Original Article

The validity of diabetic retinopathy screening using nonmydriatic fundus camera and optical coherence tomography in comparison to clinical examination

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Abstract:

PURPOSE: To evaluate the use of non-mydriatic fundus camera as a screening modality for diabetic retinopathy in a sample of population in Riyadh, Saudi Arabia.

METHODS: Patients coming, from April 2015 till September 2018, for their diabetic check up at the diabetic center clinics in King Abdul-Aziz University hospital were screened using a non-mydriatic fundus camera (NMFC). Photos were graded by retina specialist and compared to the findings of dilated fundus examination (DFE) by retina specialists.

RESULTS: The grading results of NMFC and DFE were compared and the overall sensitivity and specificity for detection of diabetic retinopathy within one grade of retinopathy was 98.7% and 80% respectively. The sensitivity for detection of sight threatening conditions such as proliferative diabetic retinopathy, severe non-proliferative diabetic retinopathy, and diabetic macular edema (by Ocular Coherence Tomography) was found to be 86.7%, 90.3% and 100% respectively; while the specificity was found to be 96.5%, 93%, and 100% respectively.

CONCLUSION: Non-mydriatic fundus camera has a high sensitivity and specificity in screening for diabetic retinopathy. It is a great screening tool, which is user friendly and can be operated by trained nurses in primary clinics during patient's regular routine diabetic checkups. It aids in early detection of sight threatening conditions which need urgent referral to ophthalmologists.

Keywords:

Diabetes, diabetic retinopathy, fundus camera, nonmydriatic, screening

Introduction

Diabetic retinopathy (DR) is one of the leading causes of blindness.[1,2] The overall global prevalence of DR in diabetic patients is estimated to be 34.6%. In Saudi Arabia, the prevalence of DR is relatively high at about 31% (42.5% in patients with insulin-dependent diabetes mellitus and 25.3% in noninsulin-dependent diabetes mellitus).[3,4]

Health education and screening programs for early detection and referral of diabetic patients can prevent visual loss and hence are the mainstay for prevention of blindness due to DR.[5,6]

Although screening for DR was emphasized by several World Health Organization reports, still the adherence to follow these screening guidelines is poor. Studies show that the reasons behind poor adherence are highly affected by patient's age, lifelong duration of the disease, the need for long-term follow-up, limited access to screening programs, and the long duration of examination due to the need for pupil dilatation.[7] According to a study done in Riyadh, Saudi Arabia, the adherence to DR screening among patients was found to be 61.4%. The most significant causes for poor adherence were poor knowledge, long duration of the disease, and cost.[8]

There is a need to develop new solutions to ease the accessibility and compliance to such screening programs. Nonmydriatic fundus

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camera has been used as a screening tool for DR in several countries. It takes less time as there is no need for pupil dilatation and there is less blurring to the patient. It is easily operated and can be done by trained nurses in any health center. The photos acquired by the machine can be sent to a retina specialist to be graded and decide if there is a need for further assessment or possible treatment.[9-14]

In some countries such as the United Kingdom, the use of nonmydriatic fundus photography as a screening method for DR has been adopted.[14] The University Diabetic Centre at King Abdulaziz University Hospital, Riyadh, Saudi Arabia, started a DR screening program in April 2015 using a nonmydriatic fundus camera. The purpose of this study is to evaluate and validate its use as a screening modality for DR in our population.

Methods

The Institutional Review Board Committee approval at King Saud University Medical City was obtained before the start of this cross-sectional study.

All diabetic patients who came for their endocrinologist's appointment were routinely sent to the photographic funduscopic screening clinic after filling a screening form by the referring endocrinologist which had the following demographic data for every patient: type and duration of diabetes, current treatment, glycosylated hemoglobin level, and blood pressure status (hypertensive or not). Screening was performed by trained ophthalmic nurses who measured patient's visual acuity by a Snellen's chart, and intraocular pressure was measured by an automated machine (computerized tonometer). A fundus camera (3D OCT-1 Maestro nonmydriasis fundus camera) was used to take multiple 45° fundus photos for each eye: one centered on the optic disc and the other centered on the macula. Nurses were trained on the use of the fundus camera by the camera's company representative, who offered multiple training sessions and supervised the nurses while acquisition of photos and helped in teaching them how to acquire better quality images in difficult cases.

The fundus camera model used had a macular ocular coherence tomography built in the machine, which allowed for acquisition of an ocular coherence tomography image at the same time of the acquisition of the fundus image.

All photos were graded by two graders (retina specialists). The images were evaluated on the computer screen. The graders were allowed to enhance the images using software tools (image contrast enhancement and imaging sharpening).

The International Clinical Classification of DR Disease Severity Scale was used in the grading of the level of retinopathy. A grade of no DR was given to cases when there were no changes found in the fundus related to diabetes, mild nonproliferative DR when there were microaneurysms only, moderate nonproliferative DR when there were more than microaneurysms present but less than what is needed to grade as severe nonproliferative DR.

Severe nonproliferative DR was graded if any of the following was present: more than 20 microaneurysms present in each of the four quadrants, venous beading in two or more quadrants, and presence of intraretinal microvascular abnormality in one or more quadrants. Proliferative DR was graded when there was neovascularization, vitreous hemorrhage, or preretinal hemorrhage. The presence or absence of diabetic macular edema was assessed by ocular coherence tomography images.

Patients with no DR or mild nonproliferative DR were given a 1-year follow-up in the funduscopic screening clinic, where they come for another photo visit.

Patients with moderate nonproliferative DR or stable (inactive) treated proliferative DR were given a 6-month follow-up in the funduscopic screening clinic for another photo visit.

Patients with severe nonproliferative DR, active proliferative DR (whether previously treated with pan-retinal photocoagulation or not), and macular edema were referred to the retina clinic to be evaluated by retina specialists with a dilated fundus examination for possible need of treatment.

Any patients with ungradable poor quality images due to media opacity (e.g., corneal scar and cataract) were referred to the ophthalmology screening clinic for a full ophthalmic assessment.

The data of the patients who were screened in the funduscopic screening clinic and referred to the retina clinic due to severe nonproliferative DR, active proliferative DR, and macular edema were reviewed and included in our study. We have compared the results of the grading of DR by the graders using the nonmydriatic fundus camera to the results of the dilated fundus examination done in the retina clinic by retina specialists. The sensitivity, specificity, and positive and negative predictive values of grading using a nonmydriatic fundus camera by a retina specialist were calculated after comparing them to the grading through a dilated fundus examination by a retina specialist as well.

Statistical analysis

Data were collected and stored in a spreadsheet using Microsoft Access 2010® software. Management and coding were done in Excel 2010® software. Data were analyzed using SPSS® version 21.0 (IBM Inc., Chicago, Illinois, USA). Descriptive analysis was mainly done, and categorical variables were presented in the form of frequencies and percentages and continuous variables in the form of mean (± standard deviation) and range. To calculate the required sample size for these diagnostic tests, we assume that the expected sensitivity or specificity is 0.99 and it may be found to decrease by 0.1 or 0.89 and at power = 0.95. We used the power.diagnostic.test function from the MKmisc package of R.[15] The default value of this function for the prevalence is 0.5 and for the significance level = 0.05. The required sample size is 112. The prevalence, sensitivity, specificity, accuracy, and positive and negative predictive values were calculated using the epiR package of the R programming language version 4.0.0.[16,17] The kappa statistic and McNemar test were also calculated using

the epiR package. The kappa statistic of the Fleiss method was used to examine the agreement between the two methods after excluding chance.[18] The *P* value for the kappa statistic is from one-tailed test to test the hypothesis that kappa is >0. The interpretations for the kappa statistic, according to the epi.kappa function help page, are as follows: <0.2 slight agreement, 0.2–0.4 fair agreement, 0.4–0.6 moderate agreement, 0.6–0.8 substantial agreement, >0.8 almost perfect agreement. On the other hand, the McNemar test was used to detect any systematic difference between the results of the two methods. Any $P < 0.05$ was considered statistically significant.

Results

From April 2015 until the end of September 2018, a total of 2406 patients (4812 eyes) were screened by the nonmydriatic fundus camera (3D OCT-1 Maestro nonmydriasis fundus camera). One hundred and nineteen images of patients' eyes were not clear and were referred to the ophthalmology screening clinic for a full ophthalmic assessment.

Our study population consisted of 122 patients (244 eyes) who were referred to the retina specialists' clinics for further assessment and management either due to macular edema, severe nonproliferative DR, or active proliferative DR (the required sample size was 112 eyes and our sample was more in number). These patients had a dilated fundus examination by 4 different retina specialists within 1 month of their referral; of note, one of the nonmydriatic fundus camera graders was also involved in the examination of the patients who were referred. To note, all of the examiners were blinded of the nonmydriatic fundus camera results.

Table 1: Descriptive analysis of study patients

Characteristic	*n* (%)
Age in years, Mean±SD [Range]	53.9±14.1 [19-95]
Gender	
Male	52 (42.6)
Female	70 (57.4)
Nationality - Saudi	122 (100)
DM type	
Type 1	21 (17.2)
Type 2	101 (82.8)
DM duration in years, Mean±SD [Range]	19.3±7.4 [4-42]
Medications	
OHA	23 (18.9)
Insulin	37 (30.3)
Both	62 (50.8)
Current HbA1c, Mean±SD [Range]	9.7±2.2 [5.8-25.0]
Hypertensive	43 (35.2)
Visual acuity*	
>20/40	171 (70.1)
≤20/40	71 (29.9)
Visual acuity in LogMAR, Mean±SD [Range]*	0.3±0.4 [0.15-3.00] 20/40 [20/14-HM]
IOP in mmHg, Mean±SD [Range]*	18.1±3.5 [9-27]

*per eye (*n*=244 eyes); SD-standard deviation; HM- hand movement; IOP- intraocular pressure; OHA- oral hypoglycemic agents

Descriptive analysis

Descriptive analysis of our patients is shown in Table 1. Of the 244 eyes, 11 eyes were graded as no DR by nonmydriatic fundus camera images (they were referred to retina specialists due to macular edema on ocular coherence tomography): 8 of those eyes had a compatible grading by dilated fundus examination and 3 eyes had an incompatible grading and were underestimated as they were found to have mild nonproliferative DR by dilated fundus examination.

Twenty-one eyes were graded as mild nonproliferative DR by nonmydriatic fundus camera images (they were referred to retina specialists due to macular edema on ocular coherence tomography): 18 of those eyes had a compatible grading by dilated fundus examination and 3 eyes had an incompatible grading and were underestimated as they were found to have moderate nonproliferative DR by dilated fundus examination.

One-hundred and five eyes were graded as moderate nonproliferative DR by nonmydriatic fundus camera images (they were referred to retina specialists due to macular edema on ocular coherence tomography): 79 of those eyes had a compatible grading by dilated fundus examination and 23 eyes had an incompatible grading and were overestimated as they were found to have mild nonproliferative DR by dilated fundus examination. Three eyes had an incompatible grading and were underestimated: one was found to have severe nonproliferative DR and surprisingly the two others were found to have active proliferative DR status post pan-retinal photocoagulation by dilated fundus examination.

Forty-three eyes were graded as severe nonproliferative DR by nonmydriatic fundus camera images: 29 of those eyes had a compatible grading by dilated fundus examination and 12 eyes had an incompatible grading and were overestimated. Eleven eyes were found to have moderate nonproliferative DR and one was found to have mild nonproliferative DR by dilated fundus examination. Two eyes had an incompatible grading and were underestimated, as they were found to have active proliferative DR by dilated fundus examination.

Twenty-one eyes were graded as active proliferative DR by nonmydriatic fundus camera images: 13 of those eyes had a compatible grading by dilated fundus examination and 8 eyes had an incompatible grading and were overestimated. Two eyes were found to have severe nonproliferative DR, 3 eyes were found to have moderate nonproliferative DR, and 3 eyes were found to have mild nonproliferative DR by dilated fundus examination.

Eleven eyes were graded as active proliferative DR status post pan-retinal photocoagulation by nonmydriatic fundus camera images: 6 of those eyes had a compatible grading by dilated fundus examination and 5 eyes had an incompatible grading and were overestimated as they were found to have inactive proliferative DR status post pan-retinal photocoagulation by dilated fundus examination.

Thirty-two eyes were graded as inactive proliferative DR status post pan-retinal photocoagulation by nonmydriatic fundus camera images, and all eyes had a compatible grading by dilated fundus examination.

The comparison of diabetic retinopathy grading using nonmydriatic fundus camera vs. retina specialist grading

Of the total 4182 eyes seen, 2186 were having DR. This gives a prevalence of 52.3% (95% confidence interval [CI] = 50.7–53.8).

Of the 244 eyes that were diagnosed as having DR by the nonmydriatic fundus camera, 185 eyes were having DR by retina specialists. This gives a true positive rate of 94.8% and a false positive rate of 3.5%. On the other hand, of the 1466 eyes those were not having DR by the nonmydriatic fundus camera, 1405 eyes were not having DR by retina specialists. This gives a true negative rate of 82.2% and a false negative rate of 3.6%.

The sensitivity of nonmydriatic fundus camera for detecting DR within the same grade of retinopathy was 75.2% (95% CI = 69.3–80.5) and the specificity was 96.0% (95% CI = 94.8–96.9). The accuracy was 93.0% (95% CI = 91.7–94.1), and the positive and negative predictive values were 75.8% (95% CI = 69.9–81.1) and 95.8% (95% CI = 94.7–96.8), respectively [Table 2].

When the grading results by nonmydriatic fundus camera and dilated fundus examination were matched within one grade of DR, from the 244 eyes that were diagnosed as having DR by the nonmydriatic fundus camera, 235 eyes were having DR within one grade by retina specialists. This gives a true positive rate of 94.8% and a false positive rate of 0.8%. The overall sensitivity and specificity of detecting DR within one grade of DR by nonmydriatic fundus camera compared to dilated fundus examination were 98.7% (95% CI = 96.4–99.7) and 80.0% (95% CI = 44.4–97.5), respectively, while the accuracy was 98.0%. The positive and negative predictive values were 99.1% and 72.7%, respectively [Table 3].

Table 2: The comparison between grading diabetic retinopathy using nonmydriatic fundus camera versus retina specialist grading

fundus camera	Retina specialist		
	DR+*n*(%)	DR- *n*(%)	Total
DR+*n*(%)	185 (10.8%)	59 (3.5%)	244 (14.3%)
DR- *n*(%)	61 (3.6%)	1405 (82.2%)	1466 (85.7%)
Total	246 (14.4%)	1464 (85.6%)	1710 (100%)
Sensitivity % (95% CI)	75.2% (69.3-80.5)		
Specificity % (95% CI)	96.0% (94.8-96.9)		
Accuracy % (95% CI)	93.0% (91.7-94.1)		
PPV % (95% CI)	75.8% (69.9-81.1)		
NPV % (95% CI)	95.8% (94.7-96.8)		
Kappa statistic (95% CI)	0.7 (0.7 - 0.8)		
McNemar test *P*	0.9		

DR: Diabetic Retinopathy, PPV: Positive predictive value, NPV: Negative predictive value

The inclusion of optical coherence tomography results in the comparison between nonmydriatic fundus camera and retina specialist grading

Ninety-three eyes had macular edema on ocular coherence tomography images acquired by the nonmydriatic fundus camera (3D OCT-1 Maestro nonmydriasis fundus camera), and all of them had a compatible diagnosis on dilated fundus examination by a retina specialist. Including optical coherence tomography (OCT) findings in the nonmydriatic fundus camera results when compared to retinal specialists' findings has increased the sensitivity of the camera to 82.0% (95% CI = 77.5–85.9), while the specificity remained the same at 96.0% (95% CI = 94.8–96.9). Furthermore, the accuracy slightly increased to 93.3% (95% CI = 92.1–94.5). Finally, the positive predictive value increased to 82.5% (95% CI = 78.0–86.4), while the negative predictive value remained the same at 95.8% (95% CI = 94.7–96.8) [Table 4].

The highest sensitivity of nonmydriatic fundus camera was reached in detecting severe nonproliferative DR 90.6% (95% CI = 75.0–98.0), and the highest specificity was reached in detecting inactive proliferative DR status post pan-retinal photocoagulation that is equal to 100% (95% CI = 98.2–100) [Table 3].

Of the total 4182 eyes seen, 169 were having cases of sight-threatening DR including severe nonproliferative DR, active proliferative DR, and macular edema, which gives a prevalence of 4.0% (95% CI = 3.5–4.7). The sensitivity for detecting sight-threatening conditions such as severe DR and proliferative DR by nonmydriatic fundus camera as well as diabetic macular edema by ocular coherence tomography was found to be 90.6% (95% CI = 75.0 – 98.0) for severe nonproliferative DR, 86.7% (95% CI = 59.5–98.3) for proliferative DR, and 100% (95% CI = 96.1–100) for diabetic macular edema by ocular coherence tomography, while the specificity was found to be 93.4% (95% CI = 89.2–96.3) for severe nonproliferative DR and 96.5% (95% CI = 93.2–98.5) for proliferative DR [Table 3].

Kappa testing to verify the agreement between the nonmydriatic fundus camera and retina specialist grading

The kappa statistic for the agreement between the nonmydriatic fundus camera and retina specialists was estimated to be 0.7 (95% CI = 0.7–0.8). The z-test gives a *P* value of nearly zero (5.6 × 10^−192); so, we accept the alternative hypothesis that the kappa statistic is >0. The proportion of agreements after chance has been excluded is about 0.7, and we conclude that, on the basis of this sample, there is substantial agreement between the two methods. In addition, the McNemar test gives a nonsignificant *P* value. This means that no systematic difference or bias occurs between the results of the nonmydriatic fundus camera and retina specialists [Table 2].

When OCT findings were added to the comparison between the nonmydriatic fundus camera and retina specialists, the kappa statistic increased to 0.8 (95% CI = 0.7–0.8) with a nearly zero *P* value (8.8 × 10^−242). Therefore, the kappa

Table 3: Sensitivity, specificity, accuracy, positive predictive value, and negative predictive value of grading by nonmydriatic fundus camera in comparison to grading by retina specialist (*n*=244)

Grading	Number of eyes by NMFC (%)	TP (*n*)	FP (*n*)	TN (*n*)	FN (*n*)	Accuracy (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
No DR	11 (4.5)	8	3	229	4	97.1	66.7	98.7	72.7	98.3
Mild NPDR	21 (8.6)	18	3	198	27	88.5	40.0	98.5	85.7	88.0
Moderate NPDR	105 (43.0)	79	26	121	18	81.6	81.3	81.8	74.3	87.1
Severe NPDR	43 (16.4)	29	14	198	3	92.6	90.3	93.0	65.1	98.5
Active PDR	21 (8.6)	13	8	221	2	95.9	86.7	96.5	61.9	99.1
Active S/P PRP PDR	11 (4.5)	6	5	231	2	97.1	75.0	97.9	54.5	99.1
Inactive S/P PRP PDR	32 (13.1)	32	0	207	5	98.0	86.5	100.0	100.0	97.6
Total	244	185	59	1405	61	92.9	75.0	95.8	75.0	95.8
Within one grade	244	235	2	8	3	97.9	98.7	80.0	99.1	72.7

DR=diabetic retinopathy; NPDR=non proliferative diabetic retinopathy; PDR=proliferative diabetic retinopathy; s/p PRP=status post panretinal photocoagulation; TP- true positive; FP-false positive; TN-true negative; FN-false negative; PPV-positive predictive value; NPV-negative predictive value; NMFC=Non Mydriatic Fundus Camera

Table 4: The inclusion of optical coherence tomography results in the comparison between nonmydriatic fundus camera and retina specialist grading

Fundus camera	Retina specialist		
	Disease+*n*(%)	Disease- *n*(%)	Total
Disease+*n*(%)	278 (15.4%)	59 (3.3%)	337 (18.7%)
Disease- *n*(%)	61 (3.4%)	1405 (77.9%)	1466 (81.3%)
Total	339 (18.8%)	1464 (81.2%)	1803 (100%)
Sensitivity % (95% CI)	82.0% (77.5-85.9)		
Specificity % (95% CI)	96.0% (94.8-96.9)		
Accuracy % (95% CI)	93.3% (92.1-94.5)		
PPV % (95% CI)	82.5% (78.0-86.4)		
NPV % (95% CI)	95.8% (94.7-96.8)		
Kappa statistic (95% CI)	0.8 (0.7 - 0.8)		
McNemar test *P*	0.9		

OCT: ocular coherence tomography, PPV: Positive predictive value, NPV: Negative predictive value

statistic is greater than zero, and the proportion of agreements after chance has been excluded is about 0.8. Furthermore, the McNemar test gives a nonsignificant *P* value, which means that no systematic difference occurs between the results of the nonmydriatic fundus camera and retina specialists [Table 4].

Discussion

Screening for DR is very important to prevent visual loss. It helps in early detection and treatment of vision-threatening DR. Dilated fundus examination by an ophthalmologist is the main screening method which is time-consuming as the patients need to wait till their pupil is dilated, and accessibility to an ophthalmologist is not readily available. The gold standard method to screen photographically for DR is by stereoscopic color fundus photographs in seven standard fields, as defined by the Early Treatment DR Study group. It requires a skilled photographer and special costly equipment, and it is also time-consuming to the patient.[19] That is why there is a trend worldwide toward using new screening tools which are less time-consuming and easily accessible. Photographic methods are one of the newly adopted methods for screening whether it is 35mm film, digital images, or polaroid instant film prints. Guidelines indicate that screening for DR by any method should have a sensitivity of 80% or more and a specificity of 95% or more for sight-threatening DR (defined as severe nonproliferative DR, proliferative DR, and macular edema) to be accepted as a screening method.[20]

In our study, we compared nonmydriatic fundus camera (3D OCT-1 Maestro nonmydriasis fundus camera) to dilated fundus examination which resulted in a sensitivity of 81.3%–90.3% for detecting moderate-to-severe nonproliferative DR and a specificity of 81.8%–93%. Massin P *et al.* reported a higher sensitivity and specificity for detecting moderate-to-severe nonproliferative DR 92%–100% and 85%–88%, respectively. This is because the study was done using TRC-NW6S nonmydriatic camera, without pupillary dilation, and compared it to the gold standard seven-field retinal photography,[10] as opposed to our study, which compared it to clinical examination.

When we looked into the sensitivity and specificity of detection of sight-threatening DR such as severe DR, a sensitivity of 90.3% and a specificity of 93% were found. While the sensitivity and specificity for detection of proliferative DR, another sight-threatening DR, were 86.5% and 96.5%, respectively, the sensitivity and specificity for detecting macular edema on ocular coherence tomography were 100%, respectively. These results comply with the recommended guidelines for screening tools for DR.

When looking at the consistency within one grade of retinopathy, the sensitivity was 98.7% and the specificity was 80% for detecting DR by nonmydriatic photos within one grade of that detected by dilated fundus examination.

However, the overall sensitivity was lower for screening within the same grade of DR by nonmydriatic fundus camera 75%, while the specificity was higher at 95.8%. This might be due to the fact that there were four different retina specialists grading the patients in the clinic and not one retina specialist, which may have adjusted for the variability of grading between physicians. Of note, there were 29 patients (58 eyes) who were examined in the clinic by the same grader who graded

Table 5: sensitivity and specificity of diabetic retinopathy grading by nonmydriatic fundus camera compared to grading by a single retina specialist

Grading	Number of eyes by NMFC (%)	TP (*n*)	FP (*n*)	TN (*n*)	FN (*n*)	Sensitivity (%)	Specificity (%)
Mild NPDR	3	3	0	55	0	100	100
Moderate NPDR	16	16	0	37	5	76.2	100
Severe NPDR	20	15	5	37	1	93.8	88.1
Active PDR	9	6	3	49	0	100	94.2
Active S/P PRP PDR	1	0	1	57	0	100	98.3
Inactive S/P PRP PDR	9	9	0	46	3	75	100
Total of DR	58	49	9	281	9	84.4	96.9

DR=diabetic retinopathy; NPDR=non proliferative diabetic retinopathy; PDR=proliferative diabetic retinopathy; s/p PRP=status post panretinal photocoagulation; TP- true positive; FP-false positive; TN-true negative; FN-false negative; NMFC=non mydriatic fundus camera

their photos (retina specialist); 42 eyes (72.4%) had the same grading as nonmydriatic fundus camera, 16 eyes (27.6%) were incompatible, 14 eyes were overestimated by one grade, and 2 eyes were underestimated by one grade. The overall sensitivity for detecting DR by the same grader/examiner was found to be 84.4% and the specificity was 96.9%, while the sensitivity and specificity for detecting sight-threatening conditions by the same grader/examiner were found to be 95.5% and 91.5%, respectively. Table 5 shows more details.

Other studies done on three-field nonmydriatic photos resulted in high sensitivity and specificity. Vujosevic *et al.* reported a sensitivity and specificity for detecting referable DR of 82% and 92% and for detecting diabetic macular edema 83% and 97%, respectively, when three-field nonmydriatic photography was used.[21]

Ocular coherence tomography is a high-resolution imaging modality, which takes cross-sections of the neurosensory retina providing precise details about the retinal circulation and thickness. The recently introduced spectral domain ocular coherence tomography machines have numerous improvements that obtain more reliable measurements of retinal microstructure.[22] This imaging modality is noninvasive and sensitive and shows quantitative measures rather than qualitative, so it is adopted by clinicians for the assessment of patients with cystoid macular edema.[23] It is used in multicenter trials in patients with DR like many trials included in the DR Clinical Research Network.[24] It is the screening tool for detecting diabetic macular edema in the United Kingdom.[25]

In our screening program, we relied on spectral-domain ocular coherence tomography images for the detection of macular edema instead of solely relying on fundus images as it is done in most DR screening programs. Both the sensitivity and specificity for detecting diabetic macular edema using spectral-domain ocular coherence tomography were 100%, respectively, when compared to dilated fundus examination.

Other studies showed that ocular coherence tomography is highly sensitive as a diagnostic tool for macular edema; Ozdek *et al*. found that ocular coherence tomography detected 40% more of cystoid macular edemas which were not detected by slit-lamp biomicroscopy, and it detected 63% more cystoid edema that was not detected even on fluorescein angiography. Moreve, their conclusion was that ocular coherence tomography is a better diagnostic tool to diagnose cystoid macular edema in patients with DR than biomicroscopy or fluorescein angiography.[26]

In our study, <3% of the photos were ungradable which is much less than reported in the literature 7%–17%[10,13,27] that might be due to our well-trained ophthalmology nurses, who were trained on the use of the fundus camera by the camera's company representative, who offered multiple training sessions and supervised the nurses while acquisition of photos and helped in teaching them on how to acquire better quality images in difficult cases.

Al-Fawaz *et al*. compared the quality of digital retinal images that were tele-transferred through the Saudi ministry of health system to images transferred from the research survey system. Poor quality images were 12.5% and 2.4%, respectively.[28] Scanlon reported similar results that only 1.5% of the two-field digital photographs were ungradable compared to 15.3% of the seven-field sets which were ungradable. This indicates that digital photography is much clearer than the gold standard seven-field stereo-photography.[29]

The drawbacks in our study were the retrospective nature of the study, the recruitment of cases from a tertiary hospital as opposed to being a random sample, and having four different retina specialists grade the patients who were referred for treatment. As having one retina specialist grade, the patients in the clinic would have adjusted for the variability of grading between physicians. Another important point to highlight is that the interpretation of retina specialists to both image reading and clinical examination could have resulted in the high validity of the study. This is difficult to apply at a national level, in a country like Saudi Arabia, where DM prevalence is high with a limited number of retina specialists. We recommend investing in an artificial intelligence program to help with the screening challenge.

Conclusion

Our study reported a high sensitivity and specificity for detecting sight-threatening DR such as severe nonproliferative DR and proliferative DR by nonmydriatic fundus camera as well as diabetic macular edema by OCT. It is easily

accessible during patients' routine diabetic checkups, less time-consuming, and image acquisition can be easily done by trained nurses. Graders then grade the images, and when necessary, patients are referred to an ophthalmologist for evaluation and possible treatment. The addition of OCT to the screening modality helped in accurate detection of diabetic macular edema in our study.

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Conflicts of interest

There are no conflicts of interest.

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