ORIGINAL RESEARCH

A prospective study of effects of Tadalafil in Erectile Dysfunction

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ABSTRACT
Background: Erectile dysfunction (ED), defined as the consistent inability to achieve or maintain an erection sufficient for satisfactory sexual performance. The present study assessed the effects of Tadalafil in Erectile Dysfunction. **Materials & Methods:** 117 patients in Urology OPD of Superspeciality Block and Sanjay Gandhi Memorial Hospital associated with Shyam Shah Medical College, Rewa (M.P.) during of 1st Feb. 2020 to 31st July 2021 (18 months)were prescribed 5mg tadalafil daily for three months. At the end of this period, the patients were re-evaluated using IIEF-5, IELT and IPSS. **Results:** The mean age of all patients was 35.22 years with a minimum age being 20 years and maximum age being 55 years. Maximum patients (53) were between 31 to 40 years accounting to 45.30%. Out of 117 patients in the study, 30 patients were among the age range of 41-60 years, accounting to 25.64%. Diabetes mellitus was seen in 13, LUTS in 11, dyslipidemia in 3, physical anomaly in 0 and BPH in 19 patients. Mild ED had maximum patients (11) in age group 31-40 years, moderate (29) in age group 31-40 years and severe in age group 31-40 years (13). Out of 21 mild ED, 3 had DM, out of moderate ED, 9 had DM, and out of 20 severe ED, 1 had DM.LUTS was present in 9 moderate and 2 severe ED. **Conclusion:** A daily dose of 5mg tadalafil can be safely used in the treatment of erectile dysfunction and LUTS, that prolongs the ejaculatory latency time.
Keywords: Diabetes mellitus, Erectile dysfunction, LUTS

INTRODUCTION

Erectile dysfunction (ED), defined as the consistent inability to achieve or maintain an erection sufficient for satisfactory sexual performance.The effects of erectile dysfunction can be devastating and include decreased quality of life of the patient as well as the partner′s.Erectile dysfunction is a prevalent problem.[1] It is relevant to the practice of primary care physicians who attend patients who have co-morbidities that are considered medical risk factors for erectile dysfunction. The effective management will only promote a better overall health in men, improve the quality of the doctor – patient relationship and enhance compliance of treatment for chronic conditions. The introduction of oral therapy and wide research modalities have leads to revolutionary change in E.D. management.[2]

The treatment of ED starts from minimally invasive interventions like managing the modifiable risk factors such as life style modifications and underlying conditions, oral drugs, vasodilator agents and vacuum erection devices.[3] Surgical therapies are reserved for the subset of patients having contraindication to non-surgical interventions or those having adverse effects from medical therapy and those who have penile fibrosis or penile vascular insufficiency. First-line therapy for ED is phosphodiesterase 5 inhibitors (PDE5Is), e.g. sildenafil, tadalafil, and vardenafil.[4] The differences between each PDE5I include the onset of action and duration of effect. To date, there is no guideline on which drug is more recommended for the treatment of ED. Patient's choice and physician's judgment must be considered when prescribing PDE5Is.5

Tadalafil, a PDE5I which has been licensed for the treatment of ED since 2003. To date there has been little research on E.D. in Vindhya region and knowledge gained from studies elsewhere may not be generalized.[5]The present study was conducted to

MATERIALS & METHODS

This study was carried out on 117 patients in Urology OPD of Superspeciality Block and Sanjay Gandhi Memorial Hospital associated with Shyam Shah Medical College, Rewa (M.P.) during of 1st Feb. 2020 to 31st July 2021 (18 months). All were informed regarding the study and their written consent was obtained.

Data such as name, age, etc. was recorded. For the treatment of ED, the patients were prescribed 5mg

tadalafil daily for three months. At the end of this period, the patients were re-evaluated using IIEF-5, IELT and IPSS. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table: I Distribution of cases according to age

Age group(in yrs)	No of cases	Percentage
18-30	34	29.06
31-40	53	45.30
41-50	25	21.37
51-60	5	4.27
Total	117	100.0
Mean+ SD	35.32±8.03	

Table I shows that the mean age of all patients was 35.22 years with a minimum age being 20 years and maximum age being 55 years. Maximum patients (53) were between 31 to 40 years accounting to 45.30%. Out of 117 patients in the study, 30 patients were among the age range of 41-60 years, accounting to 25.64%.

Table: II Distribution of cases according to Clinical features in ED

CF	Response	Number	%
Diabetes Mellitus	Yes	13	11.11
	No	104	88.89
LUTS	Yes	11	9.40
	No	106	90.60
Dyslipidemia	Yes	03	2.56
	No	114	97.44
Physical Anomaly	Yes	0	0.0
	No	117	100.0
BPH	Yes	19	16.23
	No	98	83.77

Table II shows that diabetes mellitus was seen in 13, LUTS in 11, dyslipidemia in 3, physical anomaly in 0 and BPH in 19 patients.

Table: III Correlation IIEF score according to age

SN	Age group (in yrs)	IIEF SCORE			Total
		Mild ED (17-30)	Moderate ED (11-16)	Severe ED (1-10)	
1	18-30	6	26	2	34
2	31-40	11	29	13	53
3	41-50	4	18	3	25
4	51-60	0	3	2	5
	Total	21	76	20	117

Table III shows that mild ED had maximum patients (11) in age group 31-40 years, moderate (29) in age group 31-40 years and severe in age group 31-40 years (13).

Table: IV Correlation IIEF score according to diabetes mellitus

SN	Diabetes Mellitus	IIEF SCORE			Total
		Mild ED (17-30)	Moderate ED (11-16)	Severe ED (1-10)	
1	Yes	03	09	01	13
2	No	18	67	19	104
	Total	21	76	20	117

Out of 21 mild ED, 3 had DM, out of moderate ED, 9 had DM, and out of 20 severe ED, 1 had DM.

Table: V Correlation IIEF score according to LUTS

SN	LUTS	IIEF SCORE			Total
		Mild ED (17-30)	Moderate ED (11-16)	Severe ED (1-10)	
1	Yes	0	09	2	11

2	No	21	67	18	106
	Total	21	76	20	117

Table: V shows that LUTS was present in 9 moderate and 2 severe ED.

DISCUSSION

The present study was based on a cross-sectioned outline of non-institutionalized men with ages distributed between 18 and 60 years, from a center designated for the treatment of urological diseases.[6]Completing a sexual activity questionnaire was only mentioned during the interview at the office.[7,8] The data in this study do not represent a randomly selected population from within a community but are from men seeking medical attention in a free screening program. It is possible, therefore, that these data might not represent the country or even regional status.[9,10] People seeking medical attention in a screening program may be more concerned with their own health that the general population but, on the other hand, patients with co-morbidity and low quality of life might have no interest in participating in this type of program.The erectile function in this study was based on subject responses to a privately administered questionnaire by a physician. [11]

We found that the mean age of all patients was 35.22 years with a minimum age being 20 years and maximum age being 55 years. Maximum patients (53) were between 31 to 40 years accounting to 45.30%. Out of 117 patients in the study, 30 patients were among the age range of 41-60 years, accounting to 25.64%.We found that Diabetes mellitus was seen in 13, LUTS in 11, dyslipidemia in 3, physical anomaly in 0 and BPH in 19 patients. We found that mild ED had maximum patients (11) in age group 31-40 years, moderate (29) in age group 31-40 years and severe in age group 31-40 years (13). We found that out of 21 mild ED, 3 had DM, out of moderate ED, 9 had DM, and out of 20 severe ED, 1 had DM.LUTS was present in 9 moderate and 2 severe ED. Karabakan et al[12]investigated the effect of a 5mg daily tadalafil treatment on the ejaculation time, erectile function and lower urinary tract symptoms (LUTS) in patients with erectile dysfunction.A total of 60 patients diagnosed with erectile dysfunction were retrospectively evaluated using the international index of erectile function questionnaire-5 (IIEF-5), intravaginal ejaculatory latency time (IELT) and international prostate symptoms scores (IPSS). After the patients were treated with 5mg tadalafil once a day for three months, their erection, ejaculation and LUTS were assessed again. The fasting levels of blood glucose, total testosterone, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol and total cholesterol were measured. The mean age of the 60 participants was 50.4±7.9 and the mean baseline serum total testosterone, total cholesterol, and fasting blood sugar were 444.6±178.6ng dL-1, 188.7±29.6mg/dL-1,104 (80-360) mg dL-1, respectively. The mean baseline scores were 2.2±1.4 min for IELT, 9.5±3.7 for IIEF-5 and 14.1±4.5 for IPSS. Following the three-month daily 5mg tadalafil treatment, the scores were found to be 3.4±1.9 min, 16.1±4.7, and 10.4±3.8 for IELT, IIEF and IPSS, respectively. When the baseline and post-treatment scores were compared, a statistically significant increase was observed in the IELTs and IIEF-5 values whereas there was a significant decrease in IPSS (p<0.01).

The shortcoming of the study is small sample size.

CONCLUSION

Authors found that a daily dose of 5mg tadalafil can be safely used in the treatment of erectile dysfunction and LUTS, that prolongs the ejaculatory latency time.

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