British Journal of Medicine & Medical Research
18(1): 1-8, 2016, Article no.BJMMR.28969
ISSN: 2231-0614, NLM ID: 101570965

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Pattern of Serum Testosterone and Glycated Haemoglobin among Adult Males with Type 2 Diabetes Mellitus and Erectile Dysfunction Attending a Tertiary Hospital in South Eastern Nigeria

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Authors' contributions

This work was carried out in collaboration between all authors. Author PCO designed the study, wrote the protocol and wrote the first draft of the manuscript. Authors ACA, CBN and FON managed the literature searches. Authors NE, OAO and ACM took care of the analyses of the materials. Authors ACI, CO and JN did the laboratory work while authors RNO, CED and SCM supervised the study. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/BJMMR/2016/28969
Editor(s):
(1) Ricardo Forastiero, Professor of Physiology and Internal Medicine, Haematology, Favaloro University, Argentina.
Reviewers:
(1) Sandra Aparecida Marinho, UEPB, Brazil.
(2) Lorna T. Enerva, Polytechnic University of the Philippines, Philippines.
Complete Peer review History: http://www.sciencedomain.org/review-history/16359

Original Research Article

Received 15th August 2016
Accepted 7th September 2016
Published 27th September 2016

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ABSTRACT

Background: The global prevalence of diabetes mellitus (DM) is steadily increasing. Diabetes mellitus is associated with acute and chronic complications including erectile dysfunction (ED). Erectile dysfunction is commoner among men with diabetes mellitus than their non-diabetic counterparts. This has been attributed to various factors among which are hormonal abnormalities and poor blood glucose control. There is paucity of data on diabetes mellitus and erectile dysfunction in south eastern Nigeria, hence this study.
Aims: To determine the pattern of serum testosterone (ST) and glycated haemoglobin (HbA1c) among adult males with type 2 diabetes mellitus (T2DM) and ED.
Study Design: Cross-sectional analytical.
Study Site: Endocrinology Clinic, Federal Medical Centre, Owerri, Nigeria between July 2015 and January 2016.
Methodology: 200 adult men with T2DM and 100 non-diabetic men were recruited consecutively. Socio-demographic characteristics and relevant medical history were obtained using questionnaires while ED was diagnosed using the international index of erectile function 5 (IIEF-5) questionnaire. Blood pressure and anthropometric indices were also measured. Serum total testosterone (ST), HbA1c and lipid profile were equally assessed. Data analysis was with SPSS version 22 and *P* – value < 0.05 was considered significant.
Results: The prevalence of ED was 86.0% among the T2DM participants and 52.0% among those without DM (*P* < 0.01). The mean ST levels were 4.83 ± 2.66 ng/ml and 6.13 ± 3.00 ng/ml among the T2DM participants and non-diabetic controls respectively (*P* < 0.01) while mean ST among T2DM participants with ED and those without ED were 4.89 ± 2.66 ng/ml and 4.46 ± 2.70 ng/ml respectively (*P* = 0.44). The mean HbA1c was 8.0 ± 2.4 % and 7.3 ± 2.2 respectively among T2DM participants with ED and those without ED (*P* = 0.13).
Conclusion: Serum testosterone levels were significantly lower among adult males with T2DM than those without DM. However, there is no significant difference in the levels of ST between adult T2DM men with ED and those without ED. Similarly, there is no significant difference in the levels of HbA1c between adult T2DM males with ED and those without ED.

Keywords: Diabetes mellitus; erectile dysfunction; serum testosterone; glycated haemoglobin.

ABBREVIATIONS

DM: Diabetes mellitus; ST: Serum testosterone; HbA1c: Glycated haemoglobin; ED: Erectile dysfunction; T2DM: Type 2 diabetes mellitus.

1. INTRODUCTION

The global prevalence of diabetes mellitus [DM] has been on a steady increase, with 171 million people and 285 million people having the condition in the year 2000 and 2010 respectively and with a projection that this will increase to 439 million by the year 2030 [1,2]. In Nigeria, the current prevalence of DM is not known but it is estimated to be in the range of 8 – 10% [3]. Out of this, T2DM constitutes > 95% [4] and the number of people with T2DM in Nigeria is persistently increasing [5]. The rising prevalence of DM in Nigeria is associated with increased morbidity and mortality from acute and chronic complications including ED [6,7]. This makes DM a costly condition to manage [8]. Erectile dysfunction is one of the chronic complications of DM and affects people with both type 1 Diabetes mellitus [T1DM] and those with type 2 Diabetes mellitus [T2DM] [9]. This complication develops within 5 – 10 years in T1DM but may be present in those with T2DM at the time of diagnosis [10]. Erectile dysfunction has also been found to be 2-3 times more common in men with DM than in men without DM and is more severe and more resistant to treatment in them [11]. The prevalence of ED among men with DM varies from place to place and ranges from 35 to 90% [12]. In a hospital based study in Ilorin, Nigeria, Olarinoye et al. [13] observed that the prevalence of ED among men with T2DM was 74%. Similarly, Adebusoye et al. [14] and Ugwu et al. [15] observed that the prevalence of ED among men with DM were 72.7% and 71.1% respectively in Ibadan and Ife both in south western Nigeria. Erectile dysfunction in DM arises as a consequence of multiple factors which act mostly in combination and include vascular, neurological, hormonal, psychological

abnormalities as well as drug treatment of co-morbid conditions like hypertension [16]. However, among these, poor glycaemic control and testosterone deficiency were found to be the strongest risk factors for ED among men with DM [15]. Testosterone has been shown to enhance libido as well as act as a vasodilator of penile arterioles and cavernous sinusoids [17]. It has also be shown that up to 40% of men with ED responded positively to testosterone replacement therapy for ED with improvement in symptoms of hypogonadism [18]. Several studies reported a positive correlation between ED and poor glycaemic control with the frequency of ED being higher among diabetic men with poor glycaemic control than those with good glycaemic control [19,12,20]. Fonseca et al. [21] observed that baseline international index of erectile function (IIEF) erectile function domain scores, which is a measure of erectile function, correlated inversely with baseline glycosylated haemoglobin (HbA1c) levels. Several studies have been done globally on erectile dysfunction among men with diabetes mellitus but there is paucity of data on this in south eastern Nigeria.

2. MATERIALS AND METHODS

The study was cross-sectional analytical and was conducted at the Endocrinology Clinic of Federal Medical Centre, Owerri which is a tertiary health institution that serves as a referral centre for Imo state and other surrounding states in south eastern Nigeria. Two hundred men who had T2DM previously diagnosed using American Diabetes Association (ADA) criteria [22] and 100 non-diabetic men, who were aged 30 years and above were recruited consecutively during the study period between July, 2015 and January, 2016. Those with altered mental status, known cardiac disease, known kidney disease, spinal cord injury and genital deformities as well as those on drugs known to cause erectile dysfunction were excluded from the study. Ethical approval for the study was obtained from the ethics committee of the hospital while written informed consent was obtained from the participants. A pre-tested structured questionnaire was used to obtain information on socio-demographics like age, sex, marital status, tribe, occupation, alcohol intake and cigarette smoking as well as relevant medical history like duration of diabetes, type of anti-diabetes treatment, history of hypertension, duration of hypertension and anti-hypertensive treatment. The abridged version of International index of erectile function (IIEF-5) [23] was used to diagnose and assess the severity of ED among the study participants. Participants with IIEF – 5 score $\leq$ 21 were diagnosed as having ED while those with scores 17 – 21, 12 – 16, 8 – 11 and 5 – 7 were classified as having mild, mild to moderate, moderate and severe ED respectively [24,23]. Blood pressure (BP) was measured with mercury sphygmomanometer (ACCUSON ENGLAND) using standard procedure, in sitting position, and on the non dominant arm after at least 5 minutes rest and diagnosis of Hypertension was based on BP ≥ 140/90 mmHg [25] and/or taking antihypertensive drug. Two consecutive measurements were done 5 minutes apart and the average obtained. Phase I Korotkoff sound was used for systolic BP and Phase V for the diastolic BP. However, where phase V sound could not be obtained; phase 1V sound was used for diastolic pressure. Anthropometric indices were measured for each participant using standard procedures [26,27]. Weight was measured to the nearest 0.5 kilogram using a standard weighing scale (Hanson, England) with the participants wearing light clothes and on bare foot. The scale was on a hard and flat surface, and calibrated frequently using known standard 10 kg weight, while the pointer of the scale was adjusted to zero before each measurement. Height was measured to the nearest 0.1 cm using a stadiometer (Avery England) in an erect position against the wall without foot wears, head scarf or caps. Body Mass Index (BMI) was then calculated by dividing the weight (W) in kg by the square of the participant's height (H^2) in meters i.e. BMI = W/H^2 in (kg/m^2) and all values were taken to the nearest one decimal place and was classified as underweight (<18.5 kg/m2), normal (18.5 - 24.9 kg/m2), overweight (25.0 - 29.9 kg/m2) and obese (≥30 kg/m2). Waist circumference (WC) was measured to the nearest 0.1 cm at the midpoint between the lower rib margin and the iliac crest while the hip circumference was measured to the nearest 0.1 cm at the point of maximum circumference of the buttocks using a non elastic measuring tape. The Waist: hip ratio (WHR) was then calculated. About 8 mls of blood was collected from each of the participants using standard procedures, after overnight fast. Out of this, 2 mls was put into ethylene-diamine-tetracetic acid (EDTA) bottle for assessing HbA1c while 6 mls was put into plain bottle for serum testosterone and lipid profile. The blood sample for serum testosterone and lipid profile was then allowed to stand for about 2 hours, after which it was spun using Centrifuge at 3000 revolutions per minute [rpm] for 10 minutes and

serum separated. The serum was then stored frozen at – 20℃ and used within one week. Serum total testosterone was assessed using enzyme immunoassay kit [Monobind Inc., [USA] while HbA1c was assessed using In2it HBA1C analyzer (BIO-RAD Laboratories) which uses the principle of boronate affinity chromatography to separate glycated fraction from non-glycated fraction of haemoglobin. Serum total cholesterol (TC) was determined by enzymatic method [28] using Biosystems reagents while triglycerides was determined by colorimetric method [29] using [TRIGS] GPO – PAP kit by Randox Diagnostics Ltd, UK. High density lipoprotein cholesterol (HDL-C) was determined by the precipitant method [30] using HDL-Chol kit (Randox Diagnostics Ltd, UK) while low density lipoprotein cholesterol (LDL-C) was calculated using the Friedewald formula [31].

2.1 Statistical Analysis

The data obtained was entered and analyzed using statistical package for social sciences (SPSS) version – 22 (IBM, USA) and then presented as tables, graphs and charts. Continuous variables were described using mean ± standard deviation (SD) if normally distributed while non-normally distributed variables were described using median (interquartile range). Categorical variables were compared using the chi-square test where appropriate while differences in group means were ascertained using the Student's t test and p-value < 0.05 was taken as significant.

3. RESULTS

Two hundred [200] participants with T2DM who met the inclusion criteria as well as 100 non-diabetic controls who did not have any of the exclusion criteria were recruited for the study. One hundred and ninety two (96%) and 94 (94%) of the T2DM and control participants respectively were married while the rest were single but had active sexual life. The T2DM participants had an age range of between 30 – 85 years with a mean of 59.85 ± 11.35 years while the control group had an age range of 30 – 84 years with a mean of 59.12 ± 12.57 years. Among the T2DM participants, 172 (86%) had ED while among the non-diabetic controls 52 (52%) had ED. Table 1 shows the clinical characteristics of the study participants while Table 2 shows the clinical characteristic of T2DM participants with ED and those without ED.

The serum testosterone among the T2DM participants ranged from 0.70 to 11.70 ng/ml with a mean of 4.83 ± 2.66 ng/ml while among the control participants, the ST ranged from 1.10 ng/ml to 16.40 ng/ml with a mean of 6.13 ± 3.10 ng/ml. Also among the T2DM participants in this study, their HbA1c were between 4.0 and 14.8% with a mean of 7.9 ± 2.4 while among the non-diabetic control participants, their HbA1c were between 3.8 and 6.0% with a mean of 5.0 ± 0.7%. Table 3 shows the levels of ST, HbA1c and lipid profile among the T2DM and control participants in this study.

Among the T2DM participants, those with ED had mean ST of 4.89 ± 2.66 while those without ED had mean ST of 4.46 ± 2.70. Table 4 shows the levels of ST, HbA1c and lipid profile among the T2DM participants with ED and those without ED while Table 5 shows the levels of ST, HbA1c and lipid profile among the T2DM participants with ED and non-diabetic controls with ED.

Table 1. Clinical characteristics of study participants (MEAN ± SD)

Variable	T2DM N = 200	Control N = 100	T – value	p-value
Age (years)	59.9 ± 11.3	59.1 ± 12.6	0.49	0.63
Weight (kg)	70.38 ± 14.26	74.56 ± 16.91	2.12	0.04
Height (m)	1.65 ± 0.08	1.65 ± 0.10	0.00	1.00
SBP (mmHg)	133.84 ± 20.87	132.51 ± 21.67	0.51	0.61
DBP (mmHg)	78.84 ± 12.00	82.83 ± 13.99	2.44	0.02
BMI (kg/m^2)	25.78 ± 4.79	27.46 ± 5.89	2.47	0.01
WC (cm	93.20 ± 12.16	91.63 ± 12.10	1.06	0.29
WHR	0.93 ± 0.06	0.89 ± 0.08	4.42	0.000
IIEF-5	13.97 ± 6.28	21.09 ± 3.32	12.84	0.000

BMI: Body mass index, IIEF-5: International index of erectile function, T2DM: Type 2 diabetes mellitus, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, WC: Waist circumference, WHR: Waist-Hip ratio

Table 2. Clinical characteristics of T2DM participants with erectile dysfunction and those without erectile dysfunction (MEAN ± SD)

	T2DM participants			
Variable	**ED present N = 172**	**ED absent N = 28**	**T- value**	**P – value**
Age (years)	60.7 ± 10.3	54.5 ± 15.8	2.00	0.05
Weight (kg)	70.78 ± 14.79	67.88 ± 10.32	1.29	0.20
Height (m)	1.65 ± 0.08	1.64 ± 0.10	0.50	0.62
SBP (mmHg)	135.23 ± 21.49	125.29 ± 14.09	3.18	0.003
DBP (mmHg)	79.33 ± 12.08	75.86 ± 11.27	1.50	0.14
BMI (kg/m^2)	25.87 ± 4.87	25.20 ± 4.28	0.75	0.46
WC (cm)	93.39 ± 12.30	92.04 ± 11.38	0.58	0.57
WHR	0.93 ± 0.06	0.93 ± 0.08	0.00	1.00
IIEF-5	12.22 ± 4.87	24.71 ± 0.46	32.75	0.000

BMI: Body mass index, IIEF-5: International index of erectile function, T2DM: Type 2 diabetes mellitus, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, WC: Waist circumference, WHR: Waist-Hip ratio

Table 3. Levels of serum testosterone, HbA1c and lipid profile among T2DM and control participants (MEAN ± SD)

Variable	**T2DM N = 200**	**Control N = 100**	**T-value**	**p-value**
ST (ng/ml)	4.83 ± 2.66	6.13 ± 3.00	3.67	0.000
HbA1c (%)	7.9 ± 2.4	5.0 ± 0.7	15.80	0.000
TC (mmol/L)	4.78 ± 1.09	4.76 ± 0.97	0.16	0.87
TG (mmol/L)	1.39 ± 0.56	1.36 ± 0.52	0.46	0.64
HDL-C (mmol/L)	1.24 ± 0.39	1.38 ± 0.49	2.49	0.01
LDL(mmol/L)	2.89 ± 0.99	2.84 ± 0.34	0.64	0.52

HbA1c: Glycated haemoglobin, TC: Total cholesterol, TG: Triglycerides, HDL-C: High density lipoprotein cholesterol, LDL-C: Low density lipoprotein cholesterol, SD: Standard deviation, ST: Serum testosterone

Table 4. Levels of serum testosterone, HbA1c and lipid profile among T2DM participants with erectile dysfunction and those without erectile dysfunction (MEAN ± SD)

	T2DM participants			
Variable	**ED present N = 172**	**ED absent N = 28**	**T- value**	**P – value**
ST (ng/ml)	4.89 ± 2.66	4.46 ± 2.70	0.78	0.44
HbA1c (%)	8.0 ± 2.4	7.3 ± 2.2	1.54	0.13
TC (mmol/L)	4.81 ± 1.12	4.60 ± 0.88	1.12	0.27
TG (mmol/L)	1.40 ± 0.57	1.34 ± 0.46	0.62	0.54
HDL-C (mmol/L)	1.24 ± 0.35	1.26 ± 0.61	0.17	0.87
LDL-C (mmol/L)	2.91 ± 1.02	2.74 ± 0.80	1.00	0.32

HbA1c: Glycated haemoglobin, TC: Total cholesterol, TG: Triglycerides, HDL-C: High density lipoprotein cholesterol, LDL-C: Low density lipoprotein cholesterol, SD: Standard deviation, ST: Serum testosterone

Table 5. Levels of serum testosterone, HbA1c and lipid profile among T2DM and control participants with erectile dysfunction (MEAN ± SD)

	Participants with erectile dysfunction			
Variable	**T2DM N = 172**	**Control N = 52**	**T- value**	**P – value**
ST (ng/ml)	4.89 ± 2.66	5.88 ± 2.86	2.22	0.03
HbA1c (%)	8.0 ± 2.4	4.9 ± 0.6	15.42	0.000
TC (mmol/L)	4.81 ± 1.12	4.79 ± 0.98	0.12	0.90
TG (mmol/L)	1.40 ± 0.57	1.38 ± 0.56	0.22	0.82
HDL-C (mmol/L)	1.24 ± 0.35	1.42 ± 0.61	2.03	0.047
LDL-C (mmol/L)	2.91 ± 1.02	2.75 ± 0.82	1.16	0.25

HbA1c: Glycated haemoglobin, TC: Total cholesterol, TG: Triglycerides, HDL-C: High density lipoprotein cholesterol, LDL-C: Low density lipoprotein cholesterol, SD: Standard deviation, ST: Serum testosterone

4. DISCUSSION

This study showed that there is a significantly higher prevalence of ED among adult men with T2DM than those without DM. This finding is in conformity with reports from similar studies in other parts of Nigeria [13,14,15].

The mean serum testosterone level among the T2DM participants in this study was significantly lower than that of the non-diabetic controls. This is in keeping with the observations from similar studies [32,33]. Grossman et al. [33] stated that low ST among men with T2DM may serve as a marker of adverse metabolic profile in them. Thus serum testosterone levels should be checked regularly among men with T2DM while those found to have low ST levels should be further evaluated for metabolic disorders like dyslipidaemia and obesity. However, while the mean ST level among T2DM participants with ED in this study was significantly lower than that of control participants with ED, there was no significant difference between the mean ST levels of T2DM participants with ED and those without ED. This observation is different from that by Ghazi et al. [34] who reported that ST levels were significantly lower among DM patients with ED than those without ED. This difference may however be explained by the differences in the design of the two studies as the study by Ghazi et al. [34] was retrospective.

As expected, the mean HbAIc was significantly higher among the T2DM participants than non-diabetic controls in this study. Diabetes mellitus is characterized by persistent hyperglycaemia and as a result of this there is increased tendency for non-enzymatic glycation of haemoglobin with formation of glycated haemoglobin (HbA1c) [35]. Monitoring of the level of HbA1c in the blood is of immense importance in the management of people with DM as it is used to monitor the level of glycaemic control over 2-3 months [36]. Furthermore, the American Diabetes Association has advocated the use of HbAIc for the diagnosis of DM [37]. On the other hand, there is no significant difference in the levels of HbA1c between T2DM participants with ED and those without ED. This may be due to improved blood glucose control among people with DM. Secondly, other risk factors among these men other than poor blood glucose control may be responsible for their ED.

5. CONCLUSION

Serum testosterone levels are significantly lower among men with T2DM than their non-diabetic counterparts but there is no significant difference in the levels of ST between T2DM men with ED and those without ED. Similarly, there is no significant difference in the levels of HbA1c between T2DM men with ED and those without ED.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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