

Telemedicine Screening of the Prevalence of Diabetic Retinopathy Among Type 2 Diabetic Filipinos in the Community



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ABSTRACT

Purpose: To determine the feasibility of telemedicine screening for diabetic retinopathy in a community setting and to determine the prevalence of diabetic retinopathy among Filipino patients with type 2 diabetes in the community.

Study Design: Cross-sectional study among patients with type 2 diabetes in six community health centers in an urban city in the Philippines.

Materials and methods: Subjects were examined from November 2018 to December 2018. A three-field non-mydratric 45' fundus photographs were taken for each patient and photographs were uploaded in cloud storage and read by a retina specialist in a tertiary hospital for assessment of diabetic retinopathy and grading of the fundus photographs. The results were sent back to local health centers.

Results: A total of 387 eyes of 195 persons were examined. Overall, 288 out of 387 eyes (95.36%) had gradable quality fundus photo (grade 3 and higher) and did not need eye dilation. Prevalence of diabetic retinopathy among the respondents was 25.26% - 3.16% had mild diabetic retinopathy, 15.79% had moderate diabetic retinopathy, 3.68% had severe diabetic retinopathy, and 3.68% had proliferative diabetic retinopathy. Other fundus

findings noted include hypertensive retinopathy, glaucomatous optic nerve, age-related macular degeneration, posterior vitreous detachment, clinically significant macular edema, and epiretinal membrane.

Conclusion: Due to the significant number of patients with diabetic retinopathy among type 2 diabetics in the community, telemedicine screening was a feasible alternative to dilated fundus examination and may be considered as part of the local health program to prevent blindness due to diabetes.

Key Words: diabetes, diabetic retinopathy, telemedicine, tele-ophthalmology, community screening

PURPOSE

Diabetes is one of the greatest health and economic burdens worldwide with over 425 million people affected in 2017.[1] The Philippines, according to the International Diabetic Foundation, has an estimate of 3.7 million people diagnosed with diabetes in 2017, with around 1.7 million people with type 2 diabetes remaining undiagnosed.[1,2]

Diabetes has major health complications and can damage the heart, blood vessels, eyes, kidneys, and nerves.[3] Diabetic retinopathy is said to be the most common cause of blindness among the working-age population in the world.[4] Developing

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countries including low to middle income countries such as India and China are also said to be most at risk for diabetic retinopathy.[5] Visual impairment and blindness in diabetic patients has been shown to be lowest in countries with the national program for diabetic retinopathy screening.[6] It is alarming to note that in the southeast Asian countries, about 84% are not receiving the minimum annual eye examination recommended for diabetic patients, more so in rural areas wherein access to basic healthcare is not available.[6]

Visual loss from diabetic retinopathy is generally preventable with early detection, close follow up, and timely treatment.[7] The International Council of Ophthalmology (ICO) recommends that known diabetic patients without diabetic retinopathy be screened every one to two years in low-resource settings, with increased frequency of follow up depending on the classification of diabetic retinopathy.[8] The minimum examination should be inclusive of visual acuity and retinal examination adequate to classify diabetic retinopathy, and may be done by non-ophthalmologists trained to do retinal examination.[8]

The prevalence of diabetic retinopathy is significantly correlated with diabetes type 1, increased duration of diabetes, HbA1c levels, blood pressure, and cholesterol.[7] Despite the identification of these risk factors in numerous epidemiologic studies and extensive clinical trials that have been done, considerable variations in consistency still make diabetic retinopathy findings arbitrary.[5]

Currently, there are no organized national screening programs for diabetic retinopathy in communities in the Philippines, just as in other developing Asian countries. Moreover, health centers in local government units are not equipped for eye screening due to the absence of visiting ophthalmologists to the centers and basic tools for eye screening.

To bridge the gap, many countries are turning to telemedicine for more efficient delivery of health care services. The American Telemedicine Association (ATA) defined telemedicine as "the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status." [9] Telemedicine uses a variety of information and communication technology tools (ICT) such as 2-way video, email, smart phones,

and internet. According to ATA, four elements that are relevant to telemedicine are the following: 1. Its purpose is to provide clinical support. 2. It is intended to overcome geographical barriers, connecting users who are not in the same physical location. 3. It involves the use of various types of ICT. 4. Its goal is to improve health outcomes.[9] Telemedicine is already being successfully used in different fields of medicine such as dermatology, telepathology, and teleradiology, wherein individuals either exchange pre-recorded data or may exchange real-time information such as videoconference.[9]

In ophthalmology, it has been employed in retinopathy of prematurity screening, glaucoma screening, screening of age-related macular degeneration, and diabetic retinopathy.[10] There are different levels of validating telemedicine screening for diabetic retinopathy according to the American Telemedicine Association (ATA): "**Category 1** validation identifies patients who have no or minimal diabetic retinopathy and those who have more than minimal diabetic retinopathy. **Category 2** validation identifies patients who do not seem to have sight-threatening diabetic retinopathy and those who have potentially sight-threatening diabetic retinopathy and require prompt referral and possible laser surgery (severe nonproliferative diabetic retinopathy [NPDR] or worse). **Category 3** validation allows patient treatment to match clinical recommendations based on clinical retinal examination through dilated pupils. **Category 4** validation indicates that a program can replace Early Treatment Diabetic Retinopathy Study (ETDRS) photographs in any clinical or research program." [10]

In the Philippines, studies on telemedicine screening of diabetic retinopathy are limited. Tayapad, et al.[11], did a pilot data collection on diabetic retinopathy using telemedicine in a multispecialty primary clinic. They concluded that teleophthalmology was an effective means of identifying which patients need referrals for treatment.

The present study aims to evaluate the prevalence of diabetic retinopathy via telemedicine in a community-based cohort sample of adults with diabetes mellitus type 2, with the aim of identifying the feasibility to establish a telemedicine program in the Philippine community setting and identify the number of patients with diabetic retinopathy. The

results of this study may also be utilized to aid in planning the diabetic eye care program in our local health centers to prevent visual impairment and visual loss from diabetes.

STUDY DESIGN

This is a cross-sectional study done to investigate the presence or absence of diabetic retinopathy in type 2 diabetic patients in the community.

MATERIALS AND METHODS

Six community health centers with regular medical screening of diabetic patients in an urban city (Quezon City) in the Philippines were chosen as study sites. The target sample size was calculated to be 190 with a 95% confidence interval (± 8). Criteria for eligibility was known type 2 diabetic patients previously diagnosed in health centers and are 18 years old and above. Pregnant, non-ambulatory patients and patients who cannot sit upright for a long time were excluded from the study.

Patients were assigned a study number. Clinical history which included baseline demographic data and characteristics, symptoms, as well as review of ocular and systemic medications were recorded. The fundus photographs of the retina of the patients were taken using the Topcon TRC NW8F Plus fundus camera with a resolution of 16.2 megapixels. Three-

field nonmydriatic 45° fundus photographs were taken for each patient using the Joslin Clinic Protocol (Figure 2). The Joslin Clinic Protocol (Figure 1B) is validated for retinal photography and has been shown to be comparable with the standard ETDRS standard 35mm stereoscopic films (Figure 1A) and clinical examination by a retina specialist.[12] Fundus photographs of patients with significant media opacity and poor quality fundus photographs were retaken after being dilated with phenylephrine + tropicamide eye drops.

Fundus photographs were masked for the patients' identity and were labeled with the patient's study number and laterality. At the end of each screening, photographs were uploaded in an Electronic Medical Records folder created in an online cloud storage (Google drive) using the desktop computer and existing internet connection in the health centers. The folder was password protected and shared with the designated reader (retina specialist), at the partner institution, University of Santo Tomas Eye Institute, for reading and assessment. All identifying patient's data were withheld and were not available for online transmission.

READING OF THE FUNDUS PHOTOGRAPHS

Fundus photographs were read by a retina specialist. The reader was masked to the personal, ophthalmic, and medical information of the patient. Fundus

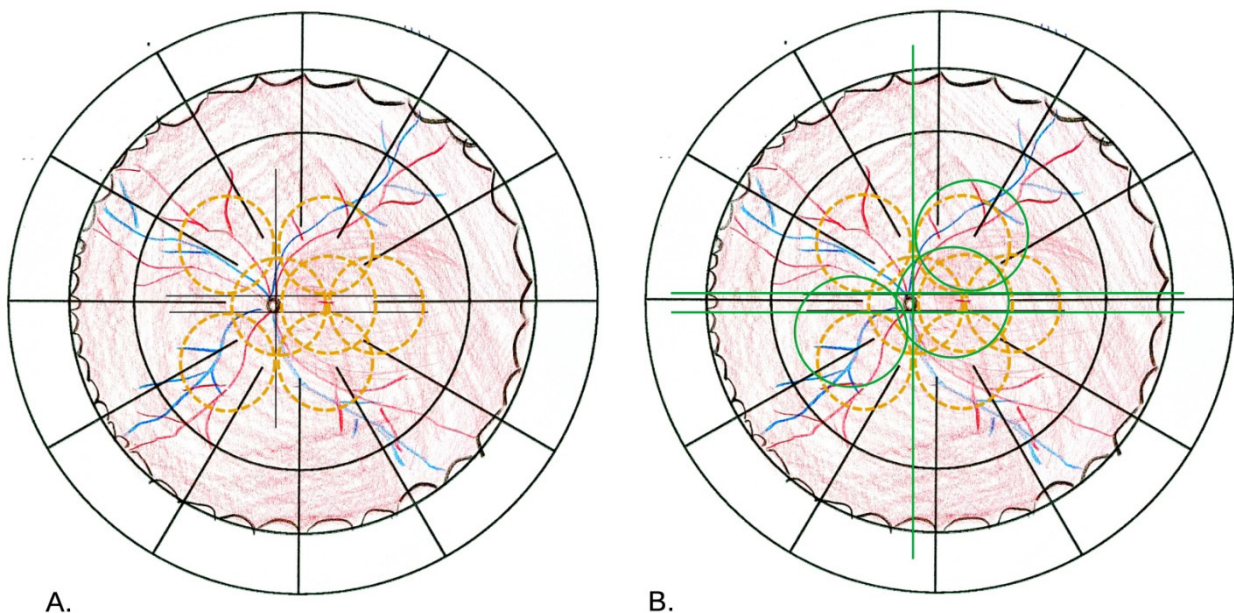


Figure 1. Illustration shows the ETDRS seven-standard-30 degree fields in yellow dotted circles (A) vs the three 45 degree fields of the Joslin Clinic Protocol in green solid circles (B) superimposed on the former.

photographs were examined for the presence or absence of diabetic retinopathy using the ICO classification for diabetic retinopathy and other pertinent posterior segment findings such as the presence of hypertensive retinopathy, glaucomatous disc, age and related macular degenerations were likewise noted. Data of the worse eye was used for analysis.

The quality of fundus photographs were also graded on a 5-point scale obtained from the FOTO-ED study of Lamirel, et al.[13] **Grade 1** being inadequate for any diagnostic purpose, **Grade 2** - unable to exclude all emergent findings, **Grade 3** - only able to exclude emergent findings, **Grade 4** - not ideal but still able to exclude subtle findings, and **Grade 5** - ideal quality. Data for each eye were used in the analysis.

After the reading, results with diagnosis and recommendations were sent back by the reader for online cloud storage (Google drive). The readings were accessed by the investigator and given to the health officer.

STATISTICAL ANALYSIS

Data were analyzed using Stata Statistical Software, Version 13, College Station, TX: StataCorp LP. A p-value of 0.05 was considered statistically significant. Continuous variables were described using mean and standard deviation while categorical variables were summarized using frequency, percentage, median, and interquartile

range. Subjects were divided into two groups based on the presence or absence of diabetic retinopathy.

Ethical considerations

The study adhered to the tenets of declaration of Helsinki 2013 and was conducted in conformance with good clinical practice (GCP) guidelines, WHO operational guidelines, national ethical guidelines 2017, and within the laws and regulations of the University of Santo Tomas Hospital and the country. Informed consent was taken from all the participants.

RESULTS

A total of 387 eyes of 195 persons were examined in the study from November 2018 to December 2018. The demographic characteristics of the respondents are shown in Table 1. The average age of the respondents was 62.78 years (± 9.28). The mean duration of being diagnosed with diabetes mellitus was 7.06 years (± 7.69). It can also be noted that 43.59% had hypertensive retinopathy. Moreover, there were incidentally detected presence of other ocular conditions - 21.03% of the respondents had glaucomatous optic nerve, 6.67% had age-related macular degeneration, 1.54% had posterior vitreous detachment, 3.07% had clinically-significant macular edema, and 1.547% had epiretinal membrane.

Photos were saved in JPEG format with an average of 150kb per photo. The results of each eye obtained

Table 1. Demographic Profile of the Respondents (N = 195)

Characteristic	Frequency (f)	Percentage (%)	Mean (SD)
Age (Years)			62.78 (± 9.28)
Duration of Diabetes Mellitus (Years)			7.06 (± 7.69)
Hypertensive Retinopathy	131	43.59%	
Other Ocular Findings			
<i>Glaucomatous Optic Nerve</i>	41	21.03%	
<i>Age-Related Macular Degeneration</i>	13	6.67%	
<i>Posterior Vitreous Detachment (PVD)</i>	3	1.54%	
<i>Clinically-Significant Macular Edema</i>	6	3.07%	
<i>Epiretinal Membrane</i>	3	1.54%	

Table 2. Comparison of the Quality of Fundus Photo according to Eye Dilatation (N = 387)

Quality of Fundus Photo	Frequency (Percentage)			z-value	p-value (Two-Tailed)
	With Dilatation (n = 85)	Without Dilatation (n = 302)	Total (n = 387)		
Inadequate for any diagnostic purpose	5 (5.88%)	9 (2.98%)	14 (3.62%)	1.27	0.206
Unable to exclude all emergent findings	8 (9.41%)	5 (1.66%)	13 (3.36%)	3.50 [†]	0.001
Only able to exclude emergent findings	32 (37.65%)	88 (29.14%)	120 (31.01%)	1.50	0.134
Not ideal but still able to exclude subtle findings	27 (31.76%)	161 (53.31%)	188 (48.58%)	-3.51 [†]	0.001
Ideal quality	13 (15.29%)	39 (12.91%)	52 (13.44%)	0.57	0.570

[†]Significant at 0.05
[‡]Significant at 0.01

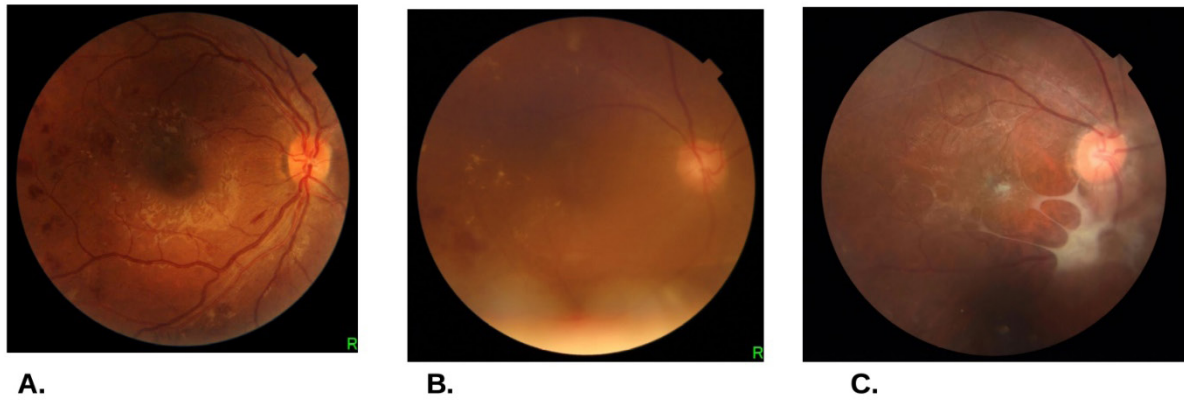


Figure 2. Sample photographs of the fundus taken during the study. A- shows mild nonproliferative diabetic retinopathy, B- moderate nonproliferative diabetic retinopathy, C- moderate nonproliferative diabetic retinopathy with severe diabetic macular edema.

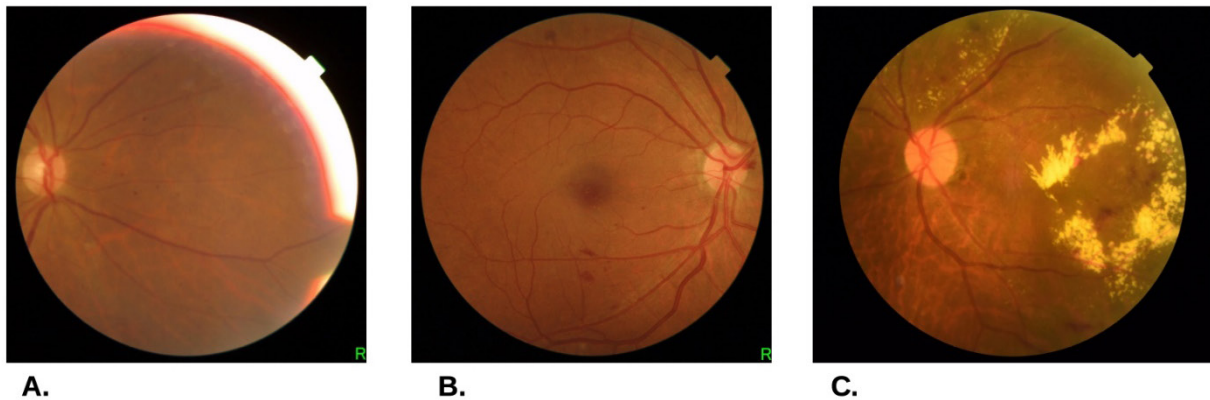


Figure 3. Sample fundus photographs taken during the study. A-severe nonproliferative diabetic retinopathy, B- hazy fundus photo due to vitreous hemorrhage, C tractional retinal membranes

per patient were recorded. As presented in Table 2, it can be seen that among patients with grade 1 quality fundus photo, 5.88% had eye dilation and 2.98% did not have eye dilation. Comparison of these two proportions was not statistically significant ($z = 1.27, p = 0.206$). Results also showed that among respondents with grade 2 quality fundus photo, 9.41% had eye dilation and only 1.66% did not have eye dilation. Comparative analysis for two sample proportions indicate that these were statistically different ($z = 3.50, p = 0.001$), indicating that the proportion of respondents with

grade 2 quality fundus photo was higher among those with eye dilation. Results also showed that the proportion of patients with grade 3 ($z = 1.50, p = 0.134$) and grade 5 ($z = 0.57, p = 0.570$) quality fundus photo were not statistically different between those who had eye dilation and who did not have eye dilation. On the other hand, the comparison of proportion of respondents with grade 4 fundus photo with eye dilation (31.76%) and those who did not have eye dilation (53.31%), results showed that the proportion was statistically higher ($z = -3.51, p = 0.001$) among those with no eye dilation. Overall,

Table 3.**Prevalence of Diabetic Retinopathy and Grade of Diabetic Retinopathy among Respondents (N = 194)**

Characteristic	Frequency (Percentage)	95% Confidence Interval
Prevalence of Diabetic Retinopathy	49 (25.26%)	19.60% – 31.90%
Grade of Diabetic Retinopathy		
<i>No Diabetic Retinopathy</i>	140 (72.16%)	66.90% – 79.50%
<i>Mild Diabetic Retinopathy</i>	6 (3.16%)	1.42% – 6.90%
<i>Moderate Diabetic Retinopathy</i>	30 (15.79%)	11.23% – 21.75%
<i>Severe Diabetic Retinopathy</i>	7 (3.68%)	1.75% – 7.57%
<i>Proliferative Diabetic Retinopathy</i>	7 (3.68%)	1.75% – 7.57%

288 out of 387 eyes (95.36%) had gradable quality fundus photo (grade 3 and higher) and did not need eye dilation.

For the prevalence of diabetic retinopathy, the result of the worse eye was used for the analysis. It can be gleaned that the prevalence of diabetic retinopathy among respondents was 25.26% (95% CI = 19.60% to 31.90%) (Table 3). Among those with diabetic retinopathy, 3.16% had mild diabetic retinopathy, 15.79% had moderate diabetic retinopathy, 3.68% had severe diabetic retinopathy, and 3.68% had proliferative diabetic retinopathy.

DISCUSSION

Diabetic retinopathy is mainly a clinical diagnosis and ancillary procedures such as fluorescein angiography or ocular coherence tomography is not required for diagnosis or to determine disease severity. The standard of care for diabetic retinopathy is to undergo dilated fundus examination by an ophthalmologist at regular intervals depending on the type of diabetic retinopathy present. Diabetic retinopathy continues to be one of the preventable causes of loss of vision worldwide. In the US, compliance to diabetic retinopathy screening was low with only 34% of the diabetic population who underwent screening[14] due to the inability of patients to undergo regular screening because of

time, expense, lack of access to ophthalmic care, and lack of noticeable change in vision.[14]

Mass-based screenings have been promoted to increase patient compliance and increase the number of screened individuals. Retinal photography is already included in the ICO guidelines for diabetic eye care as an option for retinal screening. Thus, technology, using telemedicine, is an alternative method to the dilated fundus exam to increase the detection rate of diabetic retinopathy among diabetic patients. Figure 2 and 3 shows photos of the different severity classification of diabetic retinopathy obtained.

Prevalence of Diabetic Retinopathy

In this study, no signs of diabetic retinopathy were seen in 72.16%. On the other hand, it was able to identify some form of diabetic retinopathy (mild non-proliferative diabetic retinopathy or worse) in at least one eye of 26.31%, with a prevalence of 25.26%. This value was slightly lower than in the study on global prevalence of diabetic retinopathy pooled from studies from the United States, Australia, Europe, and Asia, which revealed an age-standardized prevalence of diabetic retinopathy to be 35.6%. Available local prevalence studies are limited and all of them were done in the hospital setting. Results of this present study was not far

from the studies of Tayapad, et al.[11], studying the prevalence of diabetic retinopathy in a private multispecialty primary care clinic and the result of the study of Carandang, et al.[15] on the prevalence of diabetic retinopathy in a private medical center in the rural area with prevalence of 28.2% and 26%, respectively. However, in a study by Gomez, et al.[16] in 2005, among diabetic patients in a government-owned tertiary hospital, it was noted that patients with diabetes had diabetic retinopathy in as high as 61.8%.

Patients with no diabetic retinopathy were informed about the importance of regular screening and emphasis on strict blood pressure and glycemic control was reiterated. These patients do not need an urgent ophthalmology or retina specialist referral, hence identifying them early on would not only decrease patient load from the eye centers but this would also save patients from unnecessary expenses for transportation and consultation. For patients with some form of diabetic retinopathy (mild NPDR to PDR) and clinically significant macular edema, appropriate workup was recommended and patients were advised ophthalmology consult to the eye center of choice. For all patients screened, education on diabetic retinopathy was given.

Other findings such as glaucoma disc suspect, hypertensive retinopathy, and age-related macular degeneration were incidentally found during the screening. These patients along with patients who had ungradable photos due to media opacity were likewise recommended to seek an ophthalmology consult.

FEASIBILITY TELEMEDICINE SCREENING

Non-Mydriatic vs mydriatic

A dilated fundus examination, aside from being time consuming and difficult for patients, is not always possible due to possible risks that accompany it, especially in the setting of mass screenings wherein there will be no available ophthalmologists on standby. Non-mydriatic fundus photography makes screening faster, reduces patient discomfort, thus, increasing compliance.[17] In this study non-mydriatic fundus photography was used and fundus photos of 387 eyes were able to be taken (Table 2).

Figure 4 shows fundus photographs of different grading of the photo quality. When compared to mydriatic fundus photographs, non-mydriatic fundus

photographs produced inferior quality photos resulting in about 6-36% ungradable photographs in the study of Lamirel, et al.[13,14] In our study, 22% (85 eyes) of the subjects' eyes needed to be dilated due to poor quality fundus photo which was attributable to either media opacity or small pupil. Among these patients who were dilated, it was able to increase the photo quality from ungradable to gradable (grade 3 quality and higher) in 84.7% of dilated patients. On the other hand, 302 patients did not need eye dilation and among these patients 93.03% had gradable quality of fundus photo.

The quality of fundus photos also depends on the age group of the patient population, with the older age group having poorer quality photos due to more frequent media opacities such as age-related cataracts, miosis, and difficulty in following instructions.[13,14] Excluding the factor of age, diabetic patients also develop cataracts earlier and will have miosis due to diabetic autonomic neuropathy.[14] In which cases, dilated fundus examination could provide adequate observation of the retinal pathologies obscured by the factors mentioned above.

Non-mydriatic fundus photography may miss out on peripheral retinopathies, vitreous hemorrhage, and has poor sensitivity for cystoid macular edema. [14] However, the goal of mass screening is to provide a quick and convenient way to detect diabetic retinopathy in patients with diabetes even in areas without ophthalmologists or retina specialists. Patients with questionable findings should be referred to an ophthalmologist for a more thorough examination.

The gold standard in fundus photography is the ETDRS dilated 7-field 30 degrees stereophotography. Different protocols have been developed to decrease patient discomfort and allow reproducible photos. The protocol used in this study is the three-field non-mydriatic 45-degree photographs, Joslin Clinic Protocol (Figure 5), that allows non-mydriatic retinal imaging to be done by non-certified photographers. The protocol was validated and said to be in agreement with the ETDRS retinal photography.[12] Figure 5 shows the comparison between the areas captured using the ETDRS protocol and Joslin Clinic Protocol. Other protocols worth mentioning are the EURODIAB IDDM Complications Study European, which is two 45-degree color photographs - one centered on the macula and the other on the nasal

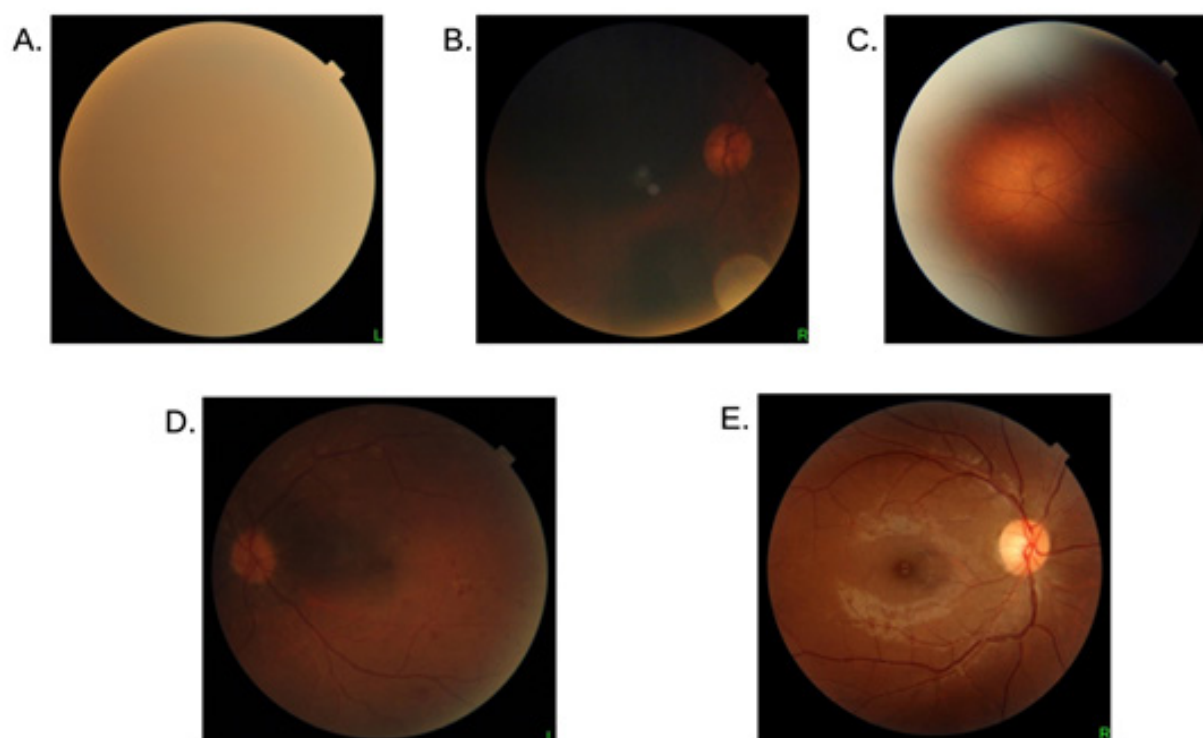


Figure 4. Representative photos of the different grades of the quality of the fundus photos in the study. In increasing order of quality- (A) Grade 1 being inadequate for any diagnostic purpose, (B) Grade 2 - unable to exclude all emergent findings, (C) Grade 3 - only able to exclude emergent findings, (D) Grade 4 - not ideal but still able to exclude subtle findings, and (E) Grade 5 - ideal quality.

field, and the single field 45-degree photograph - centered on a point halfway between the temporal edge of the optic disc and the fovea,[18] both of which were able to identify the simple presence of retinal lesions; however, there were occasional lesions that occurred outside the field of view that were not able to be identified.

Newer technologies are available to increase the quality of detection of retinal diseases. Ultrawide field Optomap imaging can take non-mydratric images of the posterior pole up to the equator (180°–200°), and can visualize the deeper retina using red-free and infrared image.[19] Portable hand-held fundus cameras and smartphone fundus photography are also used in other tele-ophthalmology studies to provide mobility. However, these portable devices have a higher learning curve and currently has lower image qualities compared to the traditional tabletop fundus camera.[17]

Barriers to Telemedicine Screening

The study was conducted in an urban setting with health centers having computers and internet connection, making the data transmission part of

the study feasible. Despite having numerous studies showing the benefits of telemedicine programs, problems such as high costs, lack of infrastructure and technical capabilities, and additional manpower pose barriers to adoption of the program, especially in developing countries.

Ideally fundus photographs should be taken by trained technicians to obtain a high quality photo. However, this is not always possible in the real world setting due to lack of dedicated staff and the amount of patients seen in primary care clinics. To address this, several studies have shown the effectiveness of trained personnel (non-technicians) to take fundus pictures. In a photo-ed study, nurse practitioners in the emergency department were able to get good quality photos with ungradable photographs amounting to less than 3%.[13]

In addition, retina specialists who will read the images and send back reports should be available. To address this, artificial intelligence software had been developed to automatically read the fundus photographs and detect the presence or absence of diabetic retinopathy.[20] However, this still has to be verified by an actual screener. The ICO guidelines for diabetic eye care have stated that a medical degree

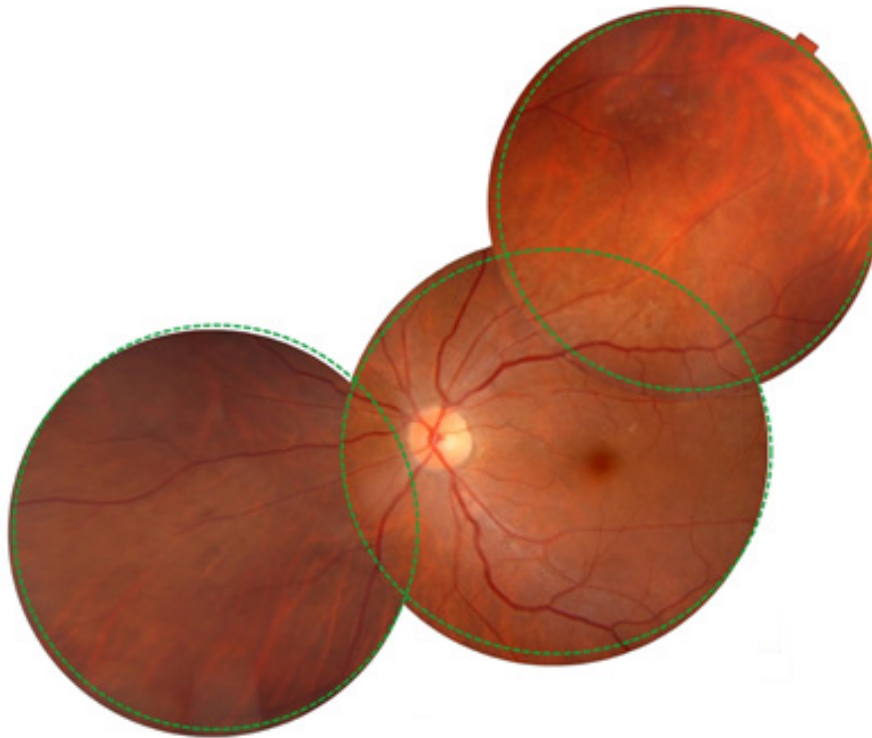


Figure 5. Collage photograph of the three-field non-mydriatic 45-degree photographs as described by the Joslin Vision Clinic protocol in one of the patients with normal fundus.

is not necessary to perform a retinal exam and may be performed by well-trained personnel to assess the severity of retinopathy. For a successful telemedicine diabetic retinopathy screening program, there should be a good partnership between the local health center and an eye referral center.

CONCLUSION

This study found that diabetic retinopathy among type 2 diabetics has a prevalence of 25.26%

(49 patients). Telemedicine screening of diabetic retinopathy is a reliable alternative to dilated fundus examination and can be done in local health centers. Hence, this screening method can be considered by the local government to be included as a part of health services with the aim of reducing blindness due to diabetes.

DECLARATION OF COMPETING INTERESTS

The authors had no conflicts of interest in this study nor supported by any means by any organization or company for the study to be completed.

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