RESEARCH

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Detection of anomalies in the red reflex test requires adequate training

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1 table and 2 figures

Background: Midwives that had completed the relevant Newborn and Infant Physical Examination (NIPE) training in the UK, were tested to determine whether they could reliably detect an abnormality in the red reflex of a model eye. Their results were compared to a group of undergraduate optometry students in their final year, who had considerably more experience with ophthalmoscopy.

Methods: Two groups of adult participants, 27 post-graduate midwives and 10 undergraduate optometry students with different levels of experience in ophthalmoscopy were recruited. A set of 10 model eyes with interchangeable simulated retinas, that produced both normal and abnormal ‘red’ reflexes, were constructed and used for the study. Participants were required to perform the red reflex test repeatedly on the model eyes under controlled conditions.

Results: A total of 1810 observations were recorded across both groups of participants. Both the sensitivity and the specificity for distinguishing between normal and abnormal reflexes were higher for the optometry (sensitivity 77.5% and specificity 96.7%) students than the midwives (sensitivity 53.9% and specificity 75.4%). The positive predictive values were 21.7% and 67.4% for the midwives and optometry students, respectively. The negative predictive values were, 92.8% for the midwives and 98.0% for the optometry students.

Conclusion: Despite completion of required training on the red reflex test, midwives were outperformed by optometry students in the detection of anomalous red reflex test simulations from a model eye. This result is likely due to differences in training in ophthalmoscopy between the two groups of participants. Additional training in the conduct of the red reflex test for midwives is therefore recommended.

In view of its importance,[1,2] the United Kingdom (UK) government recommends the visual screening of all newborn infants includes an evaluation of the pupillary red reflex.[3] The aim of vision screening is to detect potentially sight (and possibly life) threatening visual anomalies in the newborn including congenital cataract, retinoblastoma and corneal or vitreal opacities[4-9] and to enable prompt follow-on treatment.

Bruckner described a screening method to evaluate the symmetry of the pupillary reflexes which has come to be known as the (Bruckner) red reflex test.[10] The test uses the light from a direct ophthalmoscope to illuminate the patient's eyes and produce a red reflex. It may be performed by the examiner holding the ophthalmoscope directly in front of the patient at about a 30-50 cm distance, shining the light into the patient's eyes and observing through the ophthalmoscope the resulting pupillary reflexes in each eye.[1] A normal result of the red reflex test would be reflexes that appear symmetrical in colour. Variations in the type of red colouration may occur as a result of differences in pigmentation of the fundus of newborn children. Such differences are perfectly acceptable as long as there is symmetry between the two eyes. An abnormal result, however, would occur when the colouration between the red reflexes of the two eyes is asymmetric, when there is the appearance of dark areas or shadows in one or both reflexes or when the reflex is white (whole or partial leukocoria).[1] Unilateral viewing of each eye is also possible if both eyes cannot be viewed simultaneously.

Although the red reflex test is widely recommended as an effective tool for the detection of newborn ocular anomalies,[4,6-9,11-15] the low incidence of significant ocular disorders in the newborn can make it difficult to properly evaluate the test. For example, a large study by Sun and colleagues[7] evaluated the efficacy of the red reflex of 7641 newborns and concluded that the test was highly effective but only for the detection of anterior (i.e. abnormalities of the cornea, iris, aqueous and lens) but not posterior segment (i.e. abnormalities of the vitreous, retina, optic nerve or choroid) anomalies. However, in their sample only a single case of retinoblastoma was detected (although not on the red reflex test) and they based their conclusions on the test missing posterior pole anomalies that would have been difficult or impossible to detect using the red reflex method (for example, retinal haemorrhages, optic nerve cupping). Other studies have reinforced the importance of the red reflex test for the detection of congenital cataract[13,16,17] despite the low incidence of cataract in the newborn population[5] and the possibility that the red reflex screening may only detect around 47% congenital cataracts.[18]

In the UK, the red reflex test forms part of the Newborn and Infant Physical Examination (NIPE) national screening programme.[19] The examination may be performed by a doctor, or a midwife who has successfully completed an accredited course.[19] Although past evidence suggested a reluctance for midwives to conduct the newborn screening examination,[20] more recent evidence suggests that appropriately trained midwives can fulfill the responsibilities of the newborn screening examination as well (or even better) than some of their medical peers.[21] With the inclusion of newborn examination skills within the undergraduate midwifery curriculum,[22] and other factors such as the likely reduction to health costs, the increased satisfaction from parents,[21] midwives are increasingly likely to be the main providers of the NIPE in the UK.

Anglia Ruskin University has offered post-registration training and accreditation in the elements of NIPE for many years and, as elsewhere,[22] the training has now been introduced into the undergraduate, pre-registration curriculum of midwifery degree courses. A key element of the NIPE, the screening of the newborn eye including performing the red reflex test forms an important component of the training. A number of authors have suggested that the red reflex test is easy to perform and requires only a modest period of training,[11,14,15] perhaps as little as 30 minutes.[6] While gaining familiarity with an ophthalmoscope and performing the red reflex test may be relatively fast, becoming proficient in evaluating the results of a red reflex screening could take longer and may account for the poor detection rates of congenital cataract that some authors have noted.[18] Therefore, it is important to know whether the training delivered in the red reflex technique is adequate. In this study, the ability of midwives who met the required training outcomes of the NIPE in the red reflex test, was tested to determine whether they could reliably detect an abnormality in the red reflex of a model eye. Their results were compared to results obtained from a group of undergraduate optometry students, in their final year of study, with experience in performing direct ophthalmoscopy.

METHODS

Model eyes

A set of 10 model eyes (labelled A through to J), mounted into supporting wooden frames were built for the study (Figure 1). Each model eye was made from a hollow black metal tube 5 cm in length fitted with a fixed pupil aperture (either 5 or 8 mm in diameter) and optical quality focusing lens at the front and a detachable back end mount. The detachable back held the imitation retina, which was a semi-sphere made from dental impression putty painted in different saturations of red to simulate the variations in red colour of a 'normal' reflex or painted full or partially white to simulate a retinoblastoma tumour. In total 14 imitation retinas were made, 10 resulting in variations of a normal red reflex and 4 of different types of abnormal white (leukocoria) reflexes. Figure 2 depicts examples of both normal and abnormal retinas used in the study. The abnormal eyes had either a full white reflex or variations of partial (sector) white reflexes representing more peripheral lesions. The abnormal eyes were further labelled either as central (Central 1 or 2) or peripheral

(Peripheral 1 or 2) based on the nominal position and extent of the simulated white tumour (Figure 2). As a result, different combinations of 10 normal and abnormal simulated retinal reflexes could be created. One of the authors (JS), an optometrist experienced in the examination of infants and young children, checked each of the model eyes making sure that they all produced obvious, normal, or abnormal reflexes as appropriate.

Insert Figures 1 and 2 about here

Participants

For the first subject group, 27 registered midwives were recruited from a cohort attending the professional development midwifery NIPE course at Anglia Ruskin University. The midwifery participants had fulfilled the requirements of the NIPE course relevant to newborn eye screening including having opportunities for practical experience using an ophthalmoscope. The ophthalmoscopy practice involved a 2 hour period of familiarisation with the instrument and opportunities to practice observing the red reflex on each other, consistent with previous recommendations.[6] Some of the midwives claimed additional experience during their normal course of employment although this was not quantified.

A second group of 10 students, midway through their final year undergraduate optometry degree from Anglia Ruskin University, also participated in the study. As optometry students in their final year, they were very familiar and confident in the use of the direct ophthalmoscope and could be considered adequately practiced using the instrument. The group of optometry students therefore acted as a comparison group. Practical issues limited the number of participants in the student optometry group.

Procedure

The study was conducted separately for each participant group but followed, with a few exceptions, the same procedure. Prior to beginning data collection, participants were given an opportunity to familiarise themselves with the ophthalmoscope and a ‘practice’ model eye. The practice eye had a normal red reflex and was separate from the test models but was of the same construction. The ophthalmoscope used for the procedure was set at the largest circular aperture and properly charged throughout each data collection session. Participants were instructed to begin from the left side of the first supporting frame (Figure 1) and view a single model eye in turn from a distance of 15 cm. The viewing distance was measured with a ruler. Participants were required to identify whether the resulting red reflex was normal or abnormal based on their interpretation of the colour or appearance. They were instructed to view the model eye straight-on and from different angles (for example, right, left, up or down) to assess more peripheral parts of the reflex.[23] Viewing time for each model eye was restricted to 30 seconds and a response was required before moving to the next model eye. Simultaneous comparisons with adjacent model eye reflexes were not allowed. Although participants were not shown an abnormal reflex, they were told to look for any abnormality in the reflex including whether it appeared either full or partial white. Data were collected in dim room illumination to minimize external reflections from the model eye lens. All responses were recorded onto a data sheet by an examiner.

Each participant from the midwife group screened 10 model eyes in a set and each set was repeated 3 times resulting in a total of 810 individual screening results (27 x 10 x 3). Each of the optometry students also screened 10 model eyes in a set but repeated 5 times resulting in a total of 500 individual screening results (10 x 10 x 5). In a second, separate condition, the optometry students repeated the measurements (that is, another 500 individual results) using the same model eyes but now fitted with larger, 8mm pupils. Data were collected over several sessions. Each individual set of 10 model eyes had different combinations of imitation retinas (that is, different backings) selected in a pseudo-random fashion and varied for each set of 10 presentations. The reason was to ensure that for each participant, a consistent proportion of abnormal retinas containing the simulated tumour could be included, 8% for the optometry student cohort and 11% for the midwife cohort. Although participants were aware that some of the model eyes would show an abnormal reflex, they were not told how many abnormalities would be present or when they would occur. For each participant, all 4 variations of the abnormal retinas were included somewhere in the total presentations.

The research was conducted in accordance with the tenets of the Declaration of Helsinki, and written informed consent was obtained from each subject before participating and after all of the procedures and risks were explained. The study met the requirements of the institutional research ethics processes.

Responses were initially recorded on paper then transferred into a spreadsheet for further analysis. The ability of participants to correctly differentiate a normal red reflex from an abnormal reflex was determined by calculating the sensitivity, specificity and positive and negative predictive values (PPV and NPV, respectively) across each of the two groups.[24] Where needed, statistical differences were assessed using the chi-square statistic.

RESULTS

There were a total of 1810 observations recorded across both groups of participants, including, for the optometry student group, 500 additional observations using the 8mm pupil size model eyes. The principle results for both midwives and optometry student groups using the 5mm pupil model eyes are summarised in Table 1. A perfect outcome for detecting the abnormal reflexes would have been 91 correctly identified for the midwives and 40 correctly identified for the optometry students.

Insert Table 1 about here

Both the sensitivity, reflecting the ability of the red reflex test to detect those eyes with the abnormality and the specificity, reflecting the ability of the red reflex test to correctly identify the normal eye, were higher for the optometry students than the midwives. Moreover, the optometry students correctly identified the abnormal reflex containing the full white simulation (labelled as Central 1 in Figure 2) every time it appeared (10 of 10 times), whereas the midwives correctly identified the same simulation 65% (13 of 20) of the time. Although both groups found the sectoral simulations (labelled as Peripheral in Figure 2) more difficult to detect, the midwife group correctly identified the sectoral abnormality 51% (36 of 71) of the time compared to the student optometrists who correctly identified the abnormal reflex 70% (21 of 30) of the time. The corresponding positive predictive values were 21.7% and 67.4% for the midwives and optometry student groups, respectively. The negative predictive values were, 92.8% for the midwives and 98.0% for the optometry students.

The results when the 8mm pupil size was used (only for the optometry student group), were predictably better.[23] The calculated sensitivity and specificity was 95.0% and 99.8%, respectively. As with the 5mm pupil size models, the optometry students correctly identified the abnormal reflex containing the full white simulation whenever it appeared and correctly identified the sectoral (peripheral) abnormalities 93% (28 of 30) of the time. The corresponding positive predictive values and negative predictive values were 97.4% and 99.6%, respectively. The differences between the 5mm and 8mm pupil size results were significant (chi-square, $p<0.001$).

DISCUSSION

The main finding of this study is that despite completing the required NIPE training, midwives performed more poorly on the red reflex test than a comparison group of final year optometry students. The midwife group failed to detect almost half of the anomalous reflexes (~46%) compared with about 29% failure in the optometry student group. Perhaps more importantly was that the midwife group correctly identified the full white reflex (designated as Central 1 in Figure 2) only 65% of the time compared with 100% detection for the optometry student group. Although both groups were poorer in detecting the more peripheral anomalies (sectoral white pupils), the midwife group was worse, 51% positive detection compared to 70% correct for the optometry student group. This was despite both groups receiving the same specific instructions to view the model eye straight-on and from different angles.[23]

There were differences in the number of participants between each group and the resulting number of observations, which may have had an impact on the results. The midwife group comprised 27 practitioners that completed 810 observations (3 x 10 each) compared to 10 practitioners in the optometry student group that completed 500 observations (5 x 10 each) (for the same pupil size). Although the midwife group were allowed more observations in total, this did not increase their relative performance on the task. Alternatively, the participants in the optometry student group had more repetitions, which could have provided more opportunity for learning and hence increase their relative performance. Although the latter is unlikely, given that the abnormalities were (pseudo) randomized throughout the procedure, it cannot be discounted.

The midwives were skilled practitioners with experience in examining newborns and infants, and as such general clinical skills were assumed to be high. The optometry students, although not yet at the end of their training, had more experience in the use of the direct ophthalmoscope, beginning with practical skills development in their first year of studies. Thus, differences in detection of the abnormal reflexes between the two groups is more likely due to differences in the amount of training and experience in the use of the direct ophthalmoscope and/or interpretation of the red reflex. Undergraduate optometry students gain considerable experience both in performing direct ophthalmoscopy and in interpreting fundus signs, including the appearance of a normal red reflex. Midwives, on the other hand, although meeting the NIPE requirements had less practice in ophthalmoscopy and relatively little experience in observing normal red reflexes. The current results therefore, do not support the conclusions of some studies which claim only a relatively brief period of training is required to be proficient in performing the red reflex test[4,6] although they are consistent with reports suggesting better detection rates in the hands of ophthalmologists who would be experienced in ophthalmoscopy compared to non-specialists[14] with less experience. Problems in performing the red reflex test have also been implicated in the relatively poor detection rates (~47% of cases detected) of congenital cataract,[18] which, given our results, suggest issues with elements of the practical training of the test.

As the results from this study were derived using a model eye and a standard experimental procedure, comparisons with clinical studies using the red reflex test on neonates should be viewed with caution. Nevertheless, some comparisons can be made. The sensitivity and specificity of the red reflex test in the hands of optometry students, but not midwives was comparable with some clinical studies using experienced clinicians (e.g. Saiju et al,[14] Sun et al,[7]). However, such comparisons may be misleading in contemplating the importance of any clinical application of the results. Consideration of the positive values (PPV) may be more instructive. The PPV shown in the Table 1, suggest that in a real application using optometry students, only 67.4% of patients tested that had a failed red reflex test would actually have a reportable ocular condition (and considerably fewer if midwives performed the test, of 21.7%). However, the PPV is also dependent on the prevalence of the target ocular condition.[25] In the current study, a prevalence of abnormality of approximately 10% was used (11.1% for the midwives and 8% for the optometry students); which is considerably higher than the expected prevalence of significant ocular abnormality in the neonate of less than 0.1%[14]. The influence of prevalence on the PPV can be seen in an example. By reducing the prevalence to 1%, the adjusted PPV values change to 2.2% and 19.3% for the midwives and optometry student groups, respectively. The change in prevalence had little impact on the NPV for either cohort. From such an analysis, it is evident that even though the optometry student group performed considerably better than the midwives, they would still refer a large proportion of screened patients (32.6%) incorrectly, and considerably more if the prevalence was closer to the true figure for ocular abnormalities in the neonate of 1% or less. An additional limitation of the study is that participants were not able to compare two red reflexes simultaneously, as is generally recommended. This may have made the task harder for both groups of participants and led to poorer detection rates.

In addition to the 5mm pupil size models, the optometry student group performed the red reflex test on an 8mm pupil model. The results showed an improvement in both sensitivity and specificity of the test suggesting that pupil size is an important factor in detection of red reflex abnormalities.[23,26] Differences in the PPV between the results using the 8mm and 5mm pupil sizes were also apparent. The PPV was considerably better when the pupil size was 8mm (97.4% compared to 67.4%). Interestingly, if the prevalence is reduced to 1% as in the earlier example, the adjusted PPV values are 19.3% for the 5mm pupil and 81.5% for the 8mm pupil, suggesting that pupil size has an important role in improved performance for the red reflex test (at least in more experienced practitioners). It is possible that the improvement in detection found with the larger pupil size was partly due to a learning effect; however, performing the red reflex test through larger dilated pupils has resulted in better detection rates for real and simulated retinoblastoma.[23,26]

The differences between the midwife and optometry student groups in their respective ability to distinguish between normal and abnormal pupillary reflexes were striking, but these were found using a model eye and not real patients. Exposure to neonates is not readily available to undergraduate optometry students and, as such, their performance may not represent actual clinical practice. The fact that the test was not conducted on neonates may, therefore, have contributed to the student optometrist’s ease at applying the red reflex test. Nonetheless, the result clearly identifies that training and practice in using an ophthalmoscope and interpreting the red reflex requires more time than previous recommendations.[6] As a result, the training and practice of ophthalmoscopy has been incorporated from year one in the undergraduate midwives’ curriculum at Anglia Ruskin University, similar to what happens within the optometry course. The aim is that by the time the midwifery students start the NIPE module in their third year, they should be comfortable and competent using the ophthalmoscope. In addition, third year student optometrists have been seconded to facilitate the learning and use of the ophthalmoscope which has been welcomed by the student midwives.

The red reflex test performed using the direct ophthalmoscope, preferably in a darkened room to enhance pupil dilation, remains an important part of newborn screening. The results of this study suggest that specific attention to the elements of the training, in particular, more experience in the technique of direct ophthalmoscopy and visualization of both normal variations and abnormal red reflexes is required to enhance detection of abnormalities.

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Table 1. Contingency table showing the total number of reported positive (i.e. perceived as abnormal) and negative (i.e. anomaly not perceived or seen as normal) pupil reflexes following the red reflex test for both the midwife and optometry student groups. Also shown are the calculated Sensitivity, Specificity, Positive and Negative Predictive Values for each group.

	Midwife group		
	Simulated anomaly		Totals
Screening result	Present (white)	Absent (red)	
Perceived	49	177	226
Not perceived	42	542	584
	91	719	810
Sensitivity	53.9%	Positive Predictive Value	21.7%
Specificity	75.4%	Negative Predictive Value	92.8%

	Optometry student group		
	Simulated anomaly		Totals
Screening result	Present (white)	Absent (red)	
Perceived	31	15	46
Not perceived	9	445	454
	40	460	500
Sensitivity	77.5%	Positive Predictive Value	67.4%
Specificity	96.7%	Negative Predictive Value	98.0%

Figure captions:

Figure 1. Depicts the set of 10 model eyes shown with 5mm pupils, mounted in their frames. The simulated retinas were allocated to each model in a pseudo-random fashion as described in the text. The red reflexes seen in some of the models are an artefact of the photography. The same set of model eyes but with 8mm pupils was used in the second condition. Please refer to text for details.

Figure 2. Shows all (4) of the simulated tumours and examples of 2 normal retinas showing the variation in red colour that was used. Note that the abnormal simulations labelled 'Central 1 and 2' and 'Peripheral 1 and 2' were done so based on the relative location of the resultant reflex.

Figure 1.

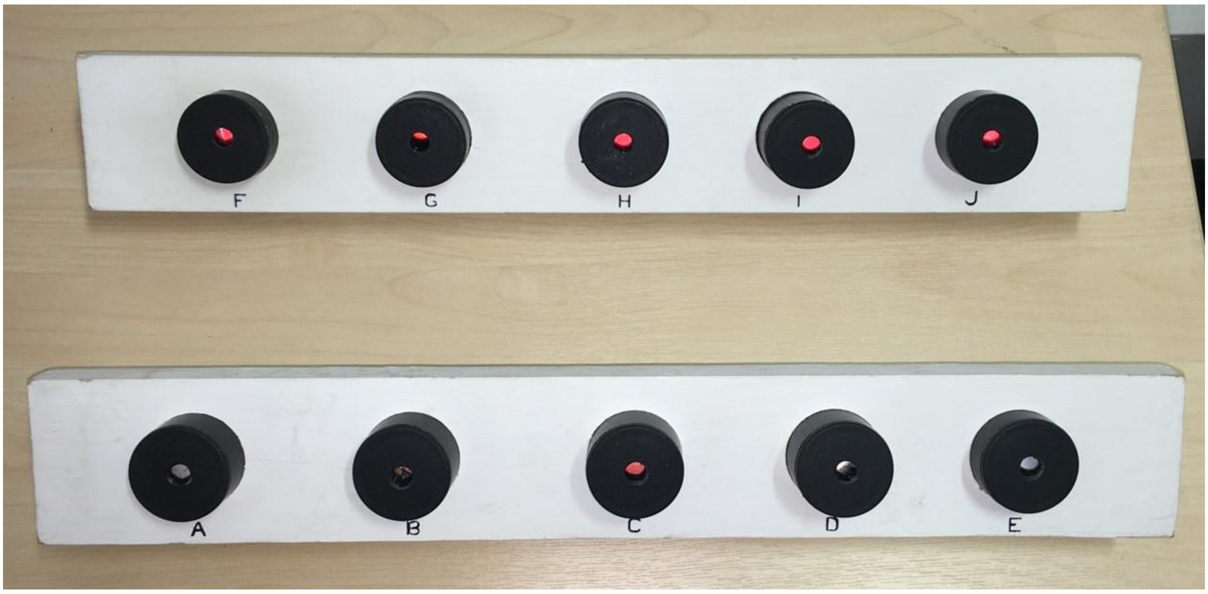

Figure 2.