Accuracy of Single-Field Nonmydriatic Digital Fundus Image in Screening for Diabetic Retinopathy

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Objective: *To determine the accuracy, the sensitivity and the specificity of a single-field nonmydriatic digital fundus image interpreted by an endocrinologist for diabetic retinopathy (DR) screening.*
Material and Method: *Two hundred and forty-eight diabetic patients who attended the Diabetic Center, BMA Medical College and Vajira Hospital between May 2007 and March 2008 were included in the present study. The fundus images of all patients, which would include optic nerve and macular area, were captured by a digital camera without any mydriatic agent. After image taking, the patients were subsequently examined for any evidence of diabetic retinopathy by an experienced ophthalmologist. The fundus images were later interpreted by a trained endocrinologist and would be compared with the findings from the ophthalmologist, which were used as a gold standard.*
Results: *The prevalence of DR was 24.2% of the population or 22.8% of the 495 eyes studied. Ninety-three fundus images were considered low quality for interpretation and were excluded from the analysis. From the remaining 402 eyes (155 patients), the Kappa value of the endocrinologist's interpretation and the ophthalmologist's findings was 0.48. The accuracy for screening DR by the image capture was 80.6% (95% confidence interval [CI], 76.4-84.3) while the sensitivity and specificity were 65.6% (95% CI, 60.9-70.2) and 84.9% (95% CI, 81.4-88.4), respectively. Positive predictive value and negative predictive value were 55.7% (95% CI, 50.8-60.5) and 89.5% (95% CI, 86.5-92.5), respectively.*
Conclusion: *Single-field nonmydriatic digital fundus image is a convenient screening tool for a diagnosis of diabetic retinopathy. The test could be achieved by a trained endocrinologist who could practically serve the patients in one visit at diabetic clinics. A referral to an ophthalmologist is still recommended in any cases with abnormal findings, or those with questionable findings, and those with poor quality photographs when diabetic retinopathy could not be definitely excluded.*

Keywords: *Diabetic retinopathy, Screening, Nonmydriatic digital fundus image*

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Diabetic retinopathy is a leading cause of blindness in a large number of populations all over the world[1]. In Thailand, the disease is also a major public health problem. The prevalence of diabetic retinopathy from a few population-based surveys in Thailand were also high, ranging from 15.3-21.9%[2-4]. Long-standing retinopathy would provoke a catastrophic event of vitreous or pre-retinal hemorrhage, followed by macular edema, retinal detachment, and blindness[5]. A timely laser photocoagulation of the pathologic retina has been proven to be an effective means in reducing the risk of blindness[6]. Since blindness is a disability that has major impacts on an individual's life resulting in a familial and public socioeconomic burden, any effective programs to prevent the condition would be useful, such as, a guideline for diabetic patients to have a screening and early detection to prevent visual impair-

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ment and blindness. Theoretically, if the guideline is followed, the number of handicapped diabetic patients would be minimized and in turn would provide a financial return on the investment of public health funds[7]. However, a large proportion of the diabetic patients do not follow recommended guidelines to prevent visual impairment and blindness because of the low self-recognition of the disease[8,9].

Several methods for diagnosis diabetic retinopathy are available nowadays. These include, for example, seven-field stereoscopic fundus photography[6,10,11], stereo contact lens biomicroscope[6,11], indirect ophthalmoscope, and slit lamp biomicroscope with high plus lens[12-14]. Because all of these procedures must be performed through a pharmacologically dilated pupil, which needs extra time and expense, they are not feasible for routine screening in a large-scale epidemiologic study. Hence, other simple screening methods for diabetic retinopathy have been developed in order to serve more patients, such as, direct ophthalmoscopy[15,16] and nonmydriatic digital fundus camera[12-14,17,18]. Many studies have shown that single-field nonmydriatic digital fundus image is an acceptable tool for screening diabetic retinopathy[13,18]. This method is proven to be cost-effective[13,14]. Further advantage is that it can be achieved with undilated pupils[12,13,17,18].

In Thailand, screening by ophthalmologists is limited by an inappropriate demographic distribution of the ophthalmologists, so the screening procedure should be delegated to other types of medical professionals. The endocrinologist who takes care of the diabetic patients would be the most appropriate alternative option because the screening can be performed at diabetic clinic, so the patients who attend the follow-up visit could undergo diabetic retinopathy screening at the same setting as a one-stop service. Nevertheless, any substitution of the personnel should be ascertained that the quality of care for the patients is comparable or there would be no excess cases of under-diagnoses. The purpose of the present study was to determine the accuracy, the sensitivity, and the specificity of single-field nonmydriatic digital fundus image interpreted by a trained endocrinologist for diabetic retinopathy screening.

Material and Method

The present study was conducted after approval from the Ethics Committee on Researches Involving Human Subjects of the institution and the Bangkok Metropolitan Administration. Two hundred and forty-eight diabetic patients who attended the Diabetic Center, BMA Medical College and Vajira Hospital from May 2007 to March 2008 were included into the present study. Inclusion criteria were diabetic patients who had no previous eye laser or surgical treatment for DR, and were consulted to the Department of Ophthalmology of the institution for detection of DR. All patients were required to give informed consent. The fundus images from both eyes of all patients were captured by an advanced nurse practitioner using digital fundus camera (Topcon® TRC-NW 100, Tokyo, Japan) without any mydriatic agent. The nurse practitioner was trained to capture the images using the digital fundus camera prior to the study. The single-field fundus image must include the optic disc and macular area. After a digital image capture, topical 1% tropicamide and 10% phenylephrine hydrochloride were instilled followed by an indirect ophthalmoscopy and slit lamp biomicroscopy with high plus lens performed by an experienced ophthalmologist. The fundus images were later sent for an interpretation by a trained endocrinologist who was blinded to the results from the ophthalmologist. The endocrinologist who had been trained for the images interpretation tested variation until reliable before research. Diabetic retinopathy in any patient was diagnosed when there was pathologic change being evidenced in at least one eye. The levels of diabetic retinopathy were classified according to the International Clinical Diabetic Retinopathy Disease Severity Scale (Appendix 1)[19].The diagnostic performances of the single-field fundus image were determined, using the results of the ophthalmologist as a gold standard. Data collected were age and gender of the patients, duration of diabetes mellitus, the most recent serum plasma glucose level (must be within 3 months), and the history of hypertension.

Statistical analysis was performed using STATA software package version 7 (College Station, Tx., USA). Demographic data of age was expressed as mean with standard deviation. The other characteristic features were categorized into groups and were presented as number with percentages. The images that could not be interpreted by the endocrinologist would be excluded from the statistical analysis. The agreement of the two methods was expressed as Kappa value while the diagnostic performances of the single-field nonmydriatic digital fundus image were expressed as the accuracy, sensitivity, specificity, positive predictive value, and negative predictive value with their 95% confidence intervals (CIs).

Appendix 1. International clinical diabetic retinopathy disease severity scale

Proposed disease severity level	Findings observable on dilated ophthalmoscopy
No apparent retinopathy	No abnormalities
Mild non-proliferative diabetic retinopathy	Microaneurysms only
Moderate non-proliferative diabetic retinopathy	More than just microaneurysm but less than severe non-proliferative diabetic retinopathy
Severe non-proliferative diabetic retinopathy	Any of the following: - more than 20 intraretinal hemorrhage in each of 4 quadrants - definite venous beading in 2 quadrants - prominent intraretinal microvascular abnormalities in 1 quadrant - no sign of proliferative retinopathy
Proliferative diabetic retinopathy	One or more of the following: neovascularization, vitreous/preretinal hemorrhage
Diabetic macular edema apparently present	Some apparent retinal thickening or hard exudates in posterior pole

Results

Of the 248 patients who met inclusion criteria, 169 of them were female (68.1%). Mean age of the patients was 61.1 $\pm$ 10.4 years (range, 30-83 years). More than half of the patients (150 patients or 60.5%) had had diabetes mellitus for less than 10 years. The serum plasma glucose level was found below 120 mg/dl in only 65 patients (26.2%), 144 patients (58.1%) had plasma glucose between 120-200 mg/dl, while 39 patients (15.7%) had poor-controlled plasma glucose (> 200 mg/dl). Only 87 patients (35.1%) had co-morbidity of hypertension. Basic demographic data of the patients are shown in Table 1.

Out of 248 patients, only 495 eyes were included in the analysis because one patient had only one eye. From the indirect ophthalmoscopy under slit lamp biomicroscopy with high plus lens performed by the ophthalmologist, diabetic retinopathy was discovered in 113 eyes (22.8%) from 60 patients (24.2%) while the remaining 382 eyes (77.2%) from 188 patients (75.8%) had no evidence of the disease. The number and percentages of the patients who did not have, or had diabetic retinopathy and the number of the eyes affected by DR at different severity are shown in Table 2. Among the 113 eyes affected by DR, almost all (109 eyes or 96.5%) from 57 patients (95.0%)

Table 1. Demographic data of diabetic patients having diabetic retinopathy screening (n = 248)

Variables	Number	Percentage
Gender		
Male	79	31.9
Female	169	68.1
Duration of diabetes		
Less than 5 years	74	29.8
5-10 years	76	30.7
10-15 years	66	26.6
More than 15 years	32	12.9
Blood glucose level		
Less than 120 mg/dl	65	26.2
120-200 mg/dl	144	58.1
More than 200 mg/dl	39	15.7
Hypertension		
With hypertension	87	35.1
Without hypertension	161	64.9

Table 2. Numbers of patients and eyes with and without diabetic retinopathy from the ophthalmoscopic examination by the ophthalmologist

Ophthalmoscopic findings	Number of patients (%) n = 248	Number of eyes (%) n = 495*
No DR	188 (75.8)	382 (77.2)
DR		
Mild to moderate NPDR**	57 (23.0)	109 (22.0)
Severe NPDR	2 (0.8)	2 (0.4)
PDR	1 (0.4)	2 (0.4)

* One patient had only one eye

** Two eyes in one patient had evidence of diabetic macular edema

Abbreviations: DR = diabetic retinopathy, NPDR = non-proliferative diabetic retinopathy, PDR = proliferative diabetic retinopathy

had only mild to moderate non-proliferative diabetic retinopathy. Macular edema was observed in two eyes of one patient who had mild to moderate non-proliferative diabetic retinopathy.

From the 495 single-field fundus image capture, 93 images (18.8%) had low quality and could not be used for the interpretation. From the remaining 402 images, 106 (26.4%) were interpreted by the endocrinologist as having evidence of DR. The majority of them (80 eyes, 75.5%) were graded as mild to moderate non-proliferative DR while 18 eyes (17.0%) were assigned as severe DR and the remaining eight eyes (7.5%) were graded as proliferative DR (Table 3).

Comparing the interpretation by images and the ophthalmoscopic findings in the 402 eyes, the Kappa statistic between the two screening tests was 0.48. The results comparing the number of eyes being diagnosed as diabetic retinopathy by the single-field nonmydriatic digital fundus image interpreted by the endocrinologist and the indirect ophthalmoscopy by the ophthalmologist are shown in Table 3. Thirty-one eyes affected by DR were missed from the imaging studied by the endocrinologist (false negative). All of these 31 eyes were diagnosed by ophthalmologist by indirect ophthalmoscopy as mild to moderate DR. On the other hand, there were 47 eyes which were over-interpreted (false positive) from the images as having mild to moderate non-proliferative DR (37 eyes), severe non-proliferative DR (seven eyes), and proliferative DR (three eyes) but were not evidenced by the ophthalmoscopic examination.

Focusing on the 59 eyes detected by the images as having DR and confirmed by ophthalmoscopy, one eye was graded as severe non-proliferative DR but was actually revealed to have proliferative DR. On the contrary, eight and five eyes that were determined by the images to have severe non-proliferative DR and proliferative DR turned out to be only mild to moderate non-proliferative DR.

The overall accuracy of nonmydriatic single-field fundus image interpreted by trained endocrinologist for screening diabetic retinopathy was 80.6% (95% CI, 76.4-84.3). The sensitivity and the specificity were 65.6% (95% CI, 60.9-70.2) and 84.9% (95% CI, 81.4-88.4), respectively. Positive predictive value and negative predictive value were 55.7% (95% CI, 50.8-60.5) and 89.5% (95% CI, 86.5-92.5), respectively.

Discussion

Many diabetic patients frequently present their eye problems in advanced stages when the treatment is difficult, expensive, and unsuccessful. Early diagnosis that could be achieved by a regular screening to facilitate therapeutic intervention for a treatable eye disease, therefore, is essential. Although there is consensus concerning the cost-effectiveness of the screening, the best method has not been established.

The present study was done to evaluate the efficacy of single-field nonmydriatic digital fundus image interpreted by a trained endocrinologist for diabetic retinopathy screening. The agreement between the single-field nonmydriatic digital fundus image and ophthalmoscopy under slit lamp biomicroscopy with high plus lens, which was used as a gold standard, was

Table 3. Comparison of diabetic retinopathy diagnosed with single-field nonmydriatic digital fundus image interpreted by the endocrinologist and the indirect ophthalmoscopy by the ophthalmologist in 402 eyes

Nonmydriatic digital fundus image interpreted by endocrinologist	Gold standard (diagnosis by ophthalmoscopy)				
	No DR	Mild to moderate NPDR	Severe NPDR	PDR	Total
No DR	265	31	0	0	296
DR					
Mild to moderate NPDR	37	43	0	0	80
Severe NPDR	7	8	2	1	18
PDR	3	5	0	0	8
Total	312	87	2	1	402

Abbreviations: DR = diabetic retinopathy, NPDR = non-proliferative diabetic retinopathy, PDR = proliferative diabetic retinopathy

only modest (Kappa value = 0.48). A previous study reported the Kappa value between the two screening tests was as high as 0.74[13]. The higher Kappa value in their study compared to the value of 0.48 in the present study was probably due to the differences in level of experience of the interpretators for the images, which were performed by an ophthalmologist in their study while the images in the present study were achieved by the endocrinologist.

The accuracy for screening DR by the digital fundus image in the present study was 80.6% while the sensitivity and the specificity were 65.6% and 84.9%, respectively. These figures were in the ranges reported by the American Academy of Ophthalmology[20] which reviewed many studies of the single-field fundus image interpreted by trained readers in comparison to the gold standard reference of a dilated ophthalmoscopy performed by an ophthalmologist. They found that the sensitivity of the former procedure ranged from 35% to 100% and specificity ranging from 75% to 100%. They finally concluded from their review that this fundus image could be used as a screening test for DR[20]. One study from the United Kingdom reported the sensitivity of the digital fundus image interpreted by the ophthalmologist was 38.0%[21]. The authors commented that additional nasal images could improve the sensitivity of the test. Although the sensitivity of the present study was only modest at 65.6%, this was comparable to the other report from Thailand[22] that reported the sensitivity of the digital fundus image interpreted by ophthalmologist was 68.6%. When the present study compared to the authors' prior study[23] in which the images were interpreted by the ophthalmologist, the sensitivity in that study was 72.6%, which was certainly higher than the sensitivity in the present study.

Of 90 DR eyes diagnosed by ophthalmoscopy, 31 of them were missed from the images inspected by the endocrinologist. After the identification of these false-negative cases, the ophthalmologist reviewed all of the 31 images and could not find any evidence of DR in those images. Klein et al reported that approximately 8%-15% of retinopathy may be missed by the image capture because exudates or microaneurysms in DR might have lain outside the single-field taken with the nonmydriatic camera[24]. One limitation of the fundus image study is the inability to diagnose the condition of macular edema[11]. Kinyoun et al. reported that diagnosis of macular edema could hardly be made from the two-dimensional view of nonmydriatic fundus photography without stereoscopic examination, especially if only a few hard exudates were present[11]. In the present study, macular edema in two eyes from one patient could not be detected from the images by the endocrinologist but were found from an ophthalmoscopic examination. These two eyes were diagnosed as having DR from the imaging study but the evidence of macular edema could not be identified. The hard exudates, which were usually found at the edge of the edema and could easily be visible by the imaging, might provide a clue to an endocrinologist that the patient should be referred to an ophthalmologist for further evaluation and treatment if the exudates are seen within one disc diameter of the center of macula.

The other 47 eyes were over-diagnosed from the images as having DR by the endocrinologist. All of these images were also reviewed by the ophthalmologist who found some misleading effect for the over interpretation. Drusens from the eyes themselves as well as some technical image artifacts which may look like the exudates had major contribution for this error[22].

Regarding the severity or grading of DR in 59 eyes, only one eye was under-graded by the imaging evaluation in the present study. This severe non-proliferative DR was revealed to be proliferative DR. On the other hand, 13 eyes were graded as severely affected by the disease (severe non-proliferative DR or proliferative DR) from the images but turned out to have only mild-moderate DR. These pitfalls might lie on the experience of the interpretator (endocrinologist) who had been trained to focus on the screening results or findings rather than the specific grading of severity. The other possibility was the timing of the study of the cases when the interpretator was in the learning curve when the interpretator gained experience over time when the cases were actually studied. The over-graded cases were mostly in the early phase when the interpretator probably would be extra-cautious of the disease and tended to make a more severe diagnosis than the later time phase.

The major disadvantage of nonmydriatic fundus photography was the high rate of un-gradable photographs. In 93 out of 495 eyes (248 patients) had low quality images that could not be used for the interpretation. These results might be related to a small pupil, media opacities, poor fixation, and poor patients cooperation, which was similar to previous studies[22,24]. These patients should be referred to the ophthalmologist for evaluation. Training of photographers and a newer nonmydriatic system may be able to overcome ungradable photographs.

The present study showed that the single-field nonmydriatic digital fundus image can serve as a screening tool for DR to identify patients with retinopathy for referral for ophthalmic evaluation and management. The procedure could be applied in an area where the access to the ophthalmologist is not feasible. However, the low sensitivity and low positive predictive value results may indicate that additional training is required for an improvement of the interpretation.

Conclusion

Single-field nonmydriatic digital fundus image is a convenient screening tool for a diagnosis of diabetic retinopathy. The test could be achieved by a trained endocrinologist who could practically serve his patients in one visit at diabetic clinics. A referral to an ophthalmologist is still recommended in any cases with abnormal findings, or those with questionable findings, and those with poor quality photographs when diabetic retinopathy could not be definitely excluded.

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ความแม่นยำของการใช้ภาพถ่ายจอตาบริเวณเดียวโดยไม่ขยายม่านตาในการคัดกรองเบาหวานขึ้นจอตา

อภิชาติ สวนศิลป์พงศ์, เพชร รอดอารีย์

วัตถุประสงค์*: เพื่อหาความแม่นยำ ความไว ความจำเพาะ ของการใช้ภาพถ่ายจอตาบริเวณเดียวโดยไม่ขยายม่านตาโดยแพทย์ต่อมไร้ท่อเป็นผู้แปลผล เพื่อตรวจกรองโรค (screening) ในภาวะจอตาเสื่อมที่มีสาเหตุจากเบาหวาน*

วัสดุและวิธีการ*: ศึกษาในผู้ป่วยเบาหวานของศูนย์โรคเบาหวานวชิระ วิทยาลัยแพทยศาสตร์กรุงเทพมหานครและวชิรพยาบาล จำนวน 248 ราย ผู้ป่วยได้รับการถ่ายภาพจอตาบริเวณเดียวด้วย nonmydriatic digital fundus camera โดยไม่ขยายม่านตาโดยถ่ายบริเวณ optic disc และ macula บันทึกภาพไว้เพื่อให้แพทย์ต่อมไร้ท่อแปลผลต่อไป ผู้ป่วยได้รับการตรวจหาเบาหวานขึ้นจอตาโดยวิธีมาตรฐานจากจักษุแพทย์ นำข้อมูลที่ได้ทั้งหมดมาวิเคราะห์ทางสถิติ*

ผลการศึกษา*: ค่าความชุกของเบาหวานขึ้นจอตาเท่ากับร้อยละ 24.2 ในจำนวนผู้ป่วย 248 ราย หรือ ร้อยละ 22.82 ในจำนวน 495 ตา ซึ่งมีผู้ป่วย 1 ราย ที่มีตาบอดหนึ่งข้าง พบว่า มีภาพถ่ายที่ไม่ชัดเจนไม่สามารถแปลผลจำนวน 93 ตา ค่าความสอดคล้อง ได้ค่า Kappa statistic เป็น 0.48, ค่าความแม่นยำ ในการคัดกรองภาวะเบาหวานขึ้นจอตาเป็นร้อยละ 80.6, ค่าความไว และค่าความจำเพาะ ในการคัดกรองเบาหวานขึ้นจอตาเป็นร้อยละ 65.6 และ 84.9 ตามลำดับ ค่าการทำนายผลบวกและค่าการทำนายผลลบเป็นร้อยละ 55.7 และ 89.5 ตามลำดับ*

สรุป*: การใช้ภาพถ่ายจอตาบริเวณเดียวโดยไม่ขยายม่านตาเป็นวิธีที่สะดวกในการคัดกรองเบาหวานขึ้นจอตาในคลินิกโรคเบาหวาน สามารถส่งต่อผู้ป่วยเพื่อให้จักษุแพทย์ทำการตรวจในกรณีที่พบความผิดปกติของจอประสาทตาหรือในรายที่ไม่แน่ใจว่ามีความผิดปกติ และในรายที่ภาพถ่ายไม่ชัดเจนไม่สามารถแปลผลได้*