Comparison of United Kingdom and United States screening criteria for detecting retinopathy of prematurity in Hong Kong

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ABSTRACT

Introduction: We examined whether the United Kingdom (UK) or the United States (US) screening criteria are more appropriate for retinopathy of prematurity (ROP) screening in Hong Kong, in terms of sensitivity for detecting type 1 ROP and the number of infants requiring screening.

Methods: In this retrospective cohort study, we reviewed the medical records of all infants who underwent ROP screening from 2009 to 2018 at a tertiary hospital in Hong Kong. During this period, all infants born at gestational age (GA) ≤31 weeks and 6 days or birth weight (BW) <1501 g (ie, the UK screening criteria) underwent ROP screening. We determined the number of infants requiring screening and the number of type 1 ROP cases that would have been missed if the US screening criteria (GA ≤30 weeks & 0 days or BW ≤1500 g) had been used.

Results: Overall, 796 infants were screened using the UK screening criteria. If the US screening criteria had been used, the number of infants requiring screening would have decreased by 21.1%; all type 1 ROP cases would have been detected (38/38, 100% sensitivity). Of the 168 infants who would not have been screened using the US screening criteria,

only four of them (2.4%) had developed ROP (all maximum stage 1 only).

Conclusion: In our population, the use of the US screening criteria could reduce the number of infants screened without compromising sensitivity for the detection of type 1 ROP requiring treatment. We suggest narrowing the GA criterion for consistency with the US screening criteria during ROP screening in Hong Kong.

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New knowledge added by this study
- In our population, the use of the United States (US) screening criteria, instead of the United Kingdom (UK) criteria, could reduce the number of infants requiring retinopathy of prematurity (ROP) screening by 21.1%.
- The use of the US screening criteria would have detected 100% of type 1 ROP cases over a 10-year period, compared with the UK screening criteria, indicating that the US screening criteria would not compromise sensitivity for the detection of type 1 ROP requiring treatment in Hong Kong.

Implications for clinical practice or policy
- There is a need to consider narrowing the gestational age criterion for consistency with the US screening criteria during ROP screening in Hong Kong.
- A review of published literature indicates that our screening outcomes considerably differ from findings in other Asian countries, suggesting that our results are not generalisable to regions outside of Hong Kong.

Introduction

Retinopathy of prematurity (ROP) is a proliferative retinal vascular disease that affects premature infants.[1] Infants born at low gestational age (GA) and/or low birth weight (BW) have a risk of ROP.[2] Without timely intervention, severe ROP can progress to retinal detachment and blindness. Currently, ROP is one of the leading preventable causes of childhood blindness worldwide.[3]

Successful management of ROP relies on appropriate screening for early detection of high-risk disease, along with prompt treatment to prevent disease progression and visual loss. The United Kingdom (UK) Guidelines (published in 2008 by the Royal College of Paediatrics and Child Health, the Royal College of Ophthalmologists, and the British

Association of Perinatal Medicine) recommend that all infants born at GA ≤31 weeks and 6 days or BW <1501 g undergo ROP screening.[4] On the other hand, the United States (US) Guidelines (published in 2013 and 2018 by the American Academy of Pediatrics, American Academy of Ophthalmology, and American Association for Pediatric Ophthalmology and Strabismus) use narrower criteria; they recommend that all infants born at GA ≤30 weeks and 0 days or BW ≤1500 g undergo ROP screening.[5,6]

In Hong Kong, many hospitals use the UK screening criteria to guide ROP detection.[7-9] Although the UK screening criteria are appropriate for ROP detection in many countries,[10-12] they are not universally appropriate.[13-18] In India[14,15,19] and China,[17,18] some infants with GA and BW above the UK screening thresholds also developed severe ROP requiring treatment. Thus, there is a need to understand the epidemiology of ROP in Hong Kong and evaluate the utility of current international guidelines for ROP detection in Hong Kong infants.

In the Early Treatment for Retinopathy of Prematurity study,[20] type 1 ROP was defined as: (1) zone I, any stage of ROP, with plus disease; (2) zone I, stage 3 ROP, without plus disease; or (3) zone II, stage 2 or 3 ROP, with plus disease. Type 1 ROP requires treatment.[4,6] Although it is important not to miss any infants who develop type 1 ROP requiring treatment, it is also important to avoid unnecessarily screening a large number of infants because the ROP screening procedure is painful and distressful for premature infants; it can lead to oxygen desaturation, tachycardia, and apnea.[2,21,22] There is also a need to limit the systemic absorption of dilating eye drops that may cause adverse events.[23,24] An effective strategy would reduce the number of infants unnecessarily screened without missing any cases of severe ROP requiring treatment. This study was conducted to determine whether the UK or the US screening criteria are more appropriate for Hong Kong, in terms of sensitivity for detecting type 1 ROP and the number of infants requiring screening.

Methods

Patients

In this retrospective cohort study, we reviewed the medical records of all premature infants who underwent ROP screening between 1 January 2009 and 31 December 2018 in Prince of Wales Hospital, Hong Kong. During the study period, all infants born at GA ≤31 weeks and 6 days or BW <1501 g (ie, UK screening criteria) underwent ROP screening. Infants with GA and BW above the UK screening threshold who had a high risk of ROP because of an unstable clinical course also underwent ROP screening at the request of the attending neonatologist. Analyses

檢測香港早產兒視網膜病變：英國與美國篩檢準則比較

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簡介：我們透過檢測第一型早產兒視網膜病變的敏感度及需要進行篩檢的嬰兒數目，研究英國還是美國的篩檢準則更適合於檢測香港的早產兒視網膜病變。

方法：我們在這回顧性隊列研究檢閱了於2009至2018年間在香港一所三級醫院進行早產兒視網膜病變篩檢的所有嬰兒的醫療紀錄。在該段時間，所有於妊娠週數≤31週又6天出生或出生體重<1501克（即英國篩檢準則）的嬰兒進行了早產兒視網膜病變篩檢。我們找出如採用美國篩檢準則（於妊娠週數≤30週又0天出生或出生體重≤1500克）則會遺漏的需要進行篩檢的嬰兒數目及第一型早產兒視網膜病變個案數目。

結果：共796名嬰兒跟從英國篩檢準則接受篩檢。如採用美國篩檢準則，需要進行篩檢的嬰兒數目會減少21.1%；所有第一型早產兒視網膜病變個案都會被找出（38/38，敏感度100%）。在那些不會被美國準則篩檢的168名嬰兒當中，只有4名（2.4%）發生早產兒視網膜病變（全部最多只達第1階段）。

結論：在我們的研究群體中，使用美國篩檢準則可減少篩檢嬰兒的數目而不影響找出需要接受治療的第一型早產兒視網膜病變患者的敏感度。我們建議收窄篩檢香港的早產兒視網膜病變的妊娠週數準則，與美國篩檢準則看齊。

were performed to determine the numbers of ROP and type 1 ROP cases that would have been detected and missed if the US screening criteria (GA ≤30 weeks & 0 days or BW ≤1500 g) had been used.

All infants who underwent ROP screening in Prince of Wales Hospital were included. Infants were excluded if they died or were transferred to other institutions before completion of ROP screening without a known ROP outcome. Data were recorded concerning GA, BW, most severe ROP stage, any treatment, and treatment outcome. ROP findings were classified in accordance with the International Classification of ROP[25] (Table 1). Treatment was indicated for infants with type 1 ROP. If the ROP stage differed between eyes in an individual infant, the more severe ROP stage was used for analysis.

Outcome measures and statistical analysis

The primary outcome measure was the sensitivity of the US screening criteria, compared with the UK screening criteria, for detection of type 1 ROP. The secondary outcome measure was the number of infants requiring screening.

R software (R version 3.6.1) was used for statistical analysis. All demographic data were expressed as medians and interquartile ranges (IQRs).

TABLE I. International Classification of Retinopathy of Prematurity (ROP)[25]

Terminology	Definition
Stage of ROP	Stage 1: Demarcation line Stage 2: Ridge Stage 3: Extraretinal fibrovascular proliferation Stage 4: Partial retinal detachment Stage 5: Total retinal detachment
Location of ROP	Zone I: Retinal area consisting of a circle centred at the optic disc, with a radius extending from the optic disc to twice the distance from the optic disc to the centre of the macula Zone II: Retinal area extending centrifugally from the edge of zone I to the nasal ora serrata Zone III: Residual crescent of the retina anterior to zone II
Plus disease	Plus disease: characterised by increased arteriolar tortuosity and venous dilatation of posterior retinal vessels; iris vascular engorgement, poor pupillary dilatation, and vitreous haze may also be present Pre-plus disease: characterised by increased arteriolar tortuosity and venous dilatation which is more severe than normal but insufficient for diagnosis of plus disease

TABLE 2. Numbers of retinopathy of prematurity (ROP) and type 1 ROP cases detected using the United Kingdom (UK) and the United States (US) screening criteria

	UK criteria (a)	US criteria (b)	(b)/(a)
Total number of infants screened	795	627	78.9%
No. of ROP detected	238	234	98.3%
No. of type 1 ROP detected	38	38	100.0%

Results

Demographic data

Of the 857 infants who underwent ROP screening in the study period, 61 were excluded because they died or were transferred to other hospitals before the completion of ROP screening. Thus, the remaining 796 infants (404 boys [50.8%] and 392 girls [49.2%]) were included in the study. The median GA was 30 weeks and 2 days (IQR=7 weeks & 3 days; range, 23 weeks & 4 days to 37 weeks & 4 days), and the median BW was 1320 g (IQR=471; range, 470-2550).

Incidences of retinopathy of prematurity and type 1 retinopathy of prematurity

In total, 238 infants (29.9%) developed ROP, including 38 infants (4.8%) who developed type 1 ROP requiring treatment. The median GA and BW of infants who developed ROP were 27 weeks and 4 days (IQR=3 weeks & 0 days; range, 23 weeks & 4 days to 35 weeks & 5 days) and 943 g (IQR=366; range, 470-2550), respectively. The median GA and

BW of infants who developed type 1 ROP were 26 weeks and 0.5 days (IQR=2 weeks & 2.5 days; range, 23 weeks & 4 days to 32 weeks & 0 days) and 781 g (IQR=315; range, 510-1240), respectively. Among the infants who developed type 1 ROP requiring treatment, 81.6% were extremely preterm (GA <28 weeks) infants and 100% were extremely low BW (<1000 g) infants. Of the treated infants, 13 had stage 2 ROP and 25 had stage 3 ROP. No infants had stage 4 or 5 ROP.

Retinopathy of prematurity cases detected using the United Kingdom screening criteria

In total, 795 infants underwent ROP screening in accordance with the UK screening criteria. One infant had a GA above the UK screening threshold; however, the infant continued to undergo screening because he was only 1 day older than the screening threshold, and the attending neonatologist concluded that he had a risk of ROP. The UK screening criteria detected all cases of ROP (n=238) and type 1 ROP requiring treatment (n=38) [Table 2].

Retinopathy of prematurity cases detected using the United States screening criteria

If the US screening criteria had been used, the number of infants receiving ROP screening would have decreased to 627 (21.1% reduction compared with the UK screening criteria) [Table 2]. The use of the US screening criteria would have detected 234 cases of ROP (98.3% of cases detected using the UK criteria, 234/238) and 38 cases of type 1 ROP (100% of cases detected using the UK criteria, 38/38) [Table 2]. Of the 168 infants who would not have been screened using the US screening criteria, only 4 of them (2.4%) had developed ROP (Table 3) and all cases were mild (maximum stage 1 only); all affected infants displayed spontaneous resolution of ROP without the need for treatment. No cases of type 1 ROP were missed by the US screening criteria (ie, 100% sensitivity) [Table 4].

Discussion

This study showed that if the US screening criteria had been used, instead of the UK screening criteria, the number of infants screened in our population would have decreased by 21.1% without missing any case of type 1 ROP requiring treatment. The number of ROP cases that would have been missed was very small (n=4), and all cases were mild (maximum stage 1).

Previous studies showed that many hospitals in Hong Kong follow the UK screening criteria for ROP screening[7-9,26,27]; consistent with our findings, the reported incidences of ROP and type 1 ROP in Hong Kong were 16% to 28%[7-9] and 3.4% to 3.8%,[7-9] respectively. In the present study, type 1 ROP mainly

TABLE 3. Numbers of infants with and without retinopathy of prematurity (ROP) of any severity that met the United Kingdom (UK) and the United States (US) screening criteria

	Met the UK screening criteria	Met the US screening criteria	
		No	Yes
Without ROP	No	1	0
	Yes	164	393
With ROP	No	0	0
	Yes	4	234

TABLE 4. Numbers of infants with and without type 1 retinopathy of prematurity (ROP) that met the United Kingdom (UK) and the United States (US) screening criteria

	Met the UK screening criteria	Met the US screening criteria	
		No	Yes
Without type 1 ROP	No	1	0
	Yes	168	589
With type 1 ROP	No	0	0
	Yes	0	38

developed in extremely preterm infants with a median GA of 26 weeks and 0.5 days (IQR=2 weeks & 2.5 days), suggesting that low GA was an important predictor of type 1 ROP in our population. Because the GA criterion is lower in the US screening criteria (≤30 weeks & 0 days) than in the UK screening criteria (≤31 weeks & 6 days), the US screening criteria may be more appropriate for Hong Kong.

Our findings were also consistent with the results of a study conducted in another hospital in Hong Kong[7]; in that study, 12.4% of infants would not have required ROP screening if the US screening criteria had been used, rather than the UK criteria, none of those infants would have developed ROP. Our results suggest similar outcomes in different hospitals across Hong Kong.

In a study conducted in Shanghai in mainland China, the screening thresholds were GA of 34 weeks and BW of 2000 g. The mean GA and BW of infants requiring ROP treatment were 29.3 weeks (range, 24-35) and 1331 g (range, 750-2550), respectively[17]; these infants were more mature and heavier than the infants in our study. The Shanghai study showed that 9% of severe ROP cases requiring treatment would have been missed if the UK screening criteria were used; 26% would have been missed if the US screening criteria were used.[17] Another study conducted in Beijing in mainland China showed that 17% of treatment-requiring ROP

cases would have been missed if the UK screening criteria were used; 21% would have been missed if the US screening criteria were used.[18] Therefore, despite sharing the same Chinese ethnicity, infants with severe ROP differed in maturity between Hong Kong and mainland China. This discrepancy could be the result of variations in comorbidities, perinatal risk factors, standard of neonatal healthcare, and level of supplemental oxygen therapy used. Long oxygen duration, mechanical ventilation, and high level of supplemental oxygen are known risk factors for ROP.[2] Therefore, the results of our study are not generalisable to regions outside of Hong Kong.

There is evidence that the UK and the US screening criteria are not appropriate for many low- and middle-income countries.[15,19,28,29] In North India, 17% of severe ROP cases would have been missed if the US screening criteria were used; 22% would have been missed if the UK screening criteria were used.[15] In South India, 8% of treatment-requiring ROP cases would have been missed if the US screening criteria were used; all of these cases were aggressive posterior ROP.[19] In Saudi Arabia, 35% of infants older than the UK screening threshold developed ROP; one infant developed severe ROP (stage 3).[28] In Turkey, severe ROP developed in 3.8% of infants born at ≥32 weeks and 6.5% of infants born at ≥1500 g.[29]

Although it is important not to miss any severe ROP cases, it is also preferable to avoid missing mild ROP cases because the detection of early ROP (even mild cases) can influence decisions regarding systemic management (eg, level of supplemental oxygen), thereby reducing the rate of ROP progression. In the present study, only four cases of mild ROP would have been missed by the US screening criteria; this number was very small, compared with the 168 infants (21.1%) who could have been excluded from screening. The number of screened infants required to detect one additional case of ROP was 42 (ie, 168/4). Considering that few mild ROP cases were missed in exchange for the exclusion of a large number of infants from screening, we conclude that it is acceptable and appropriate to use the US screening criteria for ROP screening in Hong Kong.

Benefits from reduction in number of retinopathy of prematurity screening

There are several benefits to reducing the number of infants screened without compromising the detection of severe ROP. First, this modified approach minimises unnecessary stress and the potential for ROP screening-related adverse events among infants. Previous studies revealed significant elevation of blood pressure, increase in pulse rate, and decrease in oxygen saturation, which persisted after ROP screening.[30] A significant increase in the number of apnoea events was also observed after

screening.[31] Approximately half of infants develop bradycardia from the oculocardiac reflex caused by scleral depression during screening.[32] Second, this modified approach can reduce hospital expenses. The estimated cost of ROP screening is approximately US$230 per infant in the US[33] and US$198.9 per infant in India.[34] Third, the approach can reduce the length of hospitalisation related to delays in the completion of ROP screening.[35] Finally, it may minimise unnecessary parental stress and anxiety. For example, one study showed that parents of infants undergoing ROP screening had significantly higher anxiety and depression scores compared with the general population.[36]

In recent decades, several ROP prediction models have been developed to improve screening sensitivity and specificity, including WINROP,[37,38] ROPScore,[39] CHOP ROP,[40,41] CO-ROP,[42] STEP-ROP,[43] and G-ROP.[44,45] However, these prediction models have many limitations. First, they require the collection of postnatal data such as postnatal weight gain and insulin-like growth factor 1 level, which may not be available to ophthalmologists. Second, the mechanisms by which these predictive factors would interact to affect ROP outcome are not fully understood. Third, these models were all derived from Western countries and may not be appropriate for Asian populations.[46] Finally, none of these models have been validated in Hong Kong. Considering our findings in the present study, we suggest narrowing the GA screening criterion to ≤30 weeks and 0 days, consistent with the US screening criteria; this simple and straightforward approach avoids the need for calculations required by prediction models.

Limitations

This study had several limitations. First, its retrospective design hindered the assessment of other risk factors (eg, supplemental oxygen level and comorbidities) that may affect ROP outcomes. Second, because of the retrospective design, we could not determine whether the use of a narrower GA screening criterion would reduce the number of screenings in real-world clinical practice. A prospective cohort study is needed to confirm our findings. Third, although the G-ROP screening criteria are more sensitive and specific than the current US screening criteria for populations in the US,[44,45] we could not evaluate the suitability of G-ROP criteria in our population because we lacked data concerning postnatal weight gain. Finally, data were missing regarding infants who died or were transferred to other hospitals without a known ROP outcome. Despite these limitations, our findings are robust because the present study revealed consistent results when the same screening practices were applied to a large number of infants over a study period of 10 years.

Conclusion

Compared with the UK screening criteria, the US screening criteria appeared to be more appropriate for our population because they could greatly reduce the number of infants screened without compromising sensitivity for the detection of type 1 ROP. Thus, we suggest narrowing the GA criterion for consistency with the US screening criteria during ROP screening in Hong Kong. A prospective cohort study is needed to further explore the impact of changes to the screening criteria.

Author contributions

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All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

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