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ORIGINAL RESEARCH

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Dual approach to ejaculatory control: daily paroxetine and on-demand lidocaine spray for treating premature ejaculation

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Abstract

Background: Premature ejaculation (PE) is a prevalent sexual dysfunction that affects a large number of men and can significantly impact their quality of life and intimate relationships. Current treatment options primarily include behavioral techniques and pharmacological interventions; however, the optimal therapeutic strategies remain unclear. This study aimed to evaluate the efficacy and safety of a combination treatment therapy using daily paroxetine 20 mg and on-demand lidocaine spray in men diagnosed with both erectile dysfunction and premature ejaculation. **Methods**: A cohort of men aged 18–65, diagnosed with PE and maintaining stable heterosexual relationships for over six months, received the proposed regimen. **Results**: The findings revealed a significant increase in intravaginal ejaculatory latency time (IELT) along with significant improvements in patient-reported outcomes, highlighting the potential of dual therapy to enhance sexual satisfaction. **Conclusions**: This single-arm study suggests that the combination of daily paroxetine and on-demand lidocaine spray may improve IELT and patient-reported outcomes in men with PE. However, the lack of a control group limits definitive conclusions. These preliminary findings support the need for future randomized controlled trials to validate the efficacy of this dual therapy compared to monotherapies or a placebo. **Clinical Trial Registration**: https://www.isrctn.com/ISRCTN31283266?q=ISRCTN31283266&filters=&sort=&off\set=1&totalResults=1&page=1&pageSize=10, ISRCTN31283266.

Keywords

Premature ejaculation; Paroxetine; Lidocaine; Intravaginal ejaculation latency time

1. Introduction

Sexuality is an important part of an individual's physical, psychological, and social well-being [1]. Sexual activity is not just a biological function related to reproduction but also plays a crucial role in expressing emotions between partners and providing pleasure [2]. The World Health Organization (WHO) defines sexuality as a concept that positively integrates and enriches somatic, emotional, intellectual, and social components of life, thereby shaping personality, communication, and love [3]. Therefore, when sexual health is impaired, individuals often experience significant emotional and relational challenges.

Premature ejaculation (PE) is one of the most common sexual dysfunctions in men and has a negative impact on both sexual and non-sexual relationships of the person and the partner [4]. In defining PE, three constant elements are emphasized: (a) shortened ejaculation time, (b) lack of control over ejaculation and premature ejaculation, (c) negative effects; lack of pleasure from sexual intercourse, distress to the person, and problems in relationships with partners and other people [5]. According to epidemiologic studies, the prevalence of PE is estimated to be around 20–30% [6]. In a study conducted in Türkiye involving 2593 participants with a mean age of 39.1 years (17–80), the prevalence of PE was found to be 20% [7]. Similarly, another study involving 1412 participants with a mean age of 20.4 years (18–28), the prevalence of PE was found to be 25.7% [8].

One of the current treatment strategies for PE involves the use of selective serotonin reuptake inhibitors (SSRIs) [9]. Among these medications, paroxetine has been reported to produce the most significant prolongation of the ejaculation time. Other pharmacological treatment options include clomipramine, topical anesthetics, phosphodiesterase-5 (PDE5) inhibitors, tramadol (a narcotic analgesic), and alpha-blockers [10].

Although the pathophysiology and etiology of PE are not fully understood, it is believed that ejaculation disorders may result from alterations in serotonin levels or serotonin receptor sensitivity in the ejaculation-regulating center (5-hydroxytryptamine, 5-HT) of the central nervous system [11]. Because serotonin plays a critical role in controlling

ejaculation, SSRIs are widely used in the management of PE.

Although several combination therapies have been reported in the literature, there is limited evidence specifically examining the combined use of daily paroxetine and on-demand lidocaine spray [12]. While both agents have demonstrated individual efficacy, there remains a lack of robust clinical data assessing their systematic combined use in a well-defined patient cohort. Therefore, this study aimed to evaluate the efficacy and safety of this dual therapy in a clinical setting, providing additional evidence to guide treatment strategies often considered in clinical practice.

2. Materials and methods

2.1 Study design and ethical approval

Male patients aged 18–65 years who applied to the Andrology Clinic with complaints of lifelong and acquired PE were included in the study. Ethics approval was obtained from the Ethics committee of the Memorial Hospital (2024/140). The study was designed in accordance with the Declaration of Helsinki, and all participants provided written informed consent. The participants' recruitment period was between October 2024 and January 2025.

2.2 Patient evaluation and data collection

After obtaining detailed medical and sexual history, a comprehensive physical examination was performed for each participant. Intravaginal ejaculation delay times (IELT) were recorded to confirm the PE diagnosis of the patients. The premature ejaculation diagnostic tool (PEDT), premature ejaculation profile (PEP), and International Index of Erectile Function-Erectile Function subscale (IIEF-EF) questionnaire forms were filled out. Patients with a PEDT score $\geq$11 were included in the study. Eligible patients were instructed to take 20 mg of paroxetine daily (Paxil 20 mg tb, 8699522096947, Pharmactive, Istanbul, Türkiye) and to use 10% lidocaine spray (Precoxin, 8699771001112, Aymed Drug, Ankara, Türkiye) on demand before intercourse. Patients were scheduled for a follow-up visit 4 weeks after receiving treatment, during which IELT scores were assessed, the PEP questionnaire was re-administered, and any treatment-related adverse effects were recorded.

2.3 Inclusion criteria

Participants were eligible if they met the following criteria:

Men aged between 18–65 years.

Those who have had a heterosexual relationship with a single partner for more than 6 months at the time of enrollment and will continue this relationship throughout the study.

Patients with a clinical diagnosis of erectile dysfunction and an IIEF score of >21.

Those with a premature ejaculation score of $\geq$11.

Patients and their partners agreed to have sexual intercourse 2 times per week during the study period.

Patients who commit to comply with the study protocol.

Patients who sign an informed consent form.

Patients who describe lifelong and acquired PE according to the definition of the International Society for Sexual Medicine (ISSM).

2.4 Exclusion criteria

Participants were excluded if they met any of the following:

Those with a history of urological surgery, anatomic abnormality, or neurological disorders (*e.g.*, multiple sclerosis), trauma, or infection that may be associated with the development of premature ejaculation symptoms and is thought to be a potential cause of premature ejaculation.

Those with a genital anomaly other than penile curvature that does not prevent sexual Intercourse.

Those who develop erectile dysfunction (ED) or PE due to drug withdrawal or drug use.

Those whose spouses have any problems with sexual intercourse.

Those with a history of severe psychiatric illness or suicide attempt.

Those with a history of epilepsy.

Those with a history of stroke, myocardial infarction, heart failure, unstable angina, life-threatening arrhythmia, or hypotension in the last 6 months.

Those who are not suitable for sexual intercourse due to existing health problems.

Those with resting systolic/diastolic blood pressure <90/50 mmHg and <170/100 mmHg.

Those with a history of allergy to SSRIs and lidocaine-containing drugs.

Continuing to use or discontinuing within the last 14 days, drugs such as monoamine oxidase inhibitors (MAOIs), thioridazine, selective serotonin reuptake inhibitors (SSRIs), selective-norepinephrine reuptake inhibitors (SNRIs), serotonergic drugs/herbal products, tricyclic antidepressants, and atypical antipsychotics.

Nitrates, alpha blockers, vasodilators, ketoconazole, itraconazole, ritonavir, saquinavir, telithromycin, nefazadone, nelfinavir, atazanavir, cimetidine, erythromycin, clarithromycin, fluconazole, amprenavir, fosamprenavir, aprepitant, verapamil, diltiazem, any vasodilator, antiplatelet, anticoagulant, dapoxetine, PDE5 inhibitors, alcohol, and stimulant drug users.

Alcohol and drug addicts.

Patients with a premature ejaculation diagnosis receiving other forms of therapy (behavioral therapy or other locally applied medications).

Those who may receive medication that may affect the pharmacokinetic/pharmacodynamics properties of the study drugs during the study period.

Clinically defined prostatitis or thyroid hormone disorders.

2.5 Assessment tools

Premature Ejaculation Diagnostic Tool (PEDT): A five-item questionnaire assessing ejaculation control, PE frequency, stimulation threshold, patient distress, and partner-related distress [13, 14]. A total score $\geq$11 indicates a diagnosis of PE.

Premature Ejaculation Profile (PEP): A four-item questionnaire was used to assess treatment response [14, 15]. Each item

is scored from 1 to 4, and the PEP Index score is calculated by dividing the total score by the number of items.

International Index of Erectile Function-Erectile Function subscale (IIEF-EF): Derived from questions 1–5 and 15 of the 15-item IIEF questionnaire, this subscale measures erectile function [16, 17]. An IIEF-EF score ≥21 indicates normal erectile function.

2.6 Statistical analysis

All statistical analyses were performed using SPSS version 20.0 (IBM, Armonk, NY, USA). The distribution of data was evaluated with the Kolmogorov-Smirnov test. Paired samples *t*-test and Wilcoxon test were used to measure pre- and post-treatment values. A significant *p*-value was determined as < 0.05.

3. Results

A total of 83 male patients aged 18–65 years diagnosed with premature ejaculation (PE) and in stable heterosexual relationships for at least six months were enrolled in the study. Of these, 4 patients were lost to follow-up, 3 discontinued treatment and 1 declined further participation, resulting in a final analysis of 75 patients. The results demonstrated a significant increase in intravaginal ejaculatory latency time (IELT) and significant improvements in patient-reported outcomes, highlighting the potential of dual therapy to enhance sexual satisfaction.

3.1 Baseline characteristics

The mean age of the patients was 42.11 ± 8.23 years. Before the treatment, the mean IELT of the patients was 38.22 ± 12.48 s, the mean PEDT score was 15.51 ± 3.12, the mean PEP score was 0.92 ± 0.51, and the mean IIEF-EF score was 24.48 ± 3.45 (Table 1).

TABLE 1. Demographic characteristics of the patients (n = 75).

Parameter	Mean ± SD	Range (Min–Max)
Age (yr)	42.11 ± 8.23	22–55
BMI (kg/m^2)	26.41 ± 2.12	20.12–35.08
PEDT Total Score	15.51 ± 3.12	12–20
PEP Index Score	0.92 ± 0.51	0–1.75
IELT (s)	38.22 ± 12.48	5–60
IIEF-EF	24.48 ± 3.45	23–30

Min: Minimum; Max: Maximum; PEDT: premature ejaculation diagnostic tool; PEP: premature ejaculation profile; IELT: intravaginal ejaculatory latency time; IIEF-EF: International Index of Erectile Function-Erectile Function subscale.

3.2 Treatment response

Following four weeks of dual therapy with daily paroxetine and on-demand lidocaine spray, there was a significant increase in IELT compared to baseline (99.08 ± 32.44 s *vs.* 38.22 ± 12.48 s; $p < 0.001$). Similarly, the PEP index score improved markedly after treatment (2.45 ± 1.21 *vs.* 0.92 ± 0.51; $p < 0.001$). In contrast, changes in IIEF-EF scores were minimal and not statistically significant (24.60 ± 3.96 *vs.* 24.48 ± 3.45; $p = 0.136$) (Table 2). These findings indicate that dual therapy substantially improved ejaculatory control and patient-reported outcomes without adversely affecting erectile function.

TABLE 2. The efficacy of the paroxetine and lidocaine spray treatment.

Outcome Measure	Pre-Treatment	Post-Treatment	Wilcoxon test *p*
IELT (s)	38.22 ± 12.48	99.08 ± 32.44	<0.001*
PEP Index Score	0.92 ± 0.51	2.45 ± 1.21	<0.001*
IIEF-EF	24.48 ± 3.45	24.60 ± 3.96	0.136

**p < 0.05 statistically significant. PEP: premature ejaculation profile; IELT: intravaginal ejaculatory latency time; IIEF-EF: International Index of Erectile Function-Erectile Function subscale.*

3.3 Patient satisfaction

Based on the Global Impression of Change (GIC) scale, 82.67% of patients reported satisfaction with the treatment and expressed a willingness to continue therapy.

3.4 Adverse events

Adverse effects were observed in 9 patients (12%), most of which were mild and transient. The most commonly reported side effects were headache and flushing, which resolved spontaneously without additional intervention. However, 6 patients (8%) discontinued treatment due to these adverse events.

4. Discussion

In this study, the combination therapy of daily paroxetine and on-demand lidocaine spray resulted in a significant increase in IELT and notable improvement in patient-reported outcomes in men with PE. After four weeks of treatment, the mean IELT increased from 38.22 ± 12.48 s at baseline to 99.08 ± 32.44 s ($p < 0.001$), and PEP index scores improved markedly ($p < 0.001$). Treatment compliance was high, with 82.67% of patients reporting satisfaction, and reported adverse effects were mild and transient, supporting the efficacy and tolerability of this dual therapeutic strategy.

Premature ejaculation (PE) is a prevalent condition that significantly impacts the quality of life for many men [18]. Traditional treatment approaches often focus on monotherapy; however, single-modality treatments are frequently insufficient in addressing the multifactorial nature of PE [19]. The findings from our study with 75 patients highlight that relying solely on either pharmacological or local treatment modalities may not provide optimal results. The mean IELT before treat-

ment was 38.22 s, indicating a substantial need for effective intervention. This inadequacy of monotherapy underscores the necessity for a more integrative approach to treatment that combines the strengths of different therapeutic options.

There are many oral, topical, and invasive treatment options for PE [20]. There is no clear consensus because the effects of these treatments are insufficient, and each treatment has certain side effects [10, 21]. Pharmacological therapies are often prescribed off-label, and although dapoxetine remains the only SSRI approved by the European Medicines Agency (EMA) for PE, it is less preferred by patients due to its limited ability to prolong IELT to the desired level [22].

The results of this study demonstrate that a dual therapeutic approach using paroxetine and lidocaine spray offers synergistic benefits by combining central and peripheral mechanisms of action. Our results showed a significant increase in mean IELT to 99.08 s post-treatment, alongside marked improvements in PEP scores ($p < 0.001$). This combination therapy not only addresses the physiological aspects of PE but also caters to the psychological components, which are often intertwined with sexual health issues. The high satisfaction rate of 82.67% among patients, as reported in the GIC, further emphasizes the effectiveness of this dual approach, suggesting that patients are more content when they experience both immediate relief and longer-term management of their condition.

Previous studies have explored combination therapies for PE, indicating that integrating different pharmacological agents can lead to better outcomes than monotherapy alone [23]. Research has demonstrated that combining SSRIs like paroxetine with local anesthetics can effectively prolong IELT while also improving sexual satisfaction [24]. Our study supports this growing body of evidence and highlights the clinical value of personalized combination therapy in managing PE.

Despite these encouraging findings, several limitations must be acknowledged. The most significant limitation is the lack of a control or comparator group (*e.g.*, paroxetine monotherapy, lidocaine monotherapy, or placebo), which prevents definitive conclusions about the efficacy of combination therapy relative to single treatments or placebo effects. In addition, the relatively modest sample size (n = 75) limits the generalizability of the results and precludes stratification analyses by relevant clinical variables such as age, BMI, and baseline PE severity. The short follow-up duration of four weeks also restricts conclusions regarding the long-term efficacy, tolerability, and safety of this treatment. Furthermore, given the mean baseline IELT of 38.22 s, the large improvement observed may partly reflect regression to the mean or non-specific treatment effects.

Future studies should focus on randomized controlled trials (RCTs) with larger, more diverse populations, incorporating comparator arms and extended follow-up periods. Such studies are necessary to establish the durability of treatment effects, identify potential predictors of treatment response, and assess long-term safety profiles [25, 26]. Additionally, head-to-head trials comparing dual therapy against monotherapies and placebo would provide clearer evidence for clinical decision-making.

Despite these limitations, the present study demonstrates that the combination of daily paroxetine and on-demand lidocaine spray offers a promising and well-tolerated short-term treatment option for men with PE. The therapy significantly improves IELT and patient-reported outcomes without adversely affecting erectile function. While these findings are encouraging, further high-quality randomized trials are essential to validate the efficacy, safety, and long-term benefits of this combination strategy.

5. Conclusions

This study demonstrates that the combination of daily paroxetine and on-demand lidocaine spray is a promising and well-tolerated short-term treatment option for men with premature ejaculation (PE). The dual approach significantly improved intravaginal ejaculatory latency time (IELT) and patient-reported outcomes compared with baseline. However, given the limited sample size, short follow-up period, and absence of a control group, these results should be interpreted with caution. Future randomized controlled trials with larger and more diverse populations are needed to confirm the efficacy, safety, and long-term benefits of this treatment strategy.

ABBREVIATIONS

BMI, Body Mass Index; IIEF-EF, International Index of Erectile Function-Erectile Function subscale; IELT, Intravaginal Ejaculation Latency Time; PEDT, Premature Ejaculation Diagnostic Tool; PEP, Premature Ejaculation Profile; SD, Standard Deviation; PE, Premature ejaculation; WHO, World Health Organization; SSRIs, selective serotonin reuptake inhibitors; PDE5, phosphodiesterase-5; 5-HT, 5-hydroxytryptamine; ISSM, International Society for Sexual Medicine; MAOIs, monoamine oxidase inhibitors; SNRIs, selective-norepinephrine reuptake inhibitors; GIC, Global Impression of Change; EMA, European Medicines Agency; RCTs, randomized controlled trials; ED, erectile dysfunction.

AVAILABILITY OF DATA AND MATERIALS

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

AUTHOR CONTRIBUTIONS

YIC—analysis; supervisor. YIC, DS—design; data collection; writing; editing. Both authors contributed to editorial changes in the manuscript. Both authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the Memorial Hospital Ethics Committee (Approval No: 2024/140). All participants provided written informed consent in accordance with the Declaration of Helsinki.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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