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Original Article

COMPARISON BETWEEN THE PANOPTIC OPHTHALMOSCOPE AND THE CONVENTIONAL DIRECT OPHTHALMOSCOPE IN THE DETECTION OF SIGHT THREATENING DIABETIC RETINOPATHY: THE KUCHING DIABETIC EYE STUDY

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This study was conducted in the Department of Ophthalmology, Hospital Umum Sarawak.

ABSTRACT
Objective: To determine the sensitivity and specificity of the conventional direct ophthalmoscope and the PanOptic ophthalmoscope in the detection of sight threatening retinopathy, as well as the "Ease of Use" of these equipments.
Methods: 200 diabetics, newly referred from primary health physicians were examined. Fundus examinations were performed with pupil dilatation in a dark room. The examinations were performed by a single investigator using the PanOptic ophthalmoscope, the conventional direct ophthalmoscope and slit lamp biomicroscopy.
Results: The overall sensitivity in detecting sight threatening retinopathy using the conventional direct ophthalmoscope was 73.2% (95% CI: 57.1-85.8%), specificity 93.7% (95% CI: 88.7-96.9%). For PanOptic ophthalmoscope, the overall sensitivity in detecting sight threatening retinopathy was 58.5% (95% CI: 42.1-73.7%), specificity 93.7% (95% CI: 88.7-96.9%). The conventional direct ophthalmoscope was 1.38 times (95% CI: 1.17-1.61 times) as easy to use compared to the PanOptic ophthalmoscope.
Conclusion: The PanOptic ophthalmoscope is not superior to the conventional direct ophthalmoscope for the screening of Sight Threatening Retinopathy.
Keywords: PanOptic ophthalmoscope, conventional direct ophthalmoscope, sight threatening retinopathy.
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INTRODUCTION

Diabetes is one of the most prevalent chronic conditions among Malaysians. The National Eye Survey 1996 results showed that the prevalence of diabetic retinopathy (DR) among Type 1 Diabetics (T1DM) aged 40 years and above with duration of more than five years was 14.6%.[1] Asia is expected to be home to 61% of the total global projected number of people with diabetes by 2010, as it is the most populous continent and due to increased urbanization and improved life expectancy.[2]

DR is a major public health problem.[3] Overall, between 25% and 44% of people with diabetes at any point in time, have some form of DR. The prevalence of sight threatening retinopathy (STR), from either proliferative diabetic retinopathy (PDR) or clinically significant macular oedema (CSME) varies principally by the known duration of diabetes, with minor influences due to age and the type of diabetes.

Screening of diabetic eye disease has been proven to prevent loss of sight. In at least half of patients with PDR, severe visual loss can be prevented by Pan Retinal Photocoagulation (PRP).[4] 50-60% of patients with visual impairment due to diabetic maculopathy, will improve by laser therapy as well.[5,6] Therefore, early intervention during the course of the disease will decrease the risk of complications, thereby reducing health care cost.

The Malaysia Clinical Practice Guideline: Diabetic Retinopathy (MCPG:DR) 1996, recognized that the lack of time and skill in detecting DR by conventional direct ophthalmoscopy (CO) hampers effective screening.[3] A systematic review of published reports examining the effectiveness of ophthalmoscopy in screening for STR found that the sensitivity of detecting any STR by dilated direct ophthalmoscopy alone ranged between 43% and 96% and the specificity ranged between 87% and 100%.[7] Even in the hands of an experienced ophthalmologist, however, CO is limited by weaknesses inherent to the instrument itself.[8] Ophthalmologists are the clinical "reference standard" in screening and assessment of DR.[3] Dilated slit lamp biomicroscopy (SLM) is now the clinical reference standard method for assessing the presence and severity of DR.

Bresnick GH *et al.* has developed the eye watch screening criteria (EWSC), which are based on examination of two standard retinal fields.[9] This enable screening to be done more confidently by clinicians as it is often difficult for them to visualize the peripheral retinal field with the CO.

Retinal photography is a workable option. Although the non-mydriatic fundus camera can speed up the screening process, it is not widely available at the present moment. Non-mydriatic retinal photography may be limited by reduced sensitivity for screening and detecting DR and by technical failure with ungradable photographs caused by small pupils and media opacities. Moreover, non-mydriatic fundus photography does not currently meet the National Institute for Clinical Excellence guidelines for quality assurance objectives for DR screening tests requiring sensitivity 80%, specificity 95% and technical failure rate <5%.[10]

The PanOptic ophthalmoscope (PO) was developed by Welch Allyn. The company claimed that PO has several advantages over CO. PO allows fundus examination through small undilated pupils. It also provides a dramatically wider, more panoramic view of the fundus. It enables a 25° field-of-view (FOV) versus the standard 5° FOV of the CO. It increases magnification by 26% over the standard CO and it provides greater working distance.[11]

Gill JM *et al.* concluded in their study that using PO to screen for DR by family physicians is not sufficiently accurate to replace routine referral for all patients with diabetes.[12] In their study however, the PO was used to screen for DR in undilated eyes. In another study by McComiskie JE *et al*., the medical students rated that the PO was much easier to use compared to the CO although the accuracy was similar for the two instruments.[13]

To an ophthalmologist, the advantages in terms of wider FOV and higher magnification provided by the PO is comparable to those provided by a MaxField ® STD 90D over a conventional 90D condensing lens. This potential is further enhanced by pupil dilatation. Therefore, it is timely for us to explore the full potential and limitations of the PO from the ophthalmologists' point of view. The result of this study would provide evidence-based data on the true performance of the PO. This may provide another cost-economical option for the screening of DR in the next edition of MCPG:DR.

METHODS

This study was approved by the Malaysian Medical Research Ethic Committee (NMRR-08-1220-2539) and the Research Ethics Committee, Universiti Kebangsaan Malaysia (FF-084-2010). This was an ophthalmology clinic-based, double-masked, cross-sectional observational study. All new referrals of diabetic patients to the ophthalmology clinic of Sarawak General Hospital from 1st January 2009 to 31st May 2009 were invited to join the study. Written informed consent was obtained from all participants with due regard to the Declaration of Helsinki and Malaysian Guidelines for Good Clinical Practice (GCP).

Inclusion criteria were age 20 and above, definite diagnosis of DM (T1DM or T2DM), availability of companion to accompany patient home and willingness to give a signed written informed consent.

Exclusion criteria were patients found not suitable for pupil dilatation due to medical reasons (shallow anterior chamber angle) or social reasons, pupil dilatation less than 7 mm, history of prior laser therapy (PRP, focal or grid laser photocoagulation) or posterior segment surgery (vitrectomy) and presence of significant media opacity.

PROCEDURE

Both the PO and CO are operator dependent and patient dependent. Gill *et al*. showed that there is a wide range of kappa statistic, between 0.06 to 0.70, among family physicians in the screening for DR.[12] In order to avoid inter-observer and intra-observer variation, only one investigator (TAK) was assigned to perform the examinations. A nurse would inform the investigator if there was a new referral of diabetic patient. The patient's age was determined. The patient would be asked three questions. The first question was to determine if he or she agrees to be subjected to dilated fundus examination. The second question was to determine if he or she has any companion to accompany him or her home after the examination. The third question was to determine if he or she had any prior intra-ocular surgery, including laser surgery. Next, the patient's anterior chamber depth would be assessed with a pen torch. This is to screen for patients at risk of acute angle closure attack following pupil dilatation.

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The patient would be invited to participate in this study if he or she agreed for dilated fundus examination, had companion to accompany him or her home, had no prior intra-ocular surgery and not at risk of developing acute angle closure attack. A signed written informed consent would be obtained from the patient. In order to maintain masking, there will be no further history taking at this point.

Both eyes were dilated with topical tropicamide 1.0% and phenylephrine 2.5%. After ten minutes, the pupils were examined to determine if dilatation is adequate. If pupil dilatation was inadequate (less than 7 mm), topical tropicamide 1.0% and phenylephrine 2.5% would be instilled for the second time. The eyes were re-examined after another ten minutes, if pupil dilatation was still inadequate in both eyes, the patient would be excluded from the study.

Since DM is a systemic disease, both eyes are equally affected in most patients. The knowledge of the DR status in one eye will influence the examiner's judgment of the DR status for the contra-lateral eye. Therefore, only one eye from a particular patient would be included in this study. The investigator would perform a Bruckner test using the CO to examine the red reflex of both eyes simultaneously. The eye with the least media opacity would be included in the study. If the red reflex was equal in both eyes, the right eye would be chosen.

Coin flipping was used to determine which instrument would be used first to examine the patient; "head" for PO and "tail" for CO. As the examinations were carried out by only one investigator, the knowledge of the DR status obtained by using the first instrument will inevitably influence the judgment of the DR status obtained by using the second instrument. This constitutes a limitation of the study.

The examination would first be performed using either the PO (head) or the CO (tail), then followed by CO and PO respectively, and lastly using the SLM. After the first examination, the patient would be asked to wait for one hour while the investigator attended to other patients in the busy ophthalmology clinic. This was done with the hope that the investigator will have a vague or no memory of the fundoscopic findings with the first instrument. The second examination was performed after at least an hour. There was no history taking during the first two examinations.

A thorough history would be taken before the patient was subjected to third examination using the SLM (reference standard). The patient's diabetic record would also be revealed. Both eyes would be examined using the SLM. Under the SLM, the investigator would be able to determine the true DR status of each eye. Hence, the investigator was unmasked. The patient would then be informed of his or her DR status as well and manage accordingly. All relevant findings were documented in the Case Report Form (CRF).

There were only three instruments involved: one CO, one PO and one slit lamp used in the study.

Pupil dilatation
We believe that DR grading without pupil dilatation is unacceptable; even in the busy primary health care setting. Pupil dilatation (using 0.5% to 1.0% tropicamide and/or 2.5% phenylephrine) is safe and markedly increases the sensitivity of DR screening. The Melbourne Visual Impairment Project (MVIP) and Blue Mountain Eye Study (BMES) showed high levels of patient acceptance for pupil dilatation. These studies have also confirmed the safety of pupil dilatation. The examiner will screen the patients prior to pupil dilatation as mentioned above.

Conventional direct ophthalmoscopy (CO): Welch-Allyn model 11740
Conventional direct ophthalmoscopy was performed after pupil dilatation in a dark room. For the detection and grading of DR and DME, the examiner will first examine the optic disc, then the superior nasal quadrant, superior temporal quadrant, inferior nasal quadrant, inferior temporal quadrant and lastly the macula. Examinations were also done using the red-free light.

PanOptic Ophthalmoscope (PO): Welch-Allyn model 11820
PanOptic ophthalmoscopy was performed after pupil dilatation in a dark room. The side cup provided by the manufacturer was not used. For the detection and grading of DR and DME, the examiner will first examine the optic disc, then the superior nasal quadrant, superior temporal quadrant, inferior nasal quadrant, inferior temporal quadrant and lastly the macula. Examinations were also done using the red-free light. The investigator was given a PO for three months for him to familiarize himself with the equipment.

Slit Lamp Biomicroscopy (SLM): Inami model L-0240
Slit lamp biomicroscopy was performed using the MaxField®STD 90D and Volk Double Aspheric 78D condensing lens. Examinations were also done using the red-free light.

DEFINITION OF TERMS

The Early Treatment Diabetic Retinopathy Study (ETDRS) staging system is the reference standard for grading in clinical trials and epidemiologic studies. However, its use in daily clinical practice is limited by relatively complicated rules, multiple severity levels and need to correlate with standard photographs. In September 2001, the American Academy of Ophthalmology (AAO) launched the Global Diabetic Retinopathy Project to promote the development of a common clinical severity scale for DR and diabetic macular oedema (DME), to facilitate improved communication between retina

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sub-specialists, ophthalmologists, endocrinologists/ diabetologists and primary care physicians.

The International Clinical Diabetic Retinopathy and Diabetic Macula Edema Disease (ICDR and DMED) Severity Scale proposed five severity levels of DR - none, mild, moderate, severe and proliferative; in the presence or absence of macular oedema, which is graded separately.[14,15] (The International Clinical Diabetic Retinopathy Disease Severity Scale is available at http://www.icoph.org/pdf/Diabetic-Retinopathy-Scale.pdf. The International Clinical Diabetic Macular Edema Disease Severity Scale is available at http://www.icoph.org/pdf/Macular-Edema-Scale.pdf). In this proposed new scale, the examiner might evaluate the individual lesions, but will record only the overall severity level. This clinical severity scale has been adopted by the Prevention of Blindness Committee, Ministry of Health, Malaysia, to facilitate screening and referral of DR cases among the primary health care workers.

Sight Threatening Retinopathy (STR) is defined by the presence of either:[16,17]
i. Severe NPDR or worse;
ii. Moderate DME or worse

"Ease of use" grading for CO and PO
The "Ease of use" grading for both CO and PO was adopted from the work of McComiskie *et al.*:[13]

1. Could not use this scope
2. Could not see the red reflex to even begin
3. Could not focus the fundus
4. Could see vessels but not the disc
5. Could see disc and retinal fields but it wasn't in focus
6. Determined clinical severity with high level of difficulty
7. Determined clinical severity with medium level of difficulty
8. Determined clinical severity with low level of difficulty
9. Determined clinical severity very easily

STATISTICAL ANALYSIS

Sensitivity and specificity of PO and CO in the detecting of STR were calculated using standard formula.

$$\text{Sensitivity} = \frac{\textit{number of STR detected by particular instrument}}{\textit{number of STR detected by SLM (reference standard)}}$$

$$\text{Specificity} = \frac{\textit{number of non–STR detected by particular instrument}}{\textit{number of non–STR detected by SLM (reference standard)}}$$

The 95% confidence interval of sensitivity and specificity were obtained using the biconf.exe; a stand-alone MS-DOS program which calculates exact confidence intervals for Binomial proportions and Poisson rates. The biconf.exe was downloaded free from the following Uniform Resource Locator (URL): http://www-users.york.ac.uk/~mb55/soft/soft.htm.

'Ease of use' scores were compared using chi-squared test and the method of comparison of proportion. The result was reported in 95% confidence interval for the ratio of the difference.

RESULTS

A total of 200 patients were enrolled in this study, of which 197 (98.5%) had T2DM and 3 (1.5%) had T1DM. The right eye was examined in 173 (86.5%) of patients, the left 27 (13.5%). The mean age of patients was 57.2 ± 12.1 years old (ranged from 20 to 81 years). 183 (91.5%) patients were aged 40 and above. 88 (44%) patients were male, 112 (56%) female.

Table 1: Age, ethnic and gender distribution of patients

Age group (years)	Malay		Chinese		Iban		Others		Total(%)
	Male	Female	Male	Female	Male	Female	Male	Female	
20-30	0	2	0	1	1	1	0	0	5 (2.5)
30-39	2	5	1	1	0	1	1	1	12 (6.0)
40-49	3	8	9	1	3	0	2	2	28 (14.0)
50-59	12	13	16	17	2	3	4	2	69 (34.5)
60-69	4	7	12	19	1	4	1	1	49 (24.5)
70-79	2	4	11	15	0	3	0	0	35 (17.5)
80-89	0	0	1	1	0	0	0	0	2 (1.0)
Total	23	39	50	55	7	12	8	6	200 (100)

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105 (52.5%) were Chinese, 62 (31%) were Malay, 19 (9.5%) were Iban, and 14 (5.2%) were of other ethnic groups (Table 1).

The duration of known diabetic status ranged from 0 (newly diagnosed DM) to 41 years. 45 (22.5%) patients were referred within one year of diagnosis. STR was detected in 41 (20.5%) cases, where 11 cases were due to DR alone, 16 due to diabetic maculopathy alone, and 14 due to the combination of both. 92.7% (38 cases) of STR, occur in patients aged 40 and above (Table 2).

Table 2: The prevalence of Sight Threatening Retinopathy (STR) according to age groups

Age group (years)	STR	No STR	Total
20-30	1	4	5
39-39	2	10	12
40-49	7	21	28
50-59	17	52	69
60-69	9	40	49
70-79	4	31	35
80-89	1	1	2
Total	41	159	200

Sensitivity and specificity

The examinations were performed using the PO as the initial investigation tool in 54% of eye, the CO in 46% of eyes (p=0.1). For CO, the overall sensitivity in detecting STR was 73.2% (95% CI: 57.1-85.8%), specificity 93.7% (95% CI: 88.7-96.9%), false negative 26.8% (95% CI: 14.2-42.9%), false positive 6.3% (95% CI: 3.0-11.3%), positive predictive value 75.0% (95% CI: 58.8-87.3%), and negative predictive value 93.1% (95% CI: 88.0-96.5%) (Table 3).

Table 3: The detection of Sight Threatening Retinopathy (STR) with Conventional Direct Ophthalmoscope (CO)

CO		SLM		Total
		STR	No STR	
No cataract	STR	21	7	28
	No STR	9	88	97
Cataract	STR	9	3	12
	No STR	2	61	63
	Total	41	159	200

SLM: Slit Lamp Biomicroscopy

For PO, the overall sensitivity in detecting STR was 58.5% (95% CI: 42.1-73.7%), specificity 93.7% (95% CI: 88.7-96.9%), false negative 41.4% (95% CI: 26.3-57.9%), false positive 6.3% (95% CI: 3.0-11.3%), positive predictive value 70.6% (95% CI: 52.5-84.9%), and negative predictive value 89.8% (95% CI: 84.2-93.9%) (Table 4).

Table 4: The detection of Sight Threatening Retinopathy (STR) with PanOptic Ophthalmoscope (PO)

PO		SLM		Total
		STR	No STR	
No cataract	STR	18	8	26
	No STR	12	87	99
Cataract	STR	6	2	8
	No STR	5	62	67
	Total	41	159	200

SLM: Slit Lamp Biomicroscopy

A total of 75 (37.5%) eyes have no cataract, while 125 (62.5%) eyes have mild cataract. Sub-group analysis revealed the sensitivity for the detection of STR using CO was 70.0% (95% CI: 50.6-85.2%) for eyes without cataract, and 81.8% (95% CI: 48.2-97.7%) for eyes with cataract. The sensitivity for the detection of STR using PO was 60.0% (95% CI: 40.6-77.3%) for eyes without cataract, and 54.5% (95% CI: 23.4-83.2%) for eyes with cataract. The differences were not statistically significant.

Ease of use

'Ease of use' for each examination with the PO and CO was scored. A subjective score of eight and above is considered easy, and a score of seven and below is considered difficult.[13]

The median score was greater when using the CO (median 9, IQR 8-9) compared to the PO (median 8, IQR 7-9) (Table 5).

Table 5: Frequency for "Ease of use" scores with PanOptic Ophthalmoscope (PO) and Conventional Direct Ophthalmoscope (CO)

Ease of use score	Frequency	
	PO	CO
1	0	0
2	0	0
3	0	0
4	0	0
5	8	3
6	39	13
7	33	19
8	49	59
9	71	106
Total	200	200

82.5% of examinations using the CO were rated as eight or nine, compared to PO (60.0%) (P< 0.0001). The CO was 1.38 times (95% CI: 1.17-1.61 times) as easy to use compared to the PO.

DISCUSSION

The primary objectives of this study were to determine, the sensitivity and specificity of the CO and the PO in the detection of STR. The secondary objective was to determine the "Ease of Use" of these equipments.

The results of this study indicated that the CO and the PO are comparable in sensitivity and specificity for the detection of STR. The overall sensitivity in detecting STR using the PO was 58.5% (95% CI: 42.1-73.7%), and specificity 93.7% (95% CI: 88.7-96.9%).

Screening tools with low sensitivity or high specificity are far from ideal. Many STRs would be missed due to high false negative rate. Operator dependence and higher false negative value suggest that the PO is not a good screening tool.

This study found that the CO was 1.38 times (95% CI: 1.17-1.61 times) as easy to use compared to the PO. This is in contrast to previous study which found that the PO was easier to use.[13] The "ease of use" of the PO and the CO were related to both the instruments and the patients. Instrument factors include intensity of illumination, working distance, as well as magnification of image and field of view. The intensity of illumination can be adjusted with the rheostat. The working distances were almost constant for each instrument. Magnification of image and the field of view achieved, depend on the refractive error of the patient. Patient factors include the type and the degree of refractive error, the degree of media opacity, photophobic response to ophthalmoscope light, the degree of patient's cooperation during examination, the degree of pupil dilation and the amount of light entering the fundus, hence the quality of the fundus view. The cumulative effects of these factors on each examination were translated into the "ease of use" score. Hence, the "ease of use" score will vary from patient to patient. Overall, in this study, the CO was found to be easier to use than the PO in the screening for sight threatening DR.

The working distance of the CO is 2 cm, whereas the working distance of the PO is 13 cm, about six times the working distance of the CO. Greater working distance allows more comfort during examination. Although the PO provides a wider field of view, the brightness and quality of the image is poorer than that of the CO, especially in the presence of media opacities. This is undesirable in the screening of STR, as lesions such as new vessels and macular oedema could be easily missed. The brightness of the CO is about 500 lux, the PO is slightly (30%) brighter due to the halogen HPX^{TM} lamp. Both equipments use 3.5 volt power source. The inverse square law predicts the relationship between the brightness and the distance from the light source. The brightness of the image decreases by a factor of four, when the distance between the illuminated retina and the examiner doubles. Assuming that the illuminated retina reflects light at the same luminous intensity, the brightness of the image seen by the PO is 36 times dimmer than those seen by the CO.

The CO allows greater flexibility in changing the angle of illumination. The eye-cup of the PO was not used in the study although its usage is recommended in the product usage guideline. The manufacturer claimed that the eye-cup provides a dark room effect, stabilizes the instrument and establishes a proper viewing distance while manoeuvring and focusing.

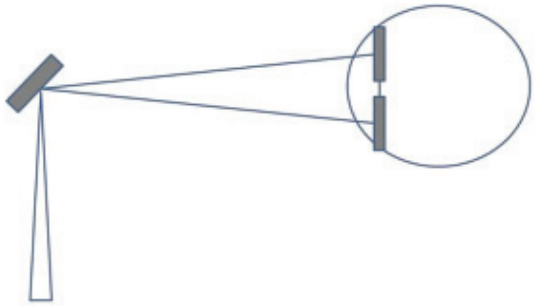
On the contrary, we found that the eye-cup failed to serve its purpose. If examination of an undilated eye is carried out in room light, the undilated pupil will still constrict due to the presence of consensual pupillary light reflex. Stimulation of the contra-lateral eye by ambient room light, will inevitably lead to constriction of both pupils. We strongly recommend examinations be performed with eyes fully dilated in a dark room.

In addition, PO with its eye-cup, allow little control over the angle of illumination, especially in eyes with undilated pupil. The eye- cup is actually a compressible rubber cup. The viewing distance provided by the eye-cup is therefore not constant. Stabilization of the PO viewing distance with the other hand, allow minor adjustment to provide the best fundus view. This simple manoeuvre also allows the examiner to monitor the patients' eye as they gaze in the desired direction, in order to bring fundus lesions into view. If the eye-cup is used, the examiner will need to remove the PO in order to ensure proper direction of gaze. Therefore, the examination with the PO is best performed without the eye-cup.

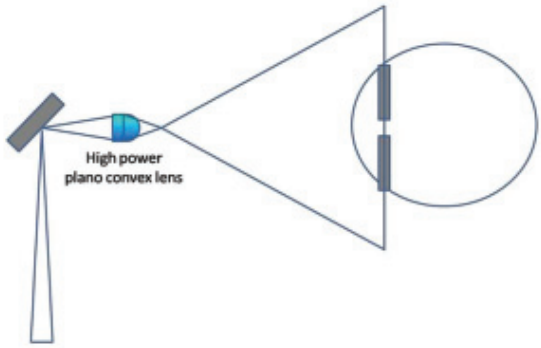
The CO is superior in viewing the red reflex. The quality of red reflex is determined by the amount of light that enter the pupil and hence reflected back from the fundus.

The illumination system of the CO sends a diverging cone of light rays to enter the subject's eye. On the other hand, to allow easy entry into small pupil, the Axial PointSource Optics Illumination system of the PO converge the light to a point at the cornea (1.45 inches in front of the PO). The illumination pathway then diverges widely to illuminate a very wide area of the fundus.[11] At a working distance of 30 cm, the amount of light rays that enter the pupil from the PO is greatly reduced, as most are diverged away from the visual axis. Therefore, red reflex is better evaluated with the CO (Figure 1).

Figure 1: Ray diagram during red reflex examination. A: Conventional direct ophthalmoscope. B: PanOptic ophthalmoscope.



A: Schematic ray diagram of conventional direct ophthalmoscope showing a diverging cone of light entering the subject's eye.



B: Schematic ray diagram of PanOptic ophthalmoscope showing a widely diverging cone of light entering the subject's eye. Less amount of light entering the eye through the pupil, produce poorer red reflex

Limitations

There are several limitations that must be considered in the interpretation of the results of this study. The PO, CO and SLM are operator dependent as well as patient dependent. Inter-observer variation and intra-observer variation is bound to occur. Gill *et al.* showed that there is a wide range of kappa statistic, between 0.06 to 0.70, among family physicians in the screening for DR.[12] In order to avoid inter-observer variation in this study, only one investigator performed all three examinations. If the lone investigator had any preconceived bias against any one of the instruments, the result will suffer. To maintain masking, there was no history taking prior to PO and CO examination. There was only one CO, one PO and one slit lamp used in the study.

The investigator was given a PO for three months for him to familiarize himself with the equipment. The three months period may not be adequate compared to his presumed long experience with the CO.

Since DM is a systemic disease, both eyes are equally affected in most patients. The knowledge of the DR status in one eye will influence the examiner's judgment of the DR status in the contra-lateral eye. Therefore, only one eye from the patient will be included in this study.

Patient factor include decrease level of co-operation during repeated examination. This can be due to photophobia or reluctance for repeated examination. In the Liverpool Diabetic Eye Study, 9% of patients failed to attend hospital clinic for repeat examination. Of the 91% who attended, 9% did so after four months.[8] The defaulter rate is expected to be higher in our population. Taking account of the above difficulties, data collection for each patient was completed in one session. The investigator may remember the fundus finding during the first examination, this constitutes a limitation of the study. Coin flipping was used to mitigate this bias.

CONCLUSION

The results of this study showed that the PO is not superior to the CO for the screening of STR, and do not support the use of the PO for this purpose.

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More bad news for dietary supplements: *folate, vitamin B6, vitamin B12 and omega-3 fatty acids do not prevent cardiovascular events in adults with prior cardiovascular disease.*

Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine (SEARCH) Collaborative Group. Effects of homocysteine-lowering with folic acid plus vitamin B12 vs placebo on mortality and major morbidity in myocardial infarction survivors: a randomized trial. *JAMA*. 2010;303(24):2486-94.

12,064 survivors of myocardial infarction were randomised to receive folic acid plus vitamin B_{12} daily or matching placebo over 6 to 7 years of follow-up. Allocation to the study vitamins reduced homocysteine but does not result in reduction of cardiovascular events