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SENSITIVITY AND SPECIFICITY OF DETECTION OF DIABETIC RETINOPATHY USING SMART PHONE BASED RETINAL IMAGING

Ophthalmology

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ABSTRACT

Images are used extensively in ophthalmology for documenting of diseases and monitoring treatment. Historically, hospitals have always used bulky and costly fundus photographic devices that require skilled technicians in order to operate. Smart phones, because of their portability and instantaneous communication capabilities are a desirable alternative for acquiring retinal images in remote, non-hospital settings. Diabetic retinopathy(DR),a complication of diabetes mellitus(DM) is one of the leading causes of preventable blindness world wide and a sizable portion of these patients do not obtain the necessary standard of care as a result of socioeconomic and geographical barriers.The versatility of smart phones can be extrapolated to the screening of chronic diseases like diabetic retinopathy(DR), especially in communities that receive sub-optimal care. This study explored the validity of smart phone photography compared to the traditional slit lamp biomicroscope as a screening tool for DR detection in patients with diabetes mellitus(DM) in a tertiary hospital setting. Smartphone ophthalmoscopy showed satisfactory agreement with slitlamp biomicroscopy for the grading of DR. Its sensitivity and specificity appears to be highest during the stages of DR that call for a particular course of treatment (severe NPDR/PDR). It may be a useful telemedicine screening modality in resource-limited settings .

KEYWORDS

Smart Phone, Slit Lamp Biomicroscopy, Diabetic Retinopathy, Dr,Diabetes Mellitus, Validity, Sensitivity, Specificity.

INTRODUCTION:

Diabetic retinopathy (DR) is a major microvascular complication of diabetes and one of the major causes of vision loss globally. Globally, there were 451 million persons with DM in 2017, and by 2045, that number is predicted to rise to 693 million.[1]India is home to over 65 million people with diabetes [2]with an estimated DR prevalence of 18%.

The global prevalence of DR and sight-threatening DR (STDR) among individuals with DM was reported to be roughly 35% and 10%, respectively.[2] Despite the growing burden of DR, it is been disregarded in medical research and planning in many low-income countries, where access to trained eye care professionals and tertiary eye care services may be limited.Majority of patients who develop DR are asymptomatic until visual impairment occurs due to the sight threatening DR.

Well-designed, nationwide screening programs that are incorporated into the monitoring and treatment of diabetes can enable early detection of DR. When weighed against the disability loss suffered by persons who become blind in the absence of a screening program, DR screening is a cost-effective measure.[3,7]

Dialated fundus examination using direct and indirect ophthalmoscopy by a trained ophthalmologist are considered to be the gold standards for DR screening. Many studies have suggested that fundus photography after dilatation is equivalent to ophthalmoscopic examination for detection of DR.[8,9] The ever advancing built-in camera technology in smart phones has captivated their interest in ophthalmic imaging domain. The portability and wireless connection capabilities of smart phones make them an attractive device for acquiring retinal pictures in remote rural settings. [4]

In instances where there is scarcity of resources or a shortage of qualified ophthalmologists, this approach can be utilized for fundus screening so that those with retinopathy changes can be promptly referred. Telemedicine does, in fact, have the ability to reach patients and communities that, due to sociocultural or geographic limitations, do not currently receive eye care.[5,6]

MATERIALS AND METHODS:

Study Population And Design:

This was a single visit, prospective cross-sectional clinic-based study. Patients attending the ophthalmology outpatient department of a tertiary care hospital were recruited. A written, informed consent was obtained from all the participants and the study was conducted over a period of 4 months, from August to November,2022 after the approval of the Institutional Ethics Committee.Adults aged 40–70 years with documented type 2 DM and who were willing to undergo retinal photography with smart cameras were included in the study.

Inclusion Criteria:

- Adults aged 40-70 years with documented type 2 DM.
- No known allergy to tropicamide eye drops.
- Those who consented to undergo retinal photography and slit lamp examination

Exclusion Criteria:

- Participants with media opacities ,dense cataract/total vitreous hemorrhage.
- Any contraindications/unwillingness for mydriasis/examination.

METHODOLOGY:

A detailed history regarding duration and type of diabetes, any visual symptoms, history of laser photocoagulation or cataract surgery, allergy to topical medications, and family history of glaucoma was obtained. Demographic details such as name, age, and gender were entered ,following which all patients underwent a complete ocular examination. A preliminary eye examination, which included a visual acuity test using an illuminated Snellen vision chart was recorded for both distance and near vision . Intra-ocular pressure measurement by rebound tonometry and a slit lamp examination of the anterior segment of the eye to assess the depth of anterior chamber and presence of media opacities like cataract was done.

After adequate mydriasis using topical 1% tropicamide, smartphone based fundus photography in conjunction with a condensing 20 diopter lens based on the principle of indirect ophthalmoscopy was performed in these patients[figure 2].Subsequently, slit-lamp biomicroscopic examination of the retina was performed by an ophthalmologist which is considered as the gold standard for this study. Diabetic retinopathy was graded independently by two ophthalmologists for the smart phone based photography and slit lamp examination according to the International Clinical Diabetic Retinopathy Disease Severity scale.[Figure 1] The grade of DR of the worse eye was considered as the final DR grade for the patient.Findings of the smart phone based fundus picture was compared to the slit-lamp based fundus findings and the sensitivity and specificity of the smart phone based fundus findings was validated.

CLASSIFICATION	OBSERVABLE FINDINGS
No apparent retinopathy	No abnormality
Mild non-proliferative DR	Microaneurysms only
Moderate non-proliferative DR	More than microaneurysms but less than severe non-proliferative DR
Severe non-proliferative DR	Any of the following: >20 intraretinal hemorrhages in each of the 4 quadrants,definite venous beading in 2+quadrants,prominent intravascular microvascular abnormalities in 1+quadrantand no signs of PDR.
Proliferative DR(PDR)	One or more of the following: neovascularisation,vitreous or preretinal hemorrhage.

Figure 1: The International Clinical Diabetic Retinopathy Disease Severity scale [10]

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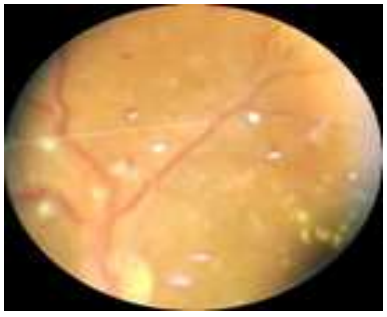

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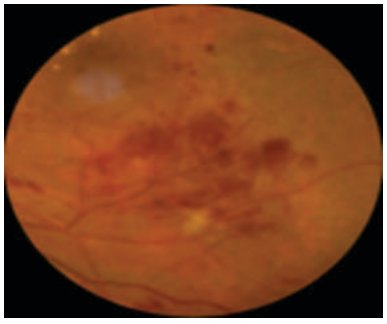

2B:

Figure 2 A and B: Smart phone based fundus photography showing DR

RESULTS:

Ninety known diabetic individuals (180 eyes) underwent slit lamp biomicroscopic examination and fundus photography with a smartphone. The mean age of the participants was 50.4 +/-9.3 years and the mean duration of diabetes mellitus recorded was 14.30+/-5.6 years . None of the images were ungradable . The overall prevalence of DR based on slit lamp biomicroscopy and fundus photography by smart phone camera was 62.2 % and 55.5% respectively. The DR detection matched in 50 out of 56 (89.2%) patients. Slit lamp biomicroscopy showed that 51% had non-proliferative DR (NPDR) and 10% had PDR while smart phone photography showed that 44.4% had NPDR and 10% had PDR. The different grades of diabetic retinopathy in the two modes of retinal evaluation used in this study are depicted in Table 3.

The sensitivity and specificity for detecting any stage and severity of DR by smart phone fundoscopy against the reference standard slit lamp biomicroscopy and the degree of agreement between the 2 methods are shown in Table 4. The degree of agreement between smart phone fundoscopy and slit lamp biomicroscopy for any DR was 0.671 (95% CI, 0.555-0.788) using the κ statistics. The sensitivity and specificity to detect severe NPDR by smart phone camera was 76.92% (95% CI 46.19% to 94.96%) and 94.81% (95%CI 87.23% to 98.57%), compared to slit lamp biomicroscopy where as the sensitivity and specificity to detect PDR by smart phone camera was 80% (95% CI 44.39% to 97.48%) and 97.5% (95%CI 91.26% to 99.70%), compared to slit lamp biomicroscopy. Similarly, the κ agreement for the mild NPDR,moderate NPDR, severe NPDR, PDR groups were also moderately good (Table 4).

Table 3. Diabetic retinopathy (DR) severity based on smart phone fundoscopy and slit lamp biomicroscopy

SMART PHONE FUNDOSCOPY	SLIT LAMP BIOMICROSCOPY					
	No DR n (%)	MILD NDPR n (%)	Moderate NDPR n (%)	Severe NDPR n (%)	PDR n (%)	Total
No DR n (%)	32(35.5)	5(5.5)	3(3.3)	0	0	40(44.4)
MILD NDPR n (%)	1(1.1)	8(8.9)	1(1.1)	0	0	10(11.1)
Moderate NDPR n (%)	1(1.1)	3(3.3)	10(11.1)	1(1.1)	1(1.1)	16(17.8)
Severe NDPR n (%)	0	0	3(3.3)	10(11.1)	1(1.1)	14(15.6)
PDR n (%)	0	0	0	2(2.2)	8(8.9)	10(11.1)
TOTAL	34(37.8)	16(17.8)	17(18.9)	13(14.4)	10(11.1)	90(100)

Table 4: Sensitivity and specificity for diabetic retinopathy detection by smart phone fundoscopy in comparison to slitlamp biomicroscopy and the kappa agreement.

Disease	Sensitivity	95% CI	Specificity	95% CI	K value	95% CI
No DR	94.12%	80.32% to 99.28%	85.71%	73.78% to 93.62%	0.772	0.639 to 0.904
Mild DR	50.00%	24.65% to 75.35%	97.30%	90.58% to 99.67%	0.554	0.313 to 0.795
Moderate DR	58.82%	32.92% to 81.56%	91.78%	82.96% to 96.92%	0.518	0.289 to 0.747
Severe DR	76.92%	46.19% to 94.96%	94.81%	87.23% to 98.57%	0.695	0.484 to 0.906
PDR	80.00%	44.39% to 97.48%	97.50%	91.26% to 99.70%	0.775	0.563 to 0.987

Overall test, Kappa= 0.671 95% CI:0.555 to 0.788 (with 5 categories of observation)

Kappa interpretation:

- Kappa < 0: No agreement
- Kappa between 0.00 and 0.20: Slight agreement
- Kappa between 0.21 and 0.40: Fair agreement
- Kappa between 0.41 and 0.60: Moderate agreement
- Kappa between 0.61 and 0.80: Substantial agreement

Kappa between 0.81 and 1.00: Almost perfect agreement

DISCUSSION:

Screening for DR is very cost effective as with early detection, treatment options are more beneficial that can prevent further neuronal damage and reduce the risk of visual morbidity. Most low-income countries require a sensitive and cost effective retinal imaging technology for routine DR screening [11]. For screening programs, the sensitivity and specificity in identifying DR that warrants a referral are crucial.[12] A viable DR screening program should have at least 80% sensitivity and 95% specificity, according to the British Diabetic Association.[13]

In a study by Russo et al [9], comparing smartphone photography using an adapter (D Eye) and slitlamp biomicroscopy for grading of DR, the kappa agreement was 0.78. Similar results were found in our study where the kappa agreement was 0.67 for any DR, with a fairly good sensitivity and specificity for the detection of severe NPDR and PDR which are sight threatening.The sensitivity was in the range from 64% to 97.9% and specificity ranged from 65.6% to 98% for detection of DR in a systematic review that evaluated the validity of non-mydriatic retinal photos, compared to seven-standard stereoscopic 30° field photographs.[14]. Furthermore , the quality of the retinal photos plays a crucial role for successful implementation of DR screening.] A significant degree of concordance between the two fundoscopy techniques used in this study as well as fairly good sensitivity and specificity especially for the detection of severe NPDR and PDR , may be attributed to dialated fundus photography, which yields reasonably good picture quality.

The smart phone photography using condensing lens has several advantages. Less than a minute is needed to take pictures of each eye, and smartphones with focusing make for crisp, good quality retinal photos. An additional benefit is the ability to zoom in on the smartphone screen to record specific retinal abnormalities and rapidly expand photographs.The comfort of the participants while retinal images were taken was better with smart phone device because of the lower intensity of the LED light ,hence there was no discomfort due to high intensity flash. The easy portability and the wireless connectivity make it easy to be utilized for screening of DR in community outreach programmes. Moreover, the retinal imaging on smart phone is far less expensive than the conventional fundus cameras currently employed in teleophthalmology.

The primary drawback of utilizing a condensing lens for handheld smart phone photography is the requirement to manually align the illuminating beam with the optical axis consistently in order to produce high-quality photographs. Since this study was undertaken in an tertiary hospital setup, the results cannot be extrapolated to a field setting and further studies will be needed in field settings to validate its use in telescreening.

CONCLUSION:

This study demonstrates that a smartphone-based retinal imaging

system can detect diabetic retinopathy of different degrees of severity with a reasonable level of sensitivity and specificity.

The combination of affordability, portability, easy transmission of images of this smartphone-aided imaging technique, offer a platform to improve the early screening and referral of patients with DR for appropriate management by a primary care physician in situations where an ophthalmologist may not always be available.

It provides scope for planning mass DR screening initiatives in India and other low and middle income countries.

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