ORIGINAL ARTICLE

Diagnostic Accuracy of Direct Ophthalmoscopy and Non-Mydriatic Retinal Photography for Screening of Diabetic Retinopathy

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ABSTRACT

Purpose: To determine the reliability of direct ophthalmoscopy and Non-Mydriatic fundus photography for screening of Diabetic Retinopathy by optometrist.

Study Design: Observational, cross sectional.

Place and Duration of Study: Al-Ibrahim eye hospital, Karachi from October to December 2018.

Material and Methods: All individuals with type 2 diabetes of ≥ 40 years of age were screened for diabetic retinopathy (DR) by two trained optometrists and an ophthalmologist. First Optometrist used Non Mydriatic Fundus Camera (NMFC) and second optometrist used direct ophthalmoscopy (DO) after dilating the pupils. Final examination was done by the Ophthalmologist with slit lamp using Volk fundus lens which was considered as reference standard. Every investigator was kept unaware of the findings of others.

Results: A total of 698 eyes of 349 respondents were screened. Ophthalmologist could not make decision by bio microscopy in 44 (6.3%) individuals as compared to 128 (18.3%) by 1st optometrist by NMFC and 142 (20.3%) by 2nd optometrist with DO. Diabetic retinopathy (DR) diagnosed with slit lamp bio microscopy was 140 (21.4%), with NMFC was 124 (19.1%), with DO was 110 (16.8%). Sensitivity of NMFC was 76% and that of DO was 64.8%. Specificity of NMFC was 97.45% and that of DO was 96.63%. Positive predictive value (PPV) of NMFC was 89.33% and that of DO was 84.3% Negative predictive value (NPV) of NMFC was 93.33% and that of DO was 90.7%.

Conclusion: NMFC is recommended tool for DR screening; but DO by well-trained optometrist can be reliable where neither ophthalmologist nor NMFC is available.

Key Words: Diabetic Retinopathy, Direct ophthalmoscopy, Non Mydriatic fundus camera, Optometrist.

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INTRODUCTION

Diabetic retinopathy is one of the leading causes of avoidable blindness in people of working age group[1,2]. It has been shown that diabetic retinopathy (DR) is present in 28.78% diabetics whereas sight threatening diabetic retinopathy (STDR) is present in 8.6% of the

diabetics[3]. The most recent survey of diabetes[4] in Pakistan reported 26.3% prevalence of diabetes, of which 19.2% had known diabetes and 7.1% were diagnosed on screening. In order to prevent progression of DR to STDR leading to gross impaired vision, at least all the known diabetics should undergo annual DR screening as per recommendations[5,6]. It is commonly observed in clinical practice that many individuals having diabetes in Pakistan present with varying degree of retinopathy and visual deterioration on their first presentation, jeopardizing the final visual outcome. This state of affairs may arise either from failure to detect retinopathy at an appropriate stage or a delay in treatment[7]. Diversity of the tools and operators has resulted in marked variations in the results attributed not only to modality by which screening was performed but to the expertise of the health care provider. Developed countries have their own screening methodologies[8]. Developing countries have to find out screening methods which are not only feasible, cost-effective but meet international standards of > 80% sensitivity, and > 95% specificity[9]. (Standards set by British Diabetic Association (BDA). Though Pakistan has an elaborative network of health care facilities at primary, secondary and tertiary care level, a proper functioning referral system is lacking[10]. This situation is further accentuated by shortage of trained and qualified ophthalmologists. Currently, country has nearly 30,000 qualified registered ophthalmologists against the required number of 100,000[11]. Thus mandatory screening of all patients by ophthalmologist as per recommended guidelines is out of questions for a long time to come. Non-Mydriatic fundus camera (NMFC) has been recommended as useful tool for mass screening[12]. It can be used at primary/secondary level by trained paramedics to lessen the burden on ophthalmologist and meet the required criteria. The cost and maintenance prevents its use in resource strained country like ours. Direct ophthalmoscopy in the hands of well-trained optometrist might be a cheaper method. A study carried in a tertiary care diabetes center reported sensitivity of 60% and specificity of 76%[13]. The findings of this study though did not validate the use of direct ophthalmoscopy by Diabetologist; authors however advocated its use and suggested to invest on the training of health care providers till financial resources allow shifting to the modern technology like fundus camera. In another study from Lahore, "direct ophthalmoscopy" in the hands of ophthalmologist considering as gold standard was compared to "Arc light", concluded that "Arc light" can be used as a replacement of Ophthalmoscope for diagnosing DR or other diseases as shown by the sensitivity and specificity analysis in this study". The researcher found optometrist almost equal to ophthalmologist in diagnosis of DR with ophthalmoscope as well as "Arc light[14] Apart from this study, sensitivity and specificity of "direct ophthalmoscope" in the hands of optometrist has been scarcely studied in Pakistan. Present study was conducted with two objectives. First, to validate the findings of an earlier study using NMFC by optometrist. Second, to find out the diagnostic accuracy of direct ophthalmoscopy in the hands of optometrist. The standard reference in the present study was bio-microscopy with 90D fundus lens by ophthalmologist.

MATERIAL AND METHODS

This was a comparative cross sectional study with non-probability, purposive sampling, carried out at diabetic eye clinic of Al Ibrahim eye hospital (AIEH). Duration of the study was from October to December 2018. All newly registered type 2 patients with diabetes, ≥ 40 years of age, irrespective of gender and ethnicity and willing for eye examination with dilated pupil were inducted whereas patients with type 1 and gestational diabetes or patient having any other eye disease were excluded from the study. All patients were examined for routine basic eye examination like refraction and best-corrected vision and entered into database. First screening was carried by an optometrist (Optometrist A) without dilatation of pupil. Two 45 degree retinal images one center to macula and other center to optic disc were taken using Non Mydriatic fundus camera (NMFC) (Cannon CR-1). The data of fundus image was saved in the HMIS (AIEH) database. The consent was obtained from the patient for dilatation of pupil after informing about transitional haziness of vision after dilatation and confirming that patient is not driving after examination. Tropicamide 0.1% was used for dilatation of pupil. After full mydriasis, Optometrist (Optometrist B) examined the fundus with direct ophthalmoscopy and entered the data in the HMIS (AIEH) database. The optometrists were instructed to identify presence or other wise of the diabetic retinopathy based on presence of hemorrhages, exudates, blood vessel changes and macular edema. They did not grade the retinopathy. In order to eliminate the observer bias both optometrists were

kept blind to the findings of each other. Final retinal examination (C) was done by the retina-trained ophthalmologist using fundus lens and slit lamp. Findings were entered into HMIS database. These findings were taken as the reference standard for this study. DR was classified as a routine examination for the purpose of management using "Early treatment diabetic retinopathy study (ETDRS– the modified Airlie House classification. DR was classified as Non–Proliferative Diabetic Retinopathy (NPDR), Proliferative Diabetic Retinopathy (PDR) and clinically significant Macular Edema (CSME) with or without NPDR/PDR. For the purpose of present study presence or absence of DR alone was compared with findings of NMFC done by Optometrist A and direct ophthalmoscopy done by Optometrist B.

Sample size calculation drawn by using on-line software Raosoft.com and inculcating 95% confidence interval, given 5% margin of error with expected population size 5000 per year. The required sample size was found to be 357. Ethical approval was taken from Research Ethical Committee (REC) of Isra Post Graduate Institute of Ophthalmology, Al Ibrahim Eye Hospital (AIEH). Statistical analysis was done by SPSS version 20.0. The entire continuous variables were presented as mean ± standard deviation. All the categorical variables were shown as frequency and percentage. Sensitivity, specificity, PPV, NPV and likelihood ratio was calculated by 2 × 2 contingency table. Kappa statistics was also done to show the association (level of agreement) between two observers.

RESULTS

A total of 698 eyes of 349 individuals with diabetes type 2 were screened for DR using NMFC without dilating pupil, using direct ophthalmoscope (DO) after dilating pupil and slit lamp with Volk's lens. Result of slit lamp examination was used as a reference standard for comparison of NMFC ophthalmoscopy.

Non-Readable fundi with bio microscopy were 44 (6.3%), with NMFC were 142 (20.3%) and with DO were 128 (18.3%). Diabetic retinopathy (DR) diagnosed with slit lamp bio microscopy was 140 (21.4%), with NMFC was 124 (19.1%), with DO was 110 (16.8%) (Table 1). Validity of the procedures is shown in Table 2.

Table 1: *N: 698 eyes (349 individuals with diabetes).*

Tool used	Examiner	Diagnosis Not Possible	DR Detection
NMFC	Optometrist	(n: 142) 20.3%	(n:124) 19.1%
Direct ophthalmoscopy	Optometrist	(n:128) 18.3%	(n: 110) 16.8%
Slit lamp bio-microscopy	Ophthalmologist	(n:44) 6.3%	(n: 140) 21.4%

Table 2: *Validity chart n = 698 eyes (349 individuals with diabetes).*

	Sensitivity	Specificity	PPV	NPV	Kappa Statistic
British Diabetic Association (BDA) recommendations	> 80%	> 95%	-	-	-
NMFC	76%	97.45%	89.62%	93.33%	0.725
Direct ophthalmoscopy	64.80%	96.63%	84.38%	90.72%	0.621

*Positive Predictive value (PPV), Negative Predictive value (NPV)

Kappa statistic in terms of DR detection by NMFC as compared to slit lamp diagnosis (standard) was found to be 0.725. This indicates good agreement between the observers of NMFC with standard. Kappa statistic in terms of DR detection with Direct Ophthalmoscopy (DO) as compared to slit lamp diagnosis (standard) was found to be 0.621. This also shows good agreement between the observers of DO with standard.

DISCUSSION

Present study showed NMFC in the hands of an optometrist has sensitivity of 76%, specificity of 96.63%, PPV of 84.3% and NPV of 90.7%. Findings of the present study not only validated the findings of earlier study with NMFC by optometrists but showed improvement over previous figures of 72% sensitivity, 86.3% specificity, 62% positive predictive value and 90% negative predictive value. Several studies have evaluated Non-Mydriatic fundus photography, and compared it with more-established methods of detecting diabetic retinal disease. The real question to be considered is whether Non-Mydriatic fundus photography will help to detect early treatable retinopathy better than the average physician using ophthalmoscopy[15-18]. This study thus supports that Digital photography with NMFC camera is a useful tool for mass screening. It is to be considered that Initial cost of NMFC is ≥ $ 20,000 and maintenance

limits use for screening of retinopathy and calls for more cost effective methodology. Ophthalmoscope is economical, age-old equipment which has been used by general physician, Diabetologists, opticians and nurses. Direct ophthalmoscopy by an optometrist can be most cost effective tool especially in community screening and primary eye care centers only if it meets the recommended criteria. Present study has shown that direct ophthalmoscopy in the hands of optometrist had Sensitivity of 64.8%, Specificity of 96.63% with PPV of 84.3% and NPV of 90.7%. The results have fallen short of recommended levels by BDA of > 80% sensitivity, and > 95% specificity. This shows that in 100 DR eyes, optometrist missed 34 cases and wrongly diagnosed 4 cases. Results of International studies are variable. Studies from the UK have shown sensitivity levels for the detection of sight-threatening diabetic retinopathy of 41 – 67% for general practitioners, 48 – 82% for optometrists, 65% for an ophthalmologist, and 27 – 67% for Diabetologist and hospital physicians using direct ophthalmoscopy[19,20]. This shows missing rates, of DO for sight threatening diabetic retinopathy screening with direct ophthalmoscopy, as high as 52% for optometrists, 45% for general practitioners and 33% for hospital physicians. These studies have suggested no or limited role of "Direct ophthalmoscopy" in screening of DR so much so that even elimination of training in direct ophthalmoscopy for medical students has been suggested[21,22]. In present times of technology, ophthalmoscopy is not considered as an option, in spite of limited availability and cost considerations of Non-Mydriatic fundus photography. On the other hand, data are available in favor of optometrists. European working group in their study concluded that direct ophthalmoscopy through dilated pupils is the recommended test to screen for diabetic retinopathy, because it is inexpensive, efficient and rapid. In the opinion of this group 60% sensitivity is good enough for DR screening purpose and very little is gained from increasing the sensitivity to 80%[23]. In view of all above studies, it can be suggested that direct ophthalmoscopy can relied upon as cost effective screening tool if the optometrists are trained well and aware of proper referral protocols.

CONCLUSION

Digital photography with NMFC is promising screening method where trained ophthalmologists are not available. Direct ophthalmoscopy in the hands of well-trained optometrist can be depended upon in the primary care setups and in the community where neither ophthalmologist nor NMFC is available.

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Ethical Approval

The study was approved by the Institutional review board/Ethical review board.

Conflict of Interest

Authors declared no conflict of interest

Authors' Designation and Contribution

Shahid Ahsan; Professor: *Manuscript writing and Final review.*

Muhammad Fahadullah; Retina Specialist: *Data collection, Final review.*

Muhammad Faisal Fahim; Statistician: *Statistical Analysis, Manuscript writing, Final review.*

Khalida Parveen; Optometrist: *Data collection, Final review.*

Sumaira Salim; Optometrist: *Data collection, Final review.*

Muhammad Saleh Memon; Director research: *Manuscript writing, Final review.*

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