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RELIABILITY AND ACCURACY OF EPICAM M AND RETCAM SHUTTLE COMPARED TO INDIRECT OPHTHALMOSCOPE IN DETECTION OF RETINOPATHY OF PREMATURITY

Meiliaty A Angky[1], Marliyanti N Akib[2], Noor Syamsu[2], Andi Muhammad Ichsan[2], Habibah S Muhiddin[2], Ema Alasiry[3]

[1] *Department of Ophthalmology, Bosowa University, Makassar, South Sulawesi, Indonesia;*
[2] *Department of Ophthalmology, Hasanuddin University, Makassar, South Sulawesi, Indonesia;*
[3] *Department of Paediatric, Hasanuddin University, Makassar, South Sulawesi, Indonesia*

Abstract

Introduction: In this study, we reported the performance of 2 retinal camera types on premature infants in Retinopathy of Prematurity (ROP) screening.

Methods: Premature infants went through : (1) examination by a pediatric ophthalmologist using indirect ophthalmoscopy as a standard of reference; (2) digital imaging by a photographer using EpiCam M and RetCam shuttle. After a month, images were interpreted randomly and single-blinded by the same pediatric ophthalmologist (grader).

Result: A total of 44 eyes from 22 premature infants were included in this study (ROP 11 subjects and non-ROP 11 subjects). Detection of ROP with EpiCam M had a moderate agreement (Kappa 0.502, p 0.009) and very good agreement with RetCam shuttle (Kappa 0.862, p <0.0001). Sensitivity, specificity, and accuracy of EpiCam M in detection of ROP were 80.95%, 69.56%, and 75%; RetCam shuttle 85.71%, 100%, and 93.18% respectively.

Conclusion: Both EpiCam M and RetCam shuttle displayed significant agreement with indirect ophthalmoscope in detecting ROP. EpiCam M can potentially be allowed to be a viable low-cost alternative device for ROP screening in low resource environments but should be noted that EpiCam M has a high false positive rate which affects its specificity and accuracy rate. Some issues also need to be considered if using epiCam M in telemedicine includes frequent glare and longer duration of documentation

Keywords: Retinopathy of prematurity, screening, Sensitivity and Specificity, telemedicine

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Correspondence to:
Meiliaty Ariesta Angky, Departement of Ophthalmology, Bosowa University,
Meiliatyangky@gmail.com

INTRODUCTION

Retinopathy of Prematurity was first introduced by Terry in 1942 as retrolental fibroplasia, which was associated with premature birth and low birth weight. [1] Ten years later, ROP became a major problem for ophthalmologists because of the effects of irreversible blindness.[2,3] The incidence of ROP continued to rise along with an increase in life expectancy among premature babies.[4] To reduce the risk of irreversible blindness, an efficient and timely retinal examination by an ophthalmologist is essential. The purpose of an effective screening program is to identify premature infants at risk who need ROP treatment to prevent blindness sequelae. A prompt examination followed by an accurate diagnosis as well as timely handling will have a major impact on the infants' vision.[5] The standard diagnostic tool for ROP is by using indirect ophthalmoscope examination but there is a major obstacle in limited expertise. These constraints encourage the development of other diagnostic tools that can simplify ROP diagnosis, especially with fundus photography systems using the concept of telemedicine. Some of the tools that are currently available will hopefully allow fundus photography to be performed even by non-physicians and make the diagnosis of ROP easier even in the absence of experts. RetCam shuttle has consistently shown satisfying performance, but the sensitivity ranges are varied between 68-100%, therefore re-examined should be done to its performance.

METHODS

The research was conducted from June to September 2019 in Wahidin Sudirohusodo Hospital's special care nursery. This research has obtained ethical permission from the Ethics Committee of the Faculty of Medicine, Universitas Hasanuddin, Makassar, Indonesia (No. 391/UN4.6.5.31/PP36/2019) prior to the start of the research.

Patients

National screening guideline for ROP were used at this institution including infants with gestational age (GA) less than 32 weeks or older, birth weight (BW) less than 1500 grams and heavier babies with higher risk for ROP as determined by the attending neonatologist.[6] Infants were excluded from this study if they had unstable general conditions, major ocular anomalies or severe media opacities.

Examination Techniques

The The infants' pupils were dilated with one drop of 0.5% tropidamide (Mydriatil, PT Cendo Pharmaceutical Industries, Indonesia) and one drop of 2.5% phenilephedrine (Efrisel, PT Cendo Pharmaceutical Industries, Indonesia) every five minutes for three doses at least 30 minutes prior to examination. Topical tetracaine 0.5% (Pantocain, PT Cendo Pharmaceutical Industries, Indonesia) was also applied and an eyelid speculum was inserted.

Indirect ophthalmoscopy with a 28-D lens and scleral depression was performed by a pediatric ophthalmologist (M.N.A). The presence or absence of ROP and plus disease was recorded. If ROP was present, the zone, stage, and extent of ROP were also recorded. The Eyelid speculum was released and the patient was placed back into an incubator or infant warmer for 10 minutes. In the next following 10 minutes, digital images were taken with the RetCam shuttle Digital Retinal Camera (Massie Research Laboratories Inc., Pleasanton, CA) using the 130° ROP lens and then EpiCam M handheld retinal camera (Epipole Ltd, Fife, UK) 10 minutes apart. The duration of documentation was also recorded.

RetCam shuttle and EpiCam M documentations were performed by a senior ophthalmology resident (M.A.A). A series of photographs and videos were taken using RetCam shuttle and EpiCam M respectively.

They were then stored in the hard drive of the RetCam machine and EpiCam's attached Laptop. The fundus documentations of EpiCam M were saved in video format and then captured and converted as images.

Reading of Digitized Images

RetCam shuttle images were transferred via a USB to another computer. EpiCam M videos were captured into images. All images were interpreted randomly by the same pediatric ophthalmologist - MNA (grader) one month after documentation. Images were viewed from the computer by a grader. Identifying patients' datas were hidden from these images such as the patients' GA, BW, race, sex, birth multiplicity, and current post conception GA (CGA). The reader examined the images for any pathological sign including immature retina, tortuosity, and dilatation of vessels, neovascularization, demarcation line, ridge, extraretinal fibro vascularization, partial and total retinal detachment, and then concluded the eyes as ROP or non ROP. If ROP was present, the stage was also recorded. We did not compare exact examination findings number of clock hours.

Statistical analysis

Data were analyzed using SPSS version 25 (IBM Corp., USA). The diagnostic accuracy and reliability that consisted of sensitivity and specificity were calculated. Agreement between the interpretation of indirect ophthalmoscope, EpiCam M, and RetCam shuttle were evaluated. The level of agreement between each method of examinations was reported as Cohen's kappa. The differences were considered significant when the p-value <0.05.

RESULT

ROP screenings were performed on a total of 44 eyes from 22 infants. GA ranges from 27 to 33 weeks with a mean GA of 31±2.14 weeks in ROP subjects and 26 to 36 weeks with a mean GA of 32,91±2,67 weeks in non-ROP subjects. BW ranges from 1060-1500 gram with a mean weight of 1316.36 ± 157.46 gram in ROP subjects and 1200-2230 gram with a mean weight of 1713.36 ± 301.56 gram in non-ROP subjects. Mean gestational age are significantly different between the 2 groups (p 0.004).

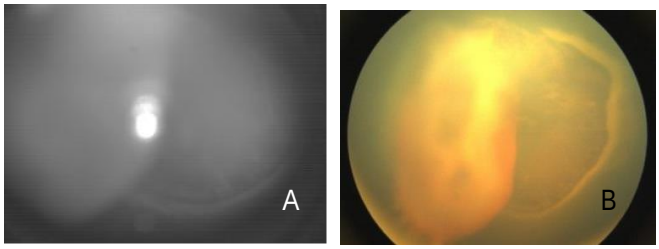

Figure 1. RetCam shuttle and epiCam M fundus photography in a patient with retinal detachment (stage 4 a). A) EpiCam M fundus photography. B) RetCam shuttle fundus photography. Grader has difficulty interpreting ablatio with EpiCam M fundus photography. The image showing hemorrhage and retinal detachment is more obvious on RetCam shuttle fundus photography and can be interpreted as stage 4 a retinal detachment by the grader.

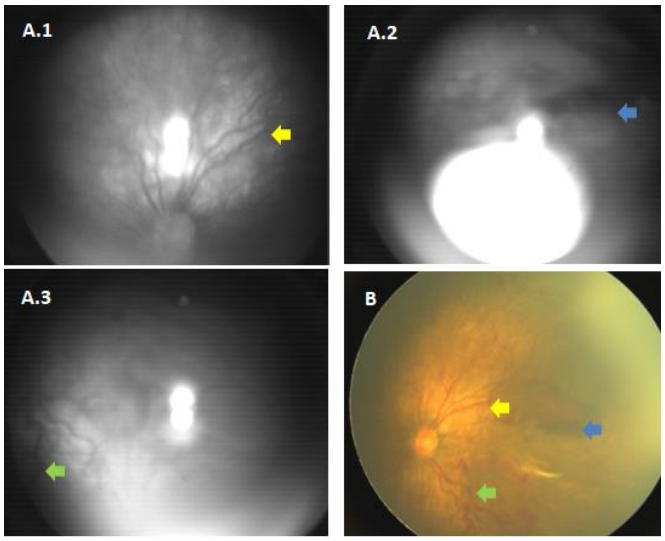

Figure 2. EpiCam M and RetCam shuttle fundus photography in a patient with APROP. A1-3) EpiCam M fundus photography. B) RetCam shuttle fundus photography. Note frequent glare with epiCam M

Neither EpiCam M nor RetCam shuttle imaging had to be aborted due to patient displaying distress symptoms. The mean duration of fundus documentation in EpiCam M is 286.54 seconds and RetCam shuttle 195.45 seconds for each eye (p 0.015). Subsequently, all the digital imaging of all

cases were adequate for ROP evaluations except in 3 cases with retinal detachment which the digital imaging were taken with EpiCam M (figure 1A, B)

Table 1. Cross Tabulation of ROP detection with EpiCam M and Retcam Shuttle Compared to Indirect Ophthalmoscope

			Indirect Ophthalmoscope			κ (p value)
			Non ROP	ROP	Total	
EpiCam M (n =44)	Non ROP	n	16	4	20	0.502 (0.009)
		%	36.4%	9.1%	45.5%	
	ROP	n	7	17	24	
		%	15.9%	38.6 %	58.5%	
	Total	n	23	21	44	
		%	52.3%	47.7 %	100%	
RetCam shuttle (n=44)	Non ROP	n	23	3	26	0.862 (<0.001)
		%	52.3%	6.8%	59.1%	
	ROP	n	0	18	18	
		%	0%	43.9 %	43.9%	
	Total	n	23	21	44	
		%	52.3%	47.7 %	100%	

Table 2. Sensitivity. Specificity. and Accuracy of ROP detection with EpiCam M and Retcam Shuttle Compared to Indirect Ophthalmoscope

	Sensitivity	Specificity	Accuracy
EpiCam M	80.95%	69.56%	75%
RetCam shuttle	85.71%	100%	93.18 %

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Detection of ROP with EpiCam M had moderate agreement (p 0.502, p 0.009) and RetCam shuttle had very good agreement (p 0.862, p <0.001) (table 1). Sensitivity, specificity, and accuracy in detection of ROP with EpiCam M and RetCam shuttle were 80.95%, 69.56%, 75% and 85.71%, 100%, 93.18% respectively (table 2).

In the epiCam M analysis. there are stage misinterpretations in 34% of the eyes (15/44). Our study found 1 eye with stage 2 ROP which is interpreted as non-ROP because the ridge occurs in the peripheral zone 2 and was not captured by the device. There were 14 eyes that were categorized as "ungradable" for stage but can still be recognized as ROP due to abnormalities of blood vessels in the posterior pole and unusual presentation of the normal fundus. There were 3 eyes with a retinal detachment that were difficult to recognize and can only be interpreted as a white shadow by grader.

In the RetCam shuttle interpretations, there were stage misinterpretations in 15% of the eyes (7/44). There were 3 eyes with ROP that were interpreted as non-ROP because abnormalities occur in peripheral zone 2 and were not captured by the device. There were 4 eyes that were categorized as ungradable for stage but still can be recognized as ROP due to abnormalities of blood vessels in posterior polus and unusual presentation of normal fundus. Eyes with retinal detachment that were difficult to recognize with epiCam M. can be recognized easily with RetCam shuttle

In comparison to RetCam shuttle, epiCam M has more limitations in documenting the peripheral zone with only 36 eyes that could be identified up to zone 2 peripherally. In addition, we also did a comparison between the mean duration of fundus documentation using epiCam M and RetCam shuttle of 286.54 seconds and 195.45 seconds respectively with a significant statistical difference (p 0.015).

DISCUSSION

RetCam shuttle has consistently shown satisfying sensitivity and specificity for detecting ROP in previous studies. The sensitivity ranges reported were 68-100% and specificity 99-100%. [7-10] Satisfactory results were also reported in studies with the application of telemedicine systems using RetCam shuttle with 100% sensitivity and 97.9%

specificity.[11,12] Research on the sensitivity and specificity of epiCam M in the diagnosis of ROP has not been previously reported and this is the first study that reports EpiCam M performance in ROP screening.

In this study. the sensitivity rate of fundus photography interpretation in detecting ROP with epiCam M is 80.95% and RetCam shuttle is 85.71%. The sensitivity on epiCam M and RetCam shuttle showed low false-negative numbers. This means both devices show good performances in detecting ROP cases so both can be used as alternatives in ROP screening in the absence of an expert, even though they cannot replace indirect ophthalmoscopes because of their limitations in capturing peripheral areas.

The specificity of fundus photography interpretation in detecting ROP with epiCam M is 69.56% and RetCam shuttle is 100% which is higher than epiCam M. Higher false positive number on epiCam M means that the detection of ROP by this device has a greater likelihood of false interpretation than RetCam shuttle. Therefore, ROP cases that are referred by epiCam M need to be analyzed further compared to results from RetCam shuttle. However, both devices showed satisfying agreement in detecting ROP with a higher agreement in RetCam Shuttle.

Previous studies have shown that ROP in peripheral zone 2 or 3 were often missed in RetCam evaluations. We also found limitations in documentation in both zone 2 anterior and 3 in both devices. In comparison to RetCam shuttle, epiCam M showed more limitations in documentation of the peripheral zone where only 36 eyes could be captured up to zone 2 peripheral while both devices cannot capture zone 3. All of the stage misinterpretation cases in both devices were caused by the documentation limitation of zone 2 peripherals. Roth et al (2001) reported that any type of fundus photography displayed limitations in the detection of zone 3 abnormalities in infants due to the presence of a speculum in the eye which prevented images from being captured by the device. [13]

The mean duration of fundus documentation between RetCam shuttle and epiCam M showed a significant statistical difference (p 0.015). In epiCam M, we encountered a difficulty that was caused by the absence of a contact lens system which increased complication in fixating the eye during documentation and as a result, caused frequent glare in the documentation process using epiCam M (figure 2). The absence of a foot pedal feature also makes documentation more difficult with epiCam M. The fundus documentation was first saved in video format and then captured and converted as an image. Therefore, these additional steps need to be considered if using epiCam M in telecommunication systems because converting video to image will take additional time.

The limitation of this study is that fundus photography does not follow the photography standards set by the Fundus Photograph Reading Center, namely the 7 fields with a radius of 35 mm so that photography is only carried out as much as possible until the photographer can conclude it can be interpreted properly. However. Chiang et al (2006) stated that taking fundus photography according to these standards in premature babies is very difficult even for professional photographers.[9] There is also a high chance of grader bias since the grader is the same person who performing fundus examination by indirect ophthalmoscopy. The bias was minimized by giving 1 month gap between image documentation and interpretation.

CONCLUSION

Both EpiCam M and RetCam shuttle displayed significant agreement with indirect ophthalmoscope in detecting ROP. EpiCam M can potentially be allowed to be a viable low-cost alternative device for ROP screening in low resource environments but should be noted that EpiCam M has a high false

positive rate which affects its specificity and accuracy rate. Some issues also need to be considered if using epiCam M in telemedicine includes frequent glare and longer duration of documentation

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