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Determination of regional screening criteria for retinopathy of prematurity in the Eastern Black Sea region of Turkey

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Background/aim: To establish a regional screening protocol for retinopathy of prematurity (ROP).

Materials and methods: Data were analyzed from the hospital records of 1241 infants with gestational age (GA) at birth ≤36 weeks and birth weight (BW) of ≤3600 g.

Results: The mean GA of the infants was 32.05 ± 2.7 weeks and the mean BW was 1780.5 ± 576 g. ROP at any stage was detected in 703 of the 1241 infants (555 female). Eleven infants with type 1 ROP were treated with 810 nm diode laser photocoagulation. No treatment was needed in infants born after 33 weeks of gestation and weighing over 1760 g. Logistic regression analysis showed a significant relationship between the development of ROP and GA, BW, number of deliveries, respiratory distress syndrome, and treatment with oxygen or mechanical ventilation. Receiver operating characteristic curve analysis showed that a GA of 33 weeks or a BW of 1770 g appears to be an appropriate criterion for identifying infants who may require ROP treatment.

Conclusion: GA ≤ 33 weeks and BW ≤ 1770 g can be used as screening criteria in terms of ROP in infants for the Eastern Black Sea region.

Key words: Premature birth, neonatal screening, retinopathy of prematurity

1. Introduction

The retinal vessels mainly develop in two periods in embryological life. The major retinal vessels develop between 14 and 21 weeks, known as the vasculogenesis phase, while vascularization of other retinal regions continues until the 40th week of gestational age (GA), known as the angiogenesis phase (1). Retinopathy of prematurity (ROP) develops in infants born prematurely, in association with lack of development of retinal vessels, and is an increasingly important cause of blindness in children, particularly in middle-income countries of Asia and other countries around the world (2–7). Although the major risk factors for the development of ROP are preterm labor and low birth weight (BW), other risk factors include excess oxygen, sepsis, asphyxia, blood exchange, and respiratory distress syndrome (RDS) (8–12).

Regular screening for and early detection and treatment of ROP are essential in preventing blindness in premature newborns. Screening and treatment should be performed on the basis of blood vessel development and the stage of ROP (13–15). Infants born before 30 weeks and weighing less than 1500 g in the United States, and before 32 weeks and under 1500 g in the United Kingdom, are usually considered to be at high risk for ROP. However, it has been recommended that developing countries should define screening criteria on the basis of their own particular conditions. Infants requiring treatment for ROP may be overlooked if screening is performed according to limits defined by developed countries (5,16–18).

The purpose of this study was to document data from a major center in the Eastern Black Sea region of Turkey and to help establish a regional screening protocol for ROP for the Eastern Black Sea region of Turkey. Another aim was to determine the incidence, risk factors, and clinical characteristics of infants with ROP in this region.

2. Materials and methods

This study was performed as a retrospective review of medical records. Premature infants were examined for ROP between January 2010 and December 2011 at the Department of Ophthalmology, Faculty of Medicine, Karadeniz Technical University, Turkey. A total of 1648

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premature babies examined at less than 36 weeks were evaluated since there are no disease-specific screening criteria for ROP in Turkey. The infants were either born at the medical faculty hospital or elsewhere, and were referred from other hospitals. Infants with ocular abnormalities or those who were unable to attend follow-up visits were excluded from the study. The study was designed not according to 2013 guideline criteria but on the basis of previous criteria recognized in the United States at the time of the study (19). The first examination was performed at 31 weeks of GA or at 4 weeks after birth, whichever came earlier. The follow-up examinations were repeated at 3-day or 3-week intervals, depending on the severity of the retinal findings, and continued until complete vascularization or progression to type I ROP requiring laser therapy. Type I ROP includes: Zone I, any stage with plus disease; Zone I, stage 3 without plus disease; and Zone II, stage 2–3 with plus disease (20). Informed consent for examination and treatment, if necessary, was obtained from the families.

All premature babies born in the Eastern Black Sea region have to undergo eye screening. At the time of preparation of the manuscript, our hospital was the only center in the region (the Eastern Black Sea region of Turkey) where premature babies were referred for examination. Therefore, we think that our examination results may sufficiently reflect the population of the region. Our hospital is still the only center in our region where ROP treatment is available. The physicians (HE, MK) performing ROP examinations have been doing this in the region for approximately 20 years.

A mixture of phenylephrine 2.5% and tropicamide 1% drops was administered 3 times at 5-min intervals in all infants before examination. Fundus examination was performed with a binocular indirect ophthalmoscope using both +20 D and +28 D lenses, a lid speculum, and a scleral depressor approximately 45 min after the first instillation. Topical anesthetic (0.5% proparacaine) was used for the examination and no other drug was given for sedation. At ophthalmological examination, dilation of the pupils, features of the lens, optic nerve, and retinal vascularization (location, stage, and absence or presence of plus disease) were assessed and recorded. BW, GA, duration of oxygen therapy, blood transfusion, asphyxia, RDS and sepsis, and number of births (single or twin) were recorded. All examinations were recorded as video files. ROP classification was performed according to the revised International Classification of ROP, including the extent, zone, and presence or absence of plus disease (13,15). All infants in the high-risk ROP group were monitored on the basis of ETROP (20) and CRYOROP (21) criteria. Eleven infants requiring treatment on the basis of ETROP (20) were treated with an 810 nm wavelength diode laser (IRIDEX, Mountain View, CA, USA). Laser treatment was performed under ketamine (0.5–1 mg/kg) anesthesia. Infants were followed up until ROP regressed after laser treatment. Examinations and treatments were performed by two authors (HE, MK) under anesthesiologist supervision in the operating room.

Infants were divided into two subgroups as appropriate for the screening criteria for ROP in the United States. Group I included infants with GA ≤ 32 weeks and infants with BW ≤ 1500 g. Group II includes infants with GA > 32 weeks and infants with BW > 1500 g. These subgroups were then compared with each other. In addition, infants with ROP requiring treatment were also compared with those not requiring treatment.

SPSS (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Descriptive data were presented as means ± SD. Student's t test was used for quantitative comparisons, and a chi-square test for qualitative comparisons. Correlations between GA, BW, number of deliveries, RDS, and treatment with oxygen or mechanical ventilation (MV) and ROP were evaluated using stepwise multivariate logistic regression analysis. $P < 0.05$ was considered significant. ROC curve analysis for BW and GA was performed to determine screening criteria for ROP for our region, since these are usually considered the best predictors for ROP.

3. Results

We initially reviewed the records of 1648 babies; 1241 babies whose records were complete were finally included in the study and followed up regularly. The mean GA of the infants was 32.05 ± 2.7 (24–36) weeks and the mean BW was 1780.5 ± 576 (620–3600) g. Five hundred and fifty-five infants (44.8%) were female and 686 (55.2%) were male. Eight hundred and eighty-seven infants (71.5%) had spent more than 7 days in the incubator, and 134 babies (7.7%) had undergone MV. RDS developed in 342 infants (27.55%). Of all infants, 184 (14.8%) were twins, 660 (53.2%) were born at 32 weeks or below, and 581 (46.8%) were born after 32 weeks. Four hundred and fifty-five babies (36.7%) weighed 1500 g or less and 786 (63.3%) babies weighed over 1500 g.

ROP at any stage was seen in 703 infants (56.7%). Of the infants with ROP, 647 (92.03%) had stage 1, 38 (5.40%) had stage 2, and 18 (2.56%) had stage 3 findings. Eight (1.1%) infants had zone 1 ROP, 126 (17.9%) had zone 2 ROP, and 569 (80.9%) had zone 3 ROP. During follow-up, type 1 ROP was observed in 11 (0.9%) infants; they received laser treatment using an 810 nm diode laser (IRIDEX) to the avascular retina. Eight of the 11 infants in the study required bilateral treatment and 3 required unilateral treatment. Since we wished to emphasize only babies requiring treatment, the number of babies was cited instead of the number of eyes. Ten infants exhibited regression, and only one received surgical treatment.

Significant differences were determined between infants with and without ROP in terms of mean GA, BW, rate of oxygen therapy, rate of MV use, number of pregnancies, and rate of RDS (Table 1).

In the evaluation of subgroups, ROP at any stage was observed in 302 infants (75.8%) in Group I and in 207 infants (39.5%) in Group II. However, the majority of infants [205 cases (99.1%)] in Group II had stage 1 ROP or immature retina. Only 2 infants in Group II had stage 2 ROP. No stage 3 ROP was detected and only 1 (0.4%) infant required treatment. In terms of GA alone, 239 infants (41.1%) with GA above 32 weeks and 369 (46.9%) infants weighing more than 1500 g had any stage of ROP. Table 2 shows the rates of ROP on the basis of subgroups and statistical results.

When comparing infants with type I ROP and infants with any stage ROP except type I, there was no significant difference in terms of sex or number of pregnancies (P = 0.889 and 0.465, respectively). On the other hand, there were significant differences in GA (28.49 ± 2.04 vs. 31.67 ± 2.59 weeks), BW (1178.8 ± 310.7 vs. 1669.3 ± 499.7 g), oxygen therapy time (30.76 ± 16.78 vs. 18.2 ± 15.15 days), mechanical ventilation time (9.17 ± 4.87 vs. 4.9 ± 6.92 days), and RDS rate (9 vs. 194) between infants with type I ROP and the other infants with ROP (P = 0.001, 0.001, 0.003, 0.02, and 0.001, respectively).

Table 1. General characteristics of infants with or without ROP.

	All infants (n = 1241)	ROP (+) (n = 703)	ROP (–) (n = 538)	P level
Gestational age (week)	32.05 ± 2.7	31.34 ± 2.71	32.98 ± 2.47	0.001
Birth weight (g)	1780.5 ± 576	1618 ± 506	1992 ± 593	0.004
Sex (n)				
Male	686	382	304	0.6
Female	555	321	234	
Oxygen therapy more than 7 days (n)	887	635	252	0.001
Mechanical ventilation (n)	134	117	27	0.001
Respiratory distress syndrome (n)	342	203	139	0.008
Single pregnancy (n)	1057	582	475	0.08
Twin pregnancy (n)	184	121	63	

Table 2. Distribution of ROP and its stages in infants on the basis of gestational age and birth weight.

	n	ROP (+) (n =703) (%)	ROP (–) (n = 538) (%)	Stages of ROP			Required treatment
				1	2	3	
Group I	398	302 (75.8%)	96 (24.1%)	267	25	10	7
Group II	524	207 (39.5%)	317 (60.5%)	205	2	-	1
P level		0.001		0.001	0.001	-	0.001
Only GA							
≤32 w	660	464 (70.3%)	196 (29.7%)	411	35	18	10
>32 w	581	239 (41.1%)	342 (58.8%)	236	3	-	1
P level		0.001		0.001	0.006	-	0.001
Only BW							
≤1500 g	455	334 (73.4%)	121 (26.5%)	298	26	10	8
>1500 g	786	369 (46.9%)	417 (53.0%)	349	12	8	3
P level		0.001		0.008	0.007	0.501	0.001

The results of logistic regression analysis investigating the relationships between risk factors and ROP are shown in Table 3. These findings show a significant positive relationship between the development of ROP and the number of deliveries, RDS, oxygen treatment, and use of MV, and a negative relationship of ROP development with GA and BW. Table 3 shows that BW, GA, duration of mechanical ventilation and oxygen therapy, and presence of RDS increased the risk for ROP development more than twofold.

Since two of the major parameters for ROP screening were BW and GA, ROC analysis was performed to define the screening criteria for ROP in infants born in the Eastern Black Sea region of Turkey. The ROP score was AUC = 0.683 (sensitivity: 64.86 and specificity: 64.5, P < 0.001) for predicting any stage of ROP in terms of BW; the BW cut-off value was ≤1770 g (Figure 1; Table 4).

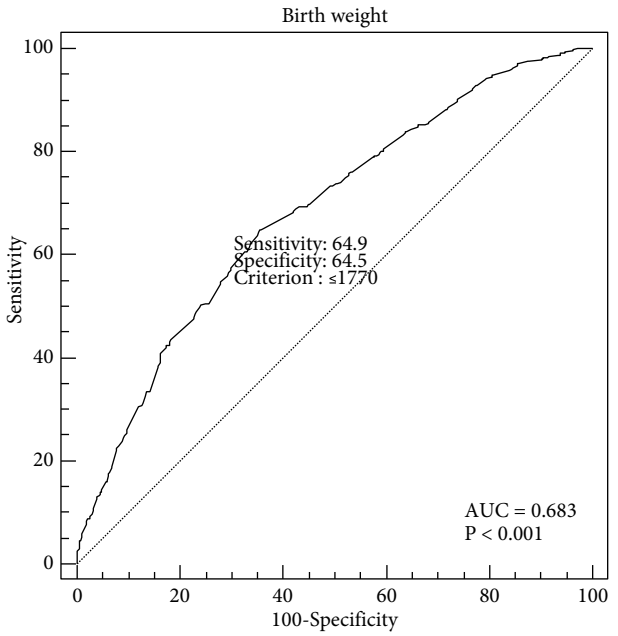

Figure 1. ROC analysis according to birth weight for determining ROP treatment requirement in premature infants.

The ROP score was AUC = 0.678 (sensitivity: 76.67 and specificity: 51.86, P < 0.001) for predicting any stage ROP in terms of GA; the GA cut-off value was ≤33 weeks (Figure 2; Table 5).

4. Discussion

The number of premature births has increased approximately 30% in the last 25 years (22,23). Parallel to this increase, the number of babies with ROP is also rising. This is an important retinal vascular disease leading to blindness in extremely premature infants. These babies should therefore be screened periodically and treated at the appropriate time. Significant risk factors for the development of ROP include GA, BW, presence of RDS, presence of sepsis, a history of blood transfusion, and duration of mechanical ventilation and oxygen therapy (8–10). The two most important risk factors for the development of ROP are BW and GA, and these factors are taken into account when screening babies. Screening criteria have been established for the early detection of ROP and for babies in risk groups in the United States and the United Kingdom. These criteria are weight under 1500 g and birth earlier than 30 weeks in the United States, and weight under 1500 g and birth earlier than 31 weeks in the United Kingdom (16,24). Infants with GA > 32 weeks or BW > 1500 g are not usually screened in developed countries.

The incidence of ROP differs by countries, regions, races, and even intensive care units (5,12,25). Although screening criteria for ROP have been defined in developed countries, it has been reported that some babies requiring treatment for ROP will still be overlooked if these criteria are also adopted for screening in developing countries (3,12,18,25–29). In a study performed in an intensive care unit in Taiwan, evidence of ROP requiring treatment was encountered in infants weighing up to 2000 g, and stage 3 ROP was identified in 2.6% of the babies born later than 30 weeks, although none required treatment (30). In a study conducted in Iran, the authors observed a rate of ROP of 18.3% in infants born after than 32 weeks, and plus disease

Table 3. Logistic regression analysis results for ROP risk parameters.

	Odds ratio	CI	P level
Gestational age	2.58	1.96–3.38	0.001
Birth weight	2.10	1.56–2.81	0.001
Number of births	1.80	1.23–2.63	0.016
Respiratory distress syndrome	2.86	2.05–4.27	0.001
Oxygen therapy	2.07	1.27–2.76	0.025
Mechanical ventilation	2.54	1.82–3.47	0.007

Table 4. ROC analysis results according to birth weight for determining ROP treatment requirement in premature infants.

Birth weight (g)	Sensitivity	95% CI	Specificity	95% CI
1750	63.73	60.0–67.3	64.87	60.7–68.9
1760	64.44	60.8–68.0	64.68	60.5–68.7
1770	64.86	61.2–68.4	64.50	60.3–68.5
1780	65.01	61.4–68.5	64.13	59.9–68.2
1790	65.15	61.5–68.7	63.75	59.5–67.8
1800	68.28	64.7–71.7	57.99	53.7–62.2

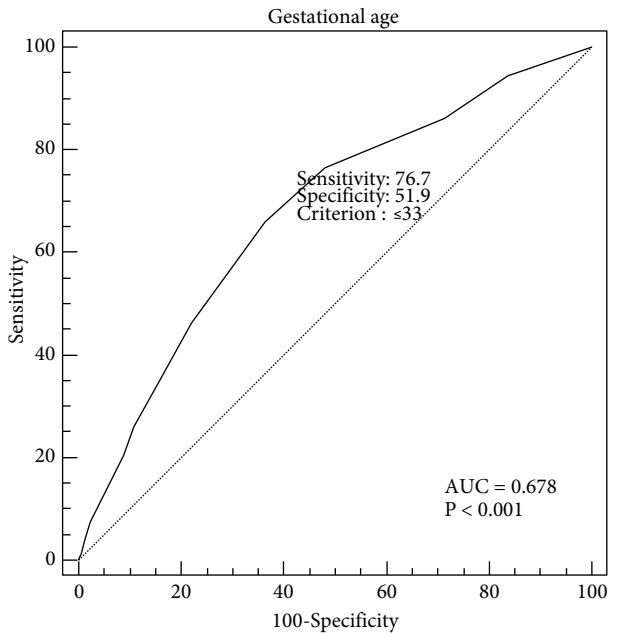

Figure 2. ROC analysis results according to gestational age for determining ROP treatment requirement in premature infants.

was determined in 2.7% of babies born after 32 weeks (25). Binkhathlan et al. (31) reported that the sensitivity of ROP screening increases from 68% to 93% when the screening protocol was changed to involve babies with GA < 34 weeks and BW < 1800 g. Another study, from China, reported that screening criteria vary according to intensive care units and recommended that each region develop its own screening criteria in light of its own characteristics (12). Gilbert et al. (5) emphasized that ROP is seen more in term infants in low- and medium-developed countries than in infants in developed countries, and suggested that such countries should establish their own local screening criteria.

There are socioeconomic and cultural differences among the various regions of Turkey. One aim of our study was to determine whether this affects the incidence of ROP and to reveal whether the incidence differs among regions. Studies intended to determine screening criteria for the weight and the age limit of infants requiring treatment in Turkey have also stated that the criteria they propose may vary from region to region. The incidence of ROP in infants with GA greater than 32 weeks has been reported as 9.3% and 11.1% in two different studies from Turkey (18,32). The incidence was calculated as 41.1% in our study. This level, being higher than those in other studies, may be due to the screening for ROP, which is still compulsory, not being fully implemented in our region; only premature infants with high risk factors are being referred to us for ROP screening. Other reasons for our results differing from those of previous studies may include regional variations in socioeconomic status, level of development in neonatal care units, and infant monitoring strategies. Our results also show that the risk of ROP in infants with GA greater than 32 weeks is higher in our region than that in developed countries. Infants with ROP may, therefore, be overlooked in screening if data from developed countries are adopted as screening criteria in our region. Studies conducted in order to determine screening criteria for ROP in Turkey have suggested that preterm babies with GA < 34 weeks and BW < 1850 g should be included in the screening (27,33). In another study, the level of ROP in infants born after 33 weeks was reported at 17.8%, and that of ROP in infants born weighing more than 2000 g was 13.1%. Screening criteria for ROP of 2000 g and 34 weeks have been suggested for Turkey (34).

In our study, of the 524 babies in Group II, 207 (39.5%) had ROP at any stage. Of these infants, 205 (99%) had stage 1 and 2 infants were stage 2 ROP. However, only 1 infant (0.5%) in this group needed treatment in the follow-up period. Based on the data obtained from infants we examined and followed, and on the results of receiver operating characteristic (ROC) analysis performed to determine the limits of ROP screening, infants with GA ≤ 33 weeks and with BW ≤ 1770 g should be included in

Table 5. ROC analysis results according to gestational age for determining ROP treatment requirement in premature infants.

Gestational age (weeks)	Sensitivity	95% CI	Specificity	95% CI
30	35.85	32.3–39.5	83.83	80.4–86.8
31	46.37	42.6–50.1	77.88	74.1–81.3
32	66.00	62.4–69.5	63.57	59.3–67.6
33	76.67	73.4–79.8	51.86	47.5–56.2
34	86.20	83.4–88.7	28.62	24.8–32.6

the screening criteria in the Eastern Black Sea region of Turkey. When we evaluated 338 infants not meeting the screening criteria (>33 weeks and >1770 g), 121 (35.8%) had ROP at any stage, but all of these findings regressed and did not require any treatment. These findings also suggest that our proposed screening criteria are reliable for ROP in this region. On the basis of these results, the cut-off values for ROP screening of 33 weeks and 1770 g will be suitable for identifying infants requiring ROP therapy in the Eastern Black Sea region of Turkey. One study from the Western Black Sea region of Turkey reported GA ≤ 32 weeks or a BW ≤ 1900 g to be a suitable screening criterion (18). Another study from the Central Black Sea region of Turkey recommended GA of <34 weeks and BW of <1800 g for screening criteria (27).

The facts that other risk factors, such as sepsis and blood transfusion, that might affect development of ROP were not included, and that the research was performed retrospectively, represent limitations of the present study.

In conclusion, low GA, low BW, multiple pregnancies, presence of RDS, and treatment with oxygen or a history of MV have been identified as regional risk factors for development of ROP in infants in the Eastern Black Sea region of Turkey. GA of ≤33 weeks and BW of ≤1770 g were significant as screening criteria in premature infants in the region. However, comorbidity of these risk factors may necessitate examination of infants outside these margins.

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