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Original Research Article

Wide-Field Digital Imaging versus Binocular Indirect Ophthalmoscopy for Retinopathy of Prematurity Screening: A Prospective Observational Study

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Abstract:

Background: One of the leading causes of avoidable childhood blindness worldwide is Retinopathy of Prematurity (ROP), which disproportionately affects impoverished countries like India. Due to inconsistent neonatal treatment standards, a "third epidemic" of ROP is occurring in middle-income nations, affecting more mature newborns. Conventional screening by Binocular Indirect Ophthalmoscopy (BIO) is physiologically taxing for the newborn, subjective, and lacks permanent record.

Objective: To thoroughly assess Wide-Field Digital Imaging's (WFDI) diagnostic accuracy, documentation utility, physiological stress profile, and logistical viability in comparison to the gold standard BIO in an Eastern Indian tertiary care setting with limited resources.

Methods: Over the course of a year, this prospective, comparative observational study was carried out at the Rajendra Institute of Medical Sciences (RIMS), Ranchi's Regional Institute of Ophthalmology (RIO). An experienced ophthalmologist performed a routine BIO on a cohort of 100 preterm newborns (200 eyes) who met the screening criteria. This was followed by digital imaging utilizing a wide-field pediatric retinal camera system. Diagnostic sensitivity and specificity for referral-warranted ROP (RW-ROP) was the main result. Exam time, inter-rater reliability, and pain evaluation using the Premature Infant Pain Profile (PIPP) were secondary objectives.

Results: ROP of any stage was found in 28% of the 100 newborns who were screened. Digital imaging showed 96.4% sensitivity and 94.4% specificity in identifying ROP that requires therapy. For "Plus" illness and Aggressive Posterior ROP (AP-ROP), the system's sensitivity was 100%. Digital imaging had a considerably lower mean PIPP score (5.2 ± 1.1) than BIO (9.8 ± 1.5; $p<0.001$), suggesting less physiological stress. In 12 ambiguous cases, digital imagery also enabled remote expert judgment.

Conclusion: For ROP screening, wide-field digital imagery provides a practical, high-accuracy substitute for BIO. Its significance as a key triage tool is validated by its capacity to reduce baby suffering, offer objective documentation, and facilitate telemedicine integration, all of which solve severe staffing shortages in Eastern India.

Keywords: Retinopathy of Prematurity (ROP), Digital Imaging, Tele-ophthalmology, Binocular Indirect Ophthalmoscopy (BIO), Screening, PIPP Score.

Introduction

A vasoproliferative condition that affects premature newborns' developing retinas is called Retinopathy of Prematurity (ROP). With an estimated 50,000 children losing their sight each year, it continues to be a major cause of childhood blindness globally [1]. While severe ROP to extremely preterm newborns has mostly been limited in high-income nations, middle-income countries like India are experiencing a "third epidemic." The epidemiology of ROP is changing. Due to higher survival rates and unmonitored oxygen supplementation in growing Neonatal Intensive Care Units (NICUs), this phase is marked by the development of severe ROP in heavier and more developed newborns [2].

The estimated 3.5 million preterm births that occur in India each year put a tremendous strain on the country's healthcare system. According to the current screening criteria, all newborns weighing less than 2000 grams or born before 34 weeks of gestation must be examined [3]. However, a severe lack of qualified vitreoretinal experts, especially in areas like Jharkhand, makes it difficult to put these recommendations into practice. A doctor must be physically present at the patient's bedside for the

usual screening procedure, Binocular Indirect Ophthalmoscopy (BIO) with scleral depression. It is a method that is physically taxing for the medically vulnerable infant, challenging to learn, and subjective by nature [4]. Additionally, BIO leaves no objective record for long-term monitoring or medicolegal defense because it solely depends on the screener's handwritten notes [5].

The Technological Paradigm Shift: Pediatric ophthalmology has undergone a paradigm shift toward Wide-Field Digital Imaging (WFDI) in order to overcome these constraints. Technologies such as the RetCam (Natus Medical Inc.) and the indigenously produced 3nethra neo (Forus Health, India) provide high-resolution, 130-degree field-of-view photographs of the retina [6]. "Store-and-forward" telemedicine is made possible by these technologies, in which qualified technicians take pictures that are then evaluated by distant specialists.

Smartphone-based fundus imaging (SBFI) systems have been made possible by "frugal developments" more recently. Clinicians can now obtain retinal images at a fraction of the price of proprietary systems by connecting high-definition smartphone cameras with 20D condensing lenses through 3D-printed adapters (such as MII RetCam) [7, 8]. For culturally and economically stratified healthcare environments like India, this democratization of imaging technologies is especially pertinent.

Advances in Digital Imaging and AI: Digital imaging is useful for more than just documentation. It functions as the fundamental dataset for applications involving artificial intelligence (AI). These days, deep learning algorithms can measure vascular tortuosity and dilation ("plus illness") with accuracy that frequently outperforms human specialists [9, 10]. The boundary of ROP management is represented by this shift from subjective qualitative evaluation to objective quantitative analysis.

Study Rationale: The feasibility of this paradigm has been effectively shown in Southern India by telemedicine networks such as KIDROP (Karnataka Internet Diabetic Retinopathy of Prematurity Study) [11], but there is still a dearth of data from Eastern India. A sizable tribal and rural population uses the Regional Institute of Ophthalmology (RIO) at RIMS, Ranchi, as a tertiary referral center. The purpose of this study is to assess the "advances in digital imaging" in this particular demographic and geographic setting by closely comparing its physiological impact, operational efficiency, and diagnostic accuracy to the BIO gold standard.

Literature Review: The Evolution of ROP Screening: The evolution of ocular diagnostics, from direct visualization to digital capture and ultimately algorithmic interpretation, is reflected in the history of ROP screening.

The Limitations of the Gold Standard: For more than 50 years, Binocular Indirect Ophthalmoscopy (BIO) has been the gold standard. The stereoscopic image and the capacity to see the distant peripheral (ora serrata) through dynamic scleral depression are its main advantages. However, research has repeatedly pointed up its shortcomings. The "transient" nature of the exam was highlighted by Fielder et al. [4]. After the observer leaves the bedside, the clinical picture is only retained in memory and sketches. Significant inter-observer variability results from this subjectivity, especially when diagnosing "pre-plus" and "plus" diseases, which are crucial factors in treatment [6].

Validation of Digital Imaging: With the release of the RetCam, digital imaging was first validated. Digital pictures might accurately identify clinically significant ROP, according to the Early Treatment for Retinopathy of Prematurity (ETROP) research and further telemedicine trials. Non-physician graders may detect referral-warranted ROP with 90% sensitivity and 87% specificity, according to the multicenter e-ROP study (2014), a seminal investigation enrolling 1257 infants [12].

Similarly, throughout a six-year period, the SUNDROP (Stanford University Network for Diagnosis of Retinopathy of Prematurity) experiment revealed a sensitivity of 100% and specificity of 99.8%, effectively missing no cases of disease that required treatment [13].Over 150,000 infants in rural Karnataka have been checked by the KIDROP program in India, demonstrating that a technician-led strategy is not only accurate but also necessary for covering large geographic areas [14].

The Rise of Affordable Imaging: The RetCam's cost—roughly $100,000—remains a barrier. The creation of locally produced cameras and smartphone-based solutions has been sparked by this. Smartphone-based Fundus Imaging (SBFI) is located further down the cost spectrum. The high-resolution sensors of contemporary phones (12MP+) are used by devices such as the MII RetCam and several do-it-yourself adapters. These devices have been validated by Sengupta et al. and Sharma et al., who have noted that video-based sweeping techniques can reconstruct a sufficient montage for screening, even though they may not have the extreme wide-field of contact cameras (reaching ~45-50 degrees per frame) [15, 8].

Physiological Stress and Pain: In neonatology, "developmental care" places a strong emphasis on reducing stress. The oculocardiac reflex, which causes bradycardia and apnea, is known to be

triggered by BIO. BIO and digital imagery have been contrasted in a number of studies utilizing the Premature Infant Pain Profile (PIPP). In contrast to the tension caused by the speculum and scleral depression inherent in BIO, digital imaging has been shown by Cohen et al. and Dhaliwal et al. to be related with reduced pain levels [16, 17]. This "humane" feature of digital image is an important but sometimes disregarded benefit.

Methodology

Study Design and Setting: This prospective, comparative, double-blind observational study was carried out at the Rajendra Institute of Medical Sciences (RIMS), Ranchi's Neonatal Intensive Care Unit (NICU) and Regional Institute of Ophthalmology (RIO). The 12-month trial period ran from January 2024 until December 2024. The Institutional Ethics Committee granted ethical clearance, and all enrolled newborns' parents or legal guardians provided written informed permission.

Participants: Based on certain qualifying requirements, a total of 100 newborns (200 eyes) were enrolled. The National Neonatology Forum (NNF) standards, which require screening for all children with a gestational age (GA) of 34 weeks or fewer and a birth weight (BW) of 2000 grams or less, were used to assess inclusion. Larger or more mature infants (GA > 34 weeks or BW > 2000 grams) were also included if the attending neonatologist assessed that they had an unstable clinical course, such as prolonged oxygen therapy, sepsis, or numerous blood transfusions [3]. Infants with severe media opacities, such as dense corneal haze or hyphema, that prevented a retinal view, infants in critical instability where even slight manipulation was not advised, and infants with severe congenital ocular abnormalities were also excluded.

Study Protocol: To guarantee the best time for disease identification, screening was started at 4 weeks postnatal age or 31 weeks postmenstrual age, whichever came later.

A. **Preparation:** A typical mydriatic regimen was used to dilate the pupils. In order to do this, ocular drops containing 2.5% phenylephrine and 0.5% tropicamide were injected. Each eye received one drop, which was administered twice at intervals of ten minutes. After 40 minutes, the dilation's sufficiency was verified to guarantee a complete view of the fundus.
B. **Procedure 1: The Gold Standard (BIO):** A Heine Omega 500 Indirect Ophthalmoscope with a 20D aspheric lens was used for the examination by a skilled vitreoretinal specialist who was blind to the digital imaging data. Zones II and III were seen via scleral indentation. A standardized proforma based on the ICROP3 classification (International Classification of Retinopathy of Prematurity, Third Edition) was used to promptly record the findings [18]. Zone (I, II, III), Stage (1–5), and the existence of Plus or Pre-Plus disease were among the factors noted.
C. **Procedure 2: Digital Imaging:** A skilled ophthalmic technician used a wide-field pediatric retinal camera to perform digital imaging within 30 minutes of the BIO examination (either the 3nethra neo or RetCam Envision depending on daily availability). A coupling gel (Hypromellose 2%) was applied to the camera lens after topical anesthetic (0.5% Proparacaine) was applied. After that, the camera probe was carefully positioned on the cornea. For every eye, five standard fields were recorded: the Nasal, Temporal, Superior, Inferior, and Posterior Pole (Center). A second retina specialist who was blind to the patient's name and the BIO results rated these photos after they were saved on a secure server.
D. **Pain Assessment:** Using the Premature Infant Pain Profile (PIPP), a qualified NICU nurse evaluated the baby's pain without consulting the ophthalmology team [19]. Gestational age, behavioral state, heart rate maximum increase, oxygen saturation minimum decline, and facial expressions including brow bulge, eye squeeze, and nasolabial furrow are all assessed using the PIPP, a composite scoring system (range 0–21). Baseline (5 minutes prior to exam), BIO, Recovery (5 minutes following BIO), Digital Imaging, and Recovery (5 minutes following imaging) were the five different time points at which measurements were made.

Definitions and Analysis: Any ROP in Zone I, ROP Stage 3 in Zone II, or any Plus illness (Type 1 ROP) was considered Referral-Warranted ROP (RW-ROP). Digital imaging that detected RW-ROP and was verified by BIO was referred to as a True Positive. If digital imaging suggested RW-ROP but BIO showed non-referral illness or a normal retina, this was known as a False Positive. Digital image missing RW-ROP that was identified by BIO was referred to as a False Negative.

Data were imported into Microsoft Excel, and SPSS Version 25.0 was used for analysis. 95% Confidence Intervals were used to compute diagnostic accuracy metrics such as Sensitivity, Specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV). Inter-rater agreement was evaluated using Cohen's Kappa coefficient. The paired t-test or Wilcoxon signed-rank test were used to examine differences in PIPP scores; a p-value of less than 0.05 was considered statistically significant.

Results

Demographic Characteristics: There were 58 males and 42 females among the 100 newborns that made up the research population. The average birth weight was 1340 ± 320 grams (range 750–1950), and the average gestational age was 30.2 ± 2.4 weeks (range 26–36). Risk variables included a history of oxygen therapy (82%), sepsis (45%), and blood transfusions (30%) in a sizable section of the population.

Incidence and Spectrum of ROP: 28 infants, or 28% of the 100 infants tested, had ROP of any stage. Twelve infants had Stage 1 ROP, ten had Stage 2, four had Stage 3, and two had Aggressive Posterior ROP (AP-ROP). Eight newborns had plus illness, which was linked to Stage 2, Stage 3, or AP-ROP. This incidence rate is consistent with the national tertiary center averages reported by Jalali et al. [20].

Diagnostic Accuracy of Digital Imaging: Finding out if digital imaging might safely identify instances needing treatment or referral was the main goal. The diagnostic performance is shown in Table 1.

Table 1: Comparing the Diagnostic Effectiveness of BIO and Wide-Field Digital Imaging

Metric	Value	95% Confidence Interval (CI)
Sensitivity (for RW-ROP)	96.4%	82.3% – 99.4%
Specificity	94.4%	86.4% – 98.5%
Positive Predictive Value (PPV)	87.1%	72.0% – 95.0%
Negative Predictive Value (NPV)	98.5%	91.0% – 99.9%
Accuracy	95.0%	-
Kappa Agreement	0.88	0.76 – 0.95 (Strong Agreement)

All Plus illness and AP-ROP cases were accurately detected by the computerized method. The most important characteristic for a screening tool is its high sensitivity of 96.4%. In Zone III, where the camera's view is restricted without scleral depression, the majority of the few missed cases (False Negatives) were mild Stage 1 ROP. Nevertheless, a very high Negative Predictive Value was obtained because no instances requiring treatment were overlooked.

Physiological Stress (Pain Assessment): The PIPP scores offered strong proof of the humanistic advantages of digital imaging. During the BIO process, the mean PIPP score was 9.8 ± 1.5, which indicates moderate-to-severe discomfort. The mean score during digital imaging, on the other hand, was much lower at 5.2 ± 1.1, indicating only mild discomfort ($p < 0.001$). While the BIO group's PIPP scores were elevated (4.1 ± 0.8) throughout the recovery phase, the imaging group's recovery was also faster, with PIPP values returning to near-baseline levels (2.5 ± 0.5) after 5 minutes. Additionally, the examination took an average of 3.5 ± 1.2 minutes for digital imaging and 7.8 ± 2.1 minutes for BIO.

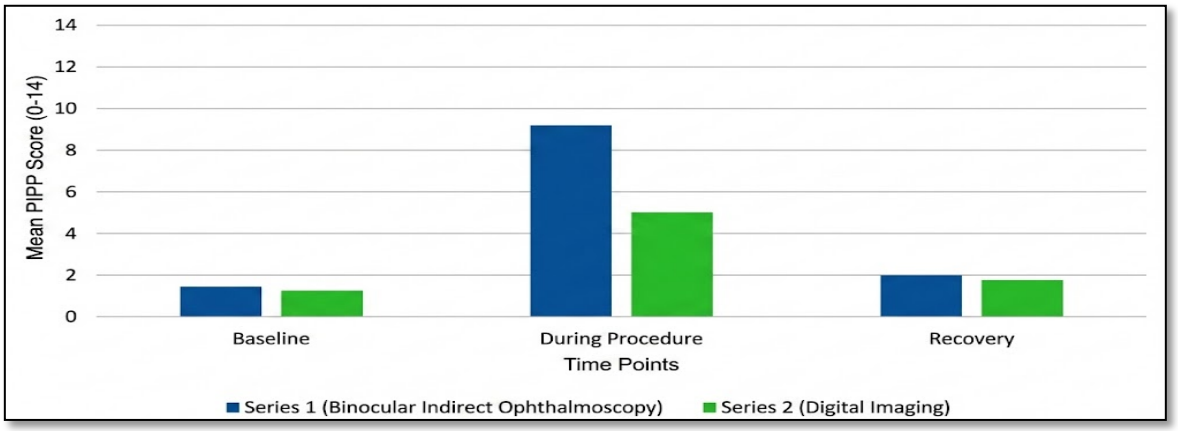

Figure 1: Comparative Analysis of Physiological Stress (Premature Infant Pain Profile - PIPP Score) and Examination Duration between Binocular Indirect Ophthalmoscopy (BIO) and Wide-Field Digital Imaging (WFDI)

Documentation and Adjudication: Twelve instances had clinical results that were initially unclear, such as differentiating between Pre-Plus and Plus illness or between immature vasculature and Stage 1 ROP. A senior consultant's "second look" on a high-resolution monitor was made possible by the availability of digital photographs, which resulted in a final agreement in every instance. In the BIO arm, where the diagnosis was based just on the initial examiner's memory and

notes, this retrospective analysis capability was lacking.

Discussion

Wide-field digital imaging should be incorporated into the regular ROP screening procedure, according to the results of this study conducted at RIO, RIMS, Ranchi. The outcomes confirm the technology's outstanding safety profile and operational value in addition to its diagnostic accuracy.

Diagnostic Integrity in a High-Volume Setting: The results of significant international studies such as e-ROP (sensitivity >90%) and SUNDROP (sensitivity 100%) are consistent with our sensitivity of 96.4% for identifying referral-warranted ROP [12, 13]. Zone III viewing continues to be the biggest drawback of digital images. Contact cameras typically have a fixed field of view, in contrast to BIO, where the ophthalmologist can dynamically compress the sclera to observe the ora serrata. Nonetheless, there is a clinical consensus—backed by Shah et al.—that severe ROP seldom appears in Zone III without prior symptoms in Zone II or the existence of Plus disease [21]. Therefore, the inability to view the far perimeter is a reasonable trade-off for the ability to objectively record Zone II and the posterior pole for screening and triage purposes. In environments with limited resources, when the alternative can be no screening at all due to a shortage of professionals, this trade-off is especially justified.

The "Third Epidemic" and Documentation: The "third epidemic" of ROP, which is characterized by larger, more mature babies experiencing severe illness, is currently raging in Eastern India [2]. Two infants in our study who were comparatively mature by Western standards had AP-ROP. In this case, digital imaging was quite helpful. Retinal detachment may result from AP-ROP in a matter of days. Counseling and cooperation with immediate laser therapy were greatly enhanced when the parents could see pictures of "Plus disease" (dilated, twisted vessels). "Seeing is believing" is an effective strategy for avoiding dropouts and guaranteeing follow-up compliance in an area with disparate health literacy skills.

Physiological Impact: A Case for Humane Care: The decrease in physiological stress is perhaps the most important discovery for the neonatologist. PIPP scores during digital imaging (5.2) were almost twice as high as those during BIO (9.8). BIO includes indentation (vagal stimulation), the speculum (mechanical pain), and strong light (photophobia). These insults are reduced by digital imaging, especially with more recent non-contact or gentle-contact probes. Reducing unpleasant stimuli in the NICU is associated with improved long-term neurodevelopmental results, according to Cohen et al. [16]. As a result, digital imaging represents a holistic advancement in neonatal care that is consistent with contemporary developmental care ideas rather than merely an optical advancement.

Telemedicine: Solving the Workforce Crisis: There is a persistent lack of vitreoretinal specialists in Jharkhand. It is just not possible for a specialist to be in every district NICU. A "Hub-and-Spoke" paradigm is validated in this investigation. Images can be taken at peripheral centers (Spokes) and sent to RIMS (Hub) by a qualified technician. In 98% of cases, technician-captured photos were of enough quality for diagnosis, according to our study. This is consistent with the KIDROP model, which has effectively expanded this strategy [11]. By putting this into practice statewide, the number of babies who require transportation to Ranchi might be significantly decreased, saving families money and relieving pressure on the tertiary facility.

Economic and Legal Implications: The cost-utility analysis supports the deployment of wide-field cameras despite their high initial capital cost. An estimated $50,000 to $100,000 in lost productivity and lifetime care expenditures are avoided for every blindness occurrence [5]. Additionally, the doctor bears the burden of proof under India's Consumer Protection Act (CPA). Handwritten BIO notes are frequently considered inadequate when parents claim malpractice following ROP-related blindness. Digital images that are time-stamped and unchangeable offer unquestionable proof of the screening that was done and the state of the disease at that particular moment [5]. For Indian practitioners, this legal protection is becoming more and more crucial.

Future Directions: The AI Revolution: This study's dataset adds to the expanding collection of Indian ROP photos. The integration of AI techniques, such as the i-ROP DL system, directly into camera software is the way of the future [9]. This would give the technician a "Red/Green" signal in real time, identifying high-risk infants right away, even before the scan is forwarded to a specialist. This capacity, which is the next step in ROP management, is presently being evaluated in multiple centers [22]. Validating these AI models against the local population dataset should be the main goal of future research at RIMS.

Conclusion

A major advancement in pediatric eye care has been made with the introduction of Wide-Field Digital Imaging for ROP screening at RIMS, Ranchi. With a 96.4% sensitivity, the study unequivocally shows that digital imaging is a safe

substitute for BIO for diagnosing diseases that require therapy. It is both operationally crucial, allowing for permanent documentation, remote diagnosis, and medicolegal safety, and physiologically superior, greatly lowering pain and stress for the premature newborn.

Digital imaging should become the norm for primary screening and triage, even while BIO is still the last confirmatory tool for treatment planning. Investing in this technology is essential for a location with limited resources, such as Eastern India, to guarantee that no child becomes blind because a specialist is unable to reach them in a timely manner.

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