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Prevalence And Correlates Of Retinopathy Of Prematurity Amongst Hospitalised Neonates In Rural Central India: A Cross Sectional Hospital Based Study

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Abstract
Background: The proliferative disease of the retinal vessels is retinopathy of prematurity (ROP). It particularly affects premature babies. The disease is asymptomatic in its early phase. It is likely to lead to serious visual impairment. It is one of the treatable and avoidable etiologies. Most of the cases of ROP regress spontaneously with little or nil visual loss, in few cases,the involved eyes progress to significant visual loss.Hence detection of ROP require on going screening programme. Advances in neonatology and improved preterm survival have increased the risk of developing ROP in the infant population.There are many risk factors but the incidence of Prematurity retinopathy is reciprocally linked to the birth weight, gestational age of the baby. Babies under 1500 g, and particularly with very low birth weight < 1000 g, are the most at risk. Infants with any of the following at higher risk to develop ROP: Oxygen exposure, septicemia ventilation, apnea, blood transfusion,hypoxia, hyperoxia, hypercarbia, hypotension, respiratory distress syndrome, and intracranial hemorrhage.
Aim: To Study the Prevalence And Correlates of Retinopathy Of Prematurity In Neonates.
Objectives:
- To assess ROP incidence.
- To study correlates of ROP.
- To study ROP's clinical profile.

Material and Method: This cross-sectional study will be conducted in the Department of Medicine, at Acharya Vinoba Bhave Rural Hospital (AVBRH), a tertiary care teaching hospital situated in the rural area of Wardha District among 125 babies, after taking inclusion and exclusion criteria into consideration.
EXPECTED RESULTS: Prevalence of Retinopathyof Prematurity is probable to be more in neonates of <32 weeks of gestational age, <1500g birth weight, history of Oxygen supplementation/ sepsis/ blood transfusion/ respiratory distress in postnatal period.

Keywords: Gestational age, Birth weight, Prematurity

Introduction

The proliferative disease of the retinal vessels is retinopathy of prematurity (ROP). It particularly affects premature babies. The disease is asymptomatic in its early phase. It is likely to lead to serious visual impairment[1]. It is one of the treatable and avoidable etiologies. Most of the cases of ROP regress spontaneously with little or nil visual loss, in few cases,the involved eyes progress to significant visual loss[2] .Hence detection of ROP require on going screening programme.

Advances in neonatology and improved preterm survival have increased the risk of developing ROP in the infant population.There are many risk factors but the incidence of Prematurity retinopathy is reciprocally linked to the birth weight, gestational age of the baby. Babies under 1500 g, and particularly with very low birth weight < 1000 g, are the most at risk[3].

Infants with any of the following are at higher risk to develop ROP: Oxygen exposure, septicemia ventilation, apnea, blood transfusion,hypoxia, hyperoxia, hypercarbia, hypotension, respiratory distress syndrome, and intracranial hemorrhage[4].

Facts about childhood blindness[5]:
Control of blindness in children is one of the important aspects of WHO's VISION 2020 – The Right To Sight Program. The essential modalities for this in first phase are cataract, trachoma, refractive errors, onchocerciasis and low vision. Blindness in children is considered a priority as it can affect their development and further well being.[1]

Pathogenesis[6]
There are two blood sources to the immature retina, namely the outer choroidal vessels and inner retinal vessels.Retinal vessels extend till nasal side of retina by 8thweek of gestation, and the temporal vessels get vascularized by about a month after birth. These vessels are immature and are hence likely to damage in the presence of oxygen. It leads to vasoconstriction.ROP has been shown to follow excessive oxygenation in the postnatal period. Due to this, the retinal arteries and eventually the veins become obliterated. This incites a phase of neovascularization.There is also proliferation and contraction of tissues which originates in the shunt area. This explains the retinal and vitreous changes in ROP.The detachments are typically tractional detachment and their form depends on if the shunt area is anterior, posterior, or equatorial.The earliest signs include dilatation of retinal veins and hazy white patches appear in the peripheral retina. These patches soon show an unlimited proliferation into the vitreous. This is due to formation of new vessels in the retina itself which outgrows into the vitreous. After this fibrous tissue develops. The fibrous tissue in due course proliferates to form a continuous mass behind the lens, which appears as a type of pseudoglioma.
Activity may be hampered at any stage and some vision maybe retained. In many cases it is progressive. The retina is detached and eye becomes microphthalmic.

STAGES OF ROP[6]
Stage 1: a discrete line of demarcation separating the anterior, immature, avascular retina from mature, vascularized retina posteriorly. A thin, greyish line is seen concentric to ora serrata with some abnormal vessels present posterior to it.
Stage 2: the demarcation line is transformed into an elevated ridge separating the avascular and vascular retina. The ridge is vascularized and some neovascular tufts can be visualized posterior to it.
Stage 3: fibrovascular ridge develops at the ridge with extraretinal neovascularization extending into the vitreous. The posterior retina now shows tortuous, dilated retinal vessels. Retinal and vitreous hemorrhages are common.
Stage 4: tractional retinal detachment extends from the periphery to the posterior pole.
Stage 5: total retinal detachment.

INTERNATIONAL CLASSIFICATION OF ROP[5]
Zone 1(posterior polar or inner zone): limit is two times the disc fovea distance in all directions from the disc.
Zone 2: From the peripheral edge of zone 1 to the tangential point of the nasal ora serrata.
Zone 3: Temporal residual retinal crescent anterior to zone 2.

ETROP STUDY(Early Treatment of ROP)[5]
Subclassification:
Type 1 ROP: zone 1 ROP, any stage ROP with Plus disease; zone 1, stage 3 ROP without plus disease; or zone 2 , stage 2 or 3 ROP with plus disease – perform retinal ablation.
Type 2 ROP: Zone 1 , Stage 1 or 2 ROP without plus disease or Zone2 , Stage 3 ROP without plus disease – Consider therapy only if it progresses towards type 1 or the ROP threshold.

Plus Disease[6]
Indicates progressive vascular incompetence.
Most prominent feature is presence of tortuous retinal arteries and dilated veins in the posterior pole.
Presence of Plus disease indicates activity and potential to progress rapidly.
In most cases, ROP resolves spontaneously with normal vascularization of retina being restored. Rest of them develop some sequelae such as myopia, temporal vitroretinal fibrosis with dragging of the disc, partial/ extensive retrolental fibrovascular tissue, secondary angle closure glaucoma, or total retinal detachment.Retrolental fibroplasia is a term used for non acute, late cicatricial changes that are seen in severe cases.

Threshold disease
Zone 1 or 2 : ROP stage 3 more than five contiguous or eight cumulative clock hours with plus disease present.

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RISK FACTORS[5]:

Definite factors:

- Prematurity/ gestational age/ birth weight
- Oxygen supplementation

Associated factors:

- Shock
- vitamin E insufficiency
- apnea with bag and mask ventilation
- asphyxia/hypoxia
- blood transfusion or exchange transfusion
- PDA/indomethacin
- Respiratory distress syndrome
- Methylxanthine administration
- In utero hypoxia
- IVH
- Acidosis or alkalosis
- Maternal anemia
- Sepsis
- Hypercarbia/hypocarbia

MANAGEMENT[6]

Most important thing in ROP is prophylaxis. All babies with birth weight of 1500g or gestational age of <32weeks should be screened with indirect ophthalmoscope between 32 to 36 weeks post conception.In neonates with birth weight of <1200g, the $pa0_2$level of blood from umbilical artery should be monitored. Levels of 50-100 mmHg are unlikely to produce constriction of immature retinal vessels.Before the child is discharged from the hospital, the temporal periphery of each retina should be examined with indirect ophthalmoscope to check for Threshold disease (a ridge with extraretinal fibrovascular proliferation and posterior venous dilatation and arteriolar tortuosity)If any minor signs are noticed, examination is to be repeated at age of 1, 3 and 6 months and every 4 months up to the age of 4 years. This is done to diagnose early retinal holes or localized detachment of retina.If in case there is definitely progressive Plus Disease or bilateral proliferative lesions in vitreous are noted, treatment by photocoagulation or cryotherapy is considered.If there is presence of mild intravitreal neovascularization, photocoagulation therapy is delayed since spontaneous resolution occurs in a high percentage of patients.Visual prognosis and treatment is ineffective once the condition has developed fully. Removal of fibrous mass by lensectomy and vitrectomy may rarely be helpful in such cases.

PERIPPHERAL RETINAL ABLATION[5]:

This is done to eliminate the avascular area, since larger the avascular zone larger amount of vasoformative factors are produced hence more is the neovascularization.

- WHEN TO DO CRYOTHERAPY/ LASER:

It is done in cases of threshold ROP and Prethreshold ROP.

- TECHNIQUE:

Cryotherapy spots are added before the ridge and then to the whole avascular retina in a continuous way, with the end point as a creamy white spot of severity and an average number of 21 spots varying from 15-30.

AIM AND OBJECTIVES

Aim: TO STUDY THE PREVELANCE AND CORRELATES OF RETINOPATHY OF PREMATURITY IN NEONATES.

Objectives:

1. To determine the incidence of ROP.
2. To study correlates of ROP
3. To study the clinical profile of ROP.

MATERIAL AND METHOD

STUDY SETTING

- All the studies will be conducted at Department of Ophthalmology, NICU and Obstetrics ward, Acharya Vinobha Bhave Rural Hospital, Sawangi (Meghe)Wardha.

RESEARCH AND DESIGN

- This is a hospital based cross sectional observational study.

PARTICIPANTS

Preterm and low birth weight babies hospitalized at AVBRH will be selected for the study after taking the inclusion and exclusion criteria intoconsideration.

SAMPLING PROCEDURE

Sampling size: 125

The sample size formula used :

$$n = \frac{Z\alpha/2 . P . (1-P)}{d^2}$$

where;

$Z\alpha/2$ is the level of significance at 5% i.e., 95% confidence interval

= 1.96

P is the Prevalence of ROP[10]

= 19.2% = 0.192

d is the Desired error of margin

= 7% = 0.007

$$n = \frac{1.96^2 \times 0.192 \times (1-0.192)}{0.072^2}$$

= 121.62

n = 125 patients needed in the study

Statistical analysis will be done by using Descriptive and Inferential statistics using Chi Square test and Students Unpaired t test and software used will be SPSS 24.0 version and Graphpad Prism 7.0 version and $P<0.05$ is considered as level of significance

DATA COLLECTION TOOLS AND PROCESS

- This study will be adhered to the tenets of the declaration of Helsinki, and it will be approved by an institutional ethic committee of DMIMSU.
- Informed consent will be obtained from parents after the nature and possible consequences of the study will be explained to them.
- History and complete ocular evaluation will be carried out on the patients.

DURATION OF STUDY

This will be a 2 years study for data collection from September 2020 to September 2022.

INCLUSION CRITERIA

- Babies with gestational age 32 weeks or less.
- Babies with birth weight 1500gm or less.
- Babies with birth weight between 1501-2000g and/or 33-35 weeks who are at higher risk of developing ROP,i.e.,
- Sepsis,
- Respiratory distress syndrome,
- Multiple blood transfusions,
- Intraventricular hemorrhage,
- Apneic episodes.
- Babies attending follow up neonatal clinic having these risk factors.

EXCLUSION CRITERIA

- Non consenting parents
- Babies who died before full vascularization of retina

EXPECTED OUTCOMES

Prevalence of Retinopathy of Prematurity is probable to be more in neonates with <32 weeks of gestational age, <1500g birth weight, history of Oxygen supplementation/ sepsis/ blood transfusion/ respiratory distress in postnatal period.

CONCLUSION

Screening neonates who are born with a birth weight of <1500g or those born at <32 weeks of gestations or those with other high risk factors may help to identify neonates who are at a higher risk to develop retinopathy of prematurity.

DISCUSSION

ROP has been marked in developing countries by two noteworthy epidemicsover the past 60 years. Retrolental Fibroplasia, now known as retinopathy of prematurity (ROP), was first described by Terry in 1942[7], who described the histological findings of what would now be thought as end stage cicatricial disease. In1951, Campbell suggested that the application of oxygen therapy to premature babies may be temporally linked to ROP.In hospitals that purchased oxygen, he established that the incidence of ROP was low relative to hospitals in which Oxygen was freely available[8].In order to hold up the hypothesis of toxic consequences of oxygen on the immature retinal vasculature, additional evidence was later developed.This epidemic came to an end following controlled oxygen administration. By1965, the percentage of blindness due to ROP dropped from 50 percent in 1950 to 14%. Reports of a second ROP outbreak appeared during the late 1970s and 1980s. Oxygen was reset, but in a more controlled way, to save the lives of babies and to avoid neurological problems.It was deduced that this epidemic was due to increased survival rate of very low birth weight babies and not due to new iatrogenic factors**.** The progress in neonatal treatment over the last few decades has contributed to improved survival of many highly LBW babies and, subsequently, to a rise in rate of ROP. A decrease in incidence, severity and progression to threshold disease due to more controlled use of O2 is suggested in more recent studies[9].

Type of Article- Original Article
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