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Original Articles

PREVALENCE OF DIABETIC RETINOPATHY IN A PRIMARY CARE SETTING USING DIGITAL RETINAL IMAGING TECHNOLOGY

Keah Say Hien *FRACGP*, Elizabeth Medical Centre, Muar, Johor.
Chng Kooi Seng *FRACGP AM*, Klinik Chng, Johor Bahru, Johor.

ABSTRACT

The objective of this study was to determine the prevalence of diabetic retinopathy in a primary care setting using digital retinal imaging technology and to quantify the degree of diabetic retinopathy using internationally accepted severity scales. Two hundred patients with type 2 diabetes were evaluated clinically followed by fundus photography. The prevalence of retinopathy and maculopathy was 47.4% and 59.2% respectively (both retinopathy and maculopathy 34.7%). The high prevalence of retinal abnormality in this study is a cause for concern as most patients had diabetes for only 5 years or less.
Keywords: diabetic retinopathy, digital retinal imaging, diabetic retinopathy severity scales.

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See also Commentary by Sagili Chandrasekhara Reddy on Page 22 and "Test Your Knowledge" on Page 39.

INTRODUCTION

Diabetic retinopathy is the commonest complication of diabetes mellitus and is the earliest manifestation of the microvascular complications of diabetes mellitus. In the Wisconsin Epidemiologic Study of Diabetic Retinopathy (WESDR), a large population based study in 10 counties in southern Wisconsin, USA, the prevalence of any retinopathy in those with onset of diabetes after the age of 30 years (presumably mostly with Type 2 DM) is 29% in those within 5 years of diagnosis and 78% in those with disease duration more than 15 years.[2] Diabetic retinopathy is the commonest cause of blindness in the working age population in the developed countries. Diabetic retinopathy fulfils all the criteria for a screening program. It occurs as a continuum, where in the early subclinical stages, changes in the retina can only be demonstrated by the use of fluorescein angiography, to the stages whereby ophthalmologic examination reveals retinopathy but the visual acuity is still unaffected, to the final stages whereby severe visual impairment and blindness occur.

In the local context, well organised screening programmes for diabetic retinopathy is still lacking in the private practice or the government hospitals. We were of the impression that screening for diabetic retinopathy in primary care locally by routine funduscopy is infrequently done and that some general practitioners may find the procedure difficult due to personal and environmental factors.

Address for correspondence: Dr Richard Keah, Elizabeth Medical Centre Sdn Bhd, 1-14 Jalan Arab, 84000 Muar, Johor. Tel: 06-9535335, Fax: 06-9543100, Email: drkeah@hotmail.com

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The objective of our study was to determine the prevalence of diabetic retinopathy in a primary care clinic and the associated demographic factors by using digital retinal imaging technology as the sole screening instrument.

MATERIALS AND METHODS

The study was conducted in a primary care clinic in Muar, Johor. This clinic provides private healthcare services to the residents in this town as well as the surrounding rural community. It is located about 2 km from Muar Hospital (Hospital Pakar Sultanah Fatimah, Muar).

This study is a cross-sectional study of all patients with type 2 diabetes mellitus 18 years and above who attended the clinic from 24th March 2005 to 24th August 2005. The diagnosis of diabetes mellitus was based on the currently accepted criteria. We included all diabetic patients seen during the study period if they gave consent but excluded those who were acutely ill or non-ambulant.

Diabetic patients answered a brief questionnaire asking for demographic details and information about their diabetes (age of onset, duration of diabetes, co-morbidities, whether the subject had ever been under the care of an ophthalmologist). Visual acuity was tested using Snellen chart at 6 metres. Distant vision was tested with and without spectacles (retested with pinhole if the subject was unable to read the 6/9 line). A general examination of the eye was done using the penlight to look for clarity of the cornea and to assess the pupil size. Ophthalmoscopic examination was performed in a darkened room to look for cataract but the fundus was not examined. Retinal photography was then performed using the Topcon TRC NW200 nonmydriatic retina camera. A single central macular view of the fundus (including the optic disc, the vascular arcades and the macula) was obtained and was used in this study for assessment of diabetic retinopathy. If the image was deemed inadequate 2 drops of a cycloplegic (Mydriacyl) was instilled into the eye and

the eye was reexamined when the pupillary dilatation was adequate. The images acquired by the camera were instantly transmitted to a computer for storage and subsequent retrieval and analysis.

The fundus photographs were carefully analysed by both authors. The retinal abnormalities were classified according to the International Clinical Diabetic Retinopathy Disease Severity Scale (Table 1) and the International Clinical Diabetic Macular Edema Disease Severity Scale (Table 2) produced by the International Council of Opthalmology.[3]

Table 1. International Clinical Diabetic Retinopathy (DR) Disease Severity Scale

Proposed disease severity level	Findings observable with dilated ophthalmoscopy
No apparent DR	No abnormalities
Mild nonproliferative DR	Microaneurysms only
Moderate nonproliferative DR	More than "mild" but less than "severe"
Severe nonproliferative DR	Any of the following: • 20 or more intraretinal haemorrhages in 4 quadrants • Definite venous beading in 2 or mare quadrants • Prominent IRMA in 1 or more quadrants and no neovascularisation
Proliferative DR	1 or more of the following : • Definite neovascularisation • Preretinal or vitreous haemorrhages

Table 2. International Clinical Diabetic Macular Edema (DME) Disease Severity Scale

Proposed disease severity level	Findings on dilated ophthalmoscopy
DME absent	No retinal thickening or hard exudates present in posterior pole
DME present	Some retinal thickening or hard exudates present in posterior pole
If DME is present, it can be categorised as follows:	
Mild DME	Some retinal thickening or hard exudates in posterior pole but distant from the centre of the macula
Moderate DME	Retinal thickening or hard exudates approaching the centre of the macula but not involving the centre
Severe DME	Retinal thickening or hard exudates involving the centre of the macula

RESULTS

Demographic characteristics

215 diabetic patients were seen during the study period, and 200 fulfilled the selection criteria. The mean age was 57.4 years (range 27-82 years). Most of the respondents were Chinese (86%), the rest were Malays (9.5%) and Indians (4.5%). Forty-four percent of them were males.

Clinical data

The duration of their diabetes was: <1 year 18%, 1-5 years 36%, 5-10 years 24.5, and >10 years 21.5%. One hundred and four of them had concomitant hypertension (53.1%). One-quarter of them had ever been seen by an ophthalmologist. These included the subjects consulting the ophthalmologist for diseases other than diabetes, for treatment of cataracts and for screening purposes. Cataracts were present in 25% of the patients studied. Very few patients (6.5%) ever received laser photocoagulation for their retinopathy. Only 12% of the patients in the study had visual acuity of 6/12 or worse in the better eye.

Retinal photography

Mydriatic eye drops were used in 26% of the patients studied (52 cases). Retinal photographs of four patients were unreadable; hence the calculation of the prevalence of retinopathy was based on 196 patients. Ninety-three patients (47.4%) were found to have retinopathy. The severity of retinopathy (based on the International Clinical Diabetic Retinopathy Disease Severity Scale) was as follow: mild nonproliferative 16.3%, moderate nonproliferative 26%, severe nonproliferative 3.1%, and proliferative 2.1%. The prevalence of maculopathy was 59.2% (based on the International Clinical Diabetic Macular Edema Disease Severity Scale): mild (hard exudates away from the macula) 2%, moderate (hard exudates within the macula but not involving the fovea) 37.3%, and severe (hard exudates encroaching upon the centre of the macula) 19.9%. Overall, 71.9% of these diabetic patients had either retinopathy or maculopathy and 34.7% had both retinopathy and maculopathy. Sight threatening eye disease (STED, defined as moderate nonproliferative diabetic retinopathy or worse, circinate maculopathy and hard exudates within 1 disc diameter from the centre of the fovea) occurred in 80 cases (40.8%).

Among these diabetic patients with concomitant hypertension, retinopathy was detected in 76 (38.8%). As shown in Table 3, most diabetic patients already had retinopathy when they sought medical treatment for their diabetes.

Table 3. Prevalence of diabetic retinopathy compared with duration of diabetes

Duration of diabetes	No of cases	Diabetic retinopathy (%)
< 1 year	36	63.9
1-5 years	71	74.6
>5 years	89	75.3

DISCUSSION

The conventional method of screening for diabetic retinopathy involves direct ophthalmoscopy using a hand-held ophthalmoscope. It may be a daunting procedure for some doctors and requires dark room facilities and pupillary dilatation. It allows only a two-dimensional view of the retina and a photographic recording is not possible. It is thus not recommended as a sole screening instrument in large scale screening programmes.

The current clinical gold standard for assessing the level of diabetic retinopathy is through the grading of seven standard field 35-mm stereoscopic colour fundus photography taken through a dilated pupil using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocols. The ETDRS 35-mm retinal photography and grading protocols have an established and documented sensitivity for detecting and assessing level of diabetic retinopathy.[4] The disadvantages with 35-mm photography are the requirements for skilled operators, the need for pupil dilatation, the lengthy sessions for the patients, the higher costs of film and film handling, and inefficient archiving with the potential for loss of data and loss or damage of slides.

Digital fundus imaging has revolutionalised retinal screening. The optical components of the retinal imaging system have not changed from the traditional photography system; rather the film camera back has been replaced by a video camera. A number of novel retinal imaging systems were soon developed including the Joslin Vision Network[5] which is a telemedicine application for the management of diabetes in general and diabetic eye care specifically.

Imaging or testing strategies will thus vary with the cost-effective strategies of the individual medical community. The systems adopted can be categorised to include the various camera types (mydriatic versus non-mydriatic), capture media (35-mm slide film, Polaroid, digital imaging), image resolution, number of fields (seven, four, three, two, one), field of view (30°, 45°, 60°) and whether or not images are stereoscopic. For example the imaging system used in this study, the Topcon TRC NW 200 is a 45° nonmydriatic digital imaging system, 3.15 mega pixel image resolution, 3 fields availability (macular, nasal and temporal), and non-stereoscopic.

The advantages of digital retinal imaging were many. Firstly, the image can be viewed immediately and when the image is not clear another can be taken. Secondly, there is increased comfort to the patient compared with the closed-up viewing in routine ophthalmoscopy. The intensity of the flash is much less discomforting. Three-quarters of our patients do not need mydriatic eyedrops. Thirdly, the images can be stored for further review, consultation and comparison with another image at a later date. Finally the potential for patient education is great. As the saying goes, a picture paints a thousand words. After viewing the photograph personally, the patient can be made aware that changes have begun to occur in his eyes. He can then be made to understand that these changes may not be permanent, as lesions like microaneurysms, blot haemorrhages, hard and soft exudates come and go and that attempts should be started without delay to improve glycaemic and blood pressure control. Every 1% reduction in updated mean HbA1C was associated with reduction in risk of 37% for diabetic retinopathy (UKPDS).[6] Despite the advantages, there is a need for validation studies to demonstrate the equivalence in diagnostic quality of digital images produced by individual systems compared with the gold standard 35 mm photography. On top of that, the sensitivity and specificity of the system will be affected by the skills of the provider in reading the images. Chia SY and co-worker showed that the use of retinal photographs to screen for diabetic eye disease achieved a high sensitivity by capturing diabetic retinal lesions and was comparable to an examination performed by the ophthalmologist.[7]

Epidemiological study of diabetic retinopathy in Malaysia is still lacking. Mafauzy reported in a primary care setting, presumably by direct ophthalmoscopy, 23.5% of the studied population had background retinopathy and 5.3% had advanced eye disease.[8] To our knowledge, there are no published studies from Malaysia using retinal photography. The high prevalence of diabetic retinopathy in our study was of great concern, especially the significantly high rates of STED, but perhaps not too surprising in view of the equally alarming high prevalence of diabetic nephropathy in Asian Type 2 diabetes reported in the Microalbuminuria Prevalence Study.[9] It was also noted that good vision was found in the majority of patients in our study. Only 12% of the respondents had visual acuity of 6/12 or worse in the better eye but approximately 3 times of that (40.8%) had STED. Hence many of the diabetics may not be inclined to seek early treatment for diabetic retinopathy.

The new international grading system used in the study is a more evidence-based approach to the classification of the disease and it incorporates data found in excellent trials such as the ETDRS and the WESDR. The main classification looks at the visible vascular events from the earliest changes (i.e. microaneurysms) to the blot haemorrhages, venous beading, intraretinal microvascular abnormalities (IRMA) and finally the advance preretinal and vitreous haemorrhages. The second part looks at the problem of exudative maculopathy which consist of macular hard exudates and macular oedema. It should be noted that macular oedema can only be appreciated if the digital imaging system has stereoscopic capabilities. However, the best method for looking at retinal thickening is still by indirect ophthalmoscopy or slit-lamp biomicroscopy. It is important also to note that any stage of diabetic retinopathy can be associated with diabetic macular oedema based on the findings of hard exudates. We realise that the classification was based on “dilated ophthalmoscopy” but our retinal photography was taken through the undilated pupils (in most patients). Since the camera we used was able to capture a clear central view of the fundus in the majority of cases, we think further dilatation of the pupils is unnecessary. Generally speaking,

we find that the classification has assisted us in the early referral of STED to the specialists.

The prevalence of diabetic retinopathy in our community is predictably high. Early identification and treatment of diabetic retinopathy through screening is a cost effective strategy for improved health care in diabetic populations.[10] Digital retinal imaging has offered a new range of imaging possibilities with comparable sensitivity and specificity as the gold standard. Thus avenues exist for more organised screening and referral programme in our country.

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COMMENTARY

Sagili Chandrasekhara Reddy *MS(Ophth) FRCS(Glasg)*, International Medical University

Reddy SC. Commentary on "Prevalence of diabetic retinopathy in a primary care setting using digital retinal imaging technology." Malaysian Family Physician. 2006;1(1):22

The prevalence of diabetic retinopathy as determined by digital retinal imaging technology in this study was surprisingly high: 71.9% overall and 63.9% among those diagnosed less than one year. The prevalence rates are higher than hospital series using dilated direct ophthalmoscopy (44.1% from University Hospital Kuala Lumpur,[1] and 48.6% from Hospital University Sains Malaysia[2]). Is this due to the high sensitivity of retinal photography or false positives? We cannot ascertain this in the absence of verification by a gold standard. Undilated ophthalmoscopy by non-ophthalmologists has low sensitivity;[3] hence retinal photography appears to offer a solution for the currently low screening rate of diabetic eyes. However, its high cost (prices vary depending on the model) raise the question as to whether it is a cost effective approach in primary care. Study in UK general practice showed that the addition of fundus photography to routine direct ophthalmoscopy improved the detection of sight-threatening retinopathy.[4] In deciding whether to provide fundus photography service, general practitioners should bear in mind the cost of the camera and its accessories, and the pictures taken (digital or otherwise) will need to be reviewed by a person familiar with retinal abnormalities, usually an ophthalmologist. The classification systems used by the authors appear to be too complicated for routine use, and they have noted the inability of non-stereoscopic camera to detect macular oedema. The digital retinal imaging has been successfully used in telemedicine diagnosis but its proper place in primary care in still unclear.

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Address for correspondence: Assoc Prof Dr SC Reddy, Department of Ophthalmology, International Medical University, IMU Clinical School, Jalan Rasah, 70300 Seremban, Negeri Sembilan. Tel: 06-7677798, Fax: 06-7677709, Email: sagili_chandrasekharareddy@imu.edu.my