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Validation of handheld fundus camera with mydriasis for retinal imaging of diabetic retinopathy screening in China: a prospective comparison study

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ABSTRACT

Objectives To investigate the clinical validity of using a handheld fundus camera to detect diabetic retinopathy (DR) in China.

Design and settings Prospective comparison study of the handheld fundus camera with a standard validated instrument in detection of DR in hospital and a community screening clinic in Guangdong Province, China.

Participants Participants aged 18 years and over with diabetes who were able to provide informed consent and agreed to attend the dilated eye examination with handheld tests and a standard desktop camera.

Primary and secondary outcome measures Primary outcome was the proportion of those with referable DR (R2 and above) identified by the handheld fundus camera (the index test) compared with the standard camera. Secondary outcome was the comparison of proportion of gradable images obtained from each test.

Results In this study, we examined 304 people (608 eyes) with each of the two cameras under mydriasis. The handheld camera detected 119 eyes (19.5%) with some level of DR, 81 (13.3%) of them were referable, while the standard camera detected 132 eyes (21.7%) with some level of DR and 83 (13.7%) were referable. It seems that the standard camera found more eyes with referable DR, although McNemar's test detected no significant difference between the two cameras.

Of the 608 eyes with images obtained by desktop camera, 598 (98.4%) images were of sufficient quality for grading, 12 (1.9%) images were not gradable. By the handheld camera, 590 (97.0%) were gradable and 20 (3.2%) images were not gradable.

The two cameras reached high agreement on diagnosis of retinopathy and maculopathy at all the levels of retinopathy.

Conclusion Although it could not take the place of standard desktop camera on clinic fundus examination, the handheld fundus camera showed promising role on preliminary DR screening at primary level in China. To ensure quality images, mydriasis is required.

Strengths and limitations of this study

- ► Study subjects recruited for this study were from both outpatient department of hospital and community screening with the variety of diabetic retinopathy for the study comparison.
- ► Two experienced graders from tertiary eye institute graded the images captured by both cameras separately and reached full agreement on grading.
- ► To avoid bias from personnel, technicians were experienced with the standard camera and received full training in using both the handheld and standard cameras.
- ► We noticed high rate of images with poor quality without dilation at the pilot study and started to give mydriasis for all the participants at the formal study, so that there were lack of data on non-mydriasis.

INTRODUCTION

Diabetes mellitus (DM) is a major cause of morbidity and mortality worldwide, responsible for 1.5 million deaths in 2012.[1] The ageing population, rising levels of obesity and lifestyle changes will increase this figure of DM further. In China, the prevalence of diabetes increased dramatically in the last 30 years, with recent prevalence estimates in adults of 10.9%.[2]

Diabetic retinopathy (DR) is a common microvascular complication causing retinal haemorrhage and oedema in people with DM (PwDM). This reduces visual acuity (VA) at a late stage in the condition/disease or when the macular is affected when the treatment is not optimal. Worldwide, it is one of the most common causes of visual impairment, particularly in working age adults, with significant economic impact.[3] In China, a systematic review showed that approximately one in five people diagnosed with diabetes has some level of DR, which is similar to other high-income countries.[4 5]

There are effective strategies to prevent and treat DR. The risk of vision loss can be reduced with metabolic management, early

detection through screening and appropriate laser intravitreous injection or vitrectomy.

DR screening (DRS) and appropriate referral for treatment have been shown to reduce blindness from DR.[6] However, studies have shown that in rural areas of China, only 10% of those with DR are diagnosed and treated.[4] This indicates a need to ensure accessible DRS services to reduce potential eye health inequalities.

The primary healthcare providers in China encourage PwDM to register and receive an annual health check in the rural township clinic and urban community health centre to monitor patients' glucose levels and detect potential complications. Primary care doctors are not trained in eye care, and PwDM are asked to travel to county hospitals for eye examinations at their own expense, which results in inequitable access.

Fundus cameras have now been installed rapidly in most of the county level hospitals since the national study on eye service in 2014 found that only 10% of the secondary level hospitals had the capacity to take fundus images (data not been published). Outreach services are limited due to the lack of specialist eye care staff in secondary care, which also leads to variation in screening uptake and consequently treatment of DR.

In a clinical review of PwDM in Guangzhou, 43.2% of people in tertiary and community urban setting had never received an eye examination. In rural clinics, 68.7% had never received an eye examination.[7]

Provision of screening at primary care level can increase uptake[8–10]; however, the cost of providing all primary care clinics in China with a digital camera would be prohibitive, together with implications of additional training of staff and maintenance of equipment. DR services are in their infancy in China.

The Zhongshan Ophthalmic Centre (ZOC), Sun Yat-sen University, is a leading eye institution, and well placed to plan and develop a DR service model in China. Currently, there are no sustainable and scalable models for delivery of DR services in rural China.

The aim of this study is to validate retinal images from a handheld portable retinal camera for DRS, using a desktop digital camera as the comparison. Findings from this study will lead to further investigation of the role of handheld cameras for the acquisition of retinal images and improving access and increasing uptake of DRS in primary care clinics in China.

METHODS

All participants provided written, informed consent. Patients with referable diabetic or other eye diseases were referred to ZOC for further examination or treatment. The study fulfilled the tenets of the Declaration of Helsinki.

Patient and public involvement statement

We talked with participants about the purpose of the study, how it could be done and what support needed from them before and during the study. These information were also disseminated by primary health workers before consent obtained from each of the participant

This was a prospective comparison study of the handheld fundus camera (index test) of Horus Scope DEC 200[11] with the desktop digital camera (standard test), Canon (model CR-2), in detection of referable DR.

Population

Eligible participants were all those aged 18 years and over with diabetes who were able to provide informed consent and agreed to attend for dilated eye examination with both index and standard tests. Diabetes was identified by self-report as well as definite medical records in hand, referral by endocrinologist, or registration in the primary healthcare centres.

Participants were recruited from hospitals in Zhenjiang District (Shaoguan prefecture), hospitals in Chenghai District (Shantou city) and community health centres in Yuexiu District (Guangzhou city) in consecutive series in Guangdong Province, China, with a range of DR severity, including patients without DR in order to obtain a representative spectrum of patients in this study.

Sample size

A sample size of 262 patients has 80% power and 5% significance level to detect a 6% difference in proportion of gradable images between the index and the standard test, where the standard test will produce 90% gradable images.

Training

The pilot study was conducted in the community screening clinic in Guangzhou city. Technicians with at least 1-year experience of operation for the handheld camera and desktop camera examined 30 cases with both undilated and dilated pupils according to the assessment on the quality of images and operation on the camera by an ophthalmologist.

In the other study sites, we trained technicians with experiences of fundus cameras to capture images on the use of the handheld camera as well as the standard camera to ensure a standardised process, including 'instal/uninstall', how to capture images with both camera and fill the data collection form. They each practiced on the handheld camera for approximately 20 pilot cases, closely supervised by experienced technician until there were no more questions on using the camera and quality of the images taken were considered acceptable by the senior ophthalmologist. The training took 2 hours and the trainer observed for the first whole day before technicians operated independently.

Data collection

A data collection form was developed, including information on the patient's age, gender, education, profession, VA (by illuminated Snellen visual chart), use of glasses, self-assessed visual function, history of eye examinations and fundus photocoagulation, history of DM,

complications, treatment of DM and hypertension (HP), fasting glucose on the day of fundus photo taken, which camera the participants preferred and why. Treatment options for DM and HP were given in multiple choices, that was five options for DM as: insulin, oral medicine, diet, Chinese Traditional Medicine (CTM) and no treatment, and four options for HP as: oral medicine, diet, CTM and no treatment.

Pilot study

Without dilation, from both cameras, approximately one-third of the images from the first eye (always right eye) were of poor quality (including ungradable and poor but still gradable), and 10% were ungradable. We asked participants to rest in a darkened room for 2 min after photographs were taken from the first eye, and up to 15 min for those with poor quality images, to facilitate pupil dilation, but there was a higher proportion of poor quality pictures from the second eye (40%) with both cameras (data not presented). This took 1 day in Guangzhou and 30 PwDM were examined with an ophthalmologist onsite for the assessment.

Due to the high rate of poor images and patients' dissatisfaction from waiting in the dark room for second camera and sometimes even for the second eye, we decided to give mydriasis to every participant for image taken in the formal study.

The formal study

All participants had the following tests in sequence during one visit in the clinic within 2 hours of the first photograph to ensure photographs from both cameras were obtained under maximal dilation: participant's basic information, VA test, anterior segment examination under slit lamp by an ophthalmologist, intraocular pressure test, dilation of both eyes, fundus photograph of both eyes by the handheld retinal camera and the desk top digital camera and finally, the questions on preference of and comments on the cameras. We randomly assigned patients to a different sequence of cameras, with sufficient time in between to minimise discomfort.

Two photos were taken for each eye of all the participants by each of the two cameras. One centred on the macula and the other on the papilla optica. One technician operated both the handheld and standard cameras for participants in each of the three study sites (total 3). The technicians for the cameras were asked the advantages and disadvantages of both cameras, the ease of use, graders were asked the acceptability of mode of photography.

The fundus photographs from all tests were uploaded on the DR online grading system and graded independently at the grading centre in ZOC where the experienced graders were masked to the mode of photograph where possible.

The two graders graded all the study images separately and then together to compare whether there was disagreement on the grading results, an ophthalmologist was used as an arbitration grader. They discussed any disagreement until they reached consensus. They had been trained appropriately as the graders in ZOC's grading centre, which serves for over 70 secondary hospitals across the country in programmes. They both had been working in this centre for at least 5 years and constantly monitored by ophthalmologist supervisors on quality of their work.

Image quality

Images were considered of good quality when features were focused, well-illuminated retinal field, showing clarity of the fundus vessels and any retinopathy. If the images were only partially focused, illuminated or retinal field showed, they were defined as poor but still gradable. If any retinopathy was detected, either DR or non-DR, the images were also defined as gradable. If images are blurred without recognition of the retinal vessels or retinopathy features, they are defined as not gradable. The patients with not gradable images were then referred to the ophthalmologist for further examination.

Grading system

To define the fundus pathology and grade the retinal changes, we used grading definitions for referable disease by the English NHS Diabetic Eye Screening Programme.[12] That is, R0 is categorised as the absence of any DR feature, including microaneurysms. Microaneurysm with or without exudation is categorised as R1 for its only presence without other DR features.

The eye is categorised as R2 if any of the following features are present: venous beading, cotton wool spots, venous reduplication, multiple blot haemorrhages and intraretinal microvascular abnormality.

If there is presenting proliferative retinopathy, that is, new blood vessels or haemorrhage within retina or in vitreous, or vitreous traction, the eye is categorised as R3a. If there is evidence of retinal laser treatment and DR features are stable, the eye is categorised as R3s. The presence of microaneurysms, haemorrhage or exudes within two disc diameters of the centre of the fovea is categorised as M1.

Statistics analysis

The data were presented as mean (SD) or median (IQR) for continuous variable and frequency (%) for categorical variable. Participants' age was categorised by interval of 10 years. Age at diagnosis of diabetes and HP was categorised by interval of 5 years. The cut-offs of 0.05 and 0.3 were used to describe VA in better-seeing eye. The data were analysed by eyes. McNemar's test was performed for comparing the standard and portable cameras. The inter-rater reliability between two cameras was measured by Cohen's kappa coefficient (95% CI). Sensitivity, specificity, positive predictive value and area under the receiver operator curve with 95% CI were calculated to indicate the accuracy of diagnosis by two cameras. All statistical analyses were performed using a commercially

available software package (Stata V.13.1, StataCorp, College Station, Texas, USA).

Comments on the cameras

Comments from both staff and the patients were simply listed and similar ones were categorised together until there were no more new comments and repeated ones were included together as one comment.

RESULTS

Participants' characteristics

Patient recruitment started in June 2018 simultaneously in three places and ended up a total of 305 people with diabetes examined by the end of the year. Mean age of the participants was 61.3 years (SD: ±10.1) and almost half (41.6%) were between 61 years and 70 years. Among them, 165 (54.1%) were female (table 1). Over one-third received high school and above education. Over half (53.6%) of the participants were retired and approximately 10% unemployed. Mean age at diagnosis of diabetes was 52.4 years (SD: ±10.5). Among these participants, around one-third had diabetes for less than 5 years, one-third for 6–10 years and the rest had over 10 years. Only 12 (3.9%) people had diabetes for over 20 years. The median duration of diabetes was 5 years (4–12 years).

On study days, we detected only 108 (35.4%) participants with fasting glucose below 7 mmol/L (table 1), which is clinically considered as good control. Insulin was used by 112 (36.7%) people and 262 (85.9%) were taking oral medication, 12 (4%) reported no treatment, not even diet.

HP was detected in 48.2% participants, nephropathy in 7.5% and cardiovascular disease in 11.2%. Of these 305 PwDM, 252 (82.6%) did not have any complications of diabetes. Mean age at diagnosis of HP was 54.4 years (SD ±11.1). Of the 147 participants with HP, eight could not remember when the problem started or being diagnosed, 59 (40.1%) people were diagnosed less than 5 years and 10 (6.8%) people over 20 years ago (table 1). Majority (85.0%) of these people with HP were taking oral medication and 16 (10.9%) received no treatment.

Of the 305 participants, 276 (90.5%) had presenting VA equal to or over 0.3, 3 (0.98%) below 0.05, while by self-assessment, only 11 (3.61%) expressed that they had excellent VA, 81 (26.6%) said their VA was good and 81 (26.6%) felt their VA was poor (table 2). Over half (59.7%) of the participants did not have their eyes examined by medical staff in the previous year. Twenty-one (6.89%) people had received laser photocoagulation.

Agreement by the two graders

Grading results from the two graders reached agreement on 606 eyes and disagreed on only two eyes for R1. They reached to consensus after discussion.

Table 1 Demographic information of participants with diabetes (N=305 subjects)

Characteristics	Statistics
Recruited sites, n (%)	
Community (registered in)	89 (29.2)
Hospital (being referred by physicians)	141 (46.2)
Hospital (walk in with medical record of diabetes)	75 (24.6)
Age, years, n (%)	
18–31	5 (1.64)
31–40	4 (1.31)
41–50	27 (8.85)
51–60	97 (31.8)
61–70	127 (41.6)
>70	45 (14.8)
Mean (SD)	61.3 (10.1)
Female sex, n (%)	165 (54.1)
Educational level, n (%)	
No formal education	68 (22.3)
Elementary school	75 (24.6)
Junior school	45 (14.8)
High school	89 (29.2)
College or above	28 (9.18)
Occupation	
Farmer	15 (4.93)
Worker	30 (9.87)
Officer/clerk	20 (6.58)
Technician	9 (2.96)
Self-employed/freelance professional	26 (8.55)
Educational/medical staff	6 (1.97)
Retired	164 (53.8)
Unemployed	35 (11.5)
Age at diagnosis of diabetes, years, mean (SD)	52.4 (10.5)
Duration of diabetes, years, n (%)	
1–5	109 (35.7)
6–10	104 (34.1)
10–15	52 (17.1)
16–20	28 (9.18)
>20	12 (3.93)
Median (IQR)	5 (4–12)
Fasting glucose level on the day of image taken, mmol/L, n (%)	
≤7	108 (35.4)
>7	197 (64.6)
Current treatment of DM, n (%)	
Insulin	112 (36.7)
Medicine	262 (85.9)

Continued

Table 1 Continued

Characteristics	Statistics
Diet control	185 (60.7)
CTM	58 (19.0)
No treatment	12 (3.93)
HP, n (%)	147 (48.2)
Age at diagnosis of HP, year, mean (SD)*	54.4 (11.1)
Duration of HP, years, n (%)	
1–5	59/147 (40.1)
6–10	42/147 (28.6)
10–15	18/147 (12.2)
16–20	10/147 (6.8)
>20	10/147 (6.8)
Not sure when HP started	8/147 (5.4%)
Median (IQR)	7 (3–12)
Diabetic complications except HP, n (%)	
Nephropathy	23 (7.54)
Cardiovascular	34 (11.2)
Ulcerated arms/legs	8 (2.62)
None	252 (82.6)
Current treatment of HP, n (%)	
Tablets	125/147 (85.0)
Diet	77/147 (52.4)
Traditional	28/147 (19.0)
No treatment	16/147 (10.9)

*Eight participants could not remember when the HP started/diagnosed.
CTM, Chinese Traditional Medicine; DM, diabetes mellitus; HP, hypertension.

Table 2 Participants' visual acuity, eye examination and treatment situation (N=305 subjects)

	n (%)
Visual acuity of better eye, n (%)	
<0.05	3 (0.98)
≥0.05 but <0.3	26 (8.52)
≥0.3	276 (90.5)
Self-assessed visual acuity, n (%)	
Excellent	11 (3.61)
Very good	22 (7.21)
Good	81 (26.6)
Fair	110 (36.1)
Poor	81 (26.6)
Frequency of having eye examinations, n (%)	
At least once in the last year	123 (40.3)
No eye examination in the last year	182 (59.7)
Whether received photocoagulation, n (%)	21 (6.89)

Table 3 The quality of images (N=610 eyes)

Items	Desktop	Portable	P value*
Number of gradable images†	598 (98.7)	590 (96.9)	0.064
Number good Images, n (%)†	482 (79.3)	479 (78.7)	0.745
Number of poor but still gradable, n (%)†	116 (19.1)	111 (18.2)	0.486

*McNemar's test was used for comparing desktop and portable cameras.
†*2 (2/305, 0.66%) eyes had missing data.

Image gradeability, referable eyes and agreement analysis

Of the 305 people (610 eyes) examined, 1 patient (2 eyes) had the images duplicated with the previous patient owing to the wrong saving name in the computer, which left 608 eyes for grading. From desktop camera, 482 (79.3%) images were of good quality and gradable, 116 (19.1%) images were poor but still gradable and 12 (1.9%) images were not gradable (table 3). From the handheld camera, 479 (78.7%) images were of good quality and gradable, 111 (18.2%) images were of poor quality, but still gradable and 20 (3.2%) images were not gradable. Between the two groups of good and poor quality but still gradable images by the two cameras, McNemar's test found no significant difference, while the two groups added together, images taken by desktop gained slightly better quality than handheld, although the difference was not significant (p>0.05%).

For the non-gradable eyes, the two cameras agreed on five eyes, two of which had vitreous opacity, the other three eyes had dense cataract. There was one eye captured as R1 by handheld camera, but the image captured by desktop was non-gradable as handheld camera happened to capture some peripheral microaneurysms although images taken by both cameras were poor from this cataractous eye.

There were cataracts in eight eyes and ascertained as R1 by desktop camera, but not gradable by the handheld camera.

There were 14 eyes graded as R1 by the desktop camera, but ungradeable by the handheld camera.

In total, there were 132 eyes (21.7%) with evidence of retinopathy (R1+R2+R3) (table 4), from images taken by desktop camera and 119 eyes (19.5%) by handheld camera. We detected referable retinopathy at R2 and above in 83 eyes (13.7%) from the desktop camera and 81 eyes (13.3%) from the handheld camera, with no evidence of a statistically significant difference. R3 was detected in 28 eyes (4.6%) by both handheld and desktop cameras. Of the 132 eyes with some level of retinopathy, 79 (59.8%) eyes had macular involvement by standard camera.

The two cameras reached high agreement on diagnosis of retinopathy and maculopathy at the levels of R1 (kappa coefficient (KC) was 0.79), R2 (KC=0.96), R3 (KC=1.0), M1 (KC=0.94) and other lesion (KC=0.82) (table 5).

Table 4 Grading results by the two cameras

			By desktop camera		
			Present	Absent	Total
By portable camera	R1	Present	35	3	38
		Absent	14	532	546
		Total	49	535	584
	R2	Present	52	1	53
		Absent	3	528	531
		Total	55	529	584
	R3	Present	28	0	28
		Absent	0	556	556
		Total	28	556	584
	M1	Present	72	1	73
		Absent	7	504	511
		Total	79	505	584
	OL	Present	14	2	16
		Absent	4	564	568
		Total	18	566	584

OL, other lesion.

We identified 49 eyes at R1 by the desktop camera and 38 eyes by the handheld camera, which resulted in a sensitivity of 71.4% (95% CI: 56.7 to 83.4), specificity of 99.4% (95% CI: 98.4 to 99.9) and positive predictive value (PPV) of 92.1% (95%CI: 78.6 to 98.3).

At the level of referable retinopathy at R2, the desktop camera detected 55 eyes and handheld detected 53 eyes, resulting in a sensitivity of 94.6% (95% CI: 84.0 to 98.9), specificity of 99.8% (95% CI: 99 to 100) and PPV to 98.1% (95% CI: 89.9 to 100). While for R3, the two cameras reached 100% agreement. The desktop camera captured six more eyes with maculopathy, while the handheld one did not detect maculopathy in these eyes and a sensitivity of 91.1% (95% CI: 82.6 to 96.4), specificity of 99.6% (95% CI: 98.9 to 100) and PPV of 98.6% (95% CI: 92.6 to 100). The desktop camera also captured two more eyes with other lesions, which the handheld camera had not.

Table 6 Camera preferred by both patients and technician (N=305 subjects)

	n (%)
Camera preferred by patients	
Standard	114 (37.4)
Portable	34 (11.1)
Same	157 (51.5)

Camera preference by both patients and technicians

Approximately half (51.2%) of the participants had no preference for either of the two cameras, 114 (37.4%) people preferred the desktop camera and 34 (11.1%) said the handheld one was preferred (table 6). Those preferring the standard camera gave reasons as follows: flash light for images taken by the standard camera was not so bright as the handheld one; it looked more complicated and was bigger, so that should be better, as recognised by most of non-medical people of the medical equipment and it was more convenient for height adjusting as it was on an elevator platform. Those participants who felt handheld was better gave reasons of simplicity, looking smart with easy mobilisation of the whole machine with or without the foldable stand (frame) for patient's chin rest.

Comments from the three experienced technicians on the two cameras were: 'for the community DR screening, the handheld one is enough'. 'It is easy to install and pack up.' They also pointed out that, with the simple stand for patient's chin rest, focusing process became much easier and quicker than when without.

Table 5 Accuracy of diagnosis (N=610 eyes)*

By desktop camera							
		Kappa (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)	Positive predictive value (95% CI)	Negative predictive value (95% CI)	AUC (95% CI)
By portable camera	R1	0.79 (0.69 to 0.89)	71.4% (56.7% to 83.4%)	99.4% (98.4% to 99.9%)	92.1% (78.6% to 98.3%)	97.4% (95.7% to 98.6%)	0.85 (0.79 to 0.92)
	R2	0.96 (0.92 to 0.999)	94.6% (84.9% to 98.9%)	99.8% (99% to 100%)	98.1% (89.9% to 100%)	99.4% (98.4% to 99.9%)	0.97 (0.94 to 1.00)
	R3	1.00 (1.00 to 1.00)	100% (87.7% to 100%)	100% (99.3% to 100%)	100% (87.7% to 100%)	100% (99.3% to 100%)	1.00 (1.00 to 1.00)
	M1	0.94 (0.90 to 0.98)	91.1% (82.6% to 96.4%)	99.8% (98.9% to 100%)	98.6% (92.6% to 100%)	98.6% (97.2% to 99.4%)	0.95 (0.92 to 0.99)
	OL	0.82 (0.68 to 0.96)	77.8% (52.4% to 93.6%)	99.7% (98.7% to 100%)	87.5% (61.7% to 98.4%)	99.3% (98.2% to 99.8%)	0.89 (0.79 to 0.99)

*Two eyes had missing data.
AUC, area under the receiver operator curve; OL, other lesion.

DISCUSSION

We compared the quality of fundus images and the referable eyes with images taken by the standard Canon CR2 desktop and a simple Forus handheld fundus cameras from the same 305 PwDM in three places of Guangdong Province, China, and our analysis found no difference on proportion of gradable images, good images and number of eyes with referable retinopathy between the two cameras when mydriasis was used.

Training for those without experience was easy and relatively quick. The handheld camera is simply designed, easy to install and to pack up. The light and foldable stand designed for the handheld camera makes it possible to be carried by hand. Its images cover the same retinal field as the standard one.

In the English national screening programme for DR, Scanlon *et al* demonstrated that two images centred on the disc and macular with 45° field camera achieved high sensitivities (>87%) and specificities (>86%) with low ungradable image rate of below 4.4% against the reference standard of seven-field stereophotography or an ophthalmologist using slit lamp biomicroscope.[13 14] The two field images method was recommended for DRS and was used as the gold standard in this study.

Overall, there was no significant difference between using the handheld camera with dilation on detecting number of referable eyes with DR compared with the standard camera. The two cameras reached a high level of agreement on grading results of DR (kappa from 0.79 at R1 to 1.00 at R3). When authors looked at the images disagreed against findings from slit lamp, we noticed the following factors: for those eyes with cataract at the stage C3N3 to C4N4[15] and those with some level of vitreous opacity, the desktop camera could still capture images of blood vessels with some degree of clarity compared with the handheld camera.

In China, primary health staff commonly hesitate to give mydriasis for fundus examinations and are normally not confident to convince patients about the low risk of complications.[16] In this study, the poor image rate reduced generally from over 30% to around 10%. This in the meantime reduced the number of people referred to secondary care for further examination and saved resources. From the findings in this study, we would recommend mydriasis for DRS at primary level with training for primary health staff to obtain patient consent and manage potential complications in future programmes.

In this study, around one-third, 108 (35.4%), of participants had their fasting glucose controlled at the recommended levels. Furthermore, 12 participants did not take any treatment for their DM, not even diet. Over half (59.7%) of the participants had not had their eyes checked by medical staff in the previous year. This emphases the importance of health education and available services for DM patients in primary healthcare.

Approximately two-thirds of study participants were recuited from the clinics of secondary-level hospitals, who were diagnosed PwDM and had medical records at hand. The rest of one-third were community health unit registry. From them, we detected a similar lower rate of DR as other studies in China[5 17 18] compared to Singapore, India and the USA,[19] while much lower than Handan eye study[4] in North China and the more likely findings from other walk-in patients in six provinces in China.[20] The study also detected 82.6% of the participants without any diabetic complications, which is mainly attributed to the median duration of diabetes was 5 years (4–12 years) and only 3.93% of participants had diabetes for over 20 years.

We detected a similar proportion of referable DR, high proportion of poor quality images at unmydriasis to the previous studies in China.[21] Findings for the comparison of the two cameras are similar to the studies in other Asian countries like Sri Lanka[22] and Thailand.[23]

This study employed experienced eye care staff, who had been performing similar work for at least 3 years, to take the images with both desktop and the handheld cameras. There were also standardised procedures and training for all staff in the different sites, which would reduce measurement error. Graders were masked from patients' history and source of images, reducing ascertainment bias. Where the two cameras differed in their images, we carried out a slit lamp examination to determine the cause of the disagreement.

This was not a population-based study and, therefore, patient characteristics were not representative of DR with respect to severity of the diseases and its complications in the context of China; however, we included the full range of DR severity in our study population, mitigating spectrum bias.

CONCLUSION

A handheld fundus camera using mydriasis may have a role to play in preliminary DRS at the primary level in China and other settings worldwide, where desktop camera are not prevalent or easily accessible or where screening programmes are not operational.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

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