Artificial Intelligence Brings DR Screening Beyond Eye-Care Practices

A new device achieves autonomous detection of vision-threatening diabetic retinopathy.

Although diabetic retinopathy (DR) screening is recommended for all diabetic patients, less than half get screened annually,[1] even in the developed world. Because more than 30 million Americans have diabetes, and diabetic patients outnumber eye-care professionals by 700 to 1 in the United States,[2] there aren't enough providers to meet the DR screening needs of this growing diabetic population. About 1.4 million US patients are diagnosed with diabetes annually.[2]

Aware of this unmet need, machine learning scientist Kaushal Solanki, PhD, founded Eyenuk, which offers the EyeArt autonomous artificial intelligence (AI) system. The device automatically detects more-than-mild diabetic retinopathy (mtmDR) and vision-threatening diabetic retinopathy (vtDR) in eyes of adults diagnosed with diabetes who have not been previously diagnosed with mtmDR.

"The system can perform DR screening at primary care physician (PCP) offices, nursing homes, pharmacies, and more, and identifies patients with DR who need care from an ophthalmologist or retina specialist," says Yi Zhang, MD, PhD, assistant professor of ophthalmology at Temple University in Philadelphia, Pennsylvania.

Says Alan L. Wagner, MD, FACS, FICS, AME, president and retinal surgeon at Wagner Macula & Retina Center in Virginia Beach, Virginia, "We had been looking for an AI solution to support and improve our community outreach and DR screening programs for decades. This robust, platform-agnostic, and validated AI solution for eye disease detection grabbed our attention."

HOW IT WORKS

The EyeArt system is the first FDA-cleared AI technology for autonomous detection of both mtmDR and vtDR in primary care or eye-care settings, says Frank Cheng, MBA, president of Eyenuk, Inc. It is designed to detect referable and vision-threatening DR in adults with diabetes.

The system is composed of 2 parts: a Canon CR-2 AF fundus camera and the EyeArt autonomous AI system. A trained staff member at a primary care office takes patients' fundus pictures without dilating their pupils, and then uploads pictures to the EyeArt AI system, Dr. Zhang says. The system analyzes the pictures and gives a report within 1 minute. The AI will confirm whether a patient has referable or vision-threatening DR. According to the International Clinical Diabetic Retinopathy (ICDR) Severity Scale, images graded as ICDR stage 2 or worse, or that have evidence of macular edema, are labeled "referable" and images graded as ICDR stage 0-1 are labeled "not referable."

BENEFITS

The EyeArt system offers many benefits over other screening methods. No dilation is needed, it's fully autonomous, results are nearly instantaneous,

Patient screening using a Canon CR-2 camera on the EyeArt artificial intelligence system.
IMAGE COURTESY OF EYENUK

no invasive imaging is needed, and no specialist is required at the point of care. "These critical factors make large population screening manageable and efficient," Dr. Zhang says. Minimal training is needed to upload the photos.

The Canon CR-2 AF fundus camera is also portable and very mobile; it sits on a motorized table that is easy to move or transport. "You can put the entire system in a van and perform screening for people in remote areas, nursing facilities, and senior living communities," Dr. Zhang says.

The system is affordable, scalable, and remarkably easy to use, Dr. Wagner says. It can be positioned within the usual patient clinic care flow. "By eliminating barriers to care, be they distance, time, or cost, health care improves," he says. "Making diabetic eye screening as easy and ubiquitous as taking a blood pressure just before visiting a health care provider will be transformative."

Kapil G. Kapoor, MD, FACS, FICS, partner and retinal surgeon at Wagner Macula & Retina Center, says the greatest benefit of the EyeArt system is that

it addresses one of the core deficits facing the field of retina today — eliminating preventable blindness from diabetic retinopathy. "The EyeArt system removes many steps in the screening process and takes a huge step toward building a more robust screening system to scale," he says.

"The EyeArt autonomous AI system has been shown to be very accurate in studies involving tens of thousands of patients," Dr. Zhang says. FDA clearance of the EyeArt system was based on analysis of participants enrolled at primary care provider and general ophthalmology sites. Results from the pivotal clinical trial were 96% sensitivity and 88% specificity for detecting mtmDR; and 92% sensitivity and 94% specificity for detecting vtDR.

"The sensitivity and specificity of this artificial intelligence technology coupled with exceptional user-friendliness and efficiency is truly unprecedented," Dr. Kapoor adds.

REDUCING WAIT TIMES

The EyeArt system has played an important role during the COVID-19 pandemic. "Many patients are worried about visiting a physician's office," Dr. Zhang says. "The system can reduce patients' visit times and minimize their exposure to infectious diseases." Since it doesn't require pupil dilation and can be performed as patients wait for an appointment, patients spend only a few minutes to have fundus photos taken and then get an immediate report. The system can be easily delivered to any other facility for a screening event to avoid hospital exposure. Cheng adds that clinician face-to-face time with patients can be reduced to 2 to 3 minutes from 20 to 30 minutes when a close-up ophthalmoscopy examination was involved.

MORE TIME FOR PATIENT CARE

The bottom line is that the EyeArt system is freeing up retina specialists' hands and time to focus on mission-critical therapeutic intervention for patients who need timely specialist treatment, Cheng says. Retina specialists no longer need to be inundated with screening diabetes patients who may or may not have treatable eye disease, because the EyeArt AI technology is validated to match retina specialists' performance in detecting DR.
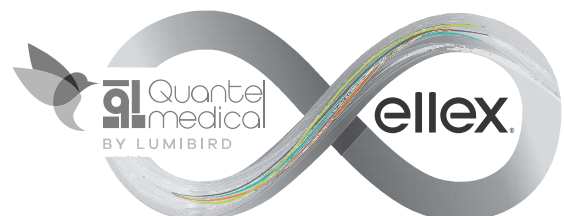
Because pharmaceutical and surgical therapeutics can effectively prevent DR-related blindness when patients are identified and treated on a timely basis, offering convenient and reliable DR screening without overburdening eye-care professionals has become a top priority of governments, health systems, and payers worldwide, Cheng concludes. **RP**

REFERENCES

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