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DETERMINE THE MEAN CHANGE IN INTRA VAGINAL EJACULATORY LATENCY TIME (IELT) AFTER ADMINISTRATION OF TRAMADOL IN PATIENTS OF PREMATURE EJACULATION

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ABSTRACT

Background: Premature ejaculation (PME) is defined as ejaculation with the minimal sexual stimulation before, on or shortly after penetration and or before a person wishes it. **Objective:** The objective of the study is to determine the mean change in intra vaginal ejaculatory latency time (IELT) after administration of tramadol in patients of premature ejaculation. **Setting:** This Quasi experimental study was conducted in Department of Urology, University Teaching Hospital/DHQ Gujranwala from April 1st, 2017 to September 30th, 2017. A total of 115 cases fulfilling the inclusion/exclusion criteria will be enrolled. Detailed history for premature ejaculation was taken. Premature ejaculation was diagnosed by a urologist with 10 years of experience. All cases were advised to receive 50 mg tramadol. The time of drug administration was 3 - 6 hours before sexual intercourse. **Results:** In this study, out of 115 cases, 44.35% (n=51) were between 20-40 years of age whereas 55.65%(n=64) were between 41-60 years of age, mean±SD was calculated as 43.07±10.11 years. Mean change in intra vaginal ejaculatory latency time (IELT) after administration of tramadol in patients of premature ejaculation shows that at baseline IELT was 69.08±4.90 seconds, after treatment it was recorded as 260.32±21.25 seconds and shows that mean change was 194.24±21.44 seconds, it shows a significant difference by calculating p value as 0.000. **Conclusion:** We concluded that the mean change is significantly higher in intra vaginal ejaculatory latency time (IELT) after administration of tramadol in patients of premature ejaculation.

KEYWORDS: Premature ejaculation, management, tramadol, intra vaginal ejaculatory latency time (IELT).

INTRODUCTION

Premature ejaculation (PME) is one of the most common male sexual dysfunctions. Prevalence PME has been estimated between 2% and 23%.[1] PME is markedly associated with poor satisfaction with sexual intercourse and high-levels of personal distress and interpersonal difficulty.[2] It is commonly defined by a short ejaculatory latency, a perceived lack of ejaculatory control; both related to self-efficacy; and distress and interpersonal difficulty.[3]

PME can be either lifelong (primary), present since first sexual experiences, or acquired (secondary), beginning later. The recently updated International Society of Sexual Medicine's Guidelines for the Diagnosis and Treatment of Premature Ejaculation (PE) propose that PE is a male sexual dysfunction characterized by ejaculation within about one minute of vaginal penetration (lifelong PE) or a reduction in latency time to ≤3 minutes (secondary PE), the inability to delay ejaculation, and negative personal consequences.[4]

To date, selective serotonin reuptake inhibitors (SSRIs) have been the most used effective treatment for premature ejaculation. SSRIs have shown efficacy on both a scheduled and pro re nata basis. Kirby et al recently reported on the efficacy of tramadol for premature ejaculation.[5]

Tramadol undergoes hepatic metabolism via the cytochrome P450 isozyme CYP2D6 and is O- and N-demethylated to five different metabolites. Of these, M1 (O-desmethyltramadol) is the most significant metabolite, because it has 200 times the m-affinity of tramadol and has an elimination half-life of 9 h compared with 6 h for tramadol. In the 6% of the population who have slow CYP2D6 activity, there is a slightly reduced analgesic effect. Phase II hepatic metabolism renders the metabolites water soluble, and they are excreted by the kidneys; thus, reduced doses may be used in renal and hepatic impairment.[6]

OBJECTIVES

The objective of the study is to

- determine the mean change in intra vaginal ejaculatory latency time (IELT) after administration of tramadol in patients of premature ejaculation.

MATERIALS AND METHODS

This Quasi experimental study was conducted in Department of Urology, University Teaching Hospital/DHQ Gujranwala from April 1st 2017 to September 30th 2017. The sample size of 115 cases is calculated with 95% confidence level, 14% margin of error and mean increase in IELT as 183±76.4.[7]

INCLUSION ITERIA

- All diagnosed cases of premature ejaculation (according to operational definition).
- All male cases between 20-60 years.

EXCLUSION CRITERIA

- Erectile dysfunction according to the IIEF, an organic cause of PE, genital infection and neurological disorders, low libido, chronic depression, psychiatric or physical illness; alcohol, drugs, or substance abuse; use of psychotropic and antidepressant medication; and serious relationship problems(it was assessed on history, lab investigations and medical record).

DATA COLLECTION PROCEDURE

A total of 115 cases fulfilling the inclusion/exclusion criteria will be enrolled from Outpatient Department of Urology, Jinnah Hospital, Lahore after approval from ethical committee (Attached). Informed consent was taken from the patients to include their data in the study. Detailed history for premature ejaculation was taken. Premature ejaculation was diagnosed by a urologist with 10 years of experience. All cases were advised to receive 50 mg tramadol. The time of drug administration was 3 - 6 hours before sexual intercourse. Ejaculation time before treatment (average time of three sexual intercourses) and after 12 weeks of treatment was recorded. Patients were advised to record time from vaginal penetration to ejaculation. Then the mean change in IELT was recorded as per operational definition by the researcher himself. Confounding variables like age of patients, duration of marriage was addressed through stratification of the data. All this information was recorded on a pre-designed proforma (Annexure).

STATISTICAL ANALYSIS

The data was entered and analyzed in SPSS version for 16.0. Mean and standard deviation was calculated for quantitative variable like age and IELT at baseline and after 12 weeks of administration of 50 mg Tramadol and mean change in IELT. Paired student t test was applied by taking $P < 0.05$ was as significant.

RESULTS

A total of 115 cases fulfilling the inclusion/exclusion criteria were enrolled to determine the mean change in intra vaginal ejaculatory latency time (IELT) after administration of tramadol in patients of premature ejaculation.

Age distribution of the patients was done, it shows that 44.35%(n=51) were between 20-40 years of age whereas 55.65%(n=64) were between 41-60 years of age, mean±sd was calculated as 43.07±10.11 years. (Table No. 1).

Mean change in intra vaginal ejaculatory latency time (IELT) after administration of tramadol in patients of premature ejaculation shows that at baseline IELT was 69.08+4.90 seconds, after treatment it was recorded as 260.32+21.25 seconds and shows that mean change was 194.24+21.44 seconds, it shows a significant difference by calculating p value as 0.000 (Table No. 2).

The data was stratified for age and duration of marriage to address the effect modifiers. Post stratification T-test was applied. P value < 0.05 was considered as significant.

Table No. 01: Mean Change In Intra Vaginal Ejaculatory Latency Time (Ielt) After Administration of Tramadol In Patients of Premature Ejaculation (N=115).

IELT	Mean	SD
At baseline	69.08	4.90
After treatment	260.32	21.44
Mean change	191.23	21.25

P value=0.000

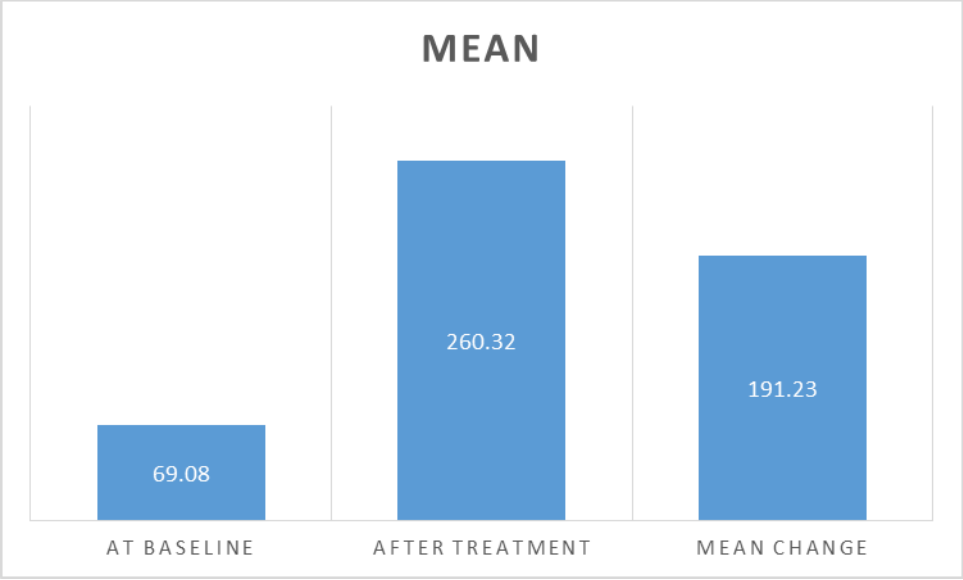

Table No. 02: Stratification with Regards to Mean Change In Intra Vaginal Ejaculatory Latency Time (Ielt) After Administration of Tramadol In Patients of Premature Ejaculation.

Age (in years)	MEAN CHANGE IN IELT	
	Mean	SD
20-40	257.06	18.49
41-60	262.92	23.03

P value=0.004

Table No. 03: Stratification With Regards To Married Period For Mean Change In Intra Vaginal Ejaculatory Latency Time (Ielt) After Administration Of Tramadol In Patients Of Premature Ejaculation.

Duration of marriage (in years)	MEAN CHANGE IN IELT	
	Mean	SD
1-10	258.11	17.64
>10	260.30	22.14

P value=0.001

DISCUSSION

Premature ejaculation (PME) is defined as ejaculation with the minimal sexual stimulation before, on or shortly after penetration and or before a person wishes it. It is a function of the time between intra-vaginal penetration and intra-vaginal ejaculation.[7] Tramadol has shown efficacy in PME when used as sporadic basis. In this study, we considered that the local data is scant while the international studies are also showing a significant variation, however the results of the current study clarified the above variation in our targeted population and also recorded the exact IELT after administration of Tramadol.[8-10]

In this study, out of 115 cases, 44.35%(n=51) were between 20-40 years of age whereas 55.65%(n=64) were between 41-60 years of age, mean$\pm$SD was calculated as 43.07$\pm$10.11 years. Mean change in intra vaginal ejaculatory latency time (IELT) after administration of tramadol in patients of premature ejaculation shows that at baseline IELT was 69.08$\pm$4.90 seconds, after treatment it was recorded as 260.32$\pm$21.25 seconds and shows that mean change was 194.24$\pm$21.44 seconds, it shows a significant difference by calculating p value as 0.000.[11-13]

We compared our results with a recent study determined the effects of Tramadol in Premature Ejaculation and recorded Intra-vaginal ejaculation latency time (IELT) at baseline 71.72±98.8

seconds and after 12 weeks administration of Tramadol (50 mg) it increased up to 254.72±175.2 seconds which shows mean increase as 183.00±76.4 seconds.[14-15]

We did not agree with another study[8] recorded these findings as 73. 1±21.7 seconds at baseline while after only 8 weeks they recorded it as 442.1±15.44 and the mean increase as 369.0±6.26 which is significantly higher than the above study while the duration of drug administration was also less than the above study, these findings showed higher IELT than recorded in our study, however, it shows that the use of Tramadol is effective for the management of premature ejaculation.[16]

In 2006, Safarinejad and Hosseini reported the results of their randomized control trial on the basis of DSM-IV-TR definition for PE, patient used a stopwatch to measure IELT whereby baseline IELTs of 19–21 s and were randomized to either placebo or tramadol HCL 50 mg to be taken 2 h prior to intercourse. The tramadol group experienced an average 3.73-min improvement in IELT relative to 0.22 min in the control ($P<0.001$) where the efficacy of tramadol was proved to be significant, Furthermore, studies evaluating a 25-mg dose of tramadol in an on-demand manner.[17-20] or placebo 1–2 h prior to intercourse and the recorded average baseline of IELT was 1.17 min. The results showed a significantly greater improvement in IELT in the treatment group relative to the placebo arm, 6.20 versus 0.84 min, respectively ($P<0.0001$). In 2012, Kaynar et al[21] found a result where tramadol HCL 25 mg or placebo was utilized with finding of 38.83 and 30.66 s, respectively. Although this represented a less robust absolute response with respect to IELT, it should be noted that the baseline IELT in the cohort of Kaynar et al was less than that in the study by Salem et al20 approximately 34 s versus 1.17 min. For each of these assessments, the tramadol group exhibited a significant improvement relative to placebo ($P<0.001$).

Considering the above facts, we are of the view that subjects presenting with premature ejaculation may be managed with tramadol.

CONCLUSION

We concluded that the mean change is significantly higher in intra vaginal ejaculatory latency time (IELT) after administration of tramadol in patients of premature ejaculation.

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PROFORMA

MEAN CHANGE IN INTRA VAGINAL EJACULATORY LATENCY TIME (IELT) AFTER ADMINISTRATION OF TRAMADOL IN PATIENTS OF PREMATURE EJACULATION

Case No. _____ Medical Reg. No. _____

Name: _____ Age: _____/yrs,

Address: _____

Contact No. _____

INTRA VAGINAL EJACULATORY LATENCY TIME

- Baseline IELT: _____/seconds
- After treatment IELT: _____/seconds
- Mean change in IELT: _____/seconds
- Duration of marriage: _____/ years