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# EFFICACY OF WIDEFIELD RETINAL IMAGING VERSUS INDIRECT OPHTHALMOSCOPY IN DETECTING RETINOPATHY OF PREMATURITY: A COMPARATIVE OBSERVATIONAL STUDY.

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**Abstract:**
The primary goal of this study is to evaluate the efficacy of RetCam and binocular indirect ophthalmoscopy (BIO) as part of the screening process for retinopathy of prematurity (ROP), the leading cause of preventable blindness in newborns globally. This research will be conducted to determine whether or not these two methods are effective. The retinopathy of prematurity, often known as ROP, is a vasoproliferative condition that, if not identified and treated promptly, can lead to blindness that cannot be reversed. A single-center, double-blind, prospective diagnostic accuracy design was utilized for this research investigation, which was carried out in a tertiary neonatal critical care facility in Cuttack. 400 tests were carried out by two qualified ophthalmologists who used RetCam and BIO to examine 202 preterm infants. Within twenty-four hours after the BIO observation, the RetCam was conducted. An examiner, who wore a disguise, examined the images to determine the presence or absence of plus disease, the stage and zone of the illness, whether the patient had ROP, and whether the disease was treatable. The results showed that RetCam was beneficial for screening ROP owing to its practicality and efficacy in identifying the illness in our context, even though BIO was better at staging and grading the condition. RetCam might be considered an adjunct to BIO for routine ROP screening.

**Keywords:** Retinopathy of prematurity, binocular indirect ophthalmoscopy, widefield digital retinal photography, RETCAM.

## Introduction:

Retinal retinopathy of prematurity (ROP) is a common condition that occurs in preterm newborns and is one of the leading causes of preventable blindness in infants. Nearly 1,500 American infants get a severe case of retinopathy of prematurity (ROP) annually. Because this disease might cause blindness, medical professionals must start treating patients immediately [1]. There is a strong

correlation between the time it takes to diagnose and treat severe retinopathy of prematurity (ROP) and the likelihood and severity of severe visual impairment. As a result, the screening procedure is a vital component of the ROP management procedure [2]. However, in recent years, some challenges have made it difficult to offer proper treatment for ROP patients. The usual approach for screening for retinopathy of prematurity (ROP), known as binocular indirect ophthalmoscopy (BIO), is not guaranteed to be accurate. This is one of the most severe difficulties. Scleral depression is required for the operation known as bioelectrical stimulation (BIOS), which may result in systemic concerns such as bradycardia brought on by the oculocardiac reflex, as well as probable ocular consequences such as vitreous and subretinal hemorrhages [3, 4, 5]. Scleral depression is necessary for the procedure.

In addition to being a labor-intensive and time-consuming surgery for ophthalmologists, there is a possibility that it might be challenging for the personnel working in neonatal critical care units to carry out. This is especially true in institutions with a limited availability of ophthalmologists with expertise screening for ROP. Records of biological findings dependent on drawings made by the ophthalmologist conducting the examination are subjective and susceptible to disagreements in ROP negligence trials [6]. In addition to this, there is a lack of available personnel to fulfill the entire demand for ROP screening programs. The increased survival rate of preterm newborns, particularly in nations with middle incomes, is one factor that contributes to the growing demand [7].

The typically accepted method for diagnosing retinopathy of prematurity (ROP) involves a biological examination (BI), which is often performed by an expert ophthalmologist [8]. However, doctors with specialized training are in short supply, so keeping up with the rising demand for ROP screening could be difficult. Therefore, WFDRP (widefield digital retinal photography) has been put up as a potential substitute for ROP screening. The widefield digital retinal imaging (WFDRI) method is another technique that uses retinal imaging to examine premature infants. One of the several procedures that necessitate retina imaging, this method has seen extensive application in ROP investigation. The primary objective of this study was to assess the suitability of BIO and RETCAM for screening, staging, and grading the illness.

**Materials & methods:**

Researchers conducted a prospective, double-blind comparative study on diagnostic accuracy at the Sishubhaban (SVVPPGI) newborn intensive care hospital in Cuttack, a tertiary neonatal intensive care center. Research took place at Cuttack. All of the research was done at Cuttack. To achieve this research goal, the sample population comprised infants who were delivered preterm. A neonatal lens was used with a Retcam II to do the WFDRI, and the BIO method was also used to screen the neonates. Two experienced ophthalmologists in ROP management performed the BIO within twenty-four hours after the Retcam examination, while two senior ophthalmology residents performed the Retcam imaging. The examiners recorded their findings and care recommendations for the 400 examinations conducted on 202 premature newborns. The seasoned ophthalmologists conducted a biomechanical examination (BI) using a 28D condensing lens to record the fundus results. A mixture of 2.5% phenylephrine and 0.5% tropicamide was used to dilate the pupils from the pupils. Using a wide field digital camera (RetCam II; Clarity Medical Systems, Pleasanton, California, USA) that allowed a field of view of 130 degrees post pupillary dilatation, senior ophthalmology residents who had undergone training performed WFDRP. This treatment followed the standard BIO within twenty-four hours. We took five pictures of each baby's eye to get the most retina possible. Located in the front, back, upper, and lower parts of the eye, these pictures were focused on the macula. The photos were sent to a site that demanded a secure connection after all identifying information was stripped and saved in separate files. By combining scleral depression with the BIO instrument, a vitreoretinal surgeon was able to do a thorough assessment of the fundus all in one appointment. Following this, a masked examiner—an ophthalmologist with experience in ROP care—evaluated the RetCam images. The presence or absence of ROP, the stage and zone of the illness, and the presence or absence of plus disease were all determined by reviewing the

pictures. Results from the BIO technique were compared with this data to determine the sensitivity and specificity of the RetCam approach.

Each baby's post-conceptional age, birth weight, and gestational age were documented throughout the examination. How much the infant weighed was also recorded. Furthermore, the mother's age was factored in. Furthermore, data on the presence or absence of reactive oxygen species (ROS), plus illness, stage, zone, and total clock hours, were retrieved from both the clinical record and the RetCam sessions. Next, the data was tabulated and compared using the two administered research procedures. A clinical trial was conducted to determine the specificity and sensitivity of the RetCam. In this analysis, the BIO was used as the gold standard.

**Results**

In all, 202 infants were enrolled in the study as part of the research. A total of 104 female and 98 male babies were studied. In the study, 74 babies were given room air to breathe, 40 babies were given nasal prong oxygen, and 86 babies were given continuous positive airway pressure with oxygen through the nose. Results showed that they were born at an average weight of 1568.42 grams (ranging from 860 to 1922 grams) and an average gestational age of 31.22 weeks (ranging from 27 to 36 weeks). The initial RetCam test reported a mean PCA of 34.23 weeks, ranging from 32.1 to 43 weeks. In the most recent RetCam assessment, the average PCA was 37.16 weeks, ranging from 32.6 to 45 weeks. At the end of the procedure, each eye received an average of five images. The examination made use of 18 eyeballs collected from 12 infants. A total of 74 exams revealed ROP in the BIO examination. On 296 occasions, the RetCam test revealed the presence of ROP. Using Retcam, there were 8 false-negative exams and 3 false-positive examinations. Based on the confidence interval of 96%, the sensitivity of RetCam was found to be 89.04%. The specificity was found to be 84.21% (Table 1).

**Table 1:** Comparison between observation by BIO and RETCAM with interpretation.

| Observation made by BIO | No. of cases out of 400 | Interpretation made by residents out of RETCAM | | Correct interpretation In % by RETCAM | Incorrect interpretation In % by RETCAM |
|---|---|---|---|---|---|
| Zone -1 immature | 20 | 16 | ZONE -1 immature | 80% | 20% |
| | | 4 | Early A-ROP | | |
| Zone -2 immature | 88 | 80 | ZONE-2 Immature | 90.9% | 09% |
| | | 08 | Early A-ROP | | |
| Zone -3 immature | 12 | 12 | Zone-3 immature | 100% | 0 |
| Stage-1 | 67 | 44 | Stage-1 | 81.96% | 18.03% |
| | | 11 | Incomplete vascularisation | | |
| Stage-2 | 76 | 59 | Stage-2 | 77.63% | 22.36% |
| | | 17 | Stage-1 | | |
| Stage-3 | 103 | 109 | Stage-3 | 96.11% | 3.88% |
| | | 04 | Stage-2 | | |
| A-ROP | 40 | 36 | A-ROP | 90% | 10% |
| | | 04 | Zone-1 immature | | |
| PLUS Dilatation | 140 | 162 | Plus | 94.28% | 5.71% |
| | | 08 | Pre-plus | | |
| Pre-plus dilatation | 48 | 20 | Pre-plus | 41.66% | 58.33% |
| | | 28 | No plus | | |

A comparison of the observations made by BIO and RETCAM, together with their interpretations, is shown in Table 2 for a total of 400 instances. RETCAM obtained results similar to those obtained by BIO. On the other hand, a more severe illness was identified by BIO in the case of stage 3, in addition to an abnormal A-ROP. However, BIO detected the illness earlier (stage 1, stage 2, and pre-plus dilatation).

**Table 2:** Clinical and RetCam examination findings

| Clinical examination | | | |
|---|---|---|---|
| RetCam examination | Positive | Negative | Total |
| Positive | 284 | 12 | 296 |
| Negative | 34 | 70 | 104 |
| Total examinations | 318 | 82 | 400 |

**Table 3:** Showing similarity in diagnosis by RETCAM and BIO.

| Total cases done | | Similarity in Diagnosis | Difference in Diagnosis |
|---|---|---|---|
| Bio | RetCam | | |
| 400 | 400 | 78 % | 63% |
| | | < 0.05 | < 0.05 |

**Table 4:** Showing which technique was picked earlier.

| Parameter | BIO picked earlier | Retcam earlier | Total Cases |
|---|---|---|---|
| Stage 1 | 61 | 67 | 128 |
| Stage 2 | 76 | 63 | 139 |
| Stage 3 | 103 | 99 | 202 |
| Pre-plus | 48 | 28 | 76 |
| Plus | 140 | 132 | 272 |
| A-ROP | 40 | 48 | 88 |

## Discussion

Preterm newborns in the Neonatal Extensive Care Unit (NICU) undergo extensive screening as the only way to diagnose Retinopathy of Prematurity (ROP). A skilled ophthalmologist will examine the juvenile retina using bioimmunophotometry (BIO) and scleral depression as part of the detection process. This examination might take a long time for the ophthalmologist and cannot be exceptionally comforting for babies. Collaboration between the ophthalmologist and the newborn intensive care unit (NICU) is also necessary to manage the timetable. Hand sketching is the only technique that can accurately depict the premature retina's state accurately. It would be great to have a screening technique that is not too invasive, that staff members in the newborn intensive care unit (NICU) may use whenever they choose, and that can promptly record any abnormalities in an infant's retina. A test's minimal sensitivity and specificity requirements for replacing the gold standard (BIO) in clinical medicine to diagnose the disease are 80% and 90%, respectively [10, 11].
According to our research, RetCam has a sensitivity of 85.71% and a specificity of 91.66%. These numbers agree with what Roth found in his earlier research [12]. Positive predictive values (PPVs) reached 96.43%, and negative predictive values (NPVs) reached 70.97%. The results corroborate those of the study conducted by Roth [12]. According to Takase et al. [13], the threshold ROP had a PPV of 100%, while the high-risk pre-threshold ROP had an NPV of 100%. This finding agrees with previous research. ROP's early and late stages were investigated in a separate trial that separated the screening into two postnatal age groups. These investigations occurred at the same time. The study found that diagnosing ROP has a sensitivity of 100% and a specificity of 76%. Additionally, about the detection of threshold ROP, both were perfect. The research conducted by Martínez-Castellanos et al. [14] and Schwartz [15] did not overlook any instances of threshold ROP.
Nine times, RetCam, an imaging technique, could not identify cases of ROP (Retinopathy of Prematurity) in infants. Most of these missed cases were in zone 3, although a small number were in outer zone 2, both of which were in stages 1 or 2. All of these circumstances eventually regressed without any intervention. Even if there is a low chance of complications, they are nonetheless possible [16]. Conversely, RetCam demonstrated high efficacy in detecting and logging ROP concerning the posterior location. Telemedicine, which is growing increasingly common in clinical

settings, has also helped the area of ophthalmology [15, 17]. RetCam is a revolutionary device that allows Neonatal Intensive Care Unit (NICU) staff members to take digital images and transmit them to specialized centers for professional evaluation. This flexible technology may benefit the ophthalmology department and the neonatal intensive care unit (NICU). We are the first to assess RetCam's use in this study at our institution. Even if RetCam might be used instead of BIO for ROP screening, BIO is still the most crucial diagnostic tool for examining children's eyes. The Biomedical Imaging (BIO) approach has several significant limitations, including its touch examination method, incompatibility with the tiny palpebral fissure in preterm babies, and high cost, especially in less developed countries like India.

There are several limitations to our research, the two most significant of which are the limited sample size and the lack of information on the duration of each retinal test we performed. However, our organizational efforts will mainly focus on certifying neonatal nurses to interpret retinal photographs. We need to determine how well our results can be repeated in different contexts to offer guidance for clinical practice.

**Conclusion:**

BOI has shown that it is superior to RetCam in staging and grading Retinopathy of Prematurity (ROP). This is even though RetCam is beneficial in screening patients and has shown that it is feasible and effective in our environment for diagnosing ROP. On the other hand, it is now advised that RetCam be implemented in routine ROP screening as a complement to BOI rather than as a replacement for BOI.

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