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ORIGINAL RESEARCH

Detection Rate of Diabetic Retinopathy Before and After Implementation of Autonomous AI-based Fundus Photograph Analysis in a Resource-Limited Area in Belize

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Purpose: To evaluate the use of an autonomous artificial intelligence (AI)-based device to screen for diabetic retinopathy (DR) and to evaluate the frequency of diabetes mellitus (DM) and DR in an under-resourced population served by the Stanford Belize Vision Clinic (SBVC).

Patients and Methods: The records of all patients from 2017 to 2024 were collected and analyzed, dividing the study into two time periods: Pre-AI (before June 2022, prior to the implementation of the LumineticsCore® device at SBVC) and Post-AI (from June 2022 to the present) and subdivided into post-COVID19 and pre-COVID19 periods. Patients were categorized based on self-reported past medical history (PMH) as DM positive (diagnosed DM) and DM negative (no PMH of DM). AI camera outcomes included: negative for more than mild DR (MTMDR), positive for MTMDR, and insufficient exam quality.

Results: A total of 1897 patients with a mean age of 47.6 years were included. The gradability of encounters by the AI device was 89.1%. The frequency of DR detection increased significantly in the Post-AI period (55/639) compared to the Pre-AI period (38/1258), including during the COVID-19 pandemic. The mean age of DR diagnosis was significantly lower in the Post-AI period (44.1 years) compared to Pre-AI period (60.7 years) among DM negative patients. There was a significant association between having DR and hypertension. Additionally, the detection rate of DM increased in the Post-AI period compared to Pre-AI period.

Conclusion: Autonomous AI-based screening significantly improves the detection of patients with DR in areas with limited healthcare resources by reducing dependence on on-field ophthalmologists. This innovative approach can be seamlessly integrated into primary care settings, with technicians capturing images quickly and efficiently within just a few minutes. This study demonstrates the effectiveness of autonomous AI in identifying patients with both DR and DM, as well as associated high-burden diseases such as hypertension, across various age ranges.

Plain Language Summary: Diabetic retinopathy (DR) is a microvascular complication of diabetes mellitus (DM) and a leading cause of blindness worldwide, ranking as the third leading cause of blindness in Belize. DR screening is crucial for timely diagnosis and intervention. Belize, a healthcare resource-limited country in Central America, faces significant challenges in managing DR due to the reliance on ophthalmologists from other countries, which places a heavy burden on both patients and the healthcare system. Implementing fully autonomous artificial intelligence (AI) for DR screening is a significant step towards improving eye healthcare accessibility and enhancing DR detection. In our study, the deployment of an AI-based image analysis technologyin Ambergris Caye, Belize, which previously relied on volunteer ophthalmologists, significantly increased the rate of DR screening. This AI-driven approach not only improved the detection of DR but also identified previously undiagnosed cases of DM. The impact of this technology was particularly pronounced with the COVID-19 pandemic when travel restrictions impeded visiting volunteer physicians. This approach is a game-changer for resource-limited areas, dramatically enhancing eye care access and advancing health equity.

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Introduction

According to the International Diabetes Federation (IDF),[1] 537 million adults aged 20–79 years were living with diabetes mellitus (DM) in 2021, and over three in four adults with diabetes live in low and middle-income countries. Out of that number, 32 million (1 in 11) live with DM in South and Central America, and this figure is expected to increase to 40 million by 2030.[1] Regrettably, one in three adults living with DM in these areas are undiagnosed.[1]

Diabetic retinopathy (DR), a complication of DM, is one of the leading causes of blindness in the world,[2] and research has demonstrated that approximately 25% of hospitalized patients were unaware of their diabetic status, with their initial diabetes diagnosis occurring as a result of an ophthalmologic examination.[3,4] In the US, only half of the patients diagnosed with diabetes undergo DR screening.[5–7] Without treatment, it has been shown that the 5-year cumulative rate of severe vision loss is 12% in patients with non-proliferative diabetic retinopathy (NPDR) and rises to 50% in patients with proliferative diabetic retinopathy (PDR) with high-risk characteristics.[8] However, with treatment, the 5-year cumulative rate of severe vision loss decreases by about 30%.[8,9] Therefore, vision-threatening complications caused by DR are preventable, making it crucial to take proper measures for early diagnosis and timely intervention.[10]

Patients with DM are recommended to undergo annual or biennial examinations for the detection of referable DR when they have no retinopathy and closer intervals with diagnosed retinopathy.[11] Providing annual dilated eye exams (mydriatic fundus photography) for patients under 30 years old who have had diabetes for at least 5 years and are not currently receiving care could save the vision of 319 out of every 1000 patients over their lifetime.[12] This practice, while crucial for early intervention and prevention of vision loss, imposes a significant screening burden on both patients and the health care system.[11] The challenge is magnified in areas where there is a shortage or complete absence of ophthalmologists to conduct these examinations.[13] The situation can be further exacerbated during critical events which disrupt routine healthcare services such as the COVID-19 pandemic.

Telemedicine and artificial intelligence (AI)-based screening solutions have emerged as effective approaches to address numerous barriers associated with DR screening.[14] A significant milestone in this field occurred in 2018 with the launch of the first FDA-approved AI-based diagnostic device for DR, known as LuminetricsCore® (formerly known as IDx.DR, Digital Diagnostics, Coralville, IA), which utilizes the Topcon NW400 retinal camera.[15] The AI camera system is designed to autonomously screen DR in patients aged 22 years and older, without requiring direct clinician oversight. This technology is specifically developed for use in primary care settings, enhancing accessibility to DR screening.[16]

Belize is a country in Central America with limited health care resources. Although the population is relatively young with about 76.7% of population are between 15 to 64 years old and only 4.71% are older than 65,[17] the country is experiencing a trend of increasing DM prevalence. According to the IDF, in 2021, the age-adjusted comparative prevalence of diabetes in adults (20–79 years) in Belize was 14.5%.[1] This figure is projected to rise to 15.7% by 2030.[1] Life expectancy at birth in Belize was 73.3 in 2021,decreased from 74.4 in 2019.[17] DM is one of the top five leading causes of death and decreased health adjusted life expectancy at birth in Belize.[17,18] The Belize Council for the Visually Impaired (BCVI) has reported an increase in the number of working age Belizeans who are visually impaired and that DR has emerged as the third leading cause of blindness in Belize.[19]

BCVI is a non-profit clinic with five branches across different districts in Belize, providing primary and secondary eye care services.[20] BCVI's current team includes one ophthalmologist, four optometrists, five ophthalmic assistants, and two ophthalmic technicians.[19] Stanford Belize Vision Clinic (SBVC)[21] is another non-profit eye care clinic, situated in Ambergris Caye. SBVC provides primary eye care services through volunteer faculty and trainees from university institutions.

The COVID-19 pandemic significantly disrupted operations at SBVC, as travel restrictions halted volunteer trips, consequently impeding patient access to eye care services. In response to this challenge and to enhance DR screening capabilities, the AI camera system was implemented at SBVC in June 2022. This AI-based screening tool aims to improve access to DR detection services, particularly in the absence of on-site specialists.

The performance metrics of the LumineticsCore AI camera have been evaluated and confirmed in several prior studies[15,16] according to the current guidelines for AI diagnostic accuracy in ophthalmology.[22] Additionally, its effectiveness has been assessed in patient follow-ups within both well-resourced[23,24] and underserved areas in the United States and achieved US FDA clearance in 2018.[25] Despite its current approval for adults aged 22 and older, the device has also been investigated for use in younger patients with diabetes.[24] However, there is a notable gap in assessing the efficacy of this device in diverse populations different form the US, especially in underserved areas that face a shortage of ophthalmologists and other essential resources.

This study aims to provide comprehensive insights into the prevalence and characteristics of DM and DR within the patient population served by the SBVC. Additionally, it seeks to evaluate the impact of the AI-based screening system in enhancing eye healthcare delivery under normal circumstances and during the challenging situation of the COVID-19 pandemic.

Materials and Methods

Study Design

This study employs a retrospective cross-sectional design to evaluate the impact of the AI camera device implementation on DR and DM screening outcomes. The cohort consists of 1879 patients of any age who were referred to the SBVC in Ambergris Caye, Belize, Central America for ocular examinations or screenings.

This study was conducted in accordance with the ethical standards of the institutional research committee and with the 1964 helsinki Declaration and its later amendments or comparable ethical standards. Ethical approval for this study was obtained from the Institutional Review Board (IRB) of Stanford University (IRB protocol #70598) and Belize Ministry of Health and Wellness (Ref: GEN/147/01/24 (36) Vol.V1). Belizekids.org[26] is a non-profit organization that supports the SBVC with equipment and facilities in Belize, and authorizes the Stanford University School of Medicine to use the data collected at their clinics, including the results from the new AI camera system. As the analysis was retrospective, a waiver of informed consent was granted. Patient confidentiality and anonymity were maintained throughout the study by assigning unique identification codes to each participant and by storing data in a secure, password-protected database.

Data Collection

Faculty and residents from the Stanford Byers Eye Institute, New York University Langone Eye Center, University of Wisconsin, University of South California, and the University of Washington make several trips annually to volunteer at SBVC. They examine patients of all ages and record their findings and diagnoses. Since the implementation of the AI camera at SBVC, patients are screened by the device regardless of their age. Although the AI camera is FDA-cleared for patients 22 years and older, this study included patients younger than 22 years in the examinations align with the other studies used the same AI device for patients younger than 22 years.[24] Patients requiring referral are then seen by ophthalmologists during their visits to Belize. The data from the ophthalmologists and camera is then de-identified and compiled into an Excel sheet, which was used for this study. The process by which AI camera analyzes images has been detailed in our previous publications.[16] To summarize, following a 2-minute dark adaptation period for patients, two images are captured per eye, one macula-centered and one optic disc-centered, using a Topcon NW400 nonmydriatic fundus camera operated by a technician in a primary care setting. These images are then sent to a cloud-based AI system for assessment of DR lesions. If the initial results are inconclusive, the image-capturing process is repeated up to four times. Otherwise, the system returns a result to the technician, indicating whether the test is negative or positive for more than mild diabetic retinopathy (MTMDR).[16]

Data Analysis

Data was analyzed using IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive data are reported as mean ± standard deviation (SD) and median where appropriate. For comparisons between groups, the Mann–Whitney *U*-test was used to compare mean ages between Pre-AI and Post-AI periods, while the Chi-Square test and Fisher's Exact test were applied for other comparisons. A p-value of less than 0.05 was considered statistically significant.

Definitions

AI Camera Outcomes

The AI camera device provides outcomes based on the following categorization system:

"**Negative for MTMDR**" (More Than Mild Diabetic Retinopathy): Indicates that the patient has no or mild diabetic retinopathy.

"**Positive for MTMDR**": Indicates that the patient has more than mild diabetic retinopathy.

"**Insufficient exam quality**": Used when the device cannot categorize the image due to quality issues.

The rest of the patients are categorized as the following:

"Technical issue": Applied when screening could not be performed due to software issues.

"Not applicable": Used for patients who did not undergo AI camera screening for any reason other than technical issues.

AI Camera Gradability

The ability of the AI camera system to grade images as either negative or positive for MTMDR across all encounters including negative for MTMDR, positive for MTMDR and insufficient exam quality.

Diabetes Mellitus Status

Patients' DM status was categorized as follows:

DM Negative: Patients with no reported history of diabetes mellitus in their past medical history. Among these DM negative patients, there was a subgroup of "undiagnosed DM" who were unaware of their diabetes, with the diagnosis made based on the presence of DR during ophthalmologic screening.

DM Positive (diagnosed DM): Patients who were known cases of diabetes mellitus, as self-reported in their past medical history.

Study Periods

The study is divided into two distinct time periods to facilitate easier comparison. The patient cohorts include all individuals who visited the clinic during the pre-AI and post-AI implementation phases, respectively. Consequently, the cohorts in each period are not identical.

Pre-AI Period: Patients were screened by ophthalmologists before the implementation of the AI camera. This period includes data collected from April 13th, 2017, to June 8th, 2022.

Post-AI Period: Patients were screened using the AI camera after its implementation at SBVC, starting on June 9th, 2022, to May 10th, 2024.

COVID-19 pandemic period: This period is defined as spanning from the first day of December 2019 to the end of December 2022. Part of this period falls within the Pre-AI period, while another part falls within the Post-AI period.

Outcomes

Primary objective of this study is to evaluate the impact of implementing the AI camera at the SBVC on screening outcomes for DR and DM. Specifically, we aimed to compare the frequencies of DM and DR diagnoses, assess changes in DR detection rates among DM-positive patients, and analyze differences in the mean age of DR diagnosis between the Pre-AI and Post-AI periods. Additionally, we sought to investigate the effectiveness of the AI camera in detecting DR among patients without a known history of DM.

Secondary objectives included comparing the detection rates of DR in patients with good visual acuity (VA 20/40 or better without correction) before and after the implementation of the AI camera; VA was assessed without correction since refraction correction could not be performed by the technician. We also aimed to examine the association between DR and other systemic diseases such as hypertension, cardiovascular disease, hyperlipidemia, and smoking history. Furthermore, we sought to analyze the impact of the COVID-19 pandemic on DR diagnosis rates and the potential benefits of AI-assisted diagnosis during critical situations where traditional healthcare delivery may be compromised.

Table 1 Demographic and Clinical Characteristics of Patients Across Different Study Periods Defined as Pre-AI and Post-AI Based on the Implementation of AI Device in Stanford Belize Vision Clinic (SBVC) With Subdivisions Based on the COVID-19 Pandemic. The Pre-AI Period Represents the Time When Patients Were Seen by Ophthalmologists Who Traveled to Ambergris Caye, Belize. The Post-AI Period Marks the Period Since the AI Camera Was Integrated Into the System, With the Screened Population Included in the Study. The Table Compares Diabetic Retinopathy (DR) and Diabetes Mellitus (DM) Screening Outcomes, as Well as the Age at Detection, at SBVC During These Two Periods. Notably, the Number and Mean Age of Patients in the Post-AI Period for DM-/DR+ Patients Were Counted Only for Those Screened by the AI Device Exclusively (Not by Ophthalmologists)

Parameters	**Study periods**				**Total**	**P value**
	Pre-AI period		**Post-AI period**			
	Before COVID19	**During COVID19**	**During COVID19**	**After COVID19**		
	Ophthalmologists		**AI device and Ophthalmologists**			
Mean age (± SD)	47.5 (18.0)		47.9 (17.9)		47.6 (17.9)	NA
Number of the patients	1258		639 (AI device: 275)		1897	NA
	1033	225	34	605		
Patients with a known Hx of DM (proportion, percent)	134 (134/1258, 10.6%)		99 (99/639, 15.5%)		233	0.002
Patients without a known Hx of DM	1124		540		1664	NA
Patients with DR	38		55		93	0.000
		3	5		8	0.001
DM+/DR+ (proportion, percent)	34 (34/134, 25.4%)		38 (38/99, 38.4%)		72	0.034
DM-/DR+ Number of cases (proportion, percent)	4 (4/1124, 0.4%)		17 (17/540, 3.1%)		21	0.000
DM-/DR+ Mean age (± SD)	60.7 (0.5)		44.1 (14.9)		45.5 (17.6)	0.018

Abbreviations: AI, Artificial Intelligence; Hx, History; +, Positive; -, Negative; NA, Not Applicable.

Results

Our cohort consisted of 1897 patients, including 215 males, 393 females, and 1289 individuals whose gender was not identified. The patients' age ranged from 17 to 98, the mean age of the total cohort was 47.6 years (±17.9) with a median of 48 years. The mean age of patients with diabetes was 60.9 years (±21.5) with a median of 61 years and the mean age of patients with DR was 58.6 years (±18.9) with a median of 60 years (Table 1). The prevalence of DM in patients 44 years old or younger was 4% (37/926). This number rose to 19.1% (209/571) in the 45–65 age group, followed by 22.9% (87/380) in patients 65 years or older.

Annual visits: The highest number of patients that visited SBVC was in 2018, peaking at around 500 visits (Figure 1). There is a notable decrease in the number of patient visits from 2020 to 2022, which aligns with the COVID-19 pandemic period (Figure 1). The number of patients referred to SBVC each year is depicted in Figure 1.

Ethnicity: The most prevalent ethnic group was Mestizo followed by Mayan (Figure 2A) and consequently the greatest number of patients with DM was among Mestizo ethnicity (Figure 2B).

AI Camera Diagnostic results and Implications

The number of patients screened by AI device was 275 out of the total 639 patients screened in Post-AI period (Table 1). The gradability of AI camera was 89.1% (205 negative for MTMDR, 40 positive for MTMDR and 30 insufficient exam

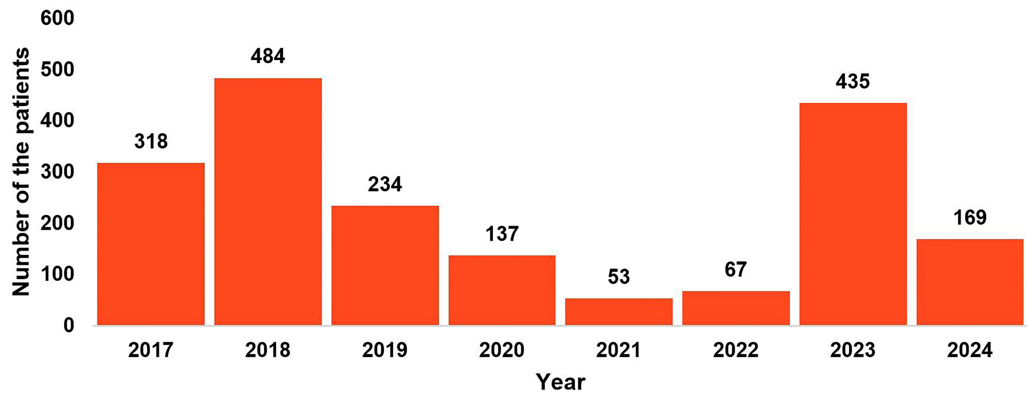

Figure 1 The number of patients visiting the Stanford Belize Vision Clinic (SBVC) annually since its establishment in 2017. The total number of patients who were screened at SBVC was 1897 patients.

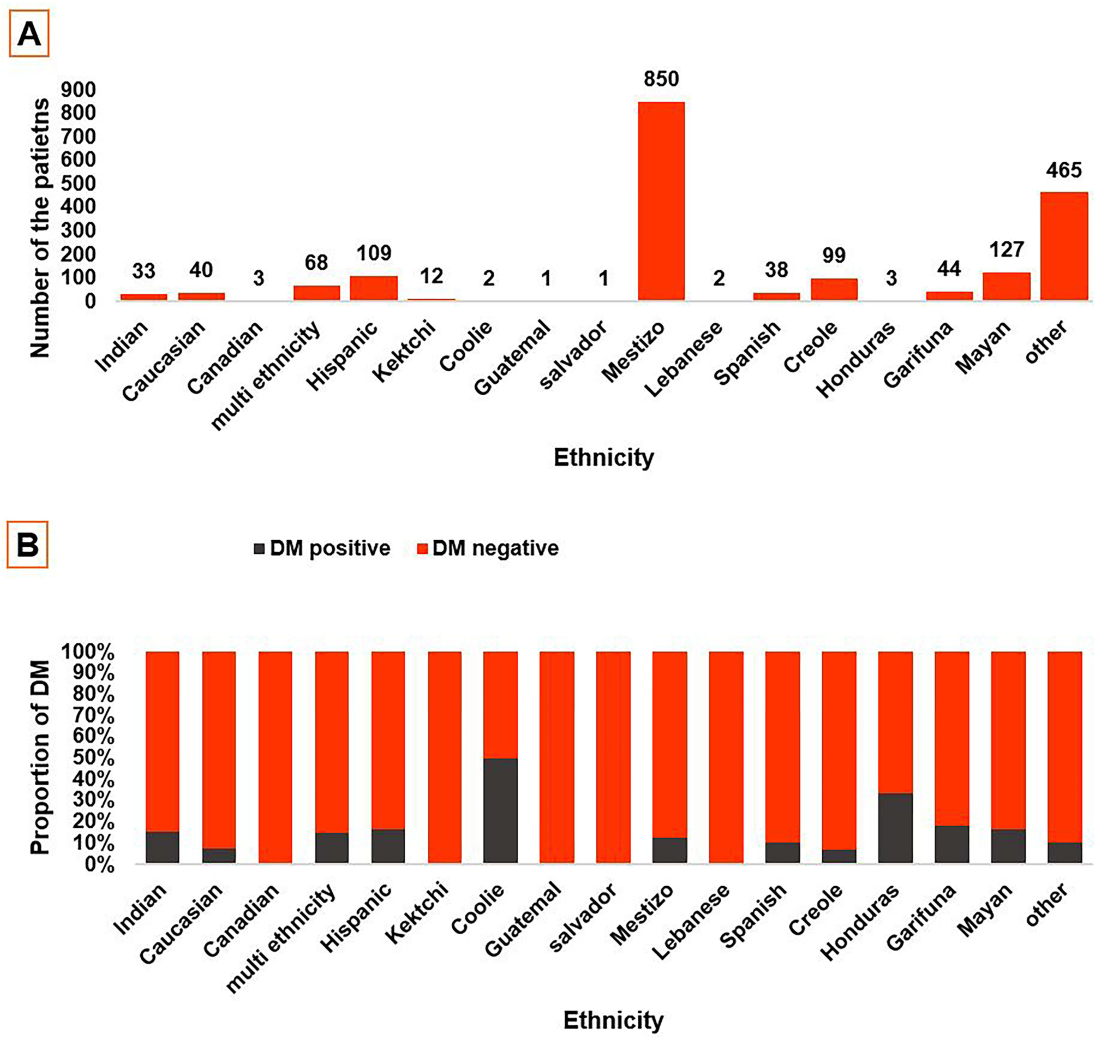

Figure 2 (**A**) Bar chart illustrating the distribution of patients across Belizean different ethnic groups out of total 1897 patients visited Stanford Belize Vision Clinic (SBVC) and included in the study. (**B**) Stacked bar chart displaying the percentage of patients diagnosed with diabetes mellitus (DM) (in gray) within each ethnic group.

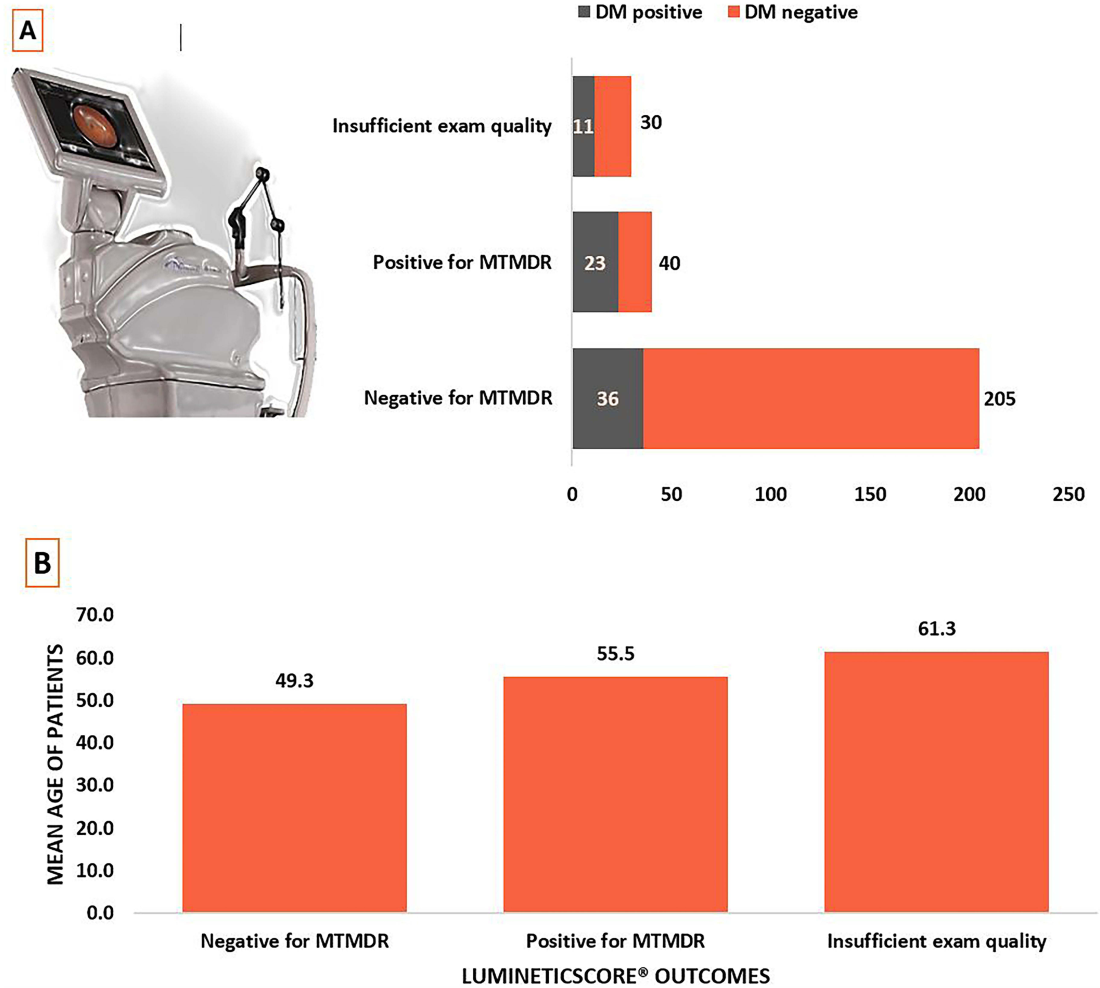

Figure 3 (**A**) Stacked bar chart presenting the diagnostic outcomes of the AI camera for diabetic retinopathy (DR) across various categories. The total number of patients who were screened by the AI-enabled camera was 275, and the distribution of diabetes mellitus (DM) status (DM positive, gray, and DM negative, Orange) are shown for each outcome category. (**B**) Bar chart illustrating the mean age of patients across different outcomes of the AI camera.
Abbreviation: MTMDR, more than mild DR.

quality). Figure 3A summarizes the diagnostic outcomes of the AI camera system. Among the 40 patients diagnosed as Positive for MTMDR, 23 were DM positive, while 17 were DM negative.

Age distribution: The mean age of patients varied across different diagnostic outcomes when screened with the AI camera system (Figure 3B). Patients diagnosed as positive for MTMDR had a mean age of 55.5 years. In contrast, those who tested negative for MTMDR had a lower mean age of 49.3 years. Notably, patients whose examinations were classified as having insufficient quality had the highest mean age at 62.1 years (Figure 3B).

Comparing Pre-AI and Post-AI Periods

Out of the total 1897 patients included in the study, 1258 visited during the pre-AI period and 639 visited during the post-AI period (Table 1).

Frequency of DR Among Patients Screened at SBVC

During the Pre-AI period, 38 out of 1258 patients (3.0%) were diagnosed with DR. In contrast, during the Post-AI period, 55 out of 639 patients (8.6%) were diagnosed with DR. Statistical analysis revealed a highly significant difference ($p < 0.05$) in DR detection rates between the two time periods, before and after the implementation of the AI camera (Table 1).

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Frequency of DM Among Patients Screened at SBVC

The total number of patients with diagnosed DM in our study was 233, representing 12.2% of the total cohort (233/1897). During the Pre-AI period, 134 out of 1258 patients (10.6%) were diagnosed with DM by ophthalmologists. In the Post-AI period, the number of diagnoses increased to 99 out of 639 patients (15.5%). This increase was statistically significant ($p < 0.05$) (Table 1).

Frequency of DR in DM-Positive Patients

Among the 233 patients who tested positive for DM, 30.9% (72 patients) were also diagnosed with DR. The detection rates of DR in DM-positive patients differed between the two periods of the study. In the Pre-AI period, 25.4% (34 out of 134) of DM-positive patients were diagnosed with DR by ophthalmologists. In contrast, during the Post-AI period, 38.4% (38 out of 99) of DM-positive patients were diagnosed with DR using a combination of the AI camera and ophthalmologist assessment. The difference in DR detection rates between the Pre-AI and Post-AI periods was found to be statistically significant ($p < 0.05$) (Table 1).

Mean Age of Patients With DR Diagnosis

The mean age of patients diagnosed with DR in DM negative patients differed between the two study periods. In the Pre-AI period, the mean age of patients diagnosed by ophthalmologists ($n = 4$) was 60.7 ± 0.5 years (median: 61 years) (Table 1). In contrast, during the Post-AI period, the mean age of patients diagnosed using the AI camera system ($n = 17$) was 44.1 ± 14.9 years (median: 44 years). The difference between the median ages of these two groups was statistically significant ($p = 0.018$), as determined by the Independent Samples Mann–Whitney *U*-test (Table 1).

Frequency of DR Diagnosis by AI Camera in DM-Negative Patients

Among the 540 patients without a known history of DM (DM-negative), 21 were diagnosed with DR, representing cases of undiagnosed DM. Of these, 17 were diagnosed with MTMDR using the AI camera system during the Post-AI period. In contrast, during the Pre-AI period, ophthalmologists diagnosed only 4 patients with DR among DM-negative patients. This difference was statistically significant ($p < 0.05$). It is important to note that the number of patients diagnosed with DR by ophthalmologists was not calculated in the Post-AI period due to potential bias. This bias could arise because ophthalmologists were aware of the AI camera results prior to their examinations during the Post-AI period (Table 1).

Potential Factors Affecting Diagnoses

Visual acuity without correction (VA_sc): We compared the detection of DR in patients who were not known to have DM and had good VA (VA of 20/40 or better without correction). In the Pre-AI period, ophthalmologists detected only one (1/795, 0.1%) as positive for DR. In contrast, during the Post-AI period, the AI camera system identified seven (7/795, 0.9%) patients as DR positive. Despite the apparent increase in detection, Fisher's exact test showed no statistically significant difference between these two periods ($p = 1.000$, 2-sided).

Cataract: The highest frequency of cataract cases was observed in the group negative for MTMDR, with a total of 50 (18.2%, 50/275) patients, followed by the insufficient exam quality group with 19 (6.9%) patients, and the positive for MTMDR group with 8 (3%) patients.

Impact of COVID-19 on Diagnosis and Role of AI Camera Device

Comparing the DR diagnosis rates within the pandemic period to those outside this timeframe (both before and after the pandemic): The COVID-19 pandemic significantly reduced ophthalmologist team visits to Belize, limiting them to once per year for a few consecutive days in 2020 and 2021. Despite this reduction, the frequency of DR diagnoses during the pandemic period (8 out of 259 patients, 3.1%) was not significantly different from the frequency outside the pandemic timeframe (85 out of 1693 patients, 5.2%, $p = 0.146$).

Comparing the DR diagnosis rates within the pandemic period before and after AI camera implementation: a notable difference emerged when comparing DR diagnoses within the pandemic period before and after AI camera implementation. Among the 259 patients seen during the pandemic (December 2019 to December 2022), the DR diagnosis rate increased from 1.3% (3 out of 225 patients) before AI camera installation to 14.7% (5 out of 34 patients) after implementation. This difference was statistically significant ($p = 0.001$). These findings underscore the potential benefits of AI-assisted diagnosis, particularly in critical situations such as pandemics, where traditional healthcare delivery may be compromised.

Association of DR With Other Systemic Diseases

An analysis was conducted to examine the relationship between DR and various health factors:

Smoking: Only four patients in the study were recorded as having a history of smoking.

Cardiovascular Disease and Hyperlipidemia: No statistically significant associations were found between DR and a history of cardiovascular disease ($p = 0.297$) or hyperlipidemia ($p = 1.00$).

Hypertension: A significant association was observed between DR and hypertension ($p < 0.001$). The likelihood of a patient having hypertension, given that they have DR, was calculated to be 36.5%.

Discussion

In this study, we observed a remarkable enhancement in the detection of diabetic retinopathy among both diagnosed (DM positive) and undiagnosed (DM negative) diabetes mellitus populations, particularly in younger ages, following the implementation of the AI-based AI camera at SBVC. Additionally, there was a notable improvement in the overall detection of DM.

DM Prevalence and Demographic Distribution

The mean age of patients with diabetes in our study was 60.9 years (±21.5), which is almost consistent with the general population reported by Wang et al,[27] where the mean age was 61.1 (SD=0.3). The percentage of *diagnosed DM* cases in our study was 12.2% of the total cohort. This is consistent with Barcelo et al study[28] but it is less than 14.5% of age adjusted diabetes that IDF diabetes Atlas reported in 2021 for Belize. However, this prevalence is higher than the US national diabetes prevalence of 11.6% (38.4 million people in the US) reported by the CDC in 2021.[29] It has been shown that the percentage of adults with diabetes increases with age, reaching 24.4% among those aged 65 years or older.[29] Our study confirmed this trend, as the frequency of patients increased with age: 37 (4%) in patients 44 years or younger, 209 (19.1%) in the 45–65 years age group, and 87 (22.9%) in patients 65 years or older.

DR Prevalence

In our study, the prevalence of DR among total population was 4.9% while it was 39.9% among DM positive (diagnosed DM) patients. These rates are significantly higher than those reported in the US, where the INSIGHT study[30] and Lundeen et al[31] found DR prevalences of 20% and 26.43% respectively, among DM positive patients.

Among DM negative patients, 1.1% were found to have DR (undiagnosed DM). This finding is lower than what CDC reports, which indicates that 3.4% of the national population has undiagnosed DM.[29] Barcelo et al[28] also reported the higher proportion of undiagnosed DM cases compared to some other central American countries. It is important to note that while the CDC's figure is based on laboratory criteria for diabetes, our study identified undiagnosed cases through the presence of DR.

AI Camera Diagnostic Results and Implications

DM prevalence: The prevalence of DM among patients visited at SBVC was significantly higher after the implementation of the AI camera (15.5%) compared to the period before (10.6%), when traditional ophthalmologic examinations were used (Table 1). These results demonstrate that the AI camera system not only aided in the diagnosis of DR among known diabetic patients but also identified potential cases of DR in individuals without a prior diabetes diagnosis. This increase could be attributed to several factors. Firstly, the AI camera's ability to provide results within minutes without requiring expert opinion potentially increases the number of patients screened at SBVC. [15], [16], [32] Additionally, AI-based systems have been shown to detect subtle retinal changes that might be overlooked in routine examinations. [33–35] The quick and non-invasive nature of the AI camera may have also encouraged greater participation across all age groups, improving patient compliance. [24] However, it is important to consider the overall increase in DM rates within the population as well. As pointed out by Beulens et al[36] in their review of diabetes trends, various socioeconomic and healthcare factors can influence diabetes prevalence.

DR prevalence and age distribution: The median age of patients after AI camera implementation (44 years old) was lower than before (61 years old). This observation can be interpreted in two ways. On one hand, this substantial difference in mean age suggests that the AI camera system facilitated earlier detection of DR and demonstrates the effectiveness of this device in detecting DR in younger age groups, perhaps due to less media opacity or less pupillary constriction. On the other hand, it could serve as a warning sign that DR is occurring at younger ages, indicating a need for improved DM management in this population.

The implementation of the AI camera significantly impacted the detection rates of DR. Among undiagnosed DM patients, the rate of DR detection increased 7.75 times after the AI camera was introduced, underscoring the potential of AI-based screening tools in identifying undiagnosed diabetes. Similarly, in DM-positive patients (diagnosed DM), the rate of DR detection rose by 1.5 times following the implementation of AI camera. These findings are particularly crucial in light of Murchison et al's[5] observation that less than 50% of DM patients adhere to their routine screening schedules. The increased detection rates may be attributed to several factors, including the higher sensitivity of AI systems compared to ophthalmology experts[37] improved patient compliance and follow-up[23]-even among younger ages.[24]

AI camera results: The gradability of encounters with AI camera in the Belize population was 89.1% which is significantly higher than the gradability reported for older aged cohorts in the US population [16,38] In our study, the mean age of patients with insufficient exam quality was higher (62.1 years old) among the AI camera output categories, which is consistent with the previous reports.[16,38] One of the main causes of insufficient images in older patients is media opacity (cataract),[38] while other factors could include small pupil size, poor fixation, technical issues, and corneal scarring.[39]

COVID-19 Pandemic

The annual visit data, peaking in 2018 and showing a significant decline during 2020–2022, clearly reflects the impact of the COVID-19 pandemic on healthcare services. This trend is consistent with global observations of reduced non-emergency medical visits during the pandemic period.[40–43] However, the finding that DR diagnosis rates during the pandemic (3.1%) were not significantly different from those outside the pandemic timeframe (5.2%, $p = 0.146$) is noteworthy. This indicates that DR diagnosis was not statistically significantly affected despite reduced ophthalmologist availability. The notable rise in DR diagnosis rates from 1.3% to 14.7% ($p = 0.001$) following the implementation of the AI camera during the pandemic is a significant finding, particularly for underserved areas where access to equitable eye care is essential.[44]

Influential Factors on Diagnosis

Visual acuity: We compared the performance of the AI camera with that of experts in diagnosing DR in undiagnosed DM patients with VA of 20/40 or better. Interestingly, among patients with good VA (20/40 or better), the device detected nine times more DR-positive patients with undiagnosed DM compared to an examination by an ophthalmologist. Visual acuity can be but is not always associated with retinal pathology in DR.[45] Thus, careful and accurate screening for retinal pathology is critical regardless of a patient's visual acuity.

Cataract: In our study, we found that the majority of cataract patients were categorized in the "Negative for MTMDR" group by the AI system. This finding was inconsistent with previous research that has shown that media opacity can significantly interfere with AI performance in interpreting color fundus photos and possibly lead AI to grade images with cataract as having insufficient exam quality.[38,46,47] However, further research is required to understand the severity of cataract in these patients and how it affects an expert ophthalmologist's interpretation of the same images.

Associations of Systemic Disease With DR

Cardiovascular disease: There was no statistically significant association between DR and CVD or hyperlipidemia. Different studies have shown that DR is associated with CVD and CVD mortality.[48,49] Mabala et al[50] showed that DR is a marker of CVD in DM type 1. Mellor et al[51] suggested that using deep learning on retinal photographs in DR screening programs might predict the risk of CVD. The lack of association in our study could be due to several factors, including sample size, population demographics, or study design.

Hyperlipidemia: Regarding the association of hyperlipidemia and DR, other studies also did not find a significant relationship.[52] However, this is somewhat controversial.[52–54]

Hypertension: The significant association between DR and hypertension ($p < 0.001$) aligns well with existing literature.[55,56] The likelihood of 36.5% for a patient with DR to have hypertension underscores the importance of blood pressure control in managing DR risk.

Eye Care Access and Cost-Effectiveness of DR Screening With AI in Primary Care Settings

In our study, the mean number of patients screened by an ophthalmologist was 16.3 patients per month, which increased to 27.7 patients per month after implementing the AI camera (Figure 1 and Table 1). Kuo et al[57] observed that only 33.9% of low-income DM patients in Metropolitan areas adhered to their ophthalmic screenings. Factors contributing to non-adherence in DM patients include younger age,[38,58] lower education levels, lower income, lack of health insurance,[58] lower health education level,[59] and social barriers such as limited accessibility to transportation.[60] Despite these barriers, AI implementation in primary care settings has led to increased adherence[24,38,61] and less cost on health care system compared to traditional screening methods,[62] and this is more prominent in underserved areas by increasing access leading to more health equity for patients with DM.[25]

Strength and limitations: Our study provided comprehensive data on the prevalence of DR and DM and evaluated the performance of the AI-based camera in a diverse population, albeit different from the US population. By utilizing real-world data and employing minimal exclusion criteria, the study aligns with previous research[15,25] and offers comprehensive information with strong external validity. This research also offers valuable information about this technology's performance compared to experts. Additionally, it highlights the benefits of autonomous AI in diagnosing prevalent diseases in underserved areas during periods of limited accessibility such as the COVID-19 pandemic, demonstrating an ability to maintain healthcare services. However, it is important to note the limitations of our study. One such limitation is that the accuracy of past medical history may be limited, as it relies on patient self-reporting, which can be subject to recall bias or incomplete information. This limitation may explain the unexpected lack of association between CVD and DR in our findings. Furthermore, AI system performance may vary across different settings and populations. This variability could explain why most cataract patients in our study were categorized differently by AI camera than we initially expected, falling into an unanticipated group.

Future research should focus on several key areas to enhance the effectiveness and applicability of AI-based screening systems in ophthalmology. Firstly, investigating the AI system's performance with various types and severities of image artifacts is crucial to ensure accurate patient categorization in real-world clinical settings. Secondly, developing a system that incorporates patients' past medical history based on lab data and reliable tests into the database where the results of DR screenings are saved and interpreted at SBVC could significantly improve the reliability of patient data in interpreting the images and AI camera results. Lastly, integrating glaucoma screening algorithms into the existing system could efficiently address another leading cause of blindness, especially in underserved areas.

Conclusion

The implementation of an AI-enabled fundus camera resulted in a higher rate of detection of DM and DR, along with a lower age of DR detectionduring the COVID-19 pandemic in a healthcare resource-limited region in Belize. This technology has the potential to decrease the cost burden on patients and healthcare systems by autonomouslyscreening for patients with diabetic eye disease in need of further evaluation by an eye care provider, thereby optimizing resource allocation and improving access to eye care in areas with limited specialist availability.

Abbreviations

AI, Artificial Intelligence; BCVI, Belize Center for Visually Impaired; DM, Diabetes mellitus; DR, Diabetic retinopathy; IDF, International Diabetes federation; MTMDR, more than mild diabetic retinopathy; SBVC, Stanford Belize Vision Clinic.

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Disclosure

The authors report no conflicts of interest in this work.

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