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ERECTILE DYSFUNCTION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND ITS CORRELATION WITH SERUM TESTOSTERONE LEVELS

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Date Received:

11st June, 2023

Date Revised:

29th September, 2023

Date Accepted:

15th January, 2024

This article may be cited as

Haider I, Malik SE, Munib N, Hassan S, Khan W, Khan RA. Erectile dysfunction in patients with type 2 diabetes mellitus and its correlation with serum testosterone levels. *J Postgrad Med Inst* 2024;38(1): 15-20. <http://doi.org/10.54079/jpmi.38.1.3273>

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ABSTRACT

Objective: To determine erectile dysfunction in patients with Type 2 Diabetes Mellitus (DM-II) and its correlation with serum testosterone levels.

Methodology: Patients with type 2 diabetes participated in this prospective cross-sectional study at Department of Medicine, Khyber Teaching Hospital Peshawar from October 2022 to April 2023. After approval from institutional ethical review board, strict inclusion/exclusion criteria were followed to minimize the confounders. The sample size was calculated by OpenEpi.com, keeping the prevalence of erectile dysfunction in Pakistani diabetics at 97.8% with 5% as the error margin and a 95% confidence level. The data were recorded on well-designed questionnaire and Lynn criteria validated these items having a threshold of 0.80 by six subject experts. An SPSS version 22.0 was used to analyze various variables statistically and a p-value of 0.05 or lower was regarded as significant.

Results: Amongst one hundred and fifty type- 2 diabetic male patients, 87 (58%) of the study population had ED. Fifty-three (35.3 %) had hypertension (HTN), 18 (12%) had dyslipidemia, and 63 (42%) had diabetic complications as co-existent co-morbidities. There were more patients with Low testosterone and ED 58.6% (n=51) than those with normal testosterone and ED 43.1% (n=36). Among T2DM patients with ED (n=87), 75.8% had poor glycemic control (HbA1c >8%) and among hypertensive patients (n=53), 81.1% had ED.

Conclusion: Erectile dysfunction is common in poorly controlled diabetics and diabetes of long duration. In our study, there is no substantial relationship between testosterone levels and ED.

Keywords: Diabetes Mellitus; Erectile Dysfunction; Testosterone

INTRODUCTION

Diabetes mellitus (DM) is a protean of metabolic syndrome with features of hyperglycemia having underlying etiology of abnormal insulin secretion, action, or both. Diabetes is becoming an epidemic in the 21st century. In the near future, it poses a threat to overwhelm the healthcare system. Diabetes mellitus is a worldwide epidemic that is prevalent in regions experiencing socioeconomic transition. According to estimates by the World Health Organization, about 90 to 95 percent of all diabetes cases are type-2 diabetes mellitus (T2DM) in affluent nations and an even greater proportion in developing nations.¹

Statistical data from the International Diabetes Federation for 2021 show 33 million Pakistanis and 537 million persons worldwide have diabetes.² Pakistan has the highest prevalence rate (30.8%) of diabetic patients in the globe.

Sexual dysfunction is one of the most prevalent and underappreciated diabetes complications. The three primary manifestations of male sexual dysfunction are decreased libido, difficulty ejaculating, and erection problems.³ All these three types of dysfunctions can significantly diminish life satisfaction. This study focuses predominantly on erectile dysfunction, although diabetic men can suffer from all three types.

The failure to achieve or sustain an erection strong enough for acceptable sexual performance is known as erectile dysfunction (ED). Diabetes is an ED risk factor for men.⁴ Prior research indicates a prevalence of 20-85%, occurring more frequently at early age in comparison to the general population. Falahi M conducted descriptive research on Iranian male patients (n=69) and discovered that most participants had erectile dysfunction.⁵

Multiple factors contribute to erectile dysfunction in

males with diabetes. It can have neurologic, vasogenic, or psychogenic root causes. Diabetes decreases neuronal and endothelial-generated NO (Nitric Oxide). This NO is a crucial mediator in the relaxation of smooth muscles of penis, and thus consequently, penile erection.⁶ Mikhailichenko VV discovered copulative dysfunction in 51.1% of diabetic patients. These patients exhibited elevated serum levels of prolactin, lutropin, and dehydroepiandrosterone but low testosterone. These observations and literature data led to the conclusion that insulin deficiency, resulting in hyperglycemia, causes an increase in prolactin and dehydroepiandrosterone levels, which may diminish receptor sensitivity and impede testosterone release in the testes.⁷ When ED coexisted with normal sexual impulses, it increases mental stress level, disrupted interpersonal relationships, and impeded sexual life. Hence, ED is one of the significant factors contributing to diabetic patient's decreased quality of life (QOL). A global study found that diabetic males with erectile dysfunction have profound dysfunction and a reduced quality of life than non-diabetic males with ED.⁸ Another research by Rance J is documenting that diabetic males irrespective of suffering from erectile dysfunction (ED) consider ED to have a significant impact on their QOL and it is essential to manage it just like other diabetes-related scenarios. According to another study, ED is the third most prevalent diabetes complication, but diabetic men without ED view it as less severe than foot ulcers and hypertension.⁹

Erectile dysfunction is an undiagnosed and under-reported condition mainly due to patients' unwillingness to cooperate when questioned by clinicians. Therefore, it is preferable to use validated surveys either in self-administered anonymous or neutral settings. Using the questionnaire of IIEF-5 (International Index of Erectile Function), this study intends to assess the severity of erectile dysfunction in patients with type 2

diabetes who seek tertiary care. This study also tends to find any possible relationship of ED to age, dyslipidemia, the duration of diabetes, diabetic complications, and testosterone levels.

METHODOLOGY

This research was carried out at Department of Medicine, Khyber Teaching Hospital Peshawar from October 2022 to April 2023, in which we enrolled all the willing type 2 diabetic male patients. Male type-2 diabetics eliciting willingness for participation, inpatient and OPD, were included in this sample. Patients who were taking beta-blockers, amitriptyline, spironolactone (spiromide/Aldactone), on testosterone replacement therapy, having other endocrinopathies causing hypogonadism, critically ill with a GCS score of less than 15, immunocompromised patients or receiving immunosuppressive treatments, having mental or psychiatric issues, taking psychiatric medications, or having neurological deficits were all excluded to minimize the confounders.

The research commenced following the authorization from the ethics committee (Reference Number 769/DME/KMC; Date: October 21, 2022). All the data were collected and recorded in a well-designed and validated questionnaire, including baseline characteristics, duration and complication of diabetes and its management, ED, hypertension and its duration, and lipidemia. Lynn criteria were utilized for validation with a threshold of 0.80 by six subject experts. The sample size was calculated by OpenEpi.com, keeping the prevalence of erectile dysfunction in Pakistani diabetics at 97.8%, with 5 % error margin and 95 % level of confidence.¹⁰ The size of sample turned out to be 139. However, it was kept as 150, keeping in mind the dropouts. Patients who had ED as per questionnaire of IIEF-5 (International Index of Erectile Function), their Samples were collected by venipuncture and blood was

collected in gel tube for testosterone levels. After centrifugation, a testosterone test was performed using the electrochemiluminescence Immunoassay principle and HbA1C was performed using TINIA (Turbidimetric Inhibition Immunoassay), both on Roche Cobas 6000. The normal range of testosterone as per specified machine was 2.5-8.5 ng/ml. Levels below 2.5 ng/ml was taken as low testosterone and level in the range was taken as normal testosterone. Patients were categorized as having Good ($\leq 7\%$), Fair (7.1 to 8%) and Poor ($> 8\%$) control on basis of HbA1c. Version 22.0 of SPSS was used for the statistical analysis of all the relevant variables including qualitative and quantitative. For qualitative variables, percentages and frequencies were determined. Fisher exact test and independent sample T-test were utilized for comparison of data. A p-value of 0.05 or lower was regarded as significant.

RESULTS

In this study, 150 males with type 2 diabetes are included. Eighty-seven (58%) of the study population had ED, according to our findings. The participants were classified into two age groups: 20 (13.3%) were 40- 49 years old, while the remaining 130 (86.6%) were 50 and above. Regarding other co-morbidities, 53 (35.3%) had hypertension (HTN), 18 (12%) had dyslipidemia, and 63 (42%) had diabetic complications (Table 1).

In addition, the results revealed a difference with statistical significance of $p < 0.05$ in the severity of ED and the duration of diabetes. (Table 2) Forty-three (81.1%) of 53 hypertensive patients had erectile dysfunction, and there was a difference of statistical significance of $p < 0.05$ in the severity of ED and the duration of HTN (Table 2). In terms of prevalence, there was a statistically significant difference in erectile dysfunction of diabetics who developed complications and

Table 1: Participant's demographic information

Patient characteristics		Frequency (n)	Percentage (%)
Age (Years)	40-49	20	13.3
	50 and above	130	86.6
Residential Status	Urban	83	55.3
	Rural	67	44.7
Education	Yes	129	86
	No	21	14
Marital Status	Single	0	0
	Married	150	100
BMI	Normal weight (BMI < 23 kg/m ²)	20	13.3
	Overweight (BMI 23- 27.4 kg/m ²)	46	30.7
	Obese (BMI ≥ 27.5 kg/m ²)	84	56.0
Any Treatment for Diabetes	No	01	0.7
	Oral	66	44
	Both oral and insulin	50	33.3
	Insulin only	33	22
Other Co-Morbidities	Hypertension	53	35.3
	Dyslipidemia	18	12
	Complications of Diabetes	63	42

Table 2: Classification based on co-morbidities and their duration

Co-morbidities		No Erectile Dysfunction	Mild Erectile Dysfunction	Mild to Moderate Erectile Dysfunction	Moderate Erectile Dysfunction	Severe Erectile Dysfunction	p-value
T2DM		63	43	29	14	1	0.02
Duration of T2DM	1-5 years	39	26	14	3	0	0.02
	6-10 years	20	10	13	7	0	
	11 or more	4	7	2	4	1	
Hypertension		10	17	15	10	1	0.01
Duration of Hypertension	1-5 years	7	14	11	7	0	0.001
	6-10 years	2	1	3	2	1	
	11 or more	1	2	1	1	0	
Dyslipidemia		3	4	5	6	0	0.09
Diabetes with Complications Retinopathy, CKD DFU, Stroke, MI or HF		15	14	21	10	1	0.001

*CKD- Chronic Kidney Disease, DFU-Diabetic Foot Ulcer, MI-Myocardial Infarction, HF-Heart Failure.

Table 3: Classification of Erectile Dysfunction based on Laboratory values

Laboratory investigation		Mild Erectile Dysfunction	Mild to Moderate Erectile Dysfunction	Moderate Erectile Dysfunction	Severe Erectile Dysfunction	p-value
HbA1c	Good Glycemic (≤7%)	4	2	0	0	0.037
	Fair Glycemic (7.1 to 8%)	7	7	1	0	
	Poor Glycemic (>8%)	32	20	13	1	
Testosterone Level	Normal (2.5-8.5 ng/ml)	23	9	4	0	0.11
	Low (<2.5 ng/ml)	20	20	10	1	

those who did not. Fourteen patients with complicated DM had mild ED, 21 patients had mild to moderate ED, 10 had moderate ED, and only one patient had severe ED. There were no significant statistical differences ($p=0.09$) in the prevalence of ED in patients with dyslipidemia than those without dyslipidemia, despite the fact that there were numerically more patients with dyslipidemia and ED ($n=15$) than with dyslipidemia without ED ($n=3$) (Table 2).

There was a significant difference in the severity of ED between the three categories of patients classified by HbA1c as having reasonable, fair, or poor control of diabetes. Poorly controlled diabetic patients had mild ($n=32$), mild to moderate ($n=20$), moderate ($n=13$), and severe ($n=1$) erectile dysfunction. There was no statistically significant difference in the prevalence of erectile dysfunction (ED) between those with low serum testosterone levels and those with normal testosterone levels; however, there were more patients with Low testosterone and ED 58.6% ($n=51$) than those with normal testosterone and ED 43.1% ($n=36$) (Table 3).

■ DISCUSSION

In published studies, the diabetic males are having prevalence of ED in range of 80-97.8%.¹¹ Most of these studies did not find a correlation among the severity, duration, and testosterone level of the disease.¹¹ This cross-sectional research work estimates the prevalence of ED in T2DM populations as well as the any possible relationship between testosterone levels and ED in type 2 diabetic patients.

Our study revealed that diabetes is a significant risk factor for erectile dysfunction (ED), and the risk of ED increases when other conditions, such as hypertension and dyslipidemia, coexist. The risk of ED in diabetics also depends on the management of their disease and the development of com-

plications. Moreover, the disease-duration of diabetes and hypertension also influence the severity of erectile dysfunction, such that patients with recent DM or HTN will develop mild ED, whereas those with protracted DM or HTN will develop severe ED. On the basis of HbA1c, the patients were classified into three groups: those with well-controlled, moderately-controlled, and poorly-controlled diabetes, and there was a statistical difference of significance in ED severity among these cohorts. The study also showed that testosterone level in such patients has no effect on the severity of erectile dysfunction.

Variable results have been documented by other researchers who studied and documented the prevalence of ED in diabetics. Schiavi RC conducted research on forty diabetic males devoid of other ailments or medications impairing sexual capability, along with forty healthy controls of the same age and this study demonstrated ED in 77% of patients.¹² Kloner RA documented the prevalence of erectile dysfunction of approximately 75% in diabetic males.¹³ In 1118 male diabetic patients, Sasaki H et al. found a prevalence of 90%.¹⁴ The rate of prevalence was almost twice in comparison to people without diabetes. Our study revealed that the prevalence of ED in 150 T2DM was approximately 58%.

According to Ledda A, ED was ubiquitous in diabetic patients.¹⁵ These patients had a prevalence of 75% and ED was documented at a younger age. In our study, ED prevalence augmented significantly as age advances. The prevalence augmented from 13.3% in the under-50 age group to 86.6% in the over-50 age group. Various other issues that may coexist in diabetics as well as age-related changes in the body may be attributed for the impact of age on the prevalence and severity of disease. Moreover, our findings confirmed that a prolonged duration of DM constantly augments the risk of erectile dysfunction.

One of the most precarious cardiovascular risk factors is hypertension. Hypertension is a frequent co-morbidity in men with erectile dysfunction.¹⁶ Numerous studies have verified the robust relationship between ED and HTN.¹⁷ Jensen J observed that penile circulation impairment accounted for 89% of ED cases in hypertensive men, most likely due to atherosclerosis.¹⁸ Burchardt M and colleagues found a 68.3% prevalence of erectile dysfunction in hypertensive males aged 34- 75 by utilizing questionnaires of the IIEF-5.¹⁶ About 35.2% of the Greek hypertensive patients studied by Doumas M had erectile dysfunction correlating with age, duration of HTN, and use of antihypertensive medications.¹⁹ In our study, 43 (81%) of 53 hypertensive patients had ED.

Dyslipidemia is another independent risk factor for ED in diabetics, and patients having both diabetes and ED are at 2.3-times higher risk for dyslipidemia. Specifically, TG (triglycerides), HDL (High-density lipoproteins), and LDL (Low-density lipoproteins) are documenting association with T2DM. In a study conducted by Ishikawa K, the results of the research showed that ED was common in diabetic dyslipidemia.²⁰ In contrast, the current research found no association between ED and dyslipidemia. This result aligns with research conducted in eastern Sudan.²¹ In addition, reduced testosterone levels in serum are associated with dyslipidemia, and latest data suggests that TRT (Testosterone replacement therapy) can improve lipid metabolism in hypogonadal T2DM patients.²² This may explain the statistically insignificant difference between patients with normal and low testosterone levels in the present research, as there is no difference of statistical significance in the prevalence of erectile dysfunction between dyslipidemic and non-dyslipidemic patients.

HbA1c levels indicate the glucose levels of patients with diabetes over the past 1-3 months. A HbA1c of 6% corresponds

to a glucose concentration of 126 mg/dL. Each 1% increase in HbA1c corresponds to a glucose level of 29 mg/dL. Studies have demonstrated a correlation between HbA1c and glucose levels in the blood. Increased glycemic levels are accompanied by an increase in HbA1c levels. Therefore, elevated HbA1c levels in diabetic patients can serve as an indicator of complications. In a study, HbA1c levels below 6.5% indicate a reasonable degree of control over diabetes.²³ Widyaningsih N demonstrated that the majority of diabetic patients had inadequate glycemic control (HbA1c levels > 6.5%).²⁴ Our study demonstrates that the majority of ED patients (n=43) with inadequate DM control have elevated HbA1c levels (>6.5%).

In diabetic patients, erectile dysfunction (ED) is caused by a complex interaction between vascular, neural, and hormonal factors. Dysfunction of Endothelium, impaired production of nitric oxide (NO), oxidative stress, inflammation, and impaired penile blood flow comprise the underlying pathophysiology. The transmission of neural signals required for normal erectile function is disrupted by diabetic neuropathy. To relax erectile tissue, non-adrenergic, non-cholinergic neurons and the endothelium must produce nitric oxide. In diabetic males with ED, penile smooth muscle relaxation under the influence of neurogenic and endothelial pathways is impaired in penile tissues. In addition, hormonal imbalances, such as low testosterone levels, contribute to the development of erectile dysfunction in diabetics.²⁵

Patients' ability to control their glycemic status is influenced by a multitude of variables. Failure to maintain normal blood glucose levels is primarily caused by non-compliance to a prescribed diet and a negative attitude towards diabetes mellitus. Male patients with T2DM should be mindful of ED risk factors. Blood glucose regulation, testosterone levels, and peripheral artery disease are modifiable patient risk factors.²⁶

Therefore; they should always undergo a routine exam to prevent complications from diabetes.

This study is limited by the fact that a cross-sectional design was utilized to determine the correlation between the variables. A cohort design will be the optimal approach. The correlation between age, duration of diabetes, testosterone level, Hba1c levels, and the occurrence of erectile dysfunction (ED) in T2DM patients can be rapidly described using this simple design. Another limitation is the single-center nature of the trial. A large multi-centered randomized national clinical trial needs time to generalize and validate findings.

CONCLUSIONS

This study verified the prevalence of ED in T2DM males and related them to variations in age, testosterone levels, HTN, HbA1c, dyslipidemia, and duration of DM. There is no significant relationship between testosterone levels and ED. High HbA1c levels were most significantly associated with T2DM patients having ED. Another independent risk factor for ED is HTN.

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Author's Contribution

SEM conceived the idea and provided assistance in the manuscript writing, IH and NM designed the study, collected the data, performed data analysis, and contributed to the manuscript writing. SH, WK and RAK also participated in the data collection and manuscript writing. All authors made substantial intellectual contributions to the study.

Conflict of Interest

Authors declared no conflict of interest

Grant Support and Financial Disclosure

None

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.