Neonatal Eye Screening for 203 Healthy Term Newborns Using a Wide-Field Digital Retinal Imaging System

Kenneth Teow Kheng Leong (✉ kennethteow@yahoo.com)

Pusat Perubatan Universiti Kebangsaan Malaysia <https://orcid.org/0000-0002-6883-9326>

Siti Nur Amira Abu Kassim

Hospital Kuala Lumpur

Jasvinjeet Kaur Sidhu

Hospital Kuala Lumpur

Zayani Zohari

Hospital Kuala Lumpur

Thivakar Sivalingam

Hospital Kuala Lumpur

Sunder Ramasamy

Hospital Kuala Lumpur

Safinaz Mohd Khialdin

Pusat Perubatan Universiti Kebangsaan Malaysia

Noraihan Mohd Nordin

Hospital Kuala Lumpur

Jamalia Rahmat

Hospital Kuala Lumpur

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Abstract

Purpose: This study aimed to determine the proportion and types of ocular abnormalities detected in healthy term newborns and also the risk factors associated with retinal haemorrhages.

Method: This cross-sectional study comprised of 203 participants, all healthy term newborn infants in the Obstetrics and Gynaecology ward at Hospital Kuala Lumpur over a six months period. The examination list includes external eye examination, red reflex test, and fundus imaging using a wide-field digital retinal imaging system (Phoenix Clinical ICON Paediatric Retinal Camera) by a trained Investigator. The pathologies detected were documented. The results were compared with similar studies previously published in the literature.

Results: Total ocular abnormalities were detected in 34% infants. The most common finding was retinal haemorrhage in 29.6% infants, of which 53.3% occurred bilaterally. Spontaneous vaginal delivery (SVD) remained the greatest risk factor which has nearly 3.5 times higher risk of newborns developing retinal haemorrhage compared to Lower Segment Caesarean Section (LSCS). There was a 6% increased likelihood of developing retinal haemorrhage for every 1 minute increment in the duration of 2nd stage of labour.

Conclusion: Universal eye screening for all newborns using a wide-field digital imaging system is possible, safe and useful in detecting posterior segment disorders. The most common abnormality detected is retinal haemorrhage. Although most resolve spontaneously, a longitudinal study is needed to study the long term effect of retinal haemorrhages in these infants.

Introduction

The current practice for newborn eye examination by an Ophthalmologist in Malaysian hospitals includes only those deemed at risk. Normal healthy term newborns will undergo a general examination by the Paediatrician using direct ophthalmoscope by looking at the red reflex and referred to an Ophthalmologist if those basic screening tests are grossly abnormal. Although the red reflex tests may be quick and simple to perform, a study by *Ming Sun et al.* reported that the proportion of abnormalities that were correctly classified by the red reflex test was better for the anterior segment group (sensitivity = 99.6%) rather than the posterior segment group (sensitivity = 4.1%) (2). Therefore, the red reflex test is a useful universal screening tool in the detection of anterior abnormalities. However, the test has limitations in detection of posterior abnormalities. This stresses the point that the current eye assessment protocol is insufficient and may underdiagnose certain posterior segment eye diseases. However, the main reason why neonatal eye screening is not compulsory for normal term newborns is attributed to lack of human resources, time and financial cost.

A few large studies in India and China found that abnormal ocular findings in this group of newborns ranged from 4 to 25% (3-5). A pilot study screening 481 older infants at six weeks of age in China found up to 41.2% abnormal ocular findings (6). Abnormal ocular findings detected included subconjunctival

haemorrhage, congenital microphthalmos, congenital corneal leukoma, posterior synechia, persistent pupillary membrane, congenital cataract, retinoblastoma, optic nerve defects, vitreous haemorrhage, congenital glaucoma, uveal coloboma and so on (3, 4). Some of these findings are diseases that may require urgent investigation and early treatment (7).

In 2003, a pilot study first introduced the use of retinal fundus imaging and telemedicine in the approach for the screening of retinopathy of prematurity (8). However, this approach was limited to premature newborns.

Over the past five years, universal newborn eye screening is gaining interest as a potential way to reduce long-term visual impairment through early detection and treatment of ocular abnormalities. Several studies in India, China and the United States have taken advantage of the advances in retinal fundus imaging and telemedicine for this purpose (4, 5, 9). These studies are advocating universal eye screening for all newborns and *Vinekar et al.* has shown that wide-field digital imaging is possible and safe (5). These infants showed less pain and stress at 30 seconds after completing examination to those examined with a binocular indirect ophthalmoscope (10) and the sensitivity and specificity of wide-field digital retinal image (WFDRi) acquisition system is excellent as a fundus screening tool (11).

Given the above, we designed our study using a WFDRi acquisition system device to examine healthy term newborns to determine the proportion and types of ocular abnormalities which would have been missed. We hope to improve awareness of ocular abnormalities amongst healthy newborns and wish to emphasise the importance of universal newborn eye screening.

Materials And Methods

SUBJECT SELECTION

This is a prospective, cross-sectional study of newborns delivered in the Obstetrics & Gynaecology Labour Room, Hospital Kuala Lumpur (HKL) in Malaysia from January 2019 to June 2019. Healthy term infants selected underwent an ocular examination within the first 72 hours or prior discharge. Subjects were enrolled based on a convenience sampling method. Any mother available, who has delivered and fulfils the inclusion and exclusion criteria will be invited to participate in this study. No attempts will be made to contact those mothers who had been discharged home.

The inclusion criteria included neonate (age < 28 days), born term (between 37 weeks, 0 days and 41 weeks, 6 days), birth weight ($\geq 2000\text{g}$), APGAR score ≥ 7 , any mode of delivery (e.g. spontaneous vaginal delivery, assisted birth and caesarean section), stable vital signs, informed consent given by parent(s) for participation and able to comply to all requirements of the study protocol. Exclusion criteria include born pre-term, dysmorphic babies, syndromic babies, congenital diseases, complications intra & postpartum requiring intensive care and monitoring and unstable for an eye examination.

All subjects who agreed underwent a non-invasive eye examination which consisted of a 2-part examination. The first part of the examination examined the anterior segment of the eyes while the second part of the examination looked at the posterior segment of the eyes after pupillary dilation. All of these were done at the same setting. The ocular examination included utilizing a direct retinoscope and a WFDRI acquisition system.

Part 1 examined the undilated eye including the red reflex test, external inspection and pupil examination. The newborns were brought to the examination room in the postnatal ward. Topical anaesthetic eye drops Tetracaine Hydrochloride 0.5% (Amethocaine®, Zulat Pharmacy Sdn Bhd, China) was applied to anaesthetise the eyes. Eye speculums were inserted, and light was dimmed when the examination was conducted. Bilateral eye anterior segment, pupillary light reflex and red reflex were examined using a direct ophthalmoscope. Image of the anterior segment were captured with

a wide-field digital retinal imaging system (Phoenix Clinical ICON Paediatric Retinal Camera®, Phoenix Technology Group Company, CA, USA).

Part 2 examined the fundus of the eyes after dilatation. A mixture of Phenylephrine hydrochloride 2.5% (Mydrin® 2.5%, Alcon Laboratories Inc., Texas, USA) and Tropicamide 1% (Mydracyl® 2.5% Alcon Laboratories Inc., Texas, USA) eye drops were instilled onto the eyes at 10 minutes interval up to 30 minutes. After a minimum of 6-8mm dilation was achieved, the newborns were brought back into the examination room. A video of the fundus was recorded using the ICON Paediatric Retinal Camera and still images were captured for analysis and record. Five fundus photographs were taken and they included the posterior pole (including disc and fovea), superior retina, inferior retina, temporal retina and nasal retina. Prophylactic topical antibiotic Fucidic acid 1% (Fucithalmic® 1% LEO Laboratories Limited, Dublin 12, Ireland) ointment was instilled onto both eyes after the procedure.

Ocular examinations and all imaging were done by the Investigator who is an Ophthalmology Medical Officer with more than 5 years of experience, adequately trained to use the medical instruments and is aware of safety precautions while handling these babies. The babies were then monitored by a standby nurse.

All photos recorded in the study were further re-evaluated by a Paediatric Ophthalmologist. Any abnormality detected will be referred for further management and treatment.

Statistical Analysis

Formulae for Sample Size Calculation

See formula 1 in the supplementary files.

Where n = sample size,

Z = level of confidence,

α = alpha,

p = expected prevalence or proportion, and

d = precision.

With Finite Population Correction

The sample size calculation was based on a pilot study by *Goyal P. et al.* Outcome of universal newborn eye screening with WFDRI acquisition system: a pilot study. Eye (Lond). 2017 Jul; (3)

Labour room census in HKL recorded an estimated 30 deliveries per day or 1000 deliveries per month. Therefore, we estimated a total of 12000 deliveries per year in HKL. Sample size estimation was calculated using the population proportion formulae (Lemeshow, Hosmer, Klar, Lwanga & Organization, 1990). Prior data indicated that the proportion of ocular abnormality in *Goyal P. et al.* is 0.149 and population size is 12000. If the Type 1 error probability and precision are 0.05 and 0.05, we will need to study 192 samples. Assuming a drop-out rate of 10%, we require a total of 212 participants.

Statistical analysis

Data were explored and analysed using SPSS software version 21.0. Numerical variables were presented using mean and standard deviation. Categorical variables were presented as frequency and percentage. Distributions of continuous variables between newborns with and without ocular abnormalities were compared using Student's t tests; Pearson's chi-square tests or Fisher's exact tests were used for distributions of categorical variables. Statistical significance was defined by a P value of less than 0.05. Simple Logistic Regression and Multiple Logistic Regression were used to determine the risk factors associated with ocular abnormalities among healthy term newborn, without or with adjustment of covariates. All odd ratios (ORs) are presented with 95% confidence intervals (CI).

Results

Of the 203 study newborns who had a complete eye examination, there were 69 newborns found to have ocular abnormalities. The proportion of ocular abnormalities was 34%. The distribution of demographic characteristics of 203 newborns with and without ocular abnormalities was shown in **Table 1**.

The mean newborns' age was 1.93 ± 1.49 days of life during an eye examination. There was no significant difference in newborns' weight between the group with and without ocular abnormalities. The mean weight was 2993.63 ± 431.31 gram. There was no significant difference in maternal age among these two groups. The average maternal age was around 28.64 ± 6.10 years old. There was also no significant difference in terms of gender, race, maternal gravida, birth weight and term between two groups. However, our findings showed that there was a larger proportion of newborns delivered by SVD in the abnormal ocular group ($p < 0.001$) compared to newborns with normal ocular findings.

We performed a subgroup analysis on newborns delivered by SVD, as shown in **Table 2**. In terms of duration of 1st stage and 2nd stage of labour, there was no significant difference between 2 groups. However, we found that episiotomy was more performed in abnormal ocular findings group compared to normal findings group in newborns delivered by SVD ($p=0.023$).

Table 3 showed the type of ocular abnormalities among healthy newborns. There was a total of 14 abnormalities found in anterior segments and 64 abnormalities in posterior segments. Among all these abnormalities, the most found abnormality was retinal haemorrhage, which was 93.8% of posterior segments.

Table 4 presents the eight possible associated factors of retinal haemorrhages in healthy newborns. These factors were analysed using Simple Logistic Regression with no adjustment for other covariates. Among all these factors, we found that the mode of delivery was associated with retinal haemorrhages in healthy newborns ($p<0.001$). Newborns delivered by SVD had 3.43 higher odds of having retinal haemorrhage compared to newborns delivered by LSCS (OR=3.43; 95% CI 1.73, 6.78; $p<0.001$). Others factors showed no association with retinal haemorrhage in newborns.

Multiple logistic regression was then conducted to assess which of these factors were independently related to retinal haemorrhages in healthy newborns. After adjusting all the covariates, we confirmed that SVD remained the greatest risk factor which has nearly 3.5 times higher risk of newborns having retinal haemorrhage compared to LSCS. Others factors were found no association with retinal haemorrhage using multiple logistic regression ($p>0.05$).

We also performed a subgroup analysis on associated risk factors of retinal haemorrhages among healthy term newborns delivered by SVD using Simple Logistic Regression (**Table 5**). We found that for every 1 minute increment in the duration of 2nd stage of labour, there was 6% more likely to have retinal haemorrhage (OR=1.06; 95% CI 1.01, 1.11; $p=0.025$). Besides that, we found that SVD involving episiotomy had 2.5 higher odds of associating retinal haemorrhage in newborns compared SVD without episiotomy (OR=2.50; 95% CI 1.16, 5.40; $p=0.020$). However, after adjusting all the variables using Multiple Logistic Regression, only duration of 2nd stage of labour remained as associated risk factor for retinal haemorrhage in patients delivered by SVD.

Discussion

The result of our study found that 34% of infants had abnormal ocular findings, and it was higher than the expected range of 4 to 25% in other studies (3-5). Ocular abnormalities detected in this study were subconjunctival haemorrhage, iris nevus, retinal haemorrhages, vitreous haemorrhage and congenital hypertrophy of retinal pigment epithelium (CHRPE). Compared to larger studies, we did not find any sight-threatening or life-threatening diseases such as congenital glaucoma, cataract and ocular tumours (3-5, 9, 12, 13). This suggests that such diseases are uncommon. Nonetheless, they require urgent treatment if detected.

We evaluated some of the maternal, infant and birth factors which may contribute to risk for ocular abnormalities. However, we found no significant difference in gender, race, maternal gravida, birth weight and maturity of pregnancy between both groups, except there was a larger proportion of newborns delivered by SVD in the abnormal ocular group ($p < 0.001$) compared to newborns with normal ocular findings. We further sub-analyse the SVD group to compare 1st and 2nd stages of labour and episiotomy. In terms of duration of 1st stage and 2nd stage of labour, there was no significant difference between both groups. However, amongst newborns delivered via SVD, we found that episiotomy was more common in the group with abnormal ocular findings compared to normal findings ($p = 0.023$).

In this study, the commonest abnormality was in the posterior segment, with 29.6% of infants having retinal haemorrhages. This result fell within the reported incidence of neonatal retinal haemorrhages between 2.6 to 50% (14). The wide range of incidence reported may be due to sampling biases (15) and timing of examination (16). Bilateral retinal haemorrhage was more common compared to unilateral (53.3% versus 46.6%), and this finding was similar to a systematic review by *Watts et al.* (16). The retinal haemorrhages detected in this study were 47 and 45 in the right and left eyes respectively, suggesting that chances of retinal haemorrhages were similar for both eyes.

In recent years, many authors tried explaining mechanisms and risk factors for retinal haemorrhage and proposed that the likely cause was birth-related trauma (3, 17). *Yanli et al.* proposed that compression of the foetal head during delivery causes deformation, which leads to elevated intracranial venous pressure, peripheral vascular congestion, expansion, or rupture, resulting in retinal haemorrhage (17). So far, no studies have suggested otherwise.

Overall, there were no statistically significant findings in terms of gender, race, maternal gravida, birth weight, term and age of the infant when correlation was made to determine the risk factors for retinal haemorrhages. However, many studies have reported that the mode of delivery was an associated risk factor for retinal haemorrhage (9, 16, 17). There are several other identified risk factors correlated to retinal haemorrhages such as maternal age, gravida, prolonged 2nd stage of labour and neonatal intracranial haemorrhage (17). In our study, we looked into some of the risk factors reported in those studies. A multiple logistic regression analysis indeed found that SVD remained the greatest risk factor which has nearly 3.5 times higher risk of newborns developing retinal haemorrhage compared to LSCS ($OR = 3.43$; 95% CI 1.73, 6.78; $p < 0.001$). A systematic review by *Watts et al.* found that instrument delivery had a higher risk compared to SVD (16, 18). However, we did not compare the risk of assisted/instrumental delivery as there were only 5 cases of vacuum-assisted delivery (however 3 out of 5 cases were associated with retinal haemorrhage).

Subsequently, this study also found that for every 1 minute increment in the duration of 2nd stage of labour, there was 6% more likely to have retinal haemorrhage ($OR = 1.06$; 95% CI 1.01, 1.11; $p = 0.025$). *Yanli et al.* explained that during the second stage of labour, the cervix is fully dilated, the foetal head is descended, and contractions are much stronger. At the same time, the foetus is compounded by other stresses such as intrauterine ischaemia and hypoxia. Therefore, the longer the second stage of labour, the

more serious the damage to the retinal vein and vascular endothelial cells, causing increased neonatal retinal haemorrhages (17).

At our centre episiotomy is routinely performed on most primigravida mothers who deliver via SVD. This procedure involves a surgically planned incision on the perineum and the posterior vaginal wall during the second stage of labour. The aim is to enlarge the vaginal introitus to ease and facilitate safe delivery of the foetus, to minimise overstretching and rupture of the perineal muscles and fascia, to reduce the stress and strain on the foetal head, and to shorten the second stage of labour. A result in our study showed that SVD with episiotomy had 2.5 higher odds of associating retinal haemorrhage in newborns compared SVD without episiotomy (OR=2.50; 95% CI 1.16, 5.40; p=0.020). However, it was statistically not significant after adjusting all the variables using Multiple Logistic Regression. *Emerson et al* also found that the incidence of retinal haemorrhages was not associated with episiotomy (14). This suggest that episiotomy may even be protective against retinal haemorrhages as it is performed to reduce the duration of second stage of labour.

Many of these haemorrhages resolve spontaneously within 1–2 weeks without clinically significant long-term visual impairment (4, 16). Some recover by one month (18). Only a few of those cases required intervention (12). Retinal haemorrhages rarely persist beyond six weeks, except in isolated cases, up to 58 days (16). Therefore, the early detection of retinal haemorrhages can help distinguish between newborn ocular abnormalities and non-accidental injuries such as shaken baby syndromes (18). *Choi et al.* reported a case of vitreous haemorrhage, which resolved after 3 months (19). Some authors have postulated that long-standing; dense haemorrhage obscuring the macula may limit normal optical development, potentially resulting in visual disturbances such as anisometropia and amblyopia later in life (4, 19).

The ICON Paediatric fundus digital imaging system used in this study was able to produce clear images of the fundus for the detection and identification of posterior ocular abnormalities. Images taken can be used in the form of visual education to parents. Many earlier studies reported similarly using the Retcam, and in some studies, these cameras were operated only by trained technician (3-5, 12, 13, 17, 20). Therefore, examination using the fundus camera provided an alternative to indirect ophthalmoscopy by the Ophthalmologist. Technicians can be adequately trained to manage these cameras and subsequently stationed in places of demand. This translates to better ophthalmology services, can simultaneously reducing the workload and address the issue of shortage of Ophthalmologist.

Evidence of earlier successful telemedicine programs for diabetic retinopathy and ROP suggested that it can also be extended to a universal eye screening for all newborns. Imaging of fundus abnormality allows us to record and monitor treatment and disease progression (21). Images can also facilitate the transfer of information between clinicians (21). Now, with the advent of 5G technology, examination and management of our patients can be done in real-time. However, the cost of purchasing these cameras is substantial, and the economic value has to be assessed further. A study by *Goyal P. et al.* attempted to

prove that there was a net monetary gain when taken into consideration, for example, the potential financial loss incurred by treating a blind child (3).

In our study, there was no reported adverse effect from the screening procedure conducted on these healthy term newborns. However, if present, previous studies showed that the systemic effects were mild and resolved spontaneously (2, 20, 22). Early detection of eye diseases is important, and therefore, an eye examination should be done within 24-72h after birth for all newborn unless they are unfit. In such scenario, the examination may be delayed. Further assessment by a family physician or general practitioner at six weeks of age is likely to enhance the detection rate further (7).

This study has several limitations. The simple sampling method used and relatively small sample size reduced the probability of detecting rarer ocular abnormalities. A multicenter study would give a better representation of the true proportion and types of abnormalities detected in the newborn population.

Conclusion

Universal eye screening for all newborns using a wide-field digital imaging system is possible, safe and useful in detecting posterior segment disorders. The most common abnormality detected is retinal haemorrhage. Although most resolve spontaneously, a longitudinal study is needed to study the long-term effect of retinal haemorrhages in these infants.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Universiti Kebangsaan Malaysia (UKM) Research and Ethics Committee (Ethical approval code: FF-2018-438 TB) and the Medical Research & Ethics Committee (MREC), Malaysian Health Ministry (Ethical approval code: NMRR-18-1381-41558). This study adhered to the tenets of the Declaration of Helsinki and Malaysian Guidelines for Good Clinical Practice (GCP). A written informed consent to participate was obtained from the parents/legal guardians of the minors included in this study

Consent for publication

Consent to publish was provided in writing from the appropriate parents or legal guardians of the minors included in the study, as well as the minor used in an image within the consent forms attached to the manuscript.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interest

The authors declare no conflict of interest

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None

Author's contribution

- Kenneth Teow Kheng Leong (KTKL)
- Siti Nur Amira bt Abu Kassim (SNA)
- Jasvinjeet Kaur Sidhu (JKS)
- Zayani bt Zohari (ZZ)
- Thivakar a/I Sivalingam (TS)
- Sunder Ramasamy (SR)
- Safinaz Mohd Khialdin (SMK)
- Noraihan Mohd Nordin (NMN)
- Jamalia Rahmat (JR)

SNA, JKS, ZZ and TS assisted KTKL and was involved with acquisition of data. SR conceptualised the study while KTKL, SMK, NMN and JR contributed in the design of the work. KTKL performed most roles including examination of all the newborns, and was a major contributor in writing the manuscript. All authors read and approved the final manuscript.

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Abbreviations

BIO Binocular Indirect Ophthalmoscope

CHRPE Congenital hypertrophy of retinal pigment epithelium

HKL Hospital Kuala Lumpur

HUKM Hospital Universiti Kebangsaan Malaysia

LSCS Lower segment caesarean section

MREC Medical Research Ethics Committee

NMRR National Medical Research Registry

O&G Obstetrics and Gynaecology

REC Research Ethics Committee

ROP Retinopathy of prematurity

RPE Retinal pigment epithelium

SVD Spontaneous vaginal delivery

WFDRI Wide-field Digital Retinal Image

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Figures

Figure 1

Right eye iris nevus (arrow)

Figure 2

Congenital hypertrophy of retinal pigment epithelium (arrow)

Figure 3

Retinal haemorrhages (arrow)

Figure 4

Vitreous haemorrhage (arrow)

Supplementary Files

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