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Original Article

Role of artificial intelligence-enabled hand-held fundus camera for community-based diabetic retinopathy screening

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ABSTRACT

Background: This study aimed to assess the diagnostic accuracy of an artificial intelligence (AI) system integrated with a portable handheld fundus camera for the detection of diabetic retinopathy (DR) in a community-based screening program.

Methods: A DR screening camp was organized at a tertiary care hospital in India. A cohort of 261 patients with diabetes was screened using a nonmydriatic handheld fundus camera. Retinal images were graded by specialists and compared with the AI system's output. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the receiver operating characteristic curve (AUC-ROC) were calculated. Subgroup analyses based on image quality was performed.

Results: Of the 261 patients screened, 253 had available retinal images, and 243 had gradable images. The AI system achieved a sensitivity of 85.29%, specificity of 99.04%, PPV of 93.55%, and NPV of 97.64% for detecting referable DR. The AUC-ROC was 0.93. The AI system's performance remained robust across all image-quality categories. The AI system showed strong agreement with human graders ($\kappa = 0.86$). However, it failed to identify certain non-DR pathologies detected by human graders.

Conclusions: The AI system integrated with a portable handheld fundus camera demonstrated high diagnostic accuracy for referable DR detection in a community-based screening setting. This technology shows promise for expanding DR-screening coverage in resource-limited settings.

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Introduction

Diabetic retinopathy (DR), a microvascular complication of diabetes mellitus (DM), stands as a leading cause of preventable blindness worldwide.[1] With an estimated global prevalence of 34.6% among individuals with diabetes, DR poses a significant public health challenge. Epidemiologic studies have shown that approximately 1 in 3 persons with DM has DR and that 1 in 10 has proliferative diabetic retinopathy (PDR) or diabetic macular edema (DME). However, of concern is that population surveys consistently show that half of persons with DM remain undiagnosed and that many are unaware of their risk of DR and other complications.[2] As the global diabetes epidemic continues to escalate, the burden of DR is projected to increase substantially in the coming decades, necessitating effective strategies for early detection and timely intervention.[3]

The key to preventing vision loss due to DR lies in early detection and prompt treatment.[4] Regular and repetitive screening is crucial for identifying and managing DR in patients with diabetes. Traditional screening methods, such as dilated fundus examination or color fundus photography using conventional cameras (mydriatic or nonmydriatic), face several challenges. The primary bottleneck lies in the grading of retinal images, which requires specialized retinal specialists or trained personnel who are in short supply compared to the patient load requiring screening. Moreover, many patients, particularly those residing in rural areas, face difficulties in accessing specialized screening facilities. The chronic nature of diabetes further necessitates constant follow-ups over several years, adding to the complexity of the screening process.

Artificial intelligence (AI) has emerged as a promising tool to address the challenges in DR screening. The primary goal is to develop a rapid and accurate screening tool with high sensitivity and specificity, capable of handling the diverse clinical presentations of DR. AI neural networks, when designed with multilayered architectures and extensively trained using multiple retinal images as ground truth, have the potential to revolutionize DR screening.[5] Most studies utilize the International Clinical Diabetic Retinopathy Disease (ICDR) severity scale, which categorizes DR severity into five levels: no apparent retinopathy, mild nonproliferative DR (NPDR), moderate NPDR, severe NPDR, and Proliferative Diabetic Retinopathy (PDR).[6] "Referable DR" refers to severity of DR more than mild NPDR (moderate NPDR and above with or without DME) as disease management often shifts from yearly screening to closer follow-up for moderate severity.[7]

The integration of AI with portable handheld fundus cameras offers a unique opportunity to expand DR screening coverage, particularly in resource-limited settings.[8] These devices, being more affordable, user-friendly, and operable by nonspecialists, enable community-based screening programs.[9] However, the performance of AI systems using images from portable cameras in real-world settings remains to be evaluated. The objective of this study is to assess the diagnostic accuracy of an AI system integrated with a portable handheld fundus camera for the detection of DR in a community-based screening program.

Materials and methods

Data collection

A DR screening camp was organized at a tertiary care hospital in India. This study adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from all participants, and the study was approved by the institutional review board, vide IEC S.No: IEC/2024/550 dated 14 June 2024. A cohort of 261 patients with diabetes was screened for retinal diseases using a nonmydriatic handheld fundus camera (Remidio Fundus on Phone, Remidio Innovative Solutions Pvt. Ltd., Bengaluru, India).

Image acquisition and screening protocol and grading criteria

Two fundus images were captured per patient by trained technicians: one disc-centered and one macula-centered per eye (right and left eye each) per participant under nonmydriatic conditions. Images were captured in a dimly lit room, with participants seated and the camera held approximately 33 mm from the eye.[5] The quality of each image was assessed to determine whether it was adequate for the purposes of grading. This included the following rules: (1) an image with visible referable retinopathy or maculopathy is always adequate for grading and (2) an image with adequate field definition (entire optic disc imaged and a fovea at least two-disc diameters from the image edge) and clarity (third-generation vessels radiating around the fovea must be visible) is adequate for grading. The images were further evaluated using a 5-point grading system (0–4) assessing clarity and visibility of retinal features. Grade 0 (ungradable) indicated no discernible retinal details due to media haze such as dense cataracts and vitreous hemorrhage. Grade-1 (poor) images allowed only detection of gross retinal changes. Grade-2 (fair) images permitted visualization of major retinopathy details. Grade-3 (good) images enabled clear detection of most retinopathy changes. Grade-4 (excellent) images allowed clear identification of all lesions and retinal abnormalities. Grade-0 and Grade-1 images were excluded from the study, with grades 2–4 considered gradable. Images identified as ungradable by the graders were not assessed for retinal disease.

The reference standard for AI-based DR diagnosis was established by a panel of three experienced vitreoretinal (VR) surgeons, who were masked to the AI system's output. Each image was graded independently by two VR surgeons according to the ICDR severity scale. Discrepancies were resolved by a third VR surgeon to reach a consensus grade. The reference standard for human grader-based diagnosis combined fundus examination using indirect ophthalmoscopy and 90-diopter (D) biomicroscopy. In patients demonstrating macular thickening on 90-D biomicroscopic examination, optical coherence tomography (OCT) imaging was performed using a spectral-domain OCT (SD-OCT) device (Zeiss CIRRUS™ HD-OCT 5000) for confirmation of DME.

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Fundus camera specifications and AI system architecture

The Fundus on Phone (FOP) camera is a portable, smartphone-based fundus camera with a 45-degree field of view. The FOP camera consists of an optical attachment that connects to a smartphone (iPhone 6s; Apple Inc.) and utilizes its high-resolution camera for image acquisition.[9] The FOP camera has an inbuilt AI system for automated DR detection. This system uses a two-step approach: first, an image-quality assessment algorithm ensures captured images meet diagnostic standards, and second, a DR detection mechanism utilizes dual convolutional neural networks based on the Inception-V3 architecture. The AI provides binary classification—referable DR or nonreferable DR. The entire process, from image capture to DR assessment, occurs offline on the smartphone, utilizing CoreML and OpenGL ES 2.0 technologies.[8]

Statistical analysis

Demographic and clinical characteristics of the study participants were summarized using descriptive statistics. The AI system's diagnostic performance was assessed by calculating sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), with 95% confidence intervals (CIs), using the reference standard as the ground truth. Receiver operating characteristic (ROC) curves were plotted, and the area under the ROC curve (AUC-ROC) was computed to evaluate the AI system's overall discriminative ability. The optimal probability threshold for referable DR detection was determined by maximizing the Youden index (sensitivity + specificity - 1).[10]

Subgroup analyses were performed to assess the AI system's performance stratified by image quality (excellent, good, fair, or poor). Intergrader agreement between the AI system and human graders was evaluated using Cohen's κ statistic. Statistical analyses were performed using International Business Machines (IBM) Statistical Package for the Social Sciences (SPSS), Version-27. A two-sided P-value of <0.05 was considered statistically significant.

Results

Patient flow and study population

A total of 261 patients with DM were initially screened for the study. After exclusions due to withdrawals (n = 8) and ungradable images (n = 10), the final study population consisted of 243 patients with images gradable by both the specialist and the AI system (Fig. 1). Key demographic and clinical characteristics of these participants are summarized in Table 1, including age, duration of diabetes, glycated hemoglobin levels, logarithm of the minimum angle of resolution best-corrected visual acuity, intraocular pressure, body mass index, and prevalence of hypertension and dyslipidaemia.

AI system performance metrics

The AI system achieved a sensitivity of 85.29% (95% CI: 68.94%–95.05%) and a specificity of 99.04% (95% CI: 96.59%–99.88%) for detecting referable DR. This indicates that the AI system correctly identified 29 out of 34 participants with referable DR and 207 out of 209 participants without referable DR. The PPV of the AI system was 93.55% (95% CI: 78.38%–98.31%), and the NPV was 97.64% (95% CI: 94.85%–98.94%) (Figs. 2 and 3; Table 2).

Based on the reference standard, the distribution of DR severity according to the ICDR severity scale was as follows: no apparent retinopathy (n = 169, 69.5%), mild NPDR (n = 40, 16.5%), moderate NPDR (n = 20, 8.2%), severe NPDR (n = 10, 4.1%), and PDR (n = 4, 1.6%). The overall prevalence of any DR in the study population was 30.4%. DME was present in 28 participants (11.5%), with the following distribution across DR severity levels: mild NPDR (n = 6, 15%), moderate NPDR (n = 10, 50%), severe NPDR (n = 8, 80%), and PDR (n = 4, 100%). The presence of DME was significantly associated with increasing DR severity ($P < 0.001$).

The AI system's diagnostic performance was further evaluated using likelihood ratios, the κ statistic, diagnostic odds ratio (DOR), and diagnostic effectiveness (DE). The positive likelihood ratio (LR+) was 89.13 (95% CI: 22.28–356.54), and the negative likelihood ratio (LR-) was 0.15 (95% CI: 0.07–0.33). The κ statistic, which measures the agreement between the AI system and the reference standard, was 0.86 ± 0.04 (95% CI: 0.78–0.94), indicating a strong agreement between the AI system and the human graders. The DOR was 600.3 (95% CI: 118.54–2982.08), suggesting that the AI system is 600.3 times more likely to correctly diagnose referable DR than to misdiagnose it. Finally, the DE was 97.12% (95% CI: 94.16%–98.83%), indicating that the AI system correctly classified 97.12% of the participants as either having referable DR or not having referable DR (Table 3).

The AUC-ROC for the AI system was 0.93 (95% CI: 0.88–0.97), indicating a high overall discriminative ability. The ROC curve, shown in Fig. 4, demonstrates the trade-off between sensitivity and specificity at various probability thresholds. Subgroup analyses were performed to assess the AI system's performance stratified by image quality. The AI system maintained high sensitivity and specificity across all image-quality categories (excellent, good, and fair), with no significant differences observed (Table 3).

Comparison with human graders/gold standard

The intergrader agreement between the AI system and human graders was assessed using Cohen's κ statistic. The strong agreement between the AI system and human graders, as demonstrated by the high κ value of 0.86 (95% CI: 0.78–0.94), supports the potential of the AI system to assist in DR screening by providing consistent and accurate results, comparable to those of experienced human graders.

However, it is important to note that the AI system failed to identify certain coincidental coexisting pathologies in 12.7% cases, such as age-related macular degeneration (ARMD) (n = 12, 4.9%), epiretinal membrane (ERM) (n = 8, 3.3%), glaucomatous optic disc changes (n = 6, 2.5%), hypertensive retinopathy (n = 3, 1.2%), and pale optic disc (n = 2, 0.8%). These conditions were detected by human graders but not by the AI system (Fig. 3, Table 4). The inability of the AI system to detect these conditions emphasizes the importance of human graders in providing a comprehensive evaluation of retinal

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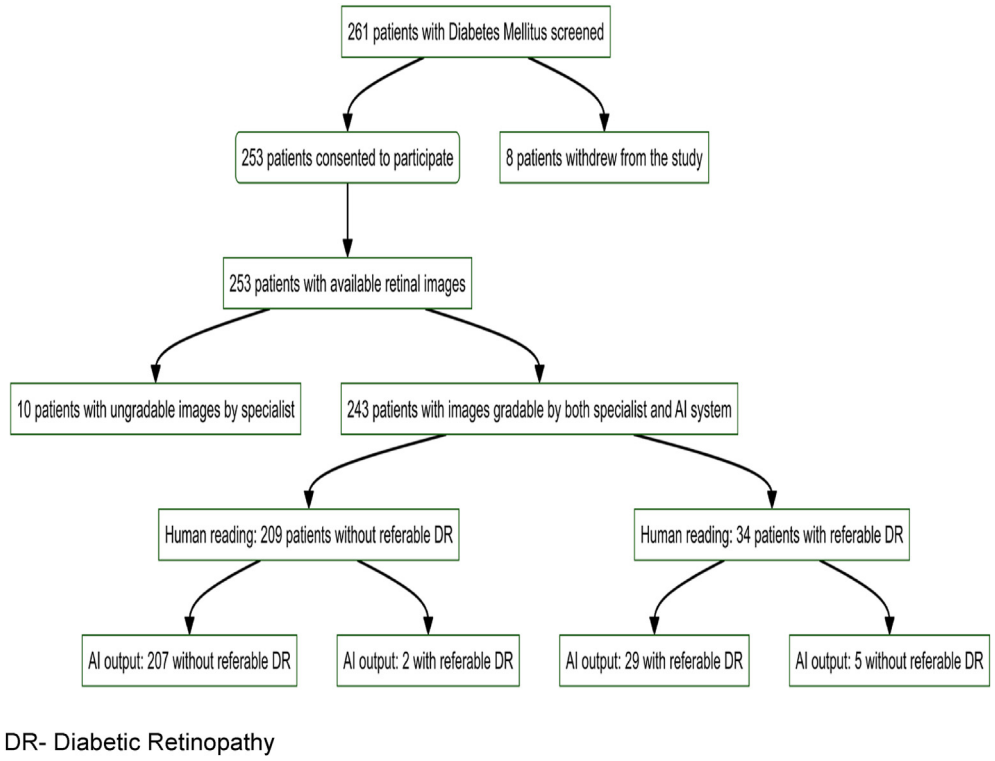

Fig. 1 – Patient flow diagram.

Table 1 – Demographic and clinical characteristics of study participants.

Characteristic	Value
Age, years (mean ± SD)	54.6 ± 10.3
Gender, n (%)	
Male	132 (54.3%)
Female	111 (45.7%)
Duration of diabetes, years (mean ± SD)	8.4 ± 6.1
HbA1c, % (mean ± SD)	7.8 ± 1.5
LogMAR BCVA (mean ± SD)	0.24 ± 0.18
IOP, mmHg (mean ± SD)	15.2 ± 3.1
BMI, kg/m^2 (mean ± SD)	26.3 ± 4.2
Hypertension, n (%)	98 (40.3%)

SD: standard deviation; HbA1c: glycated hemoglobin; Log MAR BCVA: logarithm of the minimum angle of resolution best-corrected visual acuity; IOP: intraocular pressure; BMI: body mass index.

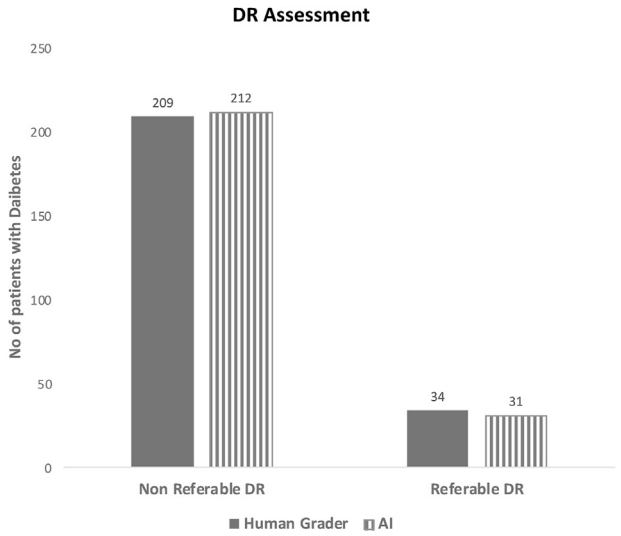

Fig. 2 – Diabetic retinopathy degree assessed by standard clinical examination and hand-held Fundus on Phone camera. DR: diabetic retinopathy.

health, beyond just the detection of DR. The overall accuracy of the AI system for detecting referable DR was 97.12% (95% CI: 94.16%–98.83%). This indicates that the AI system correctly classified 236 out of 243 participants as either having referable DR or not having referable DR.

Discussion

This study demonstrates the high diagnostic accuracy of an AI system integrated with a portable handheld fundus camera for DR screening in a community-based setting. The sensitivity and specificity in the detection of referral-warranted DR are of fundamental importance for screening programs.[11] The British Diabetic Association considers 80% sensitivity and 95% specificity for a viable DR screening program.[12] The AI system achieved high sensitivity, specificity, and predictive values in identifying referable DR, with an overall accuracy of 97.12%, significantly reducing the time and resources required for DR screening. The system's effectiveness is supported by

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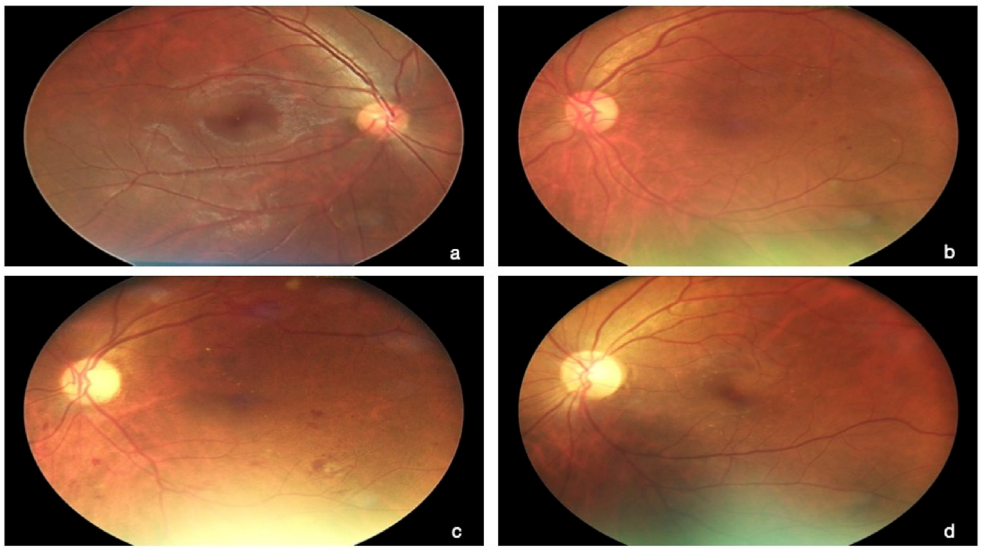

Fig. 3 – Fundus imaging using Fundus on Phone (FOP) Camera. a. Normal fundus classified as nonreferable DR by FOP. b. Mild NPDR classified as non-referable DR by FOP. c. Moderate NPDR classified as referable DR by FOP. d. Incident coexisting pathology (ARMD) missed by FOP. DR: diabetic retinopathy; NPDR: nonproliferative diabetic retinopathy; ARMD: age-related macular degeneration.

Table 2 – Confusion matrix for the AI system's performance in detecting referable diabetic retinopathy.

Device output	Human grader		Total	Predictive values
	Referable DR	Not referable DR		
Referable DR	29	2	31	93.55% PPV (78.38–98.31%)[a]
Not referable DR	5	207	212	97.64% NPV (94.85–98.94%)[a]
Total	34	209	243	
Sensitivity and specificity	Sn: 85.29% (68.94–95.05%)[a]	Sp: 99.04% (96.59–99.88%)[a]		

PPV: positive predictive value; NPV: negative predictive value; Sn: sensitivity; Sp: specificity; DR: diabetic retinopathy; AI: artificial intelligence.
[a] 95% confidence interval.

favorable likelihood ratios and DORs. The AUC-ROC value of 0.93 further underscores the AI system's excellent discriminative ability, highlighting its potential as a valuable triage tool in screening programs reducing the workload of human graders, and facilitates timely referral of patients with vision-threatening DR.[13]

Previous studies have primarily assessed AI algorithms using high-quality images captured by desktop fundus cameras in well-controlled settings.[14] By demonstrating the robustness of the AI system across various image-quality categories, our study provides compelling evidence for the feasibility of implementing AI-based screening in resource-limited settings, where access to specialized equipment and expertise may be limited. The use of the FOP offers distinct advantages over traditional desktop cameras. Its portability, offline nature, affordability, and user-friendly nature make it particularly well-suited for community-based screening programs.[8]

The subgroup analyses revealed that the AI system's performance remained robust across various image-quality categories, suggesting that AI-based screening could be effectively implemented under varying imaging conditions. The strong agreement between the AI system and human graders ($\kappa = 0.86$) demonstrates the AI system's ability to provide DR gradings comparable to those of experienced specialists. This finding suggests that AI-based screening could help alleviate the burden on healthcare systems by reducing the need for manual image grading.[15] However, it is important to acknowledge that the AI system failed to detect certain coincidental coexisting pathologies, such as ARMD, ERM, etc., which were identified by human graders. This limitation highlights the need for further refinement of AI algorithms to recognize a broader range of retinal pathologies and the importance of human oversight in the screening process.[16]

Our study's findings align with and expand upon research evaluating AI-based DR screening using portable fundus cameras. Natarajan et al. and Sosale et al. assessed the Medios AI system with Remidio FOP images and reported sensitivities of more than 85% for referable DR detection.[8,14] Sosale et al. achieved 100% sensitivity for vision-threatening DR, with an AUC-ROC value of 0.92 for referable DR.[14] Rajalakshmi et al. examined the EyeArt software using Remidio FOP images, demonstrating 99.3% sensitivity and a lower specificity of 68.8% for referable DR detection.[9] Our study's results compare

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Table 3 – AI system diagnostic measures and performance in detecting referable diabetic retinopathy.

Diagnostic accuracy measures		
Measure	Estimate	95% confidence interval
LR+ (positive likelihood ratio)	89.13	22.28–356.54
LR- (negative likelihood ratio)	0.15	0.07–0.33
κ ± SE	0.86 ± 0.04	0.78–0.94
Diagnostic odds ratio	600.3	118.54–2982.08
Diagnostic effectiveness	92.17%	84.77–97.47%
Accuracy	97.12%	94.16–98.83%
AI system performance stratified by image quality by image quality		
Excellent (Grade 4)	Sensitivity: 87.5%	72.4–95.3%
	Specificity: 99.3%	97.1–99.9%
Good (Grade 3)	Sensitivity: 86.2%	71.8–94.0%
	Specificity: 99.1%	96.8–99.8%
Fair (Grade 2)	Sensitivity: 84.8%	69.5–93.3%
	Specificity: 98.8%	96.3–99.7%

AI: artificial intelligence: LR+: positive likelihood ratio; LR-: negative likelihood ratio.

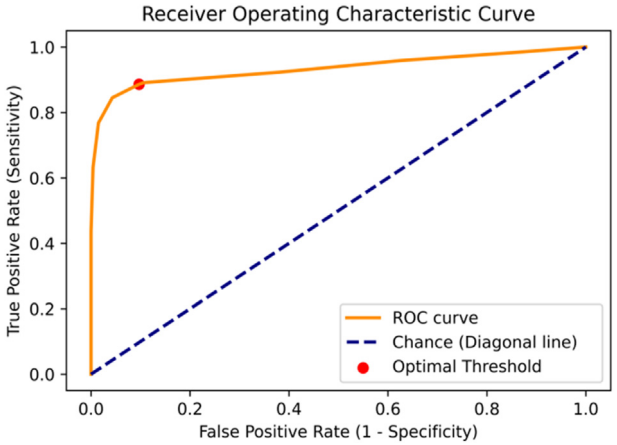

Fig. 4 – Receiver operating characteristic (ROC) curve for the AI system in detecting referable diabetic retinopathy. AI: artificial intelligence.

Table 4 – Incidental coexisting pathologies detected by human graders but not identified by the AI system.

Diagnosis	Frequency	%
ARMD	12	4.9
ERM	8	3.3
Glaucomatous optic disc changes	6	2.5
Hypertensive retinopathy	3	1.2
Pale optic disc	2	0.8
Total	31	12.7

ARMD: age-related macular degeneration; ERM: epiretinal membrane; AI: artificial intelligence.

favorably with these findings, suggesting that AI-integrated portable fundus cameras can maintain high diagnostic accuracy across various settings and populations.

While our results are promising, we acknowledge certain limitations. Our study population, even though consisting of diabetics attending a retinopathy screening camp at a tertiary care facility, may still not be fully representative of the general population. To address this, further studies are needed in more diverse settings and populations that include both diabetic and nondiabetic individuals. These will be crucial to fully assess the AI system's performance as a screening tool in real-world conditions.

Conclusion

The AI system integrated with a portable handheld fundus camera shows high diagnostic accuracy for detecting referable DR in community-based settings. With strong sensitivity and specificity, this technology has the potential to revolutionize DR screening by enabling cost-effective, large-scale screening programs that can reach underserved populations. While it requires further refinement to detect non-DR pathologies, it's still promising because patients without access to ophthalmologists will benefit from early detection that would otherwise go undetected.

Patients/ Guardians/ Participants consent

Patients informed consent was obtained.

Ethical clearance

Institute/hospital ethical clearance certificate was obtained.

Source of support

Nil.

Disclosure of competing interest

The authors have none to declare.

Acknowledgment

None.

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