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Original Article

Validation of the existing modified screening criteria for detection of all cases of Retinopathy of Prematurity in preterm babies – 11 year study from a governorate referral hospital in Oman

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Abstract

Purpose: To study appropriateness of our modified screening criteria for detection of all cases of Retinopathy of Prematurity (ROP) among preterm babies.
Method: Retrospective observational cohort study among preterm neonates who underwent ROP screening as per set protocol for 11 years at Nizwa Hospital, Al Dhakilya Governorate, Oman. We screened all babies with gestational age ⩽32 weeks or BW ⩽ 1500 g. Preterm babies >32 weeks of GA or BW > 1500 g with unstable clinical course believed to be at high risk by the attending neonatologist also were screened.
Results: During the study period 528 babies were screened for ROP of which 76 babies were excluded due to death, associated congenital ocular malformation and loss for follow-up either due to transfer to other institution or defaulting. Thus 452 babies were included in the final analysis. Incidence of ROP was 46.4% of which 27.9% had mild ROP, 11.3% had severe ROP which regressed and 7.3% had severe ROP who were treated. The incidence of ROP among infants with GA < 26 wks, 26–28 wks, 29–30 wks, 31–32 wks and above 32 weeks was 100.0%, 80.0%, 59.3%, 34.4% and 19.4% respectively.
56 babies of this cohort belonged to Extended (modified) criteria group. Among these 12 babies had ROP out of which 9 had mild ROP and 3 had severe ROP. Among cases with severe ROP, two cases regressed spontaneously and one case needed treatment. Multivariate analysis using stepwise regression model showed statistically significant association of GA and BW to development of ROP.
We would have missed few babies with ROP if we had followed other criteria.
Conclusion: Our modified screening criteria seem to be appropriate as no infant with severe ROP was missed during the study period. Incidence of severe ROP among babies in the extended criteria group (5.4%) is low but significant compared to lower gestational age. We plan to formulate a scoring system following all risk factor analysis to enable us to optimize the number of infants screened. Detection of all babies with ROP is important as they need long-term follow-up for the timely detection and management of associated ocular comorbidities.

Keywords: Retinopathy of Prematurity, Gestational age, Birth weight, Premature infant, Screening criteria, Risk factors, Oman

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Introduction

Retinopathy of prematurity (ROP) is a vasoproliferative disorder affecting preterm infants that can potentially lead to blindness if not treated in time. With recent improvement in neonatal care, extremely low birth weight babies and extreme preterm babies are increasingly surviving and hence the incidence of ROP has been frequently reported from developing countries.

Retinopathy of prematurity was established in developed countries at the end of 1980s after the American CRYO-ROP study report was published.[1] Some low and middle income countries introduced ROP screening in the 1990s[2] and some still do not have programmes or their screening coverage is either low or only selectively implemented in some urban centres.[3] The aim of the screening should be to target those who are most at risk, but the gold standard remains to detect and treat every possible case of ROP. The profile of babies developing ROP in countries with moderate and low human development index differs from countries with high human development index as bigger and more mature babies are also found to develop this disorder in these settings.[2,4,5]

The United Kingdom (UK) screening guidelines by the Royal College of Ophthalmologists, UK and British Association of Perinatal Medicine (RCOS-BAPM) recommend screening of infants with gestational age (GA) less than 32 weeks (up to 31 weeks and 6 days) or birth weight (BW) less than 1501 g.[6] The American Academy of Paediatrics (AAP) updated the recommendations and has proposed screening for infants with BW $\leqslant$ 1500 g or GA $\leqslant$ 30 weeks with a caveat to screen heavy and older babies with unstable clinical course.[7,8] These criteria seem to have worked well in countries with high human development index.[9] In view of the inconsistency in the GA and BW of babies with severe ROP in the literature, we cannot generalize the screening criteria to all neonatal units, regions and populations alike.[5,10,11]

The low incidence of ROP and related blindness in developed nations are due to reasons including population and ethnic variations, neonatal care and organized screening and timely intervention.[9] There is a great variation in the standards of neonatal care and neonatal outcomes in different settings worldwide and hence population/institution based criteria are necessary to achieve optimal detection rates.[12] Moreover, the incidence of ROP and the need for treatment vary due to the difference in the screening criteria, observer difference as well as ethnic variation in susceptibility. To prevent adverse effects from ROP, it is mandatory to assess the population at risk, to identify the risk factors and to adopt appropriate screening criteria. This is the first study undertaken in Oman till date to validate the appropriateness of our modified ROP screening criteria. Previous studies on ROP in Oman focused on risk factors and aetiology of ROP.[13,14]

Materials and methods

This is a retrospective cohort study conducted in the Special Care Baby Unit (SCBU) and Medical Retina Clinic of Nizwa hospital, a governorate referral hospital in Al Dakhaliya governorate in Oman. This study was approved by the local research and ethical committee. It was conducted for a period of 11 years from January 1, 2003 to December 31, 2013.

We screened all the preterm babies with GA $\leqslant$ 32 weeks or BW $\leqslant$ 1500 g. Besides, preterm babies >32 weeks (up to 36 weeks) of GA or BW 1501–2000 g with any of additional risk factors such as prolonged ventilatory support more than 10 days, prolonged oxygen therapy beyond 36 weeks of postconceptual age, life threatening recurrent apnoeas, anaemias needing more than 4 blood transfusions and gram negative or fungal neonatal sepsis were also screened at the discretion of neonatologist. (Extended criteria group).

The data of all babies who underwent screening for ROP during the study period were retrospectively reviewed. Data collected for each neonate included gender, plurality, GA, BW, postmenstrual age, age of onset of ROP and age at which treatment was carried out and nature of treatment. In many cases it was found that both eyes were affected except in 20 cases. Most severely affected eye was included in ROP grading, when ROP involved both the eyes. Initial screening was done at 31 weeks of postmenstrual age in babies with GA < 27 weeks and at 4 weeks of postnatal age in babies born with GA > 27 Weeks.[7] Gestational age was calculated from the history given by the pregnant mothers about their last menstrual period (LMP). When there was a discrepancy, the mean of GA by LMP and GA by ultrasound was computed. Screening was done exclusively by two of the senior ophthalmologists with expertise in ROP.

Pupillary dilatation was done with 1% Phenylephrine and 0.5% Tropicamide starting two hours before the examination. Fundoscopy was done with binocular indirect ophthalmoscope using +28 Diopter Volk lens. Paediatric speculum and scleral depressor were used whenever needed. ROP was classified based on the international classification of ROP.[15] In cases of Immature retina, follow-up examinations were made every two weeks till the vessels reached retinal periphery. On detection of ROP, babies were reviewed weekly or more frequently as per the discretion of the ophthalmologist. ROP stages 1 and 2 were labelled as mild ROP, and Stages 3–5 and aggressive posterior ROP were labelled as severe ROP.

Decision for treatment was taken as described in ''Early Treatment of ROP randomized Trial'' (ET-ROP).[16] Infants with severe ROP needing treatment were also reviewed by vitreoretinal surgeons at tertiary care ophthalmic service and treatment was carried out after their ratification. Treatment was by Laser photocoagulation till year 2009 and either Laser treatment and/or intravitreal injection of Anti Vascular Endothelial Growth Factor agent during period after year 2009. Treatment was carried out within 72 h of decision to treat.

Statistical analysis was carried out using commercially available statistical software package (SPSS version 16). We considered the p value to be statistically significant when it was less than 0.05. Chi square test and logistic regression were used to find the odds ratio in univariate and multivariate analysis respectively.

Results

Among the 528 babies screened for ROP during the study period, seven babies expired before completing the ROP evaluation and two were excluded due to associated