

ORIGINAL ARTICLE

**CLINICAL CHARACTERISTICS OF DIABETIC RETINOPATHY
IN DIABETES MELLITUS PATIENTS IN TEMPURAN
DISTRICT, KARAWANG REGENCY, WEST JAVA**

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ABSTRACT

Introduction: Diabetic retinopathy (DR) is a major diabetic microvascular complication, affects 1 in 3 person with Diabetes Mellitus (DM). DR remains a leading cause of severe, irreversible visual impairment, and blindness in working aged population worldwide. Screening, early detection and prompt treatment of Vision-Threatening Diabetic Retinopathy (VTDR) allow prevention of diabetes-related visual impairment. Poor access to eye health care in rural area may become a factor of increasing number of underdiagnosed of DR.

Objective: To identify characteristic of DR and its associated risk factor in primary health care in Tempuran, Karawang, West Java.

Methods: A cross-sectional study was conducted on participants who met the inclusion criteria and the fundus photograph was done to evaluate the retinal status. Demographic data, visual acuity, and other ocular comorbidities was also documented.

Results: A total of 57 participants with diabetes were examined for fundus photograph. Any DR, diabetic macular edema (DME), and VTDR in this study were found 54,4%, 14%, and 15,8% respectively. DR were found higher in participants with older age, women, shorter duration of diabetes, hyperglycemia, and hypertension.

Conclusion: This study identified the characteristic of DR in primary health care in Tempuran, Karawang, West Java. The results of this study may become a recommendation for periodic diabetes screening of DR in the region.

Keywords: diabetic retinopathy, diabetes mellitus, screening of DR

ABSTRAK

Latar Belakang: Retinopati diabetik (*Diabetic retinopathy/DR*) merupakan komplikasi mikrovaskular diabetes utama yang mempengaruhi 1 dari 3 orang dengan Diabetes Melitus (DM). DR tetap menjadi penyebab utama dari gangguan penglihatan yang berat serta kebutaan pada populasi usia kerja di seluruh dunia. Skrining, deteksi dini, dan tatalaksana secara dini dari retinopati diabetik yang mengancam penglihatan (*Vision-Threatening Diabetic Retinopathy/VTDR*) memungkinkan pencegahan kebutaan akibat diabetes melitus. Kurangnya akses ke pelayanan kesehatan mata di daerah pedesaan dapat menjadi faktor meningkatnya jumlah DR yang tidak terdiagnosis.

Tujuan: Untuk mengidentifikasi karakteristik klinis retinopati diabetik dan faktor risiko terkait di layanan kesehatan primer di Kecamatan Tempuran, Kabupaten Karawang, Jawa Barat.

Metode: Penelitian ini merupakan penelitian *cross-sectional* yang dilakukan pada penderita DM yang memenuhi kriteria inklusi dan dilakukan foto fundus untuk mengevaluasi status retina. Data demografis, tajam penglihatan, dan komorbiditas okular lainnya juga didokumentasikan.

Hasil: Sebanyak 57 pasien dengan diabetes yang memenuhi kriteria inklusi dilakukan foto fundus. Pada penelitian ini ditemukan *any-DR*, edema makula diabetik (DME), dan VTDR sebesar 54,4%, 14%, dan

15,8%. DR ditemukan lebih tinggi pada peserta dengan usia yang lebih tua, wanita, durasi diabetes yang lebih pendek, hiperglikemia, dan hipertensi.

Kesimpulan: Penelitian ini mengidentifikasi karakteristik klinis DR di layanan kesehatan primer di Kecamatan Tempuran, Kabupaten Karawang, Jawa Barat. Hasil penelitian ini dapat menjadi rekomendasi untuk skrining retinopati diabetik secara berkala di wilayah tersebut.

Kata Kunci: retinopati diabetik, diabetes melitus, skrining retinopati diabetik

INTRODUCTION

Diabetic retinopathy (Diabetic Retinopathy/DR) is one of the common microvascular complications that occur in Diabetes Mellitus (DM) patients. According to World Health Organization (WHO), it is estimated that the total number of people with DM will double from 171 millions people in 2000 to 366 millions people in 2030. International Diabetes Federation (IDF) stated that there were around 10.2 million cases of diabetes in Indonesia with a prevalence of 6.7% in 2017. This number did not include people with undiagnosed diabetes, which accounts for nearly 50% of total diabetes cases in the population.¹⁻⁴

Data from 35 population-based studies worldwide, estimated the prevalence of DR, Proliferative Diabetic Retinopathy (PDR), and Vision-Threatening DR (VTDR) were 34.6%, 7.0%, and 10.2% respectively in individuals with DM in 2010. The duration of DM, severity of hyperglycemia, and hypertension are risk factors and associated with the progression of DR. Blood glucose control is the standard for the management of mild NPDR (Non-Proliferative Diabetic Retinopathy) and moderate NPDR accompanied with regular clinical monitoring.^{1,5,6}

American Diabetes Association (ADA) and the American Academy of Ophthalmology (AAO) recommend that adults and children older than 10 years with type I DM should have a comprehensive ophthalmological examination by an ophthalmologist within the first 3-5 years after diagnosed with diabetes. Likewise in type 2 diabetes, patients should be screened for DR at the time of diagnosis. Presence of DR (NPDR, PDR, and macular edema) indicates referral to an ophthalmologist, recommended for more frequent evaluation, regular fundus examination, and effective laser management at the appropriate time when needed.^{7,8}

Ideal diabetic retinopathy screening strategy still does not exist. Digital photography is reported to be the best method for DR screening. Assessment of the degree of DR with fundus photography which become the reference standard for the detection of DR is by examination of the 30° stereoscopic 7-field mydriatic fundus photo with an assessment by a certified reader/grader according to the recommendations of the Early Treatment Diabetic Retinopathy Study (ETDRS). Several studies have compared stereoscopic 45° single-field and 2-field

stereoscopic retinal fundus photos. The 2-field fundus radiograph has the advantage of detecting DR in the nasal retinal area that may be missed by a single visual field examination^{7,9}

Indonesian government has developed a strategy to overcome DM in Indonesia, one of which is the Chronic disease management program (Program Penanggulangan Penyakit Kronis/PROLANIS). PROLANIS is a government health insurance service for people with diabetes and hypertension at the Primary Health Center (PHC). This study aims to determine the characteristics of DR patients in the DM population at Tempuran District Health Center, Karawang Regency, West Java, integrated with the community service program as a revitalization of Bumi Walagri, Padjadjaran University.¹⁰⁻¹²

MATERIAL AND METHOD

Design and Subject

This study is a descriptive study. Data collection was done by cross-sectional. Samples were taken consecutively on DM patients at PROLANIS and non-PROLANIS services at Lemahduhur Primary Health Center and Tempuran Primary Health Center, Tempuran District, Karawang Regency.

Data collection was carried out on September 13, 2018 at the Lemahduhur Health Center and 6 October 2018 at the Tempuran Health Center. Inclusion criteria were patients who had been diagnosed with DM or blood sugar when 200mg/dL at that time of examination and diagnosed with DM according to the DM diagnostic criteria of ADA. All participants underwent stereoscopic fundus examination for retinal evaluation.

Screening Procedure

Demographic data collection regarding age, gender, history of DM, duration of DM, education, and occupation were recorded in detail. All patients underwent initial blood pressure measurement, random blood sugar levels measured using the Accu-Check Blood Glucose Meter, visual acuity were evaluated using Snellen chart at 6 meters distance, lens status was assessed with Loupe and torch and other ocular comorbidities were recorded.

Fundus Photo and DR Classification

All participants who met the inclusion criteria were subjected to a 2-field stereoscopic fundus examination (macular and papillary centration) using the Smartscope Pro Portable Fundus Camera (Optomed, Oulu, Finland). Fundus photographs were performed by a trained ophthalmic photographer in dilated pupil after mydriatic administration of 1% tropicamide eye

drops. Fundus photo quality was rated as 1 (overall gradeable); 2 (partially gradeable); 3 (cannot be graded); 4 (no photo exist). Fundus photo with a quality that could not be assessed due to media opacity were excluded from this study. All fundus photos were evaluated by 1 certified grader, retinopathy status and DR classification were recorded.

DR classification based on ETDRS are; mild NPDR if there is at least 1 microaneurysm, moderate NPDR if there is microaneurysm, intraretinal bleeding, hard exudate, cotton-wool spot, venous beading, or Intraretinal Microvascular Abnormality (IRMA), severe NPDR if bleeding and microaneurysm in 4 quadrants exist, venous beading in at least 2 quadrants, and IRMA in at least 1 quadrant, Proliferative Diabetic Retinopathy (PDR) if there is neovascularization of the retina and around the optic disc, preretinal hemorrhage, or vitreous hemorrhage. Macular edema (DME) is said to be positive if there is a hard exudate, micronaneurism, dot-hemorrhage within 1 optic disc diameter from the central fovea. Vision-Threatening Diabetic Retinopathy (VTDR) is defined as the presence of PDR or macular edema of any degree of DR. Referral recommendations are made based on the International Council of Ophthalmology (ICO) with the following criteria: (1) visual acuity <6/12 or having visual complaints; (2) moderate degree of NPDR or more severe; (3) if visual acuity or retinal examination cannot be obtained by screening examination.¹³

Data Processing

The data was processed using Microsoft Excel Office 2013 and SPSS 24.0 ver programs. Descriptive data about the characteristics of the participants are presented in tabular form.

RESULTS

The initial participants who met the inclusion criteria were 66 people, a fundus photo was taken. Nine people were excluded because the quality of the fundus photos in both eyes could not be assessed due to media opacities. The final participants were 57 people with the characteristics of the participants described in Table 1.

Table 1. Characteristic of Study Subjects

Characteristics	N=57	Percentage (%)
Age (years)	average \pm SD	57,33 \pm 9,15
40 – 49	9	15,8%
50 – 59	20	35,1%
60 – 69	22	38,6%
\geq 70	6	10,5%
Gender		
Male	22	38,6%
Female	35	61,4%

History of DM		
Yes	46	80,7%
No/Unknown	11	19,3%
Duration of DM (years)		
<5	39	68,4%
5-10	3	5,3%
>10	4	7,0%
Unknown	11	19,3%
Random Blood Glucose(mg/dL)		
<200	26	45,6%
≥200	31	54,4%
Systolic BP (mmHg)		
< 140	28	49,1%
140 – 159	7	12,3%
160 – 179	13	22,8%
≥ 180	9	15,8%
Diastolic BP (mmHg)		
< 90	27	47,4%
≥ 90	30	52,6%
Education		
Elementary School	36	63,2%
Junior High School	4	7%
Senior High School	1	1,7%
College graduate	2	3,5%
No education	14	24,6%
Occupation		
Farmer/Labourer	15	26,3%
Merchant/Salesman	7	12,3%
Housewives	23	40,4%
Unemployed	6	10,5%
Etc	6	10,5%

SD=standar deviation; BP=blood pressure

The mean age of the participants in the study was 57.33 ± 9.15 . Most of the participants were in the age group 60-69 years (38.6%) dominated by female with percentage of 61.4%. As many as 80.7% of participants knew of their history of DM. The longest duration of DM was < 5 years, found in 68.4% of participants. Random blood glucose examination results $>200\text{mg/dL}$ were found in 45.6% of participants. Systolic blood pressure $<140\text{mmHg}$ and diastolic $<90\text{mmHg}$ were found in 49.1% and 47.4% of participants, respectively.

Table 2 showed the ophthalmological status of participants with a total of 114 eyes. Visual acuity in the range $\geq 6/18$ and $3/60 - 6/60$ was found in 36.8% and 26.3% out of the total participants, respectively. The results of the lens status examination showed that 75.4% (86 eyes) had senile cataract, 7.9% (9 eyes) had pseudophakia, and 2 eyes had keratopathy causing difficulties in lens assessment. Data regarding ocular comorbidities found pterygium in 3 eyes (2.6%), keratopathy in 2 eyes (1.8%), optic atrophy in 1 eye (0.9%), and subretinal fibrosis in 4 eyes (3.5%).

Table 2. Ophthalmologic status of study subjects

Characteristics	N=114 eyes (%)
Visual acuity (uncorrected)	
≥6/18	42 (36,8)
>6/60 – <6/18	15 (13,2)
3/60 – 6/60	30 (26,3)
<3/60	27 (23,7)
Lens status	
Clear	17 (14,9)
Immature cataract	83 (72,8)
Mature cataract	3 (2,6)
Pseudophakic	9 (7,9)
Unable to assess	2 (1,8)
Ocular comorbidity	
Pterygium	3 (2,6)
Keratopathy	2 (1,8)
Optic atrophy	1 (0,9)
Subretinal fibrosis	4 (3,5)

A total of 114 eyes were examined for fundus photos, 5 eyes were excluded due to poor photo quality. Forty nine eyes diagnosed with DR (44.95%) with majority mild NPDR in 29 eyes (26.6%). DR was found in the study population as many as 31 individuals (54.4%). The classification being diagnosed in the eye with a more severe degree; mild NPDR in 17 individuals (29.8%), moderate NPDR found in 8 individuals (14%) , severe NPDR in 5 individuals (8.8%), and PDR with clinical tractional retinal detachment was found in both eyes in 1 individual. Macular edema was seen in 9 eyes of 8 individuals (14%), and VTDR was seen in 11 eyes of 9 individuals (15.8%).

Tabel 3. DR Classification

DR Classification	N (DR)	(%)
Total Eyes (n=109)	49	44,95%
Mild NPDR	29	26,6%
Moderate NPDR	10	9,2%
Severe NPDR	8	7,3%
PDR	2	1,8%
Macular edema	9	7,9%
VTDR	11	9,6%
No DR	60	55,05%
Participants (n = 57)	31	54,4%
Mild NPDR	17	29,8%
Moderate NPDR	8	14%
Severe NPDR	5	8,8%

PDR	1	1,8%
Macular edema	8	14%
VTDR	9	15,8%
No DR	26	45,6%

In this study, the majority of DR patients were aged more than 50 years in 26 participants (83.87%) and female in 19 participants (61.3%). Duration of DM less than 5 years participants with DR (67.74%). The results of high random blood sugar examination ≥ 200 mg/dl found in 17 participants (54.84%). People with SBP higher 140mmHg were 21 people (67.74%) and DBP lower than 90mmHg were 20 people (64.52%).

Tabel 4. DR Distribution based on Risk Factors

Variable	Total (n=31)	Percentage (%)
Age (year)		
< 50	5	16,13%
≥ 50	26	83,87%
Gender		
Male	12	38,7%
Female	19	61,3%
Duration of DM (years)		
<5	21	67,74%
5-10	8	25,80%
≥ 10	2	6,45%
Random blood glucose (mg/dL)		
<200	14	45,16%
≥ 200	17	54,84%
Systolic BP (mmHg)		
<140	10	32,26%
≥ 140	21	67,74%
Diastolic BP (mmHg)		
<90	11	35,48%
≥ 90	20	64,52%

DISCUSSION

In this study, DR was obtained in 31 of 57 participants (54.4%). Compare to the results of the study by Sasongko et al found that the prevalence of DR in adults with type 2 DM in Yogyakarta was 43.1%. Based on data from The DiabCare Asia 2008 study, the most diabetes complications were diabetic retinopathy, as much as 42%.^{1,13}

The prevalence of DR, DME, VTDR in the greater Bandung area, West Java obtained through the DR screening program at PROLANIS, was found to be 24.7%, 8.8%, and 9% out of the total 1649 participants with diabetes. The results in this study were found to be greater with the proportion of individuals with DR 54.4%, DME 14%, and VTDR 15.8% from a total

of 57 participants. This two studies can not be compared given the number of samples that are much different.¹⁴

The higher results in this study may be due to low access to screening in rural areas. According to research in China, the prevalence of DR ranges from 28% to 43%. Low access to screening results in a higher prevalence of DR in rural than urban areas in China. The prevalence of DR in the population in Chennai, India, was found to be 17.6%. In a hospital cohort study, of 6792 type 2 DM subjects who visited a diabetes center in Chennai in South India, the prevalence of DR was 34.1%. Raman et al. reported the prevalence of DR in the population with type 2 diabetes in rural and urban areas of 10.3% and 18%, respectively.^{2,15}

Overall prevalence of DR and VTDR in type 2 DM were 25.2% and 6.9%, respectively. According to the Liverpool Diabetic Eye Study and The United Kingdom Prospective Diabetes Study (UKPDS), prevalence of DR in type 2 DM in the UK ranges from 25% to 27%. Prevalence of DR in other European countries such as Sweden, Denmark and Italy is slightly higher ranging from 30% to 40%.^{2,16}

Age and gender can become the risk factors for increasing the incidence of DR as the risk of DM increases at older age. Accordance with this study which describes that DR is most commonly found in people over 50 years of age. This is almost the same as found in the study of Kumar et al who reported majority of DR found in the age group above 60 years. However, a study in the UK mentions age become a risk factor for the progression of DR, but not for its incidence. Age variation as a risk factor can be caused by confounding factors such as environmental and individual factors, genetic variation, and selection procedures involved when conducting research.^{15,17}

Several studies have stated that gender as risk factors of DR incidence have not clearly proven. A longitudinal study by Shani et al found that DR was more common found in women but was not shown significantly increase the risk of NPDR incidence. In this study, it was found that the highest proportion of DR was female at 61.3%.^{15,18}

Nadarajan et al. reported that the risk of DR was relatively higher for individuals in the middle socioeconomic status group, and mostly unemployed individuals. Several previous epidemiological studies evaluated the incidence of DR in patients with low socioeconomic status. Socioeconomic status is not a major risk factor in the increased incidence of DR, but poor blood sugar control, longer duration of DM, and access to nearby eye health services may be more common in groups with lower socioeconomic status. Avon and Somerset stated that patients with lower levels of education were more likely to develop DR than individuals with higher levels of education. This is in accordance with the results of this study which found that

the majority of participants with low socioeconomic status and education levels may be the cause of high DR incidence in this study.^{15,19}

Systemic risk factors such as duration of DM, blood sugar control, hypertension, and obesity have an effect on increasing the incidence of DR. A study in Malaysia by Kumar et al found the highest prevalence of DR with DM duration of 5-10 years, whereas in the study by Keah et al in primary health care, found that the highest DR incidence in the group with DM duration of less than 5 years. This is in accordance with this study, the highest DR incidence found in participants with DM duration of less than 5 years.^{17,20,21}

The Jamaican Study reported that adherence to DM treatment and an increase in mean blood glucose levels were more likely to develop DR and increase DR progression. Diabetes has twice the risk for developing hypertension than non-diabetic individuals according to the Jamaican Hypertension Prevalence Study. A study by Jee et al in South Korea reported that duration of DM, HbA1C (glycated hemoglobin) level, and systolic blood pressure levels were confirmed as independent risk factors for diabetic retinopathy. In this study, high blood sugar was found in 54.84% of participants with DR, and systolic blood pressure over than 140mmHg was found in 67.74%. Other risk factors that may be associated with DR include obesity and lipid profile. The Jamaican Study also reported >80% of diabetic patients had a body mass index (BMI) >25kg/m². This study did not evaluate HbA1C, BMI, and lipid profile, but it can be suggested for further research.^{5,16,20,22}

Another comorbidity found in participants in this study was cataract. Cataracts are considered to be the main cause of visual impairment in diabetic patients with the increasing incidence of cataracts in diabetic patients. Becker et al reported the results of an observational study that the incidence of cataract diagnosis in patients with diabetes was higher than in non-diabetics, especially at younger ages. The risk of cataract doubled with respect to diabetes and increased with duration of diabetes. In line with visual disturbances in the participants of this study were not only caused by DR, but also due to cataracts. Referral for more complete examination to an ophthalmologist, performed in DR patients based on ICO referral recommendations, and in patients with cataracts causing severe visual impairment.^{23,24}

Retinal status examination with mydriatic 2-field stereoscopic fundus photo is an advantage of this study. Fundus examination of single field of view and without mydriatics is said decreasing the sensitivity of DR detection. One of the limitations of this study is the small number of samples so that it cannot represent the population at risk in the area. This study also has limited data regarding other risk factors associated with DR such as; DM treatment, BMI, lipid profile, HbA1C, hypertension treatment, and smoking risk factors. This is due to the

limitations of the examination tools. Further research is recommended to be carried out in a population with a larger sample, recording and measuring complete data on risk factors related to diabetes mellitus and diabetic retinopathy.

CONCLUSION

Diabetic retinopathy was found to be quite high in the population at risk at the Puskesmas Tempuran District, Karawang Regency in this study. However, this cannot describe the entire population at risk in this region because not all patients with diabetes have been screened for diabetic retinopathy. Risk factors such as age, gender, blood sugar control, hypertension, and socioeconomic status may play a role in the incidence of DR in this region. The clinical findings in this study can serve as a reference for further improvement of the screening program and referral system for diabetic retinopathy in this region. Further research and screening is needed using the total sampling method or cluster random sampling in order to describe the incidence of the disease in the population, and continued with the analysis of risk factors and prevalence of individuals with diabetic retinopathy.

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