• Investigation •

Descriptive assessment on diabetic retinopathy screening in an awareness programme in Malaysia

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Abstract

● **AIM:** To determine the prevalence of diabetic retinopathy (DR) among diabetic patients at the primary health clinics in Selangor, Malaysia.

● **METHODS:** All diabetic patients were screened in Retinal Disease Awareness Programme (RDAP) and those who had significant DR changes were referred to the hospital for further management. Descriptive analyses were done to determine the prevalence of DR and sociodemographic characteristics among patients with diabetic. Univariate and multivariable analysis using Logistic regression were performed to find association and predictor factors in this screening.

● **RESULTS:** A total of 3305 patients aged 40y and above were screened for DR. Of the patients screened, 9% patients were found to have DR and other visual complication such as maculopathy (0.9%), cataract (4.8%) and glaucoma (0.4%). The mean age of patients without retinopathy was 57.82±8.470y and the mean age of patients with DR was 63.93±9.857y. About 61.5% of the patients screened were aged below 60y and 38.5% were aged 60y and above. Majority of the patients screened were women 58.5% and Malay in the age group of 50-59y, while 27% were aged 60-69y. Significant association were found between age, sex, race, visual loss and DR.

● **CONCLUSION:** Although the prevalence of DR among patients is not alarming, effective interventions need to be implemented soon to avert a large burden of visual loss from DR.

● **KEYWORDS:** diabetic retinopathy; retinal disease awareness programme; eye screening; Selangor
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INTRODUCTION

Diabetic retinopathy (DR) is one of the main causes of avoidable blindness and commonly found among diabetic patients in low- and middle-income countries[1]. The burden of diabetes indicates a rapid increment in developing countries[2]; this is no exception to Malaysia.

The prevalence of DR among patients with diabetes is 34.6% worldwide[3], while DR was the cause of blindness in 10.4% of

Malaysian older persons, as seen in the National Eye Survey in Malaysia (NESII)[4]. However, blindness from DR can be prevented if the disorder is detected early[5], which requires timely screening and treatment[6]. Early detection depends on regular eye examination involving both visual acuity assessment and ophthalmoscopy through dilated pupils by experienced personnel.

The World Health Organization (WHO) criteria for screening programs of DR stipulate that the condition has to be in the early recognizable or at latent stages, with effective, well-accepted treatment options, and the condition must be an important public health concern[7]. The government's efforts to increase patient screening should be also proportionate to the awareness of DR among the population. Generally, DR screening in high income countries are done as systematic screening. In low-income settings, the common practise is opportunistic screening and case detection[8] *via* direct ophthalmoscopy, which has a lower diagnostic accuracy and is less effective even after training[9].

Retinal Disease Awareness Programme (RDAP) in Selangor, Malaysia was initiated to enhance the existing screening programmes conducted by the local health clinics under the Ministry of Health (MoH), Malaysia since 2010. These efforts were meant for the population especially those who live at the outskirts of urban areas and small cities across the country. On the other hand, it also fulfils the needs of people living with diabetes (PLWD) to identify barriers to uptake of screening for DR. This paper aims to determine the distribution of DR among diabetic patients who take part in RDAP in the primary health care setting in Selangor, Malaysia. Indirectly, the health promotion programme will be strengthened especially on knowledge and awareness through evidence informed policy. Support and participation by the local community in order to identify high-risk groups that do not receive screening is important for improvement in their uncontrolled diabetes as well as their vision. Furthermore, a systematic database of diabetic patients related to retina diseases will be able to be established in Selangor.

SUBJECTS AND METHODS

Ethical Approval This study was registered under the Malaysia National Medical Research Registry (NMRR) with the identification number NMRR-18-2010-43185 and funded by MoH. The Malaysian guideline permits the use of secondary data from the registry if the data are anonymised. Hence, the data were de-identified prior to analysis.

Data for this study was obtained from RDAP registry. The RDAP routinely records information on patients with diabetes mellitus (DM) managed by MoH participating health clinics. RDAP is a program targeting all the diabetic patients in government primary health clinics under MoH. DR screening was done as an opportunistic screening and case detection that is common in Malaysia setting. Hence, all patients diagnosed with diabetes who attended RDAP programme were screened for DR.

Data Collection A total of 3879 diabetic patients were identified in 21 participating primary health clinics in Selangor between March 2015 and December 2016 from the RDAP registry. We excluded patients that were not in the index clinic according to the address of the patient or if patients attended more than once, only the latest screening was used. After filtering the data, 21 duplicates were found and 326 patients were excluded. We also excluded patients with incomplete information and loss to follow up, newly diagnosed diabetic and patient less than 40y. Therefore, a total number of patients eligible for screening were 3532 across Selangor. Of 3532, only 3305 patients aged 40 years old and above were included for the final analysis. Patients with significant DR changes were then referred to the nearest hospital for further management. The ophthalmology team from every hospital in Selangor, Kuala Lumpur and Putrajaya participated in this program. The patients underwent an eye examination and fundus photography which is a non-invasive and safe procedure[10].

The eye examination was conducted by the ophthalmology team. The examination consisted of visual acuity testing by Snellen chart followed by fundus photography for DR assessment. Eyes were dilated prior to fundoscopy assessment. Visual loss was classified as mild (6/9 to 6/12), moderate (6/18 to 6/60) and severe (worse than 6/60). Each eye was subjected to two non-stereoscopic 45º photographs; macula-centred and optic disc centred photograph. The photographic fields were equivalent to Diabetic Retinopathy Study (DRS) standard fields 1 and 2. A trained photographer took retinal images and sent them to a remote trained reader (typically an ophthalmologist or optometrist) for interpretation (Figure 1).

The international clinical DR severity scale by the American Academy of Ophthalmology (AAO) were used to classify patients into non-proliferative diabetic retinopathy (NPDR), proliferative diabetic retinopathy (PDR) and maculopathy[11]. NPDR was defined as presence of any of the following: micro-aneurysms, intra retinal haemorrhage, venous beading, or intra retinal microvascular abnormalities (IRMAs) and no signs of proliferative retinopathy. PDR was defined as neovascularization or vitreous or pre-retinal haemorrhage. Fundus photographs then were graded as having no DR, NPDR, PDR, advanced diabetic eye disease (ADED), cataract, maculopathy and glaucoma suspect[12]. A study showed that fundus photography telemedicine has acceptable sensitivity and specificity for screening of DR compared to in-person screens. In addition, it is more cost-effective and well-liked by

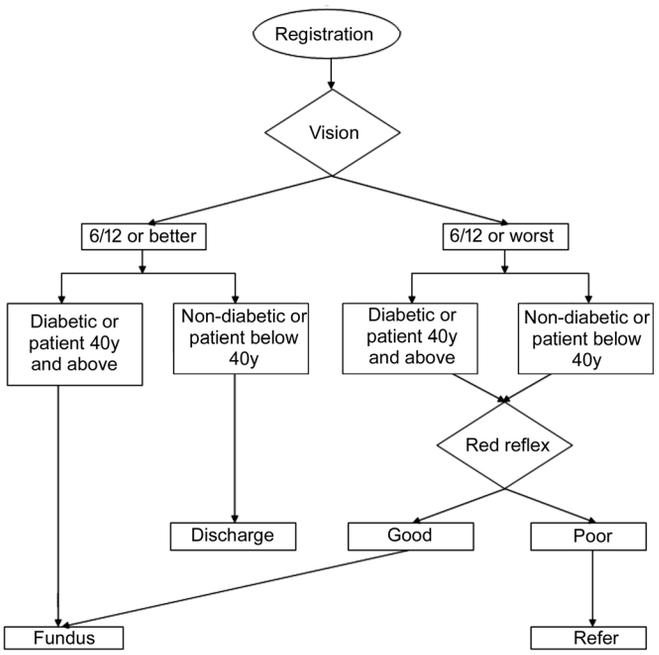

Figure 1 Workflow for RDAP outreach.

patients[13-14]. In Malaysia, DR screening is conducted by using non-mydriatic mobile digital fundus camera in diabetic eye. These cameras are operated by paramedical staff who capture the fundus images. Fundus images that are captured can be graded at site at selected centre and send *via* internet to hospital or clinics with eye care providers such as ophthalmologist and optometrist. This will help reduce the waiting time among patients and appropriate referral to the ophthalmology clinic can be achieved in shorter time. This will minimise cost of travelling to the designated hospital and treatment can be advice in shorter duration[15].

Statistical Analysis Basic characteristics of the patients and eye-related variables were described and performed using frequencies, means (SD) or percentages for continuous and categorical variables. Univariate and multivariable analysis using logistic regression was used to investigate the relationship between DR and a number of explanatory variables such as age, gender, race and left and right eyesight. *P*-value of <0.05 was considered to indicate statistical significance and all analyses were performed using SPSS version 22.

RESULTS

The mean age of the screening population was 58.36±8.774 years old and 58.5% were women and from this 57.3% were diagnosed to have DR. The mean age of patients without DR was 57.82±8.470 years old and the mean age of patients with DR was 63.93±9.857 years old. Based on age group, the commonest was those aged below 60 years old consisting of about 61.5% as compared to those aged 60 and above years old which comprised of 38.5% of the population (*n*=3305). Of this 15% were DR and aged 60 and above years old. In terms of ethnicity, Malay was predominant ethnic group at approximately 62.6%, whereas non-Malay which consists of Chinese and Indian, comprised about 37.4%. Approximately 30.9% and 30.8% of the population have normal vision for their right and left eyesight respectively. However, vision loss categorised as mild, moderate and severe categories was more than 65% for both eyes. The basic characteristics of the patients including age, sex, race, eyesight and ocular co-morbidity were showed in Table 1.

Table 1 Basic characteristics of patients with and without DR in RDAP in Selangor 2015-2016

Characteristic	Total (*n*=3305)	No DR (*n*=3012)	DR (*n*=293)
Age mean±SD	58.36±8.774	57.82±8.470	63.93±9.857
Age category			
Below 60 years old	2034 (61.5)	1927 (94.7)	107 (5.3)
60 and above years old	1271 (38.5)	1085 (85.4)	186 14.5)
Sex			
Male	1373 (41.5)	1248 (41.4)	125 (42.7)
Female	1932 (58.5)	1764 (58.6)	168 (57.3)
Race			
Malay	2070 (62.6)	1940 (64.4)	130 (44.4)
Non-Malay	1235 (37.4)	1072 (35.6)	163 (55.6)
Right eyesight			
Normal	1022 (30.9)	1022 (33.93)	0
Mild	1936 (58.6)	1929 (64.04)	7 (2.39)
Moderate	347 (10.5)	61 (2.03)	286 (97.61)
Left eyesight			
Normal	1018 (30.8)	1018 (33.80)	0
Mild	2145 (64.9)	1957 (64.97)	188 (64.16)
Moderate	142 (4.3)	37 (1.23)	105 (35.84)
Ocular co-morbidity			
No	3105 (94.0)	2921 (96.98)	184 (62.80)
Yes	200 (6.0)	91 (3.02)	109 (37.20)

RDAP: Retinal Disease Awareness Program; DR: Diabetic retinopathy.

Based on fundus camera's screening criteria for DR, about 9% of the patients screened were found to have DR and out of 3305 patients screened, 200 were detected having ocular co-morbidity, *i.e.* 0.9% patients have maculopathy, 4.8% of patients have cataract and 0.4 % patients have glaucoma. In terms of DR, the majority had NPDR (8.2%), while the rest had PDR (0.2%) and ADED (0.1%) as depicted in Table 2. Among all the fundus photographs, 3.3% (109/3305) were graded as ungradable for one or both eyes mostly because of poor image quality due to ocular media opacity or a too small pupil.

Those with DR were significantly associated with older age, female, Malay, abnormal left and right eyesight. No significant association was found between presence of ocular co-morbidity and DR. Multivariable logistic regression analysis revealed that 2 variables age and sex were protective against the outcomes. Patient getting older for every one year of

increment in their age are less likely to have DR as compared to those younger patients and female is less likely to have DR as compared to male. On the other hand, Malay is 2 times more likely to getting DR as compared to non-Malay. Abnormal eyesight of left and right are also 2 times more likely to have DR as compared to normal eyesight for both eyes (Table 3).

DISCUSSION

DR is increasingly becoming a serious complication of diabetes and a major cause of blindness in adults aged 20-60y[16]. In general, we found that prevalence of DR was nearly 9% aged ranging from 40 to 89 years old. Other eye diseases that may compromise vision, such as cataract and glaucoma appear to increase the prevalence among patients with diabetes[17].

According to Goh *et al*[15], prevalence of DR in Malaysia based on the 2007 Diabetic Eye Registry was 36.8%, which is comparable to the Singapore Malay Eye Study 2006 in which the prevalence was 35%[18]. However, other unpublished local data obtained from primary care screening centres showed a prevalence ranging between 12.3% and 16.9%[19-20]. Most of the patients having DR were those aged 40y and above that represented 85% of the screening population. We considered our prevalence quite low compared to worldwide estimates prevalence ranging from 17.6% of a study in India to 33.2% from United States[21]. One of the reasons could be that our sample population was small compared to a study done by Rema *et al*[22] in Urban India that involved big sample of populations (n=26 001) aged 20 years old and above. In addition, the Malaysian National Health and Morbidity Survey (NHMS) in 2006 found that 45% of the diabetic patients never underwent eye screenings, a finding comparable to United States and Australia[15]. Other reasons such as lack of awareness among healthcare providers (HCP) related to the need for diabetic eye screening, non-adherence to the clinical practice guidelines (CPG), patients defaulting on follow-up examinations, overcrowding at public health clinics or HCPs not being proficient in the use of direct ophthalmoscopes to examine the fundus have affected diabetic patients undergoing eye examination[22].

Recent findings by Piyasena *et al*[23] also stated that lack of knowledge and awareness, socio-cultural, economic and institutional factors were the main domains of barriers to access DR screening services in Sri Lanka.

In this RDAP, most patients were female. A population-based study done in Korea also showed that prevalence of DR was higher in women (16.0%-17.7%) than in men (12.7%-14.3%)[24]. According to Kollias and Ulbig[25], women are more likely to have diabetes compared to men and risk of blindness is almost twice in women. This was supported by Marburg University Department of Ophthalmology which revealed 446 women and 233 men with diabetes in the state of Hesse were severely visually impaired. Moreover, pregnancy can lead to progression of DR[25]. Study done by Kyari *et al*[26] in Nigeria reported over 10% of people with diabetes aged ≥40y had sight-threatening DR possibly due to uncontrolled diabetes and hypertension. Our data also showed high proportion of vision loss among patients with diabetic and aged 40 and above years old. These data will enable better public health strategies in order to control diabetes and planning services for DR in preventing vision loss. According to Zheng *et al*[27] vision loss among patients with diabetes were due to lack of adherence to diabetes vision care guidelines for example in USA, one-third of the patients with diabetes failed to follow vision care guidelines and in China, this issue has reached crisis proportion of more than 60%.

In many locations around Selangor, diabetes patients are being seen for initial eye examinations, however it is a bigger challenge to retain these patients for their follow-up. This difficulty in following up with patients is not just a

Table 2 Distribution of patients with visual complication during DR screening in RDAP 2015-2016

Type of visual complications	Frequency	Percent (%)
NPDR	282	8.2
PDR	8	0.2
ADED	3	0.1
Maculopathy	30	0.9
Cataract	158	4.8
Glaucoma suspect	12	0.4
Total	493	14.6

RDAP: Retinal disease awareness program; DR: Diabetic retinopathy.

Table 3 Univariate and multivariable logistic regression analysis for factors associated with the presence of DR

Characteristic	Univariable analysis			Multivariable analysis		
	OR	95%CI	*P*	Adjusted OR	95%CI	*P*
Age mean±SD	0.963	0.961-0.965	<0.001	0.941	0.935-0.947	<0.001
Sex						
Male	0.095	0.081-0.112	<0.001	0.649	0.51 -0.816	<0.001
Female						
Race						
Malay	0.152	0.129-0.179	<0.001	1.688	1.335-2.133	<0.001
Non-Malay						
Right eyesight						
Normal	0.147	0.130-0.166	<0.001	2.398	1.542-3.730	<0.001
Abnormal						
Left eyesight						
Normal	0.147	0.13-0.166	<0.001	2.229	1.440-3.451	<0.001
Abnormal						
Ocular co-morbidity						
No	1.198	0.907-1.582	0.204			
Yes						

Significant when P<0.05. DR: Diabetic retinopathy.

local phenomenon but also happens in other countries. Based on NHMS 2006, Goh *et al*[15] reported a low percentage of diabetics who had undergone eye examinations due to lack of awareness among HCP regarding the need for diabetic eye screening, non-adherence to the CPG, patients defaulting on follow-up examinations, overcrowding at public health clinics or HCPs not being proficient in the use of direct ophthalmoscope to examine the fundus.

A recent study conducted by Keenum *et al*[28] which was based largely in an urban setting of African American population also showed less than 30% of the study participants fulfilled their recommended follow-up ophthalmic examinations[28]. In addition, Gibson[29] also reported that based on 2005-2008 National Health and Nutrition Examination Survey (NHANES), 73% of adults aged 40 and over with DR were unaware of their condition especially in patients with less severe DR, shorter diabetes duration, and lack of a recent eye examination. Ideally patients with diabetes should have eye examination done at least once a year[30]. Ting *et al*[31] reported that optimal management of DR includes annual screening, adequate control of risk factors and timely treatment. Furthermore, improvement of awareness and education among diabetic patients is undervalued[32-33] and enhancement on these issues could lead to more effective strategies.

The fundus photographs were 3.3% ungradable and it is still acceptable in accordance to UK minimum standard requirement of less than 10%[34]. There are no data available on the outcomes of the quality control even though our consultants have received additional training on grading DR in the UK. It is important that adequate quality control is incorporated into screening programmes which could be addressed through partnership with accredited international reading centres and a better collaboration between endocrinologists and ophthalmologists is required to improve screening outcomes[35]. In conclusion, this is considered the largest study estimating the prevalence of DR from a regional DR screening programme in Selangor, Malaysia. The prevalence of DR was nearly 9% provides an important data for policymakers to aid in planning DR services, identifying the reasons and strategies to improve follow-up of patients after screening in Malaysia. Visual disabilities due to DR are likely to increase in the coming years. An organized public health approach must be adopted and all stakeholders must work together to control severe visual disabilities due to DR.

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