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ORIGINAL RESEARCH

Comparison of Silodosin and Dapoxetine in "on-demand" treatment of Premature ejaculation:A randomized controlled study

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ABSTRACT

Aim: To compare Silodosin and Dapoxetine in the "on-demand" treatment of premature ejaculation.

Material and method: The study was conducted in the department of urology and renal transplant S.M.S. Medical College Jaipur from 1st January 2018 to 31st December 2018. We enrolled 90 self-reported casesof PME and excluded the patients below 18 years and above 50 years; patients suffering from orthostatic hypotension, renal impairment, and hepatic impairment. All patients were divided equally into three groups by a simple randomization method using computer-generated random numbers i.e.,Group A(Silodosin 4 mg on-demand), Group B (Dapoxetine 30 mg on-demand), and Group C (placebo on demand). Intravaginal ejaculatory latency time (IELT), premature ejaculation profile (PEP), and the clinical global impression of change for premature ejaculation (CGIC) were recorded in patients, before the initiation of the treatment and after ten coital activities or after one month. Any adverse effects reported by the patients were also recorded.

Results: There was a significant improvement in intravaginal ejaculation latency time in both Silodosin and Dapoxetine groups. Patients of group A and group B reported better scores in all aspects of premature ejaculation profile as compared to placebo. Only three patients reported a reduced amount of ejaculate with silodosin but it was not bothersome to patients.

Conclusion: Silodosin 4 mg may be used safely as a treatment option for PME as its safety profile in LUTS is already well established. It is as effective as Dapoxetine 30 mg with a better side effect profile in the management of premature ejaculation.

Keywords: Premature Ejaculation, Silodosin, Dapoxetine, IELT

INTRODUCTION

Premature ejaculation (PME) is a common sexual problem that also influences the quality of life in patients.Its prevalence is reported as up to 30% in studies.[1]Till date there is no consensus on the definition, classification, and treatment of premature ejaculation**.** According to the Diagnostic and Statistical Manual of Mental Disorders, 4th edition, text revision (DMS-IV-TR) it is defined as "Persistent or recurrent ejaculation with minimal stimulation before, on or shortly after penetration and before the person wishes it", which is associated with "marked distress and interpersonal relationship difficulty".

There are various treatment modalities described in literature ranging from behavioral and psychotherapy to local application. Although behavioral and psychotherapy are the first

treatment options for PME, culturaland socioeconomic factors play a significant role. Hence pharmacotherapy becomes significant.

Selective serotonin reuptake inhibitors (SSRIs) have been used for PME worldwide. They are used for PME at least for 2-6 weeks as continuous dosing, except Dapoxetine which in the dose of 30 mg can be used on a demand basis. This drug has some adverse effects such as reduced libido and serotonergic symptoms like mild headaches, nausea, sweating, and dizziness.

Seminal vesicles an important part of the ejaculation process have alpha-1 adrenergic receptors. Blocking the alpha receptors in seminal vesicles may have a beneficial effect on premature ejaculation. Clinical studies on Silodosin have shown its significant role in premature ejaculation compared to other alpha-blockers. This side effect of Silodosin has the potential for treating premature ejaculation.[2, 3]

In this study, we compared the efficacy of Dapoxetine 30 mg and Silodosin 4mg in PMEon a demand basis.

MATERIAL AND METHODS

We enrolled 90self-reportedcases of PME and excluded the patients below 18 years and above 50 years; patients suffering from orthostatic hypotension, renal impairment, and hepatic impairment. The study was conducted in the department of urology and renal transplant S.M.S. Medical college Jaipurfrom 1st January 2018 to 31st December 2018. Approval for the proposed study was taken from the Institutional ethics committee. Before inclusion in the study, written informed consent was obtained from each patient and his partner.

All patients were divided into three groups by a simple randomization method using computer-generated random numbers. Thirty patients were kept in each group.

Group A- Silodosin 4 mg on-demand Group B – Dapoxetine 30 mg on-demand Group C – placeboon demand

A detailed history was taken and routine blood investigations were performed. Patients of group A group B, and group C received Silodosin 4mg, Dapoxetine 30 mg,and placebo two hours before sexual intercourse respectively. Intravaginal ejaculatory latency time (IELT), premature ejaculation profile (PEP), and the clinical global impression of change for premature ejaculation (CGIC) were recorded in patients, before the initiation of the treatment and after ten coital activities or after one month. Any adverse effects reported by the patients were also recorded.

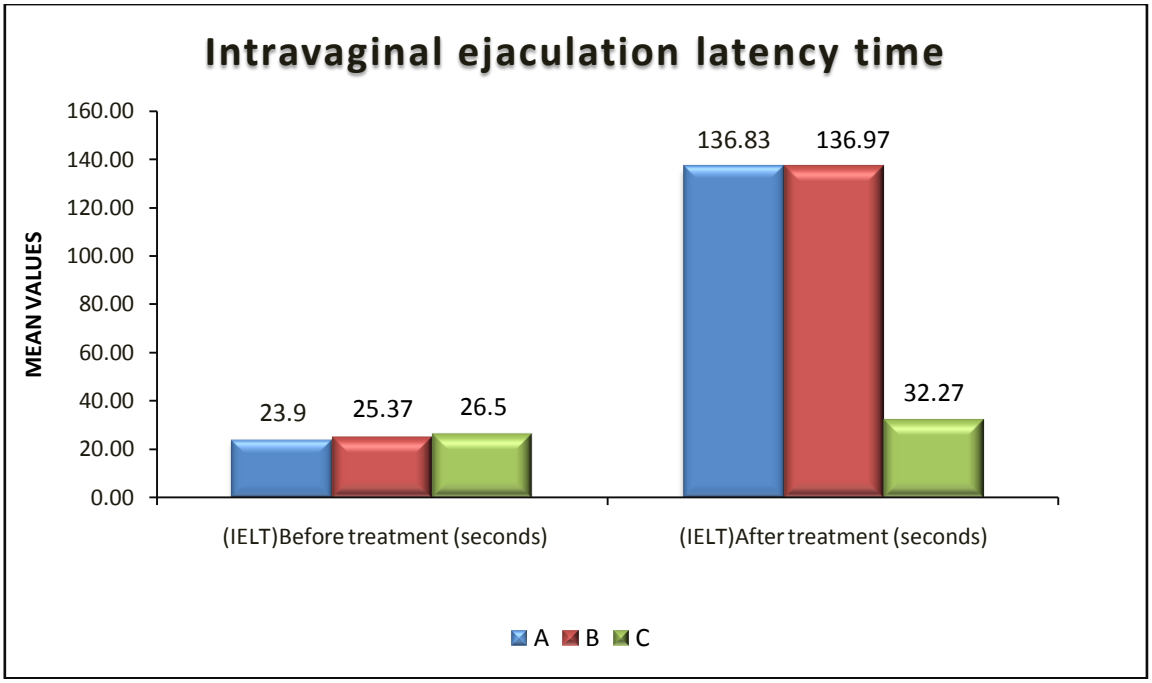
STATISTICAL ANALYSIS

Quantitative variables were compared using the student T-test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups and ANOVA/Kruskal Wallis test between three groups. A P value of <0.05 was considered statistically significant. The data was entered in the MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS

The mean age of patients in Group A was 30.3 ± 4.03 years, whereas the mean age of patients in Group B was30.57 ± 4.68years. The mean age of patients in group C was30.47 ± 4.87 years. There was no statistical difference between these groups.

The Intravaginal ejaculatory latency time (IELT), was recorded with a stopwatch before treatment and after treatment and showed significant improvement in groups A and Bas shown in graph1.



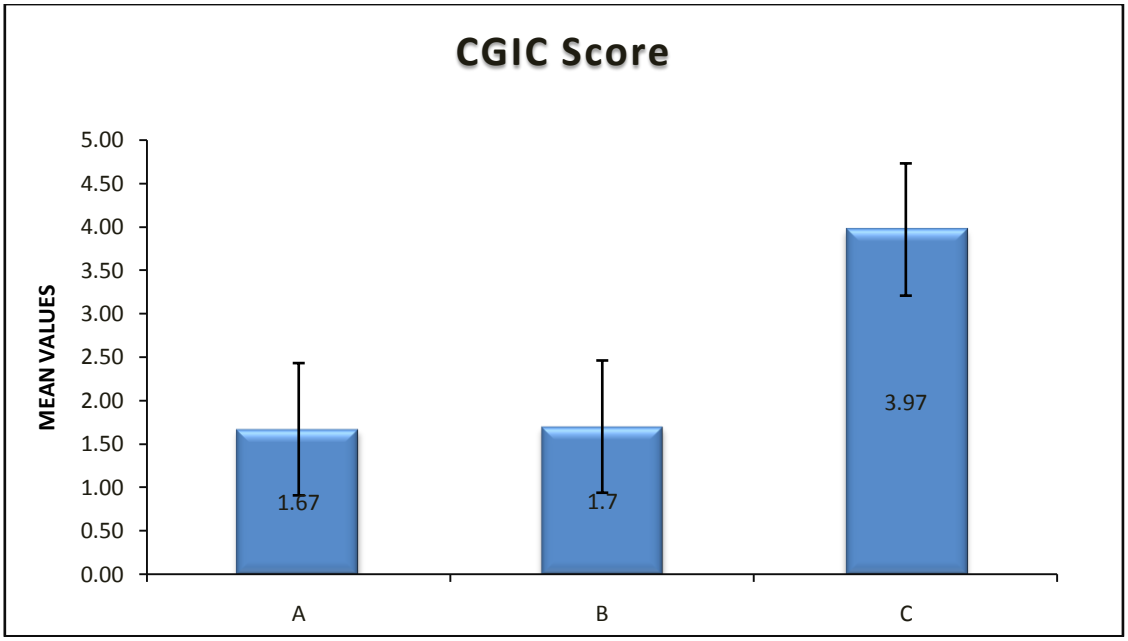
Graph 1

The premature ejaculation profile consisted of four questions related to satisfaction with sexual intercourse, control over ejaculation, ejaculation-related distress, and ejaculation-related difficulty in interpersonal relationships respectively. The first two questions i.e., satisfaction with sexual intercourse and control over ejaculation were assessed according to a five-point, ascending scale, with one representing very poor and five representing very good. The last two questions, i.e., ejaculation-related distress and ejaculation-related difficulty in interpersonal relationships were assessed in descending order, with five representing extreme and one representing negligible or nil (Table 2).

	Group A		**Group B**		**GROUP C**	
PEP subset	Pre-treatment score	Post-treatment score	Pre-treatment score	Post-treatment score	Pre-treatment score	Post-treatment score
Satisfaction with intercourse	1.6	4.37	1.47	4.37	1.53	1.83
Control over ejaculation	1.6	4.53	1.6	4.47	1.53	1.77
Ejaculation related distress	4.57	1.50	4.47	1.57	4.50	4.13
Ejaculation related difficulty in interpersonal relationships	4.47	1.47	4.57	1.50	4.43	4.1

Table - 2

Mean scores of premature ejaculation profile subsets in all three groups show statistically significant improvement in group A and group B as compared to group C($p<.05$). The effect of treatment on premature ejaculation was noted using a seven-point response scale to measureClinicalGlobal Impression of Changefor premature ejaculation. The seven points correspond to very much improved (1), much improved (2), minimally improved (3), no change(4), minimally worse(5), much worse(6), and very much worse(7) respectively.



Graph- 2

CGIC score was 1.67 and 1.7 in group A and group B respectively which is indicative of significant improvement whereas the score was 3.97 in group c indicative of no improvement.Three patients reported a reduced quantity of ejaculate but it was not bothersome. Five patients reported dizziness with Dapoxetine. But no patient discontinued treatment due to these side effects (graph 2).

DISCUSSION

Premature ejaculation is defined as a male sexual dysfunction characterized by (1) - ejaculation which always or nearly always occurs before or within about one minute of vaginal penetration from the first sexual experience or a clinically significant bothersome reduction in latency time often to about 3 minutes or less(2)-the inability to delay ejaculation on all or nearly all vaginal penetrations;and(3)negative personal consequences, such as distress,botherfrustration,and/or the avoidance of sexual intimacy. [6] SSRI specificallyDapoxetine forms the mainstay of treatment because it causes a delay in ejaculation by inhibiting descending pathways from higher centers. [7] SSRIs are associated with psychiatric and neurological complications and sexual side effects on regular treatment. [8] Dapoxetine is associated with nausea, loss of libido, and dizziness when it is used on an on-demand basis. [9] Thus,the search for optimal pharmacotherapy is continuing.

Alpha-blockers are used for patients suffering from LUTS.Some alpha-blockers are associated with retrograde ejaculation and anejaculation. Alpha 1a receptors present on seminal vesicles are responsible for these effects. [10] Silodosin is a highly effective antagonist and some recent reports suggested a very effective role in premature ejaculation profile. In our study, we intended to compare the effectiveness of Silodosin and Dapoxetine in premature ejaculation profiles on-demand basis.8 mg of Silodosinis associated with a significant incidence of retrograde ejaculation and anejaculation.So,we reduced the dose of Silodosin to 4 mg to avoid this problem.

In our study, there was a significant improvement in intravaginal ejaculation latency time in both Silodosin and Dapoxetinegroups. Patients of group A and group B reported better scores in all aspects of premature ejaculation profile as compared to placebo. Only three patients reported a reduced amount of ejaculate with silodosin but it was not bothersome to patients.

Higher incidence (20-25%) of anejaculation was related in earlier studies but in our study, no patient complained of anejaculation. [2]

Alpha-blockers are in use for LUTS for more than three decades and their safety is well established. [(11)]Patients on alpha-blockers for LUTS usually complain of delayed ejaculation and anejaculation.Masciovecchio S et al. and Sato Y et al. used this side effect for benefit of patients with premature ejaculation profiles. [(1)]

In our study, we compared the efficacy of both drugs and theirside effectprofile. In our study efficacy of both drugs was found almost the same.Both Silodosin and Dapoxetine were well tolerated and did not show any significant systemic side effects. Results of the study suggest that we can recommend Silodosin as an alternative for Dapoxetineor in Dapoxetineunresponsive cases on a demand basis.

As a small sample size is one of the limitations of the present study, a larger sample sizecan give more insight into thetreatment of premature ejaculation with Silodosin.

CONCLUSION

Silodosin 4 mg may be used safely as a treatment option for PMEas its safety profile in LUTS is already well established. It is as effective as Dapoxetine 30 mg with a better side effect profile in the management of premature ejaculation.

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