Research Article

Efficacy of cost-effective, portable nonmydriatic fundus camera, manufactured in India, to detect retinal pathology in comparison with regular mydriatic fundus camera

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Abstract

Background: Diabetic retinopathy is a major public health problem and causes a huge economic burden. Therefore, a cost-effective screening tool for its detection is warranted. This study analyzes the efficacy of a low-cost, portable, Indian-made, nonmydriatic fundus camera as a tool for mass screening.

Objective: To assess the potential to detect retinal pathology by cost-effective, portable, nonmydriatic fundus camera compared with regular dilated fundus imaging system and to assess its utility as a screening tool.

Materials and Methods: A cross-sectional study was carried out at Kasturba Medical College, Manipal, Karnataka, India. The study period was from February 2011 to April 2011. Retinal images (n = 451) were captured using nonmydriatic fundus/test camera and regular mydriatic fundus camera. Diagnosis of normal fundus (n = 167), diabetic retinopathy (n = 180), and abnormal cup:disc ratio (n = 104) was made by a senior ophthalmologist, and then, the retinal images were classified by two ophthalmologist who were blinded to each other's findings. SPSS, version 15, and kappa coefficient were used for statistical analysis.

Results: Nonmydriatic camera was noted to have a sensitivity of 88.3% (159/180 images) and 100% in detecting diabetic retinopathy and abnormal cup-to-disc ratio, respectively. Diagnostic accuracy of 91.1% was noted in the detection of diabetic retinopathy with nonmydriatic camera in comparison with the regular camera, with kappa coefficient being 0.82 and $p < 0.001$.

Conclusion: Nonmydriatic fundus camera being cost-effective, quick, convenient, and portable, with high sensitivity and diagnostic accuracy is a useful tool for mass screening of diabetic retinopathy and glaucoma.

KEY WORDS: Cost effective, diabetic retinopathy, Indian made, nonmydriatic fundus camera, screening tool

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Introduction

Alarming increase in the incidence of diabetes in India poses a major public health problem leading to a huge economic burden. The number of diabetic patients in India, by the year 2025, is predicted to rise to almost 70 million.[1] The cost burden on diabetic patients with retinopathy or nephropathy is almost three times more than the amount spent by those diabetic patients without these complications.[2] In addition, a study by Agarwal et al.[3] found a high rate of non-response by the patients to undergo ocular examination following screening. Therefore, National Program for Control of Blindness in India recommends to utilize every opportunity of contact with diabetic patients and/or diabetic retinopathy (DR) for creating awareness, screening, diagnosis, and referral.

Assessment of DR may be done by ophthalmoscopy, slit-lamp biomicroscopy, fundus photography, or optical coherence tomography.[4–9] Fundus photography helps in storage of data for future reference. Imaging using nonmydriatic fundus camera has additional advantage of not interfering with the patient's routine activity. There are not many Indian studies in the literature where DR screening was performed using nonmydriatic fundus camera.[10]

Current study utilizes a cost-effective, nonmydiatic portable (test) fundus camera, which is manufactured in India and assesses its potential to detect the retinal pathology when compared with regular dilated fundus imaging system. This camera may be utilized as screening tool by physicians/non-ophthalmic health-care personnel for early detection of DR.

Materials and Methods

A cross-sectional study was carried out in the outpatient Department of Ophthalmology at Kasturba Medical College, Manipal, Karnataka, India, during the period February 2011 to April 2011, after obtaining the ethical committee clearance.

A pilot study was conducted before the commencement of the study. The test camera or the nonmydriatic fundus camera was used to capture the undilated retinal images. Those images were then compared with the regular mydriatic camera to look for any inadequacies in the test camera. About 50 fundus images of normal persons captured by the nonmydriatic camera and the regular dilated camera were analyzed. The result of the pilot study showed misclassification of the normal retinal images as abnormal (specificity, 35.3%) because of overexposure, which was decreased after necessary technical changes. The current study was then started.

The study included all those patients who were seen by a single ophthalmologist (with 10 years of experience), attending the outpatient department during the study period. All these patients underwent fundus imaging by the nonmydriatic fundus (test) camera, after which they were dilated using 1% tropicamide eye drops. Dilated fiundus images were then captured by the regular fundus (mydriatic) camera. Later, the ophthalmologist assessed the dilated fundus of these patients by slit-lamp biomicroscpic examination (using a +90 D lens). The ophthalmologist was blinded to the fundus photographs of the patients. These patients were divided into three groups on the basis of the presence of DR, glaucoma suspects (disc suspects with abnormal cup-to-disc ratio), and normal fundus (who came for other ocular complaints causing no fundus abnormality). Clinical diagnosis made by the ophthalmologist was taken as the standard .The fundus images were analyzed at a later date by two different ophthalmologists (blinded to each other's findings) and, then, were compared with the clinical diagnosis based on the findings recorded in the case records. Informed consent was obtained from all the subjects.

Inclusion criteria were as follows:

a. Patients should be seen by a single ophthalmologist in the outpatient department throughout the study period.
b. Those willing to give the consent.
c. Those patients whose pupil was more than or equal to 3mm in size and those without significant cataract (mature or hypermature cortical cataract, or nuclear sclerosis grade III/more), which helped easy capturing of retinal photographs.

Exclusion criteria were as follows:

a. Those patients who had other retinal changes such as age-related macular degeneration and old choroidal scar.
b. Those patients not willing to participate in the study or not willing for dilated fundus evaluation.

Sample Collection

The data were collected by convenient sampling technique. All patients attending the outpatient at the Department of Ophthalmology meeting the inclusion criteria during the study period constituted the convenient sample. A total of 511 eyes of 256 patients were initially seen by the ophthalmologist. Of these, nine patients (18 eyes) were not willing to participate, 14 patients (28 eyes) were found to have other fundus abnormalities (age-related macular degeneration/old choroidal scar, etc.), and seven patients (14 eyes) could not be imaged by nonmydriatic camera because of very small pupil (<3 mm pupil size) or significant cataract (mature or hypermature cortical cataract or nuclear sclerosis grade III/more). Thus, a total of 451 retinal images of 226 patients (one patient had surgical anophthalmos in one eye) were included in the study.

A fixed protocol was followed for all the participants. All the eyes underwent a complete ophthalmologic examination, which included recording of visual acuity, anterior segment slit-lamp evaluation, and applanation tonometry, following which undilated fundus photograph was taken using nonmydriatic (test) fundus camera. The image capturing using the nonmydriatic camera including the entry of patient's data took approximately 10 min. The patients' eyes were then dilated, and fundus photograph was again taken with regular dilated fundus camera. These patients were examined then by the same ophthalmologist, and diagnosis was made depending on the fundus findings.

Nonmydriatic fundus camera photographed central 40τ–45° degree of fundus, and regular dilated fundus camera captured central 50°, both including the optic disc, macula, superotemporal area, and the inferotemporal area of macula in a single image. Specifications of nonmydriatic camera are listed in Table 1 and of regular dilated fundus camera in Table 2.

All the images obtained by nonmydriatic fundus camera were taken by a single-trained technician and images captured using the regular dilated fundus camera by another trained technician. Both of them were comparable in their skills and experience.

Table 1: Nonmydriatic fundus (test) camera (3 Nethra NPS 1008 Beta) (made in India)

Specifications (cost approximately 5 lakhs)	
Field of view	40°– 45°
Optical resolution	6.7 μm
Minimum pupil diameter	3 mm
Image resolution	2048 × 1536, 24 bits per pixel
Interface	Universal serial bus 2.0
Dimensions	340 mm × 498 mm × 620 mm
Weight	13.5 kg
Power consumption	5–10 W
Power supply	AC 100–240 V, 50/60 Hz

Table 2: Regular dilated fundus camera

Specifications (approximate cost 30 lakhs)			
Field angle	50°	30°	20°
View magnification	11×	19×	29×
Power consumption	660 VA (maximum)		
Power supply	AC: 220–240 V; 50 Hz		
Dimensions	430 × 310 × 800 mm^3		
Weight	21.5 kg		

As the test camera was used only for the purpose of screening DR, staging of DR was not done. The criteria for DR detection was the presence of retinal changes suggestive of DR (such as microanuerysm, dot blot hemorrhages, hard/soft exudates, venous beading, intraretinal microvascular abnormalities, and new vessels) and an abnormal cup:disc ratio (C:D of > 0.5:1 or discrepancy of C:D ratio between two eyes was >0.2) for glaucoma suspect.

The normal fundus images were also analyzed in the same manner. These were those patients who came for change of glasses, dry eyes, itching, and so on.

Two ophthalmologists interpreted all the images independently to establish the reproducibility of interpretation of images captured by the test (nonmydriatic) camera versus the regular dilated camera.

Statistical Analysis

The results were analyzed using the SPSS, version 15 (SPSS South Asia, Bangalore, India). The distribution of retinopathy changes were expressed as frequency with percentages. An agreement between the test instrument, that is, nonmydriatic fundus camera, and the regular dilated camera to detect DR and glaucomatous changes was analyzed using kappa coefficient. The interobserver reliability was assessed using kappa statistics.

Results

Of the 451 retinal images, 180 showed DR changes, 104 showed disc changes, and 167 were normal fundus pictures.

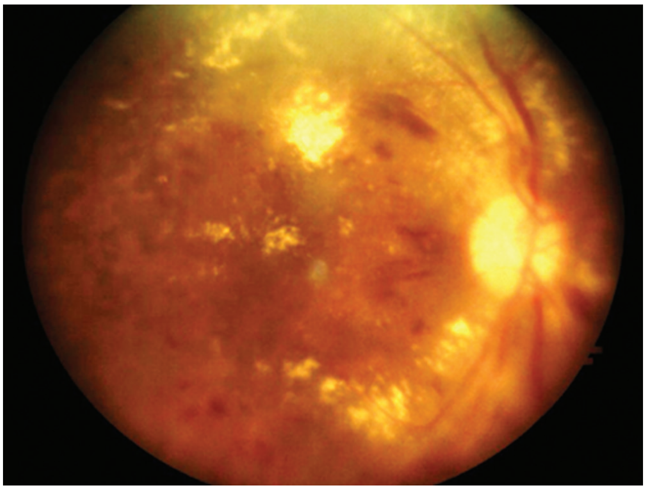

Figure 1: Diabetic retinopathy in undilated nonmydriatic camera.

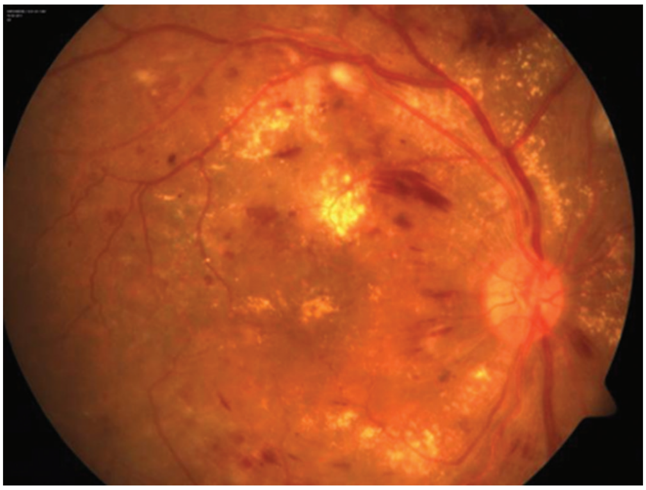

Figure 2: DR in regular dilated camera (29 kb; 713 × 539; 178 dpi).

Analysis of Diabetic Retinopathy Images

DR was detected by both the cameras: undilated nonmydriatic camera [Figure 1] and dilated regular camera [Figure 2] in 153 eyes [Table 3]. Retinopathy was missed in 21 eyes by nonmydriatic fundus camera. Regular dilated camera missed the detection of DR in six eyes (because of poor dilatation and media opacity), which was, however, detected by nonmydriatic fundus camera.

A higher diagnostic accuracy (91.1%) was seen in the detection of DR between nonmydriatic fundus camera and regular camera, the kappa coefficient being 0.82 and $p < 0.001$ (using SPSS software). A sensitivity of 88.3% was found for detection of DR by nonmydriatic fundus camera [Table 4].

Test of Reproducibility: The kappa statistics was found to be 0.696. The agreement between the two observers was high (70%) for DR. The interobserver reliability was assessed by masking the two observers.

Table 3: The distribution of retinopathy changes

S. No	Variable	Detected in both the images	Missed by nonmydriatic camera	Missed by dilated regular camera
1	Dot and blot hemorrhages ($n = 157$)	117 (74.5%)	37 (23.6%)	3 (1.9%)
2	Hard exudates ($n = 118$)	100 (84.7%)	14 (11.9%)	4 (3.4%)
3	Soft exudates($n = 55$)	31 (56.4%)	23 (41.8%)	1 (1.8%)
4	Superficial hemorrhages ($n = 22$)	17 (77.3%)	5 (22.7%)	0
5	Neovascularization elsewhere ($n = 7$)	0	7 (100%)	0
6	Neovascularization of the disc ($n = 3$)	3 (100%)	0	0
7	Tractional bands ($n = 7$)	5 (71.4%)	2 (28.6%)	0
8	Laser marks (along the arcades) ($n = 33$)	18 (54.5%)	12 (36.4%)	3 (9.1%)

Expressed as frequency with percentages.

Table 4: Agreement between the test (nonmydriatic) camera and the regular dilated camera

Diabetic retinopathy using nonmydriatic fundus camera	Regular camera diabetic retinopathy	
	Present	Absent
Present	153	6
Absent	21	122

Kappa coefficient = 0.82 and $p < 0.001$.

Analysis of Glaucomatous Changes

Hundred four eyes suspected to have glaucomatous optic disc change were analyzed. The glaucomatous changes were detected by the two cameras [Figures 3 and 4] in all these eyes (100% sensitivity). However, 14 eyes (13.5%) showed a higher cup-to-disc ratio in nonmydriatic camera when compared with regular camera. The reason for this variation could be overexposure in those pictures captured by the nonmydriatic camera.

Test of Reproducibility: Interobserver reliability was assessed using kappa statistics, and the identification of glaucoma showed 100% agreement between the two observers.

Analysis of Normal Fundus Pictures

Of 167 eyes with normal retinal images, 45 eyes were detected as abnormal (disc appeared pale or increased cup-to-disc ratio suspicious of glaucomatous change) by nonmydriatic camera (test camera), and, thus, the test camera was found to have 73.12% specificity. This was because of persistence of minimal overexposure in few eyes.

Discussion

Rapid urbanization and lifestyle changes have increased the prevalence of diabetes and its complications such as neuropathy, nephropathy, vascular diseases, and retinopathy. DR is one of the important causes of avoidable blindness in India.[1] Early diagnosis and early treatment interventions of DR can reduce the burden of blindness. Early screening helps in early diagnosis and early referral to tertiary eye-care centers.[1] Screening for DR by ophthalmologist visiting peripheral centers and performing dilated fundus evaluation are not feasible for mass screening. Hence, fundus imaging using dilated fundus camera and teleophthalmology was tried. With the advent of nonmydriatic camera, the screening procedure is very easy to perform and the patients can carry on with their day-to-day

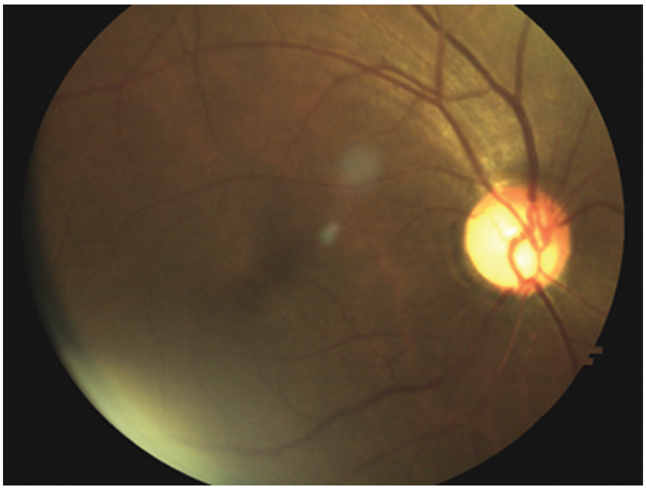

Figure 3: Glaucoma in undilated nonmydriatic fundus camera.

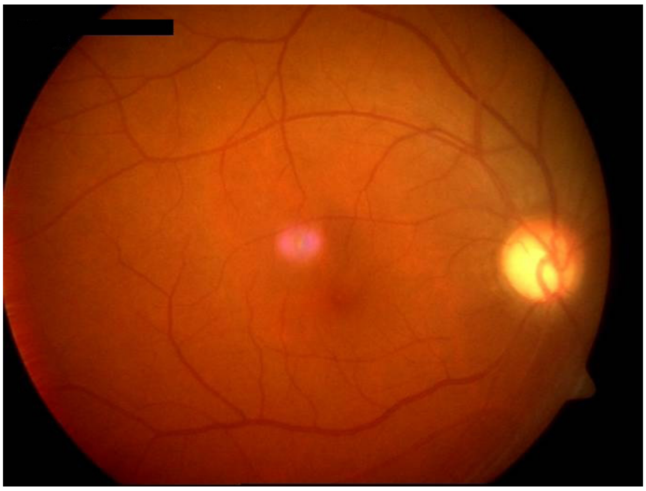

Figure 4: Glaucoma in dilated regular camera.

Figure 5: Easy packing of the nonmydriatic camera.

Figure 6: DR screening using nonmydriatic camera (face masked).

activity without any problem, as their pupils will not be dilated. Screening using nonmydriatic camera has better patients' compliance. The idea of nonmydriatic camera as a screening tool dates back to 1980s as shown in studies done by Mohan et al.[11] and Williams et al.[11]

The accuracy of such nonmydriatic cameras to detect retinal pathology has to be analyzed to avoid misclassification of abnormal as normal. To the best of our knowledge, very few studies are conducted in India to assess the accuracy of nonmydriatic camera in analyzing retinopathy.[10]

This study analyzed the efficacy of a cost-effective, Indian-made, nonmydriatic camera (test camera) in detecting retinal pathologies such as DR and disc suspects for glaucoma. The test camera had a sensitivity of 88.3% in detecting DR changes and 100% in detecting glaucomatous optic nerve head change. The imaging was performed by a technician, and it had a short learning curve (just 2 weeks) with simple image storing and retrieving system. In addition, the test camera was portable, easy to pack, and carry it to the peripheral centers for screening [Figures 5 and 6].

A study conducted in Singapore demonstrated that trained nonphysician graders (NPGs) were able to provide good detection of DR and maculopathy from fundus photographs and suggested that DR screening by trained NPGs may provide a cost-effective alternative to family physicians.[12]

Similar to the observation of study by Tarabishy et al.,[13] this study also showed high sensitivity of nonmydriatic camera resulting in detection of at least more than three-fourth of the patients with retinopathy.[13]

On the contrary, Ding et al.[14] showed that two-field fundus photograph following mydriasis was superior to single-field nonmydriatic fundus imaging and concluded that technical failure should be taken into consideration when screening strategies for DR are determined.[14]

Another significant finding of the current study was that the nonmydriatic camera was able to capture retinal images even in the presence of immature cataract with undilated pupil, which was not easy with regular fundus camera even after dilatation. Retinopathy changes such as hard exudates (shiny lesions) were detected very easily by nonmydriatic camera although retinal hemorrhages, fine new vessels, and cotton wool spots were difficult to identify.

Nonmydriatic (test)camera captures 40°–45° field (as against 50° field by regular camera), which, as a screening tool, is sufficient to detect abnormality at the posterior pole (as in DR). Those individuals detected to have retinopathy or glaucomatous optic nerve changes need to be referred to higher center for further examination and management.

A study conducted in South Africa concluded that nonmydriatic digital fundus imaging is a cost-effective measure in the screening and diagnosis of DR in a primary-care setting.[15] Leeprechanon[16] in his study showed that, in conjunction with intraocular pressure measurement, a nonmydriatic fundus camera can make a useful tool for glaucoma screening.[16]

To reduce the cost burden of blindness and ocular examination, the current study proposes to utilize a low-cost nonmydriatic fundus camera manufactured in India for screening of retinopathy in peripheral clinics and by the physicians.

In addition to fundus images, the test (nonmydriatic fundus) camera can capture anterior segment photographs too. This camera can be used to detect corneal abnormalities, DR, glaucomatous optic nerve change, age-related macular degeneration and so on.

A study done Addoor et al.[17] showed that although people are aware of the ocular complications associated with diabetes, very few seek ophthalmologist's opinion.[17] Another study done in South India concluded that quite a high percentage of people were aware (having just heard about eye problem) that diabetes could affect the eye but very few understood this and, thus, never went to an ophthalmologist.[18]

Authors suggest that, to increase this understanding, several steps could be taken, of which information and referral from the treating physician could play an important role.

This highlights the proposal of putting up low-cost, portable, nonmydriatic fundus camera in diabetic clinic, which would be useful to all—physicians, ophthalmologists, and, most importantly, patients. The test camera can work with the help of solar battery, which makes it beneficial to take it to primary health centers or even house-to-house screening without the need of power supply.

Limitations

1. The overexposure of the images has led to the lower specificity of the test camera.
2. The study would have been more authentic if the results could be obtained by extending it into the community.

Conclusion

The cost effectiveness of screening is well known. Various studies have varied opinions about using nonmydriatic camera for retinopathy screening. This study has analyzed the efficacy of an Indian-made, cost-effective, nonmydriatic fundus camera by comparing it with the regular mydriatic camera. The study results showed that the test camera had 88.3% sensitivity in detecting DR changes and 100% sensitivity in detecting glaucomatous optic disc changes. Hence, it appears ideal for rural screening and is affordable to most of the ophthalmologists or physicians who would want to join hands in reducing the avoidable blindness.

The provision of a photographic service in a general diabetic clinic, or in the community, with later interpretation of the photographs by ophthalmologist would be an accurate and cost-effective method of screening for DR.

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