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The Association of Body Mass Index and Incidence of Diabetic Retinopathy in newly diagnosed Type 2 diabetes: A longitudinal Study in Karachi

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ABSTRACT

OBJECTIVE: To elucidate the relationship between BMI, 25-29.9 kg/m²/obesity, and the incidence of Diabetic Retinopathy **(**DR) among DM patients.
METHODOLOGY: This is a prospective cohort study. The newly diagnosed Diabetes Mellitus II patients were enrolled in a baseline of 1675 subjects. Systematic random sampling was used to select the recruited patients at the Ophthalmology Department of Sindh Government Qatar Hospital, Karachi. Incident diabetic retinopathy (DR) was determined if any of the photos received a high rating for DR. Exclusively, participants with DR grades available results from the 2022 subsequent examinations were considered for inclusion in this study. Diabetic Retinopathy (DR) is classified into five stages per the ICDR scale: (1) no retinopathy, (2) mild NPDR, (3) moderate NPDR, (4) severe NPDR, and (5) PDR. BMI criteria: <25 kg/m² (normal/underweight), 25–29.9 kg/m² (overweight), and ≥30 kg/m² (Obese). Univariate and multivariate logistic regression models were employed by SPSS version 27.
RESULTS: In total, with a mean (SD) age of 61(7.5) years. Of these participants, 59.5% were male. A significant number of the participants were <25 kg/m² 821(49%). 856(51%) of the patients came for the follow-up after approximately 365 days. Diabetic Retinopathy was in 197 (23%) of the patients.
CONCLUSION: In summary, our study, conducted within a substantial cohort of adults, demonstrated a correlation between higher Body Mass Index (BMI) and an increased risk of incident Diabetic Retinopathy (DR) over a 1-year follow-up period.

KEYWORDS: Body Mass Index, Diabetic Retinopathy, incidence of diabetes Retinopathy, Type 2 diabetes mellitus, Obesity, Karachi

INTRODUCTION

Diabetic Retinopathy (DR), a prevalent system of tiny blood vessels complexity of diabetes mellitus (DM), stands as the foremost cause of vision loss among individuals aged 20 to 74 in developed nations[1]. In the United States alone, patients older than 40 have DR, and approximately 4.2 million have DM. Annually, an estimated 23,000 individuals experience permanent blindness attributed to DM, incurring a substantial medical expenditure averaging USD 500 million[2].

Sedentary lifestyles and increasing levels of Obesity, particularly prevalent in Asia, are contributing to an escalation. While poor glycemic control, longer diabetes duration, and hypertension have a strong relationship with DR, numerous research studies do not entirely explain DR risk. In other studies, obese individuals are primarily associated with DR[3].

Several risk factors contribute to the development of DR, with its prevalence escalating with prolonged DM duration. Notably, over half of DM individuals with a disease period exceeding twenty years manifest DR[4]. Chronic disease, poor glucose management, uncontrolled blood pressure, and cholesterol levels in the blood are said to be fundamental risk factors for DR[5].

Furthermore, patients having higher values of BMI have a potential of developing DR, as reported in a study[6], although contradicting statements exist in few studies. One study from the Wisconsin Epidemiologic Study of DR (WESDR) indicates no significant link between Obesity and DR incidence among DM patients with older-onset diabetes[7]. In a study, Obesity is identified as a risk factor for diabetic nephropathy (DR)[8], sharing common pathogenic mechanisms with DR. However, consensus regarding the impact of high BMI on DR risk remains elusive.

Significantly, the comparison of BMI in Asian and Western individuals is contrasting; in a study, an Asian with a BMI similar to a Western individual usually have a higher probability of encountering unfavorable health outcomes due to variations in how body fat is distributed[9]. Another study from the Singapore Malay Eye Study (SiMES) shows a lower occurrence of Diabetic Retinopathy (DR) among patients with higher BMIs[10].

Pakistan is also observing a concerning increase in obesity rates, demonstrating an increasing health issue[11]. World Health Organization (WHO) reports that 26% of women and 19% of men in Pakistan are obese; most of them dwell in urban region[12]. These studies highlight the crucial steps that should be taken for selective lifestyle interventions and public health campaigns to tackle the escalating obesity issue and its associated health dangers in Pakistan and globally.

In light of the burgeoning DM and DR prevalence, particularly within Asian nations, our objective is to elucidate the relationship between BMI, 25–29.9 kg/m²/obesity, and the incidence of DR among DM patients, thereby contributing to a better understanding of this complex interplay.

METHODOLOGY

This is a prospective cohort study. The research began with assessments conducted between 2019 and 2022 at the Sindh Government Qatar Hospital in Karachi, Pakistan. Participants newly diagnosed with Type II Diabetes Mellitus were enrolled, forming a baseline cohort of 1675 individuals. All ethical protocols were followed as declared in the Helsinki Declaration 1975, revised in 2000. Approval for the study was granted by the hospital's Ethical Review Committee (ERC/2015/187/07), and participants provided informed consent before participation. Subsequently, all participants were scheduled for follow-up examinations over one year.

Inclusion criteria consisted of individuals diagnosed with diabetes within a month before the baseline assessment, with recorded baseline Body Mass Index (BMI) data and available results for referable Diabetic Retinopathy (DR). These patients were then monitored for at least one year.

Initial assessment, including clinical evaluation and assessment form interviews, occurred in the Ophthalmology department of the Sindh government Qatar Hospital in Karachi, Pakistan. Medical history, including any prior diagnosis of Diabetes Mellitus (DM), was verified through medical records and blood glucose levels. Demographic information such as age, gender, and education level was documented, and smoking habits were assessed through a baseline Assessment form.

Systolic and diastolic blood pressure measurements were taken according to standard procedures using a manual upper-arm blood pressure monitor by trained nursing staff. Height and weight measurements were obtained with participants standing, using a height and weight scale. Height was measured in centimetres, while weight was measured in kilograms. The height and weight were measured at the baseline, and BMI categories characterized the patients according to W.H.O.

Triglycerides (TG), high-density lipoprotein cholesterol (HDL), low-density lipoprotein cholesterol (LDL), and fasting glucose (FG) levels were assessed following standardized protocols. Consistent examination protocols were adhered to during all subsequent follow-up visits. Moreover, a brief assessment form was administered at each follow-up session, incorporating questions regarding self-reported changes in chronic disease status, including diabetes, hypertension, and stroke.

During the study visit, the retinal image was captured from one eye of the participant. The retinal camera images were taken, centred on the macula and the optic disc (Topcon, Japan). Suppose the image shows signs of initial diabetic Retinopathy. In that case, it is considered a Vision-threatening DR (VTDR) or a more severe stage, diabetic macular edema, or a combination of both conditions.

Incident diabetic retinopathy (DR) was determined if any of the photos received a high rating for DR. The inclusion criteria of the patients were the grading results of VTDR from the 2022 follow-up examinations were available. Clinically, diabetic Retinopathy (DR) is categorized into five distinct stages according to the International Clinical Diabetic Retinopathy (ICDR) classification scale. These stages include: (1) no evident retinopathy (grade 0), (2) mild non-proliferative diabetic retinopathy (NPDR, grade 1), (3) moderate NPDR (grade 2), (4) severe NPDR (grade 3), and (5) proliferative diabetic Retinopathy (PDR, grade 4)[13].

The minimum sample size required for the study is 634, with a 5% margin of error, 95% confidence interval and 80% power of the study. The sample size was calculated with the odds ratio of 2.45 for the incidence of Diabetic Retinopathy in obese patients[14]. The Open Epi online version was assessed for sample size calculation.

Statistical analyses were conducted on SPSS version 25. Educational level was categorized into Matriculation, Intermediate, Graduation and Post-graduation. Body Mass Index (BMI) was calculated as the weight in kilograms divided by the square of the height in meters. Participants were then categorized into three groups according to the World Health Organization (WHO) criteria, BMI criteria: <25 kg/m², 25–29.9 kg/m², and ≥ 30 kg/m². Diabetes mellitus (DM) was defined based on self-reported DM during follow-up Assessment form interviews, fasting glucose (FG) >120 mg/dl at the baseline.

Mean (SD) were reported for continuous variables after the assessment of normality using the Shapiro-Wilk test. The independent sample t-test was utilized for constant variables. At the same time, the Chi-square test was applied to categorical variables to compare the characteristics of participants with DR throughout the evaluation period.

Logistic regression analysis was utilized to investigate the relationship between BMI and DR. Both univariate and multivariate logistic models were applied, adjusting for confounding variables identified in the multivariate analysis. Statistical significance was defined as a p-value of less than 0.05.

RESULTS

In total, 1,675 participants enrolled in the study had a mean (SD) age of 61(7.5) years. Of these participants, 59.5% were male and included at baseline. A significant number of the participants were <25 kg/m² 821(49%). 486(29%) were 25–29.9 kg/m² and 369(22%) were obese, **Table I** refer to the clinical and demographic characteristics.

856(51%) of the patients came for the follow-up after approximately 365 days. The incidence of Diabetic Retinopathy was observed in 197 patients, representing 23% of the total cohort. The mean (SD) age of patients was 63(3.2), significantly higher than patients with no incidence of DR, 59.3(1.3) (p-value <0.001). 124(63%) males had diabetic retinopathy while 379(57.5%) had no diabetic retinopathy. The difference was statistically significant as the p-value is <0.001. Significant differences were observed in Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Fasting Glucose (FG), triglyceride (TG), and low-density lipoprotein (LDL) levels between patients with and without Diabetic Retinopathy, with a p-value of less than 0.001. 104(53%) of the 25–29.9 kg/m² individuals were diagnosed with DR, while 77(39%) normal underweight had DR, in obese patients, 16(8%) of individuals were diagnosed with DR. While in the no DR group <25 kg/m² were 469(71.1%), 177(26.8%) were 25–29.9 kg/m² and 14(2.1%) were Obese, p-value showed significant difference between the patients with Diabetic Retinopathy and Non Diabetic Retinopathy, (**Table II**)

In logistic regression, univariate analysis, Obesity and incidence of DR were significantly associated as the p-value was 0.03 OR CI 95% 2.65(0.78 to 8.3). On multivariate analysis, the OR (CI 95%) demonstrated 2.71(0.81 to 9.65) times higher chances of DR concerning the patients who were <25 kg/m² (p-value 0.08) (**Table III**).

Table I: Baseline Characteristics (n=1675)

Age (years)	Mean ± SD	61±7.5
Male	n (%)	997(59.5%)
Education n (%)	Matriculation	248(14.8)
	Intermediate	590(35.2)
	Graduation	489(29.2)
	Post-Graduation	348(21)
SBP (mmHg)	Mean ± SD	138±19.5
DBP (mmHg)	Mean ± SD	86±15.2
FG (mg/dl)	Mean ± SD	115±17.8
TG (mg/dl)	Mean ± SD	198±17.9
LDL (mg/dl)	Mean ± SD	187±18.5
HDL (mg/dl)	Mean ± SD	38±17.5
Current smoker	n (%)	378(22.57)
<25 kg/m²	n (%)	821(49)
25–29.9 kg/m²	n (%)	486(29)
Obese	n (%)	369(22)

Table II: Association of Diabetic Retinopathy with Clinical Characteristics (n=856)

		Diabetic Retinopathy		
		Yes 197(23)	No 659(77)	
Age (years)	Mean ± SD	63±3.2	59.3±1.3	<0.001
Male	n (%)	124(63)	379(57.5)	<0.001
Female		73(37)	280(42.5)	
Education n (%)	≤Matriculation	26(13)	99(15)	0.43
	Intermediate	53(27)	191(29)	
	Graduate	69(35)	211(32)	
	Post-Graduate	49(25)	158(24)	
SBP (mmHg)	Mean ± SD	142±17.2	123±16.7	<0.001
DBP (mmHg)	Mean ± SD	85±10.4	76±12.3	<0.001
FG (mg/dl)	Mean ± SD	130±14.1	95±5	<0.001
TG (mg/dl)	Mean ± SD	168±13	132±1.7	<0.001
LDL (mg/dl)	Mean ± SD	185±7.5	158±3.8	<0.001
HDL (mg/dl)	Mean ± SD	32±15	63±3.4	<0.001
Current smoker	n (%)	17(8.4)	79(12)	0.5
<25 kg/m²	n (%)	77(39)	469(71.1)	<0.001
25–29.9 kg/m²	n (%)	104(53)	177(26.8)	
Obese	n (%)	16(8)	14(2.1)	

Table III: Logistic Regression Analysis of Diabetic Retinopathy and BMI

BMI Group	Univariate	P-value	Multivariate	P-value
<25 kg/m²	Ref		Ref	
25–29.9 kg/m²	1.09 (0.58 to 2.07)	0.04	1.15 (0.61 to 2.25)	0.34
Obese	2.65 (0.78 to 8.30)	0.03	2.71 (0.81 to 9.65)	0.08
Age (years)	1.72 (1.02 to 2.57)	<0.001	1.02 (0.21 to 1.82)	0.21
SBP (mmHg)	1.57 (0.9 to 1.98)	<0.001	0.85 (0.35 to 1.5)	0.35

* Controlled for age (years), SBP, FPG, TC, HDL and LDL.

DISCUSSION

In this study cohort comprising adult individuals of Pakistani descent, it was demonstrated that a higher Body Mass Index (BMI) was linked to an increased likelihood of developing Diabetic Retinopathy (DR) during a 1-year follow-up period. These findings remained consistent even after adjusting for confounding factors such as age, gender, blood pressure (BP), fasting glucose (FG), and blood lipid levels.

The incidence of DR was higher in males than the females in this study. Gender disparities in the burden of diabetic Retinopathy (DR)-related vision loss have been observed across different years, age groups, and socioeconomic regions[15]. Over the past decade, accumulating evidence indicates that women are disproportionately affected by blindness and visual impairment compared to men. Globally, women represent approximately 64% of all individuals who are blind, as highlighted by **Courtright and Lewallen** et al.[16]. Similarly, **Gretchen and Stevens et al.**[17] reported that two-thirds of blind individuals worldwide are women. This significant gender disparity is consistent across both developed and developing nations[15].

Overweight has been extensively recorded as a risk factor for diabetes mellitus (DM), and clinical practice recommendations endorse weight regulation in diabetes management[18,19]. Following prior research, our study emphasized the critical role of BMI as a notable risk factor for the onset of Diabetic Retinopathy (DR), even after adjusting for other recognized risk determinants, encompassing blood pressure, fasting plasma glucose levels, and lipid profiles. Previous studies have elucidated the mechanisms that underpin the positive correlations between body mass index and diabetes mellitus, citing factors such as insulin resistance and progressive dysfunction of pancreatic beta cells associated with obesity[19-21].

The association between body mass index (BMI) and diabetic Retinopathy (DR) has been extensively explored in epidemiological and clinical research, yet findings remain inconsistent. These discrepancies may arise from ethnic differences, research methodology variations, and sample size limitations. While studies in Western nations generally report a positive correlation between BMI and DR, some research conducted in Asian populations indicates a probable shielding effect of Obesity against DR. For example, research reports identified an inverse relationship between 25–29.9 kg/m² obesity and the incidence of DR in a community with different ethnicities in an Asian cohort. Similar protective effects have been noted in investigations from India and Iran. Furthermore, another research reported a U-shaped relationship between categories of BMI and patients having DR among the Chinese population with diabetes mellitus type 2. However, it is essential to highlight that most of these studies on the topic had a cross-sectional design, and the limitation of this design is it can't determine the causal effect between baseline BMI and subsequent DR risk[14].

A reason for the obesity paradox with DR might be BMI is limited in its ability to distinguish between general obesity and central (centripetal) obesity, each of which may have distinct implications for the progression of diabetes. Additionally, all participants in this study were community-dwelling individuals who had received a diabetes diagnosis at a hospital before enrollment. However, patients with severe complications, those with a low inclination to seek medical care, or those with mobility impairments were likely underrepresented, introducing potential selection bias into the study.

In our study, individuals who developed new cases of diabetic Retinopathy (DR) showed higher systolic blood pressure (SBP) and fasting glucose (FG) levels, which is consistent with earlier research findings[22]. Moreover, in line with the previously mentioned observational reports from

Asia, it was concluded that the onset of diabetic Retinopathy is related to BMI. These results differ from those of the Shanghai Study, which found no relationship between Obesity and the increased prevalence of DR in individuals with type 2 diabetes[23]. A separate longitudinal study explored the influence of BMI on the onset of diabetes mellitus (DM) and diabetic Retinopathy (DR) in Asian populations. The study concluded that, although 25-29.9 kg/m² status elevated the likelihood of developing DM, it was associated with a lower risk of DR and demonstrated no significant association with the risk of vision-threatening diabetic Retinopathy (VTDR)[20].

In the cross-sectional study from **Sharif S. et al.**[24]**,** the average age of patients diagnosed with diabetic Retinopathy (DR) was 55.24±0.47 years, while for those without DR, it was 52.23±0.51 years. Similarly, in our study, the higher age was associated with DR.

A systematic review assessing the relationship between Body Mass Index (BMI) and diabetic Retinopathy (DR) found significant variability among the analyzed reports. It determined that individuals with excessive weight don't pose a heightened risk for DR[25]. Therefore, the contradictory relationship between BMI and DR observed in prior observational studies, especially concerning VTDR, requires confirmation through further longitudinal research involving diverse ethnic groups[26].

Strengths of our study include the accessibility of longitudinal data spanning one year, consideration of numerous potential confounding factors, and utilization of a standardized protocol for grading DR via fundus photography. However, several limitations warrant consideration. Information on diabetes management, an essential factor in the progression of diabetes and the development of diabetic Retinopathy, was not accessible. Nonetheless, additional corrections for diabetes control in the logistic analysis are unlikely to meaningfully modify the identified relationships between Body Mass Index, diabetes, and vision-threatening diabetic Retinopathy.

CONCLUSION

Our study, conducted within a substantial cohort of adults, demonstrated a positive correlation between higher Body Mass Index (BMI) and an increased risk of incident Diabetic Retinopathy (DR) over a 1-year longitudinal period. Additionally, prolonged studies are necessary to gain a deeper understanding of the diverse effects of BMI on both Diabetes Mellitus (DM) and DR within varied populations.

Strengths of the Study

The study's focus on examining the relationship between body mass index (BMI) and diabetic Retinopathy (DR) is highly pertinent to public health, particularly in light of the rising prevalence of diabetes and Obesity, which are significant global health challenges. By addressing this intersection, the research contributes valuable insights into a critical preventive and therapeutic care area. The longitudinal design employed in the study is a significant strength, as it allows for observing DR incidence and exploring potential causal links between BMI and the progression of Retinopathy over time. This design is particularly advantageous for capturing dynamic changes and establishing temporal relationships, strengthening the findings' validity and reliability. Moreover, the study highlights an important and underexplored aspect of DR, potentially paving the way for future research and public health interventions to mitigate disease progression.

Limitations of the Study

Despite its strengths, the study has several notable limitations. A primary limitation is the lack of monitoring for patient compliance, which could significantly impact the study outcomes. Variability in follow-up adherence may have been influenced by the diverse geographic origins of the patients, as they were recruited from different regions across the state. This diversity might have introduced heterogeneity in healthcare access, socioeconomic factors, and follow-up behaviors, potentially affecting the robustness of the findings.

Additionally, the study was conducted at a single center, which limits the generalizability of its results to broader populations. Multi-centre studies are often better equipped to capture the variability in patient demographics, healthcare practices, and environmental factors, contributing to more comprehensive and externally valid conclusions. The single-centre approach in this study, while understandable due to resource constraints, restricts the applicability of the findings to other settings or populations with differing characteristics.

Another significant limitation is the relatively short follow-up period of one year. Diabetic Retinopathy is a progressive condition that often requires extended periods of observation to fully understand its natural history, patterns of progression, and potential associations with risk factors like BMI. A longer follow-up would have provided a more detailed picture of the relationship between BMI and DR and could have accounted for delayed effects or long-term trends.

Lastly, while the study's focus on BMI is relevant, it does not account for other confounding factors that may also contribute to DR, such as glycemic control, duration of diabetes, hypertension, or lipid profiles. Addressing these variables in future studies could strengthen the understanding of the complex interactions between metabolic health and the progression of diabetic Retinopathy.

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AUTHOR CONTRIBUTION

Ahmed I:	Principal investigator with the idea of the study, collected data, wrote the manuscript, and reviewed it.
Mustafa A:	Data collection, helped in manuscript writing.
Hussain Z:	Literature review; helped write the manuscript.
Junaid Z:	Write the discussion and review the article.
Nizamuddin M:	Data analysis, wrote the results, and helped with the discussion.

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