

Socio-Demographic and Clinical Correlates of Erectile Dysfunction among Men with Type 2 Diabetes Mellitus: A Cross-Sectional Study in South India.

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Abstract

Objective: Erectile dysfunction (ED) is a common complications in men with type 2 diabetes. The present study was undertaken to investigate to find out the socio-demographic and clinical correlates of erectile dysfunction among men with type 2 diabetes mellitus.

Materials and methods: Married men aged 20-60 years with a diagnosis of non-insulin-dependent (Type 2) diabetics attending the outpatient unit of Department of Endocrinology at PSG Hospitals, Coimbatore during the months of May and June 2019 were enrolled. Erectile function was assessed using International index of Erectile Function(IIEF-5). All subjects were evaluated for obesity, physical activity, hypertension, retinopathy, glycated hemoglobin, total cholesterol, and medication use.

Results: Among 204 patients studied, 65 (31.86%) were found to have erectile dysfunction. Mild to

moderate, moderate and severe ED was present in 17.2%, 11.8% and 2.9% patients respectively. In unadjusted analysis, ED was significantly associated with patients who were having less physical activity ($p=0.003$), hypertension ($p=0.001$), obesity ($p=0.021$) and retinopathy ($p=0.000$). In the multivariate linear regression analysis, less physical activity (odds ratio (OR)=2.395 (95% confidence interval (CI):1.171-4.899, $p=0.017$) and diabetic retinopathy (OR=3.869 (95% CI:1.568-9.606, $p=0.004$)) were found to be significant independent predictors of ED in the study population.

Conclusion: Prevalence of ED was higher in type 2 diabetic male patients. Diabetic retinopathy and less physical activity was significant risk factors associated with ED, making it possibly a preventable condition.

Keywords: Type 2 diabetes; Erectile dysfunction; Risk factor; Prevalence; Diabetic retinopathy; Physical activity.

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Introduction

Diabetes mellitus (DM) is a chronic metabolic a disorder associated with significant morbidity.¹ The prevalence of erectile dysfunction in men ranges from 35-75% versus 26% in general population and affects more than 150 million worldwide, with that number is expected to be double to 322 million men by the year 2025.²⁻⁶ Various forms of sexual dysfunction occur in men with DM, including disorder of libido, ejaculatory problem, and erectile dysfunction (ED). DM is one of the most common comorbidities of ED.⁷ ED is the inability to attain or sustain an erection satisfactory for sexual

intercourse.^{1,7-14} It is defined as the persistent inability to achieve or maintain penile erection sufficient for satisfactory sexual performance.⁷ The penis has two chambers inside it called the corpora cavernosa. These chambers extend from the head of the penis deep into the pelvis. The insides of these chambers are made of spongy tissue and have the ability to gain blood volume and grow in size. In response to physical or mental stimulation, The brain sends signals to trigger a hormonal response that allows those arteries that supply blood to the penis will open completely. Open arteries allow more blood to enter the corpora cavernosa. The blood enters faster than it can leave through the veins. The veins get compressed, trapping blood in the penis. These chain reaction helps to achieve and maintain an erection and the absence of it can lead to ED. Men experiencing ED have demonstrated severe deficiency within their personal relationships, self-confidence and overall quality of life.²

Obtaining accurate data about sexual dysfunction is difficult because it is a personal and sensitive nature of the information. Many factors discourage survey respondents from being entirely truthful, so it has proved difficult to obtain an assessment of the incidence of erectile problems in a representative sample of the general population.¹⁵ Despite these difficulties, several studies were conducted to investigate the associated factors of ED among the general population and among patients with diabetes^[16]. McCulloch et al.¹⁷ in a study conducted in the UK, reported 35% prevalence of ED for both Type 1 and Type 2 diabetic patients. Brunner et al.¹⁸ in a study conducted by the Department of Internal Medicine, Urology and Psychiatry at the University of Graz, reported 49% of ED in 59 Type 1 diabetic patient. In a study involving 125 type 2 diabetic patients in Massachusetts, Nathan et al.¹⁹ observed a prevalence of 71% of ED. Diabetic men may be stricken by a multitude of concomitants, including cigarette smoking, alcohol consumption, hypertension, overweight, or obesity, and all these may affect ED.¹² To the best of our knowledge, only very few studies were done in India to investigate the associated factors of ED among type 2 diabetes. More studies are needed to assess whether ED is a preventable condition among type 2 diabetes. The aim of the present study is to investigate whether there is any significant association between the socio-demographic factors, clinical factors and the medication use with ED among patients with type 2 diabetes.

Materials and Methods

This was a cross-sectional study conducted at the Department of Endocrinology, PSG Hospital, Coimbatore during the months of May-June 2019. The data were collected from all confirmed type 2 diabetic patients attending the out-patient unit of Department of Endocrinology at PSG Hospital during the months of May and June 2019. With an expected prevalence of ED among diabetic patients as 40% and 20% allowable error of the prevalence, 95% confidence limits and 25% non-response, the sample size for this study is 200 to get reliable estimates. Married male patients diagnosed with type 2 diabetes, aged 20-60 years, staying with their wife minimum for the past one month were included using non-probability consecutive sampling. Patients with a history of a coronary event (myocardial infarction, coronary artery bypass surgery, or coronary angioplasty) in the previous 4 weeks and patients with liver diseases, renal diseases, and dialysis were excluded. Thus, we studied a total of 204 patients. All were invited to a confidential interview during the visit when they were identified. The ethical clearance was obtained from Institute Human Ethics Committee at PSG Hospitals, Coimbatore before the start of the study. Consent of the patients was taken. Confidentiality of the participants was ensured.

The study tool has 2 parts. First part contains collection of subject's demographic factors and clinical parameters from their records. The demographic factors studied were age (in years (<=45, 46-55, 56-60)), current smoking status (Yes, No), current alcohol consumption (Yes, No), obesity (Yes: Body Mass Index (BMI) (Kg/m²) >=30, No: BMI (Kg/m²) <30), central obesity (waist circumference in inches more than or equals 37 vs less than 37), physical activity (Yes: >=40 minutes in an average per day, No: <40 minutes in an average per day). Clinical parameters evaluated were duration of diabetes (from the time which patients were biochemically diagnosed was categorically classified as 1-5, 6-10 and 11-30 in years), hypertension (Yes: those with blood pressure 140/90 mm/Hg or those who were taken anti-hypertensive drugs, No: others), retinopathy (Yes: retinal changes such as aneurysm, haemorrhages, exudates, cotton wool spots and neovascularization, No: others), glycated haemoglobin (mmol/mol) [(Poor (HbA1c >=7), Good (HbA1c <7)] and total cholesterol (mg/dl) (Yes: >=200 mg/dl, No: <200 mg/dl). In addition, we have collected various medications they are taking include antihypertensive (Yes, No),

cardiovascular (Yes, No), hormonal agents (Yes, No) and H² receptors (Yes, No) drugs. In the second part, the patients were interviewed face to face to get the information on ED using the validated International Index of Erectile Function (IIEF-5) questionnaire.²⁰ The questionnaire comprises of 15 questions. Patients were classified based on the IIEF scores as: patients with ED (score as: ≤14 out of 30) and patients without ED (score as: >14 out of 30). Erectile function status of subjects was classified as follows: normal erectile function (score <21), mild ED (score 17-21), mild to moderate ED (score 12-16), moderate ED (score 8-12) and severe ED (score <8). The IIEF score was computed by adding the scores of replies on the six questions (how often were you able to get an erection during sexual activity?, when you had erections with sexual stimulations, how often were your erections hard enough for penetration?, when you attempted intercourse, how often were you able to penetrate (enter) your partner?, 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?, how do you rate your confidence that you could get and keep an erection?).

Data were analyzed using SPSS (SPSS Inc., Chicago, Ill., USA) version 24. Mean and standard deviation was calculated for continuous variables, number and percentage for categorical variables. To test for independent predictors of ED, all the variable that showed significant association with ED at the univariate analysis was subjected to binary logistic regression to compute their odds ratio and 95% confidence interval (CI). In addition, unadjusted and age-adjusted logistic regression analysis was used to evaluate the association of various medications with ED. pvalue <0.05 was considered as statistically significant.

Results

Prevalence of erectile dysfunction in the study population

Out of the 204 diabetic patients who completed the survey, 65 (31.86%) had varying erectile dysfunction. 35 (17.2%) were mild to moderate, 24 (11.8%) were moderate and 6 (2.9%) were severe as per the IIEF score. The details are presented in Table 1.

Table 1: Erectile function scores of the study population.

| Erectile function status | Frequency | Percentage |
|---|-----------|------------|
| Normal erectile function (IIEF-5 score >21) | 139 | 68.1 |
| Mild ED (IIEF-5 score 17-21) | 0 | 0.0 |
| Mild-to-moderate ED (IIEF-5 score 12-16) | 35 | 17.2 |
| Moderate ED (IIEF-5 score 8-11) | 24 | 11.8 |
| Severe ED (IIEF-5 score <8) | 6 | 2.9 |
| Total | 204 | 100.0 |

Association of variables with erectile dysfunction

Table 2 shows a comparative analysis of the socio demographic and metabolic variables between the participants who had ED and those who don't have ED. There was no association between the age of the participants and ED. The current smoking status, alcohol consumption, obesity, waist circumference, glycated hemoglobin and total cholesterol were not significantly associated with ED. Less physical activity (p <0.01), hypertension (p <0.01), obesity (p <0.05) and retinopathy (p <0.001) were significantly associated with ED.

Independent predictors of erectile dysfunction

In the multiple logistic regression analysis, it was observed that less physical activity (OR=2.395 (95% CI:1.171-4.899, p <0.05)) and retinopathy (OR=3.869 (95% CI:1.568-9.606, p <0.01)) were found to be significant independent predictors of ED in the study population (Table 3).

Association of medication usage with erectile dysfunction

It was observed that usage of antihypertensive drugs (OR=2.648 (95% CI:1.369-5.119, p <0.01), cardiovascular drugs (OR=3.389 (95% CI:1.787-6.427, p <0.001) and hormonal agent (OR=5.506 (95% CI:2.348-12.912, p <0.001) were significantly associated with ED even after adjusting the effects of age (Table 4).

Discussion:

ED is a common problem amongst men who have DM.²¹⁻²⁶ In the present study, out of 204 diabetic male patients, the erectile dysfunction was present in 65 (31.86%) patients of which 35 (17.2%) had mild-to-moderate ED, 24 (11.8%) patients had moderate and 6 (2.9%) patients had severe ED. Various other studies have reported the prevalence of ED in diabetic patients with variable results. In a study

of 96 men with diabetes at Lagos, Adedokunet et al.²⁷. 34% prevalence of ED was observed. In a multicentric study involving 9756 diabetes patients on Italy, Domenico Fedele et al. observed a prevalence of 37%. In India, Sumeet Garget et al.⁷ reported a prevalence of 78% among 50 patient studied. These observed differences may be attributed to the presence of other confounding comorbidities and the differences in the socio-demographic characteristics. Nevertheless, most authors agree that ED is not only a common complication on DM, but it is also frequently under-diagnosed.

In unadjusted analysis, obesity, less physical activity, hypertension and retinopathy were significantly associated with erectile dysfunction. However, in the multivariate-adjusted, diabetic retinopathy and less physical activity were only significantly associated with ED whereas hypertension was not significantly associated with ED. Few studies have been explored the relationship between diabetic retinopathy (DR) and ED. Some of these studies have reported an increased frequency of self-reported ED in individuals with DR. Oren Heniset et al.⁸ observed a significant association between ED and DR. However, Yu et al.²⁸ found

Table 2: Prevalence of erectile dysfunction according to demographic and metabolic parameters.

| Variables | Total studied | Number | Percentage | P-value |
|--------------------------------|-----------------|--------|------------|---------|
| Age (in years) | <45 | 56 | 15 | 26.8 |
| | 45-55 | 71 | 27 | 38 |
| | 56-60 | 77 | 23 | 29.9 |
| Current smokers | Yes | 7 | 3 | 42.9 |
| | No | 197 | 62 | 31.5 |
| Alcohol use | Yes | 22 | 7 | 31.8 |
| | No | 182 | 58 | 31.9 |
| Obesity | BMI>=30 | 25 | 13 | 52 |
| | BMI<30 | 179 | 52 | 29.1 |
| Physical activity (in minutes) | <40 | 120 | 48 | 40 |
| | >=40 | 84 | 17 | 20.2 |
| Hypertension | Yes | 76 | 35 | 46.1 |
| | No | 128 | 30 | 23.4 |
| Diabetic retinopathy | Yes | 35 | 22 | 62.9 |
| | No | 169 | 43 | 25.4 |
| Waist circumference (inches) | >=37 | 110 | 40 | 36.4 |
| | <37 | 94 | 25 | 26.6 |
| Glycated haemoglobin (%) | Poor (HbA1c>=7) | 121 | 40 | 33.1 |
| | Good (HbA1c<7) | 83 | 25 | 30.1 |
| Total Cholesterol (mg/dl) | >=200 | 17 | 5 | 29.4 |
| | <200 | 187 | 60 | 32.1 |

Table 3: Independent predictors of Erectile Dysfunction in the study population

| Variables | Odds Ratio for ED | 95% Confidence interval | p value |
|-------------------------------|-------------------|-------------------------|-------------|
| Physical activity(in minutes) | >=40 | 1 | 1 |
| | <40 | 2.395 | 1.171-4.899 |
| Diabetic retinopathy | No | 1 | 1 |
| | Yes | 3.869 | 1.558-9.606 |

Table 4: Distribution of Type 2 diabetic subjects according to presence of erectile dysfunction(ED) and medication use

| Drugs | Use | Total studied | Number of patients with erectile dysfunction | Percentage | Unadjusted odds ratio(95% confidence limits) | Age adjusted odds ratio(95% confidence limits) |
|----------------------|-----|---------------|--|------------|--|--|
| Antihypertensive | No | 152 | 40 | 26.3 | 1 | 1 |
| | Yes | 52 | 25 | 48.1 | 2.593(1.350-4.98)p=0.004* | 2.648(1.369-5.119)p=0.004* |
| Cardiovascular drugs | No | 136 | 32 | 23.5 | 1 | 1 |
| | Yes | 68 | 33 | 48.5 | 3.064(1.650-5.691) P=0.000 | 3.389(1.787-6.427) P=0.000 |
| Hormonal agents | No | 175 | 46 | 26.3 | 1 | 1 |
| | Yes | 29 | 19 | 65.5 | 5.328(2.308-12.289)P=0.000 | 5.506(2.348-12.912)=0.000 |
| H2 receptor | No | 195 | 64 | 32.8 | 1 | 1 |
| | Yes | 9 | 1 | 11.1 | 0.256(0.31-2.090)p=0.203 | 0.279(0.034-2.300)p =0.236 |

*= significant with p value<0.05

no association between ED and DR. However, the patients in their study were considered having a milder ED. An independent association between ED and DR among diabetic men were also found by Siu et al.²⁹ However, they did not use a validated questionnaire to detect ED. DR is the result of microvascular retinal changes, which include endothelial dysfunction and increased vasculature permeability. DR affects most patients with long-standing DM. Just like ED, DR precedes diabetic macrovascular complications such as ischemic heart disease. ED and DR are closely related since the retina is the only site in the body where arteries can be seen directly and non-invasively.⁸ Hence, retinal examination in higher frequencies should be included in the routine screening of diabetic men with ED.

In our study, we observed a significant association between physical activity (PA) and arterial ED. PA can potentially decrease ED and it has been identified as the lifestyle factor that strongly correlated with erectile function. Many randomized controlled clinical trials suggested that PA is an effective intervention to treat ED. Helle Gerbildet et al.⁹ reported that aerobic PA with moderate to vigorous intensity as a rational recommendation for men with ED, indicating a potential key role in the treatment of arterial ED. Khoet et al.³⁰ indicated that weekly exercise of 200 to 300 minutes of moderate-intensity training results in a much greater improvement of IIEF score in obese men than 90 to 150 minutes of weekly training. The result of this review indicates that 40 minutes of supervised PA per day can improve erectile function for men with arterial ED.

We have also observed that ED was more frequent in type 2 diabetic patients those who taken a certain group of medications which includes antihypertensive, cardiovascular treatments and

hormonal agents. These drugs may treat a disease or condition, but can also affect a man's hormone, nerves, or blood circulation, resulting in ED or increase the risk of ED. Some medications can affect libido (desire) and others can affect the ability to become aroused or achieve orgasm. A similar observation was reported by Domenico Fedele et al.¹⁶ It was reported in some studies that some types of drugs used to treat high blood pressure may prevent smooth muscles in the penis from relaxations. This prevents enough blood flow to the penis which can lead to ED. In addition, some of the drugs may decrease the level of testosterone which can decrease the interest in sex. However, a drug-related effect on ED is difficult to distinguish from the effect of the disease and from concomitant exposure to other drugs.¹⁶ Therefore, a much larger survey in a clinical population would be required to establish any aspects of medication effects on ED.

In many studies increasing age has been shown to be a significant risk factor for ED both in the general population and in diabetic cohorts.^{1,5} Aging is associated with a decline in several organs functions including cognitive, cardiac and renal functions and erectile function may not be an exception. Several of the well-known risk factors for ED such as hypertension, hypogonadism and atherosclerosis are also higher in older age and diabetes on its own increases the risk of developing these associated risk factors. However, in our study, older age was not significantly associated with ED. This suggests that the effect of age on ED may not be direct but may act indirectly through other risk factors.

Hypertension is well-established risk factor for ED in the general population.¹ Studies addressed in diabetic population was observed a similar association and also reported the closed association to the development of atherosclerosis. However, in

the multivariate analyzes, we have failed to show a significant association between hypertension and ED and this supports the findings of Ugwu et al.¹ It is also interesting to note that, we observed an association between antihypertensive drugs and ED. Hence, the association observed may be due to antihypertensive medication rather than hypertension per se.

We were encountered with some limitations. Patients with major depression and other psychological disorders were excluded from our study. The prevalence of ED is difficult to establish accurately because of limitations related to the populations screened, the unwillingness of subjects to participate and unreliability of the answers due to personal embarrassment. Another limitation of ours is that our examination of ED was cross-sectional in nature. Finally, this study was conducted in a small population of men with type 2 DM. Hence, larger studies would have added strength to the result. Despite these limitations, the study has several strengths. We have used the internationally validated questionnaire for measuring of ED. All respondents were asked the same set of questions in the same order by the same interviewer to minimize the potential observer bias.

In conclusion, we have observed a high prevalence of ED among type 2 diabetic patients. DR and less PA were associated with ED. These results encourage for implementation of current medical guidelines that put intensive lifestyle changes as the first step of the management of type 2 diabetes. Further analyzes of the association of duration of diabetes with ED will be reported in a subsequent paper.

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