Analysis of the parental satisfaction for retinopathy of prematurity screening using binocular indirect ophthalmoscopy versus wide field retinal imaging

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Purpose: Analysis of the parental satisfaction for retinopathy of prematurity screening using binocular indirect ophthalmoscopy versus wide field retinal imaging. Methods: This was an observational, questionnaire survey-based study. The study cohort comprised of parents/legal guardians of consecutive Asian Indian premature infants enrolled for retinopathy of prematurity screening (for infants less than 2000 gms and/or 34-weeks gestational age) using binocular indirect ophthalmoscopy (BIO) with scleral depression and b) wide field retinal imaging using the 3Nethra Neo Camera (Forus Health, India). We evaluated the retina for the presence or absence of stages of ROP and plus disease. The survey analysis used closed-ended (multiple-choice) and open-ended questions for assessing 1) parents' experience/preference among the two screening modalities namely, BIO and wide field imaging used in the study, 2) knowledge prior to ROP screening, 3) knowledge gained post ROP screening, in the outpatient ophthalmologic care unit in our hospital. Results: Parents/legal guardians of 90 infants were included in the study. Among the 90 parents who filled in the questionnaire, 62.3% were referred by their pediatrician, 23.3% came for self check-up and 14.4% incidentally came to the hospital for complaints like ocular discharge and were screened. 93.3% parents were satisfied with either ROP screening modality in our study, with 54.4% stated a preference for retinal imaging. In the study, 20% of the parents felt that retinal imaging was painful for the infant and 31.1% felt that BIO was painful for the infant. Conclusion: Wide field imaging is increasingly becoming an effective tool and screening tool in ROP screening and helps in better understanding of the disease amongst parents.

Key words: 3nethra neo fundus camera, binocular indirect ophthalmoscopy, retinopathy of prematurity, wide field retinal imaging

Retinopathy of prematurity (ROP) is a vaso-proliferative disease of the preterm retina with the potential to cause irreversible blindness. The demand for ROP screening has increased globally; following increased survival of extremely preterm infants thus timely screening and treatment of ROP cannot be understated. The gold standard screening method for ROP involves binocular indirect ophthalmoscopy (BIO) performed by a qualified ophthalmologist.[1]

However, considering the shortage of such specialized workforce, it may be difficult to meet the increasing demands for ROP screening in India to prevent blindness due to ROP.[2] To meet the increasing demands of screening for ROP, multiple advancements in imaging modalities have become available such as RetCam (Natus Medical Systems, Inc., Pleasanton, CA, US), RetCam Shuttle, ICON (Phoenix Clinical, Inc., Pleasanton, CA, US), the 3nethra neo (Forus Health, Bangalore, India), Panocam (Visunex Medical Systems, Inc., Fremont, CA, US). Newer developments in smartphone-based models for retinal imaging have been developed, including the D-eye system, the Portable Eye Examination Kit (PEEK), Ocular CellScope, and a prototype by Harvard Medical School.[3] These devices have allowed telemedicine screening for ROP in urban and remote areas, evident by the success of the KID-ROP project.[2]

Parents are essential partners for ensuring timely ROP care in low-birth-weight infants and given the time-sensitive nature of ROP, parents understanding of the disease is essential for maintaining timely follow up and early treatment.[2,4] Monica EW et al., in their study concluded that parents of infants with very low birth weight, particularly those with limited educational proficiency and low health literacy, lack knowledge about ROP.[4]

This study aims to analyze the parental satisfaction with the two screening modalities for ROP using BIO and wide field retinal imaging and to evaluate how these factors impact parents’ ROP knowledge and experience.

Methods

This was an observational, questionnaire survey-based study conducted on parents/legal guardians of 90 premature infant (180 eyes) examinations, referred to a tertiary eye clinic...
in north India for ROP screening during time period of July 2019-July 2020. The screening modalities included both; a) BIO with scleral depression and b) wide field retinal imaging using the 3Nethra Neo Camera (Forus Health, India). The study cohort comprised of parents/legal guardians of consecutive Asian Indian premature infants enrolled for ROP screening of infants who were less than 2000 gm and/or 34-weeks gestational age or less or were less than 30 days of life when first screened, as per the national guidelines.[9] 7

The study was conducted according to the tenets of the Declaration of Helsinki and was approved by the institutional ethics committee and review board for ensuring proper counseling and obtaining informed consent from all parents/legal guardians accompanying the infants. It was approved on 15 may 2019. The infants were fed prior to the process of pupillary dilatation which was achieved by instilling a commercially available combination of Phenytoin 2.5% and Tropicamide 0.8% (Trophtha P Semi). Pupils were dilated 30-60 minutes before the screening procedure. In order to reduce the risk of aspiration, the next feed was given after a period of 30-45 minutes after examination. For each patient, gestational age, birth weight and post gestational age at the time of each examination was noted. The presence or absence of plus disease with the presence or absence of ROP, the stage, and number of clock hours involved was classified according to the international classification for ROP.8 The examination was conducted in the presence of the parents or the accompanying guardian of the infant.

Wide-field imaging was performed by a trained vitreo-retina consultant (AD). The imaging was performed by a contact camera using the 3Nethra Neo Camera [Fig. 1], which was placed over the cornea of the infant’s eye using a coupling agent (Lignocaine gel 2%). The eye examination was done using a sterile infant wire speculum. A series of photographs were taken to adequately capture the posterior pole, and the peripheral retina to the extent possible.

This was followed by retinal examination using BIO by a trained vitreoretinal surgeon with 20-dioptre lens and scleral depression under topical anesthesia using 0.5% Proparacaine. The anterior segment was examined first with 20D lens by going close to the eye. Posterior pole was examined next, followed by peripheral retina with scleral depression. The examining clinician had sufficient knowledge and experience to accurately identify the location and sequential retinal changes of ROP. The examinations were continued until either the retina was completely vascularized or retinopathy developed. The order of using the screening modality was randomized by coin toss method, to limit bias.

Parents were explained about the presence or absence of ROP staging, prognostic importance in the examined infant by the screening ophthalmologist. Following this, a questionnaire survey (supplementary file attached) was administered by a single trained ophthalmic assistant who explained and assisted in the filling of the questionnaire in the vernacular language when needed. We developed survey questions based on qualitative data for parents which was validated by all the authors in study. Multiple-choice and open-ended questions assessed parents’ 1) parents’ experience/preference among the two screening modalities namely, BIO and wide field imaging used in the study, 2) knowledge prior to ROP screening, 3) knowledge gained post ROP screening, in the outpatient ophthalmologic care unit in our hospital. We designated the parents as per the Census of India 2011 in rural and urban population.

Statistical analysis
Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences) for Windows (version 24.0). Categorical variables were described as frequency (percentage), mean ± standard deviation was used for continuous parameters. Differences between two categorical groups were compared by the Chi-square test and Fischer Exact test. For determining the correlation between two parametric variables, the Karl Pearson’s Correlation analysis was performed. For all analyses, a two-tailed P value of <0.05 was considered statistically significant.

Results
Parents/legal guardians of a total of 90 preterm infants (180 eyes) were included in the study, of which 50 (55.6%) were males and 40 (44.4%) were female infants. The mean birth weight of infants in the study was 1749.04±465.167 gm, (range 700-3000 gm) and the mean gestational age of infants was 32.84 ± 2.702 weeks, (range of 25-39 weeks). The mean post gestational age at first evaluation was 38.58±2.880 weeks (range 32-47 weeks). The demographic data of infants in the study is shown in Table 1. The mean time duration of ROP screening of infants using BIO (after the application of speculum) was 67 ± 9.31 seconds (56-96 seconds) and for wide field imaging was 81.5 ± 15.144 seconds (63-135 seconds) with no statistically significant difference between screening time for either modality (P value = 0.65; P > 0.05).

Demography
On presenting the questionnaire to the 90 parents, regarding the source of awareness, 56 parents (62.3%) were referred by the pediatrician, 21 parents (23.3%) were well aware regarding ROP and came for self check-up for the infant and 13 parents (14.4%) presented incidentally to the hospital with the chief complaint of discharge from the infant’s eyes with no prior knowledge of ROP but were examined for ROP as per the defined protocol. [Fig. 2].

The survey questionnaire addressed the following points.

1: Parents satisfaction with ROP screening method.
In this study all infants were screened as per the defined protocol using both BIO and wide field retinal imaging modality. On questioning with regard to satisfaction for ROP screening with either screening modality, 84 parents (93.3%) were satisfied with both screening modalities, 5 parents (5.6%) were neither satisfied or dissatisfied with the screening, 1 parent (1.1%) was not satisfied with either screening modality and found it painful for the infant [Fig. 3]. 49 parents (54.4%) recommended wide field retinal imaging as the first choice as a screening modality while 41 parents (45.6%) recommended BIO as their preferred choice.

2: Parental opinion for the procedure being painful.
Of the 90 parents who answered the questionnaire, 18 parents (20%) felt that wide field retinal imaging was painful for the infant, 28 parents (31.1%) felt that BIO was painful for the infant. However, 44 parents (48.9%) did not feel either of the procedure to be painful for the infant.

3: Knowledge of ROP according to area of residence (urban versus rural population)
Of the 90 parents who filled the questionnaire for ROP screening, 46 parents (51%) belonged to rural areas and 44

| Table 1: Demography of the screened Preterm infants |
|---------------------------------|-------------|-----------|
| Parameter                        | Mean±SD     | Range     |
| Gestational age (weeks)          | 32.84±2.702 | 25-38     |
| Post-gestational Age (weeks)     | 38.58±2.880 | 32-47     |
| Birth weight (grams)             | 1749.04±465.167 | 700-3000 |
parents (49%) were from urban areas. We compared the awareness for ROP evaluation in the current population and observed that the area of residence has a significant association with knowledge. People living in urban areas had a significantly higher level of knowledge for ROP as compared to people living in rural areas (P value = 0.005). No significant correlation was noted with regard to the choice and preference of screening modality in comparing the rural versus urban background. We observed that infants screened in urban areas had a 100% follow up over the following year for visual assessment, however, a 30% (14 infants) drop out in follow up even after a telephonic reminder to the parents from rural region at 6-month of the chronological age.

Discussion

At present, ROP detection requires an ophthalmologist experienced with BIO and scleral depression or trained ophthalmic assistant or doctors trained in using wide field imaging devices to take photographic documentation in examining pediatric retina. In the current scenario in India and other middle-income countries, the number of ROP specialists required to screen the increasing number of premature infants is grossly inadequate. In the past BIO with scleral depression was the gold standard in examination of ROP babies, however, there exist several limitations such as the scarcity of trained specialists, lack of objectivity, lack of photo-documentation, medico-legal concerns, low or no reimbursement, remote or poorly accessible locations of neonatal care centers, and ergonomic and logistic difficulties. With recent emergence of cost effective infant retinal imaging devices, retinal examination is being achieved as a primary examination modality and also as a tele-screening modality to reach the rural areas.

There is existing literature which states the sensitivity of wide field imaging in detection of ROP disease to range from 81.9% to 90%. The success of KIDROP project with the screening and training of peripheral ophthalmologists and ophthalmic assistants, were able to achieve an 85.9% detection in ROP which improved to 94.3% using wide field imaging.

In our study, we observed that 62.2% were referred by the pediatrician at discharge and a very similar observation was made by Patwardhan SD, et al. who demonstrated that, the overall percentage of pediatricians arranging for ROP screening was 64%. We also observed that 23.3% of the parents were well aware regarding ROP and came for self check-up for the infant using the internet as a medium of awareness and 14.4% of the parents presented incidentally to the outpatient department with the chief complaint of discharge from the infant’s eyes. This in comparison with western world as observed by Monica EW et al. stated that of the 131 parents included in their study, 109 parents (83%) had preexisting knowledge about ROP as an eye disease affecting the premature retina. They observed that 12% of parents used online resources as medium of self-education for ROP. Such high level of awareness amongst parents is because of ROP related education being provided, 2 weeks prior to discharge and written material on ROP is given at the time of discharge from the hospitals.

We compared the awareness for ROP, between urban versus rural population and observed that that area of residence of
parents had a significant association with knowledge for ROP. People living in urban areas had a higher level of knowledge for ROP as compared to people living in rural areas. This difference can be attributed to the barriers such as dearth of specialized ophthalmologists, poverty, psychosocial stressors which prevent parents from taking infants to outpatient ROP appointments.[4]

We observed that BIO versus wide field retinal imaging as ROP screening modalities, 93.3% of the parents were highly satisfied with either modality, while 5.6% were neither satisfied nor dissatisfied with the screening and 1.1% were not satisfied with any screening modality and found it painful for the infant. We observed that, 54.4% recommended retinal imaging for ROP screening as first choice in screening modality while 45.6% recommended BIO as their preferred choice. This can be attributed to the learning curve for the examining VR surgeon for using the wide field imaging, thereby utilizing longer time in comparison to BIO. Also, acquisition of images in infants more 45 weeks of gestational age is difficult with wide field modality. It has been noted in literature that most wide field imaging devices have a distinct learning curve in using them and time for examination ranges between 2-11 minutes which is comparable to our observation.[12-14]

Another attribute to ROP screening and parents’ preference for wide field imaging can be that in our study 31.1% of parents observed BIO to be more painful for the infant in comparison to wide field imaging (20%). Similar results have been studied in literature wherein it was observed that there is less pain and stress following completion of the exam in wide field imaging in comparison to BIO.[13-15] Mehta et al., compared examination using wide field imaging with speculum and BIO with and without speculum in a series of 12 infants and observed less pain with BIO when the examination was performed without speculum, and concluded that it might be appropriate not to use a speculum in particularly ill infants.[16] It was concluded that scleral indentation was not necessary to visualize the peripheral retina in wide field imaging devices and is of paramount importance as it is significantly related to pain and stress.[13,14]

Conclusion

In conclusion, we observed in our study, that wide field imaging with Trinethra neo is a safe and well accepted technique by parents of ROP infants coming for retinal examination in outpatient department and can be an alternative to BIO for screening of ROP at primary level. We have found that good documentation greatly improves the communication with the parents concerned and thereby ensures better compliance in understanding of the disease, treatment and in future follow-up. Our limitation is small sample size and study limited to one tertiary eye care center and telemedicine for ROP screening in rural area is the need for the hour, as the biggest challenge is scarcity of trained ophthalmologist in ROP screening and ‘remote experts’ or technicians who can grade the images so as to bridge the gap and decrease the fall out in regular follow up. Given parents’ lack of knowledge about ROP, future studies should examine best practices for teaching parents about ROP and test whether these practices improve parents’ adherence to follow-up care.

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Conflicts of interest
There are no conflicts of interest.

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