Non-mydriatic fundus photography as an alternative to indirect ophthalmoscopy for screening of diabetic retinopathy in community settings: a comparative pilot study in rural and tribal India

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ABSTRACT

Objectives The impending and increasing prevalence of diabetic retinopathy (DR) in India has necessitated a need for affordable and valid community outreach screening programme for DR, especially in rural and far to reach indigenous local communities. The present study is a pilot study aimed to compare non-mydriatic fundus photography with indirect ophthalmoscopy for its utilisation as a feasible and logistically convenient screening modality for DR in an older age, rural, tribal population in Western India.

Design and setting This community-based, cross-sectional, prospective population study was a part of a module using Rapid Assessment of Avoidable Blindness and DR methodology in 8340 sampled participants with ≥50 years age. In this study, the diabetics identified were screened for DR using two methods: non-mydriatic fundus photography on the field by trained professionals, that were then graded by a retina specialist at the base hospital and indirect ophthalmoscopy by expert ophthalmologists in the field with masking of each other’s findings for its utility and comparison.

Results The prevalence of DR, sight threatening DR and maculopathy using indirect ophthalmoscopy was found to be 12.1%, 2.1% and 6.6%, respectively. A fair agreement (κ=0.48 for DR and 0.59 for maculopathy) was observed between both the detection methods. The sensitivity and specificity of fundus photographic evaluation compared with indirect ophthalmoscopy were found to be 54.8% and 92.1% (for DR), 60.7% and 90.8% (for any DR) and 84.2% and 94.8% (for only maculopathy), respectively.

Conclusion Non-mydriatic fundus photography has the potential to identify DR (any retinopathy or maculopathy) in community settings in Indian population. Its utility as an affordable and logistically convenient modality is demonstrable. The sensitivity of this screening modality can be further increased by investing in better resolution cameras, capturing quality images and training and validation of imagers.

Trial registration number CTRI/2020/01/023025; Clinical Trial Registry, India (CTRI).

INTRODUCTION

Diabetic retinopathy (DR) is a microvascular complication of diabetes causing retinal damage due to chronic hyperglycaemia. It is the fifth leading cause of permanent blindness and vision impairment (VI) globally. In 2019, DR and sight-threatening DR (STDR) were prevalent in 30.3 and 8.9 million diabetics in Southeast Asia and projected to increase by 174% by 2045. STDR is defined as proliferative retinopathy, referable diabetic maculopathy or both. In India, DR is prevalent among 9.6%–21.7% of the diabetic population. Furthermore, 5%–10% of this population may develop progressive STDR. Owing to these reasons, DR is a major emerging eye disease of concern among

Strengths and limitations of this study

► The screening method (non-mydriatic fundus imaging) used in the current study is logistically more convenient in field situations, easier to undertake, cheaper and less time-consuming.
► Since the current study is a pilot study, more detailed study is required in future along with cost-effectiveness analysis of this modality in rural and tribal regions of India.
► The limitation of the study included resolution of the images captured and training of the team visiting the field as they can affect the sensitivity of the modality.
► The existing limitations can be avoided by using high-resolution non-mydriatic cameras currently available, more rigorous training of the staff and capture of good-quality images in field conditions.
► The patients identified with sight-threatening diabetic retinopathy were provided the treatment according to local protocols and regularly followed-up.

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professionals and government, and especially included in the National Programme for Control of Blindness and Visual Impairment, Vision 2020: The Right to Sight India Programme as well as WHO report on vision.

The screening of visual acuity and fundus at regular intervals (preferably once a year) can reduce the progression to vision loss in diabetic patients by timely help. In lieu of this, regular screening and providing appropriate treatment have been a part of operational guidelines for DR. However, middle to low-income countries like India and especially rural regions have limited information and access to eye examinations along with other challenges.

The detection of DR is mainly done by classical methods like direct or indirect ophthalmoscopy, fundus photography, slit-lamp examination or fluorescein angiography. However, these methods are lengthy, manual and require ophthalmologists (retina experts). Ophthalmologists are usually not present in primary healthcare teams that lead to delays in screening as well as treatment of DR. There are about 22,000+ trained ophthalmologists in India as per All India Ophthalmological Society with a further reduction in the number of retina specialists in the country. Due to lack of trained experts and huge numbers of diabetics, timely screening and treatment of DR are becoming significant concern in many rural areas of India. Moreover, financial crisis adds to this problem.

Considering the aforementioned reasons, there is a need for simple, cost-effective method with valid tools for the early identification/detection of DR in a community, which could be performed by trained, allied eye care professionals. Non-mydriatic fundus photography can be performed with different types of fundus cameras or lens. Fundus photography can be performed by any healthcare professional (ophthalmic assistants, optometrists, nurses, general physicians in primary healthcare team) using simple non-mydriatic fundus cameras after appropriate training. Logistically, it appears to be convenient and non-cumbersome as the images could be sent to a cloud server and a reading centre at the base hospital could be used or transferred with a storage device for manual reading. Thus, it can be the mainstay for screening large population in rural communities. However, the sensitivity and specificity of non-mydriatic cameras for screening DR in Indians eyes (dark brown iris) have been reported in very few studies. Gupta et al reported a sensitivity of 84.7% and specificity of 99.6% for detecting any DR via non-mydriatic digital imaging. This study was, however, conducted under clinic settings by trained ophthalmologists. Furthermore, Bawankar et al also reported a sensitivity and specificity of 91% and 97% of non-mydriatic fundus imaging compared with gold standard (seven-standard-field 35 mm stereoscopic colour retinal imaging) but with the images were read by a software (Bosch DR algorithm) instead of an ophthalmologist or trained technician and conducted in clinic settings. To the best of our knowledge, none of the studies in Indian population has yet reported the sensitivity and specificity of non-mydriatic fundus imaging for DR screening managed under on-field settings in tribal regions. Such an approach can improve the screening and treatment of DR in a population with poor access to healthcare facilities.

We carried out a Rapid Assessment of Avoidable Blindness and DR (RAAB & DR) survey in rural-tribal Gujarat in the catchment area of the base hospital to capture programmatic information and as its offshoot, the present pilot study was planned. The study compared the fundus imaging using non-mydriatic fundus camera and indirect ophthalmoscopy by experts for the sensitivity and specificity of DR detection in an older age, rural, tribal population of Tapi district of Gujarat state, India.

MATERIALS AND METHODS

The current study was a prospective, cross-sectional, comparative, non-interventional, population survey conducted in Tapi district of Gujarat, Western India. It was conducted among individuals aged 50 years or more from the month of January 2020 to March 2020 using a standardised methodology of population-based survey for blindness and VI, RAAB & DR, developed by International Centre for Eye Health, London. The study was conducted by strictly adhering to the principles and guidelines of Helsinki declaration. Informed consent from the village head as well as written informed consent from all the participants was obtained beforehand for the study. The detailed survey protocol was followed as per the RAAB+DR module.

Sampling

A sample size of 8340 participants (age: ≥50 years) was calculated by the RAAB & DR software based on an expected prevalence of DR to be 2%, a required CI of 95%, a precision of 20%, design effect of 1.6, a non-response rate of 10% and population size of Tapi district, 807,022 (727,535 and 79,487, rural and urban individuals, respectively) with 90% tribal population.

Thus, 139 clusters comprising of 60 participants in each were formed and evaluated. The clusters were selected by systematic sampling (stratified cluster random sampling) with a probability proportional to size using the RAAB & DR software. The clusters were then divided into multiple segments following compact segment sampling method. The field workers helped in segmentation and random selection of a segment through lottery, 2 days prior to the proposed date of survey. The cluster informers informed the participants regarding the date and time of visit at least a day prior, so that they are available at home and non-response can be reduced. Each household in the selected segment approached until 60 individuals with age 50 or above were examined. If less than 60 participants were obtained in a selected segment, then the next segment was randomly selected to reach the target of 60.
Examination and data collection

Data were collected by a pretested standard RAAB & DR questionnaire, which included general information (age, gender, education, residence, occupation, etc), visual acuity measurement and other eye examination, history of diabetes as well as awareness of DR. All the participants were tested for visual acuity using Snellen chart. They were categorised as normal vision, mild, moderate or severe vision impairment or blindness based on WHO’s convention and the RAAB survey methodology V.6. Later, the anterior segment of all the participants was evaluated by torch light examination and red glow test by indirect ophthalmoscope (AAIO wireless, Appasamy Associates, India). Individuals with early VI (<6/12) or worse were examined further for the cause of impairment.

All the participants then underwent a random blood sugar level test in the field. Individuals with blood sugar level >11.1 mmol/L (200 mg/dL) and no prior screening for diabetes were labelled as newly diagnosed diabetics. All the diabetic individuals (known or newly diagnosed) were then subjected to retinal examination with simple fundus imaging using hand-held non-mydriatic fundus camera (Horus scope 200, Medical Imaging Innovation Solution Partner, Taiwan). Two different trained technicians were employed who took the images using the fundus camera. These images were then graded by a retinal specialist at the base hospital after the team returned from the field. Furthermore, dilated retinal examination (minimum of 30 min of dilatation) was conducted by indirect ophthalmoscopy using a 20 D lens. The dilatation was obtained using Tropicacyl plus eye drops (tropicamide 0.8% + phenylephrine 5%, Entod Pharmaceuticals). The assessment and grading of DR using indirect ophthalmoscopy were completed by three general ophthalmologists who were accompanying the team in the field. The grading of retinopathy and maculopathy was done using Scottish classification. However, the retinal expert at the base hospital was masked from the findings of indirect ophthalmoscopy conducted at the field. The interobserver bias among the trained technician and field ophthalmologists was previously evaluated in a separate interobserver variation study carried out at our centre. Based on the results obtained, retraining of the technicians and field ophthalmologists was conducted to reduce the interobserver variability. The patients with proliferative changes and central macular oedema were labelled as suffering from STDR. Furthermore, all the previously known diabetics were asked about their last known retinal examination. All the participants with a treatable cause of VI or blindness were referred to the base hospital for further treatment.

Data entry and analysis

Data were entered into the RAAB & DR V.6 software as well as Epi Info and STATA V.11 (statistical analysis software) by data entry operator daily. The data consistency and validity were checked with the help of double entry method (ie, two different data entry operators) as well as by the consistency check menu of the Epi Info and STATA V.11 software. These data were analysed for the prevalence of DR and diabetes (95% CI). The strength of associations was calculated using OR with 95% CI. The data for the DR and maculopathy grading by indirect ophthalmoscopy were entered in the RAAB & DR software.

Furthermore, the grading data of both methods (indirect ophthalmoscopy and fundus photography) were entered in Microsoft Excel. It was used to analyse the sensitivity and specificity of fundus photography to detect DR as compared with indirect ophthalmoscopy as the gold standard. Furthermore, the kappa (κ) statistics was used to assess the reliability of the diagnosis of DR and maculopathy by both the methods, that is, indirect ophthalmoscopy and fundus photography. It was calculated using STATA V.11 software and interpreted as no agreement (κ<0), poor (κ=0–0.19), fair (κ=0.20–0.39), moderate (κ=0.40–0.59), substantial (κ=0.60–0.79) and perfect agreement (κ=0.80–1.0).

Patient and public involvement

It was not possible to involve patients or the public in the design, or conduct, or reporting or dissemination plans of our research.

RESULTS

A total of 8340 individuals were enrolled in the study of which eligible samples were obtained from 7835 individuals: a response rate of 94%. The prevalence of diabetes in the sample was found to be 4.9% (381/7835) (95% CI 4.2 to 5.5). The study included 4255 women and 3580 men within the age group of 50–80+ years. The prevalence of diabetes among different age groups and gender is depicted in table 1.

Of the 381 diabetics, 31.5% (120/381) were newly diagnosed while 55.2% (144/261) of known diabetics were having blood sugar level >11.1 mmol/L (200 mg/dL). It was found that 93.1% (243/261) of them were taking treatment for their condition and most of them (90%, 235/261) were on oral hypoglycaemic drugs. It was interesting to note that majority of the diabetics (59.8%, 156/261) were screened for DR at least once in last 12 months while 18.8% (49/261) were never screened for DR.

The prevalence of retinopathy and maculopathy in the present study was found to be 12.1% (95% CI 8.3 to 15.8) and 6.6% (95% CI 3.9 to 9.3), respectively, while the total prevalence of any DR (retinopathy/maculopathy) was found to be 16.3% (95% CI 12.9 to 20.3), based on the grading and assessment of retinal images by indirect ophthalmoscopy. The prevalence of STDR was reported to be 2.5% (95% CI 1.2 to 4.5) (table 2). To compare the assessment and grading (by expert ophthalmologists) for retinopathy and maculopathy using indirect ophthalmoscopy with fundus photography, data from 404 eye examinations (217 individuals) were available. (Note: details from 30 eye examinations were not available due to various reasons, including refusal to go through the process or loss of one of the eyes). Table 3 shows the control for various confounding variables, such as age, gender, education, and residence.
comparison of grading of DR performed using indirect ophthalmoscopy and fundus imaging of the same 217 diabetic patients (404 eyes).

The grade of DR was agreed on for 75% examinations (301/404) using both the detection methods. The κ coefficient for both the detection methods was found to be 0.48 for DR and 0.59 for maculopathy. The ophthalmologists detected DR in 19.7% individuals using indirect ophthalmoscopy and in 26.49% using fundus photograph evaluation. The sensitivity, specificity, positive predictive value (PPV) and the negative predictive value (NPV) for detecting the presence of DR, maculopathy or any retinopathy and/or maculopathy are enlisted in table 4.

**DISCUSSION**

The prevalence of DR was found to be 12.1% (95% CI 8.3 to 15.8) in our study based on indirect ophthalmoscopy grading. This was estimated using the RAAB V.6 software with an additional module of DR. RAAB software has been shown to provide reliable information on the DR prevalence within limited time and cost. A difference in DR prevalence in urban and rural regions of India has been reported. The urban prevalence reports between 13% and 21.7% while the rural prevalence ranges from 9% to 10%. However, it is now perceived that the difference in prevalence among urban and rural regions will no longer continue as the whole country is progressing towards increased prevalence of diabetes. The prevalence in the present study, involving rural population of Gujarat, was found to be slightly increased than the reported prevalence until. Thus, an increasing prevalence of DR among rural population in India underlines the importance of population or community screening. Furthermore, our study notably depicted satisfying compliance of an eye examination within the last year.

**Table 1** Prevalence of diabetes by age group and gender

| Age groups | Total (N) | Diabetic (N) | % (95% CI) | Total (N) | Diabetic (N) | % (95% CI) | Total (N) | Diabetic (N) | % (95% CI) |
|------------|-----------|--------------|------------|-----------|--------------|------------|-----------|--------------|------------|
| 50–59      | 1768      | 71           | 4.0 (3.0 to 5.0) | 2245      | 70           | 3.1 (2.3 to 3.9) | 4013      | 141          | 3.5 (2.8 to 4.2) |
| 60–69      | 1085      | 62           | 5.7 (4.2 to 7.2) | 1172      | 77           | 6.6 (5.0 to 8.1) | 2257      | 139          | 6.2 (4.9 to 7.4) |
| 70–79      | 522       | 36           | 6.9 (4.6 to 9.2) | 565       | 41           | 7.3 (4.8 to 9.7) | 1087      | 77           | 7.1 (5.3 to 8.9) |
| 80+        | 205       | 12           | 5.9 (2.1 to 9.6) | 273       | 12           | 4.4 (2.2 to 6.6) | 478       | 24           | 5.0 (3.0 to 7.0) |
| All ages   | 3580      | 181          | 5.1 (4.2 to 6.0) | 4255      | 200          | 4.7 (3.9 to 5.5) | 7835      | 381          | 4.9 (4.2 to 5.5) |

| Retinopathy grade | N | % (95% CI) | N | % (95% CI) |
|--------------------|---|------------|---|------------|
| No retinopathy (R0) | 326 | 80.69 (76.50 to 84.43) | 297 | 73.51 (68.93 to 77.76) |
| Background DR—mild (R1) | 40 | 9.9 (7.17 to 13.24) | 36 | 8.91 (6.32 to 12.12) |
| Background DR—observable (R2) | 18 | 4.45 (2.66 to 6.95) | 10 | 2.47 (1.19 to 4.50) |
| Background DR—referable (R3) | 6 | 1.49 (0.55 to 3.20) | 10 | 2.47 (1.19 to 4.50) |
| Proliferative DR (R4) | 2 | 0.49 (0.06 to 1.78) | 2 | 0.49 (0.06 to 1.78) |
| Ungradable DR (R6) | 12 | 2.97 (1.54 to 5.13) | 49 | 12.13 (9.11 to 15.72) |
| Total | 404 | 100 | 404 | 100 |

| Maculopathy grade | N | % (95% CI) | N | % (95% CI) |
|--------------------|---|------------|---|------------|
| No maculopathy (M0) | 373 | 92.33 (89.28 to 94.73) | 314 | 77.72 (73.35 to 81.69) |
| Maculopathy—observable (M1) | 10 | 2.47 (1.19 to 4.50) | 20 | 4.95 (3.05 to 7.54) |
| Maculopathy—referable (M2) | 9 | 2.23 (1.02 to 4.19) | 13 | 3.22 (1.72 to 5.44) |
| Maculopathy—ungradable (M6) | 12 | 2.97 (1.54 to 5.13) | 57 | 14.11 (10.86 to 17.89) |
| Total | 404 | 100 | 404 | 100 |

| Any retinopathy and/or maculopathy | N | % (95% CI) | N | % (95% CI) |
|-----------------------------------|---|------------|---|------------|
| Sight threatening DR (R4 and/or M2) | 66 | 16.34 (12.87 to 20.31) | 56 | 13.86 (10.64 to 17.62) |
| Total | 10 | 2.48 (1.19 to 4.5) | 14 | 3.47 (1.91 to 5.75) |

DR, diabetic retinopathy.
which was even higher than an urban metropolitan area like Pune.24

DR screening is essential in rural community areas to detect cases, which require early referral to expert ophthalmologists for full evaluation.11 A simple non-mydriatic fundus photography is increasingly being used for this purpose owing to its feasibility cum logistical practicality and cost-effectiveness within such population.25–28 The present study compared the sensitivity and specificity of non-mydriatic fundus photography with the indirect ophthalmoscopy to be employed in a rural community for the annual DR screening of patients with diabetes. Our results indicate a fair agreement (κ=0.48 for DR and 0.59 for maculopathy) between both the detection methods.

The bias in grading was also controlled in the present study as the ophthalmologists at the base hospital (fundus photography grading) were not informed about the grading results by indirect ophthalmoscopy conducted in the field. Previous studies across the globe have indicated non-significant differences (with moderate agreement) between remotely graded image-assisted fundus examination and other dilated fundus examinations by experts for DR diagnosis.22 25 27 29–31 Our results are consistent with these studies showing fair reliability of fundus photography to be used for mass screening.

In a low-to-middle-income country like India, it is recommended to have a population DR screening of diabetic patients on annual basis to reduce its prevalence by timely referral and treatment.3 However, the current status of eye care in India poses with several challenges to execute the annual screening programme. Some of these challenges include high number of diabetic patients, significant number of patients waiting for the treatment of STDR, poor control of diabetes, lack of knowledge and awareness among rural population, lack of optimum numbers of retina specialists and shortage of transport and clinical facilities in the rural areas.11 32 Thus, a community-based screening model would be feasible to screen patients at their homes by primary healthcare workers and/or voluntary field workers.5 A community DR screening programme (house-to-house survey) conducted in the urban slum areas of New Delhi, India depicted a handheld non-mydriatic fundus camera by an optometrist is a feasible option for identifying patients with DR by trained technicians on field.33

Seven-field stereoscopic dilated fundus photography is considered as a gold standard for the diagnosis of DR conducted by retinal experts.5 Also, direct and indirect ophthalmoscopy are reliable with good sensitivity and specificity when performed by ophthalmologists.15 However, coloured fundus photography could be useful for the detection of DR at early stages and can be conducted by non-expert professionals like general physicians, ophthalmic nurses or other allied health professionals with proper training. Improvements in this technique can be achieved by combining it with telemedicine and involving experts for remote grading.25 28 34 Our study reported low sensitivity but high specificity in DR detection.

| Table 3 Validity of indirect ophthalmoscopy and fundus photography for the assessment and grading of the diabetic population (n=217, 434 eyes) for the presence of diabetic retinopathy using two detection methods |
|---------------------------------|----------------|----------------|---------|
|                                | Indirect ophthalmoscopy | Fundus photograph |      |
| Presence of retinopathy        | Positive | Negative | Total |
| Fundus photograph              | Positive | 34       | 23     | 57     |
|                                | Negative | 28       | 268    | 296    |
| Total                          | 62       | 291      | 353*†  |
| Presence of maculopathy        | Positive | 16       | 17     | 33     |
| Fundus photograph              | Negative | 3        | 310    | 313    |
| Total                          | 19       | 327      | 346*‡  |

*30 eye examinations were not available due to various reasons, including refusal to go through the process or loss of one of the eyes.
†51 eyes were labelled as R6 and thus could not be graded and thus excluded from the assessment.
‡58 eyes were labelled as M6 and thus could not be graded and excluded from the assessment.

| Table 4 Sensitivity and specificity of fundus photograph for detecting diabetic retinopathy as compared with indirect ophthalmoscopy |
|-----------------|----------------|----------------|---------|
| Diabetic retinopathy | Sensitivity | Specificity | PPV | NPV |
| Presence of retinopathy | 54.8 (34/62×100) | 92.1 (268/291×100) | 59.6 (34/57×100) | 83.9 (268/296×100) |
| Presence of maculopathy | 84.2 (16/19×100) | 94.8 (310/327×100) | 48.5 (16/33×100) | 99.0 (310/313×100) |
| Presence of any retinopathy and/ or maculopathy | 60.7 (34/56×100) | 90.8 (316/348×100) | 51.5 (34/66×100) | 93.5 (316/338×100) |

Sensitivity: positives in indirect ophthalmoscopy/total positives in both detection methods; specificity: negatives in indirect ophthalmoscopy/total negatives in both detection methods; PPV: (positives in indirect ophthalmoscopy/positives in fundus photography) ×100; NPV: (negatives in indirect ophthalmoscopy/negatives in fundus photography) ×100. NPV, negative predictive value; PPV, positive predictive value.
using fundus photographs while that of detecting maculopathy was found to be in acceptable range. A sensitivity and specificity of 80% and 95%, respectively, are acceptable as per the UK National Institute for Clinical Excellence guidelines. However, in India, it is important to have a community screening programme, which could strike a balance between standardised screening protocols and acceptable screening protocols as the requirement is identification of overt DR at a community level at least and especially those that can be managed soon.

The PPV of fundus photography was found to be between 48% and 60% with high NPV (82%–99%) in our study. The PPV is a direct indicator of the comparison of two examination techniques, and 48%–60% PPV indicates good matching between non-mydriatic fundus photography and indirect ophthalmoscopy. It indicates that the non-mydriatic fundus photography can be used for door-to-door screening in villages without much reduction in the diagnostic efficacy.

Gupta et al have proposed limited use of fundus photographs as a screening system in Indian population due to high number of ungradable images. Our study also reported high number of ungradable images (12%) using fundus photographs. But we propose it to be useful for population screening for DR, especially in rural regions in India as the community outreach programme. The issue of ungradable images can be handled in future by replacing the existing fundus cameras with currently available high-resolution cameras and more stringent training of the staff to capture images. Furthermore, sending the captured images on the spot to the expert ophthalmologist at the base hospital via use of internet to confirm the resolution can be helpful as low-resolution, ungradable images can be replaced instantaneously. The patients who are identified with STDR or ungradable retinopathy were further referred to expert ophthalmologists at the base hospital for full evaluation. They were provided the treatment (free of cost) and called for regular follow-up visits. Another advantage of employing the primary healthcare workers for the DR screening is increased compliance by the rural population. The tribal people who are hesitant to approach secondary/tertiary care hospitals can also be screened by the primary healthcare workers or voluntary field workers. Furthermore, employing primary healthcare workers can make the process faster and obviate the need for dilatation. Such communities may be resistant regarding dilatation because they assume dilatation to affect vision owing to the aftereffects of the dilated state. Moreover, this could help to increase awareness of this highly disabling eye disease and allow for timely intervention.

There were certain limitations encountered in the study. Since the initial study was conducted as a RAAB survey, the present study was conducted as a pilot project to test the feasibility of using non-mydriatic fundus camera versus the indirect ophthalmoscopy. Thus, a detailed study analysing the sensitivity of this screening modality is required in future. Although the fundus images taken in the study were having good resolution, it could be further improved using better versions of fundus camera available currently. Furthermore, training of the teams (especially the ophthalmologist and technician) going for field visits can affect the sensitivity and specificity of the detection methods to a great extent. The fundus photography in our study was conducted by trained technicians with 10 years of experience in conducting fluorescein angiography. However, specific training of the technicians with respect to use of hand-held fundus camera can lead to improvement in the quality of the images. High-resolution fundus camera and more rigorous training of the technicians can also potentially reduce the number of ungradable images and improve the \( \kappa \) coefficient between both the detection methods. Another limitation of our study was lack of cost-effectiveness analysis for the use of fundus camera in field screening for DR. The application of fundus photography is reported to be a cost-effective approach for regular screening of DR in a long run. However, we propose to conduct cost-effectiveness analysis as one of our future approach to establish the utility of fundus imaging for mass community screening in rural regions. Further, newer developments in the modality of DR screening like ultrawide field fundus imaging, portable fundus photography, macular optical coherence tomography and artificial intelligence can further come to our rescue in future with increased accuracy, efficiency and economical advantage.

In conclusion, based on the results of this pilot study, we propose simple, high-resolution, non-mydriatic fundus photography, operated by trained imagers, to be a reliable screening method for DR in rural community in Indian population as compared with ophthalmoscopic evaluation in the field, which is resource intensive and requires dilatation.

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REFERENCES

1. Burton MJ, Ramke J, Marques AP, et al. The Lancet global health Commission on global eye health: vision beyond 2020. *Lancet Glob Health* 2021;9:e898–551.

2. Zachariah S, Wykes W, Yorston D. Grading diabetic retinopathy (DR) using the Scottish grading protocol. *Community Eye Health* 2015;28:72–3.

3. Gadkari S, Maskati Q, Nayak B. Prevalence of diabetic retinopathy in India: the all India Ophthalmological Society diabetic retinopathy eye screening study 2014. *Indian J Ophthalmol* 2016;64:38–44.

4. Jonas JB, Nangia V, Khare A, et al. Prevalence and associated factors of diabetic retinopathy in rural central India. *Diabetes Care* 2013;36:669.

5. Raman R, Ramasamy K, Rajalakshmi R, et al. Diabetic retinopathy screening guidelines in India: all India Ophthalmological Society diabetic retinopathy Task force and vitreoretinal Society of India consensus statement. *Indian J Ophthalmol* 2021;69:678–88.

6. Pandey S, Sharma V. World diabetes day 2018: Battling the emerging epidemic of diabetic retinopathy. *Indian J Ophthalmol* 2018;66:1652–3.

7. DGHS Directorate General of Health Services,. Government of India. National programme for control of blindness and visual impairment, 2017. Available: https://dghs.gov.in/content/1354_3_NationalProgRammeforControlBlindness/visual.aspx [Accessed 02 Jul 2021].

8. WHO report on vision, 2019. Available: https://www.who.int/publications/i/item/9789241516570 [Accessed 02 Jul 2021].

9. 9 Vision 2020 India. Guidelines for the comprehensive management of diabetic retinopathy in India, 2008. Available: https://www.iapb.org/wp-content/uploads/Guidelines-for-the-Comprehensive-Management-of-DR-in-India.pdf [Accessed 02 Jul 2021].

10. Murthy GVS, Sundar G, Gilbert C, et al. Operational guidelines for diabetic retinopathy in India: summary. *Indian J Ophthalmol* 2020;68:59–62.

11. Gupta V, Bansal R, Gupta A, et al. Sensitivity and specificity of nonmydriatic digital imaging in screening diabetic retinopathy in Indian eyes. *Indian J Ophthalmol* 2014;62:851–6.

12. Kumar A, Megha PM, Meenakshy K. Diabetic retinopathy detection & classification techniques: A review. *Int J Sci Tech Res* 2020;3:1621–8.

13. Indian Institute of Public Health, Hyderabad. Guidelines for the prevention and management of diabetic retinopathy and diabetic eye disease in India. Hyderabad, India, 2019. Available: https://phl.org/wp-content/uploads/2019/09/2019-Guidelines-for-the-Prevention-and-Management-of-Diabetic-Retinopathy.pdf [Accessed 02 Jul 2021].

14. Sengupta S, Honavar SG, Sachdev MS, et al. All India Ophthalmological Society - Indian Journal of Ophthalmology consensus statement on preferred practices during the COVID-19 pandemic. *Indian J Ophthalmol* 2020;68:711–24.

15. Kumar S, Kumar G, Velu S, et al. Patient and provider perspectives on barriers to screening for diabetic retinopathy: an exploratory study from southern India. *BMJ Open* 2020;10:e037277.

16. Wong TY, Sabanayagam C. The war on diabetic retinopathy: where are we now? *Asia Pac J Ophthalmol* 2019;8:448–56.

17. Bawankar P, Shanbhag N, K. SS, et al. Sensitivity and specificity of automated analysis of single-field non-mydriadic fundus photographs by Bosch DR Algorithm—Comparison with mydriadic fundus photography (ETDRS) for screening in undiagnosed diabetic retinopathy. *PLoS One* 2017;12:e0189954.

18. Kuper H, Polack S, Limburg H. Rapid assessment of avoidable blindness. *Community Eye Health* 2006;19:68–9.

19. Census 2011. Tapi District : Population 2011-2021 data, 2011. Available: https://www.census2011.co.in/census/district/207-tapi.html [Accessed 02 Jul 2021].

20. WHO. Blindness and vision impairment, 2021. Available: https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment [Accessed 02 Jul 2021].

21. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;33:159–74.

22. Ruamviboonsuk P, Teerasuwannajak K, Tiensuwan M, et al. Interobserver agreement in the interpretation of single-field digital fundus images for diabetic retinopathy screening. *Ophthalmology* 2006;113:826–32.

23. Misra N, Khanna RC. Commentary: rapid assessment of avoidable blindness and diabetic retinopathy in India. *Indian J Ophthalmol* 2020;68:381–2.

24. Kulkarni S, Kondalkar S, Mactaggart I, et al. Estimating the magnitude of diabetes mellitus and diabetic retinopathy in an older age urban population in Pune, Western India. *BMJ Open Ophthalm* 2019;4:e002001.

25. Cunha LP, Figueiredo EA, Araújo HP, et al. Non-mydriadic fundus retinography in screening for diabetic retinopathy: agreement between family physicians, general ophthalmologists, and a retina specialist. *Front Endocrinol* 2018;9:251.

26. Hu J, Chen R, Lu Y, et al. Single-field non-mydriadic fundus photography for diabetic retinopathy screening: a systematic review and meta-analysis. *Ophthalmic Res* 2019;62:61–7.

27. Lopez-Rubio S, Rivas J, Perez-Peralta L. Non-mydriatic fundus photography vs. clinical ophthalmoscopy for diabetic retinopathy in patients with early diabetes diagnosis. *Invest Ophthalmol Vis Sci* 2015;56:1406–06.

28. Malerbi FK, Carneiro ABM, Kats M, et al. Retinal exams requested at primary care unit: indications, results and alternative strategies of evaluation. *Einstein* 2019;18:e54913.

29. Brown K, Sewell JM, Trempe C, et al. Comparison of image-assisted versus traditional fundus examination. *Eye Brain* 2013;5:1–8.

30. Li Z, Wu C, Olayiwola JN, et al. Telemedicine-based digital retinal imaging vs standard ophthalmologic evaluation for the assessment of diabetic retinopathy. *Conn Med* 2012;76:85–90.

31. Davila JR, Sengupta SS, Niziol LM, et al. Predictors of photographic quality with a handheld nonmydriatic fundus camera used for screening of vision-threatening diabetic retinopathy. *Ophthalmologica* 2017;238:89–99.

32. Gilbert CE, Babu RG, Gudlavalleti ASV, et al. Eye care infrastructure and human resources for managing diabetic retinopathy in India: the India 11-city 9-state study. *Indian J Endocrinol Metab* 2016;20:3–10.

33. Wadhvani M, Vashist P, Singh SS, et al. Diabetic retinopathy screening programme utilising non-mydriadic fundus imaging in slum populations of new Delhi, India. *Trop Med Int Health* 2018;23:405–14.

34. Salz DA, Witkin AJ. Imaging in diabetic retinopathy. *Middle East Afr J Ophthalmol* 2015;22:145–50.

35. Malerbi FK, Morales PH, Farah ME, et al. Comparison between binocular indirect ophthalmoscopy and digital retinography for diabetic retinopathy screening: the multicenter Brazilian type 1 diabetes study. *Diabetol Metab Syndr* 2015;7:116.

36. Fenner BJ, Wong RLM, Lam W-C, et al. Advances in retinal imaging and applications in diabetic retinopathy screening: a review. *Ophthalmol Ther* 2018;7:333–46.

37. Lim G, Bellermo V, Xie Y, et al. Different fundus imaging modalities and technical advantages in AI scoring for diabetic retinopathy: a review. *Eye Vis* 2020;7:21.