Original Article

Validation of the Postnatal Growth and Retinopathy of Prematurity (G-ROP) screening criteria

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ABSTRACT

Background: Retinopathy of prematurity (ROP) is a leading cause of irreversible blindness in infants. The Postnatal Growth and ROP (G-ROP) study proposed new screening criteria for ROP. This study aimed to validate the G-ROP screening criteria in a group of Iranian premature infants who were treated in the neonatal intensive care unit (NICU) for at least 40 days.

Methods: In this retrospective study, we extracted the data pertaining to infants admitted to the NICU from January 2020 to December 2021. We screened all the included infants for ROP based on the Iranian national screening criteria. We applied the G-ROP criteria to our study population, and if no criterion was met, the infant was exempted from ROP screening. We determined the sensitivity and specificity of the G-ROP guidelines for ROP detection, along with its capacity for predicting the requirement for ROP treatment. Moreover, we compared the G-ROP guidelines with the Iranian and North American guidelines for ROP screening.

Results: A total of 166 premature infants with complete datasets were included: 130 had ROP, of whom 61 were treated. There were 109 female infants (65.7%). The mean (standard deviation [SD]) birth weight and gestational age were 1080 (256) g and 28.28 (1.97) weeks, respectively. Applying the G-ROP criteria, 127 of 130 infants with ROP were identified (sensitivity, 97.69%; 95% confidence interval [CI], 95.11% – 100%), and of 36 infants without ROP, three were correctly excluded (specificity, 8.33%; 95% CI, 0% – 17.36%). The G-ROP criteria did not fail to identify infants who required treatment for ROP (sensitivity, 100%; 95% CI, 98.29 – 100) and had a specificity of 8.69% (95% CI, 2.04% – 15.34%). Although the Iranian and North American criteria had 100% sensitivity for infants with any stage of ROP, they could not detect infants without ROP (0% specificity).

Conclusions: The G-ROP screening criteria had a sensitivity of 100% in identifying infants requiring treatment for ROP in our high-risk group; however, specificity was not sufficiently high. Further studies with larger numbers of referred infants could confirm a decrease in the burden of retinal examinations using these criteria.

KEYWORDS

retinopathy of prematurity, premature infant, sensitivity and specificity, insulin like growth factor I, IGF-I, screening, weight gain, validation study

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INTRODUCTION

Retinopathy of prematurity (ROP) is a leading cause of irreversible blindness in infants. Blindness can be prevented with timely diagnosis using serial retinal screening examinations in at-risk infants and applying timely treatment with laser photocoagulation and/or anti-vascular endothelial growth factor (VEGF) [1, 2]. An effective screening program is vital for achieving the best treatment outcomes [3]. The ideal screening program would detect all infants requiring treatment while minimizing the burden on the healthcare system. This paradigm must be underscored in low- to middle-income countries, which have a high preterm birth prevalence [4], limited resources, and a greater need for an efficient system.

The current North American criteria advocate screening based on the two most important risk factors: birth weight (BW) < 1501 g and gestational age (GA) ≤ 30 weeks [5]. A drawback of these criteria is their low specificity, as only 5% – 10% of examined infants require treatment [6, 7]. Additionally, the guidelines add a third, somewhat vague, criterion advocating screening of larger and older infants who have a poor postnatal course as judged by the neonatologist [8].

A 2016 cohort study of 1,932 infants born in Iran showed that by following the American guidelines, 8.4% of infants who required treatment for ROP were missed [9]. Therefore, Iranian domestic criteria for ROP screening have been devised (GA ≤ 32 weeks and BW ≤ 2000 g) [9]. Recently, this national guideline has been revisited, considering that more sophisticated neonatal intensive care unit (NICU) management and screening may have altered the national incidence of ROP [9-11].

Recent advances in the knowledge of ROP pathogenesis have linked low serum levels of insulin-like growth factor 1 (IGF-1) to arrested retinal vascular development, which leads to ROP [12, 13]. In recent models, postnatal weight gain has been considered to reflect levels of IGF-1, which triggers production of vascular endothelial growth factor (VEGF), which in turn stimulates retinal vascular development. Incorporating weight gain as a surrogate for increased IGF-1 levels, along with BW, GA, and the presence of hydrocephalus, the Postnatal Growth and Retinopathy of Prematurity (G-ROP) study developed a simple and valid model based on a large cohort of at-risk infants [14]. Subsequently, the G-ROP criteria have been validated in other centers and countries [15-20]. However, concerns remain regarding generalization of the G-ROP criteria to developing neonatal care systems, in which older and larger infants are still developing ROP. In these situations, the influence of intensive oxygen therapy prevails over that of IGF-1 levels, which might make weight gain a less reliable criterion [21, 22].

Herein, we investigated infants admitted to a single tertiary neonatal center to evaluate the validity of the G-ROP model in these high-risk infants, and to compare the validity of the G-ROP criteria with those of the current Iranian national and North American guidelines for screening of ROP.

METHODS

This retrospective cohort study was conducted at Farabi Eye Hospital, a tertiary referral center in Tehran, Iran. The Ethics Committee of Tehran University of Medical Sciences approved the study protocol and design (ethical code: IR.TUMS.FARABIH.REC.1399.039). Informed consent was obtained from parents or guardians of the infants. This study adhered to the tenets of the Declaration of Helsinki.

The records created from January 2020 to December 2021 were reviewed. Infants who met the national ROP screening criteria, had complete data on weight gain measurements until day 40 after birth, and had available datasets on retinal examination were included. For the available data on weight gain, infants admitted to the NICU or ward for at least 40 days were included. Infants with known ROP outcomes were included. Outcomes were recorded as one of the following definitions: type I or type II ROP in either eye based on the Early Treatment for Retinopathy of Prematurity Study [1], or documented ROP treatment; bilateral mature retinal vasculature; immature vasculature reaching zone III without any prior disease in zone I or II; or regressed ROP without meeting criteria for type I or II ROP. Infants with an incomplete dataset, those without documentation of ROP outcomes or regular measurements of daily weight, and infants with coexisting ocular diseases such as familial exudative vitreoretinopathy or incontinentia pigmenti were excluded.

The Iranian national criteria require screening of premature infants with GA ≤ 32 weeks, BW ≤ 2000 g, or a poor postnatal clinical course as judged by the neonatologist [9]. The initial fundus examination for ROP screening was performed at 31–33 weeks postmenstrual age, or 4–6 weeks postnatal age, whichever occurred later. Screening was conducted by three experienced ophthalmologists (N.E., A.F., M.I.F.) in accordance with follow-up schedules, and treatment indications were those recommended by the American Academy of Ophthalmology [5]. Infants were examined until complete vascularization, regression of ROP, or treatment

with either intravitreal anti-VEGF or laser photocoagulation. Infants with type I ROP were considered to have required ROP treatment.

The examination procedure was as follows. Pupil dilatation was performed, and infants then underwent a detailed fundus examination using an indirect ophthalmoscope (Welch Allyn Inc., Skaneateles Falls, NY, USA) and a 30-diopter lens (VOLK Optical, Mentor, OH, USA). A sterile eyelid speculum was placed and a scleral depressor was employed to manipulate the eye.

The following data were collected from the medical records: demographic data including sex, GA, and BW; age at ROP diagnosis; stage and zone of ROP; timing and type of treatment if performed; and daily weight plot. Using a digital scale, infants were weighed in the morning, before feeding, wearing diapers but no other dressing. From the obtained weight, 100 g was subtracted to compensate for diaper weight. The presence of hydrocephalus, based on ultrasonographic definitions, was also recorded.

The G-ROP model for predicting ROP [14] consists of six criteria: (1) GA < 28 weeks, (2) BW < 1051 g, (3) weight gain < 120 g between 10 and 19 days of age, (4) weight gain < 180 g between 20 and 29 days of age, (5) weight gain < 170 g between 30 and 39 days of age, and (6) hydrocephalus. If criterion (1) or (2) is met, then the criteria for weight gain and hydrocephalus are investigated. If any one of these criteria is met, the infant undergoes a retinal examination; if none of the criteria are applicable, the infant does not undergo ROP screening examination. The North American screening criteria recommend screening for infants with BW < 1501 g, GA ≤ 30 weeks, or an unstable course as judged by the neonatologist [5]. Both the G-ROP and North American guidelines were applied to the infants' data to determine the sensitivity and specificity of each model for detecting any stage of ROP and the need for treatment. The reference standard in this regard was the fundus examination data obtained by one of our experts in this field.

Statistical analyses were performed using IBM SPSS Statistics for Windows (version 25.0; IBM Corp., Armonk, NY, USA). The performance of each screening guideline (Iranian, North American, and G-ROP) was evaluated by calculating its sensitivity and specificity to detect the presence of ROP and the need for treatment. The Wilson score method was used to determine 95% confidence intervals.

RESULTS

The records of 516 infants screened for ROP were reviewed. Among these infants, 166 had complete body weight measurements up to day 40, fulfilled the inclusion criteria, and were recruited for this study. One hundred nine (65.7%) patients were female. Mean (standard deviation [SD]) GA was 28.28 (1.97) weeks (range: 25 – 35), and mean (SD) BW was 1080 (256) g (range: 600 – 2000). Overall, 130 (78.3%) infants had some degree of ROP, and 61 were treated. Table 1 presents the characteristics of the included infants.

The G-ROP model recommended 160 infants for ROP screening. Sixty-five infants were selected due to GA < 28 weeks, 37 for BW < 1051 g, 28 for weight gain < 120 g between days 10 and 19, 24 for weight gain < 180 g between days 20 and 29, and 6 for weight gain < 170 g between days 30 and 39. None of the infants was selected for screening based on the presence of hydrocephalus. Six infants did not require screening based on the G-ROP criteria. Three infants showed no signs of ROP, and 3 infants had type II ROP with eventual complete retinal vascularization and no intervention. The sensitivity and specificity of the G-ROP model for detecting any stage of ROP were 97.69% and 8.33%, respectively (Table 2). Using this model to detect the need for ROP treatment, no infant requiring treatment was missed, achieving a sensitivity of 100% and specificity of 8.69% (Table 3). No ROP cases were missed using the Iranian national criteria; however, the specificity was 0%. The North American criteria had 100% sensitivity for detecting any stage of ROP and the requirement for ROP treatment; however, it could not detect any infants who did not require screening (0% specificity) (Tables 2 and 3).

Table 1. Characteristics of included premature infants

Variable	All (n = 166)	No ROP (n = 36)	Spontaneously regressed ROP (n = 69)	Treated ROP (n = 61)
Sex (Male / Female), n (%)	57 (34.3) / 109 (65.7)	14 (39.9) / 22 (61.1)	21 (30.4) / 48 (69.6)	22 (36.1) /39 (63.9)
GA (w), Mean ± SD (Range)	28.28 ± 1.97 (25 to 35)	28.86 ± 1.98 (25 to 32)	28.44 ± 2.08 (25 to 35)	27.77 ± 1.73 (25 to 32)
BW (g), Mean ± SD (Range)	1080 ± 256 (600 to 2000)	1117 ± 291 (720 to 1900)	1095 ± 196 (650 to 1580)	1039 ± 290 (600 to 2000)

Abbreviations: ROP, retinopathy of prematurity; n, number; %, percentage; GA, gestational age; w, weeks; SD: standard deviation; BW, body weight; g, grams.

Table 2. Sensitivity and specificity of three different screening criteria to detect any stage of ROP

Screening criteria	ROP	No ROP
Iran, n +	130	36
Iran, n -	0	0
Sensitivity, % (95% CI) **Specificity, % (95% CI)**	100 (98.48 – 100 0.0 (0.0 – 1.52)	
North America, n +	130	36
North America, n -	0	0
Sensitivity, % (95% CI) **Specificity, % (95% CI)**	100 (98.48 – 100) 0.0 (0.0 – 1.52)	
G-ROP, n +	127	33
G-ROP, n -	3	3
Sensitivity, % (95% CI) **Specificity, % (95% CI)**	97.69 (95.11 – 100) 8.33 (0.0 – 17.36)	

Abbreviations: ROP, retinopathy of prematurity; n, number of infants; Iran, Iranian national guideline for screening of ROP; North America, North American guideline for screening of ROP; G-ROP, the Postnatal Growth and Retinopathy of Prematurity screening criteria; CI, confidence interval.

Table 3. Sensitivity and specificity of three different screening criteria to detect TR-ROP

Screening criteria	TR-ROP	Non TR-ROP
Iran, n +	61	69
Iran, n -	0	0
Sensitivity, % (95% CI) **Specificity, % (95% CI)**	100 (98.29 – 100) 0 (0 – 1.71)	
North America, n +	61	69
North America, n -	0	0
Sensitivity, % (95% CI) **Specificity, % (95% CI)**	100 (98.29 – 100) 0 (0 – 1.71)	
G-ROP, n +	61	63
G-ROP, n -	0	6
Sensitivity, % (95% CI) **Specificity, % (95% CI)**	100 (98.29 – 100) 8.69 (2.04 – 15.34)	

Abbreviations: TR-ROP, treatment-requiring ROP; ROP, retinopathy of prematurity; n, number of infants; Iran, Iranian national guideline for screening of ROP; North America, North American guideline for screening of ROP; G-ROP, the Postnatal Growth and Retinopathy of Prematurity screening criteria; CI, confidence interval.

DISCUSSION

In this retrospective cohort of infants, we demonstrated that the G-ROP model correctly detected 127 of 130 infants with any stage of ROP, and all those who required treatment, while maintaining specificity of 8.33% and 8.69%, respectively, reducing unnecessary examinations in six infants without ROP requiring treatment. Although this may seem to be a small number, among this high-risk population, this can be valuable in reducing the number of examinations in vulnerable infants with complicated clinical courses. Although the Iranian national and North American criteria yielded 100% sensitivity for detecting ROP, they could not exclude any infant in whom examination was unnecessary.

To obtain exact measurements of weight gain up to day 40, we assessed infants who remained admitted to the NICU or under the care of a neonatologist. Therefore, in contrast to other validation studies, we assessed a high-risk group of infants with an average GA of 28 weeks and BW of 1080 g. Despite this selection bias, we showed that the G-ROP criteria were reliable for detecting all infants with ROP requiring treatment. We also minimized the burden of examination by applying these criteria. Considering that the G-ROP criteria constitute a new screening method for ROP, many researchers in the field have begun to examine their own populations using these criteria [14-18, 23-28]. Table 4 summarizes the main findings and validation outcomes of previously published articles on this topic, as compared with those of the current study.

G-ROP is the most recently proposed, transparent, and easy-to-use screening model [14]. It was developed using a large multicenter cohort, which avoided over-fitting and reduced sensitivity compared to the designs of previous weight-gain-based models of ROP prediction, such as weight gain, IGF-1, and neonatal retinopathy

Table 4. Summary of studies on validation of G-ROP screening criteria

Author (Year of Publication)	Number of infants	Methodology	Validation results
Chinwuba (2022) [23]	901	Retrospective	- For treatment requiring ROP: Sensitivity: 99.2% Specificity: not mentioned
Vinayahalingam (2022) [25]	322	Retrospective	- For treatment requiring ROP: Sensitivity: 100% (95% CI, 70 – 100%) Specificity: 41% (95% CI, 0.35 – 0.47) - Reduction in the number of infants requiring screening: one third
Huang (2022) [17]	303	Retrospective	- For treatment requiring ROP: Sensitivity: 96.6% Specificity: 42.3% - Reduction in the number of infants requiring screening: 32.6%
Ahmed (2022) [26]	605 (504 infants in Egyptian cohort and 101 in UK cohort)	Retrospective	- For treatment requiring ROP: Sensitivity: 100% (95% CI, 91.1 – 100% in the Egyptian cohort and 65.5 – 100% in the UK cohort) Specificity: not mentioned - Reduction in the number of infants requiring screening: 14.1% in the Egyptian cohort and 21.8% in the UK cohort
Almeida (2022) [24]	313	Retrospective	- For treatment requiring ROP: Sensitivity: 90.9% (95% CI, 70.8 – 99.0%) Specificity: 16.7% (95% CI, 8.9 – 27.3%)
Caruggi (2021) [18]	475	Retrospective	- For treatment requiring ROP: Sensitivity: 100% Specificity: 100% - For any type ROP: Sensitivity: 87.4% Specificity: 100% - Reduction in the number of infants requiring screening: 50%
Wadley (2020) [15]	484	Retrospective	- For treatment requiring ROP: Sensitivity: 100% (95% CI, 91.19 – 100%) - For any type of ROP: Sensitivity: 100% (95% CI, 87.2 – 100%) - Reduction in the number of infants requiring screening: 35.7%
Yabas Kiziloglu (2020) [27]	242	Retrospective	- For treatment requiring ROP: Sensitivity: 91.2% Specificity: 34.1% - For any stage of ROP: Sensitivity: 88.3% Specificity: 51.7%
Binenbaum (2020) [16]	3,981	Prospective	- For treatment requiring ROP: Sensitivity: 100% (95% CI, 98.3 – 100%) Specificity: not mentioned - Reduction in the number of infants requiring screening: 35.6%
Shiraki (2019) [28]	537	Retrospective	- For treatment requiring ROP: Sensitivity: 100% (95% CI, 95.4 – 100%) Specificity: not mentioned - For any stage of ROP: Sensitivity: 91.9% (95% CI, 88.3 – 94.5%) Specificity: not mentioned - Reduction in the number of infants requiring screening: 24.5%
Binenbaum (2018) [14]	7,483	Retrospective	- For treatment requiring ROP: Sensitivity: 100% (95% CI, 99.2 – 100%) Specificity: not mentioned - For any stage of ROP: Sensitivity: 98.7% (95% CI, 97.3 – 99.4%) Specificity: not mentioned - Reduction in the number of infants requiring screening: 30.3%
Current Study	166	Retrospective	- For treatment requiring ROP: Sensitivity: 100% (95% CI, 98.29 – 100) Specificity: 8.69% (95% CI, 2.04 – 15.34%) - For any stage of ROP: Sensitivity: 97.69% (95% CI, 95.11 – 100%) Specificity: 8.33% (95% CI, 0.0 – 17.36%) - Reduction in the number of infants requiring screening: cannot be determined, as the study included a selective high-risk group

Abbreviations: G-ROP, the Postnatal Growth and Retinopathy of Prematurity screening criteria; ROP, retinopathy of prematurity; CI, confidence interval.

of prematurity (WINROP), premature infants in need of transfusion (PINT) ROP, Children's Hospital of Philadelphia (CHOP) ROP, and Colorado retinopathy of prematurity (CO-ROP) [14, 29]. Screening for ROP is recommended if one item of the G-ROP criteria is present. The model has been previously validated in various high-income countries [18, 25, 26, 28]. However, some modifications, such as considering the development of bronchopulmonary dysplasia, were needed to achieve 100% sensitivity to detect all treatment-requiring infants in other regions [17, 27]. Therefore, concerns remain regarding the validity of the current model, especially in low-income countries, where larger infants with greater estimated GA still develop severe ROP [30, 31]. In these countries, the burden of examining larger infants is greater than that in developed countries.

Based on our findings, G-ROP could achieve 97.69% sensitivity to detect any stage of ROP without missing infants requiring treatment. A recent Turkish validation study using the G-ROP criteria missed three infants with ROP who required treatment [27]. This dissimilarity could be attributed to differences in ethnicity and the characteristics of the included infants. Regarding specificity, or the ability to correctly exclude from retinal examination those infants with no ROP or no need for ROP treatment, we found lower values in our study (8.33% and 8.69%, respectively) compared to the results from the US and Canada [14]. This may be due to our selection bias toward higher-risk infants.

Compared to a national study conducted in 2016 [9], we achieved superior results by applying the North American guidelines for screening our infants. Based on their cohort, Roohipoor et al. [9] reported that by using the American Academy of Pediatrics guidelines for their premature infants, 25.4% of infants with ROP and 8.4% of infants with ROP requiring treatment would be missed. However, we did not miss a single infant with ROP using the North American criteria. This may indicate an improvement in the standard of care administered in our referral NICU. There may still be differences in socioeconomic status and neonatal care between the US and Canada, as with the relatively similar BW and GA in the original study and ours [14], a higher percentage of included infants in our study developed ROP (78.3% versus 43%). Applying either the Iranian national criteria or the North American criteria could not decrease the burden of unnecessary examinations in our study.

This was the first study conducted in Iran using weight gain for the prediction of ROP. Assessing the reliability, reproducibility, and generalizability of our observations to less resourceful centers requires larger multi-center cohort studies. Several cautions should be considered when interpreting the results of this study. The first is the relatively small sample size and the retrospective nature of this study. Second, the data were extracted from a single, well-equipped center with academic standards. Furthermore, if we had the weight gain data for all premature infants referred for ROP screening, using the G-ROP criteria, we could have excluded a larger number of babies from unnecessary examinations, while maintaining the excellent ability to detect ROP requiring treatment. Data on bronchopulmonary dysplasia were not collected in our study. Although this was not part of the original G-ROP study model, it was evaluated as a part of the study by Yabas Kiziloglu [27]. Due to the retrospective study design, details of other risk factors such as necrotizing enterocolitis, intraventricular hemorrhage, bronchopulmonary dysplasia, neonatal sepsis, and oxygen supplementation were not available for all of our cohort. Future multicenter national studies that include more premature infants could lead to more robust conclusions.

CONCLUSIONS

Incorporation of the G-ROP model in a group of high-risk infants could result in the detection of all infants requiring treatment (100% sensitivity) and could decrease the burden of unnecessary screenings by 8.69%. This may be generalizable to lower-risk infants referred for ROP screening. Validation of these results requires further multicenter studies with larger cohorts.

ETHICAL DECLARATIONS

Ethical approval: The Ethics Committee of Tehran University of Medical Sciences approved the study protocol and design (ethical code: IR.TUMS.FARABIH.REC.1399.039). Informed consent was obtained from parents or guardians of the infants. This study adhered to the tenets of the Declaration of Helsinki.
Conflict of interests: None

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