Original Article

Utility of a smartphone assisted direct ophthalmoscope camera for a general practitioner in screening of diabetic retinopathy at a primary health care center

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Purpose: To assess the use of smartphone-based direct ophthalmoscope photography for screening of diabetic retinopathy (DR) in known diabetic patients walking into a general practitioner's clinic and referring them to a vitreoretinal specialist for further evaluation and management if required. **Methodos:** The study included 94 eyes of 47 walk-in patients in a general practitioner's OPD who were known to have type 2 diabetes mellitus and were already on treatment for the same. **Results:** The study included 47 patients with diabetes with a mean age of 56.2 ± 9.4 years. The Cohen's kappa values revealed that the diagnosis related to the DR status made using a camera was in substantial agreement with the clinical diagnosis (Kappa value: 0.770). The Cohen's kappa values revealed that the diagnosis related to the DME made using a camera was in moderate agreement with the clinical diagnosis (Kappa value: 0.410). The agreement between the findings of the camera and clinical diagnosis was statistically significant ($P < 0.05$). **Conclusion:** Direct ophthalmoscope-based smartphone imaging can be a useful tool in the OPD of a general practitioner. These images can be assessed for retinopathy, and patients can be referred to a vitreoretinal specialist for further evaluation and management if needed. Hence, the burden of vision loss due to complications of DR in the rural sector can be abridged.

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Diabetes mellitus has been recognized as a growing global epidemic, with India having the second-highest number of cases, next only to China, at an estimated 77 million people affected in 2019 and a projected number of 134 million by 2045.[1] With a reported prevalence ranging across states from 5% to 16%, a large number of diabetics in India remain undiagnosed till they culminate into complications.[2] As diabetic retinopathy (DR) is the most common ocular microvascular complication, regular screening for sight-threatening DR (STDR), which includes proliferative DR (PDR) and diabetic macular edema (DME), among known diabetics is recommended. The estimated prevalence for STDR among diabetics in India is 5%–10%, which highlights the importance of screening and referral for these patients.[3] Initiating treatment before the onset of advanced DR is highly effective in preventing visual loss.[4,5] However, patients often remain asymptomatic and do not present until advanced complications such as vitreous hemorrhage or retinal detachment develop. By this time, treatment outcomes are less favorable and often incur high costs.[6,7] Thus, it is important to screen high-risk individuals and initiate treatment before complications develop. As the ophthalmologist to population ratio for our country (1:100,000) is one of the lowest in the world, there is an unmet need for resource-effective and practical DR screening and referral models.[8] Teleophthalmology holds promise in this regard, especially in the context of the present COVID-19 scenario and how it is likely to impact access to health care.[9] Various models for teleophthalmological DR screening techniques have evolved, from conventional stereoscopic 7-field retinal imaging to single-field or double-field photography and more recently to smartphone-based fundus cameras.[10-13] This has made the process more affordable and universally accessible and has obviated the need for trained personnel to capture the images. Some of these devices have drawbacks, such as limited field of view, poor image quality, and restricted compatibility of the camera adaptors with particular models of smartphones.[13,14]

The present study reports the results with a monocular direct ophthalmoscope developed by oDocs Nun (New Zealand) with a smartphone adaptor that is compatible with a wide array of smartphones. This device has shown good preliminary results for fundus imaging through a dilated pupil, especially for posterior pole capture, is affordable, compact, has a short learning curve, and is convenient to use.[15] Aim of the

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study was to assess the reliability of smartphone-assisted direct ophthalmoscope cameras in diagnosing DR and thus to assess whether this device in the hands of a general practitioner can help in recognition and referral of patients with sight-threatening DR for further management to an ophthalmologist.

Methods

This cross-sectional study included 94 eyes (of 47 diabetic patients). The enrollment of participants was done by convenience sampling. The study duration was January 2021–March 2021 (3 months). The study was conducted at a tertiary eye care center in central India.

Between January 2021 and March 2021, 47 eligible subjects were recruited at a physician's clinic. The study was approved by the institute's review board. Written informed consent was obtained from study subjects, and the study complied with the tenets of the Declaration of Helsinki. The inclusion and exclusion criteria for the study are mentioned in Table 1.

The methodology is described in a flowchart in Fig. 1, and the management of the enrolled patients is mentioned in Fig. 2. In summary, the study involved 4 hours of didactic lecture and providing a training set of retinal images both with and without DR to the physician for training. He was also trained in performing examination of anterior chamber depth using a torchlight. Once he was trained, 47 patients with diabetes were recruited in his outpatient clinic. Eligible subjects were dilated using tropicamide 1% eyedrop. A single posterior pole retinal photograph centered at fovea was captured by the physician using the ODocs Nun camera. The grading of the retinal images for grade of DR and macular edema was done by the physician, and all patients were referred to a vitreoretinal consultant, who did a clinical grading using indirect ophthalmoscopy and slit-lamp biomicroscopy; moreover, an OCT was taken. The data were analyzed using Statistical Package for Social Sciences 20.0 version. The degree of agreement between photographic and clinical diagnosis of different variables was analyzed using Cohen's Kappa. $P < 0.05$ was considered statistically significant. The confidence interval was set at 95%.

Table 1: Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1.1: Patients willing to participate in the study and providing written informed consent	2.1: Patients with inadequate media clarity, e.g., corneal opacity, dense cataract, and vitreous hemorrhage
1.2: Patients aged between 20 years and 60 years	2.2: Patients with contraindications for dilatation, e.g., occludable angles and allergic to mydriatic drugs
1.3: Patients who are able to follow verbal commands e.g., Looking in a particular direction of gaze	2.3: Patients with extreme photophobia, status post trauma, blepharospasm, severe ptosis, nerve palsies

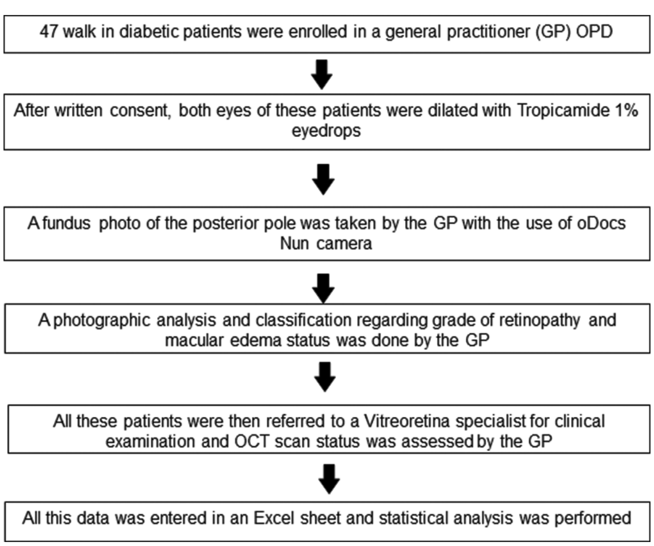

Figure 1: Methodology used in the study

Results

This study included 47 diabetic patients with a mean age of 56.2 ± 9.4 years. The study included 19 (40.4%) males and 28 (59.6%) females. In total, 94 eyes were examined. Twenty-five eyes (26.6%) had clear lens, 52 (55.3%) had early cataract changes, 16 (17.0%) had pseudophakia, and 1 (1.1%) had aphakia. DR was present in 23.4% of diabetic patients, and DME was present in 10.6% of patients. However, with the aid of the camera, the physician could diagnose DR and DME in 21.27% and 2.12% patients, respectively [Table 2].

The Cohen's kappa values revealed that the diagnosis of DR status made using camera was in substantial agreement with the clinical diagnosis (Kappa value: 0.770), and the diagnosis of DME made using camera was in moderate agreement with the clinical diagnosis (Kappa value: 0.410). The agreement between the findings of the camera and clinical diagnosis was statistically significant ($P < 0.05$) [Table 2]. The sensitivity of the device in diagnosing the DR was 90.9% and specificity was 100%, whereas the sensitivity of the device in diagnosing the DME was 20% and specificity was 100%.

Discussion

Teleophthalmological programs for DR screening have been adopted across the world for their cost-effectiveness and improved population coverage since their inception almost

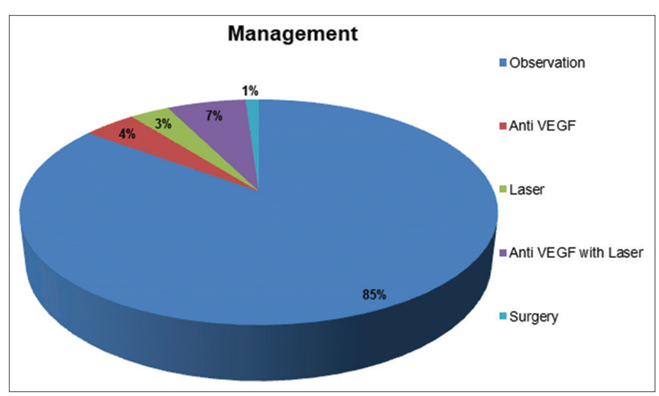

Figure 2: Frequency distribution of study patients based on the treatment provided

three decades back.[11] Smartphone-based fundus imaging has evolved from tandem use of a handheld smartphone camera and light source with a condensing 20D lens creating an indirect ophthalmoscope-like setup to clip-on lens attachments that provide a highly magnified and erect direct ophthalmoscope-like system using the smartphone's inbuilt light source as a coaxial beam of light.[16]

oDocs Nun is a monocular direct ophthalmoscopic fundus camera with a smartphone adaptor [Fig. 3] that provides retinal images of 45° with a pupil diameter of 6 mm and above and a 20° image with undilated 2-mm pupil.[15] In the present study, the agreement between the findings of oDocs Nun camera and clinical diagnosis was substantial and moderate with respect to DR and DME, respectively, which is not acceptable, indicating that the general practitioner could not significantly identify DR lesions via fundus photography captured by smartphone camera through a dilated pupil in his own OPD [Fig. 4]. The sensitivity of the device in diagnosing the DR was 90.9% and specificity was 100%, whereas the sensitivity of the device in diagnosing the DME was 20% and specificity was 100%. This is in concordance with previous studies that have reported a good sensitivity and specificity for detection of referable DR using mydriatic smartphone-based cameras, in the range of 81%–94% and 86%–98%, respectively.[10] Severity grading in terms of NPDR and PDR as assessed by the general practitioner did not show a very high correlation with the assessment made by the VR surgeon in this study, indicating that the oDocs Nun device utility could be restricted to identification of referable DR but not for grading of severity. Further larger-sized trials with the device can help corroborate this finding, but based on this study, the device meets only the ATA category 1 telemedicine standard.[10] Previous reviews have mentioned increasing sensitivity and specificity trends of diagnosis using smartphone-based devices as the severity progresses through NPDR to PDR and STDR.[17,18] In addition, the images obtained through an undilated pupil were noted to have distortion and could not be used to classify the lesions. With the exception of a few devices such as the Fundus on phone nonmydriatic smartphone camera (Remedio innovative solutions, Bangalore, India),[17,19] most other smartphone-based devices currently require mydriasis to produce good quality gradable images, and this seems to be the case with the oDocs Nun device as well.

Figure 3: A photo of the camera setup along with the smartphone attachment

The agreement rate between DME diagnosed using images obtained using this device and assessment by a vitreoretinal specialist was moderate (Kappa value: 0.410). This corroborates with studies done previously using two-dimensional fundus imaging, which reported high false positive and negative rates using surrogate markers for DME, such as hard exudates and microaneurysms close to the fovea.[10] Rajalakshmi *et al.*[12] reported good agreement for DME detection between Zeiss 7-field imaging and the Fundus on Phone retinal camera. Hence, for assessment of DME, a clinical examination with an OCT scan is essential.

The preliminary results of the oDocs Nun camera in the hands of a general practitioner look promising for screening and referral of patients with existing DR. The applicability of this device for use in peripheral health centers and vision centers is theoretically good considering that only a day of training is required for learning image acquisition with the device and the device is compact and handy to use [Fig. 4]. Trained optometrists, paramedical staff, and nonspecialized health care workers can also be easily utilized in widespread screening programs with this device to promote larger population coverage. However, interpretation of the images warranting referral might be a challenge for paramedical staff or nonspecialized health care personnel. To overcome this gap, some authors, such as Rajalakshmi *et al.*[20] and Bhat *et al.*,[21] have suggested integration of artificial intelligence-based deep learning algorithms with imaging devices. Such integration with the oDocs Nun device can make a screening program more cost-effective and convenient.

Table 2: Degree of agreement between photographic and clinical diagnosis of different variables

Variable	Diagnosis using camera	Clinical diagnosis	Cohen's Kappa		*P*
			Value	Interpretation	
Diabetic retinopathy					
No retinopathy	74	72	0.770	Substantial	0.000*
NPDR	16	12			
PDR	4	10			
DME (diabetic macular edema)					
Present	2	10	0.410	Moderate	0.000*
Absent	86	84			
Nonappreciable	6	0			

*$P<0.05$ was considered statistically significant

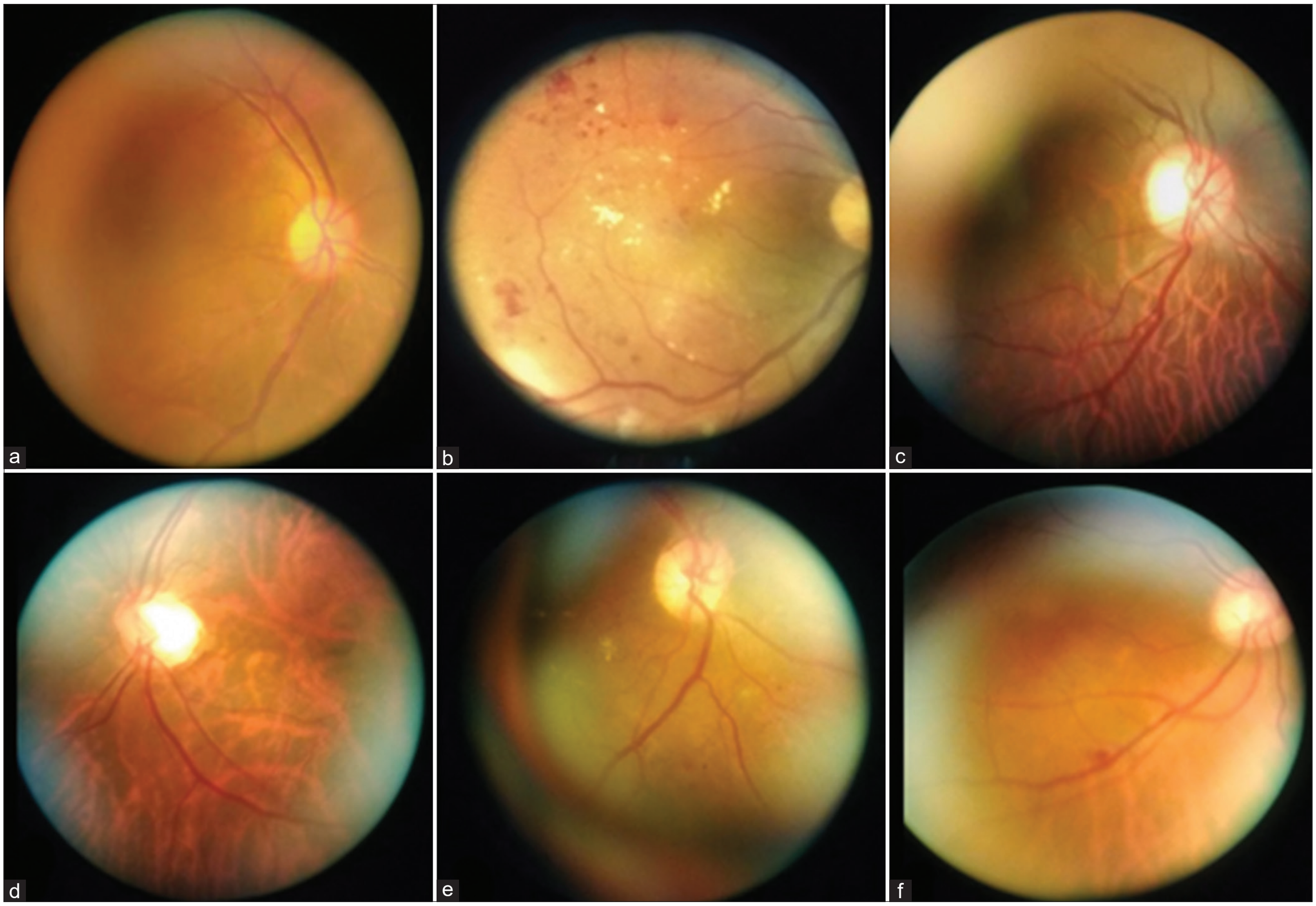

Figure 4: Some of the Fundus photos clicked using the camera. (a) shows a normal fundus photo (posterior pole) with visible disc and macula; (b) shows hard exudates and hemorrhages over the macula; (c and d) show myopic tessellations; (e) shows circinate maculopathy; (f) shows a small frown of neovascularization along the inferior arcade

The inadequate rates of DME detection using two-dimensional imaging have prompted several authors to suggest utilizing OCT integrated fundus imaging to screen for DME. Prescott *et al*.[22] found that the use of OCT in cases with suspected DME on fundus imaging resulted in direct cost savings of 16%–17% because of fewer unnecessary referrals. Such integration with the present device is an avenue warranting further research.

Some authors, such as Xu *et al*., have suggested integration of functional retinal imaging to pick up subtle changes in retinal blood flow, metabolic alterations, and hidden vasculature that may be found in early DR prior to onset of morphological damage, which is a prospect for detection of early DR.[23,24]

The major limitations of the study include smaller sample size, inability of the camera to capture the fundus photo via small pupil, difficulty in capturing peripheral lesions, and inadequate rates of DME detection.

Conclusion

This research is a promising project for screening of DR as the disease is on a relentless rise and the outreach is fairly low. Upon integration of artificial intelligence-based deep learning algorithms with such imaging devices, a strong teleophthalmology setup can be established. Henceforth, patients with early retinopathy can be referred to a specialist for appropriate and timely management, thereby reducing the burden of blindness incurred due to complications of DR.

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Conflicts of interest

There are no conflicts of interest.

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