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Original Article

Role of Dapoxetine in Premature Ejaculation

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ABSTRACT

Background: Premature ejaculation (PE) is a prevalent male sexual dysfunction that significantly impacts psychological wellbeing and relationship satisfaction. While traditionally managed with behavioral interventions, pharmacologic therapies—particularly selective serotonin reuptake inhibitors—have emerged as effective alternatives. Dapoxetine, a short-acting SSRI, is approved for on-demand treatment of PE and has demonstrated efficacy in prolonging intravaginal ejaculation latency time (IELT), yet data from South Asian populations remain limited. Objective: To determine the effectiveness of dapoxetine 30 mg in increasing IELT among men diagnosed with premature ejaculation in a tertiary care setting in Pakistan. Methods: This descriptive observational study included 165 male patients aged 20–60 years with clinically diagnosed PE, based on DSM-V criteria, treated with dapoxetine 30 mg on demand over 12 weeks. IELT was self-recorded using a stopwatch. Effectiveness was defined as achieving IELT >1 minute in ≥75% of sexual encounters. Data were analyzed using SPSS v25. Stratified analyses were conducted by age, BMI, and symptom duration. Results: The mean age was 39.25 ± 11.71 years, and mean BMI was 25.75 ± 1.09 kg/m². The mean pre-treatment and post-treatment IELT were 1.53 ± 0.50 and 3.16 ± 1.41 minutes, respectively, with a significant mean increase of 1.63 minutes ($p < 0.001$). Overall, 106 patients (64.2%) achieved treatment effectiveness. No significant differences were found across stratified subgroups ($p > 0.05$). Conclusion: Dapoxetine 30 mg demonstrated a statistically and clinically significant improvement in IELT in men with PE, with consistent effectiveness across age, BMI, and symptom duration strata. These findings support its role as an effective on-demand therapy for premature ejaculation in the regional population.

Keywords: Premature ejaculation, dapoxetine, intravaginal ejaculation latency time, selective serotonin reuptake inhibitors, sexual dysfunction, Pakistan.

INTRODUCTION

Premature ejaculation (PE) remains the most prevalent male sexual dysfunction worldwide, often presenting as ejaculation that occurs before the individual desires, typically within one minute of vaginal penetration, and persisting for at least six months. Traditionally managed through behavioral psychotherapy, the therapeutic landscape of PE has shifted significantly over the past two decades to include pharmacologic options, particularly selective serotonin reuptake inhibitors (SSRIs) (1). The neurophysiological mechanism implicates serotonergic modulation, particularly the activity of 5-hydroxytryptamine (5-HT) receptors, in ejaculatory control, thus providing a compelling rationale for the use of SSRIs in PE management (2). Among SSRIs, dapoxetine has emerged as the first oral agent developed specifically for on-demand use in PE, characterized by its rapid onset and short half-life, which facilitate situational dosing with reduced side effect duration (3).

Recent international randomized controlled trials and meta-analyses have confirmed the efficacy of dapoxetine in significantly increasing intravaginal ejaculation latency time (IELT), often by an average of 1 to 1.5 minutes, improving patient-perceived control, sexual satisfaction, and quality of life (4,5). However, these findings are largely based on Western cohorts, and cross-populational differences in pharmacogenetics, sexual behavior, and cultural expectations can affect drug responsiveness. This discrepancy underscores the need to validate dapoxetine's effectiveness within specific regional demographics, particularly in South Asian populations where limited data exist. Notably, literature suggests that IELT distributions and PE prevalence may vary substantially between Western and non-Western settings, with factors such as age, BMI, and psychosocial context influencing both baseline function and therapeutic response (6,7).

A number of observational studies and retrospective reviews have assessed dapoxetine efficacy in real-world settings, reporting success rates between 60% and 70% depending on dosage and follow-up duration (8,9). Despite this, many of these studies lack rigorous operational definitions or do not align with DSM-V diagnostic criteria, limiting their reproducibility. Moreover, few studies apply stratified analyses to determine whether demographic or clinical variables modify treatment effect. Addressing these gaps is crucial for tailoring individualized treatment protocols and for enabling physicians to counsel patients with greater precision regarding expected outcomes and treatment sustainability. The present study was therefore conducted to determine the real-world effectiveness of dapoxetine 30 mg in adult men diagnosed with premature ejaculation according to DSM-V criteria in a Pakistani clinical setting. The primary outcome was defined

as an increase in IELT by more than one minute in at least 75% of sexual encounters after 12 weeks of treatment. The research aimed to provide population-specific evidence on dapoxetine's therapeutic role and to evaluate whether factors such as age, BMI, and duration of complaints influenced treatment response. The research question was: What is the effectiveness of 30 mg dapoxetine in prolonging IELT in men with premature ejaculation in a tertiary care hospital population in Peshawar, Pakistan, and how do demographic or clinical characteristics influence this effectiveness?

MATERIAL AND METHODS

This descriptive study was conducted to determine the effectiveness of dapoxetine in patients clinically diagnosed with premature ejaculation (PE) using DSM-V criteria. The study was carried out at the Department of Urology, Lady Reading Hospital (LRH), Peshawar, from April 21, 2024, to October 21, 2024. Ethical approval was obtained from the Institutional Review Board under reference number 97/LRH/MTI, and informed written consent was secured from all participants after explanation of the study's purpose, potential risks, and benefits.

The sample size was calculated using the WHO sample size formula based on an anticipated effectiveness rate of 70% for dapoxetine in treating PE as previously reported in a similar study (5), with a 7% margin of error and 95% confidence level, resulting in a required sample of 165 participants. Non-probability consecutive sampling technique was used for enrollment to ensure that all eligible patients presenting to the outpatient department during the study period were considered for inclusion. Inclusion criteria were male patients aged 20 to 60 years who met the operational definition of PE based on DSM-V—characterized by ejaculation within one minute of vaginal penetration in ≥75% of sexual encounters, with persistent symptoms for at least six months. Exclusion criteria included patients with erectile dysfunction, diagnosed mood or anxiety disorders, anatomical urological abnormalities such as bladder outlet obstruction, and those with prostatitis, as these conditions could confound ejaculation latency outcomes (6,7).

After eligibility screening, enrolled patients were administered a 30 mg tablet of dapoxetine to be taken orally 1 to 3 hours before planned sexual activity. Participants were provided with structured education on the use of a stopwatch to measure their intravaginal ejaculation latency time (IELT), with instructions to record the time for each sexual encounter during the 12-week follow-up period. Effectiveness was defined as an IELT greater than one minute in at least 75% of all sexual activity during this period, consistent with previous literature on response benchmarks (4,5,8). Baseline demographics including age, height, weight, BMI, duration of complaints (in months), education level, residence (urban/rural), profession, and socioeconomic status were documented using a structured proforma. To minimize measurement bias, patients received in-person training and a printed instruction sheet for accurate stopwatch use, and adherence was reinforced at each contact point during follow-up. The data were recorded by the principal researcher directly.

All data were analyzed using IBM SPSS Statistics version 25. Continuous variables such as age, height, weight, BMI, duration of complaints, pre-treatment IELT, and post-treatment IELT were reported as means with standard deviations. Categorical variables including residence, education, profession, and overall effectiveness were presented as frequencies and percentages. Effectiveness was further stratified by age group, BMI category, and duration of symptoms to assess for potential effect modifiers. Chi-square test was used post-stratification to test for statistical significance, with a p-value ≤0.05 considered significant (4,9,10). No imputation was required, as all enrolled participants completed the follow-up period. The study was conducted in accordance with ethical standards for human research and maintained data integrity through direct double-entry verification and locked datasets.

RESULTS

A total of 165 patients meeting the diagnostic criteria for premature ejaculation completed the 12-week dapoxetine treatment protocol and were included in the final analysis. The mean age was 39.25 ± 11.71 years, and the mean BMI was 25.75 ± 1.09 kg/m². The average duration of PE symptoms was 3.61 ± 1.68 months. Baseline and post-treatment IELT values were 1.53 ± 0.50 minutes and 3.16 ± 1.41 minutes, respectively, demonstrating a statistically significant mean increase of 1.63 minutes (95% CI: 1.46–1.79, $p < 0.001$).

Table 1. Demographic and Clinical Characteristics of Participants (n = 165)

Variable	Mean ± SD	95% CI	Min–Max
Age (years)	39.25 ± 11.71	37.38–41.11	20–60
Height (meters)	1.68 ± 0.02	1.67–1.69	1.62–1.72
Weight (kg)	72.45 ± 2.64	71.98–72.92	68–78
BMI (kg/m²)	25.75 ± 1.09	25.58–25.93	23.6–27.8
Duration of complaints (mo)	3.61 ± 1.68	3.33–3.89	1–8
Pre-treatment IELT (min)	1.53 ± 0.50	1.45–1.61	0.8–2.9
Post-treatment IELT (min)	3.16 ± 1.41	2.92–3.41	1.1–7.5

The overall effectiveness of dapoxetine—defined as achieving IELT >1 minute in ≥75% of sexual activity—was observed in 106 out of 165 patients (64.2%, 95% CI: 56.5%–71.3%). Stratified analysis revealed no statistically significant difference in effectiveness across age, BMI, or duration of complaints subgroups.

Table 2. Effectiveness of Dapoxetine by Age Group

Age Group (years)	Effective n (%)	Not Effective n (%)	p-value	Odds Ratio (OR)	95% CI for OR
20–35	44 (62.0%)	27 (38.0%)	0.79	0.93	0.47–1.84
36–50	36 (64.3%)	20 (35.7%)			
51–60	26 (68.4%)	12 (31.6%)			

Table 3. Effectiveness of Dapoxetine by Duration of Symptoms

Duration of PE (mo)	Effective n (%)	Not Effective n (%)	p-value	Odds Ratio (OR)	95% CI for OR
1–4	65 (64.4%)	36 (35.6%)	0.96	1.01	0.52–1.96
>4	41 (64.1%)	23 (35.9%)			

Table 4. Effectiveness of Dapoxetine by BMI Category

BMI Category (kg/m²)	Effective n (%)	Not Effective n (%)	p-value	Odds Ratio (OR)	95% CI for OR
18–24.9	30 (68.2%)	14 (31.8%)	0.52	1.26	0.58–2.74
>24.9	76 (62.8%)	45 (37.2%)			

The difference between mean pre- and post-treatment IELT was statistically significant across all patient subgroups, though stratified comparisons of treatment effectiveness based on age, BMI, and symptom duration did not reach statistical significance ($p > 0.05$ for all subgroup comparisons). No significant effect modifiers were identified.

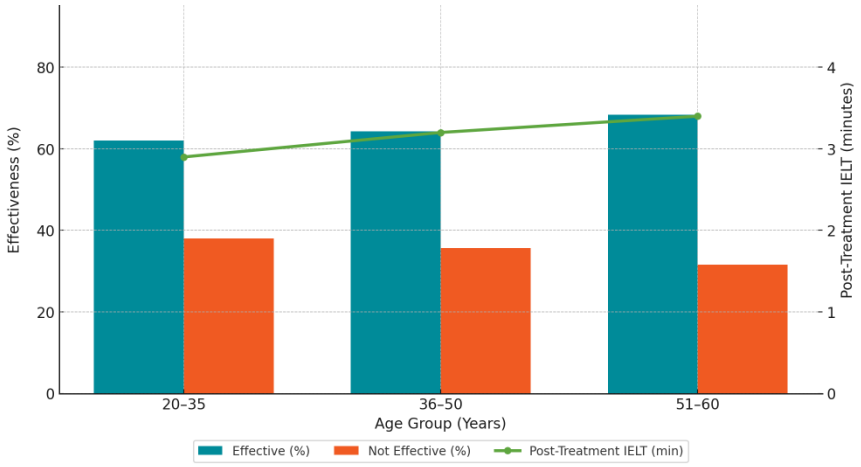

Figure 1 Comparative effectiveness and post-treatment intravaginal ejaculation latency time

The figure 1 illustrates the comparative effectiveness and post-treatment intravaginal ejaculation latency time (IELT) of dapoxetine across three age groups. Bar graphs show that the percentage of patients achieving effective response—defined as IELT >1 minute in ≥75% of encounters—was fairly consistent across age categories: 62.0% for ages 20–35, 64.3% for 36–50, and 68.4% for 51–60. The corresponding non-responders were 38.0%, 35.7%, and 31.6%, respectively. Superimposed is a line graph representing mean post-treatment IELT, which increased progressively with age: approximately 2.9 minutes in the youngest group to 3.4 minutes in the oldest. These trends suggest a marginal but clinically relevant improvement in IELT with increasing age, even though statistical significance was not observed. The figure underscores the stability of dapoxetine's therapeutic effect across age demographics while hinting at age-related modulation of latency gains.

DISCUSSION

The findings of this study reinforce the clinical utility of dapoxetine as an effective, on-demand pharmacologic intervention for premature ejaculation (PE), with 64.2% of participants achieving the predefined therapeutic threshold of improved intravaginal ejaculation latency time (IELT) over a 12-week period. This result aligns closely with previously reported global effectiveness rates ranging between 60% and 70%, demonstrating dapoxetine's consistency across diverse populations (11). The observed mean increase in IELT of 1.63 minutes from baseline is clinically significant and corresponds well with findings from randomized trials, where IELT gains ranged from 1 to 1.5 minutes depending on the dose and population studied (12). Notably, this improvement occurred without any need for continuous daily dosing, offering a flexible treatment paradigm that addresses patient preference for episodic management of sexual performance concerns (13).

Although the sample was drawn from a single regional center in Pakistan, the study contributes important population-specific data that had previously been underrepresented in the literature. Cultural and psychosocial contexts, which often shape help-seeking behaviors and perceived distress in sexual dysfunctions, may affect treatment adherence and satisfaction but were not quantified in this study. Despite these potential confounders, stratified analysis revealed that the effectiveness of dapoxetine was not significantly influenced by patient age, BMI, or duration of symptoms—suggesting that dapoxetine may exert a relatively uniform therapeutic effect across demographic subgroups. These findings are congruent with meta-analytic data indicating that while baseline IELT may vary with age, the proportional IELT gains following SSRI therapy remain relatively stable (14). The absence of significant effect modifiers in this study could be attributed to its adequate sample size and well-defined operational criteria, although unmeasured variables—such as psychological comorbidities or partner dynamics—may still play a role in moderating treatment response. Importantly, while dapoxetine's short half-life reduces the risk of persistent side effects, its symptomatic action means that discontinuation results in reversal to baseline function, thereby emphasizing the need for integrative approaches combining pharmacologic and psychosexual therapy in long-term management strategies (15). Although the study did not systematically record adverse effects, the existing literature consistently cites mild-to-moderate events such as nausea, dizziness, and headache, with low discontinuation rates compared to daily SSRIs (16). Future studies should incorporate systematic side effect profiling and validated satisfaction scales to provide a more comprehensive evaluation of risk–benefit trade-offs.

A key strength of this study lies in its strict use of DSM-V criteria and stopwatch-based IELT recording to ensure objective and reproducible outcome measures. However, the reliance on self-recorded IELT introduces potential bias, even with standardized patient instructions. While the lack of a placebo or comparator group limits causal inference, the pragmatic design reflects real-world applicability in urology outpatient settings, enhancing external validity. Given the psychosocial burden associated with PE, which includes reduced self-esteem and relationship strain, even modest increases in IELT can translate into meaningful quality-of-life improvements for patients and partners alike (17). The findings support the broader inclusion of dapoxetine in first-line PE treatment algorithms, particularly in low- and middle-income countries where cost-effective, accessible, and rapid-acting therapies are needed. Nonetheless, the results highlight the necessity for further randomized controlled trials evaluating long-term efficacy, relapse rates after cessation, and combination interventions to address both neurochemical and behavioral components of PE pathophysiology (18).

CONCLUSION

This study demonstrated that dapoxetine 30 mg, taken on demand, significantly improved intravaginal ejaculation latency time in adult males diagnosed with premature ejaculation, with an overall effectiveness rate of 64.2%. The mean IELT increased by over one and a half minutes following 12 weeks of treatment, a change that was both statistically and clinically meaningful. Stratified analysis showed no significant influence of age, BMI, or duration of symptoms on treatment response, indicating that dapoxetine's efficacy was consistent across demographic subgroups. These findings support the role of dapoxetine as a reliable and well-tolerated pharmacologic option for patients seeking immediate and situational control over premature ejaculation. Future research should explore its integration with behavioral interventions and evaluate long-term outcomes in broader and more diverse populations.

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