

Revolutionising Diabetic Retinopathy Screening: The Transformative Role of Artificial Intelligence

Rehman Siddiqui¹⁻², Altamash Shahriyar Ghazanfar³

Pakistan is estimated to have the highest age standardised prevalence of diabetes (DM) globally.¹ Diabetic retinopathy (DR) is estimated to be present in 28.78% of people with DM in Pakistan.² DR has 4 stages: mild non-proliferative DR (NPDR), moderate NPDR, severe NPDR and proliferative DR (PDR). Maculopathy is defined as DR lesions (exudates or haemorrhages) within one disc diameter of macula. Patients with DM may lose vision from complications of PDR or macular oedema. Early diagnosis and treatment of DR through systematic screening is essential to detect DR early and prevent vision loss. Referable DR (RDR) is a term which encompasses moderate NPDR, severe NPDR, PDR or maculopathy. Vision loss can be prevented if patients with RDR are referred to ophthalmologists for prompt evaluation and treatment.

Systematic screening programmes increase burden on local ophthalmologists. Therefore, in most European DR screening programmes, dilated fundus images are assessed by trained graders. Each patient is then either referred to an ophthalmologist or reassured and advised to attend their next scheduled screening appointment in accordance with local guidelines. The United Kingdom (UK) National Health Service (NHS) diabetic eye screening programme was established in 2003 and within 12 years it reduced the local prevalence of sight-threatening DR from 13.4% to 3.4%.

Artificial intelligence (AI) has the potential to revolutionise healthcare. The utility of AI, especially deep learning systems (DLS), in DR screening is showing great potential. There are currently only 3 AI models approved for use by the US Food and Drug Administration (FDA). The first of these was the IDx-DR DLS. The other two models are named EyeArt and AEYE-DS. There are around 23 AI models for DR screening which have received regulatory approval in Europe.³ AI is successfully integrated into the Scottish and Portuguese national DR screening programmes and was tested in the Thailand national screening programme during a prospective cohort study.

However, AI models are heavily reliant on the datasets used

^{1,3}Department of Ophthalmology and Visual Sciences, Aga Khan University Hospital, Karachi, Pakistan; ²Retina & Eyecare Centre, Karachi, Pakistan.

Correspondence: Rehman Siddiqui. e-mail: rehman.siddiqui@gmail.com

ORCID ID:

to train them. There are multiple publicly available datasets of DR such as EyePACS and Messidor.⁴ However, it is important to note that the demographic characteristics of a dataset can limit the accuracy of AI models for different ethnicities. Therefore, it is important to use a local dataset when developing a local AI model. There are currently no publicly available datasets of fundus images of Pakistani DM patients.

AI is shown to be either near equivalent or superior to human graders across multiple studies. Studies conducted in India and Thailand determined that the automated retinal disease assessment (ARDA) DLS developed by Google and Verily Life Sciences has a sensitivity and specificity of around 95%.⁵ Other DLS have shown similar performances, with both sensitivity and specificity being in excess of 90% in studies in Singapore and the UK.⁴ AI was also assessed in youth with DM and reported a sensitivity around 85% and specificity near 80% vs a retina specialist.⁶ Considering that sensitivity values > 80% are considered acceptable for DR screening, these DLS are well-beyond this cut-off. To the best of our knowledge, there are only 2 studies in the existing literature which assessed the effectiveness of AI for DR screening in Pakistan.^{7,8} In one study, fundus images were acquired through smartphone photography while using a 20D lens, which is not the standard approach for fundus photography. Consequently, validation accuracy was found to be below 75%.⁷ This is lower than the acceptable accuracy for DR screening. However, the second study adopted a standard approach for fundus photography and reported acceptable sensitivity, specificity and accuracy of greater than 90%.⁸

An important metric of the success of any screening programme is its acceptance. AI significantly improves patient compliance, likely due to the immediate availability of results. A randomised controlled trial (RCT) in Rwanda also found a statistically significant increase in adherence with recommended follow-up appointments in the AI group vs the human grader group.⁹ Another RCT conducted in the US found that youth with DM assigned to the AI group showed 100% compliance with attending their scheduled eye exams, compared with 22% in the control group.¹⁰ Multiple studies have shown high satisfaction rates with AI DR screening systems.^{9,10}

Innovative approaches such as mobile van based AI DR screening is shown to have up to 10 times the reach of fixed centres. Portable handheld fundus cameras with integrated AI functionality are also viable options. The non-mydratic Remedio Fundus on Phone camera with built in AI functionality has a reported sensitivity of 85% and a specificity of 99%.¹¹ Such approaches may be useful in areas of Pakistan with limited ophthalmology infrastructure. However, poorly developed roads, safety issues, electricity shortages and inconsistent mobile data coverage may prove to be significant obstacles to adopting such an approach. Success of the Ministry of Information Technology and Telecommunication's 5G policy would result in a more conducive environment for tele-ophthalmology initiatives.

Financial feasibility is essential when promoting adoption of new technology, such as AI in DR detection. An economic analysis modelling study, based on 39,006 consecutive DM patients in Singapore, found that semi-automated and fully automated AI screening cost \$15 and \$11 less than a human only model respectively.¹² They found that the most significant expense in the running of a screening programme is the workforce cost. Specificity was the most important factor affecting costs because low specificity is associated with a higher number of incorrect referrals. For a country like Pakistan, which has limited health budget and a non-existent DR screening system, a fully automated AI setup may be more economically feasible. This is because a fully automated AI approach would only entail the AI development and maintenance cost as well as infrastructure to acquire fundus images. A semi-automated approach would include the added expense of training graders because we lack this component which is already present in countries with existing DR screening programmes. To compound this further, there are currently no established training courses of DR grading in Pakistan.

Despite considerable benefits of AI in DR screening, there are important limitations. A scoping review, which included 131 articles, found that only 38% of studies were conducted independently of manufacturers.³ Only 8% of current AI studies are prospective, while the majority are conducted on retrospective data. Additionally, we need prospective studies to evaluate integration of AI into healthcare systems beyond sensitivity and specificity.

AI has proven to have satisfactory performance, acceptance and financial feasibility for DR screening. It has the potential to transform DR screening in Pakistan. More AI studies using both established AI models and locally developed models trained on local datasets are needed to

revolutionise the Pakistani DR screening landscape. Policy makers should facilitate and encourage the development of local datasets and AI models for DR screening.

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