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A Prospective Comparative Study of Oral Dapoxetine and Tadalafil Versus Topical Lidocaine for Treating Lifelong Premature Ejaculation

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***Abstract**: This study aimed to evaluate the effectiveness of on-demand oral dapoxetine combined with tadalafil in comparison to topical lidocaine for lifelong premature ejaculation (PME). Patients diagnosed with lifelong PME were divided into two groups: Group A received oral dapoxetine (30 mg) plus tadalafil (10 mg), while Group B was treated with a 10% lidocaine spray. Key parameters, including intravaginal ejaculatory latency time (IELT), AIPE scores, and weekly intercourse frequency, were measured at baseline and after three months of treatment. The findings indicated that both treatments significantly improved IELT and AIPE scores compared to baseline, with topical lidocaine demonstrating superior results (184.4s vs. 72s vs. 18s, $p < .05$). Based on the Global Efficacy Question assessing drug effectiveness, lidocaine was deemed effective in 40 out of 46 cases (86.96%) and ineffective in 6 cases (13.04%). In contrast, Group A showed effectiveness in 14 out of 48 cases (29.17%), while 34 cases (70.83%) found it ineffective, with a significant difference between groups. These findings suggest that topical lidocaine is more effective than on-demand oral dapoxetine plus tadalafil for treating lifelong PME.*

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I. INTRODUCTION:

Premature ejaculation (PME) is a widespread sexual dysfunction that affects 20% to 30% of men worldwide[1]. It is defined by (a) ejaculation that consistently or almost always happens before or within approximately one minute of vaginal penetration (lifelong PE) or a significant, distressing reduction in latency time, typically around three minutes or less (acquired PE); (b) an inability to control ejaculation during nearly all instances of vaginal intercourse; and (c) adverse personal effects such as frustration, distress, and avoidance of sexual intimacy. Various treatment options exist for PME, though their effectiveness varies[2].

Dapoxetine hydrochloride, a short-acting selective serotonin reuptake inhibitor (SSRI), has recently gained popularity as an on-demand treatment for PME. A pooled analysis conducted by McMahon et al. (2011) found that taking 30 mg of oral dapoxetine increased the baseline geometric intravaginal ejaculatory latency time (IELT) from 0.8 minutes to 2 minutes, representing a 2.5- to 3-fold improvement, while a placebo extended IELT to 1.3 minutes, a 1.6-fold increase[3]. Another meta-analysis by JianWei, Ye, Li, and Wang (2018) indicated that the overall success rate of 30 mg dapoxetine was 24.2%, with no withdrawal symptoms reported upon discontinuation[4]. The most frequently reported side effects of dapoxetine include nausea, dizziness, and headaches[5].

Additionally, topical anesthetics have been widely used as off-label treatments for PME, with multiple clinical trials confirming their effectiveness[6]. Different formulations and concentrations of topical anesthetics have been studied, showing varying degrees of IELT prolongation. A meta-analysis by Jian et al. (2018) reported a 90% success rate in improving IELT with topical anesthetics[4]. Moreover, a randomized controlled trial (RCT) by Moheiddin Alghobary (2020) found that topical lidocaine was more effective as an on-demand treatment for lifelong PE compared to oral dapoxetine[7]. Despite these findings, no studies have directly compared the effectiveness of oral dapoxetine combined with tadalafil versus topical lidocaine spray as on-demand treatments for PME. This research aims to evaluate and compare these two treatment methods for lifelong PME.

II. MATERIAL & METHODS:

A prospective, randomized comparative study was conducted in the Department of Urology in a Government Super speciality hospital , between January 1, 2023, and December 31, 2024. Out of 231 male patients who visited Urology OPD after screenig 110 individuals who met the inclusion criteria were enrolled after obtaining ethical approval and informed written consent. The sample size was selected arbitrarily rather than based on statistical calculations. A total of 121 patients were excluded for various reasons, including recent drug

use affecting ejaculation, sexual desire, erectile dysfunction, chronic medical conditions, or mental health disorders.

The study included heterosexual males aged 18–40 years who had a regular sexual partner and a baseline intravaginal ejaculatory latency time (IELT) of 60 seconds or less. Participants were randomly divided into two treatment groups of 55 each using a random number table. All patients underwent a thorough medical history assessment, clinical examination, and baseline IELT measurement. Additionally, the Arabic Index of Premature Ejaculation (AIPE) was used to evaluate symptoms. This index consists of seven items rated on a scale of 1 to 5, assessing aspects such as libido, erection, IELT, ejaculation control, male satisfaction, female satisfaction, and sexual distress, with a total possible score ranging from 7 to 35.

IELT was considered the primary outcome measure, recorded one month before treatment initiation using a stopwatch. The pharmacological interventions lasted three months. Group A received oral dapoxetine (30 mg) and tadalafil (10 mg) on an on-demand basis, with dapoxetine taken 1–2 hours before intercourse and tadalafil 30 minutes to 1 hour prior. Group B was administered a 10% lidocaine spray topically, with five puffs applied to the glans penis 10–15 minutes before intercourse. Three patients from Group A and five from Group B did not return for follow-up, leaving 48 participants in Group A and 46 in Group B for final analysis.

Participants were advised to engage in regular sexual activity (at least once per week) without using a condom, while documenting the date of intercourse, IELT during the first attempt (measured with a stopwatch), and any side effects of medicines. At the end of the three-month period, the study assessed mean IELT, weekly intercourse frequency, and adverse effects. Patients also responded to the Global Efficacy Question (GEQ): "Did you find the treatment you received effective?" with a yes or no response. Data were analyzed using the Statistical Package for Social Science (SPSS) software, version 22. The mean IELT of both groups was compared using Mann-Whitney U test, while qualitative data were analyzed with the chi-square test. A p-value of less than 0.05 was considered statistically significant.

III. RESULTS:

A total of 110 participants met the study's inclusion criteria. However, 20 individuals withdrew—9 from Group A and 11 from Group B. Consequently, 94 participants successfully completed the study, with an average age of 29 ± 11 years and a median BMI of 25.2 kg/m². All participants were literate and resided in North India.

At baseline, the average Intravaginal Ejaculatory Latency Time (IELT) was 18 seconds. Following treatment, IELT significantly increased to 72 seconds with oral dapoxetine and to 184.4 seconds with topical lidocaine, showing a notable difference between the two interventions. The initial median AIPE score was 16, and the median frequency of sexual activity was once per week (Table 1).

Regarding treatment effectiveness based on the Global Efficacy Question (GEQ), 40 out of 46 participants (86.96%) in Group B reported a positive outcome, while 6 (13.04%) found it ineffective. In contrast, in Group A, only 14 out of 48 participants (29.17%) experienced benefits, whereas 34 (70.83%) did not observe any improvement, marking a statistically significant difference between the groups.

Adverse effects in Group A (oral dapoxetine) included nausea in 10 cases (20.83%), headache in 6 cases (12.5%), dizziness in 4 cases (8.3%), and myalgia in 7 cases (14.6%) associated with tadalafil use. In Group B (topical lidocaine), 15 cases (32.6%) experienced reduced erection, though it did not interfere with sexual performance, and 2 cases (4.3%) reported glans penis irritation.

IV. DISCUSSION:

This study found that using topical lidocaine spray significantly increased IELT, nearly ten times the baseline, and also improved AIPE scores and weekly intercourse frequency. These results suggest that topical lidocaine is an effective treatment for lifelong PME.

Previous research has also examined the benefits of topical lidocaine for PME. Steggall et al. (2008) studied 44 patients, including those with lifelong and acquired PME, as well as individuals with multiple partners. They compared the effects of topical lidocaine spray combined with behavioral therapy to oral paroxetine with behavioral therapy. Despite differences in study methods, their results showed that IELT increased about nine times from a baseline of 30 seconds[8]. Similarly, Dell'Atti et al. (2017) tested 78 patients with lifelong PME by dividing them into three groups: one using only topical lidocaine 10%, another taking daily tadalafil 5 mg, and a third receiving both daily tadalafil 5 mg and on-demand topical lidocaine. They found significant IELT improvement in all groups, with the best results in the combination group[9]. However, the lidocaine-only group saw IELT increase about three times after three months, but the study did not use standard tools to measure changes in erection or ejaculation.

In this study, oral dapoxetine also significantly increased IELT, nearly tripling the baseline. AIPE scores and weekly intercourse frequency also improved, showing that dapoxetine can be useful as an on-demand treatment for lifelong PME. These findings are similar to previous studies[10]. However, patient satisfaction,

measured by GEQ, showed that only 29.17% of participants found dapoxetine effective. One reason for this could be the low baseline IELT of 18 seconds. Patients with severe PME, who ejaculate within seconds, may not get the desired benefit from dapoxetine. Similar findings were reported by Waldinger and Schweitzer in their studies[11]. Jian et al. (2018) found a 38.5% success rate with dapoxetine 60 mg[12].

Overall, patients in this study preferred topical lidocaine spray over oral dapoxetine combined with tadalafil. This difference may be due to how these treatments work. Dapoxetine is a short-acting SSRI, tadalafil is a PDE5 inhibitor, while lidocaine is a local anesthetic that reduces sensitivity in the glans penis. PME is believed to be caused by high sensitivity in the glans and issues in the nerve pathways controlling ejaculation[13]. The strong response to topical lidocaine in patients with very short IELT may be because of their high glans sensitivity. The GEQ results showed that more patients found topical lidocaine helpful. This may be because it not only delayed ejaculation better but also helped reduce stress and embarrassment, leading to greater satisfaction compared to dapoxetine plus tadalafil.

V. CONCLUSION:

Topical lidocaine has proven to be a more effective on-demand treatment for lifelong PME than oral dapoxetine combined with tadalafil. However, this study has several limitations, such as a small sample size, being conducted at a single center, and the lack of randomization. Furthermore, female partners were not interviewed, and their sexual function was not thoroughly assessed before and after treatment using validated evaluation tools.

CONFLICT OF INTEREST: None

Table 1 Changes of IELT, AIPE Score and frequency of sexual intercourse per week(Median)

	Baseline	Group A	Group B	P value
IELTs (median)	18	72	184.4	<0.05
Frequency /Week (median)	1.75	1.75	2	<0.05
AIPE (median)	16	18	28	<0.05

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