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Use of the WINROP Screening Algorithm for the Prediction of Retinopathy of Prematurity (ROP): A Hospital-Based Study

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Abstract

Background: Retinopathy of prematurity (ROP) may be the blinding disease that affects the retina of neonates. WINROP utilizes the rate of postnatal weight increase as a replication of IGF-1 or uses weight increase and IGF-1 levels together as highly analytical markers for those infants at increased risk for the development of proliferative ROP. So this study was undertaken to find out the sensitivity and specificity of this algorithm concerning international screening guidelines to predict retinopathy of prematurity. **Material & Methods:** A prospective cross-sectional study was carried out in the Department of Neonatology, Bangladesh Shishu Hospital & Institute from January 2017 to December 2018. A total of 50 neonates (N=50) with proper documentation following the inclusion and exclusion criteria were confirmed as the study population. Informed written consent was obtained from all the parents or guardians after they were thoroughly briefed about the nature and purpose of the study. Data were processed and analyzed using statistical package for social sciences (SPSS-22 version) software (SPSS Inc., Chicago, IL, USA). The ethical review board of the Bangladesh Institute of Child Health approved the protocol of this study. **Results:** The mean gestational age was 29±1.17 weeks in ROP-positive cases and 31.79±0.51 weeks in ROP-negative cases. The mean weight was 1121.9±94.34 grams in ROP-positive cases and 1302.7±139.72 grams in ROP-negative cases. It was observed that the majority 92.3% of the ROP positive cases had weight gain ≤10gm/kg/day for 4 weeks but 87.5% of the ROP negative cases had weight gain >10gm/kg/day. The validity test of WINROP for the prediction of retinopathy has a sensitivity of 92.3%, specificity of 87.5%, and positive predictive value of 88.9% and negative predictive value of 91.3%. Low-grade ROP - In zone II or III and stage 1. High-grade ROP - In zone I and stage 2 or more and plus disease. **Conclusion:** Retinopathy of prematurity (ROP) is a severe eye infection that can affect premature neonates. In this study, WINROP predicted 92.3% sensitivity and 88.9% positive predictive value in comparison to the gold standard screening method for detecting ROP within 2 weeks of birth.

Keywords:- Retinopathy of prematurity, Birth- weight, Neonates.

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INTRODUCTION

Retinopathy of prematurity is a disorder of developing retinas in preterm newborns and is a leading cause of preventable childhood blindness. The spectrum of ROP ranges from the mild, transient change in the retina to severe progressive vaso-proliferation but most cases of ROP are mild and regress spontaneously; however, severe ROP can lead to retinal detachment and permanent vision loss.[1] WHO Health Organization's Vision 2020 program has recognized retinopathy of prematurity as an important cause of childhood blindness in industrialized and developing countries.[2] Over 50,000 children are probably blind worldwide from ROP each year. So early treatment of ROP through screening will decrease the incidence of severe vision loss and unfavorable outcomes.[3] ROP is a multifactorial disease, and the main postnatal risk factors are adapting to extra-uterine life, energy deficiency, hyperglycemia, infections, low serum IGF-1, un-physiologic oxygenation with periods of hyperoxia as well as hypoxia, low gestational age (GA), low birth weight (BW), intraventricular haemorrhage, blood transfusion and use of indomethacin, surfactant and erythropoietin.[4] ROP screening programs generally include infants based on gestational age and birth weight. Several recent studies showed that poor weight gain in the first few weeks of postnatal life can predict the highest risk of retinopathy.[5] These studies also suggested low serum IGF-1 as a linked parameter for poor postnatal weight gain. IGF-1 is necessary for normal retinal angiogenesis by activating VEGF.[6] Based on these studies, which gave rise to an understanding of the relationship between IGF-I, postnatal growth and angiogenesis, a new diagnostic algorithm "Weight, IGF-1 and Neonatal ROP" (WINROP) was developed in 2006 in Sweden.[7] WINROP utilizes the rate of postnatal weight gain as a reflection of IGF-1 or uses weight gain and IGF-1 levels together as highly predictive markers for those infants at increased risk for the development of proliferative ROP.[8] The strong correlation between serum IGF-1 and weight gain made it possible to use WINROP based on weight development alone, thus avoiding blood sampling. After the initial validations using postnatal changes in both IGF-1 and weight gain, this algorithm has been used since 2009 with postnatal weight gain alone with validation in >10,000 infants worldwide.[9] The sensitivity (90%-100%), as well as the specificity (38.7%-81.7%), has varied in different international preterm populations in Sweden, Switzerland, Canada, the US, Brazil, and Mexico.[10,11] This tool also helped to determine early which infants are at low risk thus reducing the number of eye examinations in that population while concentrating observation on those infants at high risk.[12] In Bangladesh, the WINROP algorithm has not been used yet to predict ROP. So this study was undertaken to find out the sensitivity and specificity of this algorithm about international screening guidelines to predict retinopathy of prematurity.

Objectives

To assess WINROP, an algorithm using postnatal weight measurements and serum insulin like growth factor-1 (IGF-1), as a tool for the prediction of retinopathy of prematurity.

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MATERIAL AND METHODS

A prospective cross-sectional study was carried out in the Department of Neonatology, Bangladesh Shishu Hospital & Institute from January 2017 to December 2018. A total of 50 neonates (N=50) with proper documentation following the inclusion and exclusion criteria were confirmed as the study population. Non probability, the convenient and purposive sampling method was followed. A standard questionnaire including cardinal points of the history, examination findings and investigation results prepared by the investigator was used to collect data. The ethical review board of the Bangladesh Institute of Child Health approved the protocol. Informed written consent was obtained from all the parents or guardians after they were thoroughly briefed about the nature and purpose of the study. Reassurance was given to the parents as there were no harmful effects on the babies or economic loss. Data edition were done through checking and rechecking. Data were processed and analyzed using statistical package for social sciences (SPSS-22 version) software (SPSS Inc, Chicago, IL, USA). The results were presented in tables and figures. The statistical terms include in the study were mean, standard deviation, sensitivity, specificity, positive predictive value and negative predictive value. Here unpaired t test and validity test, were performed to justify the study results where $p<0.05$ considered as the level of significance with 95%CI.

Inclusion criteria

- Preterm neonates with gestational age ≤ 32 weeks and birth weight or weight at enrollment ≤ 1500 grams
- Day of enrollment ≤ 3 days

Exclusion criteria

- Gestational age > 32 weeks
- Intrauterine growth retardation (IUGR)
- Neonates having non physiologic weight gain (hydrocephalus)
- Syndromic babies
- Absence of other eye conditions like cataract and corneal opacity
- Who did not give consent

RESULTS

Among the study population there was a statistically significant difference (($p<0.05$) in gestational age, weight at enrollment, length and OFC between ROP positive and ROP negative cases. It was observed that the mean weight gains in 1st week was 16.04±8.0 grams in ROP-positive cases and 26.79±10.33 grams in ROP-negative cases. Weight gain in 4th week was 54.58±15.02 grams in ROP-positive cases and 89.71±17.05 grams in ROP-negative cases. There was a statistically significant difference ($p<0.05$) between weight gain weekly for 4 weeks [Table 1]. It was observed that the majority 92.3% of the ROP positive cases had weight gain ≤10gm/kg/day for 4 weeks but 87.5% of the ROP negative cases had weight gain >10gm/kg/day. The mean net weight gain of 4 weeks was 156.19±22.33 grams in ROP-positive cases and 278±34.60 grams in ROP-negative cases. The difference was statistically significant ($p<0.05$). It was observed that the majority 92.3% of the ROP-positive cases had serum IGF-1 ≤65 ng/ml and 87.5% of the ROP-negative cases had serum IGF-1 within normal limit. The mean serum IGF-1 was 45.82±21.02 ng/ml in ROP-positive cases and 127.59±26.85 ng/ml in ROP-negative cases. The difference was statistically significant ($p<0.05$) [Table 2].

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True positive 24 cases, false positive 3 cases, false negative 2 and true negative 21 cases were identified by the gold standard method [Table 3]. The validity test of WINROP for the prediction of retinopathy has a sensitivity of 92.3%, specificity of 87.5%, positive predictive value of 88.9% and negative predictive value of 91.3% [Table 4]. Low-grade ROP - In zone II or III and stage 1. High-grade ROP - In zone I and stage 2 or more and plus disease [Table 5]

Table 1: Distribution of the study patients by demographic characteristics (N=50).

Variables	**ROP(+ve) (n=26) Mean± SD**	**ROP(-ve) (n=24) Mean± SD**	**p value**
Gestational age(weeks)	29±1.17	31.79±0.51	0.001^{s}
Weight at enrollment (grams)	1121.9±94.34	1302.7±139.72	0.001^{s}
Length (cm)	45±1.06	46.54±1.25	0.001^{s}
OFC (cm)	31.38±0.8	31.83±0.76	0.047^{s}
Day of enrollment	2.5±0.51	2.54±0.51	0.783^{ns}
Weight gain(grams/week)			
At 1st week	16.04±8.0	26.79±10.33	0.001^{s}
At 2nd week	44.42±10.28	69.92±15.05	0.001^{s}
At 3rd week	50.81±13.99	83.42±17.15	0.001^{s}
At 4th week	54.58±15.02	89.71±17.05	0.001^{s}

Table 2: Distribution of the study patients by net weight gain of 4 weeks (N=50).

Net weight gain of 4 weeks (grams)	**ROP(+ve) (n=26)**	**ROP(ve) (n=24)**	**p value**
≤10gm/kg/d	24,92.3%	3,12.5%	
>10gm/kg/d	2,7.7%	21,67.5%	
Mean± SD	156.19±22.33	278±34.60	0.001^{s}
Serum IGF-1 (ng/ml)			
≤65	24,92.3%	3,12.5%	
65–184	2,7.7%	21,67.5%	
Mean± SD	45.82±21.02	127.59±26.85	0.001^{s}

Table 3: Comparison of the study patients with WINROP and gold standard screening (N=50).

WINROP alarm at the end of 2nd week after birth	**ROP Screening (Gold Standard method) at 4 weeks after birth**		**Total**
	Positive (n=26)	**Negative (n=24)**	
Alarm- Risk of ROP (n=27)	24 (true positive)	3 (false positive)	27
No alarm- No risk of ROP(n=23)	2 (false negative)	21 (true negative)	23
Total	26	24	50

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Table 4: Sensitivity, specificity, positive and negative predictive values of WINROP for the prediction of retinopathy of prematurity

Validity test	**Percentage (%)**
Sensitivity	92.3%
Specificity	87.5%
Positive predictive value	88.9%
Negative predictive value	91.3%

Table 5: Distribution of ROP of the studied neonates by stages, zones and plus disease at first screening (n=26).

ROP	**(n,%)**
Stages	
1	15,57.7%
2	6,23.1%
3	4,15.4%
4	1,3.8%
Zones	
I	11,42.3%
II	5,19.2%
III	10,38.5%
Plus Disease	
Present	5,19.2%

DISCUSSION

Retinopathy of prematurity is a potentially preventable cause of blindness especially in developing countries. To control blindness due to ROP in middle-income countries there is an urgent need to increase awareness among the public, health professionals and parents. This observational cohort study was conducted in the Department of Neonatology, Bangladesh Shishu Hospital & Institute in Bangladesh to predict the screening algorithm WINROP to detect ROP. In this study, the mean gestational age among preterm neonates was 29±1.17 weeks in ROP-positive cases and the mean birth weight was 1121.9±94.34 grams in ROP-positive patients. In our country, a study reported that babies <1000 grams had an ROP incidence of 44.4%, if the birth weight was between 1000 to1499 grams the incidence was 11.8% and when the birth weight was ≥ 1500 grams the babies had no ROP.[13] Another study suggested that newborns that developed retinopathy of prematurity had a lower birth weight of 1175±226 grams and gestational age of 29.9±1.8 weeks than the non-retinopathy of prematurity counterpart.[14] A related article showed the similar type of results with a median gestational age of 28 weeks and median birth weight of 1075 grams who developed ROP.[15] A median gestational age of 26 weeks and a median birth weight of 955 grams developed ROP in his study which is dissimilar to the result depicted in another article.[16] In this study weekly weight gains were measured and there was a

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significant difference in weight gain for 4 weeks. ROP-positive cases gained weights ≤ 10g/kg/day compared to ROP-negative cases who gained weights > 10g/kg/day. Several studies reported the relationship between weight gain and ROP. Some authors reported in a study done on 317 preterm infants that low weight gain by six weeks of life is an important factor for ROP.[17] Another study found that weekly weight gain triggered an alarm for eye examination and identified 66 out of 67 preterm infants with a sensitivity of 99%, among them 33 infants got treatment.[18] A similar study revealed weight gain at completed 4 and 6 weeks of life and found stage 3+ retinopathy was significantly associated with poor weight gain.[19] In the current study serum, IGF-1 was measured in the 2nd week and was significantly lower in ROP-positive cases and correlate with weight gain. Several studies reported the high sensitivity and specificity and highest predictive value of serum IGF-1 in the 2nd week after birth to predict ROP. A relevant study reported that serum levels of IGF-1 in the 3rd week after birth had more sensitivity and specificity to detect ROP.[20] The incidence of ROP in this study was 52% which is similar to different parts of the world, particularly in Asian countries.[21] In this study, an algorithm WINROP was used based on postnatal weight gain up to 4 weeks after birth and serum IGF-1 at the 2nd week. WINROP signaled alarm weeks/ months before the development of severe ROP or retinal detachment giving the physician an early prediction of the infant's future.50 neonates were included in this study and WINROP predicted alarm for 54% of the neonates within 2 weeks of birth who later developed retinopathy of prematurity in this study. A similar article found, WINROP predicted alarm in the majority of neonates which is 74.28% and in 52.85% of neonates within 2 weeks of life in his longitudinal cohort study.[15] In the current study, WINROP sensitivity was 92.3%, specificity was 87.5%, positive predictive value was 88.9% and negative predictive value was 91.3%. A similar analysis showed that WINROP sensitivity was 100% with 81.7% specificity and 100% negative predictive value.[6] Another similar article showed a sensitivity of WINROP 84.7% and a specificity of 26.6% in a retrospective cohort done on 377 neonates.[22] Some similar articles depicted that WINROP sensitivity was 95.7%, 90% and 87.5% respectively with a specificity of 23%, 52.55% and 26.6%.[7,23,24] In 2014, another published article found WINROP sensitivity at 87% in a study of 289 neonates.[25] Finally, in a study performed on 199 neonates the sensitivity of WINROP was 90.3% with a specificity of 38.4%, a positive predictive value of 53.84% and a negative predictive value was 38.45%.[15]

CONCLUSIONS

Retinopathy of prematurity (ROP) is a severe eye infection that can affect neonates. In this study, WINROP predicted 92.3% sensitivity and 88.9% positive predictive value in comparison to the gold standard screening method for detecting ROP within 2 weeks of birth. Early exposure and observation of ROP, optimal oxygen therapy, control of anaemia, infection prevention, nutritional support, family history screening, and optimal birth management are important measures that can help lessen the occurrence and severity of ROP.

Recommendations

WINROP can be used to predict ROP as early as possible. This screening algorithm WINROP will increase the awareness and importance of

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eye examinations of premature babies and will reduce the number of dropped-out cases from ROP screening schedules. As IGF-1 and postnatal weight gain was parallel so excluding blood samples for IGF-1 only postnatal weight gain can be used to predict ROP as early as possible in future. This study will act as a model for further research work on retinopathy of prematurity using the WINROP algorithm. A study with an increased sample size is recommended to establish the findings of the present study and to explore the benefits of WINROP in premature neonates to detect ROP. By implementing these recommendations, healthcare providers can help reduce the incidence and severity of ROP and improve the long-term visual outcomes of premature infants.

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