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A Review of Artificial Intelligence in Diabetic Retinopathy Detection

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ABSTRACT

Diabetic retinopathy (DR) alongside diabetes is rising among the population twenty-first century and is one of the leading sight threatening cause worldwide. With early treatment in the initial stage possible, detecting the problem before it worsens is important. Different methods of eye evaluation for the changes in retina are mainly hospital based and not accessible to rural remote areas. AI methods can aid the process and provide warnings beforehand in places with inaccessible or poor health facilities. In this review, we discuss four applications - IDx- DR, Eye Art, RetinaLyze, and Bosch DR Algorithm - that are in use in real-world or under study for screening retinopathy.

Keywords: *Diabetic Retinopathy, Artificial Intelligence, Retina Screening, Early Detection, Remote Healthcare.*

INTRODUCTION

Diabetes is a chronic disease that results in insufficiency or inability to produce Insulin, a hormone critical for regulating blood sugar levels. Due to these abnormalities, increasing amounts of glucose build up in the bloodstream, which over time causes damage to the blood vessels [1].

This increase in glucose called hyperglycemia, leads to deposition of fat in the arteries followed by thickening and blockage of arteries. The smaller vessels are particularly affected by hyperglycemia leading to leaky vessels, and new vessel formation (neovascularization). The changes produce a series of pathological effects on the vessels supplying, mainly the eyes, nerves, kidneys and heart and thus complications like diabetic retinopathy, neuropathy, nephropathy and cardiomyopathy respectively [2].

The incidence of diabetes is increasing in this twenty-first century and so with it, diabetic retinopathy (DR) is also on the rise. It has become one of the primary cause of vision loss and blindness worldwide. The prevalence of DR among diabetic patients is estimated to be 103 million worldwide and by 2045 they might be a rise to 161 million individuals [3].

DR is a spectrum of changes in the eye produced by the ischaemic changes in the blood vessels. It is initially characterized by damage to neurons, new vessel formation, microaneurysms and haemorrhages. This initial stage is usually asymptomatic and is known as Non-proliferative Diabetic retinopathy (NPDR). NPDR is further classified into mild, moderate, severe and very severe stages on the basis of the changes in the retina [4]

Later the vessels become leaky and there will be features like cotton wool spots, venous bleeding and intraretinal microvascular abnormalities [1]. The ischemia when prolonged leads to hypoxia releasing vascular endothelial growth factor leading to proliferative diabetic retinopathy (PDR). This is a sight threatening condition [5].

Evidence suggests that early diagnosis and timely treatment can prevent vision loss from DR [6,7].

Regular and annual eye screenings of diabetic patients are mandatory to identify the earliest signs of retinopathy and, allowing for timely intervention. However, due to inadequate well equiped health facilities and the scarcity of ophthalmologists in the rural areas, the follow up of the patient with DR is limited.

The integration of artificial intelligence (AI) into the field of ophthalmology, for the management of DR and its complications can remarkably changes the approach to diabetes-associated ocular diseases [8].

Artificial intelligence applications with machine learning (ML), deep learning (DL) and computer vision (CV) techniques can automate the analysis of retinal images. It can accurately classify the stages of diabetic retinopathy based on retinal features and can also predict disease progression.

Retinopathy screening is demanding and time-consuming for healthcare professionals, so the use of AI has been proposed as a potential solution to enhance diagnostic performance and save human resources [9]. Automated DR detection systems would greatly benefit the early screening and treatment of DR and prevent vision loss.

This review aims to look into and summarize some of the available DR screening AI technologies and approaches published so far.

METHODOLOGY

This analysis focuses on the use of AI and deep learning to identify effectiveness for screening purposes of diabetic retinopathy. The study is based upon a systematic review of literatures for four of the available AI-technology models IDx- DR, Eye Art, RetinaLyze, and Bosch DR Algorithm.

DISCUSSION

Diabetic retinopathy is one of the most common preventable cause of blindness. This condition is managed by early identification through screening and early intervention. The screening is done by direct ophthalmoscopic evaluation. Computer assisted tomography, fundus photography in tertiary level hospitals, eye clinics and eye care centers. So routine screening of all the population at risk and timely referral of the sight threatening conditions to the ophthalmologists is limited in rural settings.

In this era the use of Artificial intelligence is and promising alternative to facilitate screening purposes, thus reducing the costs, save human resources. Machine learning uses inputs from features like recognition of shape, colour and locations of particular lesions which helps to recognize and classify DR. Algorithm based on Deep learning (DL) by convolutional neural networks (CNNs) can also help in identifying and classifying DR.

There have been many studies around the world to identify the right and efficient method to screen DR. Several AI models have been identified. Some are FDA approved and some are in the process of approval. This article compares and analyses 4 different methods highlighting its advantages, pitfall and cost effectiveness. This also looks into the usefulness of this technology in an underdeveloped country like Nepal.

The various methods for comparison in this study are :-

IDx- DR
EyeArt
RetinaLyze
Bosch DR algorithm

IDx-DR (Digital Diagnostics, Coralville, IA, USA)

IDx-DR or "Index Dynamic Resampling" is an image based diagnostics developed by IDx Technologies, University of Iowa. It is used for image enhancement and recognition, hence can be used effectively in medical diagnosis. In 2018, IDx-DR became the first FDA approved AI system , for autonomous use in medical diagnostics. In case of Diabetic retinopathy, it uses a deep learning algorithm on retinal images to identify changes like microaneurysms, hemorrhages, cotton wool spots and exudates [10].

The Topcon TRC-NW400, a fully automated nonmydriatic retinal camera is used in case of IDx-DR system. The use of the camera is easy and can be taught to the clinic staffs without involvement of clinicians and experts. The images are then transferred to the AI program and the results are produced instantly within minutes. [11]

This FDA approval has facilitated its use in clinical settings and has high regulatory standards. Hence ensuring accurate detection of DR and Macular Edema from fundus images. A study by Gulshan et al. (2016) reported an accuracy of 94.5% in detecting diabetic retinopathy with IDx-DR in a large-scale clinical trial [12]. Another study done in 2021 reported a sensitivity and specificity of almost 93-94% for DR positive and DR negative patients [13]. The major draw back of this technique is that it requires high quality images, hardware requirements and FDA approved medical devices and thus incurring high costs.

EyeArt (EyeNuk, Inc.)

EyeArt was developed by EyeNuk Inc. and uses convolutional neural networks (CNNs) to assess images. It is one of the most validated AI technology by experts at different multicenter clinical trials on early diagnosis and treatment of diabetic retinopathy. Integration with simple cameras. EyeArt analyses the captured images from the cloud bassed AI medical devices and generates reports within minutes. Thus making this screening system On site, realtime DR screening at all different kinds of health facilities.

This technology is also FDA-approved and CE-marked, indicating its regulatory approval for use in clinical settings in the United States and Europe [14,15].

RetinaLyze (RetinaLyze System A/S ,Copenhagen, Denmark)

An application of artificial intelligence for ophthalmic diagnostics, Retinalyze was developed by RetinaLyze AI. It is a web based service and analyses each image separately. It can analyze the images quickly and is efficient for large-scale screening.

RetinaLyze has received various regulatory approvals, including CE marking, which allows it to be used in European Union markets. It is designed to be integrated into existing healthcare workflows thus enhancing the efficiency and accessibility of DR screening [16]. The company claims a high level of accuracy of this method, however large scale peer reviewed studies are lacking to validate its effectiveness in clinical settings.

Bosch DR (Bosch Healthcare Solutions GmbH, Germany)

Bosch DR algorithm uses deep CNN to detect the retinal image with DR. The computational models have numerous layers and it identifies features of DR [17]. Bosch Healthcare Solutions designed Bosch DR, a machine learning algorithm with comprehensive system, capable of detecting multiple stages of DR.

The system works on automated image analysis and can reduce the workload of healthcare providers, increases screening efficiency and enables earlier diagnosis especially in primary care settings. Bosch-DR has been primarily used in research trials. The research has shown it as a competitive technology in detecting diabetic retinopathy when compared with other AI tools. However specific peer-reviewed publications on its effectiveness are not widely available.

The following table 1 compares these four AI Technologies. The various studies have shown good sensitivity and predictive value of these techniques as compared in the following table.

Parameter	**IDx-DR**	**RetinaLyze**	**EyeArt**	**Bosch-DR**
Sensitivity	93.33 [9] 82-92 [11]	74.1 - 89.66% [8]	91.3%(90.9-91.7)[19] 94.2-95.2% [18]	91% [17]
Specificity	95.45%[9] 87-92% [11]	71.8 - 93.64 [8]	91.1% [19](90.0-91.3)	96%[17]
Positive Predictive Value (PPV)	91.80% [9] 68-77 [11]	62.65 - 86.0 [8]	72.5% [19] (71.9- 73.0)	94%[17]
Negative Predictive Value (NPV)	96.33% [9] 94-97 [9]	87.29 - 92.9[8]	97.6%[19] (97.5-97.7)	95%[17]
Cost	$ 101 [9] $13,000 - 22000 initially for camera, plus an additional $25 per patient screened. High (requires high-quality fundus camera and cloud infrastructure)	The cost is usually $ 0.43 to $ 2.15 (£0.35 to £1.73). [18] There are additional costs for data management and storage Moderate (cloud-based, integration with cameras)	$49.58 (£39.93) per patient for the EyeArt test,[18] Moderate (hardware + software cost)	Moderate to Low (can be implemented with existing retinal imaging devices)
Efficiency	High (real-time AI analysis, integrates with EHR systems)	High (automated image analysis, quick results)	High (real-time, automated analysis)	Moderate (depends on integration and speed of system)

All these techniques are being used in different parts of the world.

The British Diabetic Association recommends that screening programs for DR should have specificity and specificity levels of 80% of higher [17] and the IDxDR, Eyeartand Bosch DR Algorithm comfortably surpasses this requirement.

The adoption of these AI tools is growing, particularly in regions with high rates of diabetes and limited access to specialized care, where AI can bridge the gap by providing accurate, measurable and cost-effective solutions for DR screening and management.

Clinical Implementation by Country:

AI System	Countries
IDX-DR	United States, Europe (UK, Germany, Netherlands), India, Australia
RetinaLyze	United Kingdom, India, Middle East (UAE, Saudi Arabia)
EyeArt	United States, Europe (UK, Germany, Netherlands), India, Australia
Bosch-DR	Germany (Research), United States (Research), India, China

IDx-DR and EyeArt are the most widely implemented AI-based DR detection systems, particularly in the United States and Europe, as well as in India and Australia, addressing both urban and rural screening needs. [20,21]
RetinaLyze is mainly in use or under trial in Europe and India, with some interest in the Middle East.[22]
Bosch-DR is applied in Germany, India [23,24] , and China [25], mainly for research and development rather than widespread clinical practice.
In Nepal, AI has been incorporated into various health sectors recently in the post-COVID-19 era. AI is being used to diagnose breast cancer, cervical cancer brain tumors like glioma. It has also been involved in detecting endoscopic and colonoscopic gastrointestinal tract lesions [26]. The adoption of AI-based diabetic retinopathy (DR) screening technologies is still in the nascent stages [26-28]. The limitation is posed by people acceptance of the advance technology, ethical concerns regarding privacy of the patient and technological limitations [29]. To implement AI-based diabetic retinopathy (DR) detection tools like IDx-DR or EyeArt in Nepal, a cost-effective, integrated approach is the key. The geographical limitations for accessibility of health care, scarcity of health care professional and lack of education demands the use of these AI base models even more for better coverage at community levels. They can use existing infrastructure, look for cloud-based solutions, train local providers including Female Health Care workers, Auxillary Health workers(AHW) to reduce staffing expenses, and build partnerships with governments and NGOs to reduce operational costs.

CONCLUSION

AI can bridge the gap in healthcare access, particularly in remote and underserved regions. Incorporation of telemedicine, and referral pathways also provides effective remote management of the patient in areas where access to health care is limited [26,30]. This eliminates the need for specialist involvement, enabling quicker diagnoses and earlier interventions. This timely detection can significantly reduce the risk of blindness for patients with diabetes. To ensure the sustainability of the program, the models can also be linked with existing health care management systems running in the government sectors. The programs can be made financially compatible by subsidized pricing models and integration into the existing national health insurance or social welfare schemes. Education, public awareness campaigns and collaborations with local organizations also engages communities and help in maintaining sustainable screening programs [27,31]. As AI technology becomes more cost-effective, regular screenings could become a standard part of diabetic care. With ongoing improvements to algorithms and a focus on personalized treatment, AI has the power to revolutionize the global effort to combat diabetic retinopathy, offering hope for better outcomes and healthier lives.

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