

Study on risk factors associated with diabetic retinopathy among the patients with type 2 diabetes mellitus in South India

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印度南部 2 型糖尿病患者糖尿病视网膜病变相关危险因素的研究

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摘要

目的:探究 2 型糖尿病患者糖尿病视网膜病变(DR)的严重程度及受试者中糖尿病视网膜病变严重程度与其病程、糖化血红蛋白水平、高血压史、年龄和性别的相关性。

方法:横断面研究。2012-05/06,采取简单随机抽样方法进行结构化问卷调查,收集 100 例年龄 ≥ 35 岁糖尿病视网膜病变患者。进行描述性统计、单变量和多变量有序逻辑回归分析。用 excel 表进行数据录入,并用 SPSS 21.0 进行数据分析($P < 0.05$)。

结果:100 例患者,平均年龄 53.16 ± 10.81 (35 ~ 78) 岁。通过单因素分析发现,糖尿病视网膜病变严重程度与年龄($P < 0.01$),糖尿病病程($P < 0.001$),糖化血红蛋白水平($P < 0.001$),糖尿病家族史($P < 0.01$),高血压病史($P < 0.05$),均呈正相关,高密度脂蛋白(HDL)及年龄与 DR 严重程度无相关性。除年龄因素外,上述所有因素均为影响糖尿病视网膜病变严重程度的独立危险因素。

结论:研究表明,糖尿病病程、糖化血红蛋白水平、糖尿病家族史、高血压病史以及性别与糖尿病视网膜病变严重程度密切相关。但多因素分析中,年龄、HDL 因素与 DR 严重程度无关。因此,利用现有治疗手段的有效性和及时控制,可以预防和消除视力威胁性疾病,延缓 DR 的发生。

关键词:糖尿病视网膜病变;危险因素;糖尿病视网膜病变严重程度;多变量分析

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Abstract

• **AIM:** To find the severities status of diabetic retinopathy (DR) among the patients with type 2 diabetes mellitus and to determine the association of the severities of diabetic retinopathy with duration of DR, HbA1C levels, history of hypertension, age and gender in the study population.

• **METHODS:** Hospital based cross-sectional studies with sample of 100 patients with DR were selected by using simple random sampling technique with a structured questionnaire was conducted in May to June 2012. The study participants those who with DR aged ≥ 35 years were included in this study and an oral consent was also collected from the study participants. Descriptive statistics, univariate and multivariate ordinal logistic regression analysis were performed. MS Excel spread sheet was used for data entry and data analysis was done by using SPSS 21.0 version. Statistical significance was taken as $P < 0.05$.

• **RESULTS:** Out of 100 patients, mean age of the patient was found as 53.16 ± 10.81 (range 35-78) y. By univariate analysis, there was a positive relationship between diabetic retinopathy severity and age ($P < 0.01$), duration of DM ($P < 0.001$), HbA1C levels ($P < 0.001$), history of hypertension, family history of DM ($P < 0.05$) were highly significant, high density lipoprotein (HDL) (mmol/L) and age were not significant with $P > 0.05$ by Mann Whitney u - test. All these factors were found as independent risk factors with the severity of DR except the factor age.

• **CONCLUSION:** This study was concluded that the duration of DM, HbA1C levels, family history of DM, History of hypertension and gender were independently associated with severity of DR. However, the factors like age and HDL weren't significant with severity of DR in multivariate analysis. Therefore, by using the availability of the existing treatments and controlling in time, which can prevent and free from the vision threatening diseases or delay the occurrence of DR in their life.

• **KEYWORDS:** diabetic retinopathy; risk factors; severity of DR; multivariate analysis
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INTRODUCTION

Type 2 diabetes mellitus and its complications are the most common problems in diabetes patients in India^[1]. The prevalence of type 2 DM is very high in urban and rural populations in India^[2]. Diabetic retinopathy (DR) is the microvascular complication of diabetes and a public health problem in both developed and developing countries^[3-4]. Diabetes mellitus (DM) affects four percent of the world's population, and in that half of them have some stages of DR at a particular time period^[8]. An individual having more severe diabetes for a longer period of time then DM will increase and also getting chance of DR. It is the cause of severe blindness commonly in adult's age between 20 and 74 in developed country like United States of America and proliferative diabetic retinopathy (PDR) is the main reason to the vision loss^[5-6]. DR caused by blood vessels in the retina space may swell and leakages of fluid and it have become a worst retina^[7]. By prolong period of DR with uncontrolled high blood sugar level, this eyes are becoming worst and vision loss would happen. An individual has had diabetes more than 30y and above, then will show the signs of DR. Any one poorly controlled their diabetes, and then they will get this disease very early and severely. DR can affect the one or both eyes at a time and called as the word 'vision threatening disease'. DR having four stages and in that last stage only it affects the eye very worst and severely^[8-9]. The vision loss by DR has happen as following: firstly, it happened by developing blood vessels can develop and leak blood from it and went to the centre of the eye and it gives blurring vision. The last stage of this disease is mentioned as proliferative retinopathy and this is the most advanced stage of it. Secondly, PDR can happen by fluid leak into the centre of the macula and makes it swell and finally it causes the blurring vision^[8]. DR main symptoms are as follows: 1) The formation of block spots in the vision area and affects the vision of an individual; 2) Sensation of blurred vision to DR patient; 3) Appearing of an empty spot in the center of the vision in an individual; 4) Night time one can felt difficulty in their eye sight. Recommendations were already given by American Optometric Association that those who are having diabetes, they would have been undergone in a comprehensive dilated eye examination in an authorized eye care hospital once in a year. One can prevent or delay the development or progression of DR by using prescribed medications, controlling their sugar level in blood, controlling the high blood pressure, prescribed diet control by a dietician, doing exercises and walking regularly in the

morning and evening and avoiding consume of alcohol and smoking habits^[8]. The present study was conducted with the objectives of finding the severities status of diabetic retinopathy among the patients with type 2 diabetes mellitus and to determine the association of the severities of DR with age, gender, duration of DR, HbA1C levels, high density lipoprotein (HDL), triglycerides, family history of DM and history of hypertension in the study population.

SUBJECTS AND METHODS

In this present study, we have done a hospital based cross-sectional study and by using the simple random sampling method and found a sample of 100 diabetic retinopathy with type 2 DM patients were selected and included. This study was done in May to June 2012 in Aravind Eye Hospital, Thavalakuppam, Puducherry (UT), South India. The main objectives were finding the severities status of diabetic retinopathy among the patients with type 2 diabetes mellitus and to determine the association of the severities of DR with duration of DR, HbA1C levels, history of hypertension, age and gender in the study population.

Selection Method of the Study Participants All the study participants were screened those who were attended for their eye check-up on the data collection date by a comprehensive dilated funduscopy examination and to detect DR by in direct ophthalmoscopy testing by an ophthalmologist and all other clinical data were obtained from medical record sheet from the medical laboratory of the hospital after getting the proper permission from the chief doctor and ophthalmologist, Aravind Eye Hospital, Pondicherry. Pre-designed and pre-tested questionnaire was used to collect the data.

Inclusion criteria as defined as, those who are having type 2 diabetes mellitus at least one year and willing to participate were included in this study. Patients with aged $\geq 35y$ and those who were the residence of Puducherry with more than one year were included and data collected from them by using a structured questionnaire and received the oral consent from the study participants. No stipend was given to the participants in this study. Exclusion criteria: those who are affected by the other diseases like coronary heart diseases and chronic diseases. Those who weren't willing or not giving oral consent to participate in the study and non-residence of Puducherry. Ethical issues aren't applicable to our study because this study was purely based on applied statistical model. Oral consent had obtained from the study participants. Classification of severity and definition of the stages of diabetic retinopathy as follows, in this study, we have used the four stages of diabetic retinopathy and as follows. 0 indicates (Mild non-proliferative retinopathy): this the first stage in DR, and form Micro aneurysms^[9-10]. They are small, its causes swelling in retina's very small blood vessels and it is visible. 1 indicates (Moderate non-proliferative retinopathy): this is the second stage in DR. The disease progresses, some blood vessels that bulged in size in the retina and are blocked it. 2 indicates (Severe non-proliferative retinopathy): this is the third stage in DR. Most of the blood

vessels are blocked, and blood supply were stopped in the retina. The blocked areas of the retina only send the signals to the body and help to grow new blood vessels for nourishment. 3 indicates (Proliferative retinopathy); this is the fourth and advanced stage in DR. This stage is called proliferative retinopathy (PDR). In this stage, new blood vessels were abnormally growing in the retina, surface of its vision area and a leakage of vitreous gel inside of the eye. If the walls are leak blood into the center of the retina, then the severe vision loss and finally blindness can also be happened to an individual. In this study, we have taken the diabetic retinopathy severity as follows: 1) Mild non – proliferative retinopathy; 2) Moderate non – proliferative retinopathy; 3) Severe non – proliferative retinopathy; 4) Proliferative retinopathy. Classification of the factors age, gender, duration of DM, HDL, HbA1C, Family history of DM and history of hypertension as follows. In our present study, the significant variables were taken as an ordinal variable like as follows: Age taken as 0 denotes 35 – 44y; 1 denotes 45 – 54y and 2 denotes 55y and above; Gender = 1, if male and = 0, female otherwise; Family history of DM = 1 if one individual had diabetes mellitus and otherwise = 0. History of hypertension = 1 if one individual had hypertension and otherwise = 0; Duration of DM was also taken as 0 denotes 1 to 5 years, 1 denotes 6 to 10y, 2 denotes 11 – 15y and 3 denotes 16y and above; HDL was taken as 0 denotes 30 – 39 mg/dL, 1 denotes 40 – 49 mg/dL, 2 denotes 50 and above (mmol/L); HbA1C level were also mentioned as 0 which was denotes less than 7% , 1 denotes 7 – 8.5% , and 2 denotes >8.5% .

Software Used for Data Entry, Compilation and Statistical Analysis Microsoft Excel spread sheet was used for data entry and data analysis was done by using the SPSS 21.0 version. In this study, we have used the quantitative data were expressed in term of descriptive statistics like mean and standard deviation and proportions. For finding the association between duration of DR with HbA1C we used Chi-Square test were performed. In our study, the statistical analysis were performed as 1) Univariate Analysis: the association between DR severity and other variables were obtained by using spearman’s rho (correlation coefficient) or Mann Whitney *U* – test for independent samples wherever applicable; 2) Multivariate analysis: multivariate ordinal logistic regression analysis was used. By univariate analysis the relationship between the severity of DR and the variables like, age, gender, HbA1C, triglycerides, HDL, family History of DM, duration of DM, history of hypertension. In our study, the severity of DR was taken as a dependent variable. The variables which were found significant by univariate analysis and they were entered as an independent variable in multivariate analysis and backward selection of variables was performed. Statistical significance was taken as $P < 0.05$.

RESULTS

In our study, out of 100 patients 59 (59%) were male and 41 (41%) female. The mean age of the study participants with

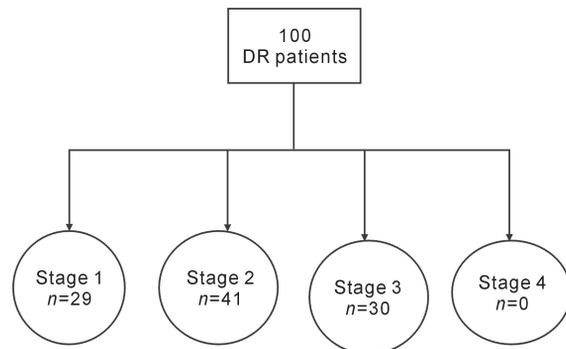


Figure 1 Distribution of the study participants with diabetic retinopathy among the severity of diabetic retinopathy.

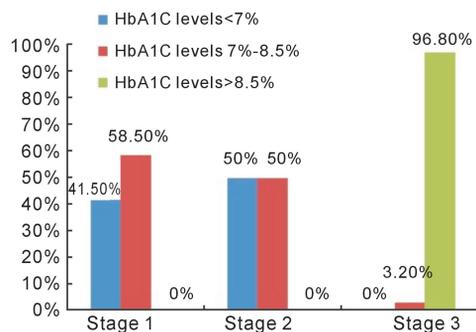


Figure 2 Distribution of severity of DR, HbA₁C levels and its association with severity of diabetic retinopathy.

known type 2 diabetes mellitus was found as 53.16 ± 10.81 (range:35 – 78) y. The median age of the study participants was 53 years. Among the study participants, 36% of patients in the age – group of 45 – 54y, 26% were under the age – group of 55 – 64y and followed by 17% patients under the age – group of above 65y. The 85th and 95th percentiles of the age were 65.85y and 74.95y respectively. The mean HbA1C (%) was found as 7.22 ± 3.11 , mean triglyceride (mg/dL) was 74.99 ± 12.07 , mean HDL (mg/dL) was 41.88 ± 6.22 and mean duration of diabetes was 9.67 ± 4.48 . The level of HbA1C was higher in patients with severe PDR and its mean value was found as 11.58% than in patients with Non – PDR mean was 5.44%. Among 100 patients, 29% of them were in stage 1 (Non – PDR), 41% in stage 2 (moderate PDR), 30% in stage 3 (severe PDR) and none of them in stage 4 (PDR) as shown in Figure 1.

By univariate analysis, there was a negative association between DR severity and age was obtained as Spearman’s rho = -0.288 , $P = 0.004$ and it was found as statistically significant. Positive association was found in between HbA1C levels and DR severity as Spearman’s rho = 0.706 , $P < 0.001$ and which was significant. The above multiple bar diagram shows that the association between severity of DR and HbA1C with $P = 0.041$ ($P < 0.05$) which was statistically significant as shown in Figure 2.

Positive association was found in between duration of DM and DR severity as Spearman’s rho value 0.345 with $P < 0.001$ and which was statistically significant as shown in Table 1.

Table 1 Distribution and association between the severity of diabetic retinopathy and duration of diabetes mellitus

Stages and severity of diabetic retinopathy	Duration of DM (in years)				Total n=100(%)
	1-5a, n=15(%)	6-10a, n=53(%)	11-15a, n=20(%)	16a and above, n=12(%)	
Mild NPDR (Stage 1)	6 (40.0)	18 (34.0)	3 (15.0)	2 (16.7)	29 (29.0)
Moderate NPDR (Stage 2)	6 (40.0)	24 (45.3)	9 (45.0)	2 (16.7)	41 (41.0)
Severe NPDR (Stage 3)	3 (20.0)	11 (20.8)	8 (40.0)	8 (66.7)	30 (30.0)

Negative association was found in between HDL and the DR severity as -0.254 with $P=0.011$, $P<0.05$. Triglyceride (mmol/L) wasn't statistically significant with severity of DR in univariate analysis. Male gender 2.10 ± 1.41 vs 1.59 ± 1.61 for female patients; $P=0.040$, $P<0.05$ was found as statistically significant by Mann Whitney U -test. This revealed that the male gender patients were exhibited more advanced DR than the female patients. History of hypertension 1.89 ± 1.51 vs 0.77 ± 0.42 for patients without hypertension with $P<0.001$ was also found as very highly statistically significant. From this, we must conclude that the patients with hypertension presented with more severe DR. By multivariate analysis model factors those were statistically significant with severity of DR in univariate analysis that were taken and substitute in multiple ordinal logistic regression analysis and the results were found as gender with $OR=3.38$ (95% $CI=1.58-6.73$, $P<0.001$), duration of DM; $OR=4.22$ (95% $CI=1.09-6.20$, $P<0.001$); HbA1C levels $OR=4.73$ (95% $CI=2.83-10.75$, $P<0.05$); Family history of DM $OR=2.52$ (95% $CI=1.63-7.24$, $P<0.01$) and history of hypertension $OR=3.96$ (95% $CI=1.48-15.45$, $P<0.05$). In this analysis, the factors like gender, duration of DM, HbA1C, family history of DM, history of hypertension were significant except the factors age and HDL of the DR patients weren't statistically significant with $P>0.05$.

DISCUSSION

In the older age group, the eye threatening diseases were common and less number of the DM patients of severe blindness was due to diabetic retinopathy. In this study, we have no patients under the stage 4 (PDR) and the results was showed that the mean age of the study participants with type 2 DM was calculated as $53.16\pm 10.81y$ (mean \pm SD). Similar types of results have been shown by Senthilvel *et al* in their study related to prediction of influencing factors and the probability of developing DR and similar type of results have been shown in another one study related to probability to the development of DR in each period Cox's regression model in DR^[11-12]. DR is the main causes of visual loss in individual's age-group of 20-64y^[6, 12]. Type 2 DM patients would have got some degree of DR after a long period of years with diabetes^[6, 13]. Therefore, the older people those who are having type 2 DM must utilize the present advancement of treatments in ophthalmology, then only they will have to free from the vision threatening diseases in time or delay the onset

of vision threatening disease DR. By using the present technology to determine the screening interval of the diabetic patients and to reduce their screening visits, expenses and to reduce the increase of DR patients in the world level^[14]. Similar type of findings was found in our study between duration of DM with the severity of DR. In other studies also confirmed that the duration of DM was an independent risk factor associated with the development of DR among type 2 DM patients of the population of China^[15-16]. In our study, also we have found that the most similar results in the mean duration of diabetes of type 2 DM patients. Number of studies have revealed and concluded in results that the prevalence of DR is highly related to the duration of type 2 diabetes mellitus^[15-17].

Leske *et al*^[18] have been reported in his study, that reducing the complications of DR related problems and to decrease the vision loss in the type 2 DM patients by controlling of diabetes mellitus and hypertension from this present study, it was found that the duration of DM, HbA1C level were significant with severity of DR. Yoon *et al*^[19] have reported that the longer duration of DM and the higher level of HbA1C were the common risk factors for the development and progression of DR. Kajiwarra *et al*^[20] have revealed and concluded in his study that the female gender is an independent risk factor for the progression of DR. In our present study, the gender was a prominent risk factor for developing diabetic retinopathy in diabetes mellitus patients and especially male gender exhibited more advanced diabetic retinopathy than female patients. Senthilvel *et al*^[21] have been reported in their study that duration of DM, HbA1C level, family history of DM, history of hypertension were independent risk factors in the development or progression of DR. Furthermore, Senthilvel *et al*^[21] have been reported that the HDL wasn't an independent factor for the development or progression of diabetic retinopathy. Nevin *et al*^[22] have also revealed in their study that the HDL and triglyceride were not independent risk with diabetic retinopathy patients. Shrote *et al*^[23] have mentioned about the finding of the DM and DR in time by using the recent technologies in rural population and by controlling DM and should be prevent or to prolong the vision threatening disease in the DM patients.

From this study, we have to conclude that the duration of DM, HbA1C levels, family history of DM, history of hypertension and gender were independently associated with the severity of diabetic retinopathy. However, the factors like

age and HDL of the DR patients weren't independent risk factors with the severity of DR in multivariate ordinal logistic regression analysis. Therefore, one individual wants to prevent themselves from the vision threatening disease they will follow some precautionary measures like, identifying and also controlling the risk factors through the advice of the ophthalmologist by clinically, taking the exact treatment in correct time and in correct place, by availing the existing treatments to DR and also by using the latest laser photocoagulation therapy in the medical field of ophthalmology. By the above mentioned ways, one can prevent from the vision threatening disease (or) to make delay the occurrence of disease burden to their eyes. Any one of the stages of DR patients can make themselves to retain their eye sight in the same stage for a longer or a prolonged period.

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