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Retinopathy of prematurity in a tertiary facility: an initial report of a screening programme

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Abstract*: Background:*
Retinopathy of prematurity (ROP) screening in Nigeria is at a nascent stage and at the moment there are no National guidelines for ROP screening in Nigeria. Thus it is desirable for screening programs to report findings amongst screened preterm infants in order to facilitate the development of national ROP screening criteria and guidelines. The aim of this report is to describe the frequency, severity and risk factors for retinopathy of prematurity (ROP) among preterm and very low-birth-weight babies screened within the first year of initiating an ROP screening program at a Nigerian tertiary facility.
Methods: A cross-sectional study of infants born at less than 34 weeks gestational age; or with birth weight less than 1500g between May 2016 and May 2017. ROP screening examinations were performed by ophthalmologists with the use of an indirect ophthalmoscope, after pupillary dilation, in collaboration with the neonatology team. Information on gestational age at birth, birth weight, oxygen therapy and presence of other risk factors were recorded and analyzed.
Results: A total of 74 infants were screened during the period. There were 36 (48.6%) males. Mean gestational age at birth was 29.6 (±2.35) weeks. Mean birth weight was 1.26 (±0.27) kg with a range of 800 to 1950g. ROP was detected in 9 (12.2%) infants. Two (22.2%) of these had Threshold ROP. There was no significant difference between the mean birth weight and mean gestational age of the infants who had ROP compared to those without ROP. The two infants with Threshold ROP were treated with intravitreal Bevazicumab and had regression of ROP.
Conclusion: Retinopathy of prematurity was diagnosed in at risk infants in this facility. There is, therefore, a need to establish ROP screening programs in all neonatal units across the country. In addition, established programs need to evaluate their screening criteria with a view towards developing country-specific screening guidelines.

Keywords: Retinopathy; Prematurity; Preterm; Neonates; Nigeria; Africa

Introduction

Retinopathy of prematurity (ROP) is a vasoproliferative disease of the retina, which occurs in preterm and low birth weight babies. This potentially blinding disease is the most common ophthalmic condition associated with preterm delivery and is seen more commonly in babies born before 32 weeks gestational age or birth weight 1500g or less.[1] Other ocular effects of prematurity include refractive errors, strabismus, cerebral visual impairment, visual field defects, colour vision deficits, reduced contrast sensitivity and decreased visual acuity.[1]

ROP is a leading cause of childhood blindness in developed countries and is the 5th leading cause of bilateral childhood blindness globally.[2] It is also becoming an important cause of childhood blindness in developing countries.[3,4] However, the proportion of blindness that is due to ROP varies widely between countries, depending on their level of development and is influenced by the quality and outcomes of neonatal care, as well as the availability of effective ROP screening and treatment programs.[5]

Blindness that occurs in early childhood is, potentially, a life-long burden, both in terms of social dependence and

economic loss. The World Health Organization (WHO) "Vision 2020: The Right to Sight" programme identified ROP as an important cause of blindness in children.[6] The strategy proposed by the WHO to reduce the burden of this potentially avoidable cause of blindness is that infants at risk for ROP should undergo screening eye examinations by the 4th week of life and have access to prompt treatment.[7] This is because timely retinal examination and treatment of high-risk preterm infants is important in preventing the progression to advanced stages of ROP which has been reported to occur in up to 31% of babies with ROP[8]. In addition, infants who undergo early screening and treatment for ROP have better structural and visual outcomes in the long-term.[2]

Previously, it was thought that ROP was rare in African children.[9-11] This is probably because there were no screening programs for ROP in the past and the early studies on blindness in African children did not find any children that were blind from ROP.[12,13] A few recent studies, however, have demonstrated its occurrence among African children[11], and this is thought to be due to relative improvement in the survival of preterm babies.[14,15]

Reports from ROP screening programs in Kenya and South Africa documented the frequency of ROP to be 41.7%[16] and 16.3%[17] respectively. The first study on ROP in Nigeria was conducted in the University College Hospital, Ibadan over two decades ago and only 5.5% of the babies examined had the disease.[18] In the last five years, three more studies have been reported from tertiary hospitals in different regions of the country, with the prevalence of ROP ranging between 15% and 47.2%.[19-21]

These reports have provided evidence for the increasing calls for the establishment of ROP screening programs in neonatal intensive care units across Nigeria. A screening program for ROP was initiated at the neonatal unit of our facility in May 2016. This is a report of the first one year of the ROP screening program and the aim is to document the frequency, severity and risk factors for ROP amongst the preterm babies screened.

Methods

Screening location and subjects

The screening program was conducted at the inborn neonatal ward (Special Care Baby unit); the out-born neonatal ward as well as the neonatal clinic of the University College Hospital Ibadan. Infants born at less than 34 weeks' gestational age (GA); or with birth weight less than 1500g who underwent screening for retinopathy of prematurity between May 2016 and May 2017 were included in this report. Other preterm babies (GA less than 37 weeks) or babies with birth weight less than 2000gwho had risk factors such as sepsis, respiratory distress, multiple blood transfusions, multiple births, intraventricular heamorrhage, supplemental oxygen therapy, apnoeic episode also underwent ROP screening and were included in the report.

ROP screening method

Screening examinations were performed at about four weeks of life in the Special Care baby unit and the out-born ward (for in-patients) and at the neonatal clinic (for neonates who were discharged before four weeks of age or required repeat examinations). Ocular examinations were done by ophthalmologists after pupillary dilation in collaboration with the neonatology team who monitored the vital signs during and after the examination. Anterior segment examinations were performed using a pen torch while the posterior segments (retina and vitreous) were examined with the use of an indirect ophthalmoscope plus a 20-dioptre lens.

Pupillary dilatation was achieved with the use of two to three instillations of dilating drops (Tropicamide 1% and Phenylepherine 2.5%) applied five minutes apart over 15-20 minutes. Gentle pressure was applied over the medial canthal region to prevent systemic absorption. In addition, care was taken to wipe (with sterile cotton/ tissue) eye drops that overflowed onto the cheeks. Tetracaine hydrochloride (0.5%) eye drops were instilled into each eye to achievetopical anaesthesiaprior to insertion of a lid speculum to aid eye examination.

ROP staging

The stage of disease was determined based on the revised version of the International Classification of ROP.[22] Babies were classified according to the most advanced stage of ROP in the worse eye. Subsequent screening examinations were performed to ascertain disease regression or progression. These repeat examinations were done either weekly or fortnightly as indicated by the maturity of the retinal vasculature or severity of the disease. Infants with pre-threshold disease were examined every 3-4 days, while those with threshold disease were administered with intravitreal injections of anti- vascular endothelia growth factor (anti-VEGF), specifically, intravitreal Bevazicumab within 48 hours of diagnosis.

The screening protocol adhered to the tenets of the Declaration of Helsinki. Oral consent was obtained from the parents and in cases where there was initial parental refusal, it was documented in the records of the baby to enable the neonatologist counsel further in order to ensure no baby was denied screening.

Infants' demographic characteristics as well information on gestational age at birth, birth weight, oxygen therapy, and presence of other risk factors were retrieved from their records. Data was analysed with the use of IBM SPSS version 22. With regards to bivariate analyses, Fisher's exact test was used for categorical variables while Student T-test was used for continuous variables; and p values less than 0.05 were considered significant.

Results

A total of 74 infants were screened during the period. The mean age at screening was 49.1 (± 19.9) days.

There were 36 (48.6%) males giving a male to female ratio of 0.95: 1. The mean gestational age at birth was 29.6 (± 2.35) weeks, with a range of 23 to 38 weeks. The mean birth weight was 1.26 (± 0.27) kg with a range of 800 to 1950 grams. The mode of delivery was vaginal delivery for 48 (64.9%) infants and emergency caesarean section for 25 (33.8%) infants.

Twenty-eight mothers (37.8%) had prolonged rupture of membranes, nine (12.2%) had pre-eclampsia, and 9 (12.2%) had antepartum heamorrhage. Eighteen (24.3%) infants were products of multiple gestations,62 (83.8%) received supplemental oxygen therapy, while 20 (27.0%) had sepsis. The frequency distribution of the infants' co-morbidities and treatment interventions administered are presented in Table 1

Table 1: Systemic co-morbidities and treatment interventions in 74 infants

Systemic co-morbidities and interventions	Number of infants (n)	%
Systemic co-morbidities		
Hyperbilirubinemia	55	74.3
Respiratory distress syndrome	45	60.8
Anaemia	27	36.5
Sepsis (Confirmed)	20	27.0
Foetal asphyxia	15	20.3
Electrolyte/ Metabolic Imbalance	12	16.2
Apneic spells	11	14.9
Congenital Malformations	3	4.1
Necrotizing enterocolitis	3	4.1
Treatment interventions		
Supplemental oxygen therapy	62	83.8
Phototherapy	55	74.3
Blood transfusion	35	47.3

ROP was detected in 9 (12.2%) infants (Figures 1 and 2). With regards to severity, three (33.3%) infants had stage 1 ROP, four (44.4%) had stage 2 disease, while 2 (22.2%) had stage 3 disease. None of the infants examined had stage 4 or 5 ROP. The two (22.2%) infants with stage 3 disease also had Threshold ROP and were treated with intravitreal Bevazicumab with consequent regression of ROP. The remaining seven infants were observed and subsequent retinal examinations showed regression of ROP.

Fig 1: A retinal photograph of an infant with ROP showing avascular retina separated from the vascularized retina by a ridge (arrow).

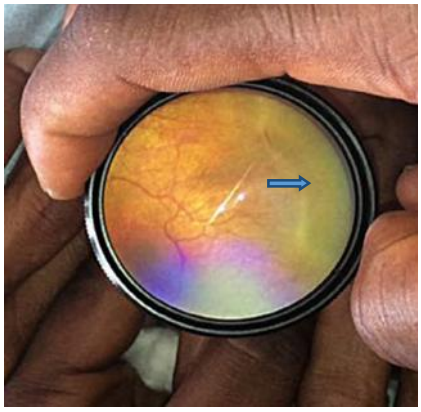
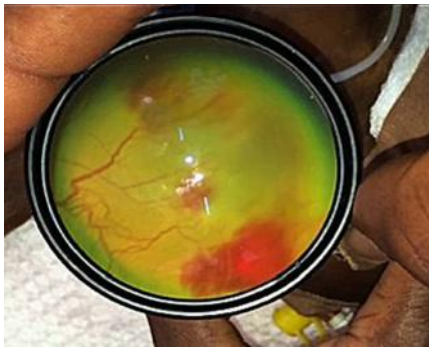


Fig 2: A retinal photograph of an infant with ROP showing tortuous retinal vessels and retinal haemorrhages



The mean birth weight of the infants who had ROP was 1.14 (± 0.27) kg compared with 1.28 (± 0.27) kg for ROP-free infants (p = 0.17). In addition, the mean gestational age of ROP infants was 29.8 (± 2.1) weeks compared with29.6 (± 2.4) weeks for ROP-free infants (p = 0.84). The proportion of infants with ROP was higher among those with birth weight <1250g (15.2%) compared to those with birth weight ≥1250g (10.0%) [p= 0.72, Table 2]. On the contrary, the proportion of infants with ROP was lower among those with gestational age <30 weeks (10.5%) compared to those with gestational age ≥30 weeks (13.9%) [p= 0.73, Table 2]. None of the other infant or maternal characteristics was significantly associated with the occurrence of ROP except necrotizing enterocolitis (Table 2).

Among the infants who developed ROP, the mean birth weight of the infants who developed Threshold ROP was 0.90 (± 0.07) kg compared with 1.21 (± 0.27) kg for infants who had less severe disease (p = 0.18). While the mean gestational age of Threshold ROP infants was 28.0 (±0.0) weeks compared to30.0 (± 2.1) weeks for the other infants with ROP (p = 0.40). Furthermore, two (40.0%) of the infants with ROP and birth weight <1250g developed Threshold ROP compared to none (0.0%) of the ROP infants with birth weight ≥1250g (p= 0.44, Table 3). Similarly, two (50.0%) of the infants with ROP and gestational age <30 weeks developed Threshold ROP compared to none (0.0%) of the ROP infants with gestational age ≥30 weeks (p= 0.17, Table 3). None of the other infant or maternal characteristics was significantly associated with the occurrence of Threshold ROP among the infants with ROP except Electrolyte/ Metabolic Imbalance (Table 3).

Challenges encountered during the course of the period included lack of awareness about ROP on the part of parents of the infants and nurses on the paediatric wards and clinic; lack/inadequacy of equipment such as retinal imaging devices and pulse oximeters; as well as suboptimal communication between ophthalmologists and neonatologists regarding newly admitted infants eligible for screening. In addition, there were challenges with obtaining parental consent (some mothers were not willing to wait for eye examination) as well as difficulty with the logistics of scheduling follow up examinations particularly for infants who had been discharged from the ward.

Table 2: Association between infant characteristics and occurrence of ROP (N=74)

Variable	Occurrence of ROP Yes n (%)	No n (%)	p value (Fisher's Exact Test)
Gestational Age (weeks)			
< 30	4 (10.5%)	34 (89.5%)	0.73
≥30	5 (13.9%)	31 (86.1%)	
Gender of infant			
Male	4 (11.1%)	32 (88.9%)	0.99
Female	5 (13.2%)	33 (86.8%)	
Birth weight (grams)			
<1250	5 (15.2%)	28 (84.8%)	0.72
≥1250	4 (10.0%)	36 (90.0%)	
Pre-eclampsia			
Yes	1 (11.1%)	8 (88.9%)	0.99
No	7 (10.9%)	57 (89.1%)	
Antepartum haemorrhage			
Yes	1 (11.1%)	8 (88.9%)	0.99
No	8 (12.3%)	57 (87.7%)	
Prolonged rupture of membranes			
Yes	3 (10.7%)	25 (89.3%)	0.99
No	6 (13.0%)	40 (87.0%)	
Multiple gestation			
Yes	1 (5.6%)	17 (94.4%)	0.67
No	7 (12.7%)	48 (87.3%)	
Supplemental Oxygen			
Yes	8 (12.9%)	54 (87.1%)	0.99
No	1 (8.3%)	11 (91.7%)	
Perinatal Asphyxia			
Yes	2 (13.3%)	13 (86.7%)	0.67
No	6 (10.5%)	51 (89.5%)	
Respiratory distress syndrome			
Yes	6 (13.3%)	39 (86.7%)	0.99
No	3 (10.7%)	25 (89.3%)	
Apneic spells			
Yes	2 (18.2%)	9 (81.8%)	0.29
No	5 (14.5%)	56 (91.8%)	
Hyperbilirubinemia			
Yes	5 (9.1%)	50 (90.9%)	0.38
No	3 (17.6%)	14 (82.4%)	
Blood transfusion			
Yes	3 (8.6%)	32 (91.4%)	0.49
No	6 (15.4%)	33 (84.6%)	
Sepsis (Confirmed)			
Yes	3 (15.0%)	17 (85.0%)	0.70
No	6 (11.1%)	48 (88.9%)	
Anaemia			
Yes	4 (14.8%)	23 (85.2%)	0.72
No	5 (10.9%)	41 (89.1%)	
Necrotizing enterocolitis			
Yes	2 (66.7%)	1 (33.3%)	0.04*
No	7 (9.9%)	64 (90.1%)	
Electrolyte/ Metabolic Imbalance			
Yes	2 (16.7%)	10 (83.3%)	0.64
No	7 (11.5%)	54 (88.5%)	

* p value < 0.05 (i.e. significant)

Table 3: Association between infant characteristics and occurrence of Threshold ROP (N=9)

Variable	Occurrence of ROP Yes n (%)	No n (%)	p value (Fisher's Exact Test)
Gestational Age (weeks)			
< 30	1 (33.3%)	2 (67.7%)	0.38
≥30	0 (0.0%)	5 (100.0%)	
Gender of infant			
Male	1 (25.0%)	3 (75.0%)	0.99
Female	1 (20.0%)	4 (80.0%)	
Birth weight (grams)			
<1250	2 (40.0%)	3 (60.0%)	0.44
≥1250	0 (0.0%)	4 (100.0%)	
Pre-eclampsia			
Yes	0 (0.0%)	1 (100.0%)	0.99
No	2 (28.6%)	5 (71.4%)	
Antepartum haemorrhage			
Yes	0 (0.0%)	1 (100.0%)	0.99
No	2 (25.0%)	6 (75.0%)	
Prolonged rupture of membranes			
Yes	1 (33.3%)	2 (67.7%)	0.99
No	1 (16.7%)	5 (83.3%)	
Multiple gestation			
Yes	0 (0.0%)	1 (100.0%)	0.99
No	2 (28.6%)	5 (71.4%)	
Supplemental Oxygen			
Yes	2 (25.0%)	6 (75.0%)	0.99
No	0 (0.0%)	1 (100.0%)	
Perinatalasphyxia			
Yes	0 (0.0%)	2 (100.0%)	0.99
No	2 (33.3%)	4 (67.7%)	
Respiratory distress syndrome			
Yes	2 (33.3%)	4 (67.7%)	0.50
No	0 (0.0%)	3 (100.0%)	
Apneic spells			
Yes	1 (50.0%)	1 (50.0%)	0.29
No	0 (0.0%)	5 (100.0%)	
Hyperbilirubinemia			
Yes	1 (20.0%)	4 (80.0%)	0.99
No	0 (0.0%)	3 (100.0%)	
Blood transfusion			
Yes	1 (33.3%)	2 (67.7%)	0.99
No	1 (16.7%)	5 (83.3%)	
Sepsis (Confirmed)			
Yes	1 (33.3%)	2 (67.7%)	0.99
No	1 (16.7%)	5 (83.3%)	
Anaemia			
Yes	2 (50.0%)	2 (50.0%)	0.17
No	0 (0.0%)	5 (100.0%)	
Necrotizing enterocolitis			
Yes	1 (50.0%)	1 (50.0%)	0.42
No	1 (14.3%)	6 (85.7%)	
Electrolyte/ Metabolic Imbalance			
Yes	2(100.0%)	0 (0.0%)	0.03*
No	0 (0.0%)	7 (100.0%)	

* p value < 0.05 (i.e. significant)

Discussion

The incidence of ROP in our hospital is similar to an earlier report from Lagos University Teaching Hospital, Lagos state (15%).[21] However, it is much less than the figure of 47.2% reported from University of Port Harcourt Teaching Hospital, Rivers state.[20] There are a few subtle differences between our study and the Port Harcourt study. Firstly, the mean GA of the infants in the Port Harcourt study (approx. 29 weeks) was slightly less than that of the infants in our study (approx. 30 weeks). Secondly, the mean birth weight of the Port Harcourt infants (1.41kg) was higher than our finding of 1.26kg. Thirdly, our screening criteria included preterm infants with GA up to 34 weeks while they screened babies with GA of 32 weeks and below. These differences, however, may not entirely explain the marked dissimilarity in the incidence figures from the two studies and further research especially from other neonatal units in the country may be necessary.

On the other hand, the proportion of treatable ROP in the Port Harcourt study (1.89%) was less than in our study (2.7%).[20] While the proportion in the Lagos study (7.5%) was more than double the proportion of treatable ROP found in our study.[21] This differences may reflect differences in the severity of systemic co-morbidities as well as the quality of neonatal care across the populations of infants in the three studies. Further reports of ROP screening programs in other centers across the country may shed more light on this.

With regards to the risk factors for ROP, we found that, on average, the infants who had ROP had lower birth weight than those without ROP; while those with ROP had slightly greater GA at birth than those without ROP. These differences were, however, not statistically significant. Similarly, the Lagos and Port Harcourt studies did not find any significant differences between the mean birth-weight and mean gestational age of the infants who had ROP compared to those who did not have ROP.[20,21] These findings may suggest that there are other factors apart from birth weight and gestational age that are more important risk factors for ROP in Nigerian infants.

Yet, other well known risk factors for ROP such as use of supplemental oxygen, sepsis, anaemia, respiratory distress, multiple gestation, blood transfusion and jaundice were found not to be significantly associated with the occurrence of ROP in this study. Only necrotizing enterocolitis was significantly associated with ROP. This may be related to the relatively small number of babies screened. In the same vein, the Lagos study did not find any associations between these risk factors and ROP.[21] While, the Port Harcourt study found that supplemental oxygen therapy, sepsis and blood transfusions were significantly associated with ROP.[20] Additional studies, preferably multi-center studies, are necessary to further investigate the risk factors for ROP in Nigerian infants. The identification of such risk factors would aid the development of country specific screening criteria and guidelines.

This report provides further evidence that ROP is not rare in Africans, as was previously thought. Increasing neonatal survival rates as a result of improvement in care have been suggested as the reason for the apparent increase in incidence of ROP.[9,11] Nevertheless, the increasing incidence of ROP is a cause for grave concern as it could easily translate to an increase in the incidence of childhood blindness in the country. When it is not detected and treated, ROP may progress to advanced disease that often results in incurable blindness. Therefore, early detection and prompt treatment of ROP in babies at risk is crucial in preventing blindness from ROP.

Furthermore, Nigeria has one of the highest rates of preterm delivery in the world.[9] As at 2018, the World Health Organization ranked Nigeria as the third among the 10 countries with the highest number of preterm deliveries, estimated at 773,600 preterm births annually.[23] This makes ROP screening programs to be of paramount importance in the country. Unfortunately, there are currently no national guidelines nor policies for ROP screening in Nigeria.[11] In addition, recent studies conducted amongst both paediatricians and ophthalmologist have shown that rates of screening for ROP are low.[24,25] Thus, there is a very urgent need for the establishment of national ROP screening and treatment protocols and guidelines in anticipation of the upsurge of ROP in surviving preterm neonates.

The challenges encountered are similar to some of the challenges reported by other programs.[9] Surmounting some of these challenges would involve solutions such as parental counselling and education, assigning a specific person to the role of coordinating the identification and screening of infants at risk, as well the use of mobile phone retinal imaging for ROP screening.[9,10,19] It is also expedient to incorporate information on documented risk factors from developed countries in parental and neonatal practitioners' education in order to forestall the likely upsurge in incidence of ROP associated with improved preterm survival as this evolves in our low resource setting.

Limitation

The limitation of this study is its retrospective nature and also the fact that the babies were not examined by a single ophthalmologist which could have led to inter observer variation. However, steps were taken to address this by having a facility based standardized protocol for screening and examination.

Conclusion

In conclusion, ROP may be emerging as a significant health problem that must be addressed as the survival rates of preterm infants improve. Neonatal care units across the country are encouraged to ensure that all infants at risk are screened or referred to centres where

they can be screened. In addition, there is a need to develop country-specific guidelines for ROP screening. This can be facilitated by further research to evaluate the screening criteria of established programs and investigation of specific risk factors associated with ROP in Nigerian infants.

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