RESEARCH ARTICLE

Validity of Hand Held Fundus Camera by Optometrist using Slit lamp 90D bio microscopy as a reference standard for screening of Diabetes Retinopathy

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Abstract

Objective: To find out the validity of hand-held fundus camera by optometrist using slit lamp 90D biomicroscopy as reference standard for screening of diabetes retinopathy.

Method: The observational cross-sectional study was conducted at the diabetic clinic of Al-Ibrahim Eye Hospital, Karachi, from August 2020 to May 2021, and comprised diabetics of either gender aged >16 years visiting the outpatient department. Un-dilated fundus photograph of both eyes were taken with non-mydriatic fundus camera. Pupils were then mid-dilated with one drop of tropicamide 1% before capturing retinal images by handheld fundus camera by another optometrist. Both the optometrists identified and recorded the presence and absence of diabetic retinopathy. Subsequently, a retinal specialist examined the fundus with slit lamp 90 D biomicroscopy. Data was analysed using SPSS 23.

Results: Of the 500 subjects, 291(58.2%) were males and 209(41.8%) were females. The overall mean age was 54.49±9.16 years (range: 16-83 years). Of the 1000 eyes, fundus was not readable in 130(13%) by hand-held fundus camera, 296(29.6%) eyes by non-mydriatic fundus camera and 76(7.6%) eyes by slit lamp. Sensitivity and specificity of hand-held fundus camera compared to non-mydriatic fundus camera was 89.86% and 80.36%, respectively. In comparison with slit lamp, the sensitivity was 91.71% and specificity was 71.10%. Kappa statistic for diabetic retinopathy detection by hand-held fundus camera versus non-mydriatic fundus camera was 0.705, indicating substantial agreement. Kappa statistic for diabetic retinopathy detection with hand-held fundus camera versus slit lamp (standard) was 0.609, indicating good agreement.

Conclusion: Handheld fundus camera with semi-dilated pupil was found to be a valid screening tool in the hand of optometrist for preliminary screening of diabetic retinopathy.

Keywords: Retinal screening, Hand-held fundus camera, Optometrist, Sensitivity, Specificity. (JPMA 72: 2189; 2022)

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Introduction

The first national survey on diabetes mellitus (DM), conducted in 1994, reported 10-15% prevalence of the disease in Pakistan.[1,2] The figure rose 21-26% in a recent national survey in 2018.[3] According to the International Diabetes Federation (IDF)[4] Pakistan, with 19.4 million diabetics, ranked 4th in the world in 2019, and is expected to acquire the 3rd position by 2045, with 37.1 million people expected to be afflicted by DM. With increasing DM prevalence, there is a corresponding rise in diabetic retinopathy (DR). Available statistics regarding DR in Pakistan vary a great deal. Most of the studies done have been hospital-based, and, hence, do not reflect the national scale. One study (2006-08)[5] showed DR prevalence in Gaddap area to be 26.43%. An urban study in 2015[6] showed DR prevalence of 21.2%, and a systemic review in 2018[7] reported DR prevalence as 28.78%. Based on such studies, it can be assumed that at least one in four diabetics in the country has DR. Thus, there is a great need of retinopathy management in the community. DM-related blindness can be controlled at three levels.[8,9]

At the primary level, mid-level eyecare providers can prevent/delay DR onset. This can be done by creating awareness among the diabetics regarding DM-related ocular problems, importance of self-monitoring of blood glucose, blood pressure (BP) control and regular periodic retinal screening.[10] All diabetics at their first consultation must be screened for retinopathy. Individuals with normal fundus should undergo rescreen one to two years later.[11] It has been seen that early diagnosis and timely treatment at the primary level (blood pressure and glycaemic control) and/or secondary level (laser photocoagulation and anti-angiogenic injection), reduced the risk of blindness by 5%.[12,13] DR patients are referred to secondary-level facilities where grading is done. Patients with non-sight threatening diabetic retinopathy (NSTDR) are called for follow-up depending upon DR severity. Sight-threatening diabetic retinopathy (STDR) is offered laser/intra-vitreal injection of anti-vascular endothelial growth factor (VEGF) therapy. Non-responding cases and those with advanced diabetic eye disease (ADED) are referred to the tertiary level of

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eyecare. Tertiary level management consists of reassessment retinopathy, use of anti-VEGF, laser photocoagulation or/and ocular surgery.

Awareness and education as well as retinal screening of all diabetics are the two most important pillars for DR prevention. There is a need of putting in place a coordinated national screening programme to identify and initiate treatment of potential STDR individuals before complications develop.[8,14]

The standard method of retinal screening in Pakistan is slit lamp biomicroscopy using fundal lenses by retina specialist available as a few centres, or consultant ophthalmologists in most cases. The facility of retina screening is usually available at tertiary care teaching centres situated mostly in the cities or big towns. This makes early screening beyond the reach and affordability of the majority, resulting in poor service uptake. A 10-year study in Gaddap town showed that in spite of relative intensive awareness campaigns in the community, DM screening was availed by 42% of the population, 55.6% of the diabetics turned out at tertiary centre for retinal screening out of whom 42.2% were referred. Acceptance of laser therapy was 68.4%. Awareness activities and accessible services did not improve acceptance of retinal screening beyond 55.6%.[15] This calls for a cost-effective, reliable technology operated by an optometrist or well-trained ophthalmic technician that can be taken to as near to the patient as possible. Easily available, age-old and cost-effective technology is direct ophthalmoscopy which can be used even as a bed-side tool. Studies have shown that direct ophthalmoscopy by trained optometrist or ophthalmic technician can be relied upon as an effective tool for retinal screening. It has been recommended where non-mydriatic fundus camera (NMFC) is not available.[16] NMFC has also been found more reliable than direct ophthalmoscopy for retinal screening.[17] However, initial cost and sustained maintenance in rural areas are the limiting factors. While considering cost efficacy, arc light as a screening tool has been used by some researchers to compare it with direct ophthalmoscope[18] and was found comparable to ophthalmoscope and reliable. However, the images cannot be stored in this technology and are not reproducible either.

Recently, hand held fundus camera (HHFC), a relatively inexpensive and mobile facility, has become available for retinal screening. The current study was planned to find out the validity of HHFC using slit lamp 90D biomicroscopy as reference standard for DR screening.

Patients and Methods

The observational cross-sectional study was conducted at the diabetic clinic of Al-Ibrahim Eye Hospital, Karachi, from August 2020 to May 2021. After approval from the institutional ethics review committee, the sample size was calculated using OpenEpi calculator with 50% hypothesised prevalence and 95% confidence interval (CI).

Five optometrists were trained under the supervision of a senior retina specialist for one month about how to take retinal image using HHFC, and to identify the retinopathy sign. Initially, they practised by taking HHFC images of about 20 patients per day. After a month of training, the assessment of all optometrists was done by the senior retina specialist before they were allowed to operate independently.

Each day, 20 new diabetics of either gender aged >16 years were selected using convenience sampling technique from the outpatient department (OPD) of the diabetic clinic. Follow-up patients, and those with other ocular pathologies, like glaucoma, age-related macular degeneration (ARMD) and corneal opacity, were excluded.

Images were taken and data was collected after taking informed consent from each subject. To start with, one optometrist took images of the retina using NMFC (Canon CR2) through un-dilated pupil. The pupil was then dilated with one drop of Tropicamide 1% and a different optometrist took images of all 20 patients with HHFC (Nidek DS-20). Both optometrists identified signs of DR. Confirmation was done on the same day by retina specialist with slit lamp 90 D biomicroscopy, while blinded to the results of the optometrists.

Statistical analysis was done using SPSS 23. Continuous variables, like age, were presented as mean±standard deviation, while categorical variables, like gender and age groups, were expressed as frequencies and percentages. A 2×2 contingency table was used for the calculation of sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). The level of agreement between the two observers was determined by the application of Kappa test.

Results

Of the 500 subjects, 291(58.2%) were males and 209(41.8%) were females. The overall mean age was 54.49±9.16 years (range: 16-83 years) (Table 1).

Of the 1000 eyes, fundus was not readable in 130(13%) by HHFC, 296(29.6%) eyes by NMFC and 76(7.6%) eyes by slit lamp. DR was detected in 505(50.5%) of the eyes screened by HHFC, in 424(42.4%) of the eyes by NMFC, and in 396(39.6%) eyes with slit lamp. Normal fundus was identified in 365(36.5%) eyes by HHFC, in 280(28%) by NMFC, and in 528 (52.8%) eyes through slit lamp (Table 2).

Table-1: Demographic characteristics (n=500).

Characteristics	n (%)
Age Group (years)	
16-30	8 (1.6)
31-45	95 (19)
46-60	282 (56.4)
> 60	115 (23)
Gender	
Male	291 (58.2)
Female	209 (41.8)

Table-2: Demographic Diagnosis of Diabetic Retinopathy (DR) by Handheld Fundus Camera (HHFC), Non-Mydriatic Fundus Camera (NMFC) and Slit Lamp Biomicroscopy.

Screening Tools	Diabetic retinopathy No. of eyes (%)	Normal Fundus No. of eyes (%)	Fundus not Visible No. of eyes (%)
Handheld Fundus Camera	505 (50.5)	365 (36.5)	130 (13.0)
Non-Mydriatic Fundus Camera	424 (42.4)	280 (28)	296 (29.6)
Slit lamp biomicroscopy	396 (39.6)	528 (52.8)	76 (7.6)

Table-3: Validity of Handheld Fundus Camera (HHFC) with Non-Mydriatic Fundus Camera (NMFC) and Slit Lamp Biomicroscopy for the diagnosis of Diabetic Retinopathy (DR).

Screening Tools	Sensitivity	Specificity	PPV	NPV	Kappa Statistic
Handheld Vs NMFC	89.8%	80.3%	87.3%	83.9%	0.705
Handheld Vs Slit Lamp	91.7%	71.1%	74.4%	90.2%	0.609

PPV: Positive Predictive Value, NPV: Negative Predictive Value.

Sensitivity and specificity of HHFC compared to NMFC was 89.86% and 80.36%, respectively. In comparison with slit lamp, the sensitivity was 91.71% and specificity was 71.10%. Kappa statistic for DR detection by HHFC versus NMFC was 0.705, indicating substantial agreement. Kappa statistic for DR detection with HHFC versus slit lamp (standard) was 0.609, indicating good agreement (Table 3).

Discussion

According to the guidelines of the International Council of Ophthalmology (ICO), selection of a modality for DR screening depends on the development level of the country.[19] Various screening modalities are in use, ranging from subjective visualisation of retina by direct ophthalmoscopy to a slit lamp biomicroscopy to capturing of fundus images through dilated or undilated pupils with or without optical coherence tomography (OCT).[20] Though slit lamp biomicroscopy is still considered the gold standard against which other DR screening approaches are assessed, fundus photography being the most cost effective can be used for mass screening of diabetics for the presence of retinopathy.[21]

Since the last decade, digital imaging has been gaining popularity and is now a useful tool in ophthalmology because of its ease of use. Images captured by these devices can be stored, reproduced and transmitted for remote analysis. Recently, portable screening devices have hit the market. These devices are comparatively inexpensive and are user-friendly to local health workers who might be trained on it. Performance of these devices in their hand must be validated in terms of sensitivity and specificity.

The key management in terms of prevention of diabetic-related blindness (DRB) is timely detection through retinal screening. Eye screening of retina has been recommended at the first detection of DM, followed by annually, half-yearly and even monthly examinations depending on the presence or absence of DR and its severity at the initial examination.[11] The HHFC is designed so that it can be easily carried by hand and paramedics, like optometrists, and experienced ophthalmics can learn to use it easily. Readable photo covering 350 field is obtained. Quality of fundus images taken by HHFC is comparable with the images taken by the standard Canon CR2 desktop.

In the present study slit lamp biomicroscopy examination with 90D by an ophthalmologist was used as the gold standard. HHFC and NMFC were operated by optometrist.

The British Diabetic Association (Diabetes UK) has established standard values for any DR screening programme of at least 80% sensitivity and 95% specificity.[19] The present study showed sensitivity and specificity of HHFC compared to NMFC as 89.8% and 80.3%. Sensitivity is comparable to other studies, whereas specificity needs to be improved. While in comparison with slit lamp, sensitivity was 91.7% and specificity was 71.1%. Kappa statistic in terms of DR detection by HHFC compared to NMFC was 0.705, indicating substantial agreement between the observers of HHFC and NMFC. Kappa statistics in terms of DR detection with HHFC compared to slit lamp diagnosis (standard) was 0.609, showing good agreement between the observers of HHFC with the standard.

A study in China resulted in a high-level agreement between handheld and desktop camera with sensitivity of 91.1% (95% CI: 82.6-96.4), specificity of 99.6% (95% CI: 98.9-100) and PPV of 98.6% (95% CI: 92.6-100).[22] Studies from Sri Lanka[23] showed sensitivity of 88.7% (95% CI: 81.7-93.8%) and PPV 59.1% using mydriatic imaging, and specificity 94.9% (95% CI: 93.6-96.0%). A study in Thailand[24] showed sensitivity and specificity of 65.6% (95% CI: 60.9-70.2) and 84.9% (95% CI: 81.4-88.4), respectively. PPV and NPV were 55.7% (95% CI: 50.8-60.5) and 89.5% (95% CI: 86.5-92.5), respectively.

The current study has limitations. DR screening by HHFC was done by five optometrists, and subjective variations in

sensitivity and specificity compared to NMFC and slit lamp examination were observed. The interpretation of the findings, as such, needs to be done with due caution. Further training of optometrists is needed to improve specificity.

Conclusion

Retinopathy screening with HHFC by optometrist with mid-dilated pupil was found to be reliable enough to play an important role in preliminary DR screening at the primary level in Pakistan.

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