ASSESSMENT OF ARTIFICIAL INTELLIGENCE SOFTWARE FOR AUTOMATIC SCREENING OF DIABETIC RETINOPATHY BASED ON FUNDUS PHOTOGRAPHS IN MELANODERM SUBJECTS

SODA MBAYE, MD, AÏSSATOU AW, MD, EL HADJI MALICK SY, MD, ALY MBARA KA, MD, JEAN PIERRE DIAGNE, MD, HAWO MADINA DIALLO, MD, AUDREY SAMRA, MD, PAPA AMADOU NDIAYE

Purpose: To assess the Gaiha Prio Retino +™ Artificial Intelligence (AI) software for detecting diabetic retinopathy (DR).

Methods: This prospective study was conducted from March 1, 2021, to September 30, 2022, in the Ophthalmology Department of the Abass NDAO Hospital (Dakar, Senegal). The clinical classification of DR was based on American Academy of Ophthalmology. The clinical results were compared with those obtained from the automated reading of retinophotos taken using Gaiha Prio Retino +™, a software designed to detect DR.

Results: The study covered 305 eyes. Referable DR was observed in 104 eyes by the ophthalmologist and in 96 eyes by AI, corresponding with a sensitivity of 92.31%, a specificity of 99%, and an area under the curve of 0.989. Vision-threatening DR was detected in 102 eyes by the ophthalmologist and in 94 eyes by AI, with a corresponding sensitivity of 92.16%, specificity of 99.01%, and an area under the curve of 0.975. Maculopathy was identified in 93 eyes by the ophthalmologist and in 89 eyes by AI, with a corresponding sensitivity of 95.7%, specificity of 97.17%, and an area under the curve of 0.988.

Conclusion: Considering these results, the authors may conclude that Gaiha Prio Retino +™ is an effective tool for screening referable DR.

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Diabetic retinopathy (DR) is a public health issue. According to a recent report by the World Health Organization (WHO), this is the third cause of blindness in industrialized countries and the fourth globally.[1] In sub-Saharan Africa, the prevalence of DR ranges from 15% to 52%.[2] In Senegal, it is estimated to be 60.78%.[3]

This high prevalence provides a rationale for the adoption of diagnostic tools allowing the early detection of DR to thus limit the rate of blindness related to diabetes. The use of portable nonmydriatic retinal cameras, with deferred reading of photographs by ophthalmologists, marked the first step toward the digitization of DR screening. However, in recent years, automated retinal photography reading platforms built on AI standards have been developed, replacing the need for ophthalmologist interpretation.

Most studies on DR screening using AI software have been performed in developed countries. The application of this technology in developing countries, where access to care and the number of specialists are limited, is therefore well-founded.

From the Abass Ndao Hospital, University of Cheikh Anta DIOP, Dakar, Sénégal.

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Reprint requests: Papa Amadou Ndiaye, Mermoz, 21051 Dakar Ponty, Senegal; e-mail: pagets001@gmail.com

We thus conducted this study to assess an AI software (Gaiha Prio Retino +™) by comparing its results from the automated reading of retinal photographs of diabetic patients to the clinical interpretation by ophthalmologists.

Materials and Methods

This was a prospective, descriptive, and observational study performed for over 18 months (from March 1, 2021, to September 30, 2022) in the Ophthalmology department of the Abass NDAO Hospital (Dakar-Senegal) with the approval of the Committee of Research Ethics at the Cheikh Anta Diop University of Dakar.

We included patients monitored for DR (with or without macular edema) and diabetic patients referred for ophthalmological assessment by the hospital's diabetology center. We informed patients about the purpose of our study, and they gave us their consent. Data were collected with strict compliance to medical confidentiality.

Each diabetic patient underwent a complete ophthalmological examination, and 2 specialist physicians performed the clinical classification of DR based on that of the American Academy of Ophthalmology.

Color fundus photographs were taken following pupil dilation using Topcon's TRC-NW8 and OCT-Triton cameras with a 45° field of view centered on the macula. At least 2 photographs of each eye were taken (at least 1 centered on the macula) and then uploaded to the AI software. The results were compared with the ophthalmologist's findings based on a given percentage of probability.

AI software Gaiha Prio Retino +™ is a sophisticated set of algorithms capable of processing and analyzing images, built on computer vision and convolutional neural networks to accurately detect DR. This software as a service (SaaS) contains 5,020 images in its database, including 3,765 of nonreferable RD and 1,255 of referable RD. The so-called referable DR (rDR) is also known as more-than-mild DR (mtDR) and vision-threatening DR (vtDR). rDR includes moderate or severe nonproliferative retinopathy or proliferative retinopathy with or without macular edema. vtDR is characterized by severe nonproliferative retinopathy or proliferative retinopathy with or without macular edema. It should be noted that vtDR is a subset of mtDR and constitutes an advanced stage of DR.

Gaiha Prio Retino +™ allows switching languages between English, French, and Portuguese. It also has the capacity to enhance image processing before analysis (Figure 1).

Statistical Analysis

The data were analyzed using Excel 2016 and SPSS18.

The sensitivity, specificity, and area under the curve (AUC) of the software for detecting DR, rDR, and maculopathy were calculated. Overall, 95% percent confidence intervals were used for sensitivity (Se), specificity (Sp), positive predictive value (PPV), and negative predictive value (NPV). For all statistical tests, a P-value of <0.05 was considered significant.

The Youden index was used to determine the diagnostic accuracy of the software. The index depends on Se and Sp (Se + Sp −1). The test is effective if the index is close to 1.

Results

Altogether, 156 diabetic patients (305 eyes) were included, 93.6% of whom were suffering from type 2 diabetes. 77,44% were women and 26,56% were men, resulting in a sex ratio of 0.38. The average age of patients with DR was 58.45 years. Both the ophthalmologist and the AI found that the fundus was normal in 58.68% and DR was diagnosed in 41.31% of the cases by the ophthalmologists and in 38.03% by AI.

Nonreferable DR was observed in 65.90% of the cases by the ophthalmologist and in 65.24% by AI, and referable DR in 34.09% and 31.47% of the cases, respectively. vtDR was found in 33.44% of the cases by the ophthalmologist and in 30.81% by AI, and maculopathy was found in 30.49% and 29.18% of the cases, respectively.

The AUC for the receiver operating characteristic (ROC) was 0.989 for referable DR (Figure 2), with a sensitivity of 92.31% and a specificity of 99%. For VtDR, the AUC was 0.975 (Figure 3) with a sensitivity of 92.16% and specificity of 99.01%. For maculopathy, the AUC was 0.988 (Figure 4), with a sensitivity of 95.7% and a specificity of 97.17%. All these data were reported on Table 1.

Discussion

The statistical data revealed that the AI algorithm used in our study showed very good sensitivity and specificity in diagnosing all types of DR, with values of 92.06% and 100%, respectively, and an AUC of 0.968. For DR, sensitivity reached 92.31%, specificity was 99%, and AUC was 0.989. These results are comparable to those of existing AI software used in DR screening.[4–9]

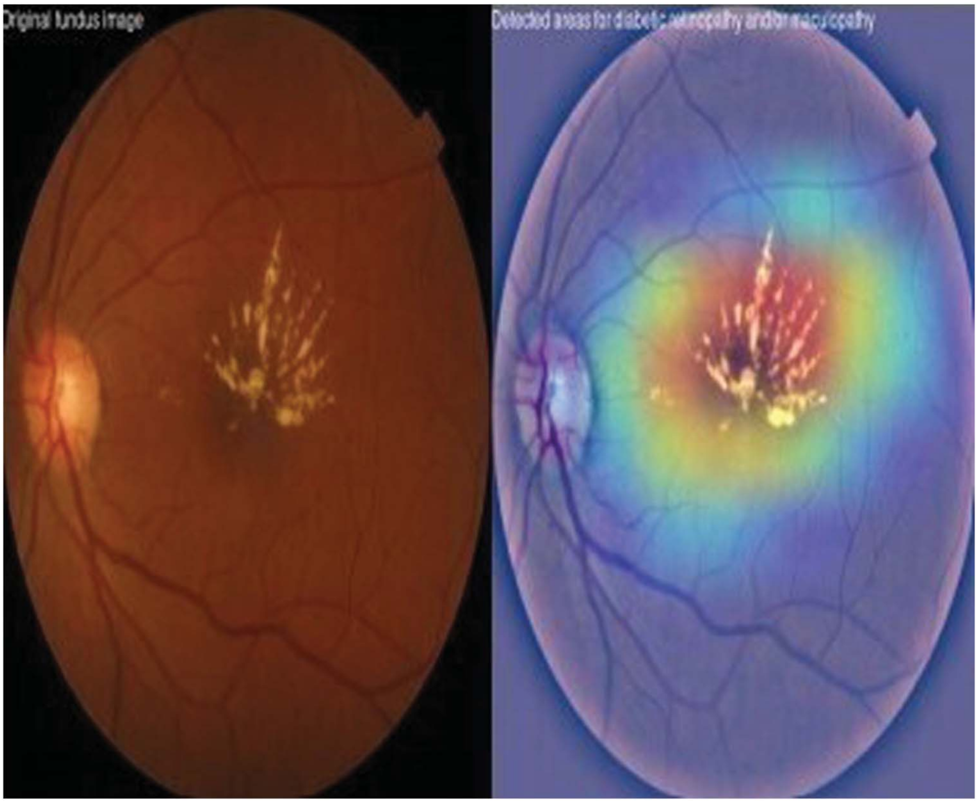

Fig. 1. Automatic screening of a fundus photograph by the Gaiha Prio Retino +™, showing a referable diabetic retinopathy detected with a probability of 0.9 for P3.

Deep learning, the tool upon which our software is based, has revolutionized the design of DR screening algorithms, thanks to the large amount of data used. This is shown by Abramoff,[4] who compared the performance of the improved algorithm IDx-DR version X2.1 to the previously published performance of the same algorithm without deep learning. The IDx-DR X2.1 device performed significantly better in detecting referenceable DR, showing a 30% increase in specificity.

For Gaiha Prio Retino +™, an algorithm was developed using multiethnic data with a fairly broad spectrum, including fundus images of melanoderm subjects. This allowed it to integrate various clinical presentations of the disease, thus rendering it more efficient.

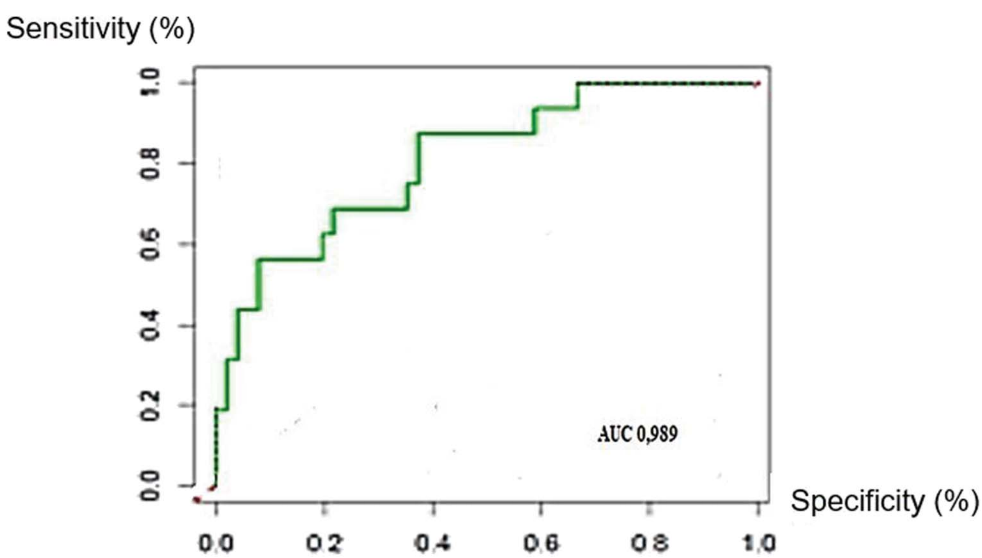

Fig. 2. Performance of Gaiha Prio Retino + ™ in detection of rDR.

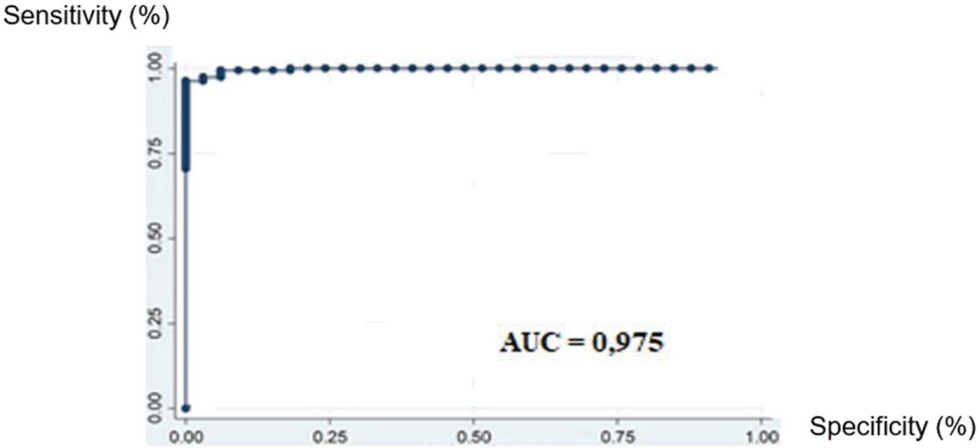

Fig. 3. Performance of Gaiha Prio Retino +™ in detection of VtDR.

Within the rDR group, we calculated the detection rate of vision-threatening DR and maculopathy and found a sensitivity of 92.16% and 95.7%, a specificity of 99.01% and 97.17%, and an AUC of 0.975 and 0.985, respectively. These data confirm that the tested algorithm is a suitable diagnostic tool for advanced stages of DR and maculopathy able to engage the functional prognosis and allow patients to be referred in time. However, sensitivity could be improved because undiagnosed positive cases are exposed to the risk of blindness.

In Africa, AI software for DR screening was applied to Zambian subjects and showed an AUC of 0.973 for rRD, with a sensitivity of 92.25% and a specificity of 89.04%, an AUC for vtDR of 0.934, with a sensitivity of 99.42%, and an AUC for maculopathy of 0.942, with a sensitivity of 97.19%.[6] These results are substantially superimposable to ours, considering a similar racial profile.

In India, Rajalakshmi[9] assessed the role of an automated AI algorithm in detecting DR in a tertiary diabetes care center using a smartphone as an imaging device. The software showed a sensitivity of 99.3% and a specificity of 68.8% for rDR, a sensitivity of 99.1% and a specificity of 80.4% for vtDR, and a sensitivity of 97% and a specificity of 75.8% for maculopathy.

The less pronounced specificity of the software could be attributed to a higher rate of moderate nonproliferative DR (NPDR) diagnosed related to nondiabetic lesions, such as drusenoid, vascular, or pigmented lesions, leading to false positives. Fundus photographs showing nonspecific lesions were not included in our software to avoid false positives.

Sensitivity is a crucial element in a DR detection system, and it requires the detection of even minimal signs of RD. However, these signs are easily covered in a low-contrast, blurry, or low-resolution photograph. Image quality is, therefore, an essential factor in improving the reliability of screening models. The Gaiha Prio Retino software is able to enhance the processing of an image before analysis. Images of poor quality, often attributed to media disturbances, were not included in the study.

Retinal photographs uploaded to Gaiha Prio Retino were taken after pupillary dilation. However, in the

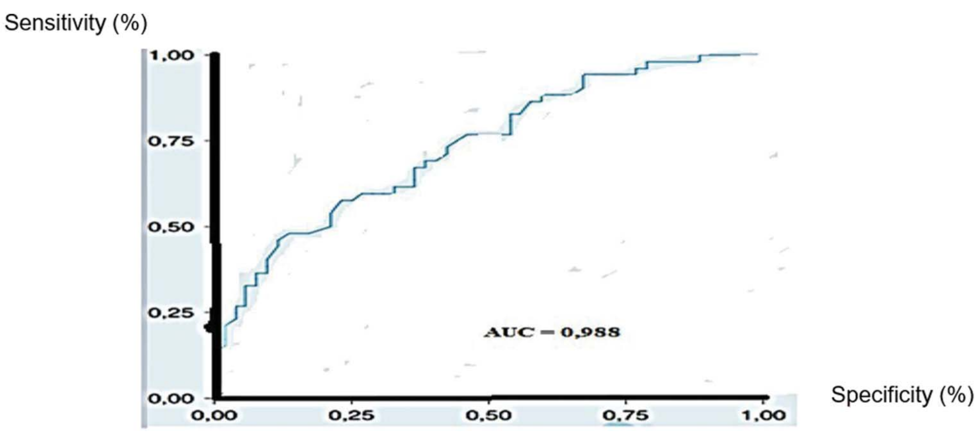

Fig. 4. Performance of Gaiha Prio Retino +™ in detection of maculopathy.

Table 1. Performance Criteria of Gaiha Prio Retino+™

	All RD	rDR	vtDR	Maculopathy
Se	92.06%	92.31%	92.16%	95.7%
Sp	100%	99%	99.01%	97.17%
PPV	100%	97.96%	97.92%	93.68%
NPV	94.71%	96.14%	96.17%	98.1%
Youden index	0.92	0.91	0.91	0.93
AUC	0,968	0.989	0.975	0.988

United States, an AI software tested on retinal photographs taken by nonmydriatic devices showed a sensitivity of 66.4% and a specificity of 72.8% in the screening of vision-threatening DR. This limited sensitivity could be related to the absence of pupillary dilation, which could affect the quality of the image.[10]

In India, an AI algorithm capable of identifying DR lesions and labeling them on a photograph has been developed, thus allowing a better comparison between AI's and the ophthalmologist's findings, as well as better monitoring of the progression of the disease.[11]

Although DR is the flagship ocular pathology for which automated screening algorithms have been developed, it has been increasingly combined with other pathologies. This is the case for Ting.[12] In their primary validation dataset, Ting developed an algorithm for screening DR, glaucoma, and age-related macular degeneration. The algorithm showed a sensitivity of 90.5% and a specificity of 91.6% for detecting referable DR, with an AUC of 0.936; a sensitivity of 96.4% and a specificity of 87.2% for possible glaucoma; and a sensitivity of 93.2% and a specificity of 88.7% for age-related macular degeneration.

A possible extension of the Gaiha Prio Retino software to glaucoma screening, which remains one of the main etiologies of blindness in our regions, is being planned.

Limitations of the Study

The sample used in our study is relatively limited. The algorithm should therefore be tested on a larger number of patients to improve its sensitivity.

Conclusion

Gaiha Prio Retino is a feasible tool for the screening of referable diabetic retinopathy in melanoderm patients with a sensitivity of 92.31% and a specificity of 99%.

This constitutes an applicable model for preventing blindness related to diabetic retinopathy in resource-limited countries, where regular screening remains an unmet need. The tool will contribute to enhancing the quality of care by relieving specialist physicians, who are already scarce, and also facilitating access to healthcare as it requires minimal human resources.

Key words: diabetic retinopathy screening, artificial intelligence.

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