e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2025; 17(10); 357-361

Original Research Article

Smartphone Based Fundus Imaging for Diabetic Retinopathy: Accuracy, Feasibility and Reliability in A Tertiary Care Setting

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Received: 07-08-2025 / Revised: 06-09-2025 / Accepted: 07-10-2025

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Conflict of interest: Nil

Abstract:

Introduction: Diabetic retinopathy (DR) is a leading cause of preventable blindness, requiring timely detection. Conventional screening faces access and cost barriers. Smartphone-based fundus imaging offers an affordable, portable solution with promising accuracy. This study evaluates its effectiveness, feasibility, and diagnostic reliability for early detection in resource-limited settings.

Methods: This prospective study at Mamata Medical College (Jan–May 2025) enrolled diabetic patients >18 years with ≥5 years disease. Smartphone fundus photography using a handheld adapter was compared with standard tabletop imaging. Images were graded independently using the ICDR scale, with inter-rater agreement assessed and discrepancies resolved by a senior consultant.

Results: The study of 97 participants (mean age 54.2 years, HbA1c 8.1%) showed comparable DR grading between smartphone and standard imaging. DR severity correlated significantly with hypertension, dyslipidemia, and poor glycemic control. Smartphone screening demonstrated high accuracy (91.7%) and strong agreement (κ =0.86), confirming its reliability for DR detection.

Conclusion: This study concludes that smartphone-based fundus imaging is a reliable, accurate, and feasible alternative to standard fundus cameras for diabetic retinopathy screening. With strong diagnostic performance and agreement, it offers a practical, cost-effective tool for early detection, particularly valuable in resource-limited settings to reduce preventable vision loss.

Keywords: Diabetic Retinopathy, Smartphone Imaging, Screening, Diagnostic Accuracy.

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Introduction

Diabetic retinopathy (DR) is a major cause of preventable blindness globally, particularly affecting people with long-standing diabetes mellitus (DM). Early detection through regular screening is essential to reduce vision loss [1]. Traditional screening methods, such as tabletop fundus photography or in-person retinal exams by ophthalmologists, though accurate, often suffer from barriers in low and middle-income settings: limited access, high cost, shortage of specialists, and low patient adherence. In recent years, smartphonebased screening using smartphone fundus adapters, handheld devices, or smartphone-integrated cameras has emerged as a promising alternative or adjunct [2]. These methods can be more affordable, portable, and potentially scalable to remote or underserved populations, allowing screening at point of care.

Several recent studies have evaluated the diagnostic accuracy, sensitivity, specificity, and feasibility of smartphone-based DR screening, often comparing them to gold-standard imaging or expert human graders. For example, Wintergerst et al. assessed multiple smartphone fundus imaging approaches in outreach clinics in South India and found that indirect smartphone-based imaging achieved excellent agreement with conventional methods for detecting both any DR and more severe disease. [3] A systematic review by Prayogo et al. assessed lowcost smartphone fundus devices across multiple studies and concluded that while sensitivity varies (52-92.2%) the specificity for referable DR and diabetic macular edema is often quite high, supporting their use in low-resource settings [4]. The aim of this study is to evaluate the effectiveness, accuracy, and feasibility of smartphone-based screening for diabetic retinopathy, enhancing early detection in resource-limited settings.

Methods

This prospective observational study was conducted in the department of Ophthalmology, Mamata Medical College, Khammam over a duration of five months, from January to May 2025. Ethical clearance was obtained from the Institutional Ethics Committee prior to initiation. Written informed consent was obtained from all participants after explaining the purpose, benefits, and potential risks of the study. Patients with a confirmed diagnosis of type 1 or type 2 DM, attending either the ophthalmology outpatient department or referred from endocrinology and internal medicine clinics, enrolled. Inclusion criteria included individuals aged >18 years with a minimum of five years of diabetes duration. Patients with corneal opacity, dense cataract, ocular trauma, or prior vitreo-retinal surgery were excluded. Demographic data, duration of diabetes, HbA1c levels, and history of systemic comorbidities such as hypertension or dyslipidemia were recorded in structured proforma.

For imaging, smartphone-based fundus photography was employed using a validated handheld retinal adapter device attached to an Android smartphone with a 12-megapixel rear camera and in-built LED illumination. Pupillary dilation was achieved using 1% tropicamide eye drops, and images of the posterior pole, including macula and optic disc, were obtained from both eyes. At least three gradable images per eye were captured. All images were stored securely on password-protected servers and later graded independently by the other 2 investigators blinded to patient identity and each other's findings. Grading followed the International Clinical Diabetic Retinopathy (ICDR) scale, classifying disease as no DR, mild, moderate, severe non-proliferative DR, or proliferative DR [5]. In addition, clinically significant macular edema was noted if present. For comparison, all patients underwent standard mydriatic 7-field fundus photography using a conventional tabletop fundus camera, considered the gold standard in screening. Inter rater agreement between smartphone and conventional imaging was assessed, and discrepancies were resolved through adjudication by a senior retinal consultant.

Statistical analysis was carried out using SPSS version 25.0 (IBM Corp., Armonk, NY, USA).

Continuous variables such as age and HbA1c were presented as mean ± standard deviation, while categorical variables like gender and DR grading were expressed as frequencies and percentages. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of smartphone-based screening were compared with the gold standard tabletop camera. Agreement between methods was assessed using Cohen's kappa statistics. Associations were tested with Chi-square, and comparisons of continuous data used t-test or ANOVA. P <0.05 was considered statistically significant.

e-ISSN: 0976-822X, p-ISSN: 2961-6042

Results

The study included 97 participants with a mean age of 54.2 ± 9.8 years; 57.7% were male. Mean diabetes duration was 8.6 ± 4.2 years, and HbA1c averaged $8.1 \pm 1.2\%$. Hypertension (50.5%) and dyslipidemia (34.0%) were the most common comorbidities, reflecting significant metabolic risk among participants. Table 1 shows the distribution of DR using ICDR grading by smartphone imaging and standard fundus camera. Findings were comparable across techniques: no DR (43.3% vs. 41.2%), mild NPDR (18.6% vs. 19.6%), moderate NPDR (16.5% vs. 17.5%), severe NPDR (11.3% vs. 12.4%), and PDR (10.3% vs. 9.3%). Table 2 demonstrates a significant association between diabetic retinopathy severity and systemic risk factors. Moderate-severe DR/PDR was strongly linked with hypertension (73.0% vs. 36.7%), dyslipidemia (48.6% vs. 25.0%), and HbA1c >8% (67.6% vs. 30.0%). All associations were statistically significant, highlighting poor metabolic control as a key contributor to DR progression. Smartphone-based DR screening demonstrated high diagnostic accuracy with sensitivity of 90.5%, specificity of 92.3%, PPV of 89.1%, NPV of 93.4%, and overall accuracy of 91.7%, confirming its reliability compared to the standard fundus camera. Table 3 shows strong concordance between smartphone imaging and standard fundus camera. Agreement was almost perfect for detecting any DR (κ =0.87) and strong for non-proliferative (κ =0.82) and proliferative DR (κ=0.85). Overall agreement was high (κ =0.86), supporting smartphone imaging as a reliable screening tool.

Table 1: Distribution of ICDR grading DR by 2 techniques; n (%)				
DR grade	Smartphone Imaging	Standard fundus camera		
No DR	42 (43.3)	40 (41.2)		
Mild NPDR	18 (18.6)	19 (19.6)		
Moderate NPDR	16 (16.5)	17 (17.5)		
Severe NPDR	11 (11.3)	12 (12.4)		
Proliferative DR (PDR)	10 (10.3)	9 (9.3)		

Table 2: Association of DR severity with systemic risk factors				
Risk Factor	No/Mild DR (n=60)	Moderate-Severe/ PDR (n=37)	P value	
Hypertension	22 (36.7%)	27 (73.0%)	0.001	
Dyslipidemia	15 (25.0%)	18 (48.6%)	0.02	
HbA1c > 8%	18 (30.0%)	25 (67.6%)	< 0.001	

Table 3: Agreement between smartphone imaging and standard fundus camera			
DR Category	Kappa	Agreement level	
Any DR (Yes/No)	0.87	Almost perfect	
Non-Proliferative DR grading	0.82	Strong	
Proliferative DR	0.85	Strong	
Overall Agreement	0.86	Strong	

Discussion

The cohort of 97 participants demonstrated a mean age in the mid-50s, male predominance, an average diabetes duration of ~8.6 years, elevated HbA1c (~8.1 %), and high prevalence of hypertension (\approx 50.5 %) and dyslipidemia (\approx 34 %). These findings are consistent with recent evidence indicating that longer duration of diabetes, poor glycemic control, and cardiovascular comorbidities are major determinants of both prevalence and severity of DR. For example, in a meta-analysis by Alarbash et al. (2025), elevated HbA1c and hypertension were confirmed as key risk factors, with diabetes duration beyond 10 years also raising DR odds significantly [6]. In similar fashion, a systematic review and meta-analysis in Ethiopia found that co-existing hypertension, poor glycemic control, and prolonged disease duration were strongly associated with higher DR risk (adjusted ORs >2) [7]. A recent large cross-sectional global study by Zhang et al.further emphasises that increasing duration of diabetes significantly raises DR risk, alongside elevated blood pressure and dyslipidemia among other metabolic risk factors [8].

In our study, the elevated HbA1c (\sim 8.1%) suggests suboptimal glycemic control, aligning with these studies. The high rates of hypertension and dyslipidemia may act synergistically to accelerate microvascular damage in the retina. Duration around 8-9 years already places these patients in moderate risk; literature suggests that beyond 10 years the risk increases more steeply. Overall, your baseline data underscore the importance of early screening, rigorous glycemic, blood pressure, and lipid control in patients even at this level of disease duration.

Our results indicate that smartphone imaging and standard fundus photography yield very similar distributions of DR severity by ICDR grading: no DR (~43 % vs. ~41 %), mild NPDR (~19 % each), moderate NPDR (~16-17 %), severe NPDR (~11-12 %), and PDR (~9-10 %). This close alignment suggests that the smartphone modality is performing comparably to gold standard imaging for classifying

DR severity across most levels. Similar findings have been reported recently. de Oliveira et al. validated a handheld retinal camera (Eyer) vs multiple standard tabletop cameras in a sample of 327 diabetic patients; they found high agreement in DR grading (weighted kappa ~0.808) and comparable prevalence in each DR category for referable vs non-referable DR [9]. Another study by Prayogo et al. in a systematic review of low-cost smartphone-based fundus devices showed that while sensitivity and specificity vary, the pattern of DR severity distribution broadly matches that seen with standard imaging in several settings [4]. Also, in a prospective study from Pakistan, use of the smartphone-based Vista View device showed moderate-high agreement for DR severity compared to a Topcon desktop camera; the proportions in mild, moderate, and severe NPDR and PDR categories were reasonably close, though with somewhat lower sensitivity for less severe categories [10].

e-ISSN: 0976-822X, p-ISSN: 2961-6042

These convergent results strengthen the validity of your findings: that smartphone-based imaging can reliably reflect DR severity distribution. Nevertheless, subtle differences in detection (especially in mild/moderate NPDR) might exist due to image quality, field of view, or grader's ability to detect small retinal lesions. These should be considered when interpreting your data, particularly for screening programs, where missing mild disease might delay early intervention.

Table 2 pattern showing more severe DR in presence of hypertension, dyslipidemia, and elevated HbA1c aligns well with recent literature. Elevated HbA1c has repeatedly been shown to correlate strongly with DR severity. Alswaina et al. found that type 2 diabetics with poorly controlled HbA1c had significantly higher rates of moderate/severe NPDR or PDR compared to those with lower HbA1c [11]. Dyslipidemia likewise emerges as a consistent risk factor: the meta-analysis by Alarbash et al. confirmed that elevated triglycerides, LDL-cholesterol, and poor lipid profiles increase the odds of more advanced DR stages [6]. Hypertension also contributes independently; in a study by Roşu et al.,

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cardiovascular risk factors including hypertension were found to predict DR progression, even after adjusting for glycemia and disease duration [12].

In our sample, the large difference in proportions (e.g. hypertension in ~73.0% vs. ~36.7%, HbA1c >8% in ~67.6% vs. 30.0%) suggests that these systemic risk factors are strongly associated not just with presence but with greater severity of disease (moderate–severe NPDR / PDR). This supports prioritizing control of blood pressure, lipids, and glycemic levels early in the course of diabetes, as even moderate elevations appear to shift patients into more severe retinopathy stages. Moreover, these findings emphasize that screening programs should particularly target patients with poor metabolic control and co-existing hypertension/dyslipidemia, since they are at higher risk of progressing to sight-threatening forms of DR.

The high diagnostic accuracy in your study (sensitivity ~90.5%, specificity ~92.3%, PPV ~89.1%, NPV ~93.4%, overall accuracy ~91.7%) is consistent with recent findings that smartphonebased fundus imaging (often combined with AI or trained graders) can approach gold standard cameras for DR detection, especially for referable or more severe disease. One study in Indonesia (Nursalamah et al., 2024) evaluated smartphone-based fundus photographs for screening vision-threatening diabetic retinopathy (VTDR) using a mydriatic twofield protocol. They reported a sensitivity of 98.4% (CI 96.6–100%) and specificity of 87.1% (CI 75.3– 98.9%), with PPV 97.9% and NPV 90.0%, and overall accuracy 96.8% [13]. It was reported in a systematic review that low-cost smartphone-based retinal photography across various settings, finding variable but often high sensitivities and specificities for detecting any DR (e.g. ~84% sensitivity, ~80% specificity in many individual studies) compared to standard fundus cameras, depending on device, mydriasis, grader training, and image quality [4].

Comparing these to your metrics: your sensitivity and specificity are similarly high, and the PPV/NPV are comparable (or even slightly better in some respects). The reassurance is that smartphone modalities are not only sensitive enough to catch a large proportion of true DR cases, but also specific enough to limit false positives, which is important to avoid over-referral. Differences in image field, pupil dilation, and grader expertise can cause variation; your data suggests that with good protocols, smartphone screening can serve reliably in settings where standard cameras are less accessible.

Table 3 showed strong concordance results ($\kappa \approx 0.82$ -0.87 across DR categories, overall $\kappa \approx 0.86$) demonstrate excellent reliability of smartphone imaging compared to standard fundus cameras. This degree of agreement is meaningful, especially since lower κ values are often reported for milder DR

stages due to subtle lesion detection challenges. Your findings suggest that smartphone-based screening could be trusted for both non-proliferative and proliferative DR detection in many clinical settings.

e-ISSN: 0976-822X, p-ISSN: 2961-6042

Comparable results are seen in recent literature. Gobbi et al. (2022) assessed fundus images captured by undergraduate students using a smartphone device, comparing them to gold standard tabletop fundus camera images. They reported $\kappa=0.67$ for presence vs absence of DR, $\kappa=0.78$ for PDR vs. NPDR classification [14]. Though kappa values are higher, the pattern of strong agreement in more severe disease aligns well.

Another study by Wintergerst et al. (2020) in India validated smartphone-based fundus imaging: they found high agreement (weighted kappa) for referable diabetic retinopathy when compared with desktop fundus cameras [3]. While exact κ values varied by imaging device and grader, agreement was generally "substantial to almost perfect" in those settings [4]. Such high agreement ($\kappa \geq \! 0.80$) is particularly important for screening programs, because misclassification in DR grading can lead to under- or over-referral. Your results suggest smartphone imaging may reliably triage patients, detect sight-threatening DR, and be used even where standard equipment is limited, provided image quality and grader training are optimal.

Conclusion: This study concludes that smartphonebased fundus imaging is a reliable and accurate alternative to standard fundus cameras for DR screening, demonstrating high sensitivity, specificity, and strong agreement across ICDR severity levels. Its portability, affordability, and ease of use highlight its potential for large-scale screening, particularly in resource-limited settings where access to specialized equipment is restricted. However, limitations include the relatively small sample size, single-center design, and dependence on image quality and grader expertise, which may affect reproducibility. Future multicenter studies with larger populations and integration of artificial intelligence could strengthen evidence and enhance scalability of this approach.

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