Original Article

Retrospective Validation of the Postnatal Growth and Retinopathy of Prematurity (G-ROP) Criteria in a Developing Country

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ABSTRACT

Background: The characteristics of premature infants vary from country to country rendering it challenging to apply retinopathy of prematurity (ROP) screening algorithm globally. The screening criteria for postnatal growth and ROP (G-ROP) for preterm infants are known to be beneficial, but it is not clear whether these criteria can be used universally. **Aim:** The aim of this study is to validate the accuracy of the G-ROP criteria in screening preterm infants in Saudi Arabia. **Subjects and Methods:** This single-center retrospective study included 300 premature infants (mean gestational age [GA], 28.72 ± 2.2 weeks; range, 21–36 weeks) at a referral center who were screened for ROP between 2015 and 2021. The inclusion criteria were the availability of data on ROP outcome and body weight up until day 40 after birth. The G-ROP 1 and G-ROP 2 models were examined for their ability and accuracy in identifying infants with any stage ROP and treatable ROP. **Results:** The G-ROP 1 and G-ROP 2 models identified 233 and 255 infants for screening, respectively. The sensitivity of G-ROP 1 and G-ROP 2 for detecting treated ROP was 96.7% and 100%, respectively, and the specificity for detecting treatable ROP was 24.4% and 16.7%, respectively. Incorporation of the G-ROP 2 model, which did not miss any infant with type 1 ROP, would have reduced the number of screened infants by 15%. **Conclusion:** G-ROP 2 was more sensitive than G-ROP 1 for identifying infants who required treatment and could potentially reduce the burden of ROP screening.

KEYWORDS: *Birth weight, gestational age, preterm, screening, validation*

INTRODUCTION

Retinopathy of prematurity (ROP) is an eye disorder that affects premature infants and is characterized by abnormal retinal vasculature.[1] Despite advances in neonatal care and management guidelines, severe ROP, if left untreated, can lead to severe visual impairment from retinal detachment and remains a major cause of childhood blindness around the world.[2] In addition, regular examination of infants who may require ROP treatment is necessary, as timely treatment can prevent damage to vision and associated consequences, including blindness in the future.[3,4] Early treatment with anti-vascular endothelial growth factor therapy and laser photocoagulation has been found to improve patient outcomes, but this is only possible through timely screening and diagnosis.[5]

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The occurrence and severity of ROP are affected by various factors, but most of the screening criteria include only birth weight (BW) and gestational age (GA).[6] For example, the revised ROP guidelines of the American Academy of Pediatrics recommend screening infants with BW ≤1500 g or GA ≤30 weeks, as well as those with BW of 1500–2000 g or GA >30 weeks who have an unstable clinical course.[7] However, these screening criteria lack specificity, as less than 10%

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of the examined infants develop ROP that requires treatment (type 1 ROP); this means that most of the ophthalmic examinations are conducted on children who will never require treatment.[8] The development of more specific criteria could reduce the number of examinations performed and, thereby, the costs associated with this.

Currently, there are many ongoing efforts to develop new ROP prediction models to avoid unnecessary and costly examinations.[9-13] Recently, the postnatal growth and ROP (G-ROP) study created new screening criteria that were examined in a retrospective cohort study performed at North American hospitals and found to have 100% sensitivity for type 1 ROP and resulted in a 30% decrease in the number of infants who required examinations.[10] Screening with the G-ROP criteria proved to be more economical than conventional screening.[14] However, as the socioeconomic context has a big influence on the characteristics and outcomes of premature infants, it is challenging to apply the G-ROP screening criteria globally. In developed countries, there has been a decrease in the incidence of blindness caused by ROP on account of the improved quality of neonatal care and the adoption of localized screening and treatment guidelines.[15] As a result, in developed countries, the chances of severe ROP are low in infants with >31 weeks of gestation.[16,17] In contrast, in developing countries, it has been reported that severe ROP developed in infants even up to 34 weeks.[18-21] This has been attributed to the rapidly developing neonatal intensive care systems with limited health resources to care for infants in developing countries leading to blindness from untreated ROP being encountered more in more mature babies than in developed countries.[18] As the primary study on the G-ROP criteria included only infants in North American hospitals, it would be especially difficult to apply these findings to developing countries.[10] Despite this, the G-ROP guidelines have been applied in several countries. For example, Switzerland, Italy, the UK, Japan, and Taiwan reported 100% sensitivity for the detection of treatable ROP.[22-25] Furthermore, a study in Egypt demonstrated 100% (91.1–100%) sensitivity for type 1 ROP detection,[26] whereas another study conducted in a tertiary center in Turkey reported the sensitivity to be 91.2% for treated ROP.[27] As mentioned earlier, the differences in sensitivities could be attributed to differences in patient characteristics, socioeconomic status, ethnicity, and neonatal care practices. Importantly, the criteria need to be tested in different populations around the world to understand their applicability.

In the present retrospective study, the G-ROP criteria were evaluated in a cohort of premature infants at a tertiary hospital in Jeddah, Saudi Arabia. We believe that the findings will shed light on the accuracy of this set of criteria for the detection of ROP in developing countries.

Materials and Methods

This was a retrospective cohort study carried out at King Abdulaziz University Hospital, a tertiary center in Jeddah, Saudi Arabia. Data on premature infants who underwent ROP examinations between January 2015 and August 2021 were collected for analysis.

We followed the guidelines of the American Academy of Pediatrics for ROP screening. We considered 533 eligible infants with BW <1501 g, GA <31 weeks, or high risk for ROP (based on the assessment of a neonatologist).[28] Out of the initial 533 infants, 233 were excluded because their ROP outcome was unknown or their data were incomplete. Clinical examinations and treatment strategies were in accordance with the Early Treatment for ROP guidelines.[29]

Data on ROP outcomes were obtained from the medical records of the patients; in addition, data on sequential body weight values, GA, BW, sex, and the presence of concomitant hydrocephalus were also obtained. In patients with ROP, we collected the following data: stage and zone of ROP, date of diagnosis, the outcome (regressed or treated), and the type of treatment (laser or intravitreal injections). G-ROP 1 and G-ROP 2 criteria proposed by two large-scale multi-center studies were applied. According to the G-ROP 1 screening criteria, an infant is eligible for examination if one or more of the following criteria are met: GA <28 weeks, BW <1051 g, weight gain between age 10 and 19 days <120 g, weight gain between age 20 and 29 days <180 g, weight gain between 30 and 39 days <170 g, and hydrocephalus.[10] The G-ROP 2 criteria are the same, except that all three weight gain thresholds are set at <180 g.[8] Hydrocephalus was included as a sixth criterion as the source of non-physiologic weight gain.[8] For infants with complete data (n = 300), the abovementioned G-ROP criteria were applied to determine whether they warrant ROP examination or not.

Statistical analysis

All analyses were conducted using IBM SPSS version 23 (IBM Corp., Armonk, NY, USA). Variables are presented as simple descriptive statistics in the form of counts and percentages for categorical and nominal variables and mean and standard deviations for continuous variables. The Chi-square test was used to examine the association between categorical variables. For comparing the means of more than two groups, a one-way analysis of variance (ANOVA) with a post-hoc least significant difference (LSD) test

was used. For these tests, it was assumed that the data were normally distributed. Otherwise, the Games–Howell procedure was performed as the post-hoc test. Sensitivity, specificity, ROP prevalence, positive and negative predictive value, and accuracy are expressed as percentages. For sensitivity, specificity, and accuracy, "exact" Clopper–Pearson confidence intervals were calculated. The significance level was set at $P < 0.05$.

Ethical approval

The study was approved by the Institutional Review Board (approval no. 420-20). Due to the retrospective nature of the study, the need for obtaining the informed consent of the participants was waived. The study was conducted in compliance with the tenets of the 1964 Helsinki Declaration.

Results

In total, 300 preterm infants were included in this study. Out of the 300 infants, 115 (37.2%) developed ROP, 85 (73.9%) developed any-stage ROP, and 30 (26.1%) developed type 1 ROP. Among the affected, 76 (66.1%) had stage 1 ROP, 25 (21.7%) had stage 2 ROP, and 14 (12.2%) had stage 3 ROP in right eyes and 79 (68.7%) had stage 1 ROP, 22 (19.1%) had stage 2 ROP, 13 (11.3%) had stage 3 ROP, and 1 (0.87%) had stage 4 ROP in left eyes. In 85 (73.9%) infants, ROP regressed spontaneously. The laser was the most commonly used modality in treated cases (24 patients, 20.9%), and it was followed by intravitreal injections in five patients and combined treatment in one patient. The mean birth weight in this cohort was 1123.54 ± 282.95 g. The mean length of NICU stay was 58.93 ± 39.6 days and the mean GA was 28.72 ± 2.2 weeks. Further, 54% of the patients were females, and two-thirds (67%) were delivered by cesarean section. More than half of the patients were of Saudi nationality (57.7%), whereas the remaining were of different nationalities (42.3%). The characteristics of the study population according to ROP status are shown in Table 1. Infants who did not have ROP had significantly higher mean BW and GA and significantly lower mean length of NICU stay ($P \leq 0.001$). Table 2 shows the accuracy of the G-ROP 1 and G-ROP2 criteria for the detection of any stage ROP. Eight out of 115 infants with any stage ROP were missed by the G-ROP 1 criteria (sensitivity, 93%), whereas five were missed

Table 1: Difference between cases with no ROP, treatable ROP, and any stage ROP according to birth weight, gestational age, length of NICU stay, and sex

Variables	Total	ROP			*P*
		No ROP	Any stage ROP	Treatable ROP	
Total	300	185 (61.7%)	85 (28.3%)	30 (10.0%)	
Birth weight (g)	300	1226.46±254.4	1013.71±237.6	800.07±200.3	<0.001[a]
Gestational age (weeks)	300	29.43±2.0	28.05±1.7	26.27±1.9	<0.001[a]
Length of NICU stay (days)	289	45.72±30.5	67.71±30.2	112.87±55.3	<0.001[a]
Sex					
Male	137	88 (64.2%)	35 (25.5%)	14 (10.2%)	0.615
Female	163	97 (59.5%)	50 (30.7%)	16 (9.8%)	
BW <1051 g					
Yes	70	21 (30.0%)	28 (40.0%)	21 (30.0%)	<0.001[b]
No	230	164 (71.3%)	57 (24.8%)	9 (3.9%)	
GA <28 weeks					
Yes	123	46 (37.4%)	50 (40.7%)	27 (22.0%)	<0.001[b]
No	177	139 (78.5%)	35 (19.8%)	3 (1.7%)	

[a]Significant using one-way ANOVA at <0.05. [b]Significant using the Chi-square test at <0.05

Table 2: Sensitivity, specificity, disease prevalence, positive predictive value, negative predictive value, and accuracy of conventional, Group 1, and Group 2 screening for cases with any stage ROP

Variable	Any stage ROP		
	Conventional (birth weight ≤1500 g or gestational age ≤30 weeks)	Group 1	Group 2
Sensitivity, % (95% CI)	100.0 (96.84-100.00)	93.0 (86.75-96.95)	95.7 (90.15-98.57)
Specificity, % (95% CI)	6.7 (3.62-11.19)	31.9 (25.25-39.13)	21.6 (15.92-28.26)
Disease prevalence, % (95% CI)	37.2 (31.81-42.87)	38.3 (32.80-44.10)	38.3 (32.80-44.10)
Positive predictive value, % (95% CI)	38.9 (37.96-39.75)	45.9 (43.19-48.68)	43.1 (41.06-45.24)
Negative predictive value, % (95% CI)	100.0 (71.66-100.00)	88.1 (78.54-93.70)	88.9 (76.48-95.16)
Accuracy, % (95% CI)	41.4 (35.88-47.14)	55.3 (49.51-61.05)	50.0 (44.20-55.80)

Table 3: Sensitivity, specificity, disease prevalence, positive predictive value, negative predictive value, and accuracy of conventional, Group 1, and Group 2 screening for cases with treatable ROP

Treatable ROP	Conventional (birth weight ≤1500 or gestational age ≤30 weeks)	Group 1	Group 2
Sensitivity, % (95% CI)	100.0 (88.43-100.00)	96.7 (82.78-99.92)	100.0 (88.43-100.00)
Specificity, % (95% CI)	5.4 (2.93-9.12)	24.4 (19.44-30.02)	16.7 (12.42-21.66)
Disease prevalence, % (95% CI)	11.2 (7.65-15.54)	10.0 (6.85-13.97)	10.0 (6.85-13.97)
Positive predictive value, % (95% CI)	11.7 (11.41-12.04)	12.5 (11.45-13.52)	11.8 (11.22-12.33)
Negative predictive value, % (95% CI)	100.0 (71.66-100.00)	98.5 (90.48-99.78)	100.0 (90.20-100.00)
Accuracy, % (95% CI)	16.0 (11.82-20.92)	31.7 (26.44-37.26)	25.0 (20.20-30.30)

by the G-ROP 2 criteria (sensitivity, 95.7%). Table 3 depicts the accuracy of the G-ROP 1 and G ROP-2 criteria for the detection of treatable ROP. One out of 30 infants requiring treatment was missed by G-ROP 1, but all infants with type 1 ROP were identified by G-ROP2. Application of the G-ROP 1 and G-ROP 2 would have achieved a 22% (66/300) and 15% (45/300) reduction in the number of infants screened, respectively.

Discussion

This study examined the validity and efficacy of the G-ROP criteria in a developing country, to contribute to the literature on its applicability on a global scale. Our study demonstrated that 38.3.% of preterm infants had any stage ROP, with 10% having treatable ROP. This is lower than the incidence reported by Binkhathlan *et al*.[5] who reported a rate of 56% for any stage ROP in Saudi Arabia with 15% suffering from stage 3 ROP. However, the incidence is similar to that reported by Al-Amro *et al*.[30] who reported a 37.4% rate, with more infants reaching severe ROP requiring treatment at 26%.

Low insulin-like growth factor (IGF-1) concentrations have been associated with ROP pathogenesis and poor weight gain.[31] Several postnatal weight gain-based algorithms such as CO-ROP and CHOP-ROP have been established recently as simple and effective tools to correctly identify infants at risk of treatable ROP.[32-34] The G-ROP model has been recently developed in a multicenter study including a large cohort of infants[10] and validated further in several countries.[24,25,27]A multi-institutional validation study conducted on premature infants in Egypt and the UK reported that with the G-ROP criteria, it was possible to identify all type 1 ROP cases (sensitivity, 100%).[26] Further, the number of newborns who required examinations was reduced by 14.1% and 21.8% in the Egypt cohort and the UK cohort, respectively.[26] Similarly, according to our findings, using the G-ROP1 and G-ROP2 criteria resulted in a 22% and 15% decrease, respectively, in the number of screened infants. This reduction in the number of screened individuals receiving ROP examinations is more of an intuitive measure of the specificity of the criteria wherein G-ROP 2 showed higher specificity for both any stage ROP and treatable ROP compared to G-ROP 1. In our study, the G-ROP 2 model had higher sensitivity than the G-ROP 1 model (100% vs. 96.7%), but G-ROP 2 had lower specificity than G-ROP-1 for the detection of treatable ROP. Sensitivity of the G-ROP criteria has been reported to be higher at 100% in high-income countries such as the US, Switzerland, and Japan,[10,24,25] whereas lower sensitivities have been reported in Turkey[27] at 91.9%. These differences may be attributed to different neonatal health care practices in addition to differences in population characteristics between these different regions.[35]

A primary strength of this study is that it is the first such study in Saudi Arabia that validates the G-ROP criteria in a diverse cosmopolitan population in a developing country. Importantly, the model performed reasonably well in terms of detecting infants with any stage ROP, with G-ROP 1, and G-ROP-2 exhibiting a sensitivity of 93% and 95.7%, respectively; further, they exhibited 96.7% and 100% sensitivity, respectively, for detecting treatable ROP. In addition, there is evidence that implementing the G-ROP 2 model would have resulted in a reduction in the number of infants who require examinations without missing out on any infants with treatable ROP. However, some limitations of our study need to be mentioned. The main limitations are the small sample size, the single tertiary center setting, and the retrospective design. In the future, larger-scale studies should be conducted to verify the reproducibility and reliability of this promising noninvasive complementary tool for the screening and diagnosis of ROP.

Conclusion

G-ROP was found to be beneficial for ROP screening in our cohort, as reported in previous studies. In particular, the G-ROP-2 criteria were identified as a promising adjunctive tool for the detection of clinically significant ROP, whereas ensuring that fewer infants

would require examinations. Thus, it was both clinically and cost-effective. Larger cohort studies are needed to determine the wider-scale applicability of the G-ROP2 criteria in developing countries. In addition, developing algorithms with higher specificities that are more suitable to the context by taking into consideration country-specific risk factors is essential.

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Author contribution

LR contributed to the conception and design of this study; NB, RA, RA, AA, and WA collected the data and drafted the manuscript; LR critically reviewed the manuscript and supervised the whole study process. All authors read and approved the final manuscript.

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Conflicts of interest

There are no conflicts of interest.

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