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Retinopathy of prematurity among infants admitted to two neonatal intensive care units in Ethiopia

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ABSTRACT

Objective This study was conducted to determine the prevalence and risk factors for retinopathy of prematurity (ROP) in two neonatal intensive care units (NICUs) in Addis Ababa, Ethiopia.

Methods and analysis A prospective screening survey was conducted from June 2019 to June 2020 in two level 3 public NICUs. Infants with a birth weight (BW) of ≤1500 g or gestational age (GA) of ≤32 weeks and those with a BW of >1500 g and GA of >32 weeks with an unstable clinical course were included. Data on demographic and neonatal characteristics, neonatal and maternal comorbidities, and therapeutic interventions were collected. Logistic regression analysis was used to identify predictors of ROP.

Results Two hundred and two infants were included: mean BW: 1658g (range: 700–2400 g) and mean GA: 32.4 weeks (range: 26–34 weeks). 32.2% had any stage of ROP, and 6.4% had Type 1 ROP. Lower BW, smaller GA and total days on oxygen were independent risk factors for severe ROP (Type 1 or worse). All 13 neonates with severe ROP were treated.

Conclusion ROP is emerging as a concern in Ethiopia. ROP screening should include neonates with BW of <1800 g or GAs of ≤33 weeks, but further studies are needed in level 2 and private NICUs. Screening guidelines need to be developed and implemented in all hospitals with NICUs.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ In many low-income and middle-income countries, the survival of preterm infants has improved as neonatal systems have improved.
⇒ As a consequence, the risk of infants becoming blind from retinopathy of prematurity (ROP) has also increased in sub-Saharan African countries.

WHAT THIS STUDY ADDS

⇒ This study, which was conducted in two neonatal intensive care units in a sub-Saharan country, shows that preterm infants developing sight threatening ROP are more mature than in high income countries, and supplemental oxygen, respiratory distress and low gestational age and birth weight were independent risk factors.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Findings of this study provide some evidence for ROP screening guidelines, but further studies are needed.

INTRODUCTION

Retinopathy of prematurity (ROP) is a vasoproliferative disorder that affects the developing retinal vessels of premature newborns.[1] ROP is a leading preventable cause of blindness in children, particularly in middle-income countries. In 2010, the annual incidence of blindness and vision impairment due to ROP was estimated to be 32 300 infants.[2]

In sub-Saharan Africa, ROP is beginning to emerge as a cause of blindness in children as neonatal intensive care services expand.[3]

The risk of ROP is inversely related to gestational age (GA) and birth weight (BW) and the risk is higher in those with neonatal comorbidities.[4] Poorly monitored supplemental oxygen leading to hyperoxia is a recognised risk factor for treatment-requiring ROP,[5] as are low serum IGF-1, poor postnatal weight gain, sepsis, blood transfusion[4] and thrombocytopenia.[6]

In high-income countries, treatment-requiring Type 1 ROP usually only affects extremely preterm (<30 weeks), low BW (<1000 g) infants, with the risk being much lower in more mature preterm infants.[5] These findings reflect the high quality of perinatal and neonatal care these infants receive. In low-income countries, rates of Type 1 ROP can also be low, as most infants at risk do not survive. A different picture is seen in middle-income countries, where neonatal care can be suboptimal, and infants are exposed to risk factors, such as poorly regulated supplemental oxygen and sepsis, which are largely controlled in high-income settings. In middle-income countries, rates of Type 1 can be high, and can affect infants with a GA of >34 weeks or BW of >1500 g.[3 7 8] The same picture is beginning to emerge in sub-Saharan African countries,[9] where neonatal care is developing

and expanding, but where infants can be exposed to poorly regulated oxygen and other risk factors.

In 2014, the global preterm birth rate was estimated to be 10.6%, with 14.84 million live preterm births; Asia and Sub-Saharan Africa accounted for 12 million preterm births (81.1%).[10] Survival rates for preterm infants have improved in many low-income and middle-income countries as neonatal systems have improved. ROP has not been documented as a significant cause of blindness in low-income countries, but the expansion of neonatal care[11 12] has increased survival and hence the risk of developing ROP. In Africa, South Africa, Nigeria and Kenya have ROP screening guidelines.[9 13 14]

Ethiopia planned to reduce neonatal mortality from 28/1000 in 2015/2016 to 10/1000 in 2019/2020, and to end preventable deaths among newborns and children under 5 years by 2030.[15] Ethiopia is the second most populous country in Africa, and 11.4% of births are preterm (<37 weeks of gestation), that is, approximately 320 000 babies each year.[16] Before 2020, blindness from ROP was not reported in Ethiopia, including from studies in school for the blind.[17 18] However, in 2020, a retrospective study by a paediatric ophthalmologist in a private eye centre showed that 12.9% of the infants born preterm who presented were blind from advanced ROP.[19] The study was undertaken in two neonatal intensive care units (NICUs) in the capital city, Addis Ababa: Tikur Anbessa Specialized Hospital (TASH), which is a leading government owned university teaching hospital, and Menelik II, a government referral hospital. The purpose of this prospective study was to determine the proportion of preterm newborns who develop ROP, to identify risk factors for ROP and to describe the outcomes of ROP management.

METHODS

Study design

Written informed consent was obtained from all guardians of study participants. Patients or the public were not involved in our research's design, conduct, reporting or dissemination plans.

Study setting

The NICUs of Menelik II and TASH are the leading neonatology units in Ethiopia. The NICU at TASH is a level 2 unit with 40 beds, which admits 250–300 neonates per month. The unit has 3 neonatology consultants, 8 paediatric residents, 10 interns and 14 nurses. The NICU at TASH has access to portable ultrasound and blood transfusion services. Menilik II hospital is also a referral hospital with access to blood transfusion services. The level 3 NICU has 21 neonatal beds and the unit is staffed by 1 paediatrician, 1 general practitioner and 24 nurses.

Inclusion and exclusion criteria

The study population included all consecutive preterm infants admitted to the 2 NICUs from June 2019 to June 2020 with a GA of ≤34 weeks or a BW of ≤1500 g. Infants with a BW between 1500 g and 2500 g and a GA of >34 weeks to <37 weeks with sickness criteria (ie, needed cardiorespiratory support, prolonged oxygen therapy, apnoea of prematurity, anaemia needing blood transfusion and neonatal sepsis) or who were believed by their attending paediatrician or neonatologist to be at high risk were also included. Parents of neonates who met these criteria were asked to provide informed consent. Neonates with congenital ophthalmic abnormalities and parents who refused to participate were excluded.

Clinical characteristics

Eligible neonates were identified by reviewing medical records and the following data were extracted: antenatal risk factors: maternal age, in vitro fertilisation, antenatal corticosteroids, pre-eclampsia/eclampsia, diabetes, HIV/AIDS, chorioamnionitis, mode of delivery and multiple births. Neonatal factors included sex, GA, BW, resuscitation in the delivery room, respiratory distress syndrome (RDS), duration of invasive/non-invasive mechanical ventilation and oxygen therapy, intracranial haemorrhage, patent ductus arteriosus (PDA), neonatal sepsis, necrotising enterocolitis (NEC), the number of blood transfusions, intraventricular haemorrhage (IVH) and bronchopulmonary dysplasia.

Definitions

GA was ascertained from the maternal last menstrual period (LMP), or first trimester ultrasound parameters if LMP was not certain. Sepsis was diagnosed based on positive blood cultures. PDA was confirmed by two-dimensional echo cardiography. IVH and hydrocephalus were diagnosed by serial transfontanelle ultrasound. RDS was confirmed using clinical and radiological characteristics.

Eye examination

Screening was undertaken by the lead author, an ophthalmologist qualified to conduct ROP screening. The first screening took place during the fourth postnatal week, and thereafter at 1–2 weekly intervals using the schedule for follow-up recommended by American Academy of Pediatrics, American Academy of Ophthalmology and American Association for Pediatrics Ophthalmology and Strabismus.[20] Pupils were dilated with topical phenylephrine 2.5% and tropicamide 1% applied 1 hour before examination. Indirect ophthalmoscopy with a 28-diopter lens was performed with a speculum and scleral depressor under topical anaesthesia. A drop of dextrose 14% was given orally to promote pain relief. Pacifiers, nesting and swaddling were also used to facilitate examination.

The International Classification of ROP (2005 revision) was used to record the stage, zone and signs of plus disease.[21] Ophthalmic examinations were continued until full retinal vascularisation or complete regression, or until the infant had reached the postmenstrual age of 45 completed weeks. The primary outcomes were (1) the presence of any of the five stages of ROP and (2) the

presence of Type 1 ROP, based on the Early Treatment for Retinopathy of Prematurity trial in one or both eyes.[21] The data were analysed using the most advanced stage of ROP in the most affected eye.

Statistical analyses

Basic descriptive statistical analysis was undertaken using IBM SPSS Statistics (V.21.0). Associations between ROP and continuous and categorical variables were computed using Fisher's exact test and Pearson χ^2 test, respectively. Continuous variables were compared using Analysis of variance (ANOVA). Values of p <0.05 were considered statistically significant. Binary logistic regression analysis was used to assesses risk factors for ROP. Variables which were significant at the 0.25 level in univariable analysis were used in the multivariable mode. The goodness of fit of the final model was assessed using the Hosmer and Lemeshow test[22] and the final model fitted the data well (p=0.876). Adjusted ORs are reported with 95% CIs; a p value of <0.05 was considered statistically significant.

RESULTS

During the study period, 4382 infants (1240 at Menelik II hospital; 3142 at TASH) were admitted. Two hundred and two infants (158 at Menilik II; 44 at TASH) met the criteria for ROP screening and were included in this study.

Characteristics of the study population

Slightly more males than females were screened (52.9% and 47.1%, respectively) (table 1). Ninety seven of the 202 neonates (48%) had a GA ≤32 weeks and 88 (43.6%) had a BW ≤1500 g. BW ranged from 700 g to 2400 g with a mean of 1658.04 g (SD: 426.1 g); GA ranged from 26 weeks to 34 weeks, with a mean of 32.4 weeks (SD: 1.8 weeks). The mean BW of neonates from Menelik II and TASH NICUs was 1671.83±424.64 g (700–2700 g) and 1497.81±422.86 g (900–2700 g), respectively; mean GAs were 32.41±1.77[23–31] weeks and 32.13±2.1[25–31] weeks, respectively. Differences in these parameters were not statistically significant (table 2).

One hundred and twenty three newborns (60.9%) were delivered vaginally and 61 (30.2%) had a multiple gestation. Four neonates (2%) were born to mothers with diabetes, and 6 (3%) mothers tested positive for HIV.

ROP and risk factors

In both NICUs, the mode of oxygen delivery was either through a nasal cannula or continuous positive airway pressure. None of the neonates were intubated for resuscitation.

Overall, 65 (32.2%) of the neonates had any stage of ROP: 35 (15.9%) had stage 1, 18 (8.9%) had stage 2, 11 (5.4%) had stage 3 and 1 had stage 4 (0.05%). No neonates had aggressive posterior ROP (APROP). There was no statistically significant difference in characteristics of the infants screened nor in the proportion of infants developing ROP between the two NICUs (table 2).

Table 1 Characteristics of premature neonates screened for ROP

Variable	N	%
Sex		
Male	107	53
Female	95	47
BW		
<1000 g	7	3.5
1000–1500 g	81	40.1
1501–2500 g	110	54.5
>2500 g	4	2
GA		
<28 weeks	3	1.5
28–32 weeks	94	46.5
32.1–34 weeks	105	52
Mode of delivery		
Vaginal delivery	123	60.9
Caesarean section	79	39.1
Multiple gestation		
No	141	69.8
Twin	56	27.7
Triplet	5	2.5
Maternal HIV status		
HIV positive	6	3
HIV negative	196	97
Maternal diabetes		
Yes	4	2
No	198	98

BW, birth weight; GA, gestational age; ROP, retinopathy of prematurity.

Overall, 12 neonates (5.9%) had Type 1 ROP, and 1 had stage 4. Four (9.1%) of the severe ROP cases (ie, Type 1 ROP or worse) were from TASH, and 9 (5.7%) from Menelik II hospital (p=0.42).

The mean GA of the 65 neonates with any ROP was 31.3±1.7 weeks (range: 26–34 weeks) and 32.91±1.59 weeks (range: 26–34 weeks) for neonates without ROP (p<0.05) (table 3). Fifty-five neonates (84.6%) with any ROP had a GA of <32 weeks and the mean GA for those with stages 3 or 4 ROP was 28.2 weeks. The mean BW was 1367.31±344.42 g (700–2300 g) among infants with ROP and 1795.99±391.03 g (900–2700 g) in infants without ROP (p<0.05). The mean BW of neonates with stages 3 or 4 ROP was 1324.08±343.69 g (700–2000 g).

Most neonates with severe ROP (10/13) had BW <1500 g (table 3). Fifty five of the 65 neonates with any ROP had a GA ≤32 weeks and all had a BW of less than 2500 g. Only 1 neonate with severe ROP had a GA of >32 weeks and a BW of >1500 g (figure 1). The mean BW and

Table 2 bComparison of GA, BW and ROP between the 2 NICUs

Variables	Menelik II (n=158)	TASH (n=44)	P value
Screened for ROP			
Mean GA (weeks)	32.41±1.77	32.13±2.1	0.631
Mean BW (g)	1671.83±424.64	1497.81±422.86	0.483
Severe ROP, n (%)	9 (5.7%)	4 (9.1%)	0.42
Mean GA (weeks)	30.7±1.7	28±0	0.681
Mean BW (g)	1255±280	1135±191	0.322

BW, birth weight; GA, gestational age; NICUs, neonatal intensive care units; ROP, retinopathy of prematurity; TASH, Tikur Anbessa Specialized Hospital.

GA of neonates with severe ROP were 1236.5+264.2 g and 30.3+1.9 weeks, respectively.

Neonatal comorbidities and maternal characteristics

Neonatal comorbidities were as follows: sepsis 145 babies (71.8%); RDS 135 (66.8%); NEC 7 (3.5%), IVH 2 (1%) and PDA 2 (1%). Seventy five babies (37.1%) had phototherapy for jaundice and 28 (13.9%) had blood transfusions. The mean age of mothers was 27.4+5.1 years (range: 18–40 years); 17 mothers had pregnancy-induced hypertension (14 pre-eclampsia, 3 eclampsia), 6 had HIV and 4 (2%) had diabetes.

In univariate analysis, there was a significant association between ROP and lower GA (p≤0.001), being female (p=0.026), lower BW (p≤0.001), oxygen therapy (p=0.018), oxygen treatment for more than a week (p=0.001) and RDS (p=0.001) (table 4). In multivariate analyses, the following were independent risk factors for any ROP: GA (for every week) (OR: 0.72, 95% CI 0.543 to 0.954; p=0.022), BW (for every 100 g) (OR: 0.997, 95% CI 0.995 to 0.998; p<0.0001), supplemental oxygen (p<0.0001), duration of oxygen (for 1 more week on oxygen) (OR: 2.338; 95% CI 0.802 to 6815; p=0.12) and RDS (p=0.025).

Among the 65 infants with ROP, 52 (80%) spontaneously regressed and 13 (20%) required intervention. The median GA of infants treated was 30.3±1.9[24–30] weeks, and the median BW was 1236±264 g (700–1700 g). Twelve infants were given intravitreal bevacizumab (IVB) and one underwent pars plana vitrectomy. Among those treated with IVB, the ROP regressed in 10 and two required a second injection.

DISCUSSION

This is the first prospective, descriptive study of rates of and risk factors for ROP in Ethiopia's leading teaching NICUs, and one of only a few studies from sub-Saharan Africa. The rate of neonatal death in sub-Saharan Africa has decreased by 40% since 1990, reflecting improvements in newborn care, which is likely to lead to an increase in ROP.[32] Although Africa has been described as the 'new frontier' of ROP blindness,[33] data on ROP in sub-Saharan Africa are limited, and studies in schools for the visually impaired and hospitals in eastern Africa suggest currently that only a low proportion of children of school-going age have retinal disorders, including ROP.[17 18 23 34]

Since 2013, intensive neonatal care has expanded in many public hospitals and private NICUs in Ethiopia,[24] and neonatal mortality per thousand live births has declined modestly from 39 in 2000 to 33 in 2019.[15]

Table 3 ROP in relation to GA and BW

	Screened (n=202)	Any ROP (n=65)		Severe ROP (n=13, %)	
Variable	N	N	%	N	%
GA					
<28 weeks	3	2	66.7%	1	33.3%
28–32 weeks	94	53	56.4%	11	11.7%
32.1–34 weeks	105	10	9.5%	1	1.0%
BW					
<1000 g	7	6	85.7%	1	14.3%
1000–1500 g	81	38	46.9%	9	11.1%
1501–2500 g	110	21	19.1%	3	2.7%
>2500 g	4	0	0.0%	0	0.0%

BW, birth weight; GA, gestational age; ROP, retinopathy of prematurity.

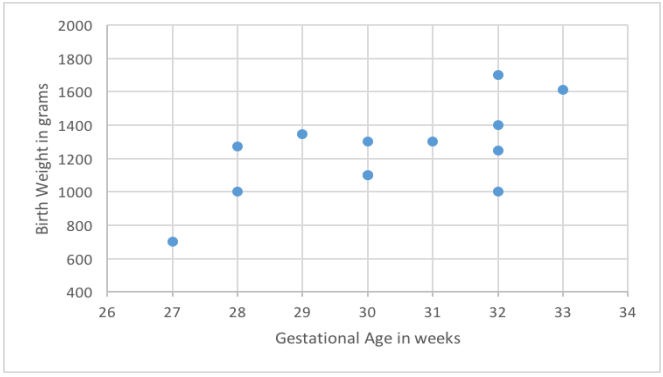

Figure 1 GA and BW of infants with Type 1 or stage 4/5 ROP at Menelik II and TASH NICUs, Addis Ababa, Ethiopia (n=13). BW, birth weight; GA, gestational age; NICUs, neonatal intensive care units; ROP, retinopathy of prematurity; TASH, Tikur Anbessa Specialised Hospital.

Despite the increasing number of NICUs, there are no national screening guidelines nor a programme for ROP, apart from pilot screening at TASH and Menelik II hospital.

In our study, a third of neonates had ROP of any severity. Similar findings have been reported from South Africa (29.6%),[25] India (30%),[26] Pakistan (32.4%),[27] Oman (34%)[28] and Iran (29%),[25] which is perhaps surprising given the variation in screening criteria, and likely variation in the quality of neonatal care and survival of preterm infants most at risk.[7] The findings in our study are comparable with those from other low-income and middle-income countries, indicating that more mature and heavier newborns also develop severe ROP. In our study, severe ROP developed in 6.9% of neonates, which is comparable to other studies in Africa, that is, from Rwanda (3.9%),[29] South Africa (5.9%),[30] Sudan (5.2%),[31] Nigeria (7.5%)[35] and Kenya (8.7%)[36] (online supplemental table 1). All studies showed that more mature, heavier newborns were affected than in high-income countries. In our study, no infant developed APROP, as in other studies from sub-Saharan Africa, and none became blind from ROP. APROP usually occurs in extremely preterm, low BW infants, the majority of whom do not survive in this setting.[21]

In univariate analysis, the following variables were associated with ROP of any severity: lower BW, lower GA, being female, RDS, oxygen supplementation and oxygen therapy for more than 7 days. In multivariable analysis, lower BW and GA, RDS and oxygen supplementation

Table 4 Risk factors for any ROP among neonates admitted to two NICUs in Addis Ababa, Ethiopia

Variable	Category	Total	Any ROP (%) n=65	No ROP (%) n=137	Univariate analysis		Multivariable analysis	
					OR (95% CI)	P value	OR (95% CI)	P value
Birth weight (g)	≤1500	92	46 (50%)	46 (50%)	4.79 (2.52 to 9.09)	<0.001	2.74 (1.22 to 6.19)	<0.001
	>1500	110	19 (17%)	91 (83%)	Ref.			
Gestational age (weeks)	≤32	96	55 (57%)	41 (43%)	12.44 (5.79 to 26.75)	<0.001	10.35 (4.06 to 26.39)	0.022
	>32	106	10 (9%)	96 (91%)	Ref			
Supplemental oxygen	Yes	170	61 (36%)	109 (64%)	3.74 (1.25 to 11.20)	0.018	7.48 (2.95 to 15.32)	<0.001
	No	32	4 (12%)	28 (88%)	Ref.			
RDS	Yes	135	54 (40%)	81 (60%)	3.39 (1.63 to 7.06)	0.001	4.72 (1.21 to 18.38)	0.025
	No	67	11 (16%)	56 (84%)	Ref.			
Sex	Female	95	38 (36%)	57 (64%)	1.98 (1.09 to 3.60)	0.026	1.50 (0.60 to 3.72)	0.384
	Male	107	27 (25%)	80 (75%)	Ref.			
Multiple birth	No	141	45 (32%)	96 (68%)	0.995 (0.53 to 1.89)	0.987	0.64 (0.23 to 1.77)	0.392
	Yes	61	20 (33%)	41 (67%)	Ref.			
Mode of delivery	Vaginal delivery	123	40 (33%)	83 (67%)	1.04 (0.57 to 1.91)	0.897	0.84 (0.33 to 2.15)	0.715
	Caesarean section	79	25 (32%)	54 (68%)	Ref.			
Duration of oxygen therapy (weeks)	>1	44	26 (59%)	18 (41%)	3.22 (1.61 to 6.45)	0.001	2.34 (0.82 to 68)	0.12
	≤1	126	35 (28%)	91 (72%)	Ref.			
Blood transfusion	Yes	28	14 (50%)	14 (50%)	2.41 (1.07 to 5.42)	0.033	0.73 (0.20–2.61)	0.624
	No	174	51 (29%)	123 (71%)	Ref.			
Phototherapy	Yes	75	27 (36%)	48 (64%)	2.41 (1.07 to 5.42)	0.033	0.73 (0.20–2.61)	0.624
	No	127	38 (30%)	89 (70%)	Ref.			
Sepsis	Yes	145	52 (36%)	93 (64%)	1.89 (0.93 to 3.83)	0.076	1.75 (0.66–4.66)	0.262
	No	57	13 (29%)	44 (77%)	Ref.			

NICUs, neonatal intensive care units; RDS, Respiratory distress syndrome; ROP, retinopathy of prematurity.

were independent risk factors for ROP. Lower BW and GA are well-recognised risk factors for ROP, as is exposure to supplemental oxygen.[4] Measuring exposure to hyperoxia in preterm infants is challenging, as this requires continuous monitoring over several weeks using monitors which record the periods when oxygen saturation is above or below specified thresholds. A large cohort study showed that the number of days infants received supplemental oxygen in the first 4 weeks of postnatal life was associated with severe ROP,[5] but this was not an independent risk factor in our study. The advantage of using days in oxygen as an exposure measure is that it is easier to collect these data rather than measuring the duration and degree of exposure to hyperoxia over several weeks.

Over half of the neonates in our study with a BW <1500 g and a GA <32 weeks developed ROP. This is consistent with the findings from Singapore,[37] Brazil[38] and the USA.[39] In our study, the mean GA of newborns with severe ROP was higher than the GA of 26 weeks reported in industrialised countries; the mean BW was 1236.5 g. Both of these values are within the range reported in other low-income and middle-income countries (903–1527 g and 26.8–33.5 weeks, respectively).[7]

Poorer control of potentially modifiable risk factors, such as hyperoxia, sepsis and poor weight gain, is the likely explanation. In our study, mode of delivery, which is not consistently associated with ROP in other studies,[4] was not associated with ROP.

Being female was a statistically significant risk factor in our study, but sex differences have not been consistently reported in other studies. Indeed, a recent meta-analysis reported no sex differences among infants treated for ROP.[4]

All 12 infants with Type 1 ROP were treated with IVB, only two of whom required a repeat injection. In our setting, IVB is the only treatment possible, as a portable laser and general anaesthesia for neonates are not available.

A strength of the study is that it was a multicentre, prospective cohort study. Limitations are that data were not collected on thrombocytopenia, and the 2005 revision of the International Classification of ROP was used and not the 2021 revision.[40] However, the definition of Type 1 ROP has not changed.

CONCLUSIONS

In conclusion, rates of ROP in these two units in Ethiopia were comparable to findings from other sub-Saharan African countries. Lower GA and BW, RDS and oxygen administration were all significant risk factors for severe ROP. As the two NICUs included in the study are the main neonatal referral centres in Ethiopia, it can be postulated that ROP is emerging as a potentially avoidable cause of blindness in Ethiopia, which is likely to increase as neonatal care services continue to expand. ROP screening criteria should encompass neonates most at risk of Type 1 ROP, which in these two NICUs would be a BW of <1800 g or a GA of ≤33 weeks. Further studies are needed to refine the criteria in level 2 and private NICUs. Screening and treatment guidelines need be developed, and ROP services provided in all hospitals with neonatal care facilities, which is likely to require raising awareness among neonatologists and paediatricians.

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Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval This study involves human participants. This cross-sectional study was approved by the the Institute Ethics Committee of Department of Ophthalmology, Addis Ababa University (ref. no.: 008/19/AAUDO). All study procedures adhered to the principles outlined in the Declaration of Helsinki for research involving humans. Participants gave informed consent to participate in the study before taking part.

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