision threatening ROP	No Vision threatening ROP	Odds Ratio
< 1000	08	06	02	1
>1000 - <1500	25	04	21	0.063
≥1500	36	06	30	0.067

Chi Square for trend (Extended Mantel Haenszel): 9
p value: 0.0026

increased risk of ROP.

In the West, treatable ROP is not seen in babies with birth weight ≥1500g[15]. Experts there do not recommend ROP screening in babies with birth weight ≥1500g, regardless of exposure to supplemental oxygen[16,17]. In contrast, cases of ROP, even of the aggressive variety; have been reported in babies with birth weight ≥1500g, in India[18]. As a result, the National Guidelines for ROP screening in India, mandates screening for all infants weighing ≤2000. Our study confirms the importance of following this guideline, as ROP was seen in 36(10.5%) of the 343 babies with birth weight ≥1500g to 2000g (Group C). 6 (1.7%) of these 343 babies progressed to vision threatening ROP and had to be treated with Laser.

With a recent Supreme Court of India judgment bringing ROP screening into the medicolegal focus, it has now become imperative for all neonatal units to provide for appropriate ROP screening[19]. However, there are few ROP trained specialists available in remote parts of the country, like the northern part of West Bengal, leading to lack of any ROP screening program in most SNCUs. Ideally the ROP screening program should be repeated on a weekly basis. As there was only one trained ROP specialist available to the group, we agreed to initiate the program by conducting at least one screening camp every month.

Of the 31 pre-fixed ROP screening camps, we could conduct only 19 camps mostly due to the unavailability of the retina specialist. Similar irregularity in screening has been noted in 1/3rd of the SNCUs in Mexico, due to unavailability of the screening doctor[20].

Irregularity in the screening schedule lead to delayed screening of 180 (35.4%) babies, who did not receive their first ROP screening within 30 days of life. The odds of detecting more ROP cases among the babies screened later than the mandated 30 days of birth was 2.08 times higher than in those screened within 30 days. Timely screening is of paramount importance to avoid blindness due to ROP. Delayed screening has been reported to be associated with a higher possibility of any stage of ROP or progression to vision threatening ROP[21]. Lack of timely screening has been also reported to be a major cause of stage 5 ROP blindness in a tertiary eye care setup from India[22].

Lack of alternate trained ROP specialists in the region covered by the study and remoteness of the study SNCUs from (blinded), (location of the Retina Institute) makes us believe that it is not feasible to successfully conduct a physical specialist dependent screening program regularly, over a long period. Given these facts, we highly recommend a technology driven, ROP fundus camera-based screening programme like the Karnataka Internet Assisted Diagnosis of Retinopathy of Prematurity (KID-ROP) programme[11]. The KID-ROP programme has successfully screened over 45,000 infants from 126 centres spread across Karnataka and treated over 2250 babies[23]. A possible objection to a KIDROP like model of ROP screening program in our region can be that, it requires significant financial and non-financial resources[24]. Such a model requires 3-4 trained ophthalmic staff, a specialised fundus camera and a laptop equipped with additional special software to record ROP images which are assessed by ophthalmologist elsewhere. However, in our mind these additional burdens are offset by the fact that the KID-ROP program was seen to have the scope of preventing blind-person years (BPY) accounting for over 200 million USD annually in ten states of the country[25]. Based on our experience we feel that the for a successful, sustained ROP screening programme in North Bengal a ROP-trained ophthalmologist should act as the central resource person. But he or she should not have to travel physically to all the SNCUs. Trained operators can visit the SNCUs under the programme, once a week, along with the ROP fundus camera and upload images over internet for grading by the trained specialist. This way we are unlikely to miss out most of the eligible neonates admitted in the SNCUs.

Our study had some limitations. Firstly, our study covered only two SNCUs out of the 11 present in the public sector in North Bengal and our findings may not be representative of the other districts. However, it does highlight the existence of the problem of ROP in the region, its underreporting and the highlights the risk of childhood blindness, associated with the near absence of any regular screening program in the region. Secondly, our program did not cover the privately managed SNCUs in (blinded) district, thus limiting our ability to give a true estimate of the incidence of ROP in the district. However, we have been able to highlight the problem of ROP in the region. Thirdly, a monthly screening program, as attempted by us is less than ideal. However, our intention was to provide some access to ROP screening, where none previously existed, in which we succeeded to some extent. Fourthly, we had only 12 babies (2.4%) in the extremely low birth weight group (Birth weight ≤1000g), which is low compared to other studies. However, this is explained by the fact that these extremely premature and sick babies either did not survive or were often referred by the paediatricians to the tertiary level government managed SNCUs at North Bengal Medical College, Siliguri or Coochbehar Medical College, Coochbehar due to lack of beds.

There are 11 SNCUs managed by State Government in the five Northern Districts (Darjeeling, Kalimpong, Jalpaiguri, Coochbehar and Alipurduar) of West Bengal. As per the data from Facility Based Newborn Care Cell of the State Health Department, West Bengal, 1951 premature babies (gestational age <34 weeks or birth weight ≤2000g) were admitted in the remaining 9 SNCUs, in 2019. Of these 139 babies had birth weight ≤1000g (Group A in our study), 496 babies had birth weight between >1000g-<1500g (Group B) and 1316 babies had birth weight between 1500g-≤2000g (Group C). Based on the incidence of ROP as revealed in this study, we estimate 312 babies to have developed ROP in 2019 of which 104 would have progressed to vision threatening ROP, requiring urgent intervention.In absence of any regular ROP screening program in these 9 SNCUs however, it is difficult to verify our conclusions.

This study, which is the first of its kind in the region, highlights the urgent need to develop a regular ROP screening programme covering all the SNCUs in North Bengal. It also highlights the urgent need to move away from a physical specialist dependent ROP screening program to a technology driven retinal camera based tele-screening program with the trained uploading of retinal images to be sent to the scarcely available retina specialist using tele-ROP platform and facilitating definitive interventions in specialised institutions with facility for interventions, including medical and laser managements.

References

1 Varughese S, Jain S, Gupta N, Singh S, Tyagi V, Puliyel JM — Magnitude of the problem of retinopathy of prematurity. Experience in a large maternity unit with a medium size level-3 nursery. *Indian J Ophthalmol* 2001; **49:** 187-8.

2 Gupta VP, Dhaliwal U, Sharma R, Gupta P, Rohatgi J — Retinopathy of prematurity—risk factors. *Indian J Pediatr* 2004; **71:** 887-92.

3 Rekha S, Battu RR — Retinopathy of prematurity: Incidence and risk factors. *Indian Pediatr* 1996; **33:** 999-1003.

4 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.

5 Vedantham V — Retinopathy of prematurity screening in the Indian population: It's time to set our own guidelines! *Indian J Ophthalmol* 2007; **55:** 329-30.

6 Chakraborty S — Retinopathy of Prematurity: Screening Delayed is Screening Denied. *EC Ophthalmology* 2019; **10(12):** 1-5.

7 Good WV — Early Treatment for Retinopathy of Prematurity Cooperative Group. Final Results of The Early Treatment for Retinopathy of Prematurity (ETROP) Trans. *Am Ophthalmol Soc* 2004; **102:** 233-50.

8 Dogra MR, Katoch D — Retinopathy of Prematurity: An emerging and evolving challenge. *Indian J Ophthalmol* 2017; **65:** 782-4

9 Pejaver RK, Vinekar A, Bilagi A — A National Neonatology Foundation's Evidence Based Clinical Practice Guidelines for Retinopathy of Prematurity, NNF, India, Guidelines, 2010. P 253-62

10 Vinekar A, Azad R, Dogra MR, Narendran V, Jalali S, Bende P — The Indian retinopathy of prematurity society: A baby step towards tackling the retinopathy of prematurity epidemic in India. *Ann Eye Sci* 2017; **2:** 1-6.

11 Vinekar A, Gilbert C, Dogra M, Kurian M, Shainesh G, Shetty B, *et al* — The KIDROP model of combining strategies for providing retinopathy of prematurity screening in underserved areas in India using wide-field imaging, tele-medicine, non-physician graders and smart phone reporting. *Indian J Ophthalmol* 2014; **62:** 41-9.

12 The committee for the classification of Retinopathy of prematurity. An International classification for retinopathy of prematurity. *Arch Ophthalmol* 1984; **102:** 1130-4.

13 Le C, Basani LB, Zurakowski D, Ayyala RS, Agraharam SG — Retinopathy of prematurity: Incidence, prevalence, risk factors, and outcomes at a tertiary care center in Telangana. *J Clin Ophthalmol Res* 2016; **4:** 119-22.

14 Dhingra D, Katoch D, Dutta S, Samanta R, Aggarwal K, Dogra MR — Change in the incidence and severity of Retinopathy of Prematurity (ROP) in a Neonatal Intensive Care Unit in Northern India after 20 years: Comparison of two similar prospective cohort studies. *Ophthalmic Epidemiology* 2019; **26(3):** 169-74.

15 Yanovitch TL, Siatkowski RM, McCaffree MA, Corff KE— Retinopathy of prematurity in infants with birth weight ≤1250 grams-Incidence, severity and screening guideline cost-analysis. *J AAPOS* 2006; **10:** 128-34.

16 Right K, Anderson ME, Walker E, Lorch V — Should fewer premature infants be screened for retinopathy of prematurity in the managed care era? *Pediatrics* 1998; 102: 31-4.

17 Andruscavage L, Weissgold DJ — Screening for retinopathy of prematurity. *Br J Ophthalmol* 2002; **86:** 1127-30.

18 Sanghi G, Dogra MR, Katoch D, Gupta A — Aggressive posterior retinopathy of prematurity in infants ≤1500 g birth weight. *Indian J Ophthalmol* 2014; **62:** 254-7.

19 Supreme Court Judgement. Available from: http://www.supremecourtofindia.nic.in/FileServer/2015 07 02_1435823185.pdf

20 Zepeda Romero LC, Gilbert C— Limitations in ROP programs in 32 Neonatal Intensive Care Units in five states in Mexico. *Biomed Res Int* 2015; 2015: 712624.

21 Gopal DP, Rani PK, Rao HL, Jalali S — Prospective study of factors influencing timely versus delayed presentation of preterm babies for retinopathy of prematurity screening at a tertiary eye hospital in India The Indian Twin Cities ROP Screening (ITCROPS) data base report number 6. *Indian J Ophthalmol* 2019; **67(6):** 855-59.

22 Azad R, Chandra P, Gangwe A, Kumar V — Lack of screening underlies most stage-5 retinopathy of prematurity among cases presenting to a tertiary eye center in india. *Indian Pediatr* 2016; **53(Suppl 2):** S103-6.

23 Vinekar A, Dogra M, Azad RV, Gilbert C, Gopal L, Trese M — The changing scenario of retinopathy of prematurity in middle and low income countries: Unique solutions for unique problems. *Indian J Ophthalmol* 2019; **67(6):** 717-9.

24 Goyal A, Gopalakrishnan M, Anantharaman G, Chandrashekharan DP, Thachil T, Sharma A — Smartphone guided wide-field imaging for retinopathy of prematurity in neonatal intensive care unit - a Smart ROP (SROP) initiative. *Indian J Ophthalmol* 2019; **67(6):** 840-5.

25 Vinekar A, Mangalesh S, Jayadev C, Gilbert C, Dogra M, Shetty B — Impact of expansion of telemedicine screening for retinopathy of prematurity in India. *Indian J Ophthalmol* 2017; **65:** 390-5.