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Real-world performance of an offline, automatic algorithm for diabetic retinopathy detection embedded in a handheld smartphone-based retinal camera, on two ethnically diverse populations

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Abstract

Purpose : Artificial intelligence (AI) algorithms need robust performance across diverse populations for real world deployment. We performed a retrospective, observational study to evaluate the performance of an algorithm embedded in a handheld retinal camera for the detection of diabetic retinopathy (DR) across two clinically and ethnically diverse populations.

Methods : Retinal images (field of view: 55^{o}) of 1257 individuals with diabetes, aged (mean, standard deviation) 61.5 ± 11.9 years, 59% women, were collected during volunteer-based, high-volume DR screening events in two Brazilian settings, in November 2024: 565 individuals in Itabuna (Northeastern Brazil, population predominantly of African descent), human development index (HDI) 0.712; and 692 individuals in Blumenau (Southern Brazil, predominantly of European descent), HDI 0.806. Images were acquired mostly by non-medical volunteers with heterogeneous expertise in retinal imaging. The AI tool was trained for the detection of more than mild (mtm) DR; ground truth labels were given by three independent retinal experts.

Results : Diabetes duration (mean, standard deviation), use of insulin and systemic hypertension rates were 13.0 ± 12.0 years, 53% and 70%, respectively. Overall image gradeability rate was 93.6%; gradeability was associated with shorter diabetes duration and a lower rate of insulin use ($p<0.05$). Patients from Itabuna had a higher rate of mtmDR (25%) than those from Blumenau (18%); the former had shorter diabetes duration, used less insulin and had higher rates of systemic hypertension ($p<0.05$). AI sensitivity, specificity and area under the ROC curve for the detection of mtmDR were 0.93, 0.94 and 0.97, respectively for Itabuna and 0.92, 0.93 and 0.97, respectively for Blumenau.

Conclusions : The AI tool attained an accurate, consistent diagnostic performance across two clinically, geographically and ethnically diverse samples, with image collection performed in real-world conditions, including non-professional photographers and high-burden settings. Low-cost, user-friendly devices, along with automatic detection tools, can play a significant role in avoiding blindness secondary to diabetes. Validation over diverse populations is fundamental to minimize algorithmic bias.

This abstract was presented at the 2026 ARVO Annual Meeting, held in Denver, CO, May 3-7, 2026.

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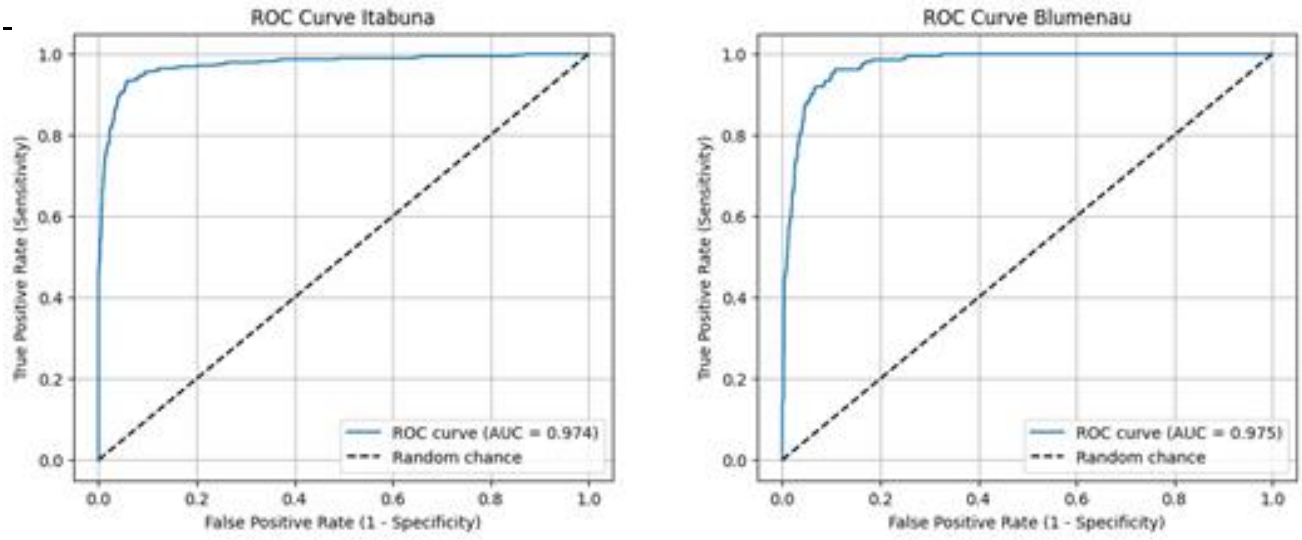
Map of Brazil showing Itabuna, Blumenau



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ROC curves of algorithmic performance