RETINOPATHY OF PREMATURITY: INCIDENCE AND RISK FACTORS AT MUHIMBILI NATIONAL HOSPITAL DAR ES SALAAM, TANZANIA.

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A Dissertation Submitted In (Partial) Fulfillment of the Requirements for Degree of Masters of Medicine (Ophthalmology) of Muhimbili University of Health and Allied Sciences

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MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

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Retinopathy of Prematurity: Incidence and Risk Factors at Muhimbili National Hospital Dar es Salaam, Tanzania.

By

Yusta A. Mtogo

A Dissertation Submitted in (Partial) Fulfillment of the Requirements for Degree of Masters of Medicine (Ophthalmology) of Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by the Muhimbili University of Health and Allied Sciences a dissertation entitled: **"Retinopathy of Prematurity: Incidence and Risk Factors at Muhimbili National Hospital Dar es Salaam**, **Tanzania"** in partial fulfilment of the requirements for the degree of Master of Medicine (Ophthalmology) of the Muhimbili University of Health and Allied Sciences.

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DECLARATION AND COPYRIGHT

I, Yusta A. Mtogo declare that this dissertation is my own original work and it has not been presented and will never be presented to any other university for a similar or any other degree award.

Signature: ..... **Date: .....**

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DEDICATION

This work is dedicated to my lovely husband Dr. Bakari Gillah and our two lovely children, Amina and Absheikh and to my parents. Their love, patience, encouragement, understanding and sacrifices made all this work possible.May almighty God bless them all.

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LIST OF ABBREVIATIONS

ART	:	Assisted Reproductive technology
Bwt	:	Birth weight
CBC	:	Complete blood count.
CI	:	Confidence interval
COECSA	:	College of Ophthalmology of Eastern, Central and Southern Africa
C/S	:	Caesarian section
ET-ROP	:	Early Treatment for Retinopathy of Prematurity
GA	:	Gestational age
HR	:	Hazard rate
ICROP	:	International Classification of Retinopathy of Prematurity
IGF-1	:	Insulin like growth factor one
IVH	:	Intraventricular hemorrhage
LTFU	:	Lost to follow up
MMed	:	Masters of medicine
MNH	:	Muhimbili National Hospital
MUHAS	:	Muhimbili University of Health and Allied Sciences
NICU	:	Neonatal intensive care unit.
PMA	:	Post menstrual age
RBG	:	Random blood glucose
RCH	:	Reproductive and child health
RDS	:	Respiratory distress syndrome
ROP	:	Retinopathy of prematurity.
RR	:	Relative risk
SSA	:	Sub Saharan Africa
SVD	:	Spontaneous Vertex Delivery
TDHS	:	Tanzania Demographic Health Survey
TOS	:	Tanzania Ophthalmology Society
USA	:	United States of America
UTI	:	Urinary tract infection
VEGF	:	Vascular endothelial growth factor
WHO	:	World Health Organization

DEFINITION OF KEY TERMS

Premature newborn: Is a live born baby before the completion of 37 weeks of gestation.

Retinopathy of Prematurity: Is an eye disorder affecting premature infants characterized by abnormal blood vessel development in the retina.

ABSTRACT

Background: Retinopathy of prematurity (ROP) is a vasoproliferative retinal disorder affecting premature newborns. It is one of the leading causes of preventable childhood blindness. In Tanzania, improvement in neonatal care has led to increased survival of preterm babies. However, data on the incidence and risk factors for ROP are scarce.

Aim: This study was done to determine the incidence and risk factors associated with ROP among preterm babies at Muhimbili National Hospital.

Methods: A prospective cohort study was conducted among 193 preterm newborns of gestational age (GA) ≤34 weeks and birth weight (Bwt) ≤2000g as well as those with unstable clinical course from June 2020 to February 2021. ROP screening entailed a dilated fundus examination using an indirect ophthalmoscope. Cumulative incidence was determined as the proportion of babies clinically diagnosed with ROP by the end of the study period. Risk factors associated with ROP were analyzed. P value of <0.05 was considered statistically significant.

Results

The cumulative incidence of ROP was 29% (56/193) and severe ROP incidence of 8.8% (17/193). Majority of infants with ROP had stage two 41.1% and zone two disease 73.2%.Also, 8.93% had aggressive posterior retinopathy of prematurity. Multivariate analysis revealed 6 factors as significant independent predictors of ROP occurrence, GA less than 32weeks with hazard ratio (HR) 6.8 and p value 0.000), Bwt less than 1500 (2.1, 0.021), Apgar score less than 7 (1.9, 0.029), RDS (3.3, 0.013), oxygen supplementation for more than a week (0.74, 0.034) and Intraventricular hemorrhage (9.7, 0.001). Surfactant use had a protective role with HR of 0.2 and p value of 0.027.

Conclusion

ROP incidence is relatively high at MNH. Screening is essential to prevent visual morbidity and blindness that may result from the disease.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Retinopathy of prematurity (ROP) is a neovascular disorder of the retina that occurs in premature infants [1]. It is an important cause of preventable blindness in children, accounting for about 10% of childhood blindness[1,2,3]. Worldwide, about 10.6 percent of newborns are delivered prematurely each year and 60% of world preterm births occur in Asia and Sub-Saharan Africa[3]. Prematurity is the leading cause of death in infants and a cause of significant morbidity later in life. In Tanzania, 236,000 newborns are delivered prematurely each year [4]. Improvements in health care systems, including the availability of high-quality neonatal intensive care units has led to considerable decline in neonatal mortality in many countries. The Tanzania Demographic Health Survey 2015/16 reported improved under five survival rates including premature babies in the past two decades. However, the improved survival of very premature infants has also resulted in an increased rate of prematurity complications including ROP [1]. Again, more premature infants are also surviving in developing countries, where uncontrolled oxygen delivery for management of respiratory distress syndrome (RDS) is still being used, causing an increase in ROP cases in developing countries around the world [5].

The pathogenesis of ROP is related to disruption of normal retinal neuronal and vascular development in premature infants. After premature birth, there is a change from relatively hypoxic intrauterine life to hyperoxic extra-uterine life. With this change, a disruption of the normal angiogenesis and vascularization of the retina happens as a result of reduction in vascular endothelial growth factor (VEGF) and Insulin like growth factor 1 (IGF-1) in the retinal tissues due to relative hyperoxia. This will culminate in the arrest of retinal vascularization. Following the arrest of growth of retinal vessels, the developing retinal tissue becomes ischemic and hypoxic, causing up-regulation of VEGF leading to neovascularization [6,7]. The growing abnormal blood vessels are fragile and leaky, they can cause vitreous hemorrhage. The new vessels are also accompanied by fibroblast proliferation, which produces fibrous scar tissue. When this scar tissue contracts, it pulls the retina out of position causing

tractional retinal detachment [8]. Retinal detachment is the end stage of the disease, leading to visual impairment and blindness in ROP [3]. The peak onset of ROP is 32 weeks post menstrual age (PMA), and the most severe disease occurs in the 35-39 weeks post menstrual age (PMA) period. Larger, more mature infants tend to develop ROP a bit earlier than very low birth weight newborns [6].

Many factors contribute to the development of ROP [8]. There are several risk factors that have been reported in different studies some of which can cause severe forms of the disease. Low birth weight, prematurity, supplemental oxygen, prolonged mechanical ventilation, low Apgar score, pulmonary complications like RDS, anemia requiring blood transfusion, intraventricular hemorrhage (IVH), necrotizing enterocolitis, and sepsis are some of the risk factors for ROP [7,8,9,10,11,12,13]. The identification of those risk factors is of importance to the neonatologists and ophthalmologists for effective screening, execution of accurate diagnosis and prevention of development of the disease [2].

Clinical features of ROP depend on the extent and severity of the disease. The disease is classified according to the International Classification of ROP (ICROP) using retinal landmarks so as minimize inter-examiner variability. ROP is classified based on the zone, extent of disease, stage, and followed by documentation of the status of the vessels in the posterior pole (plus disease) [6]. Stage 1 is a faint demarcation line, stage 2 is an elevated ridge, stage three is the extraretinal fibrovascular proliferation, stage 4 is partial retinal detachment and stage 5 is total retinal detachment. Plus disease may be present at any stage and reflects increased blood flow through the retina. In plus disease there is significant vascular dilatation and tortuosity observed at the posterior pole equivalent to a standard photograph [3,6,8].

Timely examination and treatment of ROP has a major impact on visual outcome. Screening requires significant infrastructure investment, coordination, planning, skilled ophthalmologists, and teamwork. Dilated fundus examination using binocular indirect ophthalmoscope scleral depressor and 28 Diopter condensing lens is the gold standard for ROP screening[6]. Timely treatment is essential in reducing the risk of visual loss. Carefully timed

retinal examinations should be performed for all at risk infants with an ophthalmologist trained in ROP screening. Gestational age at birth and low birth weight are the main factors that determine the timing of the first ROP screening [6]. The severity of disease found on the first screening will determine the subsequent follow-up screening schedule. It is important that all people taking care of the baby be aware of the screening schedule, including the parents as well as pediatricians. Screening will help identify those with sight threatening disease for early intervention as ROP can lead to permanent blindness [6,14,15].

Severe retinopathy of prematurity has long term negative outcomes for the child, family and society at large. The child may have severe visual impairment and blindness [6,14,15]. The disease is also associated with refractive errors, specifically myopia [14]. Anisometropia, amblyopia, strabismus, retinal traction and retinal detachment may also occur. Furthermore, impairment of visual acuity, contrast sensitivity, visual field, convergence and accommodation may happen at a later point in life in the affected children hence the need for lifelong ophthalmic follow-up [14,15]. ROP is also associated with poor neurodevelopmental outcome and some infants remain with some forms of visual disability despite treatment. These children might suffer educational difficulties as a result of visual impairments. Therefore, they need special schools, qualified teachers as well as visual aids to enhance their abilities [14,15]. Due to all these complications,there is significant economic and social burden to the family and community as a whole hence the need to know the magnitude of ROP in Tanzanian setting.

In Tanzania, ROP screening is still on its infancy and not widely practiced all over the country. This is the first study done in our settingto determine the incidence and risk factors associated with ROP.

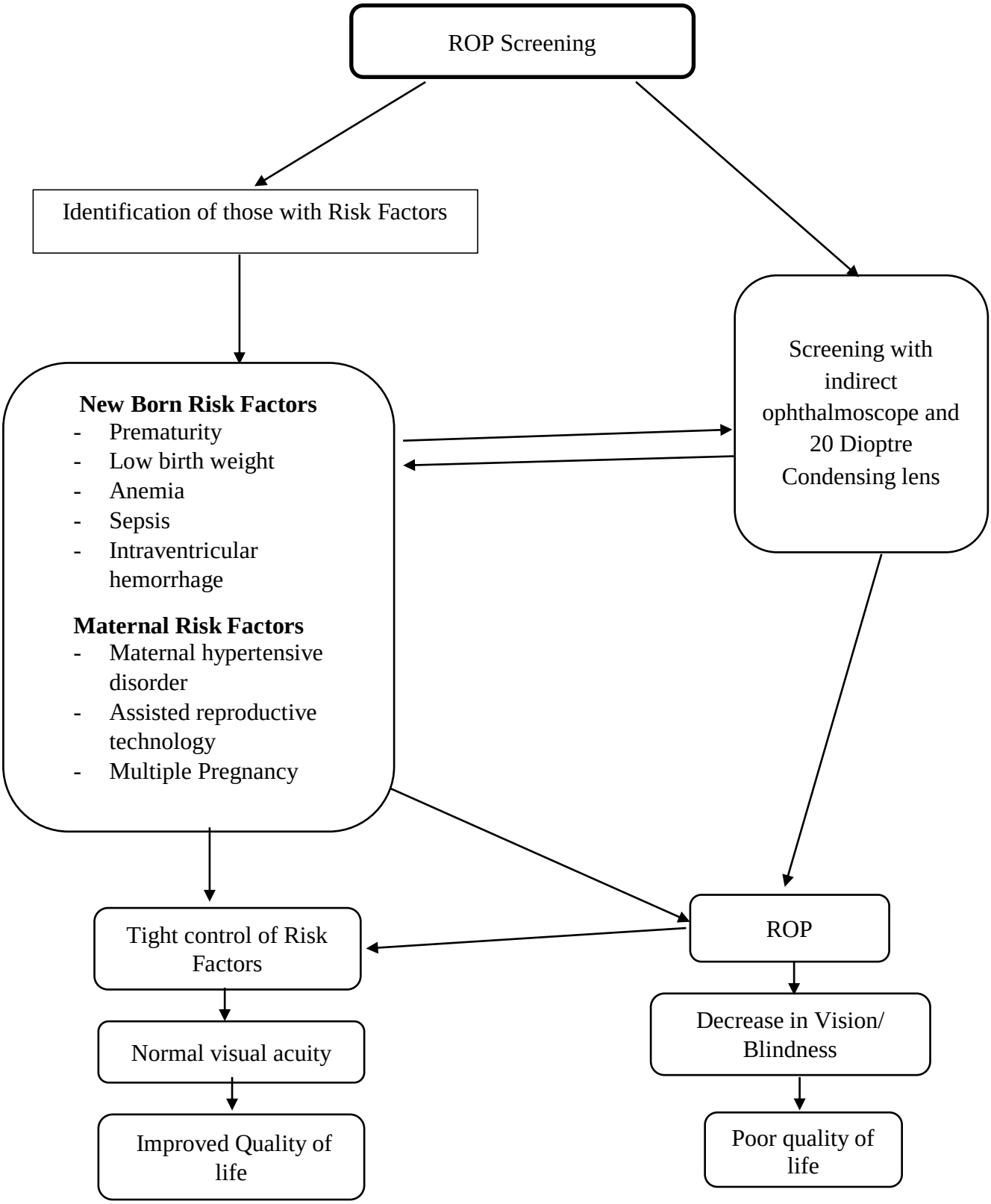
1.2 Problem statement

Retinopathy of prematurity (ROP) is an important cause of preventable blindness in children accounting for about 10% of childhood blindness in developed countries and an unknown contribution in developing countries [1,2,3].

It is a potentially blinding disease with a huge social and economic burden worldwide. It is among the priority diseases targeted for control of childhood blindness by the WHO (WHO VISION 2020). Today, with advances in neonatal care, smaller and more premature babies survive, having higher risk for ROP and blindness in childhood as a complication [8,13]. Blind person years from childhood blindness ranks second only after cataract because children have lifetime blindness ahead of them [32]. Children who survive with blindness suffer from emotional, social and economic cost, difficulties in learning, social dependency as well as reduced productivity as adults. The family and society suffer the same as well [12,32]. Therefore, there is a need to screen those at risk to allow early treatment and visual rehabilitation for those affected.

In Africa, studies have been done in some countries with varying incidences. However, data in our settings are lacking regarding incidence and risk factors, as well as treatment outcomes. This study was therefore done to determine the incidence and risk factors associated with retinopathy of prematurity in a Tanzanian setting.

Figure 1: Conceptual Framework



1.3 Rationale

A lot has been done in Tanzania to improve premature babies' survival as demonstrated by TDHS 2015/2016 posing the risk for increased incidence of ROP as a complication. Unfortunately, data on ROP incidence and risk factors are scarce, thus, there was a need to study those at risk to understand the situation in our country.

This study has provided baseline information on ROP situation at MNH and the data obtained will help increase awareness among health care workers and parents for maximum care of premature newborns. Since permanent blindness from ROP can be prevented by early identification of cases and treatment at early stages, the results will also help plan appropriate treatment and rehabilitation services among children with severe visual impairment and blindness due to ROP at MNH and in similar settings elsewhere.

Again, the information obtained from this study will help to advise policy makers regarding ROP prevention strategies, also the establishment of local standardized guidelines (MNH) for screening and treatment that may later be adapted to other health facilities in the country.

Lastly, the findings obtained have provided baseline information for further studies.

1.4 Research questions

1. What is the incidence of ROP at MNH, Dar es Salaam, Tanzania?
2. What are the risk factors associated with ROP among preterm infants at MNH Dar es Salaam, Tanzania?

1.5 Objectives

1.5.1 Broad objective

To determine the incidence of ROP and its associated risk factors among preterm infants admitted to Muhimbili National Hospital, Dar es Salaam, Tanzania.

1.5.2 Specific objectives

1. To determine the incidence of ROP among premature newborns admitted to Muhimbili National Hospital, Dar es Salaam, Tanzania.
2. To determine the risk factors associated with ROP among premature newborns admitted to Muhimbili National Hospital, Dar es Salaam, Tanzania.

1.6 Literature review

Globally, there is an emerging epidemic of children at risk for blinding eye disease due to retinopathy of prematurity (ROP). In many countries in Sub-Saharan Africa (SSA), ROP has not been considered as a significant cause of blindness due to under development of neonatal intensive care units and high neonatal mortality rate [4,16]. Thus, its magnitude, risk factors, treatment outcomes as well as long term complications are unknown in many countries of Sub-Saharan Africa (SSA),Tanzania included [12,13]. However, due to improved neonatal care in many developing countries, many premature babies do survive and the rates are expected to increase in the coming years, leading to an epidemic of childhood blindness [12]. ROP is a growing problem as screening and treatment programmes do not exist in many parts of SSA [16].

1.2.1 Incidence and prevalence

The incidence of ROP varies globally depending on neonatal and ophthalmic care, ranging from 10% to over 68% [11,17]. In USA, ET-ROP study reported ROP incidence of 68% among newborns <1251g and Owen et al 13 years later showed the incidence to be 47.5% among newborns <1250g birth weight or GA <30weeks[10,11].

In Latin America, particularly Brazil and Argentina, the incidence of ROP is 44.5% and 26.2% as found by Gonçalves et al and Lomuto et al respectively among newborns with BW < 1500 g or GA <32 weeks [18,19].

Furthermore, ROP incidence of 11.9% was obtained in China by Quiping Li and his colleagues in 2016. In this study, the screened newborns were less than or equal to either 2000g or 34 weeks of GA [20].

There are several studies in India with some variations in ROP incidence depending on the screening criteria. Ahuja et al demonstrated 32.6% ROP incidence among premature newborns less than 1900g and less than 36 weeks GA [21].

There is growing evidence that the population at risk for ROP is increasing in Africa as a result of changing health care systems. In 2017 in Egypt, Bassiouny et al revealed an incidence of 59% among newborns less than 37 weeks GA [22]. In Port Harcourt University teaching hospital Nigeria, among preterm babies less than 32 weeks GA or 1500g birth weight, ROP prevalence of 47.2% was reported [23]. One of the South African studies reported ROP incidence of 29.6% among preterm babies <1251g bwt or <31 weeks GA [24].

In East Africa, Onyango et al in Kenya (2018), reported ROP prevalence of 41.7% among newborns < 32 weeks gestational age or weighing ≤1500g [13] whereas the prevalence of 37% was reported among preterm babies admitted at Soba NICU South Sudan in 2014 [25].

1.2.2 Risk factors

ROP is a multifactorial disease. Many studies report several risk factors associated with this condition. Some risk factors can cause severe ROP including birth weight and gestational age [7]. Others include supplemental oxygen, prolonged mechanical ventilation, Low Apgar score, pulmonary complications, anemia, intraventricular hemorrhage (IVH), necrotizing enterocolitis and sepsis [13,24,26,27,28].

1.2.2.1 Prematurity

WHO defines preterm birth as babies born alive before 37 weeks of pregnancy are completed [4]. Extreme prematurity has been the dominant driving factor of ROP, with most cases being in the most preterm newborns, i.e., gestational age (GA) < 28 weeks [2]. Many studies have shown that the incidence of ROP increases with decrease in GA and that children affected with ROP have significantly lower GA compared to those not affected [2,6,8,22,25]. More mature and heavier babies can also develop ROP, especially in developing countries because of insufficient awareness of the risk factors, shortage of skilled personnel and/or a shortage of essential equipment to care for infants [26].

1.2.2.2 Low birth weight

Low birth weight is another important risk factor for ROP. This is most significant for very low and extreme low birth weight infants. The Vermont Oxford Network database, which collects data from more than 1000 NICUs worldwide, estimated in 2010 an incidence of 33.2% of ROP in neonates with Bwt < 1500 g. Gonçalves et al [21] in Brazil 2014 found that a BW < 1500g, whereas Freitas et al [7] in 2018 found that Bwt < 1000g, was associated with development of ROP of any stage. Several studies have shown similar findings with those below 1250g birth weight having the highest risk. [6,10,22,25]. Low birth weight and prematurity often coexist, increasing the risk for ROP development in preterm babies.

1.2.2.3 Unmonitored oxygen supplementation

ROP as an important cause of blindness became evident in 1940s-1950 in high-income countries. This was due to improvement of survival of VLBW babies <1,500 g or approximately <32 weeks gestation as a result of widespread use of unrestricted supplemental oxygen [2]. Normal oxygen concentration is toxic to immature tissues, including retina; thus, it should be given to those who require it and adequately monitored [8]. Again, several studies have reported that prolonged as well as unmonitored oxygen supplementation is strongly associated with ROP in premature, low birth weight infants [17,22,26]. Mechanical ventilation is also a risk factor for ROP [13].

1.2.2.4 Sepsis

Sepsis is an important and significant predictor of ROP occurrence, including severe ROP. Sepsis may increase oxygen demand and interfere with oxygen tension, which increases retinal ischemia, resulting in ROP [22]. Bas et al in Turkey reported that late onset sepsis was an independent risk factor for severe ROP in VLBW infants [26]. Several other studies had similar findings [17,18,27]. Thus, early detection and prevention of sepsis may decrease the incidence of ROP requiring treatment.

1.2.2.5 Anemia requiring blood transfusion

This has also been reported as an important risk factor for ROP. Transfusions increases oxygen delivery to the retina because of the lower oxygen affinity of adult hemoglobin compared to fetal hemoglobin. Again, repeated transfusions may increase free iron load which may react with various intermediates of oxygen generating highly reactive oxygen radicals [26,28]. Several other studies have reported an association between blood transfusion and ROP[3,1718,25].

1.2.2.6 Intraventricular hemorrhage

IVH is another known risk factor for ROP. This is bleeding in the brain ventricles. It is also a complication of prematurity. IVH is characterized by tissue ischemia and vascular immaturity which also happens in ROP. Some guidelines recommend IVH as an important risk factor in selection of patients to be screened for ROP [7]

1.2.2.7 Pulmonary diseases

Pulmonary diseases like bronchopulmonary dysplasia [7] and RDS [17] have been reported in some studies as risk factors for ROP as well. Newborns with pulmonary diseases need larger amounts of supplemental oxygen with increased episodes of hypoxia and fluctuation in oxygen concentration [7]. This poses a risk for ROP development as prolonged supplemental oxygen plays a role in the pathogenesis of ROP [9,25,26]. There are other risk factors for ROP including antioxidant deficiency, acidosis, apnea and patent ductus arteriosus [8,17].

1.2.2.8 Maternal risk factors

Several studies have been done to assess maternal risk factors associated with ROP. Mothers with essential hypertension prior pregnancy, pre-eclampsia as well as urinary tract infections prior to delivery are more likely to deliver infants with ROP [29,30]. Again, mothers who conceived through assisted reproductive technology (ART) such as in vitro fertilization have a higher risk of having multiple births and subsequently premature deliveries, raising the risk of having newborns with ROP [31]

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study Design

The study design was a hospital based prospective cohort study**.**

2.2 Study Area

The study was conducted at Muhimbili National Hospital (MNH) Upanga. MNH is one of the main national referral hospitals, Research Centre and University teaching hospital located in Ilala District, Dar es salaam, Tanzania. It has 1,500 beds and a big and busy neonatal unit with 150 bed capacity. It receives all sick neonates born from its maternity wards as well as referrals from five districts of Dar Es Salaam region without adequate neonatal facilities. It also receives some referrals from upcountry. The rate of preterm baby admissions averages at 280 newborns per month and about 50% of them are extreme low birth weight infants(<1000g)

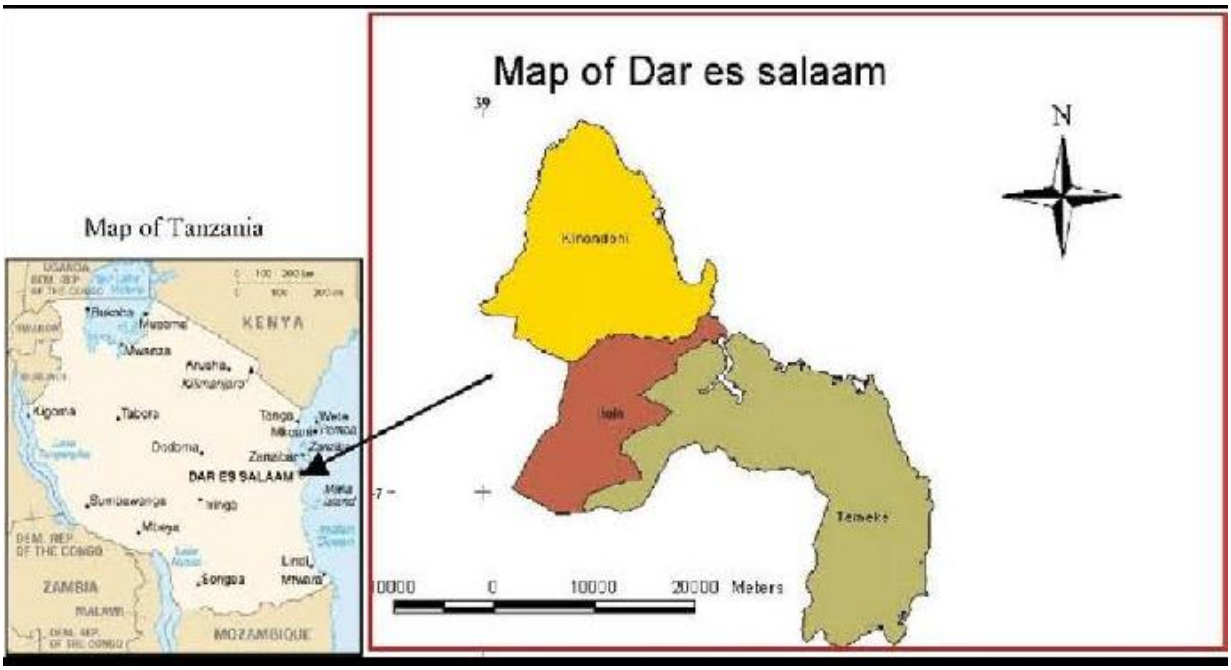


Figure 2: Map of Dar es Salaam city.

2.3 Study Population

The study population constituted all premature newborns admitted to the neonatal ward at MNH during the study period.

2.3.1 Inclusion criteria

- All preterm infants less than or equal to 34weeks GA.
- All preterm infants less than or equal to 2000g birth weight.
- All preterm infants with more than 2000g and or 34weeks GA but with high risk of developing ROP as a result of an unstable clinical course.

2.3.2 Exclusion criteria:

- Ocular congenital anomalies that would have compromised the screening process.
- Incomplete ROP screening procedure due to death before completion of retinal vascularization or lost to follow up (LTFU).

2.4 Study Duration

This study was conducted over a period of 8 months from July 2020 to February 2021

2.5 Sample Size

Sample size will be calculated using the formula below;

$$n=Z^2_{1-a/2}[(1-Pl)/Pl + (1-P_2)/P_2]/[loge(1-e)]^2$$

n is the sample size

CI is the level of confidence interval 95% (Z=1.96)

E is the relative precision

P1 is the anticipated probability of disease in the exposed group to the factor of interest

P2 is the anticipated probability of disease in the exposed group to the factor of interest

RR=p1/p2

Using previous literature p2=0.38, RR=2, ci=95% (Z=1.96), Relative Precision=20%

Substituting the information in the formulae above we get the sample size 176

Adding 10% of lost to follow-up and missing information 176 +16 =192

The required sample size is 192 premature newborns.

2.6 Sampling Method

Consecutive sampling technique method was used so as to screen every newborn who meets the criteria until the required sample size was reached. This is because; all premature newborns are at risk of developing ROP.

2.7 Data Collection Procedure.

Screening was done to all premature newborns with birth weight less than or equal to 2000g and gestational age less or equal to 34 weeks at 4 weeks post-delivery**.** Heavier newborns or those with GA >34 weeks were screened only if they had an unstable clinical course, that is those who were very sick post-delivery and had prolonged oxygen therapy or multiple blood transfusions or other ROP risk factors as per a pediatrician opinion. During screening, fundus examination of both eyes was done. The newborns eyes were dilated with 2.5% phenylephrine and 0.5% tropicamide 2-3 times at 10 minutes intervals before fundus examination. Phenylephrine 5% was diluted to make it half strength as 2.5% phenylephrine is not available commercially in our setting. Topical anesthetic agents were applied prior to examination to reduce pain and discomfort. Any drops that came out of the eyes were wiped carefully with sterile cotton wool. Parents were told not to feed the baby 30 minutes before examination to minimize the risk to the child of vomiting and /or aspirating. Each child was examined using anaseptic technique in a room with dim light andtemperature favorable for the new born. Neonatal wire speculum was used to keep the eyelids apart. Binocular indirect ophthalmoscope (AAIO Wireless Appasamy Associates), scleral depressor and 20 Diopter Volk condensing lens were used to facilitate retinal visualization. Anterior segment examination was carried out to look for tunica vasculosa lentis, pupillary dilatation and media clarity then retinal examination of both posterior poles and the peripheral retina for zone and stage if present. Visualization of peripheral retina was aided by the use of a scleral depressor, taking care not to put too much pressure on the globe. The stage of the disease, zone and signs of plus disease were recorded based on the guidelines of IC- ROP. After a thorough retinal examination, antibiotic eye drops were applied. Fundus examinations continued at varying intervals depending on the findings of the first examination. For those whose first screening was negative for ROP, followup screening was done after one week, two weeks and three weeks for zone one, two and three immature retina respectively. Screening

continued until full retinal vascularization or recording of most advanced stage of ROP in the eye with the most severe disease.

Medical records were reviewed to provide details on gestational age at birth in weeks, birth weight in grams as well as number of days of oxygen therapy to ascertain prematurity, low birth weight and prolonged and unmonitored oxygen supplementation as risk factors for ROP. Again, medical records were further scrutinized to assess if the child had a diagnosis of clinical sepsis and/or intraventricular hemorrhage based on signs and symptoms as well as supportive laboratory investigation such as blood culture results and cranial ultrasound results if available. Anemia requiring blood transfusion was assessed based on the amount of blood units transfused. Furthermore, any other diagnosis of the child during the course of treatment such as pulmonary diseases like RDS and bronchopulmonary dysplasia was recorded. Maternal medical records review for other risk factors such as maternal hypertensive disorders, IVF, twin pregnancy as well as any other maternal comorbidities was done as well.

Occurance of ROP of any stage was considered as a dependant variable where as risk factors associated with it were independent variables.

2.8 Data Analysis

Data entry and analysis was performed using SPSS version 23. Determination of incidence and description of clinical aspects of those with ROP was done through frequencies and percentages. Cumulative incidence was the proportion of babies clinically diagnosed with ROP by the end of study period, Log rank test was used to compare equality of ROP occurrence between the two groups as well as to determine the relative risk. Cox proportional hazard model was then used to investigate the association of selected characteristics and their hazard(risk) of developing ROP on univariate and multivariate analysis.

The P-value < 0.05 was considered statistically significant showing the significant risk factors associated with the occurrence of ROP. The main outcome measure was the cumulative incidence of any stage of ROP and its associated risk factors.

2.9 Quality Control

Necessary precautions were taken to ensure the quality of this study. Questionnaire cross checking by the principal investigator for completeness before use as well as pre testing was done. All mydriatic drugs were checked for expiry date as well as storage conditions before use by the principal investigator. For those drugs which needed dilution, careful titration of volumes was done so as to maintain potency of the drugs.

Findings upon screening of newborns were verified by a single retinal specialist trained in ROP for consistency of the data.

2.10 Ethical Consideration.

Ethical clearance was sought form the MUHAS ethical committee of research and publication.

Written informed consent was obtained from the parents or caretakers of the newborns eligible for screening prior to enrollment in the study. Parents of the study participants had the right to withdraw from the study at any point in time. Every parent(s) was informed about his/her child's retinal findings after screening. They were also informed of any other abnormalities noted during screening and treatment options as well as given direction to the right place where treatment and follow-up can be offered. Patient's information was kept confidential.

2.11 Dissemination of the Study Results.

Findings from this study will be presented to the department, MUHAS scientific conference as well Tanzania Ophthalmology Society (TOS) and College of Eastern, Central and Southern Africa (COECSA) congress. Again, study results will be distributed to the department of Ophthalmology MUHAS and MNH and Library and this work will also be submitted to a reputable peer- reviewed journal for publication.

CHAPTER THREE

3.0 RESULTS

The response rate of the study participants was 40.5%

Study flow chart

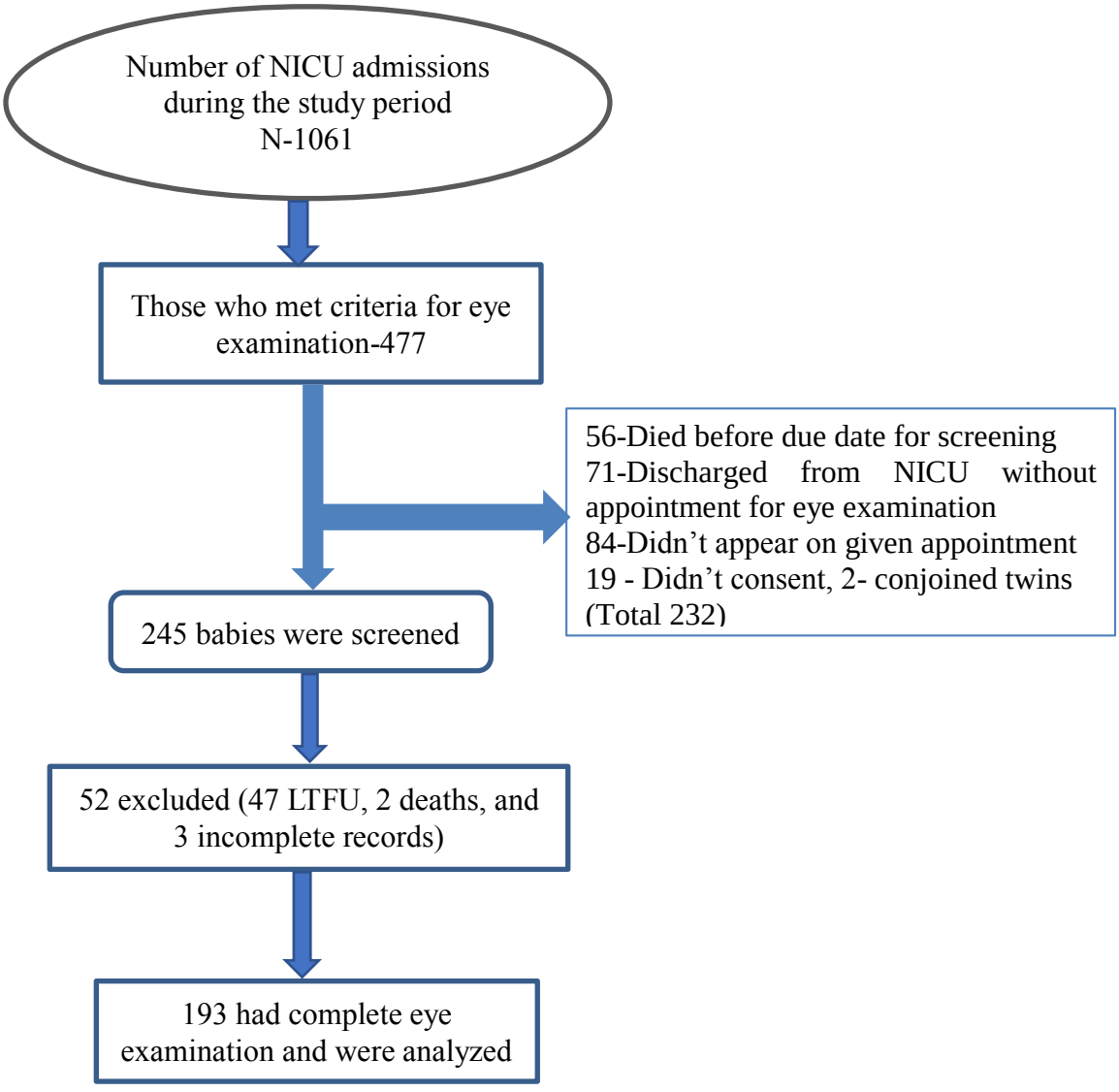


Figure 3 Flow diagram of study participants

Table 1 : Demographic and clinical characteristics of the study participants N=193

Sex	Male	96 (49.7%)
	Female	97 (50.3%)
Type of gestation	Single	117 (60.6%)
	Multiple	76 (39.4%)
GA		31.3 ± 2.6 weeks
BWT		1380 ± 331g
PMA		36.6± 3.1 weeks
Mode of Conception	Normal	183 (95.4%)
	ART	10 (5.2%)
Mode of delivery	SVD	123 (63.7%)
	C/S	70 (36.3%)
Gestational age(weeks):	<32	100 (51.8%)
	≥32	93 (48.2%)
Birth weight(g):	<1500	128 (66.3%)
	≥1500	65 (33.7%)
Apgar score at 5^{th} minute	≤ 6	12 (8.8%)
	≥7	176 (91.2%)
Clinical sepsis		49 (25.4%)
RDS		86 (44.6%)
Surfactant use		11 (5.7%)
Blood transfusion		57 (29.5%)
IVH		5 (2.6%)
Jaundice		119 (61.7%)
Phototherapy		117 (60.6%)
Apnea		14 (7.3%)
Congenital heart disease		7 (3.6%)
Oxygen therapy duration	≤7 days	84 (43.5%)
	8-14 days	30 (15.5%)
	≥15 days	9 (4.7%)
Maternal febrile illness	Urinary tract infection	4 (2.1%)
Maternal steroid use		89 (46.1%)
Maternal PPROM		69 (35.8%)
Maternal PIH		74 (38.3%)
APH		3 (1.6%)

Data are shown as either frequencies, percentages or mean ±SD

Among 193 newborns of GA ≤34 weeks (Range 24-34 weeks) who had complete eye examination and were analysed, females were 50.3%. The average PMA on the first screening was 36.6 weeks, about half of the screened babies had GA of <32 weeks and bwt <1500g (Table 1)

The cumulative incidence of any stage of ROP during the study period was 29% (56/193).

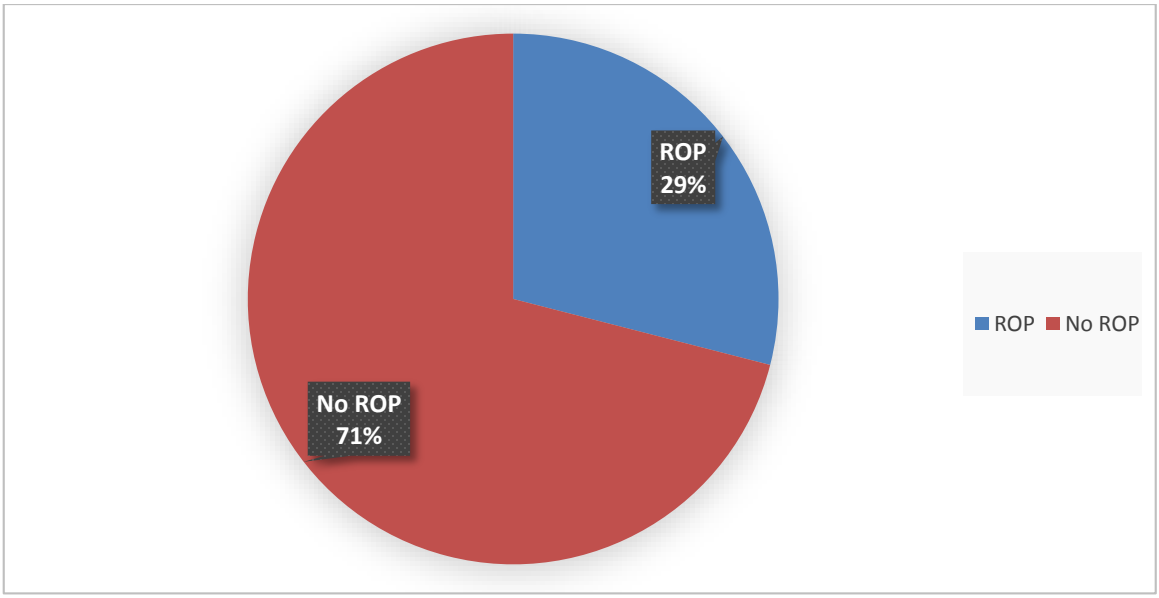


Figure 4: Incidence of any stage of ROP.

Of the 193 screened premature babies, 8.8% (17/193) developed severe disease that necessitated treatment.

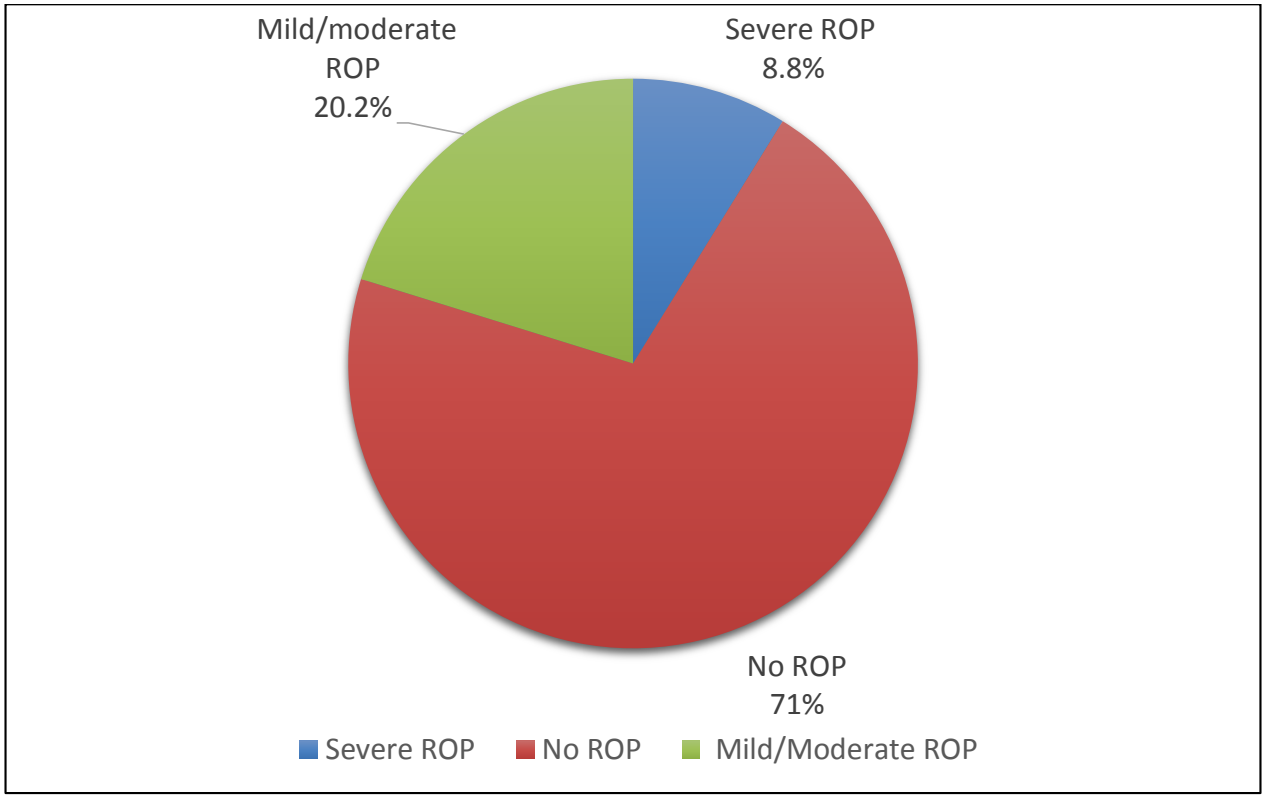


Figure 4 : Incidence of severe ROP (treatment requiring ROP)

Table 2 : Zones and Stages of ROP among the study population N=56.

ROP STAGE	ROP ZONE			
	Zone I	Zone II	Zone III	Total
Stage 1	1 (1.79%)	7 (12.50%)	3 (5.36%)	11 (19.64%)
Stage 2	0 (0%)	19 (33.93%)	4 (7.14%)	23 (41.10%)
Stage 3	2 (3.57%) 1*	13 (23.21) 5*	0 (0%)	15 (26.79%)
Stage 4	0 (0%)	2 (3.57)	0 (0%)	2 (3.57%)
Stage 5	0 (0%)	0 (0%)	0 (0%)	0 (0%)
APROP	5 (8.93%) *	0 (0%)	0 (0%)	5 (8.93%)
Total	8 (14.29%)	41 (73.21%)	7 (12.50%)	56 100%)

* Indicates those with plus disease

A majority of those with ROP had zone two and stage two disease, 73.2% and 41.1% respectively.11 children had plus disease and all with plus were either stage 3 disease or APROP (Table 2).

Table 3 : Risk factors associated with ROP among the study population

RISK FACTOR		INCIDENCE (%)		RR	P -value
		ROP	NO ROP		
Sex	Male	29.2(20.3-39.3)	70.8(60.7-79.7)	1.01	0.911
	Female	28.9(20.1-39.0)	71.1(61.0-79.9)		
GA (weeks)	<32	44(34. - 54.3)	56.0(45.7 to 65.9)	3.41	0.000
	32-34	12.9(6.8-21.5)	87.1(78.5-93.2)		
Oxygen therapy >7 days	Yes	76.9(60.7-88.9)	23.1(11.1-39.3)	4.55	0.000
	No	16.9 (11.3-23.8)	83.1(76.2-88.7)		
Neonatal sepsis	Yes	49.0(34.4-63.7)	51.0(36.3-65.6)	2.21	0.001
	No	22.2(15.7-29.9)	77.8(70.1-84.3)		
Birth weight	<1500	42.2(33.5-51.2)	57.8(48.8-66.5)	13.61	0.000
	≥1500	3.1(0.4 to 10.7)	96.9(89.3 to 99.6)		
Anemia requiring BT	Yes	42.1(29.1-55.9)	57.9(44.7 to 70.9)	1.79	0.016
	No	23.5(16.7-31.6)	76.5(68.4-83.3)		
Neonatal jaundice	Yes	36.8(28.0-46.2)	63.2(53.8-72.0)	2.15	0.006
	No	17.1(9.4-27.5)	82.9(72.5-90.6)		
RDS	Yes	57.0(45.8-67.6)	43.0(32.4-54.2)	8.77	0.000
	No	6.5(2.7-13.0)	93.5(87.0-93.7)		
Mode of delivery	SVD	36.6(28.1-45.7)	63.4(54.3-71.9)	2.33	0.004
	C/S	15.7(8.1-26.4)	84.3(73.6-91.9)		
Multiple pregnancy	Yes	23.7(14.7-34.8)	76.3(65.2-85.3)	0.73	0.25
	No	32.5(24.1-41.8)	67.5(58.2-75.9)		
CHD	Yes	85.7(42.1-99.6)	14.3(0.4-57.9)	3.19	0.013
	No	26.9(20.7-33.9)	73.1(66.1-79.3)		
Surfactant use	Yes	36.4(10.9-69.2)	63.6(30.8 to 89.1)	1.27	0.089
	No	28.6(22.1-35.7)	71.4(64.3 to 77.9)		
IVH	Yes	100(47.8 to 100)	0(0-52.2)	3.69	0.000
	No	27.1(20.9-34.1)	72.9(65.9-79.1)		
Apnea	Yes	71.4(41.9-91.6)	28.6(8.4 to 58.1)	2.78	0.028
	No	25.7(19.5-32.8)	74.3(67.2-80.5)		
Apgar score	<7	70.6 (63-76.1)	29.4 (20-45)	2.824	0.022
	≥7	25.0 (19.4-28.6)	75.0 (65-80)		
Maternal hypertensive disorders	Yes	23.0 (12.1-30.1)	77.0 (62.8-85.2)	0.70	0.371
	No	32.8 (24.1-41.8)	67.2 (54.3-71.9)		
Maternal steroid use	Yes	20.2(12.1-30.1)	79.8(69.9-87.6)	0.55	0.000
	No	36.5(27.3-46.6)	63.5(53.4-72.7)		

Log rank test was used to determine the relative risk associated with ROP occurrence.

Oxygen use > 7 days, bwt <1500g, GA<32weeks, RDS, IVH, neonatal sepsis, neonatal jaundice, SVD mode of delivery, anemia requiring BT,Apgar score <7, CHD and apneawere strongly predictive of ROP occurrence, all with p value of <0.05 and relative risk of more than 1. Maternal steroid use however was protective of ROP with RR of 0.55 and p value of 0.000 (Table 3).

Table 4 : Univariate analysis of the risk factors associated with ROP

RISK FACTOR	UNIVARIATE ANALYSIS			
	HR	95% CI		P Value
GA <32 weeks	7.976	4.641	11.918	0.028
Bwt <1500g	5.941	3.918	8.060	0.028
Apgar score <7	1.678	0.899	1.710	0.016
Neonatal sepsis	2.323	1.340	4.027	0.003
Anemia requiring BT	1.445	0.849	2.457	0.175
RDS	4.910	2.199	10.963	0.000
Mode of delivery	1.682	0.866	3.266	0.125
Neonatal jaundice	1.805	0.968	3.366	0.063
Oxygen use >7days	3.614	2.135	6.119	0.000
Surfactant use	0.473	0.168	1.329	0.155
IVH	6.181	2.245	15.754	0.000
Apnea	1.946	0.977	3.878	0.058
CHD	2.835	1.193	6.738	0.018
Maternal steroid use	0.664	0.378	1.166	0.154

Cox proportional hazard model was used in univariate analysis

On univariate analysis, GA<32weeks, bwt <1500g, oxygen use > 7 days, neonatal sepsis, RDS, CHD, IVH, Apgar score <7 were associated with development of ROP, all with hazard ratios of >1 and p-values of <0.05 (Table 4).

Table 5 : Multivariate analysis of the risk factors associated with ROP

RISK FACTOR	MULTIVARIATE ANALYSIS			
	HR	95%CI		P Value
GA <32 weeks	6.850	0.633	8.133	0.000
Bwt <1500g	2.070	0.998	3.040	0.021
Apgar score < 7	1.891	1.333	1.923	0.029
Neonatal sepsis	0.923	0.429	1.984	0.837
Anemia requiring BT	0.629	0.323	1.228	0.174
RDS	3.338	1.294	8.612	0.013
Mode of delivery	1.083	0.424	2.766	0.867
Neonatal jaundice	1.572	0.784	3.152	0.202
Oxygen use >7days	0.742	0.352	1.566	0.034
Surfactant use	0.251	0.074	0.853	0.027
IVH	9.720	2.672	35.356	0.001
Apnea	1.237	0.546	2.805	0.611
CHD	3.239	0.362	4.244	0.733
Maternal steroid use	0.837	0.401	1.747	0.636

Cox proportional hazard model was used in multivariate analysis

On multivariate analysis, GA<32weeks, bwt <1500g, oxygen use > 7 days, RDS, surfactant use and IVH, Apgar score <7 were significantly predictive of any stage of ROP (Table 5).

CHAPTER FOUR

4.0 DISCUSSION

An understanding of the incidence and risk factorsin relation to ROP in a Tanzanian setting is essential as it is one of the commonest causes of preventable irreversible childhood blindness[2]. This study has established the cumulative incidence of any stage of ROP of 29% among premature newborns at MNH. Our findings are comparable with studies done in Turkey by Bas et al, Palestine by Akkawi et al and Iran by Khordifshar et alwho reported ROP incidence of 27%, 23.5%, and 33.3% respectively[26,33,34].Fajolu et al and Braimah et al reported lower ROP incidence in their study as compared to the current study[35,36]. However, Owen et al, Adio et al and Bassiouny et al reported much higher incidences[10,23,22].

These variations in incidence rates may be due to different levels of advancement in neonatal care in different regions. Again, birth weight, GA, overall survival of premature newborns and different screening criteria can account for the observed differences. Our study adopted a wider screening criterion due to fewer studies on the topic in our country.

The incidence of severe type of ROP has regional variations as well. Our study has demonstrated the cumulative incidence of 8.8% of severe form of ROP that necessitated treatment. Our results are in line with what was found by Bas et al, Akkawi et al, Khordifshar et al and Patel et al[26,33,34,37]. This severe form of ROP may lead to blindness hence the need for screening programmes for early identification and treatment. Again, even if treated, some may end up with long term visual disabilities. Braimah et al reported a lower incidence of severe ROP and this can be explained by the wider screening criteria used as compared to this study[36].

In this study, more than half of the newborns with ROP had the disease in zone two (73.2%) unlike the findings by Bassiouny et al and Adio et al whose findings showed majority having zone 3 disease with 76% and 67.9% respectively [22,23].

Majority of the screened newborns with ROP had stage 2 disease (41.1%). Only 19.64% of those with ROP had stage one disease. Our findings are consistent with Bassiouny et al from Egypt who reported 42.6% stage 1 ROP and 48.1% stage 2 ROP in their study[22]. Again, our

findings differ from Adio et al and Celebi et alwhose incidence for stage one and two were lower than in this study[23,38].

Identification of stage one and two disease in more than half of the screened population in this study indicates that more cases were screened early however the presence of few children with stage one disease can be explained by slightly late screening as a majorityof the screened newborns had GA <32 weeks whereas the average PMA on the first screening was 36 weeks. Thus, some children with stage one disease might have been missed or rather picked while on stage 2.

In the current study, 26.8% (15/56) had stage three disease, 2 patients had stage four disease and 5 had aggressive posterior ROP. All these shows that sight threatening ROP is prevalent in our locality hence the need for timely identification of cases and treatment.

Our study has provided evidence of risk factors associated with ROP at MNH. When study participants exposed to different risk factors were compared to those who were not exposed as to the likelihood of ROP occurrence, sepsis, anemia requiring BT, neonatal jaundice, RDS, vaginal mode of delivery, CHD, maternal steroid use, IVH and apnea were statistically significantly predictive of ROP. All had P values <0.05 and relative risk (RR) more than 1.5 each. These risk factors were also reported by many other studies[7,17,18,22,25,26,31].

Furthermore, the current study found thatGA at birth of <32 weeks and bwt of <1500g are independent risk factors for ROP with p values of 0.000 each and RR of 3.4 and 13.6 respectively. These findings are similar to many other studies as low GA at birth and low birth weight have been shown to be predictors of ROP [18,22,25,26]. This study has shown that none of the screened newborns with Bwt >1600 g had ROP and severe ROP that necessitated treatment was found in only those withBwt< 1500g. This highlights the need for revising the screening criteria to minimize unnecessary stressful retinal examinations to premature newborns. It will also reduce the workload of screening to ophthalmologists.

It is also important to note therelative risk of 0.6 with P value of 0.000 in maternal steroid use which implies a protective role of prenatal steroids on ROP. This is due to enhanced lung

maturity hence less neonatal supplemental oxygen dependency postnatally. This is similar to findings reported by other studies where it has been shown that antenatal steroid use is protective of ROP and it also prevents severe forms of ROP[39].

In univariate analysis, ROP occurrence had a statistically significant association with GA less than 32 weeks, bwt less than 1500g, neonatal sepsis, RDS, oxygen supplementation for more than a week, IVH and CHD. Only 6 factors were significant in multivariate analysis, independently predicting ROP occurrence i.e., GA less than 32weeks, bwt less than 1500g, RDS, oxygen supplementation for more than a week, Apgar score < 7 and IVH. Other studies in many parts of the world reported similar findings [26,33,34,36]. Our study did not find an association between ROP and anemia requiring blood transfusion similar to Fajolu et al [35]. Importantly also, the protective role of surfactant on ROP has been revealed in our study.The risk of developing ROP in babies who used surfactant was very low with hazard ratio of 0.2 and p value of 0.027.This is due to its therapeutic effect on RDS hence less supplemental oxygen dependency in premature babies. However very few children (5.7%) received surfactant in this study hence its role in ROP at MNH must be prospectively studied with a larger sample size. Moreover, our study did not identify sex, maternal hypertensive disorders as well as multiple pregnancy as risk factors for ROP as it has been reported by other researchers[29,30,36].

Limitations of the Study

This study had relatively higher rate of lost follow-up of 19.2% despite initiatives to call the parents to remind them of follow up dates. Also many newborns were discharged without a follow-up ROP screening appointment. The cumulative incidence might have changed if all these were screened for ROP.

Levels of serum bilirubin associated with ROP development could not be studied due to poor documentation.

CHAPTER FIVE

5.0 CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study has shown a relatively high incidence of ROP among screened premature babies at MNH. Lower birth weight, GA and Apgar score, neonatal sepsis, RDS, oxygen supplementation more than 7 days and IVH have been identified as important risk factors for ROP development. However, maternal steroid use and surfactant use were found to be protective.

5.2 Recommendations

ROP screening should be part of the comprehensive care of premature newborns, however, screening should be done for all premature babies ≤1800g or ≤34weeks GA to minimize stressful retinal examinations to these newborns. Screening should also be done to those with GA 34-36 weeks or bwt >1800g with risk factors for ROP. Cautious use of supplemental oxygen is essential so as to reduce the incidence of ROP. Furthermore, comprehensive studies with larger sample size are needed to clarify some of the risk factors associated with ROP such as serum bilirubin levels, ART and surfactant use. In addition to that, a study should also be done to find out the reason behind the low response rate as reported in the current study.

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CONSENT AND ANNEXES

ANNEX I: Informed Consent Form – English Version

Consent to participate in the study on Retinopathy of Prematurity: Incidence and Risk Factors among premature newborns at Muhimbili National Hospital Dar es salaam, Tanzania.

Dear Sir/Madam,

My Name is Dr. Yusta Mtogo, a resident doctor in the department of Ophthalmology at Muhimbili University of Health and Allied Sciences (MUHAS). I am conducting a research on Retinopathy of Prematurity: Incidence and Risk Factors among premature newborns at Muhimbili National Hospital Dar es salaam, Tanzania.

I hereby request your participation.

Purpose of the study:

The aim of this study is to determine the magnitude of retinopathy of prematurity and risk factors associated with it at MNH.

How to participate:

Parents who are willing for their newborns to participate in this study will have to sign a consent form.

Short interview will be done with parents, newborns will be examined their eyes and retina and a review of medical records will be done.

Confidentiality:

Information obtained you will be kept confidential and results that will be obtained from this study will be very helpful in promoting health of children who are born prematurely.

Costs:

You will not be required to pay any amount for your participation in this study but you will pay for some of the investigation as routine services to the hospital pertaining to your child's illness.

Voluntary participation and the right to withdraw from the study:

Your participation is voluntary and you have the right to withdraw from participating in this study at any time. Whatever your decision may be, it will have no effect in any

way to your child's rights to care and treatment.

Risks:

The child might experience mild ocular discomfort due to topical medications and this disappears after 4-6 hours. The child might also have red eyes post the procedure which disappears after few days. These effects are mild and there are no major risks of participating in this study to you or your child.

Benefits:

Your child's participation in this study will help you know about presence or absence of retinopathy of prematurity as well as any other eye problem. You will also get the benefit of your child getting appropriate treatment as per need.

I hope that the information from this research will be useful in contributing to improve the quality of premature newborn health in Tanzania.

Contact persons:

If you have any inquiries about this study, please do not hesitate to contact: **Dr. Yusta Mtogo**

Principal Investigator

Muhimbili University of Health and Allied Sciences (MUHAS)

Department of Ophthalmology

P.O. Box 65001 Dar es Salaam

Tel. 0685957009

OR

Dr. Celina Mhina Supervisor of this research.

Muhimbili University of Health and Allied Sciences (MUHAS)

Department of Ophthalmology

P.O. Box 65001 Dar es Salaam.

Tel. 0719326498

OR

Dr.Anna Sanyiwa

Co-supervisor,

Muhimbili University of Health and Allied Sciences (MUHAS)

Department of Ophthalmology.

P.O. Box 65001 Dar es Salaam.

Tel.0784 717461

OR

In case of any information about your child's rights as a participant in this study please contact:

The Chairperson of Research and Publication Committee

Muhimbili University of Health and Allied Sciences (MUHAS)

P.O. Box 65001 Dar

es Salaam Tel. 022-

2152489

I will be grateful if you will agree to participate in this study.

I have understood the above information and my questions have been answered by the investigator to my satisfaction. I willingly agree to take part in this research.

Name of the parent: _____

Signature ofthe parent:_____Date: _____

Signature of Investigator: _____Date: _____

ANNEX II: Fomu ya Ridhaa kwa Kiswahili

Ridhaa ya kushiriki katika utafiti wa kuangalia ugonjwa wa ukuta wa macho unaowapata watoto waliozaliwa kabla ya wakati (njiti) na viambata hatarishi vya ugonjwa huo miongoni mwa watoto waliozaliwa kabla ya wakati katika hospitali ya taifa Muhimbili Tanzania.

Kwa bwana / bibi ……

Jina langu ni Dr. YUSTA MTOGO, mwanafunzi wa udaktari bingwa kutoka chuo kikuu cha afya na sayansi shirikishi Muhimbili, idara ya macho. Ninafanya utafiti kuhusu ugonjwa wa pazia la macho unaowapata watoto waliozaliwa kabla ya wakati (njiti) na viambatahatarishi vya ugonjwa huo miongoni mwa watoto waliozaliwa kabla ya wakati katika hospitali ya taifa Muhimbili Tanzania.

Tafadhali ninaomba ushiriki wako.

Lengo la utafitihuu:

Lengo la utafiti huu ni kuweza kujua ukubwa wa tatizo na viambata hatarishi vya ugonjwa huo ambao huwa unawapata watoto wanaozaliwa kabla ya wakati katika hospitali ya Taifaya Muhimbili Tanzania.

Namnayakushiriki:

Kwa wazazi watakaoridhia watoto wao kushiriki katika utafiti huu watajaza na kusaini fomu ya ridhaa, kisha watafanyiwa mahojiano halafu watoto wataangaliwa macho yao na pazia la jicho kuona kama kuna ugonjwa huo.

Usiri:

Taarifa zote zitakazopatikana kutoka kwako zitatunzwa kwa usiri wa hali ya juu. Pia matokeo ya utafiti huu yatasaidia katika kuboresha hali ya kutoa huduma kwa watoto wanaozaliwa kabla ya siku zao.

Gharama

Hakutakuwa na gharama yoyote katika kushiriki kwenye utafiti huu isipokuwa utapaswa tuu kuendelea kulipia zile huduma na vipimo ulivyokuwa unapaswa kuvilipia kwa ajili ya mtoto pindi anapopata huduma hospitali kutokana na hali ya ugonjwa wake.

Hiyari ya kushiriki na kujitoa katika utafiti huu

Ushiriki katika utafiti huu ni wa hiyari na pia ni haki yako kujitoa katika utafiti huu muda wowote unapohisi kufanya hivyo. Maamuzi yako ya kuamua mtoto wako kutoshiriki au kujitoa katika utafiti huu hayataathiri haki yake ya kupata huduma na matibabu.

Madhara ya kushiriki utafiti

Mtoto anaweza kupata muwasho wa macho kidogo kwa sababu ya dawa za matone tutakazomuwekea lakini hali hii hupotea baada ya masaa 3-6. Mtoto anaweza kupata pia wekundu wa macho ambao hupotea baada ya siku 2-3. Hakuna madhara yeyote makubwa yatakayo kupata wewe au mtoto wako kwa kushiriki katika utafiti huu.

Manufaa ya kushiriki utafiti huu

Ushiriki wa mtoto wako katika utafiti huu utakusaidia kujua kama mtoto anashida katika pazia la jicho au laa. Pia utajulishwa kama mtoto ana tatizo lolote la macho na utapata faida ya mtoto kupata tiba stahiki kukiwa na uhitaji. Ninatumaini taarifa zitakazopatikana kutokana na utafiti huu zitasaidia kuboresha huduma za afya za watoto wachanga wanaozaliwa kabla ya muda wao**.**

Kauli ya Mtafiti

Mimi mtafiti, nakiri nimemuelewesha mzazi wa mtoto ambaye ni mshiriki wa utafiti huu kuhusu huu utafiti.

Sahihi……

Tarehe…….

Mawasiliano kwa wahusika:

Kwa maswali au maoni kuhusiana na utafiti huu tafadhali wasiliana na wafuatao:

Dr. YUSTA MTOGO

Mtafiti mkuu

Chuo kikuu cha afya na tiba shirikishi Muhimbili

Idara ya Macho

S.L.P 65001 Dar es Salaam

Nambari ya simu: 0685 957009

AU

Dr. CELINA MHINA

Msimamizi wa utafiti huu.

Chuo kikuu cha afya na tiba shirikishi Muhimbili

Idara ya Macho

S.L.P 65001 Dar es Salaam**.**

Nambari ya simu: 0719 326498

AU

Dr. ANNA SANYIWA

Msimamizi mwenza wa utafiti huu.

Chuo kikuu cha afya na tiba shirikishi Muhimbili

Idara ya Macho.

S.L.P 65001 Dar es Salaam**.**

Nambari ya simu: 0784 717461

Kwa mawasiliano zaidi kuhusiana na haki za mtoto wako kwenye utafiti huu kama mshiriki, tafadhali wasiliana na:

Mwenyekiti wa tume ya tafiti na uchapishaji wa tafiti.

Chuo kikuu cha afya na tiba shirikishi Muhimbili

S.L.P 65001 Dar es Salaam

Nambari ya simu: 022-2152489

Kauli ya Mshiriki

Natoa idhini mwenyewe bila aina yoyote ya kushurutishwa au kulazimishwa kushiriki katika utafiti uliotajwa hapa kuhusu ugonjwa wa ukuta wa macho unaowapata watoto waliozaliwa kabla ya wakati (njiti) na viambata hatarishi vya ugonjwa huo miongoni mwa watoto waliozaliwa kabla ya wakati katika hospitali ya taifa Muhimbili Tanzania. Nafanya hivi baada ya kuelewa taarifa zote nilizoelezwa na mtafiti, Dr Yusta Mtogo, na pia amenijibu na kunielewesha zaidi maswali niliyomuuliza.

Nimeelezewa kikamilifu kuhusu madhumuni ya utafiti huu na naelewa kuwa nitaulizwa maswali kadhaa na pia mtoto wangu ataangaliwa macho yake na pazia la jicho.

Pia naelewa kuwa naweza kujiondoa wakati wowote iwapo nitabadilisha mawazo.

Sahihi ya mshiriki……

Saini ya Shahidi…….

Tarehe……...

ANNEX III: Questionnaire- English Version

S/No…….

Phone no……

PART ONE

Hospital registration number……

Date of interview…….

Date of birth……

GA…….

BWT…….

SEX…….

PMA on first screening…….

PART TWO

RISK FACTORS FOR ROP

New born factors

Prematurity Yes/No

Neonatal sepsis (clinical) Yes/No

Neonatal Jaundice Yes/No, *if yes*, was the child kept on phototherapy Yes/No

serum bilirubin values…….....

Intraventricular hemorrhage Yes/No

Days on oxygen therapy…….

Respiratory distress syndrome Yes/No, if *yes* was surfactant given Yes/No

Anemia requiring blood transfusion Yes/No, *If yes* number of BT……. HB before BT…….

Apgar score at 1min……., 5min…….

Any other newborn co-morbidity Yes/No, *if yes*specify…….

Maternal risk factors

Mode of conception- Normal/ART

Twin child- Yes/No

Mode of delivery- CS /SVD

Maternal hypertensive disorders-Yes/No

If yes was the mother hypertensive prior pregnancy-yes/no

Premature rupture of membranes Yes/No

Maternal corticosteroid uses during pregnancy Yes/No

Any febrile illness prior delivery -Yes/No

If yes - UTI, Chorioamnionitis, Others specify……..

Any other maternal co-morbidity…….

If cranial USS was done, document the findings……

……

PART THREE

EXAMINATION FINDINGS.

Anterior segment- Normal/ Abnormal

If abnormal specify the abnormality……

……

……

……

Retinal findings on the first screening

Mature, Immature, ROP.

If mature do not proceed

If ROP

Zone…….

Stage…….

APROP Yes/No

Plus disease Yes/No

Retina findings on subsequent follow up visits

Second visit **Third visit**

PMA……. PMA…….

Retina- Mature, Immature, ROP Retina- Mature, Immature, ROP

If mature do notproceed *If mature do not proceed*

If ROP If ROP

Zone……. Zone……

Stage…… Stage……

APROP Yes/NoAPROP Yes/No

Plus disease Yes/NoPlus disease Yes/No

If more visits report findings as above.

Any other retinal abnormality noted Yes/No

If yes,

specify…….....……..……

……..……

……..……

ROP treatment Yes/No

If yes, give treatment

details…….....……

……