Diagnostic accuracy of non-mydriatic fundus camera for screening of diabetic retinopathy: A hospital based observational study in Pakistan

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Abstract

Objective: To determine the diagnostic accuracy of non-mydriatic fundus camera for the detection of diabetic retinopathy.

Methods: The cross-sectional study was conducted at Al Ibrahim Eye Hospital, Karachi, from January to May 2015, and comprised patients with type 2 diabetes who were screened for diabetic retinopathy. Single 45° fundus image focussed at macula was obtained and labelled using non-mydriatic fundus camera by a trained optometrist. Photos were labelled as positive (diabetic retinopathy present), negative (no diabetic retinopathy) or unreadable. The pupil was then dilated and fundi were examined by ophthalmologist with slit-lamp and fundus lens. Results of fundus examination were labelled as positive, negative or invisible/indecisive. Results of ophthalmologist were taken as the standard reference to evaluate sensitivity and speci?city for detecting diabetic retinopathy with non-mydriatic fundus camera. SPSS 20 was used for data analysis.

Results: Total eyes screened numbered 2970 related to 1485 patients. Diabetic retinopathy was found in 646(21.8%) eyes, 485(20.9%) photographs were unreadable and 1839(57.3%) were normal. Ophthalmologist on slit lamp bio-microscopy labelled 736(25%) eyes as positive for diabetes retinopathy, 335(15%) as indecisive and 1899(60%) as normal. The sensitivity of non-mydriatic fundus camera was 400/556 (72%) while specificity was 1548/1794 (86.3%). Positive predictive value and negative predictive value were 400/646 (62%) and 1548/1704 (90%) respectively. The level of agreement was moderate (k=0.0551) for optometrist compared to ophthalmologist. False positive diagnosis by optometrist numbered 78/1839 (4.24%) and false negative was 123/646(19%).

Conclusion: Non-mydriatic fundus camera was found to be a reliable screening tool for detecting and referral diabetic retinopathy cases to ophthalmologist for further evaluation and management.

Keywords: Retinal screening, Optometrist, Sensitivity, Specificity, Non-mydriatic fundus camera. (JPMA 69: 378; 2019)

Introduction

A screening test identifies persons with positive or suspicious findings to be referred to the relevant physician for confirmation of diagnosis and management. It is meant to pick up the disease before it is advanced enough to give rise to symptoms.[1] Screening test has paramount importance in type 2 diabetes mellitus (T2DM) for primary, secondary and tertiary prevention of this disease.[2] With increasing prevalence of T2DM, global data supports the assumption that number of people suffering from T2DM complications will also increase if proper strategy for the prevention of these complications is not implemented.[3] Diabetes retinopathy (DR) is one of the microvascular complications of diabetes that remains asymptomatic for fairly long time before its starts giving visual symptoms. Clinical evidences suggest that if diabetes retinopathy is diagnosed in its early stages, progression of existing DR may be either checked or even reversed.[4] International organisations, therefore, have consensus to screen diabetics for DR.[5] However, there is no recommendation about how and by whom the DR screening should be carried out.

Pakistan is confronting a rapidly growing epidemic of diabetes (prevalence 8-11% with 25% undiagnosed cases) and DR (27.4% and 21.2% DR, with 7.51% and 8.4% vision-threatening DR in suburban and urban areas respectively).[6-8] With this prevalence of diabetes and retinopathy in the community, Pakistan needs a comprehensive national DR screening programme by a reliable and reproducible albeit relatively cheap procedure. The procedure should be carried out by well-trained and experienced personnel in the field of ophthalmology and it should be done as near to the community as possible to ensure maximum coverage. Individuals with DR need to be identified in the community and referred to ophthalmologists for management.

In developing countries, bio-microscopy by an

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ophthalmologist using slit lamp and 90D lens is the standard method used for DR diagnosis. For screening on a large scale, ophthalmologists cannot be used even in countries like the United Kingdom.[9] In developing countries, non-mydriatic fundus camera (NMFC) has been used in the community as well as in hospital set-ups and has been found to be very cost-effective.[10-14] It has been operated by nurses,[15] general practitioners[16] and trained optometrists.[17,18] In Pakistan, optometrists have been inducted recently to help ophthalmologists in clinical work. Numerous studies worldwide evaluated the role of optometrists for grading of retinal images obtained by NMFC.[19,20] Reported sensitivity and specificity among these studies varied markedly. These variations were attributed not only to the experience of health professional but also to the reference screening method. Hence external validity of these studies are limited and that calls for conducting similar studies in our own setting in order to explore the diagnostic accuracy of fundal images obtained by NMFC and graded by optometrist for the detection of presence of retinopathy. In view of the above, the current study was planned to determine the diagnostic accuracy of NMFC for DR detection.

Patients and Methods

The observational cross-sectional study was conducted at Al Ibrahim Eye Hospital (AIEH), Karachi, from January to May 2015, and comprised all diabetic patients visiting the facility during the study period. Subjects were enrolled using non-probability purposive sampling after obtaining approval from the research ethics committee of Isra Post Graduate Institute of Ophthalmology, Karachi. Patients with history of any eye surgery or laser treatment or use of any ophthalmic drug for glaucoma were excluded. Informed consent for dilatation of the pupil was taken and data on demographic, anthropometric and clinical parameters were collected from each patient on a specially-designed proforma. Visual acuity (VA) was checked using Snellens chart and refraction was done to get best corrected vision. A single 45° fundus image was obtained in un-dilated pupil, using NMFC (Canon CR-1) by a trained optometrist. Photos were stored under patient's name and identification number on the hard disk and a compact disc (CD). The images were labelled as positive (DR present), negative (DR not present) or un-readable (indecisive). This data was masked. All the patients were then referred to retina trained ophthalmologist who was unaware of the results of photography. Written consent was obtained from the subjects after explaining the effects of mydriasis. Those who refused dilatation of the pupil were excluded. Pupil was dilated with two drops of Mydriacyl 1%. The ophthalmologist examined the fundi with 90-D fundus lens and slit lamp. Indirect ophthalmoscopy was done in cases where fundus was not clearly visible with bio-microscopy. DR classification was done by using International Clinical Disease Severity Scale.[21] Findings were entered into database as positive, negative or invisible (indecisive). Respondents with invisible/indecisive fundi were excluded for calculation of sensitivity and specificity.

Findings of ophthalmologist were taken as the reference standard for calculating sensitivity and specificity of NMFC in detecting DR.

Data analysis was performed using SPSS 20. All continuous variables were presented as mean± standard deviation (SD). All categorical variables were expressed as frequencies and percentages. Chi square test and Kappa statistic19 were applied to find the association between the observers and their measure of agreement was assessed. Also, 2x2 contingency tables were made to find sensitivity and specificity, positive predictive value (PPV) and negative predictive value (NPV). The NMFC image was compared with Slit Lamp Bio microscopy results to see sensitivity, specificity, PPV and NPV of NMFC as used by the optometrist. $P<0.05$ was considered statistically significant.

Results

There were 1485 subjects whose 2970 eyes were examined by both the observers. The mean age of the respondents was 53.5±10.4 years (range: 20-95 years). There were 687(52.8) male patients and 706(47.2%) were female patients. The ophthalmologist labelled 736(25%)

Table-1: Frequency of Diabetic Retinopathy by NMFC (Observer 1) & Slit Lamp Examination (Observer 2) n=2970 eyes.

	Optometrist with NMFC (Observer 1)		Retina trained Ophthalmologist with Slit lamp dilated Pupil Examination (Observer 2)	
	Frequency	%	Frequency	%
DR Positive	646	21.8%	736	25%
DR Negative	1839	57.3%	1899	60%
Un-readable fundus	485	20.9%	335	15%

*DR=Diabetic Retinopathy

*NMFC=Non Mydriatic Fundus Camera.

Table-2: Sensitivity and specificity 2x2 contingency table of Diabetic Retinopathy Diagnosis (n=2350 eyes).

NMFC Screening	Diagnosis by Slit Lamp Examination DR Positive	DR Negative	Total
DR Positive	400	246	646
DR Negative	156	1548	1704
Total	556	1794	2350
	Sensitivity= 400/556*100= 72%	Specificity= 1548/1794*100= 86.3%	

*DR=Diabetic Retinopathy
*NMFC=Non Mydriatic Fundus Camera.

eyes as positive, 1899(60%) as negative and 335(15%) as invisible fundi. The optometrist labelled 646(21.8%) images as positive, 1839(57.3%) as negative and 485(20.9%) as invisible fundi (Table-1). Sensitivity of NMFC used by optometrist was 400/556 (72%), while specificity was 1548/1794 (86.3%). PPV for optometrist was 400/646 (62%) and NPV was 1548/1704 (90%). The level of agreement for optometrist compared to ophthalmologist was moderate (K=0.551) (Table-2).

Discussion

The current study intended to validate the diagnostic accuracy of NMFC for DR screening by optometrist using findings of ophthalmologist by slit lamp bio microscopy and 90D lens as the reference standard. The sensitivity and specificity of NMFC in the study was 72% and 68.3% respectively.

Though international organisations have consensus on mandatory screening of patients with diabetes for signs of retinopathy, uncertainty yet remains about the choice of the best modality for DR screening. Besides, expertise of the healthcare provider who performs the procedure is also a confounding factor. Screening of DR in patients with diabetes can be performed by various modalities like direct ophthalmoscopy, slit lamp bio-microscopy and digital photography. Among all, ophthalmoscopy is the the most inexpensive and non-invasive method for DR screening. It can be performed by physicians/ diabetologists, family physicians and general ophthalmologists in dilated pupil.[22] Although the procedure is cost-effective as it does not require special preparation and equipment, its findings may have intra- and inter-observer variability. On the other hand, slit lamp bio-microscopy, also in dilated pupil, requires technical expertise and is thus performed by senior ophthalmologist/medical retina specialist available in tertiary eye care centres. Examination by slit lamp also has problem of reproducibility. Digital photography on the other hand can be done in any place where fundus camera and a trained photographer is available. NMFC can be used by any trained paramedic. It is patient-friendly as image acquisition can be done through un-dilated pupil and soft copy of images can be saved in the computers. These images can become the part of permanent patient's record. In developing counties, slit lamp bio-microscopy and 90D lens in the hands of consultant ophthalmologist remains the best choice, but qualified ophthalmologists are located in tertiary centres and are not available for screening programmes in peripheral areas. Thus, an alternative tool that can be operated by a person other than ophthalmologist is needed. In a country like Pakistan where per capita income is low, medical insurance coverage virtually non-existing, spending of the patients on the treatment of diabetes is inadequate. Screening of retinopathy puts financial burden. This demands formulation and implementation of a screening strategy that has been tailored as per our need. Low uptake of screening facility, inadequate eye care providers and lack of coordinated referral system demands provision of screening services at community level via out-reach approach by trained optometrist with a modality whose findings can be reproduced. NMFC is the best choice in such settings. It is also a cost-effective tool for retinal screening in patients with diabetes.[23-25]

A number of studies evaluated the role of fundal photographs as a screening modality for detection of retinopathy. Marked variations in sensitivity and specificity of fundal photographs for the presence and severity of retinopathy in these studies were reported. These variations can be attributed to the use of different reference standard for comparison (flourescine angiography, slit lamp bio-microscopy), severity of retinopathy assessed (sight-threatening vs non-sight threatening), fields of retina examined (one, two, three, four or seven fields of retina) and use of different grading systems for calculation of sensitivity and specificity among studies.[26,27] Along with this expertise of healthcare provider who assessed retinopathy is also a cofounding factor. In some studies grading was performed by trained grader or optometrist while in others ophthalmologists working at retinal centre grade these photographs.[28] Thus direct comparisons among these studies are difficult that demand conducting similar studies in one's own setting to determine the diagnostic accuracy of one field of fundal photographs for screening of retinopathy. The sensitivity and specificity of NMFC in the present study was 72% and 68.3% respectively. Both sensitivity and specificity of the present study was lower than the established standards for any diabetic

retinopathy screening programme of at least 80% sensitivity and 95% specificity recommended by British Diabetic Association (Diabetes UK).[29] In this study, false positive diagnosis by optometrist was 4.24% (78/1839) and false negative was 19% (123/646). This shows that optometrist missed 78 eyes with DR and wrongly labelled 123 eyes as DR positive. This may partly be due to lack of training which can be improved. Another possible reason was unclear photographs from cataract which is more common in patients with diabetes.[30] However, in the present study, it is to be noted that in 20.9% (485 eyes) cases, the photographs were unreadable. The current study may not match Diabetes UK recommendations,[31] but in resource-constrained countries, even lower sensitivity has been accepted as effective. An Indian study had recommended minimum of 60% sensitivity for any retinal screening method to be effective.[32]

The current study can prove to be a forerunner for future longitudinal or larger studies.

Conclusion

For screening in the community, NMFC was found to be a reliable tool which can be used by a trained optometrist. As optometrists are cost-effective and easily adjustable in community, they can assist ophthalmologists by referring only positive DR cases, thereby reducing unnecessary burden.

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