

Prevalence of Hypogonadism in Male Type 2 Diabetes Mellitus Patients: A Cross-Sectional Study

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Received: 11-03-2024 / Revised 16-04-2024 / Accepted 12-05-2024

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DOI: <https://doi.org/10.32553/ijmbs.v8i3.2795>

Conflict of interest: Nil

Abstract:

Background: Type 2 Diabetes Mellitus (T2DM) is a widespread metabolic disorder linked with various complications, including hypogonadism—a condition marked by reduced testosterone levels and symptoms such as erectile dysfunction, decreased libido, and increased fatigue. Hypogonadism remains underdiagnosed in diabetic populations, posing significant challenges to healthcare systems, especially in regions with high diabetic populations such as India.

Methods: This cross-sectional study comprised 173 male T2DM patients aged 35 to 65. The study employed the Androgen Deficiency in Aging Males (ADAM) questionnaire to screen for hypogonadism, alongside physical examinations and biochemical tests to assess testosterone levels and other metabolic parameters.

Results: The incidence of hypogonadism was found to be 27.2% among the study participants. Higher prevalence rates were related with older age, higher body mass index, greater waist circumference, and longer period of diabetes. Elevated fasting blood sugar and poor glycemic control (HbA1c \geq 7%) were also significantly correlated with low testosterone levels.

Conclusion: The significant association between T2DM and hypogonadism underscores the need for routine screening for testosterone deficiency in diabetic care, particularly given the condition's impact on quality of life and metabolic health.

Recommendations: Based on the findings, it is recommended that screening for hypogonadism be integrated into the regular management protocols for T2DM, particularly for patients presenting with metabolic syndrome features or those with poor glycemic control.

Keywords: Type 2 Diabetes Mellitus, Hypogonadism, Testosterone, Metabolic Health, Indian Population

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Introduction

The prevalence of diabetes mellitus, which is rising quickly globally, has made it a substantial public health concern in the twenty-first century. The International Diabetes Federation (IDF) approximates that 451 million adults worldwide had diabetes in 2017; if effective preventive

measures are not put in place, that number is expected to rise to 693 million by 2045 [1]. India, in particular, faces a significant burden, ranking second only to China with an estimated 77 million people affected by diabetes [2]. Among the various forms of diabetes, Type 2 Diabetes Mellitus (T2DM)

is the most predominant, primarily resulting from insulin resistance. This metabolic disorder leads to a cascade of complications affecting multiple organ systems, including the gonads.

Recent research has highlighted a strong association between T2DM and hypogonadism in men, a condition characterized by reduced testosterone levels and a range of symptoms such as erectile dysfunction, decreased libido, increased fatigue, and loss of muscle mass and strength [3]. Primary hypogonadism (testicular failure) and secondary hypogonadism (hypothalamic or pituitary dysfunction) are the two categories of hypogonadism; studies suggest that up to 40% of males with T2DM may be testosterone deficient. This is especially troubling because hypogonadism can seriously lower an affected person's quality of life and general health.

The diagnosis of hypogonadism involves both the presence of clinical symptoms and biochemical evidence of low testosterone levels. Prominent symptoms include sexual dysfunction, such as erectile dysfunction and loss of libido, alongside other manifestations like increased body fat, decreased bone mineral density, and depressed mood [4]. The condition is often underdiagnosed, partly due to the reluctance of patients to discuss sexual health issues and the lack of awareness among clinicians regarding the prevalence of hypogonadism in diabetic populations.

Studies have shown that various factors, including age, obesity, and the duration and severity of diabetes, are significant risk factors for developing hypogonadism [5]. For instance, aging is related with a gradual decrease in testosterone production, a phenomenon termed Late Onset Hypogonadism (LOH). Additionally, obesity and poor glycemic control are strongly correlated with lower testosterone levels, suggesting that metabolic health plays a crucial role in the development of hypogonadism.

The intersection of T2DM and hypogonadism represents a significant but underexplored area of endocrinology. Understanding the incidence and risk factors associated with hypogonadism in T2DM patients is crucial for developing comprehensive care strategies that can improve patient outcomes and quality of life. This study contributes to this understanding by providing valuable insights into the prevalence and correlates of hypogonadism in a specific Indian population.

The study aimed to estimate the incidence of hypogonadism in male Type 2 Diabetes Mellitus patients and to investigate its correlation with various clinical and metabolic parameters.

Methodology

Study Design

A cross-sectional observational study

Study Setting

This study was carried out at Apollo Hospitals, Bhubaneswar, Odisha, over a period of 16 months from November 2020 to February 2022.

Study Population

The study included 173 male patients aged between 35 to 65 years diagnosed with T2DM. These patients were selected from the General Medicine and Endocrinology outpatient departments of the hospital. Inclusion and exclusion criteria were applied to select the participants.

Inclusion Criteria

- Adult male T2DM patients aged 35-65 years.
- Both newly diagnosed and already confirmed T2DM patients on treatment with oral hypoglycemic agents (OHA) and/or insulin.

Exclusion Criteria

- Patients with known cases of hypogonadism already receiving hormone replacement therapy.

- Patients with severe diseases such as chronic renal disease, liver disease, advanced malignancy, debilitating diseases, inflammatory diseases, or severe psychological symptoms.

Data Collection

Data were collected using a pre-structured study proforma, which included:

- Detailed patient history (present illness, past illness, comorbidities, substance abuse, and medication use).
- Physical examination findings.
- Results from relevant laboratory investigations.

Procedure

The Androgen Deficiency in Aging Males (ADAM) questionnaire was used to screen for symptoms of hypogonadism. The ADAM questionnaire consists of ten items evaluating androgen deficiency, including decreased libido, erectile dysfunction, and other nonspecific symptoms.

Physical Examination

- Height and weight were determined to calculate Body Mass Index (BMI) as weight (kg) / height (m²).
- Waist circumference was measured at the midpoint between the iliac crest and the lower rib margin.

Laboratory Investigations

Blood samples were collected in a fasting state between 8 AM and 10 AM to ensure accurate and consistent results. The tests conducted included the following: Fasting Blood Sugar (FBS) and 2-hour Post-

Prandial Blood Sugar (PPBS) levels were measured using the Hexokinase method. Glycated hemoglobin (HbA1c) was determined through High-Performance Liquid Chromatography (HPLC), providing insight into long-term blood sugar control. The lipid profile, which comprised Total Cholesterol (TC), Triglycerides (TG), Low-Density Lipoprotein (LDL), and High-Density Lipoprotein (HDL), was analyzed using spectrophotometry. Additionally, the levels of Total Testosterone (TT), Luteinizing Hormone (LH), and Follicle-Stimulating Hormone (FSH) were measured using Chemiluminescence Immunoassay (CLIA) to assess hormonal status and identify cases of hypogonadism.

Statistical Analysis

Data were compiled and analyzed using IBM SPSS Statistics version 23.0. Variables were presented as mean \pm standard deviation (SD) or median values, and percentages. Several statistical methods were employed: linear regression and correlation analyses, unpaired t-tests or Wilcoxon tests, and Chi-square tests. A p-value of less than 0.05 was regarded as statistically significant.

Ethical Considerations

The study was approved by the Institutional Scientific and Research Committee and the Institutional Ethical Committee. Written informed consent was obtained from all participants.

Result

Table 1: Demographic and Clinical Characteristics

Characteristic	Values
Mean Age (Years)	50.38 \pm 8.09
Age Group, n (%)	
- 35-45 Years	54 (31.2%)
- 46-55 Years	60 (34.7%)
- 56-65 Years	59 (34.1%)
Mean BMI (Kg/m ²)	25.28 \pm 2.35
BMI Group, n (%)	
- <18.5 Kg/m ²	1 (0.6%)
- 18.5-22.9 Kg/m ²	26 (15.0%)
- 23.0-24.9 Kg/m ²	60 (34.7%)

- ≥ 25.0 Kg/m ²	86 (49.7%)
Mean Waist Circumference (cm)	91.74 \pm 4.33
WC Group, n (%)	
- <90 cm	58 (33.5%)
- ≥ 90 cm	115 (66.5%)
Mean Duration of DM (Years)	7.07 \pm 4.59
Duration Group, n (%)	
- 0-5 Years	69 (39.9%)
- 6-10 Years	58 (33.5%)
- 10-20 Years	44 (25.4%)
- >20 Years	2 (1.2%)
Hypertension (Present), n (%)	107 (61.8%)

The study included 173 male patients with T2DM aged between 35 to 65 years. The participants were categorized into three age groups: 35-45 years (31.2%), 46-55 years (34.7%), and 56-65 years (34.1%), with a mean age of 50.38 \pm 8.09 years. The BMI ranged from 18.10 to 32.50 kg/m², with an average of 25.28 \pm 2.35 kg/m². Nearly half

of the participants (49.7%) were classified as obese (BMI ≥ 25 kg/m²). Central obesity, indicated by a waist circumference (WC) of ≥ 90 cm, was present in 66.5% of the patients. The mean period of diabetes was 7.07 \pm 4.59 years, and 61.8% had hypertension.

Table 2: Glycaemic and Lipid profile

Parameter	Values
Mean FBS (mg/dl)	141.00 \pm 23.65
- <126 mg/dl	54 (31.2%)
- ≥ 126 mg/dl	119 (68.8%)
Mean PPBS (mg/dl)	210.99 \pm 61.36
- <200 mg/dl	98 (56.6%)
- ≥ 200 mg/dl	75 (43.4%)
Mean HbA1C (%)	8.12 \pm 1.90
- <7 %	68 (39.3%)
- ≥ 7 %	105 (60.7%)
Mean Total Cholesterol (mg/dl)	217.11 \pm 45.00
- <200 mg/dl	69 (39.9%)
- ≥ 200 mg/dl	104 (60.1%)
Mean Triglycerides (mg/dl)	195.64 \pm 85.33
- <150 mg/dl	72 (41.6%)
- ≥ 150 mg/dl	101 (58.4%)
Mean LDL (mg/dl)	112.87 \pm 30.80
- <100 mg/dl	74 (42.8%)
- ≥ 100 mg/dl	99 (57.2%)
Mean HDL (mg/dl)	40.68 \pm 7.80
- <40 mg/dl	79 (45.7%)
- ≥ 40 mg/dl	94 (54.3%)

The glycaemic profile revealed that the mean FBS level was 141.00 \pm 23.65 mg/dl, with 68.8% of the patients having an FBS of ≥ 126 mg/dl. The mean PPBS level was 210.99 \pm 61.36 mg/dl, and 43.4% of the individuals had a PPBS of ≥ 200 mg/dl. The average HbA1c level was 8.12 \pm 1.90%, with 60.7% of the patients having an HbA1c of ≥ 7 %. The lipid profile showed that the mean TC level was 217.11 \pm 45.00

mg/dl, with 60.1% of the individuals having a TC of ≥ 200 mg/dl. The mean TG level was 195.64 \pm 85.33 mg/dl, and 58.4% of the individuals had a TG level of ≥ 150 mg/dl. The mean LDL level was 112.87 \pm 30.80 mg/dl, with 57.2% having an LDL level of ≥ 100 mg/dl. The mean HDL level was 40.68 \pm 7.80 mg/dl, and 45.7% of the individuals had an HDL level of <40 mg/dl.

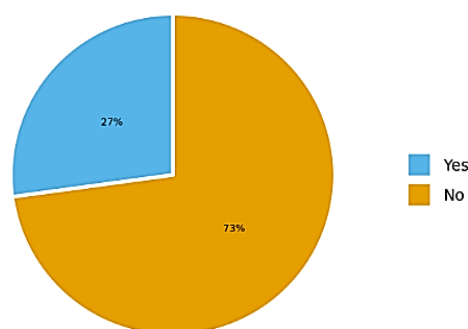


Figure 1: Distribution of Hypogonadism

The prevalence of hypogonadism in the study population was 27.2%, with 47 out of 173 patients meeting the criteria of low total testosterone (TT) levels (<300 ng/dl) combined with a positive ADAM questionnaire. Specifically, 31.8% of the patients had low TT levels, and 50.9% had a positive ADAM questionnaire. Among the patients with hypogonadism, 31.9% had primary hypogonadism (elevated LH/FSH levels), 10.6% had secondary

hypogonadism (low LH/FSH levels), and 57.4% had normogonadotropic hypogonadism (normal LH/FSH levels but low TT).

The most commonly reported symptoms among patients with hypogonadism were erectile dysfunction (ED) and decreased libido, affecting 80.9% and 70.2% of the patients with hypogonadism, respectively. Additionally, 55.3% of these patients reported both ED and decreased libido.

Table 3: Associations between hypogonadism and various factors

Factor, (Mean ± SD)	With Hypogonadism	Without Hypogonadism	p-value
Age (Years)	53.79 ± 7.37	49.11 ± 8.01	<0.001
BMI (Kg/m ²)	26.55 ± 2.27	24.81 ± 2.20	<0.001
Waist Circumference (cm)	94.05 ± 4.21	90.88 ± 4.07	<0.001
Duration of DM (Years)	9.53 ± 4.44	6.15 ± 4.31	<0.001
FBS (mg/dl)	151.81 ± 23.05	136.97 ± 22.67	<0.001
PPBS (mg/dl)	231.74 ± 67.55	203.25 ± 57.26	0.008
HbA1C (%)	8.74 ± 2.18	7.88 ± 1.74	0.005

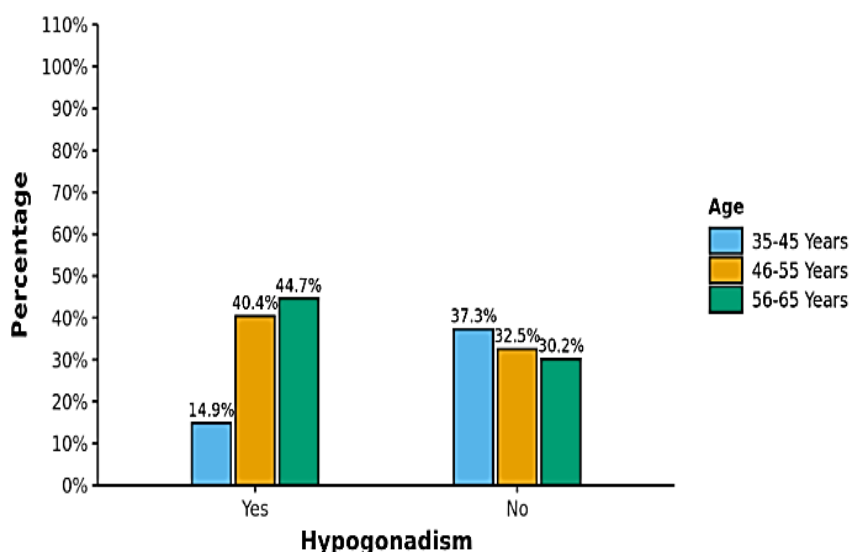


Figure 2: Association between Hypogonadism and Age

There were significant associations between hypogonadism and various clinical and metabolic parameters. Patients with hypogonadism had higher mean and median ages (53.79 ± 7.37 years vs. 49.11 ± 8.01 years, $p < 0.001$), BMI (26.55 ± 2.27 kg/m^2 vs. 24.81 ± 2.20 kg/m^2 , $p < 0.001$),

and waist circumference (94.05 ± 4.21 cm vs. 90.88 ± 4.07 cm, $p < 0.001$) compared to those without hypogonadism. The period of diabetes was also substantially longer in patients with hypogonadism (9.53 ± 4.44 years vs. 6.15 ± 4.31 years, $p < 0.001$).

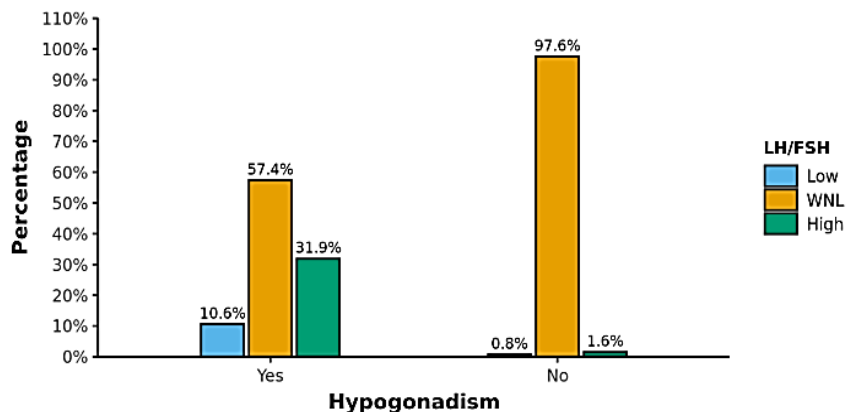


Figure 3: Association between Hypogonadism and LH/FSH

Glycemic control parameters such as FBS, PPBS, and HbA1c levels were significantly higher in individuals with hypogonadism. The mean FBS was 151.81 ± 23.05 mg/dl in patients with hypogonadism compared to 136.97 ± 22.67 mg/dl in those without ($p < 0.001$). Similarly, the mean PPBS was

231.74 ± 67.55 mg/dl in patients with hypogonadism versus 203.25 ± 57.26 mg/dl in those without ($p = 0.008$). The mean HbA1c was $8.74 \pm 2.18\%$ in patients with hypogonadism compared to $7.88 \pm 1.74\%$ in those without ($p = 0.005$).

Table 4: Correlation Between Variables and Total Testosterone (TT)

Variable	Correlation Coefficient (r)	p-value
Age (Years)	-0.45	<0.001
BMI (Kg/m ²)	-0.50	<0.001
Waist Circumference (cm)	-0.44	<0.001
Duration of DM (Years)	-0.46	<0.001
FBS (mg/dl)	-0.31	<0.001
PPBS (mg/dl)	-0.23	0.002
HbA1C (%)	-0.30	<0.001

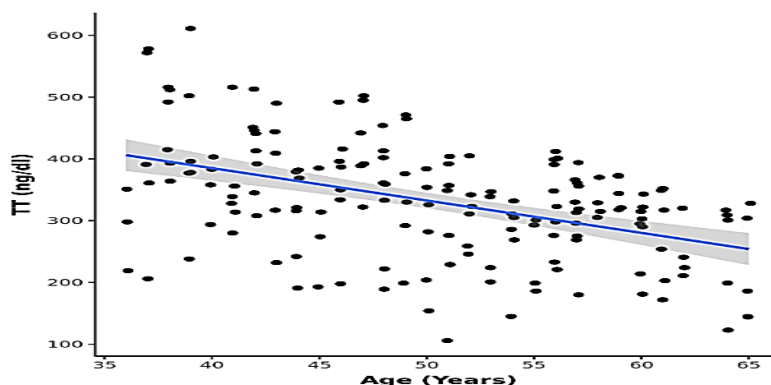


Figure 4: Correlation between Age (Years) and TT (ng/dl)

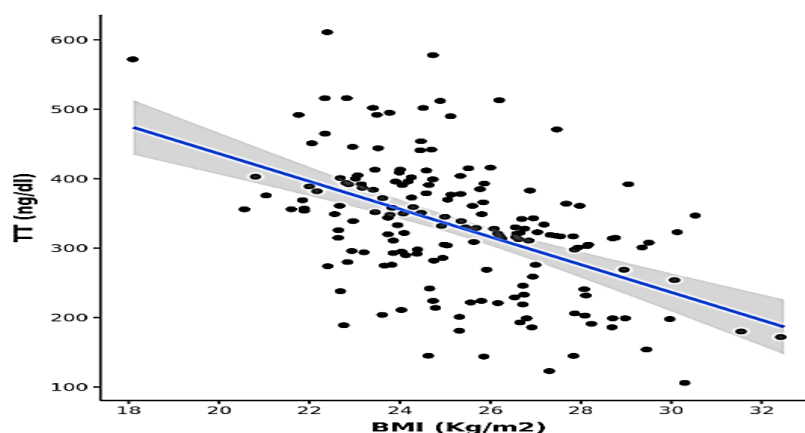


Figure 4: Correlation between BMI (kg/m²) and TT (ng/dl)

There was a moderate negative correlation between age and TT levels ($r = -0.45$, $p < 0.001$), BMI and TT levels ($r = -0.50$, $p < 0.001$), waist circumference and TT levels ($r = -0.44$, $p < 0.001$), duration of diabetes and TT levels ($r = -0.46$, $p < 0.001$), FBS and TT levels ($r = -0.31$, $p < 0.001$), PPBS and TT levels ($r = -0.23$, $p = 0.002$), and HbA1c and TT levels ($r = -0.30$, $p < 0.001$).

Discussion

The study reviewed the incidence of hypogonadism in 173 male patients with T2DM aged between 35 to 65 years. The overall prevalence of hypogonadism was found to be 27.2%. Significant associations were identified between hypogonadism and various demographic and clinical factors, including age, BMI, WC, period of diabetes, and glycemic control.

Older individuals had a higher incidence of hypogonadism. The condition was more common in the 46-55 and 56-65 age groups compared to the 35-45 age group. This finding suggests that aging is a significant risk factor for hypogonadism among T2DM patients, highlighting the need for regular screening for testosterone deficiency in older diabetic patients.

Obesity, particularly central obesity, was strongly associated with hypogonadism. The study found that patients with higher BMI, particularly those classified as obese ($\text{BMI} \geq 25 \text{ kg/m}^2$), had a higher incidence of hypogonadism. Similarly, central obesity, indicated by a waist circumference

of $\geq 90 \text{ cm}$, was significantly linked to hypogonadism. These findings emphasize the role of obesity and central obesity in the development of testosterone deficiency, suggesting that weight management and reduction of central obesity could be effective strategies in managing hypogonadism in T2DM patients.

The study also found a strong correlation between the period of diabetes and the incidence of hypogonadism. Individuals with a longer duration of diabetes had a higher prevalence of hypogonadism. This indicates that chronic hyperglycemia and its complications may contribute to the development of hypogonadism, underscoring the importance of early diagnosis and effective management of diabetes to potentially reduce the risk of developing hypogonadism.

Poor glycemic control was substantially associated with hypogonadism. Patients with higher FBS, PPBS, and HbA1c levels were more likely to have hypogonadism. This finding highlights the need for stringent glucose management in T2DM patients. Improved glycemic control might help mitigate the risk of hypogonadism, emphasizing the importance of maintaining optimal blood sugar levels in diabetic patients.

The symptoms of hypogonadism, such as erectile dysfunction (ED) and decreased libido, significantly impact the quality of life and well-being of patients. The study identified that the most common symptoms

among patients with hypogonadism were ED and decreased libido, with a substantial proportion of patients experiencing both symptoms. Addressing hypogonadism through appropriate screening, diagnosis, and management is crucial for improving the quality of life in male T2DM patients.

The study also categorized hypogonadism into primary (elevated LH/FSH levels), secondary (low LH/FSH levels), and normogonadotropic (normal LH/FSH levels but low TT) types. This variation in the types of hypogonadism suggests that tailored treatment approaches are necessary, depending on the underlying pathophysiology. Understanding the specific type of hypogonadism in each patient can guide clinicians in providing more effective and individualized treatment.

A study explored erectile dysfunction among Type 2 diabetic men in Saudi Arabia. The study reported a high prevalence of erectile dysfunction, which correlates strongly with the duration and severity of diabetes, suggesting potential underlying hormonal imbalances often associated with diabetes. This study highlights the complex relationship between chronic diabetes management and sexual health [6].

Likewise, a study focused on the prevalence and associated factors of hypogonadism in Jordanian diabetic men. The study quantitatively established a high prevalence rate, emphasizing that diabetes significantly impacts hormonal levels, which are crucial for diagnosing hypogonadism [7].

Research identified clinical and biochemical correlates in their study on Nigerian men with T2DM. The results indicate significant correlations between hypogonadism and various biochemical markers such as lower total testosterone levels compared to non-diabetic controls [8].

A comprehensive study on the incidence of hypogonadism in Indian males with T2DM, found a notably high prevalence that suggests an urgent need for regular endocrine assessment in diabetic care [9].

A study reported on the prevalence of hypogonadism in T2DM Indian men, noting a prevalence rate notably higher than in non-diabetic controls, indicating that diabetes is a strong risk factor for hypogonadism. The study points to the need for diabetes management plans to include hormonal assessments [10].

A study examined hypogonadism in male T2DM patients, specifically comparing those with and without CAD. They found hypogonadism prevalence rates of 40% in diabetic men with CAD and 32% in those without, with significantly lower testosterone levels observed in the CAD group. This study reveals that those with CAD exhibited even higher rates of hypogonadism, suggesting a compounded risk that necessitates comprehensive care strategies [11]. These findings underscore the prevalent issue of hypogonadism in diabetic male patients and the need for regular monitoring and management of this condition to improve overall patient outcomes.

Conclusion

In conclusion, the study provides compelling evidence that hypogonadism is prevalent among male T2DM patients and is closely associated with several modifiable risk factors. Regular screening for hypogonadism, along with comprehensive management of diabetes and obesity, could improve clinical outcomes and the quality of life for these patients. These findings underscore the importance of addressing hypogonadism in the overall management plan for male T2DM patients.

Limitations: Cross-sectional studies cannot prove a causal link between hypogonadism and risk factors. Lack of control group for outcome comparison is

another drawback. A hospital-based study with convenient sampling may be prone to selection bias. Free testosterone is a better indicator of androgen status than serum total testosterone, especially in T2DM patients. We could not assess free testosterone in our patients because our hospital did not have the test. Finally, this study involved a few tertiary care hospital patients. Thus, this study's conclusions should be regarded cautiously.

Recommendation: Based on the findings, it is recommended that screening for hypogonadism be integrated into the regular management protocols for T2DM, particularly for patients presenting with metabolic syndrome features or those with poor glycemic control.

Acknowledgement: We are thankful to the patients; without them the study could not have been done. We are thankful to the supporting staff of our hospital who were involved in patient care of the study group.

List of abbreviations:

T2DM: Type 2 Diabetes Mellitus

DM: Diabetes Mellitus

IDF: International Diabetes Federation

LOH: Late Onset Hypogonadism

CAD: Coronary Artery Disease

ADAM: Androgen Deficiency in Aging Males

BMI: Body Mass Index

WC: Waist Circumference

FBS: Fasting Blood Sugar

PPBS: Post-Prandial Blood Sugar

HbA1c: Glycated Hemoglobin

TC: Total Cholesterol

TG: Triglycerides

LDL: Low-Density Lipoprotein

HDL: High-Density Lipoprotein

TT: Total Testosterone

LH: Luteinizing Hormone

FSH: Follicle-Stimulating Hormone

HPLC: High-Performance Liquid

Chromatography

CLIA: Chemiluminescence Immunoassay

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