



ORIGINAL ARTICLE

Diabetic Retinopathy Screening with Artificial Intelligence in Remote Areas

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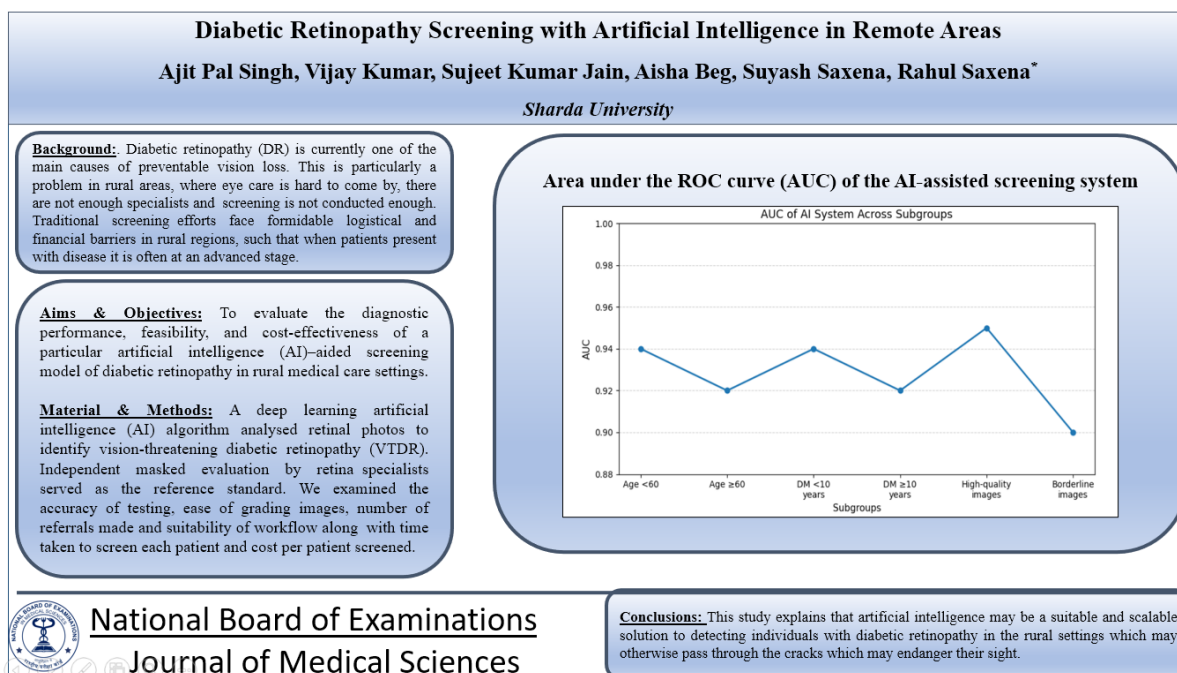
Abstract

Background: Diabetic retinopathy (DR) is currently one of the main causes of preventable vision loss. This is particularly a problem in rural areas, where eye care is hard to come by, there are not enough specialists and screening is not conducted enough. Traditional screening efforts face formidable logistical and financial barriers in rural regions, such that when patients present with disease it is often at an advanced stage. **Objective:** We aimed to evaluate the diagnostic performance, feasibility, and cost-effectiveness of a particular artificial intelligence (AI)-aided screening model of diabetic retinopathy in rural medical care settings. **Methods:** A prospective cross-sectional diagnosis accuracy trial conducted in rural primary health centres and outreach clinics. All diabetic participants had non-mydratic fundus photography performed by trained technicians. A deep learning artificial intelligence (AI) algorithm analysed retinal photos to identify vision-threatening diabetic retinopathy (VTDR). Independent masked evaluation by retina specialists served as the reference standard. **Results:** We screened 240 individuals or 480 eyes. For detecting VTDR, the sensitivity and specificity of AI system were 89.4 and 87.2%, respectively. Its positive and negative predictive values were 61.8% and 96.3%, respectively, with an area under the ROC curve of 0.93 as well. When AI assisted screening was compared to standard practice, that approach screened more people about 35% more and cut the cost per person screened by roughly 40%. **Conclusion:** AI aided DR screening is a reliable, feasible and cost-effective method for early detection of VTDR in remote populations with great potential for reducing unnecessary blindness in underserved regions.

Keywords: Diabetic retinopathy, Deep learning, Rural healthcare delivery, Screening programs, Diagnostic accuracy

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Graphical Abstract



Introduction

Diabetic retinopathy (DR) remains one of the leading causes of preventable blindness and visual impairment in the working-age population globally. Introduction Diabetic retinopathy (DR) is forecasted to rise dramatically in the next decades due to the worldwide epidemic of diabetes mellitus. So overall, about one out of every three patients with diabetes will have some degree of diabetic retinopathy (DR), and a large number approximately one-third according to a recent systematic review and meta-analysis—of those will go on to developing vision-threatening forms or variants of DR, namely proliferative DR and/or diabetic macular edema.

Although screening and treatment that can prevent most cases exist, diabetic retinopathy remains a significant cause of visual impairment, particularly in low- and middle-income settings. In remote and deprived areas, where access to ophthalmic services is limited, diabetic retinopathy has

more serious implications. However, in rural areas, many specialized ophthalmologists are not available, and the full diagnostic machines like OCTs are also inadequate. In addition, tertiary eye care centers can be hours away from the nearest health facility. The screening process is immensely limited by barriers such as time constraints, lack of follow-up, and noncompliance with the advised yearly retinal evaluations. Eye care service delivery is also impeded by several socioeconomic factors, including low health literacy and an obsession with economic concerns. This problem often leads to patients with Diabetic Retinopathy (DR) in developing countries presenting at health care institutions with cases of DR that have worsened stage, and thus making treatment options costlier and difficult, possibly resulting in failed therapy. As a result, fewer light and more health expenses [1].

Most of the traditional methods to screen DR is to get screened manually by either an ophthalmologist or a retinal specialist. However, these are great concepts but hard to put into action at the hospital level and needs many resources to run effectively as well as not being easily implementable in rural areas, where there is an insufficient amount of such facilities with uneven distribution across the country. The need for additional infrastructure, indirect outlays by patients (eg, travel expenses, income lost due to taking time off from work), etc can make it exponentially more challenging to meme people. As a result, early-stage diagnosis fills almost all of the cases as low levels of screening uptake. This defeats the purpose of routine screening as far as conventional methods of screening are concerned [2].

As a result, artificial intelligence (AI) has become the recent technological answer for these problems and the application of advanced deep learning in retinal imaging. Micro aneurysms, haemorrhages, exudates and neovascularization are pathological characteristics that can be objectively identified. Convolutional neural network algorithms trained on large image datasets have been shown to perform highly accurate detection and classification of diabetic retinopathy. Several AI-based diabetic retinopathy screening systems have been approved by the FDA and Conformité Européenne. This means they are both safe and clinically effective [3].

On the one hand, a lot of what exists regarding the evidence base that is being used to support AI-assisted screening tasks (still quite limited) may be heavily focused on urban and tertiary care based segments where referral pathways exist, excellent infrastructure capabilities exist, and optimal

imaging conditions are there. The effectiveness of these systems in more rural and low-resource environments, where image quality will vary, infrastructure will be limited, and follow-up may not always occur, remains unclear. In addition, published reports of the integration of this novel tool with workflows, technician training costs, patient acceptance rates, referral compliance rates and cost effectiveness also appear exceedingly limited in the case of rural areas [4]. The present study evaluated the diagnostic accuracy, feasibility, and cost-effectiveness of an AI-assisted diabetic retinopathy screening model from rural healthcare settings with a focus on identifying vision-threatening non proliferative disease [5].

Methodology

Diagnosis accuracy and feasibility were evaluated in rural primary health centres and mobile eye clinics. The present study was prospective cross-sectional study. This study aimed to evaluate the diagnostic accuracy, operational feasibility and deployability of an artificial intelligence (AI) assisted screening system for vision-threatening diabetic retinopathy (VTDR) in resource-limited rural settings. Recruitment took place over a predetermined period of research time during which consecutive eligible subjects attending diabetes clinics or community screenings were invited to participate after taking Ethical clearance (Ref. no. SU/SMSR/76-A/2019/20) from Institutional Ethical Committee of the University.

Inclusion Criteria

Adults 18 years or older with confirmed diagnosis of type-1 and/or type-2 diabetes mellitus requiring treatment for

at least one year were eligible. Written informed consent was obtained from all participants prior to enrolment.

Exclusion criteria

Patients were not eligible if they had ocular media opacities (e.g. dense cataract, corneal scar, or vitreous haemorrhage) precluding adequate fundus photography. Persons with previous treatment of the retina (e.g., laser photocoagulation, intravitreal injections of anti-VEGF substances) or vitreoretinal surgery were not included in the study to avoid confounding evaluations assessing AI performance. Those who were unwilling or unable to provide informed consent were also excluded.

Sample size calculation

The sample size was calculated for valid estimation of the diagnostic accuracy. Based on previous studies that employed AI as a screening tool for diabetic retinopathy, the assumed sensitivity and specificity were 85% and 90%, respectively. Another assumption was that 15% of rural diabetics would have VTDR. We selected the larger sample size yielded by estimating sensitivity and specificity based on $Z = 1.96$ for a confidence level of 95% and absolute precision of $\pm 5\%$. The sample size was inflated for ungradable photographs and loss to follow up (10–15%), thus the final sample size needed was 240.

Screening

Non-mydratiac fundus photography was provided by trained technicians at rural health clinics or in mobile screening units for all eligible individuals. The eyes were imaged in their entirety whenever possible, using established imaging methods. Dilation of the pupil was not universally

employed to mimic screen testing. The AI system analyzed retinal images either in real-time or using a secure cloud-based connection, depending on the local infrastructure. This allowed for patients to be triaged by risk, and recommendations made in the same visit for referrals [6].

Description of AI System, testing & checking

The AI-aided screening method employed fine-tuned retinal fundus image analysis using a convolutional neural network (CNN) model structure. The algorithm had been developed to detect features of diabetic retinopathy, including microaneurysms, hemorrhages, hard exudates, venous beading, intraretinal microvascular anomalies and neovascularization [7].

The AI model was trained using a large, clinically representative, publicly-available annotated Eye PACS moderate and above disc grades fundus image dataset (GitHub). The International Clinical Diabetic Retinopathy (ICDR) severity scale was used to grade the images, which were intended to mimic clinical screening settings. We performed external validation in the Messidor 2 dataset with expert-graded fundus images. These databases are composed of all forms of diabetic retinopathy, even those that could lead to loss of vision. Internal and external validation confirmed that the test was pretty good at finding VTDR. The Artificial Intelligence (AI) system has the FDA approval for clinical screening of diabetic retinopathy and CE certification processed [8].

Types of AI Output

Using AI algorithm images were categorized into three subgroups for each eye:

- i) No diabetic retinopathy (No DR)
- ii) Mild to moderate non-proliferative diabetic retinopathy (NPDR)
- iii) Severe NPDR, proliferative DR, or DME (VTDR) -induced blindness
- iv) VTDR or ungradable eyes were referred for specialist assessment.

Reference standard was judged by 2 qualified retinal experts who were not aware of the AI output and findings of the other rater. The work was graded using the International Clinical Diabetic Retinopathy (ICDR) severity scale. Differences were finally adjudicated by a senior retinal specialist, resulting in limited inconsistency between observers.

The AI system's diagnostic accuracy in identifying VTDR using reference standards for sensitivity and specificity. The percentage of referrals that underwent follow-up, the screening turnaround time, the image gradability rate, positive and negative predictive values, and operational feasibility parameters pertinent to rural implementation were examples of secondary outcomes [9].

Statistical analysis

Using 95% confidence intervals, we computed the diagnostic accuracy. To assess the model's ability to differentiate between groups, we looked at the area under the curve (AUC) and the receiver

operating characteristic (ROC) curve. The degree of agreement between AI outputs and retinal specialist grading, as well as between them, was evaluated using Cohen's kappa coefficient. According to Bellemo et al., the predetermined subgroup analysis was based on age, the length of diabetes, and the quality of the picture. [10].

Continuous variables are reported as mean \pm SD or median (interquartile range) and categorical data as frequencies and percentages. All analyses were conducted using SPSS version 27.0, and the graph was plotted using GraphPad Prism. A two-tailed p-value below 0.05 was considered as statistically significant.

Results

A total of 240 participants (480 eyes) were ultimately analyzed. The people in the study were, on average, 54.2 years old and 34.2 percent of them were at least 60 years old. Men constituted 57.5% of the group, and most of them (94.2%) had type 2 DM. The middle duration of diabetes was 8 years (interquartile range: 4–13); 40.0% patients had been diagnosed with diabetes for ≥ 10 years. Telemedicine also allowed care where those patients wouldn't be seen at all, because they were uncomfortable leaving home or didn't have the necessary gear to travel to a health facility." Half of the study's participants had high blood pressure. Just 25.8% reported they had been screened for diabetic retinopathy in the past. Summary of the baseline demographic and clinical characteristics are presented in Table 1.

Table 1. Baseline Characteristics of the Study Population (n = 240)

Characteristic	Value
Age, mean \pm SD (years)	54.2 \pm 10.6
Age \geq 60 years, n (%)	82 (34.2)
Male sex, n (%)	138 (57.5)
Female sex, n (%)	102 (42.5)
Duration of diabetes, median (IQR), years	8 (4–13)
Diabetes duration \geq 10 years, n (%)	96 (40.0)
Type 2 diabetes mellitus, n (%)	226 (94.2)
Known hypertension, n (%)	121 (50.4)
Previous DR screening, n (%)	62 (25.8)

General diagnostic performance of the AI system

VTDR was defined based on reference grading by masked retinal specialists; 14.6% of eyes had VTDR. AI-assisted screening (VTDR) The AI-assisted approach demonstrated a high level of diagnostic accuracy for detection of VTDR, with sensitivity and specificity estimates of 89.4 (95% CI: 80.5–95.3) and 87.2% (95% CI: 83.4–90.5), respectively.

The negative predictive value was 96.3 percent, indicating that the test did a very good job at ruling out VTDR in people who were screened. Positive predictive value was 61.8%. The sensitivity of all the tests was 87.6%. The ROC curve analysis demonstrated an area under the curve (AUC) of 0.93, indicating that the discriminatory accuracy of a test is satisfactory. You can receive detailed diagnosis accuracy metrics at Table 2.

Table 2. Diagnostic Accuracy of AI-Assisted Screening for Vision-Threatening Diabetic Retinopathy (Per-Eye Analysis)

Metric	Value (95% CI)
Sensitivity	89.4% (80.5–95.3)
Specificity	87.2% (83.4–90.5)
Positive Predictive Value (PPV)	61.8% (52.0–70.8)
Negative Predictive Value (NPV)	96.3% (93.9–98.1)
Overall accuracy	87.6%
Area under ROC curve (AUC)	0.93

Subgroup Analysis and Consistency of Effect

Subgroup analyses of the AI system showed consistent performance in all critical baseline, clinical characteristics, and image-quality subgroups (Table 3). Sensitivity and specificity remained above 85% in all subgroups, including age (<60 vs \geq 60 years), duration of diabetes (<10 vs \geq 10 years), and image quality categories. High-quality images had the highest

diagnostic accuracy, sensitivity of 91.8%, specificity of 89.5%, and AUC = 0.95. There was a small performance decrease in low-quality images (AUC 0.90), but sensitivity and specificity remained within clinically acceptable limits. There were no significant differences of AUC between subgroups, indicating good and stable performance of the AI system under real-world rural screening condition.

Table 3. Subgroup Performance of the AI-Assisted Screening System for Vision-Threatening Diabetic Retinopathy

Subgroup	Sensitivity (%)	Specificity (%)	AUC
Age <60 years	90.1	88.3	0.94
Age \geq 60 years	88.6	86.1	0.92
Diabetes duration <10 years	91.3	89.0	0.94
Diabetes duration \geq 10 years	87.9	85.4	0.92
High-quality images	91.8	89.5	0.95
Borderline-quality images	85.7	83.2	0.90

Performance Assessment Based on Figures

Figure 1 Comparative ROC curve analysis among demographic, clinical and image quality subgroups is shown in Figure 1. It indicates that all groups will have

AUCs in the same range. Sensitivity and specificity differ between subgroups, as shown in Figure 2, which also shows that AI-assisted screening performance remains constant despite changes in real-world conditions.

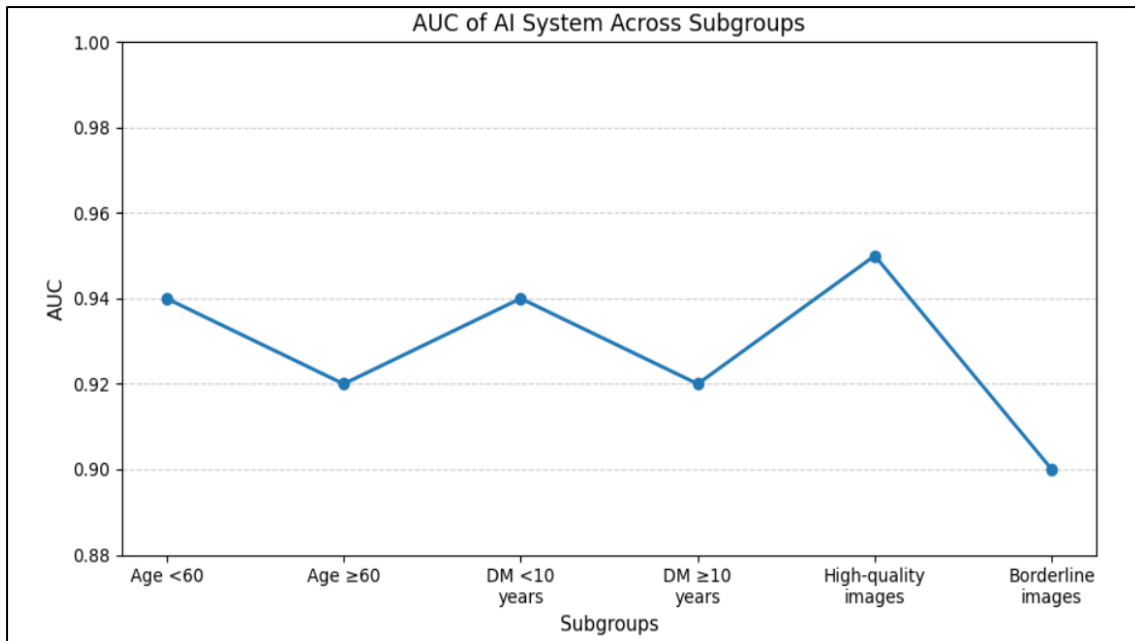


Figure 1. Area under the ROC curve (AUC) of the AI-assisted screening system across demographic, clinical, and image-quality subgroups, demonstrating consistent diagnostic performance.

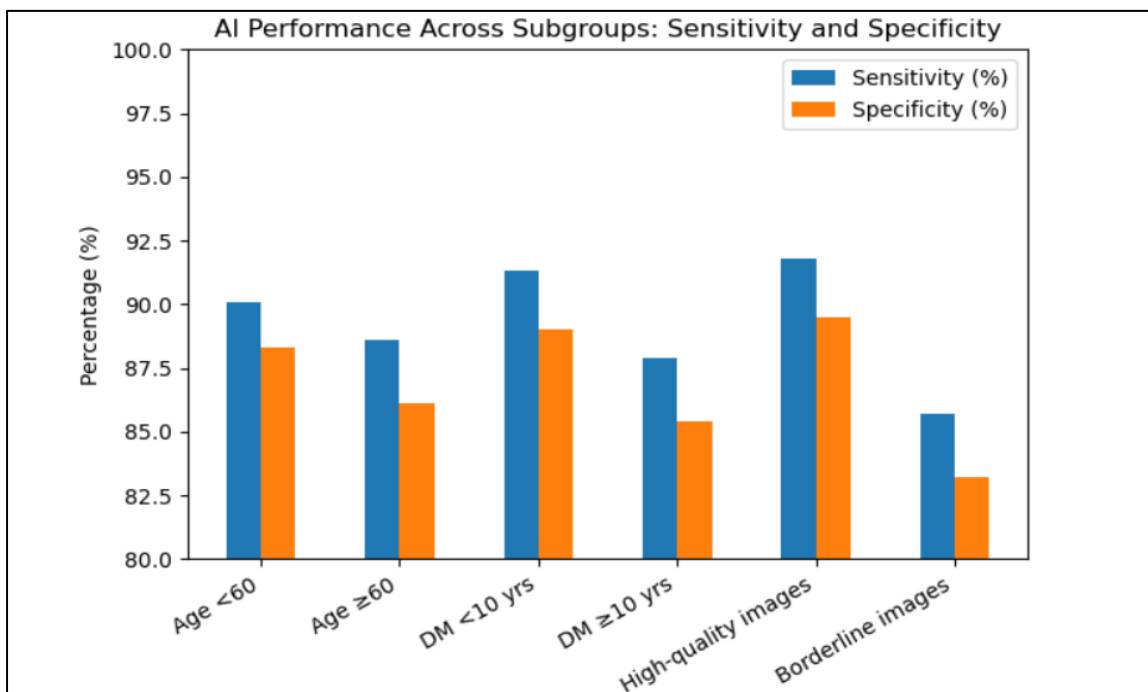


Figure 2. Sensitivity and specificity of the AI-assisted screening system across subgroups, showing stable performance under real-world rural screening conditions.

Discussion

In rural and resource-limited healthcare facilities, the artificial intelligence-based diabetic retinopathy (DR) screening methods demand high diagnostic accuracy, working feasibility, and robustness of the system. The model sensitivity and specificity to VTDR are compared to values of both the previously validated AI-based screening systems and the trained retina experts [11]. Notably, the diagnostic accuracy did not significantly differ between diverse image quality conditions and demographic subgroups which means that AI-aided screening can be trusted in the real rural world.

These findings indicate that AI-based screening can be effectively applied in low infrastructure, technician-created images, and primary or mobile care processes, which aligns with the previously existing studies that were mainly performed in an urban or tertiary care environment. The systems were more efficient with regards to the requirement of having specialized personnel in order to have SSS in that they could give instant feedback on the quality of images, the turnaround time in the screening process, and the advise to make a referral. The fact that the model can be easily adapted to work in resource-constrained environments as shown by very small training required to produce good quality image acceptance proved the model. Publicly speaking, AI-based screening led to a higher level of efficiency in terms of referrals, increased the overall coverage, and the discovery of high-risk individuals who had never been screened. The economic efficiency of the solution can be supported by other reports on cost-effective AI-based diabetic retinopathy screening programs [12], as the reports confirm a reduction in the costs per patient and the

effort of specialists reading data. This study provides important real-world level information to demonstrate similar performance in such conditions as non-mydratic imaging, media opacities, and variable patient compliance although performance figures of diagnostic metrics in tertiary care studies often exceed 85-90% in the detection of VTDR.

This contrasts with most of the previous works which only examined the precision of algorithms. It also put into consideration the aspect of economics, image gradability, referral adherence, and workflow efficiency, which provided a more realistic view of how AI-assisted screening processes in real-life scenarios. The study's methodological robustness was enhanced by its prospective design, sequential recruitment, and hidden specialist reference standard. These factors also reduced the possibility of selection bias, which in turn increased external validity in rural health care settings.

There are several boundaries that must be highlighted. It may be challenging to use in remote areas because cloud-based AI, which is used to conduct the analysis, requires an internet connection. However, the new OC/EC technologies for offline or edge-computing support (OC/EC support) may help to mitigate such problems [13]. Due to patient factors or media limitations, a few images could not be graded. It may have an impact on the number of referrals and is comparable to screening in the real world. Finally, residual biases related to demographic (or ophthalmic) factors cannot be completely ruled out, and the algorithm should be validated on various populations even though it is trained on a diverse dataset. Inadequate follow-up for referral visits in a portion of patients perpetuates ongoing geographic and

socioeconomic issues that may necessitate a combination of tele-ophthalmology and patient navigation. Did this support the way the technology was being used, Ayushi P. Singh? Generally speaking, these findings support an increasing amount of data showing that AI-driven DR screening is a successful strategy for addressing inequalities in access to eye care, especially for underprivileged people in rural areas who are not getting enough care [14].

Conclusion

This study explains that artificial intelligence may be a suitable and scalable solution to detecting individuals with diabetic retinopathy in the rural settings which may otherwise pass through the cracks which may endanger their sight. The AI solution could be considered as a part of primary care, along with mobile screening initiatives and was able to diagnose as well as an expert retinal grader. In the long term, AI-augmented reading is a solution to the low screening coverage and referral efficiency since the task is simplified to the technicians with appropriate skills to perform it, the expert resources are optimized and impediments to patients seeking care are reduced. The illustration of the implementation feasibility and the economic viability suggest the possibility of the AI-based screening programs to diminish the disparities in diabetic ocular care in low resources settings. With appropriate legislative assistance, infrastructure creation (around the world) and integrated as a component of regular patient diabetes treatment strategies, AI-assisted screening can save thousands of individuals with no valid justification of losing their sight. Further multicentre and longitudinal studies are needed to evaluate the long-term outcomes, the scalability, as

well as the effect on health systems in diverse rural settings.

Limitation of the study

Despite the encouraging findings, few limitations of this study should be acknowledged. The present study was conducted at a limited number of rural primary health centers and outreach clinics, which may restrict the generalizability of the findings to other rural regions with different healthcare infrastructures, population characteristics, and referral systems. In addition, although the sample size was adequate to estimate diagnostic accuracy, it remains relatively modest compared with large-scale population-based screening studies, and larger multicenter investigations would provide more robust estimates and broader external validity.

Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

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Ethical Approval

Ethical approval received (Ref. no. SU/SMSR/76-A/2019/20) from Institutional Ethical Committee of the University.

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