Validity and reliability of ROPScore scoring method to predict the severity of retinopathy of prematurity in premature infants

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Abstract

Abstract Purpose: To assess the accuracy and efficacy of ROPScore scoring system an ancillary method to predict the severity of retinopathy of prematurity (ROP) in very low birth weight (VLBW) premature infants. Methods: The medical records of 131 premature babies having a birth weight ? 1500 gram and gestational age (GA) [?] 30 weeks were included in this study. The ROPScore was calculated for each baby at six weeks of life using an Excel spreadsheet (Microsoft®). Area under curve (AUC) analysis was used in both any stage of ROP and type-1 (severe) ROP to ascertain the cut-off points for the scoring model. Sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV) of the scoring system with the calibrated cut-off points were analyzed. Results: The sensitivity of the ROPScore scoring system was 88.5% (95% CI 79-94) and 100% (95% CI 82-100) was for predicting any stage and type-1 retinopathy of prematurity, respectively. The PPV and NPV of the models were 62% and 74.1% for any stage of ROP and those of were 50% and 100% for type-1 ROP, respectively. In ROC analysis, the mean AUCs of ROPScore model was statistically significant compared than BW and GA for predicting type -1 ROP ($p < 0.001$). Conclusion: This study indicated that ROPScore scoring model with customized cutoff levels might be a useful method for early prediction of premature retinopathy, particularly in type-1 (severe) ROP. In addition, this model may also reduce the number of eye examinations which are essential for detecting the retinopathy of prematurity

Introduction

Retinopathy of prematurity (ROP) is one of the major causes of preventable blindness in childhood period in both developed and developing countries over the world.[1-3] The main risk factors for the development of ROP are low gestational age (GA) and birth weight (BW). Another risk factors including oxygen therapy, septicemia, blood transfusion, bronchopulmonary dysplasia have found to be associated with the development of ROP.[4-7] Novel improvements in neonatal intensive care lead to an increase in the survival rate in preterm infants and even in very low and very low birth weight (VLBW) infants.[3] Timely screening, diagnose and intervention are very crucial to prevent permanent loss of vision in preterm infants with severe ROP.[8] The presence of ROP requires consecutive stressful eye examinations assisted with scleral indentation which may lead to clinical disturbance, apnea, arrhythmia. Therefore, using predictive algorithms designed for ROP may have a significant effect on decreasing the burden of eye examinations and might be beneficial for early prediction of severe ROP before reaching sight-threatening level.[1, 2]

The ROPScore is an algorithm that was first described by Eckert et al.[9] to predict severe ROP. The scores are calculated at once based on BW, GA, proportional weight gain at the sixth week of life, receiving oxygen therapy in mechanical ventilation and history of blood transfusions. This scoring system was found to be effective in predicting of severe ROP and decreasing the number of eye examinations in different population.[9-11]

In this study, we aimed to evaluate the validation and accuracy of the ROPScore scoring algorithm for predicting of ROP in VLBW infants in neonatal intensive care unit (NICU).

Subjects and Methods

Study Design

This single-center, retrospective study was conducted from February 2016 to October 2018 in a tertiary referral center. Informed consent was obtained from the parents of infants before the examination. The study was approved by Ethics Committee of Harran University (No: 19-04/29, date: 11/04/2019) and was carried out in accordance with the Declaration of Helsinki

Participants and examination

This study consists of the medical records of 131 VLBW infants admitted in NICU. The World Health Organization (WHO) defines VLBW, a subgroup of low birth weight, as the birth weight between 1000 g and 1500 g.[12] Babies were born with a BW of [?]1500 g and/or a GA of [?]30 weeks and those with available ROP examination records and data of weights at the sixth weeks of life were included in the study.

Infants with unstable clinical course preventing ROP examination were excluded from the study. The initial screening for ROP was performed in the fourth weeks of postnatal life. Time intervals between examinations were repeated weekly or bi-weekly based on the guidelines described by the American Academy of Pediatrics, the American Academy of Ophthalmology, and the American Association for Pediatric Ophthalmology and Strabismus.[13] After pupillary dilation with 2.5% phenylephrine and 0.5% tropicamide eye drops, eye examinations assisted with binocular indirect ophthalmoscopy, 28-diopter lens and scleral indentation with an eye speculum were performed by the same ophthalmologist (SG).

The retinal findings indicating the stage of disease, location by zone and presence of plus disease were classified regarding to the current International Classification of ROP.[14] In accordance with the international classification, patients were divided into three different groups as follows; the absence of any stage of ROP (no-ROP), the presence of any stage of ROP without needing any treatment (Type-2 ROP) and severe ROP that indicates the need for an urgent intervention via laser photocoagulation or intravitreal injections (Type-1 ROP).

ROPscore algorithm

The ROPScore data management was carried out according to data at the sixth week postpartum visit by means of a Microsoft® Excel spreadsheet as previously described by Eckert et al.[9] (Figure 1) The algorithm was already set up with an equation of ß-coefficients of risk factors using a linear regression analysis.[9]The data of BW, GA, weight at sixth of life, the positive/negative history regarding blood transfusion till the first six-week check-up and the need for oxygen in mechanical ventilation was used to calculate ROP scores. To eliminate bias, another staff member, who was unaware of the ROP stage of the participants, entered all data into a separate ROPScore Excel spreadsheet.

Clinical characteristics of patients in terms of the severity of ROP, the GA, BW and type of received medical assistance in NICU were compiled retrospectively from the patients' file. The ROP scores, positive and negative predictive values were analyzed retrospectively to determine the sensitivity and specificity of the model.

ROC Analysis and Establishing ROPScore Accuracy (Sensitivity and Specificity)

At first, the accuracy of the model regarding to predict onset and severity of ROP was determined by comparing the area under curves (AUC) for the ROPScore, GA and BW to each other. Due to the unavailability of analysis in SPSS software, the comparison of data for AUCs was performed manually using a formulation described by Hanley et al.[15] The optimal cutoff points of the continuous values for sensitivity and specificity have been tailored according to this formula.

In the present study, the standard cutoff values were 11 for any stage of ROP and 14.5 for type-1 ROP according to previously described by Eckert et al.[9] To maintain optimized sensitivity, but also to optimize specificity (i.e., to decrease false positives), the best cutoff points were arranged as in several similar studies, and we set a customized value of 12.3 for any stage ROP and 14.9 for type-1 ROP.[10,11] Positive predictive values (PPVs; the likelihood of a preterm baby with a score above the cut-off point, indicating that any stage of ROP or type-1 ROP would develop) and negative predictive values (NPVs; the likelihood of a preterm infant with a score below the cutoff point, indicating that any stage of ROP or type-1 ROP would not develop) were also obtained with 95% confidence intervals (CIs) and then compared to each other for every predictors.

Statistical Analysis

Statistical significance was analyzed by using SPSS 20.0 version for Windows (SPSS Inc., Chicago, IL, USA). The Kolmogorov-Smirnov test was used to assess the conformity of the data according to the normal distribution, and the homogeneity of variances assumption was evaluated using the Levene test. The data collected from the subjects were expressed as means ± standard deviations (SDs) except for the proportional weight gain (median and 25-75 percentiles). The Chi-Square test was applied in comparisons of the proportions of the groups. For data with normal distribution, one-way ANOVA was used to compare the means of the study groups, and pairwise comparisons were calculated using the Tukey test. For data not normally distributed, the comparisons of median values of the groups was analyzed using Kruskal-Wallis test in and Mann Whitney U-test was performed to test the significance of pairwise differences using Bonferroni correction adjusted for multiple comparisons. A p-value < 0.05 was considered statistically significant.

Results

A total of 131 VLBW premature infants consisting of 71 (54%) female and 60 (46%) male were included in the study. Of these 131 infants, 70 of the infants (53.4%) haven't any sign of ROP, while 61 of the infants (46.6%) had developed ROP and 19 of them (14.5% of overall infants) had severe (type-1) ROP. The mean gestational age (GA) was 28.8±2.1 weeks (min.-max. 23-32 weeks), the mean birth weight (BW) was 1208±208 g (min.-max.730-1520 g) and the median weight gain at 6^{th} week of life was 620 g (25-75 percentile 430-840 g) in all premature infants.

The mean GA was significantly lower in patients with any stage of ROP and Type-1 ROP compared to No-ROP group **($p < 0.01$).**Furthermore, the mean BW and the mean ROPScore values were significantly different among the groups ($p < 0.01$ and $p < 0.01$, respectively). The comparison of the mean GA, BW and ROP score among groups were demonstrated in Table 1.

In ROC analysis, the mean AUC for ROPScore had more predictive value than BW and GA in terms of detecting type-1 ROP **($p < 0.001$)** . Figure 2 presents the analysis of AUCs for the ROPscore, GA and BW for any stage or ROP and type 1 ROP.

In the algorithm of CUT-OFF values, the sensitivity and specificity of the scoring system for predicting any stage of ROP was 88.5% (95% CI, 79-94) and 37.7% (95% CI, 26.6-50.2), respectively. However, the scoring system had 100% (95% CI, 82.3-100) sensitivity and 83% (95% CI, 75-88.8) specificity in terms of predicting severe type -1 ROP. Table 2 highlights the cutoff points, the positive and negative predictive values (PPVs and NPVs) of the model for patients with any stage and type-1 ROP. Our customized cut-off values (12.3 for any stage ROP, 14.9 for type-1 ROP) allowed a drop in numbers of false positives from 54 to 23 for any stage ROP and from 33 to 19 for type-1 ROP. ROPScore model in conjunction with 2018 guidelines detected 62 of 70 infants with any stage ROP, more importantly, correctly identified all of infants with type-1 ROP. ROPscore missed only 8 out of 131 (%6) babies in which none of them needed the treatment for ROP.

Discussion

In the current study, the mean ROP score was significantly higher in prematures with severe (type -1) ROP compared to the no-ROP group and type-2 ROP group. The adjusted cut-off points of the model had a high sensitivity in the prediction of ROP, particularly in type-1 ROP with a sensitivity of 100% and a

specificity of 83%. NPV of the model was 100% for infants would not develop severe ROP (type-1 ROP). The ROPScore model would provide a significant reduction in the number of examinations in patients with any stage of ROP and severe type -1 ROP. The models based on scoring algorithms are thought to be a useful method to predict the development and severity of ROP, especially in type-1 ROP. Various scoring algorithms consisting of WINROP, PINT-ROP, CHOP-ROP and CO-ROP scores were established based on the clinical risk factors, such as postnatal weight gain, serum insulin-like growth factor levels, birth weight, receiving cardiopulmonary support in NICU.[9, 11, 17, 18] However, Fierson et al.[16] stressed that using these algorithms as a ROP screening method and adapting them to the international population is still controversial.

In the present study with arranged cutoff points, the sensitivity of ROPScore was 88.5% for any stage of ROP and 100% for type-1 ROP. In consistent with our study, Eckert et al.[9] stated 96% sensitivity and Lucio et al.[10] also reported 95.4% sensitivity for type-1 ROP with their adjusted cutoff points. Another study conducted by Piermarocchi et al.[11]revealed 100% sensitivity in the ROPScore for type-1 ROP.

The negative predictive value (NPV) determined in the current study implied that the likelihood in which a premature with a ROPscore under a cutoff point of 14.9 might not develop severe type-1 ROP was 100%, whilst the probability of the same infants were not expected to be develop any stage of ROP was 74.1%. In compliance with our study, Cagliari et al.[19] reported 100% of NPV and 22% PPV for the prediction of ROP with a cutoff point of 14.5 using ROPScore algorithm. In addition, Lucio et al.[10] stated similar NPV and PPV's in premature infants with cutoff ROPscore [?]16.6. All detailed comparisons of the studies with their adjusted cutoff points for the ROPScore were summarized in table 3. The low GA and BW are the two major risk factors for development of ROP, which are used in numbers of ROP algorithms.[19-22] Our analysis revealed that the mean AUC for ROPScore was significantly higher than that of for BW and GA in type-1 ROP. Eckert et al.[9]also reported significant the mean AUCs in terms of ROP score, BW and GA both in any stage ROP and type-1 ROP.

In the present study, ROPScore algorithm hypothetically would provide a reduction in the number of examinations by 17.5% for any stage of ROP and 70.9 % for the infants with type-1 ROP (Table 3). Previous studies analyzing the ROPScore model defined various percentages related to decline in the total number of infants needing screening examination for ROP.[9,10,18-22] The discrepancies among the studies in terms of specificity, sensitivity, NPV, PPV and the total estimated reduction rate in screening examinations could be attributed to several confounding factors of the cohorts, such as diversity in patient demographics, health care systems and clinical courses. (Sepsis, chronic lung disease, interventricular hemorrhage, etc.)

Finally, a number of potential limitations need to be considered. First, as the current study had a small sample size, further studies with a large multi-centered cohort with being stratified confounding factors is required to determine the validity of the ROPScore. Second, the ROPScore model may miss aggressive posterior ROP (APROP) cases characterized by rapid progression in the very early weeks of life. Lastly, the algorithm includes only preterm infants of [?]30 weeks and/or [?]1500 g, whereas several studies have shown that older and larger preterm infants may also have any type of ROP or severe ROP, particularly in underdeveloped and developing countries.[1, 23, 24]

In conclusion

To the best of our knowledge, this is the first study investigating the efficacy of ROPScore algorithm in prediction of any stage and severe type -1 ROP in our population. The mean ROPScore was significantly higher in the infants with type -1 ROP. The ROPScore of was significantly higher than the AUCs for GA and BW in detection of severe ROP. The sensitivities of ROPScore algorithm based on adjusted cut-off values were 100% and 88.5 for severe (type -1) ROP and any stage of ROP respectively. The negative predictive value of ROPScore was 100%. The mean AUCs value for ROPScore was higher than that of BW and GA. Our study shows that ROPScore scoring model is a useful method to early identify the premature infants having high risk for development of ROP, particularly in type-1 ROP requiring prompt intervention to prevent permanent loss of vision.

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Table 1. Demographic characteristics of all 131 patients involved in the study	Table 1. Demographic characteristics of all 131 patients involved in the study	Table 1. Demographic characteristics of all 131 patients involved in the study	Table 1. Demographic characteristics of all 131 patients involved in the study	
	Group-1 No-ROP	Group-2 Any stage ROP	Group-3 Type-1 ROP	p-value
Mean. GA ± SD (week) (95% CI)	29.7 ± 1.7 (29.2-30.1)	28.4 ± 2.2 (27.8-29.0)	27.0 ± 1.7 (26.2-27.8)	**<0.01** *no-ROP vs. any ROP; p <0.001, no-ROP vs. type-1 ROP; p=0.002, any ROP vs. type-1 ROP; p=0.02
Mean BW ± SD (g) (95% CI)	1288.2 ± 167.1 (1245.4-1331.0)	1184 ± 235.1 (1117.9-1250.2)	1019.2 ± 192.2 (926.6-1111.8)	**<0.01** * no-ROP vs. any ROP; p =0.02, no-ROP vs. type-1 ROP; p<0.001, any ROP vs. type-1 ROP; p=0.01
Median WG at the 6th week of life (g) (25-75 percentile)	590 (460-860)	650 (470-840)	490 (250-710)	0.13
Mean ROPScore (95% CI)	13.0 ± 1.6 (12.6-13.5)	14.2 ± 1.9 (13.7-14.7)	16.2 ± 1.8 (15.3-17.0)	**<0.001** * no-ROP vs. any ROP; p =0.003, no-ROP vs. type-1 ROP; p<0.001, any ROP vs. type-1 ROP; p<0.001

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GA, gestational age; BW, birth weight; WG, proportional weight gain; ROP, retinopathy of prematurity; SD, standard deviation; 95%CI, 95% confidence interval **Note:** Bond font indicates data were considered statistically significant	GA, gestational age; BW, birth weight; WG, proportional weight gain; ROP, retinopathy of prematurity; SD, standard deviation; 95%CI, 95% confidence interval **Note:** Bond font indicates data were considered statistically significant	GA, gestational age; BW, birth weight; WG, proportional weight gain; ROP, retinopathy of prematurity; SD, standard deviation; 95%CI, 95% confidence interval **Note:** Bond font indicates data were considered statistically significant	GA, gestational age; BW, birth weight; WG, proportional weight gain; ROP, retinopathy of prematurity; SD, standard deviation; 95%CI, 95% confidence interval **Note:** Bond font indicates data were considered statistically significant	GA, gestational age; BW, birth weight; WG, proportional weight gain; ROP, retinopathy of prematurity; SD, standard deviation; 95%CI, 95% confidence interval **Note:** Bond font indicates data were considered statistically significant

Table 2 Prediction of any stage ROP and severe (type-1) ROP with ROPScore model based on adjusted cut-off values

Algorithm CUT-OFF VALUE	
Correctly predicted ROP/True ROP	
SENSITIVITY % (95% CI)	
Correctly predicted No - ROP/True No - ROP	
SPECIFICITIY % (95% CI)	
Correctly predicted ROP/ All predicted ROP	
POSITIVE PREDICTIVE VALUE % (95% CI)	
Correctly predicted No - ROP/ All predicted No - ROP	
NEGATIVE PREDICTIVE VALUE % (95% CI)	
ROP, retinopathy of prematurity + Customized cut-off values based on our population.	*ROP*, retinopathy of prematurity

Table 3. Comparison of similar studies with ROPScore for any stage ROP and severe ROP based on standard screening criteria+

Detection Goal ROPScore studies (Cut-off values for any stage / severe ROP)	ROPScore Any stage ROP Reduction in total number infants screened (percent)	ROPScore Severe (Type 1) ROP Reduction in total number infants screened (percent)
Eckert et al. (11 / 14.5)	94/474 (19.8%)	252/474 (53.1%)
Piermarocchi et al. (11 / 15.8)	43/399 (10.7%)	245/399 (61.4%)
Lucio et al. (16 / 16.6)	130/181 (71%)	133/181 (73%)
Cagliari et al. (11 / 14.5)	36/322 (11.1%)	165/322 (51%)

Gulkas et al. (12.3 / 14.9) (Current Study) *ROP*, retinopathy of prematurity +ROP screening based on only birth weight and gestational age[16]	23/131 (17.5%) *ROP*, retinopathy of prematurity +ROP screening based on only birth weight and gestational age[16]	93/131 (70.9%) *ROP*, retinopathy of prematurity +ROP screening based on only birth weight and gestational age[16]

Figure Legends

Figure 1. Sample of Excel spreadsheet (Microsoft®) used to calculate the ROPScore. From Eckert et al.(9)

Figure 2. Area under curves (AUCs) comparisons with of patients with any stage of ROP and severe (type-1) ROP. The graph A and graph B compare the sensitivity and specificity of birth weight (BW), gestational age (GA), and ROPScore algorithm in prediction of retinopathy of prematurity (ROP).

ROPScore Algorithm Excel Spreadsheet Sample		
BW (Birth Weight) g.	1350	Use the birth weight in grams
GA (Gestational Age) week	28	Use the gestational age in weeks
Blood Transfusion	0	Use 0 for none or 1 for yes if the baby underwent any blood transfusion
Oxygen in Mechanic Ventilation	0	Use 0 for none or 1 for yes if the baby underwent oxygen-therapy
Weight at 6th week of life	2150	Use the weight in grams measured at completed the 6th week of life
Proportional Weight Gain	0.59	Automatic Calculation - Do not fill in
ROPScore	11,46	Automatic Calculation - Do not fill in
Higher value of ROPScore = Higher risk for ROP onset (any stage ROP / type-1 ROP)		
The cut-off value for any stage ROP = 12.3 **The cut-off value for type-1 ROP = 14.9**