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Factors Associated with Erectile Dysfunction in Patients with Type 2 Diabetes Mellitus at a Tertiary Hospital in the Philippines: A Cross-Sectional Analytic Study

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Abstract

Background. This study determined the prevalence of erectile dysfunction (ED), estimated the adjusted association between serum testosterone concentration and ED, and described univariable associations between serum testosterone and variables in the prespecified adjustment set among males with type 2 diabetes mellitus (T2DM) in a tertiary hospital.

Methodology. Univariable and multivariable logistic regression analyses were performed to estimate the association between serum testosterone and ED. Serum testosterone was modeled as a continuous exposure, and the multivariable model adjusted for prespecified covariates. Odds ratios (ORs) and adjusted odds ratios (aORs) with 95% confidence intervals (CIs) were reported for serum testosterone. Separate univariable linear regression models described associations between serum testosterone and the variables in the prespecified adjustment set.

Results. Erectile dysfunction was present in 109 out of 164 participants (66.5%), with mild (32.3%) and mild-to-moderate (22.6%) disease accounting for most cases. In univariable analysis, the OR for ED per 100-ng/dL increase in serum testosterone was 1.25 (95% CI 1.00-1.59; $p = 0.052$). After adjustment for prespecified covariates, the corresponding aOR was 1.27 (95% CI 0.98-1.69; $p = 0.080$). In the secondary univariable linear analyses, BMI was inversely associated with serum testosterone concentration. The final logistic model demonstrated acceptable calibration (Hosmer-Lemeshow $p = 0.198$) and moderate explanatory performance (Nagelkerke pseudo-$R^2 = 0.32$).

Conclusion. Erectile dysfunction was highly prevalent among Filipino men with T2DM. After adjustment for prespecified covariates, the study found no statistically significant association between the serum testosterone levels and ED. Routine screening for ED should be incorporated into diabetes care to facilitate earlier recognition and comprehensive management.

Key words: erectile dysfunction, diabetes mellitus, diabetes complications

INTRODUCTION

Diabetes affects multiple systems in the body as a result of chronic hyperglycemia. Complications from chronic hyperglycemia are the major cause of morbidity and mortality of patients with this disease.[1-3] One of the overlooked complications that affects the quality of life of men with type 2 diabetes mellitus (T2DM) is erectile dysfunction (ED). ED is considered an early sign of diabetic neuropathy. It tends to increase with age and duration of diabetes in male patients.[4] Prolonged elevation of blood sugar levels leads to heightened oxidative stress and generation of reactive oxygen species which results in a cascade of adverse events including decline of nitric oxide levels, increase in prothrombotic factors, and subsequent thrombosis and vasoconstriction, contributing to the development of ED.[5] There is a significant burden of ED among patients with T2DM. A 2005 survey[6] estimated that approximately six million Filipino men were affected by ED. A 2011 Asian prevalence study[7] identified the Philippines as having the highest prevalence of ED among male patients in Asia.

The occurrence of ED can result from changes in various mechanisms such as erectile response, metabolic conditions, relational factors, and psychological factors.[3,8] ED may also

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be attributed to medications, smoking, unhealthy diet, and reduced physical activity.[9,10] The prevalence of ED is estimated to be around 25-30 cases per thousand person-years with a 1-10% increase in men under the age of 40, but increases significantly to 50–100% in men over 70.[5] According to a 2022 study by Defeudis, the prevalence of ED among diabetic patients is 3.5 times higher than those without diabetes.[5]

Among the tools available for assessing ED, the International Index of Erectile Function (IIEF) is the most widely used in urology.[11,12] A review by Rosen et al.,[13] published in the International Journal of Impotence Research, identified the IIEF as the gold standard measure for efficacy assessment in clinical trials of ED. Rosen et al. developed the 15-item version in 1997,[14] and a shorter 5-item version was subsequently introduced in 1999.[15] The IIEF has been utilized as a primary endpoint in over 50 clinical trials and has been linguistically validated in 32 languages. A validation of the Filipino translation of the IIEF-5 was done in 2009. The translated questionnaire was validated by 2 urologists. The tool was noted to be reliable and they concluded that it discriminates subjects with or without ED.[16]

Testosterone levels have a significant role in the etiology of ED. A study done by Gu et al.,[17] found that having a low testosterone state inhibits erectile function. Furthermore, the study by Rajfer in 2000,[18] noted that erections are androgen dependent based on the observation that patients with hypogonadism have significant reduction in frequency and amplitude of erection. Another recent study done by Khodamoradi in August 2024 studied the evaluation of androgen receptor markers in ED. They concluded that lower serum testosterone levels were associated with a decrease in the expression of proteins downstream of the androgen receptor.[19]

There is still no data on the prevalence of ED among male patients with T2DM in the Philippines. This study was conducted to provide local data on the prevalence and severity of ED among men with T2DM and to estimate the association between serum testosterone concentration and ED after adjustment for prespecified demographic, clinical, and lifestyle covariates. Secondary analyses described the relationships between serum testosterone concentration and variables included in the prespecified adjustment set.

OBJECTIVES

General objective

This study aimed to determine the prevalence of erectile dysfunction and evaluate the association between serum testosterone concentration and erectile dysfunction among patients with type 2 diabetes mellitus at a tertiary hospital in the Philippines.

Specific objectives

1. To describe the demographic profile and clinical characteristics of type 2 diabetic patients with and without erectile dysfunction;
2. To determine the prevalence of erectile dysfunction among type 2 diabetic patients;
3. To determine the association between serum testosterone concentration and erectile dysfunction among men with type 2 diabetes mellitus after adjustment for the prespecified potential confounders of age, body mass index (BMI), duration of diabetes mellitus, smoking status, alcohol consumption, comorbidities, and diabetes-related complications; and
4. As a secondary descriptive objective, to characterize the univariable associations between serum testosterone concentration and variables included in the prespecified adjustment set.

METHODOLOGY

Study design

This was an analytic cross-sectional study. Information on the demographic profile and clinical characteristics was collected at one point in time in one interview.

Setting

Participants were enrolled from the Wellness Center at St. Luke's Medical Center - Global City, Philippines, from December 2023 to December 2024.

Participants

Participants eligible for the study were identified as male patients with T2DM by history, aware of their diagnosis, at least 18 years of age, and signed and submitted the informed consent. Patients with anatomical abnormalities that impair erection, type 1 DM, latent autoimmune diabetes in adults, history of gonadectomy or pelvic surgery, primary diagnosis of concomitant sexual dysfunction, substance abuse or alcoholism within the past 12 months, and individuals with mental health issues as disclosed by patients or diagnoses were excluded from the study. Eligible patients were identified by physicians and nurses at the study site and subsequently referred to the study team. Consecutive sampling of patients was used. Patients were invited to participate in the study during their stay at the Wellness Center. Fifteen individuals refused to participate in the study. Participants were encouraged to complete all sections of the questionnaire.

Inclusion criteria

Participants were eligible for inclusion if they:

1. Were male and at least 18 years of age;
2. Had a diagnosis of type 2 diabetes mellitus; and
3. Provided written informed consent to participate in the study.

Exclusion criteria

Participants were excluded if they had:

1. Anatomical abnormalities of the genitalia that could impair erectile function;
2. A history of type 1 diabetes mellitus or latent autoimmune diabetes in adults (LADA);
3. A history of gonadectomy or pelvic surgery;
4. A primary diagnosis of another concomitant sexual dysfunction;
5. Alcoholism or substance abuse within the preceding 12 months; or
6. A documented mental health condition or diagnosis, such as major depressive disorder.

Variables collected

The variables collected included age, height, weight, body mass index (BMI), duration of T2DM, serum testosterone level, smoking status, alcohol intake, presence of comorbidities, and presence of diabetes-related complications. Specific comorbidities included hypertension, heart disease, cerebrovascular disease, dyslipidemia, and other documented conditions. Diabetes-related complications included cardiovascular complications, nephropathy, retinopathy, neuropathy, and diabetic foot. The IIEF-5 score was collected to assess erectile function and determine ED status and severity. Glycemic control based on HbA1c was specified in the original protocol but was not included in the final analytical dataset.

For regression analyses, erectile dysfunction was the binary outcome. Candidate variables included serum testosterone, age, weight, height, BMI, smoking status, alcohol use, duration of diabetes mellitus, comorbidities, individual comorbidities, diabetes-related complications, and individual diabetes-related complications.

Outcomes of interest

The primary analysis estimated the association between serum testosterone concentration and the presence of ED after adjustment for age, BMI, duration of diabetes, comorbidities, diabetes-related complications, smoking status, and alcohol consumption. A secondary descriptive analysis examined the univariable associations between serum testosterone concentration and the variables in this prespecified adjustment set. This analysis was intended to characterize covariate relationships and was not used to estimate causal effects.

Data sources and measurement

Presence or absence of ED and severity was measured using the English version of the IIEF-5 questionnaire which included the following questions: "How do you rate your confidence that you could get and keep an erection?," "When you had erections with sexual stimulation, how often were your erections hard enough for penetration?," "During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?," "During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?," and "When you attempted sexual intercourse, how often was it satisfactory for you?". Other than the dichotomous ED classification, a 5-tiered severity status was also measured. Participants who scored 5 to 7 had severe ED, those who scored 8 to 11 had moderate ED, those who scored 12 to 16 had mild to moderate ED, those who scored 17 to 21 had mild ED, and those who scored 22 to 25 had no ED.[12] A Filipino version of the questionnaire was also available, but all patients opted for the English version.

For this prospective study, demographic and clinical data were obtained at enrollment through direct participant interview and review of available medical records using a standardized data collection form. Age, smoking status, alcohol intake, and duration of diabetes mellitus were recorded during the study encounter. Height and weight were measured using standard clinical procedures, and BMI was calculated as weight in kilograms divided by height in meters squared. Comorbidities and diabetes-related complications were documented from the participant's clinical history and available medical records, with complications verified using available objective clinical or laboratory findings, including fundoscopic examination for diabetic retinopathy and urine albumin-to-creatinine ratio for diabetic nephropathy. Total testosterone levels were obtained in all patients. The levels were determined using the enzyme chemiluminescence method with the Siemens Atellica IM 1300 Analyzer. Low total testosterone was defined by a value of <300 ng/dL.[20] Venous blood sampling for total serum testosterone was performed in the morning to account for the physiologic diurnal variation in testosterone concentrations and to minimize the risk of falsely low measurements associated with later-day sampling. Samples were obtained before noon using standardized blood collection procedures.

Bias

There may be decreased generalizability due to recruitment at a wellness center where patients have good health-seeking behavior compared to the general population. Since this is a cross-sectional study, temporal ambiguity is a disadvantage. Participants may underreport and provide socially appropriate responses leading to response bias. Nonprobability sampling was employed in the study.

Study sample size

The sample size was estimated using the logistic regression approach described by Hsieh et al.,[21] considering serum testosterone concentration as the primary continuous exposure and erectile dysfunction (ED) as the binary outcome. The calculation assumed a two-sided significance level of 0.05, 80% statistical power, an anticipated odds ratio (OR)

of 1.50 per 100-ng/dL increase in serum testosterone, an ED prevalence of 55%, and a standard deviation of 200 ng/dL for serum testosterone. The initial sample size was calculated as:

$$n_0 = \frac{\left(Z_{1-\alpha/2} + Z_{1-\beta}\right)^2}{P(1-P)[\ln(OR)]^2\sigma_X^2}$$

where $Z_{1-\alpha/2} = 1.96$, $Z_{1-\beta} = 0.84$, $P = 0.55$, $OR = 1.50$, and $\sigma_X = 2.0$, representing the standard deviation of testosterone in units of 100 ng/dL. Substitution yielded an initial sample size of approximately 48.2 participants. To account for the correlation between serum testosterone and the prespecified adjustment variables, the sample size was inflated using $n = n_0/(1-R^2)$, assuming $R^2 = 0.20$, resulting in a minimum of 61 participants.

Model complexity was additionally considered using the conventional benchmark of ten observations in the less frequent outcome category per predictor degree of freedom.[22] The prespecified multivariable logistic regression model included nine predictor degrees of freedom. Assuming an ED prevalence of 55%, the corresponding sample size was:

$$N = \frac{10k}{\min(P, 1-P)} = \frac{10(9)}{0.45} = 200$$

where k represents the number of predictor degrees of freedom. Accordingly, 200 participants was adopted as the more conservative sample size benchmark to account for model complexity and reduce the potential for overfitting.

Consecutive sampling was conducted from December 2023 to December 2024, yielding 164 participants, of whom 109 had ED and 55 did not. The achieved sample was below the model-complexity benchmark, providing approximately 6.1 observations in the smaller outcome category per predictor degree of freedom (55/9). This indicated potential model instability, coefficient bias, and imprecise confidence intervals. The primary association was therefore interpreted based on the magnitude and precision of the adjusted OR rather than statistical significance alone.

Statistical methods

All statistical analyses were performed using R version 4.3.3 (R Foundation for Statistical Computing, Vienna, Austria). Continuous variables were summarized as mean ± standard deviation (SD) or median (range), depending on their distribution as assessed by the Shapiro-Wilk test (Appendix Table A1), while categorical variables were summarized as frequencies and percentages.

Univariable logistic regression was performed to estimate the crude associations between serum testosterone concentration, demographic and clinical characteristics, and erectile dysfunction. Crude odds ratios (ORs) with 95% confidence intervals (CIs) were reported to describe unadjusted associations and provide context for the adjusted estimates. These analyses were descriptive and were not used to select variables for multivariable modeling.

Multivariable logistic regression was performed to estimate the adjusted association between serum testosterone concentration and erectile dysfunction. Serum testosterone was designated as the primary exposure, while erectile dysfunction was the binary outcome. Age, BMI, duration of diabetes mellitus, smoking status, alcohol consumption, comorbidities, and diabetes-related complications were identified as prespecified potential confounders based on their clinical relevance and plausible relationships with both serum testosterone and erectile dysfunction. These variables were included for confounding adjustment regardless of their univariable statistical significance. Weight and height were excluded because BMI was included, while individual comorbidities and complications were represented by composite indicators. Serum testosterone was analyzed continuously, with adjusted ORs and 95% CIs reported per 100-ng/dL increase. The adjusted testosterone estimate was the primary association of interest; coefficients for the remaining variables were considered conditional associations within the adjustment model and were not interpreted as independent causal effects.

For the secondary objective, separate univariable linear regression models used serum testosterone as the dependent variable to describe its association with each adjustment-set variable. For continuous variables, beta represented the mean change in testosterone concentration per unit increase; for binary variables and diabetes-duration categories, beta represented the mean difference relative to the reference category. These estimates are presented in Table 3 and labeled on the directed acyclic graph in Figure 1.

Model assumptions and performance were assessed by evaluating multicollinearity using the generalized variance inflation factor (GVIF), calibration using the Hosmer-Lemeshow goodness-of-fit test, and overall explanatory performance using McFadden's, Cox-Snell's, and Nagelkerke's pseudo-R^2 statistics. Missing data were minimal and therefore excluded. All statistical tests were two-sided. Effect estimates were reported with 95% confidence intervals, with interpretation emphasizing the magnitude and precision of the estimates rather than statistical significance alone.

Ethics approval

This study was approved by the St. Luke's Medical Center - Global City Research and Biotechnology Group (SL-23213, RPC-184-07-23). All individuals gave informed consent before participating in the study.

RESULTS

Participants

A total of 179 individuals were recruited in the study. However, 15 patients refused to participate due to personal reasons, time constraints, and refusal to answer the IIEF-5 questionnaire, leaving a total of 164 participants included in the analysis.

Descriptive data

Among the 164 men with type 2 diabetes mellitus included in the study, the mean age was 53.24 ± 10.68 years and the median body mass index was 28.68 kg/m² (range: 18.12-55.28), with 75.0% classified as Obese I or II. Smoking and alcohol use were reported by 38.4% and 63.4% of participants, respectively, while 48.8% had been diagnosed with diabetes for less than five years. Comorbidities were

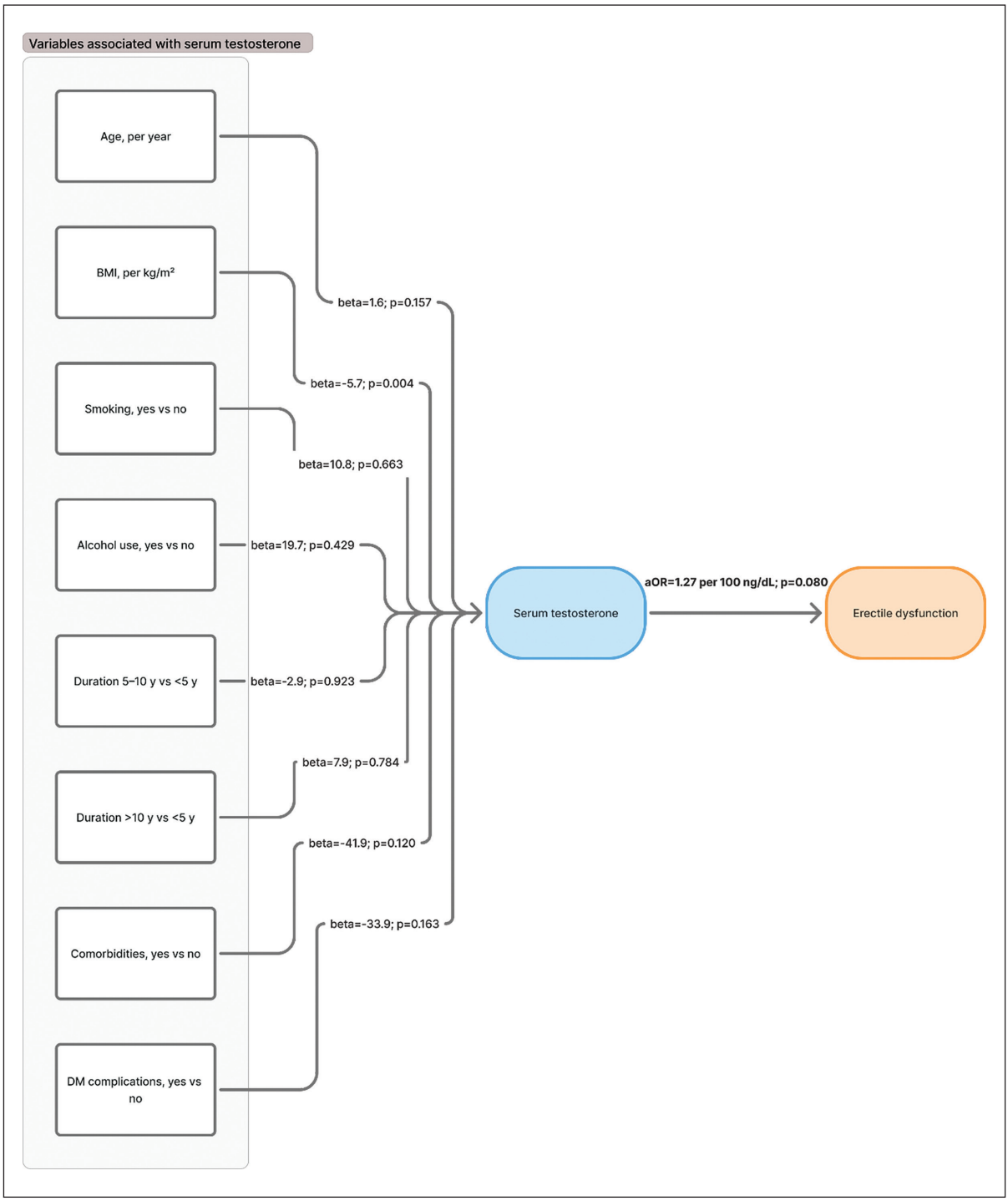

Figure 1. ***Analytical framework for the primary and secondary analyses.*** Left-to-right arrow labels show the univariable linear-regression beta or mean difference in serum testosterone (ng/dL) from Table 3. The serum testosterone-to-erectile dysfunction arrow shows the adjusted odds ratio per 100-ng/dL increase from Table 2.

present in 73.2%, most commonly hypertension (57.9%) and dyslipidemia (37.2%), while 41.5% had diabetes-related complications, particularly nephropathy (32.3%) and retinopathy (17.7%). Erectile dysfunction was identified in 109 participants (66.5%), with mild (32.3%) and mild-to-moderate (22.6%) dysfunction comprising the most frequent severity categories. The median IIEF-5 score was 19.00 (Range: 5.00 - 25.00), while the median serum testosterone concentration was 385.05 ng/dL (Range: 91.83 - 951.33 ng/dL) (Table 1).

Table 1. Baseline demographic, clinical, and erectile dysfunction characteristics of male patients with type 2 diabetes mellitus (T2DM) (n = 164)

Characteristic	Mean ± Std. Dev; Median (Range); Frequency (Proportion %)
Demographic characteristics	
Age, years	Mean: 53.24 ± 10.68
Weight, kg	Mean: 84.24 ± 19.08
Height, m	Median: 1.68 (1.52 - 1.84)
BMI, kg/m²	Median: 28.68 (18.12 - 55.28)
Underweight	2 (1.22%)
Normal	13 (7.93%)
Overweight	26 (15.85%)
Obese I	55 (33.54%)
Obese II	68 (41.46%)
Lifestyle characteristics	
Smoker	63 (38.41%)
Alcohol usage	104 (63.41%)
Diabetes mellitus characteristics	
Duration of diabetes diagnosis (years)	
<5	80 (48.78%)
5 to 10	40 (24.39%)
>10	44 (26.83%)
With comorbidities	120 (73.17%)
No comorbidities	44 (26.83%)
Hypertension	95 (57.93%)
Heart Disease	21 (12.80%)
CVA	6 (3.66%)
Dyslipidemia	61 (37.20%)
Other comorbidities	14 (8.54%)
With complications of DM	68 (41.46%)
No complications of DM	96 (58.54%)
Cardiovascular	7 (4.27%)
Nephropathy	53 (32.32%)
Retinopathy	29 (17.68%)
Neuropathy	7 (4.27%)
Diabetic foot	3 (1.83%)
Erectile dysfunction characteristics	
IIEF-5 Score (5-25)	Median: 19.00 (5.00 - 25.00)
With erectile dysfunction	109 (66.46%)
No erectile dysfunction	55 (33.54%)
ED Severity	
None	55 (33.54%)
Mild	53 (32.32%)
Mild to moderate	37 (22.56%)
Moderate	11 (6.71%)
Severe	8 (4.88%)
Laboratory findings	
Serum testosterone, ng/dL	Median: 385.05 (91.83 - 951.33)

Outcome data

Among the patients in the sample, 109/164 (66.5%, 95% CI, 59.0%-73.2%) had erectile dysfunction (ED) based on the IIEF-5. Mild ED was the most common severity category, affecting 53/164 (32.3%) participants, followed by mild-to-moderate ED in 37/164 (22.6%), moderate ED in 11/164 (6.7%), and severe ED in 8/164 (4.9%). Serum testosterone concentrations showed substantial overlap between participants with and without ED. The subsequent regression analysis estimated the association between serum testosterone and ED after prespecified confounding adjustment (Table 2).

Main results

The primary analysis evaluated the association between serum testosterone concentration and erectile dysfunction (ED) among 164 men with type 2 diabetes mellitus after adjustment for prespecified covariates. Glycemic control was specified in the original protocol but could not be included because HbA1c was unavailable in the final analytical dataset; this represents a deviation from the original analysis plan. Overall, 109 of 164 participants (66.5%) had ED based on the IIEF-5, indicating that approximately two-thirds of the study population were affected. Mild ED was the most frequent category, occurring in 53 participants (32.3%), followed by mild-to-moderate ED in 37 (22.6%), moderate ED in 11 (6.7%), and severe ED in 8 (4.9%).

Table 2 presents the crude associations between the candidate variables and ED, together with adjusted estimates from the prespecified multivariable model. The primary adjusted estimate was the association between serum testosterone concentration and ED (aOR 1.27 per 100-ng/dL increase, 95% CI 0.98–1.69; $p = 0.080$). The confidence interval included the null and was compatible with both little or no association and a potentially meaningful increase in the odds of ED. Adjusted estimates for the remaining covariates are presented only to characterize the prespecified adjustment model and were not interpreted as independent exposure effects.

The final multivariable model demonstrated acceptable calibration, with no evidence of poor fit based on the Hosmer-Lemeshow goodness-of-fit test ($p = 0.198$). The McFadden, Cox-Snell, and Nagelkerke pseudo-R^2 values were 0.21, 0.23, and 0.32, respectively. No important multicollinearity was identified among variables included in the model (all GVIFs <2).

In the secondary descriptive analyses, higher BMI was associated with lower serum testosterone concentration (β −5.7 ng/dL per kg/m², 95% CI −9.5 to −1.9; $p = 0.004$). Estimates for the remaining variables were imprecise and their confidence intervals included the null (Table 3). These analyses were descriptive and were not intended to establish independent or causal associations.

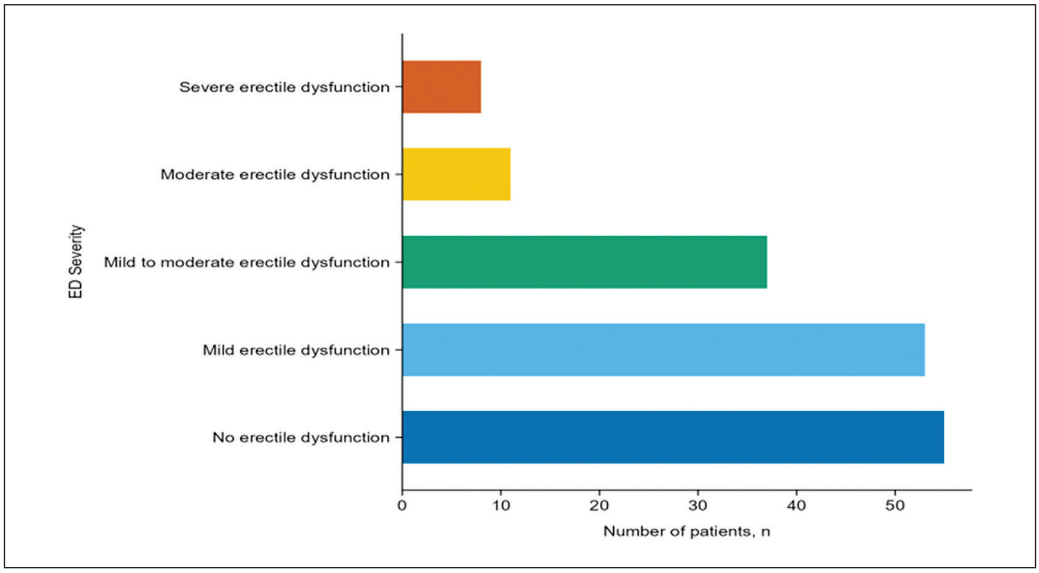

Figure 2. ***Distribution of patients in terms of severity of erectile dysfunction.*** Mild and mild-to-moderate ED were the most common severities.

Table 2. Crude associations of demographic and clinical characteristics with erectile dysfunction and adjusted association between serum testosterone concentration and erectile dysfunction among men with T2DM (n = 164)

Characteristic	Univariable Models		Multivariable Model[1]	
	Crude Odds Ratio (95% CI)	*p*-value	Adjusted Odds Ratio (95% CI)	*p*-value
Primary exposure estimate				
Testosterone, 100 ng/dL	1.25 (1, 1.59)		1.27 (0.98, 1.69)	
Adjustment-model coefficients (contextual only)				
Age, years	1.11 (1.07, 1.16)	**0.001**	1.12 (1.07, 1.18)	**0.001**
Weight, kg	0.98 (0.97, 1)	0.063	-	
Height, m	0.01 (0, 1.87)	0.087	-	
BMI, kg/m²	0.96 (0.91, 1.01)	0.155	1.02 (0.95, 1.09)	0.604
Smoker	1.63 (0.83, 3.3)	0.162	2.1 (0.94, 4.87)	0.077
Alcohol usage	0.53 (0.26, 1.06)	0.081	0.48 (0.2, 1.09)	0.087
Duration of diabetes diagnosis (years)				
<5	Reference		Reference	
5 to 10	1.67 (0.74, 3.93)	0.225	1.05 (0.41, 2.75)	0.923
>10	1.51 (0.69, 3.39)	0.308	0.49 (0.18, 1.34)	0.169
With comorbidities	0.9 (0.42, 1.86)	0.778	0.62 (0.25, 1.46)	0.280
Hypertension	1.72 (0.89, 3.33)	0.105	-	
Heart disease	1.3 (0.5, 3.85)	0.607	-	
CVA	*	0.987	-	
Dyslipidemia	0.53 (0.27, 1.03)	0.060	-	
Other comorbidities	0.47 (0.15, 1.45)	0.180	-	
With complications of DM	1.55 (0.8, 3.07)	0.202	1.36 (0.62, 3.05)	0.446
Cardiovascular	1.27 (0.26, 9.1)	0.777		
Nephropathy	1.63 (0.8, 3.44)	0.184	-	
Retinopathy	1.73 (0.72, 4.65)	0.241	-	
Neuropathy	*	0.986	-	
Diabetic foot	*	0.986	-	

Crude ORs were obtained from separate univariable logistic regression models and were presented for descriptive comparison. The multivariable model included serum testosterone concentration and the prespecified potential confounders of age, BMI, duration of diabetes mellitus, smoking status, alcohol consumption, comorbidities, and diabetes-related complications. Adjustment variables were selected based on clinical considerations rather than univariable statistical significance. The adjusted OR for serum testosterone was the primary estimate of interest. Adjusted coefficients for the remaining variables were reported as contextual conditional associations and were not interpreted as independent causal effects.

*Sparse categories yielded unstable crude estimates.

[1]Weight, height and specific comorbidities and complications not included due to multicollinearity

[1]Hosmer-Lemeshow goodness-of-fit *p*: 0.198, Pseudo R^2: McFadden = 0.21, Nagelkerke = 0.32, Cox-Snell = 0.23

[1]All GVIFs <2

In the multivariable model, covariate estimates are contextual conditional associations within the prespecified adjustment model and are not independent causal effects. The primary adjusted association of interest is serum testosterone.

Table 3. Secondary univariable associations of variables in the prespecified adjustment set with serum testosterone among adults with T2DM (n = 164)

Variable	Beta or mean difference in serum testosterone, ng/dL (95% CI)	*p*-value
Age, per year	1.6 (-0.6 to 3.8)	0.157
BMI, per kg/m²	-5.7 (-9.5 to -1.9)	**0.004**
Smoker	10.8 (-37.9 to 59.4)	0.663
Alcohol use	19.7 (-29.4 to 68.7)	0.429
Duration of diabetes diagnosis (years)		
<5	Reference	
5-10	-2.9 (-61.7 to 56.0)	0.923
>10	7.9 (-49.1 to 65.0)	0.784
With comorbidities	-41.9 (-95.0 to 11.1)	0.120
With complications of DM	-33.9 (-81.7 to 13.8)	0.163

Serum testosterone was the dependent variable in separate univariable linear regression models (n = 164). For continuous variables, beta represents the mean change in testosterone (ng/dL) per unit increase. For binary variables and duration categories, beta represents the mean difference in testosterone relative to the stated reference category.

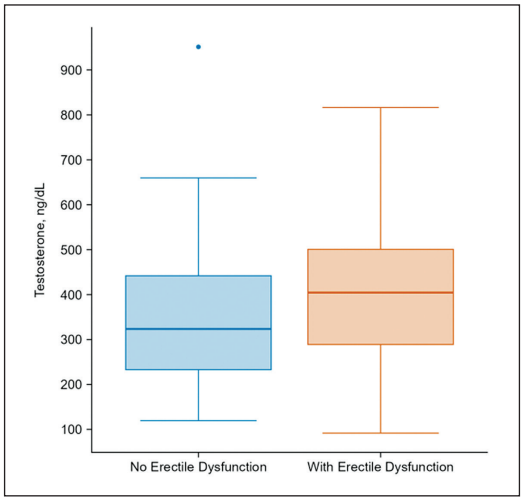

Figure 3. ***Comparison of Serum Testosterone (ng/dL) by ED Diagnosis.*** Serum testosterone concentrations overlapped between participants with and without ED; the adjusted association with ED was not statistically significant.

DISCUSSION

Erectile dysfunction (ED) was identified in 66.5% of men with type 2 diabetes mellitus (T2DM) in this tertiary hospital cohort, with mild and mild-to-moderate ED accounting for most cases. In the primary adjusted analysis, the association between serum testosterone concentration and ED did not reach statistical significance. The adjusted estimate was imprecise and included the null value. These findings demonstrate a substantial burden of ED in this clinical population; however, they do not establish an independent association between serum testosterone concentration and ED.

The prevalence of ED observed in this study (66.5%) is consistent with previous reports among men with T2DM. Defeudis et al.,[5] estimated that men with diabetes have approximately a 3.5-fold higher risk of ED than men without diabetes, while multiple studies have reported prevalence estimates ranging from 50% to 75% among patients with T2DM.[5,23,24] In comparison, the Massachusetts Male Aging Study reported an overall prevalence of approximately 52% among men in the general population,[25] highlighting the substantially greater burden of ED among individuals with diabetes. Our findings therefore support previous evidence that ED remains one of the most common yet frequently overlooked complications of T2DM.

Most participants with ED had mild or mild-to-moderate disease. Similar severity distributions have been reported in previous diabetic cohorts,[23,24] suggesting that many patients present before severe erectile impairment develops. This finding emphasizes the importance of routinely screening for sexual dysfunction during diabetes consultations, as early recognition may allow timely interventions to improve quality of life and address underlying cardiovascular risk factors.

The primary regression analysis was designed to estimate the adjusted association between serum testosterone concentration and ED. Age, BMI, smoking status, alcohol use, duration of diabetes, comorbidities, and diabetes-related complications were included as prespecified adjustment covariates. Accordingly, their coefficients are presented only as contextual estimates within the adjustment model and were not interpreted as independent exposure effects.

These adjusted covariate associations provide context for the serum testosterone estimate but should be interpreted as conditional associations within the specified model, not as independent causal effects. Table 2 presents the crude associations and contextual adjusted associations from this model. In accordance with the secondary objective, Figure 1 and Table 3 describe the separate univariable relationships between serum testosterone and the variables in the adjustment set. These estimates are associations within this cross-sectional dataset and should not be interpreted as causal effects.

First, most participants in our cohort had testosterone concentrations within the physiological range, limiting the ability to detect the stronger associations typically observed in men with overt hypogonadism. Second, ED

in T2DM is increasingly recognized as a multifactorial condition resulting from the interaction of vascular, neurologic, endocrine, and psychological mechanisms rather than testosterone deficiency alone.[5] Consequently, while testosterone remains an important consideration in symptomatic men suspected of hypogonadism, our findings suggest that serum testosterone alone is unlikely to explain most cases of ED among men with T2DM.

Clinical implications

The high prevalence of ED observed in this study supports routine screening for sexual dysfunction among men with T2DM. Because ED frequently precedes clinically overt cardiovascular disease by several years,[26,27] identifying ED should prompt broader cardiovascular risk assessment and optimization of modifiable risk factors rather than focusing solely on treatment of sexual dysfunction.

Testosterone measurement should be interpreted within the broader clinical context. While testosterone testing remains appropriate in men with symptoms suggestive of hypogonadism, the present adjusted estimate does not provide conclusive evidence that serum testosterone alone explains ED among men with T2DM. Comprehensive evaluation that considers vascular health, diabetic complications, medications, and psychosocial factors is therefore likely to provide greater clinical value.

CONCLUSION

Erectile dysfunction affected approximately two-thirds of men with T2DM in this tertiary hospital cohort, with mild and mild-to-moderate presentations accounting for most cases. The adjusted association between serum testosterone concentration and ED did not reach statistical significance. This finding should be interpreted cautiously because the confidence interval was imprecise, the model had limited observations in the less frequent no-ED category relative to its number of estimated parameters, and important metabolic, treatment-related, behavioral, and psychosocial determinants were not measured. The findings support routine, sensitive assessment of sexual health among men with T2DM together with comprehensive evaluation of cardiovascular, metabolic, endocrine, medication-related, and psychosocial contributors.

Limitations

Several limitations should be considered when interpreting these findings. First, the cross-sectional study design precludes establishing temporal or causal relationships between serum testosterone and erectile dysfunction. Second, the study was conducted at a single tertiary hospital wellness center, where patients may have better access to healthcare and improved disease control than the general diabetic population, potentially limiting generalizability. Third, important determinants of erectile dysfunction, including physical activity, depressive symptoms, medication use, relationship factors, and the quantity and duration of smoking and alcohol consumption, were not evaluated and may have resulted in residual confounding. Fourth, the study used a fixed enrollment period and consecutive sampling rather than a prospectively determined target sample size. A formal a priori power calculation for the primary testosterone association was not undertaken because the clinically meaningful effect size and its source, alpha level, power, and expected R^2 for testosterone regressed on the adjustment covariates were not specified before data collection. Any calculation made after data collection would be hypothetical rather than a valid prospective justification. The observed 95% CI for the adjusted testosterone association (0.98-1.69 per 100-ng/dL increase) provides the relevant assessment of precision. The EPV calculation is a secondary check on model stability, not a measure of power. The 55 participants without ED would support at most five parameters under a conventional minimum of 10 observations per parameter, whereas the planned model had 10 parameters and an EPV of 5.5. This shortfall may have increased the risk of overfitting, coefficient bias, and poor confidence-interval coverage. Finally, although the multivariable model demonstrated acceptable calibration and moderate explanatory performance, the observed pseudo-R^2 values indicate that additional biological, psychological, and behavioral factors not captured in this study likely contribute to erectile dysfunction among males with T2DM.

Recommendations

The findings support routine screening for erectile dysfunction using validated questionnaires as part of the clinical assessment of men with T2DM. Larger multicenter prospective studies with an a priori sample-size calculation and a prespecified testosterone adjustment set may provide more precise estimates and improve generalizability. In analyses with sparse outcome categories, parsimonious model specifications and Firth penalized logistic regression can be used to assess the robustness of estimates. Associations involving other exposures were not evaluated in the present study and would require exposure-specific adjustment sets.

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Statement of Authorship
All authors certified fulfilment of ICMJE authorship criteria.

CRediT Author Statement
FAB: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Resources, Data curation, Writing – original draft preparation, Writing – review and editing, Visualization, Project administration, Funding acquisition; **SMP:** Writing – review and

editing, Supervision, Project administration; **PWL:** Investigation; **MR:** Investigation; **KRS:** Investigation; **MPDM:** Supervision.

Author Disclosure
The authors declared no conflict of interest.

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APPENDIX

Table A1. Shapiro-Wilk test results

Variable	Shapiro-Wilk *P*-value	Interpretation
Age	0.712	Normally distributed
Height	0.336	Normally distributed
Weight	<0.001	Non-normally distributed
BMI	<0.001	Non-normally distributed
IIEF-5 score	<0.001	Non-normally distributed
Testosterone	0.002	Non-normally distributed

Table A2. Multivariable regression GVIFs

Variable	GVIF	Df	$GVIF^{1/(2*Df)}$	Interpretation
Testosterone	1.12	1	1.06	No issue
Age	1.33	1	1.15	No issue
BMI	1.15	1	1.07	No issue
Smoking	1.11	1	1.05	No issue
Alcohol	1.11	1	1.06	No issue
Duration of diabetes	1.26	2	1.06	No issue
With comorbidities	1.09	1	1.05	No issue
With DM complications	1.07	1	1.03	No issue