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Utility Of A Smartphone In Assessment Of Retinal Manifestations In Patients With Diabetes Mellitus In Chengalpattu District

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ABSTRACT

Aim:The aim of the study is to assess the sensitivity and specificity of smartphone-based fundus imaging as a screening tool for the detection and grading of diabetic retinopathy (DR), in comparison to the standard digital retinal photography.

MethodsA total of 144 individuals (288 eyes) with type 2 diabetes underwent standard seven-field digital fundus imaging using both a Canon fundus camera and the indigenous smartphone-based fundus imaging at a tertiary care center in South India. Diabetic retinopathy (DR) grading was independently conducted employing the modified Early Treatment Diabetic Retinopathy Study (ETDRS) classification system. Sight-threatening diabetic retinopathy (STDR) was defined as the presence of either proliferative DR (PDR) or diabetic macular edema (DME). Sensitivity, specificity, and image quality of the imaging modalities were evaluated.

ResultsThe mean age of the participants was 53.5 ±9.6 years and mean duration of diabetes 12.5±7.3 years. The Fundus camera showed that 43.9% had non-proliferative DR(NPDR) and 15.3% had PDR while the smartphone-based fundus imaging showed that 40.2% had NPDR and 15.3% had PDR. The sensitivity and specificity for detecting any DR by smartphone-based fundus imaging was 92.7% (95%CI 87.8–96.1) and 98.4% (95%CI 94.3–99.8) respectively and the kappa (κ) agreement was 0.90 (95%CI-0.85–0.95 p<0.001) while for STDR, the sensitivity was 87.9% (95%CI 83.2–92.9), specificity 94.9% (95%CI 89.7–98.2) and κ agreement was 0.80 (95%CI 0.71–0.89 p<0.001), compared to conventional photography.

Conclusion: Smartphone-based fundus imaging is effective for screening and diagnosis of DR and STDR with high sensitivity and specificity and has substantial agreement with conventional retinal photography..

1. INTRODUCTION

Diabetic retinopathy is a micro-vascular complication of diabetes that contributes to major ocular morbidity and preventable blindness[1]. Diabetes mellitus is a global epidemic, with India having the second-highest population of diabetics worldwide[2]. The World Health Organization (WHO) estimates 101 million people will be affected in India by 2030[3]. The prevalence of DR in India is 16.9%, and the disease's magnitude is expected to increase exponentially in the coming years.

The value of screening for diabetic retinopathy (DR) is well established as majority of the patients who develop DR have no symptoms until visual impairment occurs due to the sight threatening stages of DR namely severe diabetic macular edema (DME) and/or proliferative diabetic retinopathy (PDR) [4,5]. DR has a fairly long asymptomatic stage, during which, it can be easily identified by fundus examination or retinal photography.

Mydriatic seven-field stereoscopic color fundus photography, as established by the Early Treatment Diabetic Retinopathy Study (ETDRS), remains the gold standard for diabetic retinopathy (DR) screening [6]. However, digital retinal imaging and nonmydriatic fundus photography [7] have emerged as more feasible alternatives for screening individuals with diabetes. Major barriers to large-scale screening efforts include the limited availability of ophthalmologists, retina specialists, and trained eye care personnel, as well as the high cost and limited accessibility of conventional fundus cameras [8-10].

This study employs a novel, locally developed, compact smartphone-based device for capturing retinal color photographs, designed for use in both clinical settings and tele-ophthalmology applications for diabetic retinopathy (DR) screening.

The aim of this paper is to validate the performance of smartphone-based fundus imaging by comparing it with conventional seven-field digital fundus photography obtained using a high-end fundus camera, in terms of its ability to screen for DR and assess its severity

2. METHODS

One hundred and Forty four consecutive known diabetic patients with varying duration of diabetes were referred from rural health camps to the Eye Department of a tertiary care hospital in Chengalpattu district in southern India to participate in this prospective instrument validation study. The sample size for this study was calculated based on a pilot study conducted with 50 patients for assessing the sensitivity and specificity of Smartphone-based fundus imaging, to detect DR. The inclusion criteria for patients were age more than 18 years, type 2 diabetes, no contraindication to mydriasis, no allergy to tropicamide eye drops and willingness to undergo mydriatic retinal colour photography with two fundus cameras. A written informed consent was obtained from all the participants and the study was conducted over a period of 4 months (Feb 2025 to May 2025) after the approval of the Institutional Ethics Committee.

All participants underwent a comprehensive ophthalmic evaluation. The initial assessment included measurement of visual acuity using an illuminated Snellen chart, intraocular pressure measurement via non-contact tonometry, and slit-lamp examination of the anterior segment to evaluate anterior chamber depth and detect any media opacities, such as cataracts. Pupillary dilation was achieved using tropicamide eye drops.

Following pupillary dilation, participants first underwent retinal color imaging using the smartphone-based fundus imaging with a smartphone with camera of 12 Megapixels with an aperture of $f/1.6$ and video recording in 1080p at 30 or 60 fps and Volk +20D double aspherical lens[Fig 1]. The fields captured with the smartphone camera included the macula, optic disc, the nasal region adjacent to the disc, as well as the superior-temporal and inferior-temporal quadrants[Fig 2].

Subsequently, mydriatic seven-field digital color fundus photography using Canon Digital Retinal Camera (CF-1) was captured. The seven standard ETDRS fields included images of the macula, optic disc, superior-temporal, superior-nasal, inferior-nasal, inferior-temporal and temporal macular regions of each eye. The sensor resolution is governed by the smartphone which has a 45 degree field of view, a 33 mm working distance and an optical magnification of 5X. Traditional fundus cameras operate using a xenon flash, the illumination on smartphone uses a warm-white LED that has a life of more than 50,000 hrs. However the device does not have a mechanical tilt, as is typically available in the Canon Digital Retinal Camera. The auto-focus of the camera app, allows for sharp images of the retina to be taken, using the smartphone's touch interface.

Grading of diabetic retinopathy (DR) was carried out according to the modified Early Treatment Diabetic Retinopathy Study (ETDRS) classification system. The presence of at least one definite microaneurysm in any retinal field was considered the minimum criterion for diagnosing DR [7]. Each eye was graded independently, and a retinopathy level was assigned based on the photographic findings. The final diagnosis for each patient was based on the eye with the more advanced stage of DR, as per the ETDRS scale (Level 10: no retinopathy; Levels 20–53: non-proliferative diabetic retinopathy [NPDR]; Level ≥60: proliferative diabetic retinopathy [PDR]) [11].

Diabetic macular edema (DME) was defined as the presence of distinct hard exudates within one disc diameter of the foveal center [12]. DME can occur at any stage of DR, including both NPDR and PDR. Sight-threatening diabetic retinopathy (STDR) was defined as the presence of PDR or clinically significant DME in one or both eyes.

Image Quality Assessment

Photographs captured using both imaging systems were evaluated based on a five-point grading scale: Grade 0 – Ungradable: No discernible retinal detail due to significant media opacities, such as dense cataracts or total vitreous hemorrhage. Grade 1 – Poor: Only coarse retinal features were visible; larger lesions such as blot hemorrhages and prominent hard exudates could be identified. Grade 2 – Average: Major retinopathy features were visible, though finer abnormalities—such as microaneurysms, intraretinal microvascular abnormalities (IRMA), or subtle neovascularization—were not clearly distinguishable. Grade 3 – Good: Retinal details were reasonably clear, allowing detection of most retinopathy-related changes. Grade 4 – Excellent: All retinal structures and lesions associated with retinopathy were distinctly visible.

Statistical Analysis

All statistical analyses were conducted using SPSS software version 30.0. Continuous variables are presented as mean ± standard deviation, while categorical variables are expressed as proportions. The sensitivity and specificity of the smartphone-based fundus imaging system for detecting diabetic retinopathy (DR) and assessing its severity were calculated using the dilated 7-field fundus photography obtained with a Canon Digital Retinal Camera as the reference standard. Agreement between the smartphone-based imaging system and the gold standard Canon fundus photography was evaluated using Cohen's kappa (κ) statistic. A p-value of <0.05 was considered statistically significant.

3. RESULTS

A total of 144 patients with diabetes (288 eyes) completed retinal imaging using both methods. Among them, 93 (64.5%) were male. The participants had a mean age of 53.5 ± 9.6 years (ranging from 20 to 77 years), and the average duration of diabetes was 12.5 ± 7.3 years (with a range from 1 day to 34.6 years). All 288 retinal images were gradable, with no ungradable images observed.

The overall prevalence of diabetic retinopathy (DR) based on retinal photography was 59.1% with the Canon fundus camera and 55.5% with the smartphone-based fundus imaging system. DR detection was consistent in 84 out of 91 patients (92.3%). Conventional fundus photography revealed that 43.9% of patients had non-proliferative DR (NPDR) and 15.3% had

proliferative DR (PDR), whereas the smartphone-based imaging showed 40.2% with NPDR and 15.3% with PDR. Comparison of Retinal Imaging Using Smartphone-Based Fundus Imaging and Canon Fundus Camera is summarized in Table 1. Diabetic macular edema (DME) was identified in 39 patients (27.2%) based on grading from both cameras, with agreement observed in 34 of these patients (87.2%). Figure 3 illustrates retinal images of varying DR severity obtained using the smartphone-based system and the Canon fundus camera[Fig 3].

The sensitivity and specificity of the smartphone-based fundus imaging system for detecting any diabetic retinopathy (DR) and its varying severities, compared to the Canon fundus camera, along with the level of agreement between the two devices, are presented in Table 2. The agreement between the smartphone-based system and the Canon digital retinal camera for detecting any DR was excellent, with a kappa (κ) value of 0.90 (95% CI: 0.85–0.95, $p < 0.001$). Similarly, the κ values indicated very good agreement across the NPDR, PDR, diabetic macular edema (DME), and sight-threatening DR (STDR) categories.

The image quality of retinal photographs captured by both the Canon digital retinal camera and the smartphone-based fundus imaging system was evaluated and graded by retina specialists. None of the images from either device were ungradable (grade 0). For the Canon camera, 34.9% of images were rated as average (grade 2), 53.5% as good (grade 3), and 7.6% as excellent (grade 4). In contrast, images from the smartphone-based system were graded as average in 66.8%, good in 17.9%, and excellent in 4% of cases. Overall, the image quality obtained with the Canon digital retinal camera was superior to that of the smartphone-based system.

4. DISCUSSION

Screening for diabetic retinopathy (DR) is highly cost-effective, as early detection allows for timely treatment options that can preserve vision and reduce the risk of visual impairment. Retinal color photography offers the advantage of rapid image acquisition, along with easier storage and transmission of images. There is a pressing need for an affordable and sensitive retinal imaging system to facilitate regular DR screening, especially in middle- and low-income countries. The effectiveness of any screening method is measured by its sensitivity and specificity.

In this study, the smartphone-based fundus imaging system demonstrated high sensitivity and specificity for detecting any DR (92.7% and 98.4%, respectively) and sight-threatening DR (STDR) (87.9% and 94.9%, respectively). A recent study by Russo et al. [13], which compared smartphone photography using an adapter (D-Eye) with slit-lamp biomicroscopy for DR grading, reported a kappa agreement of 0.78. Our study showed a similar kappa agreement for any Diabetic Retinopathy. The agreement for diabetic macular edema (DME) in both studies was comparable. The use of mydriatic fundus photography, which yields relatively high-quality images, may partly explain the high sensitivity, specificity, and substantial agreement observed between the imaging systems in this study.

Nonmydriatic photography has been widely used as a practical alternative for diabetic retinopathy (DR) screening, particularly in teleophthalmology settings [14]. However, a recent study by Gupta et al [15] evaluating the sensitivity and specificity of nonmydriatic retinal imaging for detecting DR in Indian patients reported relatively low sensitivity and specificity for any DR (58.8% and 69.1%, respectively) and sight-threatening DR (STDR) (63.1% and 68.9%, respectively). Factors such as prolonged diabetes duration leading to poor pupil dilation, darker iris pigmentation common among Indians, and increased prevalence of media opacities like cataracts in older patients can impair image quality, thus reducing the accuracy of DR screening with nonmydriatic imaging . The comparatively younger average age of patients in our study may contribute to the higher sensitivity and specificity observed.

Similarly, Scanlon et al. [15] compared mydriatic and nonmydriatic digital retinal screening using dilated slit-lamp biomicroscopy as the reference standard and found that mydriatic photography was an effective screening tool, while nonmydriatic photography had a high technical failure rate and low specificity. Murgatroyd et al. [16] also reported that pupil dilation reduced the rate of ungradable photographs from 26% to 5% in DR screening using nonmydriatic cameras. In our study, no images were ungradable with either imaging device, as none of the participants had very dense cataracts or total vitreous hemorrhage .

The smartphone-based fundus imaging system offers several benefits. The autofocus feature ensures sharp, good quality images. Additionally, the ability to zoom directly on the smartphone's touchscreen allows for immediate enlargement and detailed visualization of specific retinal lesions, enhancing diagnostic precision. Participants also experienced greater comfort during imaging with the smartphone system compared to the Canon fundus camera, largely because the LED light used has lower intensity, reducing discomfort from bright flashes.

Furthermore, the smartphone-based fundus imaging device is considerably more affordable than both conventional mydriatic and non-mydriatic fundus cameras commonly employed in tele-ophthalmology, making it a cost-effective option for widespread DR screening.

Our study has certain limitations. Conducted in a single hospital outpatient setting, the findings may not be directly applicable to community or field settings. Further prospective studies in real-world environments are needed to validate the use of smartphone-based imaging in tele-ophthalmology for DR screening. Although the image quality from the smartphone-based system was not as high as that from the Canon fundus camera, the majority of images (85%) were rated from average to good. Additionally, all current smartphone-based retinal imaging systems require pupil dilation.

In conclusion, this study demonstrates that the smartphone-based retinal imaging system is reasonably sensitive and specific

for detecting diabetic retinopathy across various severity levels, making it a promising screening tool. Its affordability, portability, ease of image transmission, and other features position it well for both in-clinic use and large-scale DR screening initiatives in India and other low- and middle-income countries.

Table 1 - Comparison of Retinal Imaging Using Smartphone-Based Fundus Imaging and Canon Fundus Camera

Parameter	Smartphone-Based Fundus Imaging	Canon Digital Retinal Camera
Sample size	144 patients (288 eyes)	144 patients (288 eyes)
DR Prevalence detected(%)	55.5%	59.1%
NPDR(%)	40.2%	43.9%
PDR(%)	15.3%	15.3%
DME Prevalence(%)	27.2%	27.2%

DR – Diabetic Retinopathy; NPDR – Non Proliferative Diabetic Retinopathy; PDR – Proliferative Diabetic Retinopathy; DME – Diabetic Macular Edema

Table 2 - Sensitivity and specificity for diabetic retinopathy detection by retinal photography on smartphone-based fundus imaging in comparison to Canon digital retinal camera and the kappa agreement.

Status of Retinopathy	Sensitivity %	Specificity %	Kappa Agreement	P value
Any DR	92.7%	98.4%	0.90	<0.001
NPDR	89.8%	98.4%	0.87	<0.001
PDR	89.1%	95.8%	0.84	<0.001
DME	86.6%	94.6%	0.79	<0.001
STDR	87.9%	94.9%	0.80	<0.001

DR – Diabetic Retinopathy; NPDR – Non Proliferative Diabetic Retinopathy; PDR – Proliferative Diabetic Retinopathy; DME – Diabetic Macular Edema; STDR – Sight threatening Diabetic Retinopathy

Fig 1 – Smartphone based retinal imaging

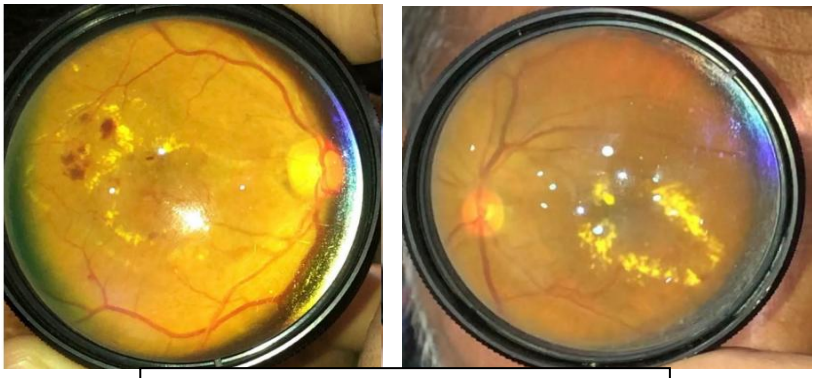

Fig 2 – Images captured via Smartphone

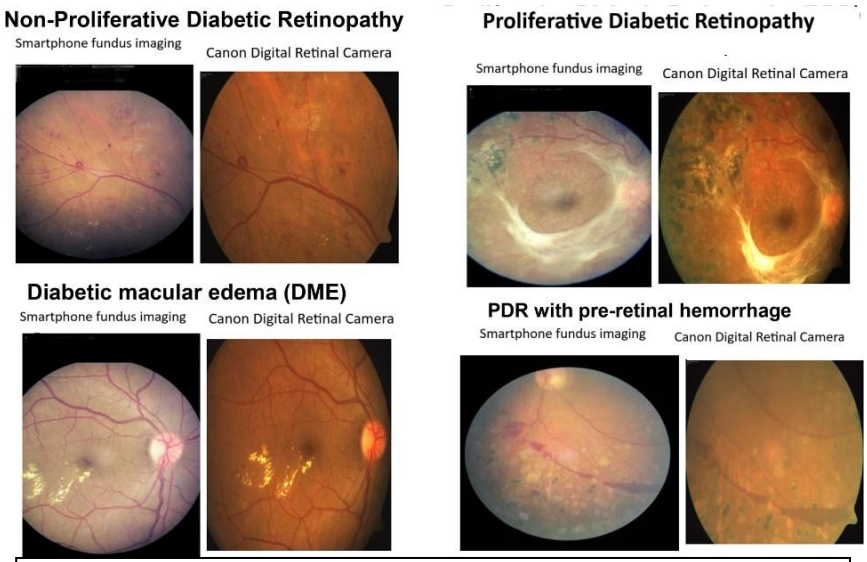

Fig 3 - Retinal images of diabetic retinopathy obtained in Smartphone fundus imaging and Canon Digital Retinal Camera

REFERENCES

1. International Diabetes Federation, Diabetes Atlas, Sixth Edition. International Diabetes Federation, Brussels, Belgium; 2014.
2. American Diabetes Association. Standards of Medical Care in Diabetes—2013. Diabetes Care. 2013 January; 36(Suppl 1): S11–S66. pmid:23264422
3. Sivaprasad S, Gupta B, Crosby-Nwaobi R, Evans J. Prevalence of diabetic retinopathy in various ethnic groups: A worldwide perspective. Surv Ophthalmol.2012;57:347–370. pmid:22542913
4. Vashist P, Singh S, Gupta N, Saxena R. Role of early screening for diabetic retinopathy in patients with diabetes mellitus: An overview. Indian J Community Med. 2011;36:247–252. pmid:22279252
5. Rajalakshmi R, Amutha A, Ranjani H, Ali MK, Unnikrishnan R, Anjana RM, et al. Prevalence and risk factors for diabetic retinopathy in Asian Indians with young onset type 1 and type 2 diabetes. J Diabetes Complications. 2014;28:291–297. pmid:24512748
6. Anjana RM, Pradeepa R, Deepa M, Datta M, Sudha V, Unnikrishnan R, et al. Prevalence of diabetes and prediabetes (impaired fasting glucose and/or impaired glucose tolerance) in urban and rural India: Phase I results of the Indian Council of Medical Research-INdia DIABetes (ICMR-INDIAB) study. Diabetologia 2011; 54:3022–3027. pmid:21959957
7. Rema M, Premkumar S, Anitha B, Deepa R, Pradeepa R, Mohan V. Prevalence of diabetic retinopathy in urban India: the Chennai Urban Rural Epidemiology Study (CURES) Eye Study-1. Invest. Ophthalmol. Vis. Sci., 2005;46:2328–2333. pmid:15980218

8. Fong DS, Aiello LP, Ferris FL 3rd, Klein R. Diabetic retinopathy. Diabetes Care. 2004; 27:2540–2553. pmid:15451934
9. Hutchinson A, McIntosh A, Peters J O'Keeffe C, Khunti K, Baker R, Booth A. Effectiveness of screening and monitoring tests for diabetic retinopathy–a systematic review. Diabet Med. 2000;17:495–506. pmid:10972578
10. Moss SE, Klein R, Kessler SD, Richie KA. Comparison between ophthalmoscopy and fundus photography in determining severity of diabetic retinopathy. Ophthalmology 1985; 92:62–67. pmid:2579361
11. Early Treatment Diabetic Retinopathy Study Research Group. Grading diabetic retinopathy from stereoscopic color fundus photographs—an extension of the modified Airlie House classification. ETDRS report number 10. Early Treatment Diabetic Retinopathy Study Research Group. Ophthalmology 1991; 98(5 Suppl):786–806. pmid:2062513
12. Raman R, Padmaja RK, Sharma T. The sensitivity and specificity of non-mydriatic digital stereoscopic retinal imaging in detecting diabetic retinopathy. Diabetes Care 2007;30:1.
13. Russo A, Morescalchi F, Costagliola C, Delcassi L, Semeraro F. Comparison of smartphone ophthalmoscopy with slitlamp biomicroscopy for grading diabetic retinopathy. Am J Ophthalmol. 2015;159:360–364. pmid:25447109
14. Scanlon PH, Malhotra R, Thomas G, et al. The effectiveness of screening for diabetic retinopathy by digital imaging photography and technician ophthalmoscopy. Diabet Med 2003; 20:467–474. pmid:12786681
15. Murgatroyd H, Ellingford A, Cox A, Binnie M, Ellis JD, MacEwen CJ, et al. Effect of mydriasis and different field strategies on digital image screening of diabetic eye disease. Br J Ophthalmol. 2004;88:920–924 pmid:15205238
16. Kumar S, Wang EH, Pokabla MJ, Noecker RJ.Teleophthalmology assessment of diabetic retinopathy fundus images: smartphone versus standard office computer workstation.Telemed J E Health. 2012;18:158–162. pmid:22304438