

# A Comparative Study of the Efficacy of Levosulpiride versus Paroxetine in Premature Ejaculation

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ABSTRACT

**Background:** Premature ejaculation (PME) can be defined as a lack in the normal voluntary control over ejaculation. It is the most common sexual dysfunction encountered by the male populace. In general, these patients presents with distress. Hence, a novel treatment to eliminate their problem is required. Although the role of SSRI has already been established, the high discontinuation rate and other types of sexual dysfunctions associated with SSRIs reduce their efficacy in controlling this menace. Levosulpiride is a new drug indicated in treatment of PE. **Aims and Objectives:** The objective is to study the efficacy of levosulpiride; paroxetine and their comparison in patients of PE. **Methodology:** Index of premature ejaculation (IPE) and intravaginal ejaculation latency time (IELT) were used. A total of 36 patients (18 in each group) were included. The patients were assessed at baseline; at 4 weeks' and at 8 weeks' interval. **Results:** On comparison the score of IPE in domains of ejaculation control, sexual satisfaction, and the total score of IPE were statistically significant on all the three visits. However, the distress score of IPE and the IELT score were statistically not significant between the two groups. **Conclusion:** No doubt both agents are efficacious in patients of PME but paroxetine is more efficacious than levosulpiride. At the same time, levosulpiride is a lesser studied and used drug hence more research should be done for it.

**KEYWORDS:** Index of premature ejaculation, intravaginal ejaculation latency time, levosulpiride, paroxetine, premature ejaculation

## INTRODUCTION

Premature ejaculation (PME) is a highly prevalent male sexual disorder. PME is defined in DSM-5 as a persistent or recurrent pattern of ejaculation occurring during sexual activity within approximately 1 min following vaginal penetration and before the individual wishes it (302.75).<sup>[1]</sup> The International Society for Sexual Medicine *ad hoc* committee for the definition of premature ejaculation defines lifelong premature ejaculation as a male sexual dysfunction characterized by:

- Ejaculation which always or nearly always occurs prior to or within about 1 min of vaginal penetration;

- Inability to delay ejaculation on all or nearly all vaginal penetrations.<sup>[2]</sup>

The presence of PME can be lifelong or acquired.

Similarly, the risk factors causing it can be genetic and physiological such as dopamine transference polymorphism or serotonin transporter gene. Other causes include thyroid abnormalities, prostatitis, and drug withdrawal to name a few. Temperamental causes such as anxiety disorders, phobia, social anxiety disorder, and performance anxiety. Recent studies do indicate

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organic reasons too.<sup>[3]</sup> The disorder is a constant source of distress for men and can lead to severe frustration along with interpersonal issues with the spouse. PME traditionally was sought to be a psychological disorder leading to emotional trauma such as low self-esteem, inferiority complex, and embarrassment in the males.<sup>[4,5]</sup>

Although the highly prevalent yet less reported type of disorder which may be because of several factors such as stigma, a false belief that sexuality will be medicine dependent, a mistaken belief that treatment will be a kind of addiction, will need to be lifelong and reluctance on the part of physicians to inquire about sexual problems.

Today, most sex therapists understand premature ejaculation as occurring when a lack of ejaculatory control interferes with sexual or emotional well-being in one or both of the partners.<sup>[6]</sup>

### Neurobiogenesis of ejaculation

Stimulation of the glans penis mucosal sensory receptors (Krause finger corpuscles) is relayed by the pudendal nerve afferent fibers to S4, and then to the hypogastric plexus at the T10–L2 sympathetic ganglia. Sensory information is relayed centrally to the brain, where three ejaculatory centers are situated. Two are in the hypothalamus (the medial preoptic area and the paraventricular nucleus) and one is in the midbrain (the periaqueductal gray). These centers integrate the peripheral events of seminal emission, ejaculation, and orgasm. The efferent dopamine output by these centers is modulated by the nucleus paragigantocellularis. This has an inhibitory influence, from its serotonergic neurons centrally and to the lumbar–sacral motor nuclei, which tonically inhibits ejaculation. Central control over the ejaculatory reflex is primarily governed by dopaminergic and serotonergic neurons; however, nitric oxide, acetylcholine, norepinephrine, neuropeptides, oxytocin, and gamma-amino-butyric acid have all been shown to play secondary roles. There have been multiple serotonergic receptors characterized that have different roles in the ejaculatory response.<sup>[7]</sup> The pathophysiology of PE could possibly be a result of hypofunction of the 5HT<sub>2C</sub> receptor and/or hyperfunction of the 5HT<sub>1A</sub> receptor. This hypofunction of the 5HT<sub>2C</sub> receptor, as well as low levels of 5HT transmission in general, is thought to be associated with a low threshold for sexual arousal and ejaculation.<sup>[8]</sup>

Pharmacological treatment<sup>[9]</sup> of PME has been researched, and drugs that increase serotonin signaling in the brain slow ejaculation and are used to treat PME examples include selective serotonin reuptake inhibitors (SSRIs), local anesthetic agent, and clomipramine. Studies

report that there is an improvement in PME with SSRI (paroxetine) in up to 60% of the patients, but these drugs are causing other types of sexual dysfunction (such as decreased sexual desire and anorgasmia) leading on to its discontinuation. A meta-analysis published in 2004 compared eight studies in which a temporal quantification of PE improvement (intravaginal ejaculation latency time [IELT]) was used to compare treatment with fluoxetine, paroxetine, and sertraline to placebo. Increased IELT was seen in all SSRI-treated groups when compared to placebo and it was reported that patients treated with paroxetine demonstrated the greatest increase in IELT (78.3%), followed by sertraline and fluoxetine. Dapoxetine is a short-acting SSRI that can be taken as needed by men with PME. It has been studied in five separate multicenter, randomized, double-blind, placebo-controlled trials involving more than 6000 men with PME. In four studies that evaluated IELT as an endpoint ( $n = 4843$ ), dapoxetine 30 and 60 mg achieved statistically significant increases in IELT versus placebo. Dapoxetine also showed statistically significant improvements in perceived control over ejaculation, PME-related personal distress, and other patient-reported outcomes in all five trials. Dapoxetine treatment is generally well-tolerated, with low incidences of discontinuation syndrome, sexual dysfunction, and treatment-emergent mood symptoms.<sup>[3]</sup> A clinically relevant effect of prolonged IELT usually occurs within 1–3 weeks of chronic administration of SSRI-based therapies for the management of PME. Of the treatments listed, “off-label” use of SSRIs is often considered first-line therapy by clinicians for the ejaculatory disorder.<sup>[7]</sup>

Thus, there is a need for a new solution for the treatment of PME. Another drug that acts as anti-dopaminergic drug is levosulpride, usually used in dyspeptic patients in anxious patients can be used to treat PME. As per our knowledge, there are only two studies that report improvement in premature ejaculation with levosulpride. Hussain *et al.*<sup>[10]</sup> in Pakistan, showed that approximately 47% of patients showed good improvement while up to 23% of patients showed some improvement. Dopamine has been shown to be facilitate sexual arousal and in decreasing ejaculatory threshold. Hence, levosulpride being a dopamine antagonist may be responsible for the beneficial effect by this mechanism. Levosulpride has a role in enhancing sexual arousal and in lowering the ejaculatory threshold. Another study by Greco *et al.*<sup>[11]</sup> showed that approximately 52% of patients showed improvement with 25–50 mg of levosulpride. Both these have been undertaken out of India.

With this background, this study was planned with an aim to know the role of levosulpiride in PME and to compare its efficacy to paroxetine in Indian male patients diagnosed as PME, so rather than comparing it to a placebo an already proven molecule with good efficacy was considered for comparison. This would shed some light in deciding the management plan for the distressed male and help in alleviating the problem.

## METHODOLOGY

This study was conducted in the Department of Psychiatry at a Medical College; it was an outpatient-based study. Institutional ethical committee approval was obtained prior to the data collection. All married heterosexual males of age group 25–50 years met the diagnostic criteria of PME according to DSM-5 and gave the written informed consent to participate in the study were included in the study. The total duration of the study was 6 months.

All unmarried males having underlying hypothyroidism, cardiac illness or any other comorbid medical illness/ endocrinal illness which may cause PME; those having erectile dysfunction or any other associated sexual dysfunction; who are taking any drugs which can cause PME in the past 6 months, such as SSRI, alcohol, opioids; those who meet criteria for any other psychiatric disorder including substance dependence/ neurological disorder and who are mentally retarded, patients with out of range values of serum testosterone, serum prolactin, and thyroid profile were excluded from the study sample. Consecutive sampling method was adopted. CONSORT guidelines were followed.

After a thorough history, general physical examination and local genital examination were done to rule out any anatomical dysfunction or signs of any local deformity, inflammation, or injury. IELT was measured using a stopwatch. The patients were first taught to measure IELT using a stopwatch and then were told to telephonically relay the information for the baseline and the patient was advised to start treatment after this. This was reported and noted as the baseline visit. All patients were given a session of psycho-education to orient about the anatomy of male and female genitalia and myths regarding sexual issues especially premature ejaculation and performance anxiety was addressed using audio-visual aids. An assessment of sexual satisfaction, ejaculation control, and distress score was done using the index of premature ejaculation (IPE).<sup>[12]</sup> IPE has ten questions with scoring from 0 to 5. After the baseline data collection, the patients were then prescribed Levosulpiride 25 mg OD or paroxetine 12.5 mg once daily. Dapoxetine was not available in pharmacy of

the tertiary hospital hence was considered for the study protocol. PME was quantified on these parameters, and then, these scores are used for comparison. The assessment was again done at follow-up after 4 weeks and then at 8 weeks from the baseline.

A sealed envelope technique was used for the allocation of groups. The patients were handed a sealed envelope with the medication enclosed in it. Half of them were prescribed levosulpiride and other half paroxetine. The primary investigator was not aware of the treatment being prescribed to the patient, so as to maintain the blinding of the study. The patients were also not aware of the medication being prescribed in the other group.

### Method of sample collection

A total of 100 consecutive patients were screened; of this only 36 patients completed the study protocol and hence formed the study sample [shown in Figure 1].

The primary investigator first screened patients under the supervision of a consultant. After that, the patient was reviewed by another consultant in-charge for the verification of the findings and prescribed the medication thereafter.

The results of the drug and psychoeducation were assessed at baseline; at 4 weeks and 8 weeks of treatment by measuring IELT using a stopwatch and rest three domains were measured using patient report outcome using IPE. The frequency and percentage of tables were used for the presentation of qualitative data. Comparison of various quantitative parameters amongst study groups was made using unpaired *t*-test and Chi-square test. A  $P < 0.05$  was taken as the level of significance. Repeated measure of analysis of variance (repeated MANOVA) was used on account of the multiple assessments.

## RESULTS

### Sociodemographic data

The sociodemographic data are represented in Table 1. No significant difference is noted in the sociodemographic profile of patients on levosulpiride and paroxetine.

IPE is the tool which assesses the overall improvement, ejaculation control, and distress score. PME is quantified in these parameters, and then these scores are used for comparison. It has ten questions with Likert scoring from 0 to 5. It was used to score ejaculation control (Q1–4), sexual satisfaction (Q5–8), and distress score (Q9–10). A decrease in scores in question 1–8 favored good responses while an increase in score 9 and 10 meant a decreased distress. The scale was administered at baseline visit then at visit 2 (week 4) and visit 3 (week 3).

**Table 1: Sociodemographic data of the sample**

Parameters	Group	
	Levosulpiride	Paroxetine
Age (years)		
Mean	32.94	32.56
Type of locality		
Rural	15 (83.3)	15 (83.3)
Urban	3 (16.7)	3 (16.7)
Education		
Graduate	4 (22.2)	6 (33.3)
Postgraduate	1 (5.6)	0 (0.0)
Uneducated	1 (5.6)	2 (11.1)
Up to 10 <sup>th</sup>	2 (11.1)	4 (22.2)
Up to 12	5 (27.8)	1 (5.6)
Up to 5 <sup>th</sup>	5 (27.8)	5 (27.8)
Occupation		
Semiskilled	4 (22.2)	5 (27.8)
Skilled	6 (33.3)	3 (16.7)
Unskilled	8 (44.4)	10 (55.6)

The patients on levosulpiride showed improvement in the score of ejaculation control from 17.22 at visit 1–15.83 at visit 2 and further to 15.28 at visit 3. There was an improvement in the score of sexual satisfaction from 17.00 at visit 1–16.17 at visit 2 and further to 15.39 at visit 3. Distress score increased from 3.94 to 4.83 at visit 2 and further to 5.28 at visit 3 showing a decrease in distress level. Improvement in sexual satisfaction and distress score improved with the *P* value of 0.005 and 0.002 respectively indicating results to be statistically significant at visit 2 as compared to visit 1. However, there was an improvement at visit 3, but the results were statistically nonsignificant compared to visit 2 [Tables 2 and 3] in all three domains of IPE.

The patients on paroxetine showed improvement in the score of ejaculation control from 14.83 to 12.67 at visit 2 and further to 11.50 at visit 3. There was an improvement in the score of sexual satisfaction from 14.61 at visit 1–12.22 at visit 2 and further to 10.39 at visit 3. Distress score increased from 3.11 at visit 1–4.00 at visit 2 and further to 4.88 at visit 3 showing a decrease in distress level. The results obtained after visit 1 to visit 2 revealed that the improvement in all three domains of IPE to be 0.000 a statistically significant. Similarly, the results obtained from visit 2 to visits 3 also revealed that the improvement in all the three domains to be very highly significant at visit 3 compared to visit 2 [Tables 4 and 5].

IELT was measured using the stop-watch technique. It is a parameter that is observed and reported by the patient himself. After proper psychoeducation, the patients regarding how and when to time the stopwatch

the finding thus reported were taken. The IELT score of the patients on levosulpiride improved from 32.50 s at baseline to 45.56 at visit 2 and further to 57.22 s at visit 3. Whereas, the IELT score improved from 36.11 to 52.22 at visit 2 and further to 63.33 seconds of patients on paroxetine. The results were statistically not significant [Table 6].

Tables 7-9 show the comparison of IELT and IPE between levosulpiride and paroxetine at visit 1 (baseline visit), visit 2 (4 weeks), and visit 3 (8 weeks). The score on IPE in domains of ejaculation control, sexual satisfaction, and the total score of IPE were statistically significant on all the three visits. However, the distress score of IPE and the IELT score were statistically not significant between the two groups.

Table 10 shows the comparison of IPE parameters between levosulpiride and paroxetine at visit 1 (baseline visit), visit 2 (4 weeks), and visit 3 (8 weeks) (repeated MANOVA). The patients on levosulpiride showed improvement in sexual satisfaction and reduction in distress from visit 1 to visit 2. However, the distress score further also showed statistically significant improvement on comparison of visit 1 to visit 3. The repeated MANOVA showed that in the group of patients on paroxetine all the domains of IPE had statistically significant improvement from visit 1 to visit 2 and visit 1 to visit 3.

## DISCUSSION

### Sociodemographic profile

Sociodemographic data of the study show that almost 83% of the patients recruited were from a rural background. This makes us wonder the factors such as lack of proper awareness, resources, and social media play an important role in increased incidence and prevalence of PME in the rural population. About 45% of the recruited patients are educated till high school or below, hence indicating lesser education leading to increased prevalence. It is seen that 50% were unskilled workers further supporting the fact that lack of knowledge is an essential factor. While the other 50% were semi-skilled or skilled workers who might indicate a lack of time, increased work pressure that may be playing a role in PME.

### The response of index of premature ejaculation on levosulpiride

The results of Tables 2 and 3 indicate that improvement is present in domains of IPE in patients on levosulpiride from visit 1 (baseline) to visit 2 (4 weeks) and is statistically significant, but on subsequent follow-up at visit 3 (8 weeks) the



**Table 2: Response of patients on levosulpiride from baseline to 2<sup>nd</sup> follow-up visit at 4 weeks (index of premature ejaculation)**

Group	Mean (SD)		<i>t</i>	<i>P</i>	95% CI of the difference	
	Visit 1	Visit 2			Lower	Upper
<b>Levosulpiride response</b>						
IPE						
Ejaculation control	17.22 (3.42)	15.83 (1.65)	2.273	0.036	0.100	2.678
Sexual satisfaction	17.00 (2.28)	16.17 (2.07)	3.220	0.005	0.287	1.379
Distress	3.94 (0.54)	4.83 (0.99)	-3.688	0.002	-1.397	-0.380

CI=Confidence interval, IPE=Index of premature ejaculation, SD=Standard deviation

**Table 3: Response of patients on levosulpiride from 2<sup>nd</sup> follow-up visit at 4 weeks to follow-up at 8 weeks (index of premature ejaculation)**

Group	Mean (SD)		<i>t</i>	<i>P</i>	95% CI of the difference	
	Visit 2	Visit 3			Lower	Upper
<b>Levosulpiride response</b>						
IPE						
Ejaculation control	15.83 (1.65)	15.28 (1.60)	2.397	0.028	0.066	1.045
Sexual satisfaction	16.17 (2.07)	15.39 (1.88)	1.982	0.064	-0.050	1.606
Distress	4.83 (0.99)	5.28 (0.96)	-2.204	0.042	-0.870	-0.019

CI=Confidence interval, IPE=Index of premature ejaculation, SD=Standard deviation

**Table 4: Improvement of patients from baseline to 2<sup>nd</sup> follow-up at 4 weeks on paroxetine (index of premature ejaculation)**

Group	Mean (SD)		<i>t</i>	<i>P</i>	95% CI of the difference	
	Visit 1	Visit 2			Lower	Upper
<b>Paroxetine response</b>						
IPE						
Ejaculation control	14.83 (2.23)	12.67 (2.35)	7.657	0.000	1.570	2.764
Sexual satisfaction	14.61 (2.30)	12.22 (2.13)	5.057	0.000	1.392	3.385
Distress	3.11 (1.41)	4.00 (1.94)	-3.688	0.002	-1.397	-0.380

CI=Confidence interval, IPE=Index of premature ejaculation, SD=Standard deviation

**Table 5: Data of improvement of patients from 2<sup>nd</sup> follow-up at 4 weeks to follow-up on 8 weeks on paroxetine (index of premature ejaculation)**

Group	Mean (SD)		<i>t</i>	<i>P</i>	95% CI of the difference	
	Visit 2	Visit 3			Lower	Upper
<b>Paroxetine response</b>						
IPE						
Ejaculation control	12.67 (2.35)	11.50 (2.31)	3.580	0.002	0.479	1.854
Sexual satisfaction	12.22 (2.13)	10.39 (3.26)	3.265	0.005	0.649	3.018
Distress	4.00 (1.94)	4.89 (2.35)	3.688	0.002	-1.397	-0.380

CI=Confidence interval, IPE=Index of premature ejaculation, SD=Standard deviation

**Table 6: Data representing the comparison of intravaginal ejaculation latency time at baseline, visit 2, and visit 3 on Levosulpiride and Paroxetine**

	Mean (SD)		<i>t</i>	<i>P</i>	95% CI of the difference	
	Levosulpiride response	Paroxetine response			Lower	Upper
IELT visit 1	32.50 (15.93)	36.11 (8.32)	-0.853	0.400	-12.219	4.997
IELT visit 2	45.56 (12.82)	52.22 (11.01)	-1.674	0.103	-14.762	1.429
IELT visit 3	57.22 (13.31)	63.33 (14.95)	-1.295	0.204	-15.699	3.477

CI=Confidence interval, IELT=Intravaginal ejaculation latency time, SD=Standard deviation

improvement was not sustained and is statistically not significant. The lack of literature in support of levosulpiride has tied our hands regarding the replicability of the results of our study.

### The response of index of premature ejaculation on paroxetine

The results of Tables 4 and 5 indicate that improvement is present in domains of IPE in patients on paroxetine

**Table 7: The comparison of intravaginal ejaculation latency time and index of premature ejaculation between levosulpiride and paroxetine at visit 1 (baseline visit)**

Visit 1	Mean (SD)		t	P	95% CI of the difference	
	Levosulpiride response	Paroxetine response			Lower	Upper
IELT	32.50 (15.93)	36.11 (8.32)	-0.853	0.400	-12.219	4.997
Ejaculation control	17.22 (3.42)	14.83 (2.23)	2.481	0.018	0.432	4.345
Sexual satisfaction	17.00 (2.28)	14.61 (2.30)	3.130	0.004	0.838	3.940
Distress	3.94 (0.54)	3.11 (1.41)	2.343	0.025	0.110	1.556
Total score	38.17 (5.08)	32.56 (4.33)	3.568	0.001	2.415	8.807

CI=Confidence interval, IELT=Intravaginal ejaculation latency time, SD=Standard deviation

**Table 8: The comparison of intravaginal ejaculation latency time and index of premature ejaculation between levosulpiride and paroxetine at visit 2 (week 4)**

Visit 2	Mean (SD)		t	P	95% CI of the difference	
	Levosulpiride response	Paroxetine response			Lower	Upper
IELT	45.56 (12.82)	52.22 (11.01)	-1.674	0.103	-14.762	1.429
Ejaculation control	15.83 (1.65)	12.67 (2.35)	4.673	0.000	1.790	4.544
Sexual satisfaction	16.17 (2.07)	12.22 (2.13)	5.641	0.000	2.523	5.365
Distress	4.83 (0.99)	4.00 (1.94)	1.625	0.113	-0.209	1.876
Total score	36.83 (3.49)	28.89 (3.48)	6.844	0.000	5.586	10.303

CI=Confidence interval, IELT=Intravaginal ejaculation latency time, SD=Standard deviation

**Table 9: The comparison of intravaginal ejaculation latency time and index of premature ejaculation between levosulpiride and paroxetine at visit 3 (week 8)**

Visit 3	Mean (SD)		t	P	95% CI of the difference	
	Levosulpiride response	Paroxetine response			Lower	Upper
IELT	57.22 (13.31)	63.33 (14.95)	-1.295	0.204	-15.699	3.477
Ejaculation control	15.28 (1.60)	11.50 (2.31)	5.706	0.000	2.432	5.123
Sexual satisfaction	15.39 (1.88)	10.39 (3.26)	5.639	0.000	3.198	6.802
Distress	5.28 (0.96)	4.89 (2.35)	0.650	0.520	-0.826	1.604
Total score	35.94 (3.54)	26.78 (3.73)	7.559	0.000	6.702	11.631

CI=Confidence interval, IELT=Intravaginal ejaculation latency time, SD=Standard deviation

from visit 1 (baseline) to visit 2 (4 weeks) and is statistically significant, the improvement on subsequent follow-up at visit 3 (8 weeks) is sustained and is statistically significant. Gameel *et al.*<sup>[13]</sup> showed in their study that paroxetine has a favorable action in improving sexual satisfaction and an overall improvement in results as per IPE.

As per the domains of IPE are considered, the comparison of levosulpiride with paroxetine indicates that improvement in the domain of ejaculation control was statistically not significant for levosulpiride and improvement in sexual satisfaction, distress though statistically significant initially was not sustained till 8 weeks indicating a solution for shorter action. On the other hand, paroxetine showed statistically significant improvement in all domains of IPE, and it was sustained until 8 weeks indicating paroxetine to be better for more prolonged action.

### The response of intravaginal ejaculation latency time on levosulpiride

Current studies report that in the age of 18–30 years, the IELT is 6 and a ½ min and in Indian males, it is 3–5 min.<sup>[14]</sup> As per the available literature on the use of levosulpiride, we could gather that the results were in concordance with the existing studies. Hussain *et al.*<sup>[10]</sup> reported that 34% of the patients showing improvement in IELT from <2 min to 5 min; while 15% of them showed improvement from <2 min to 3 min. Grecco *et al.*<sup>[11]</sup> reported 36.7% have an improvement in IELT from <2 min to 5 min and 16.3% showed improvement from <2 min to >3 min.

### The response of intravaginal ejaculation latency time on paroxetine

McMahon and Touma<sup>[15]</sup> reported an improvement in IELT in 59% of the patients out of the 61 reported and maintained improvement after 8 weeks of treatment with paroxetine. McMahon and Touma<sup>[16]</sup> conducted a controlled, single-blind study and noted an increase in

**Table 10: The comparison of parameters of index of premature ejaculation between levosulpiride and paroxetine at visit 1, 2 and 3 (repeated MANOVA)**

	Factor 1 (I)	Factor 1 (J)	Mean difference (I-J)	SE	P	95% CI for difference	
						Lower bound	Upper bound
<b>Levosulpiride</b>							
Ejaculation control	Visit 1	Visit 2	1.389*	0.611	0.036	0.100	2.678
		Visit 3	1.944*	0.707	0.014	0.453	3.436
Sexual satisfaction	Visit 2	Visit 3	0.556*	0.232	0.028	0.066	1.045
		Visit 1	0.833*	0.259	0.005	0.287	1.379
Distress	Visit 2	Visit 3	0.778	0.392	0.064	-0.050	1.606
		Visit 1	-0.889*	0.241	0.002	-1.397	-0.380
Total score	Visit 1	Visit 2	-1.333*	0.229	0.000	-1.816	-0.851
		Visit 3	-0.444*	0.202	0.042	-0.870	-0.019
		Visit 2	1.333	0.788	0.109	-0.329	2.996
Total score	Visit 2	Visit 3	2.222*	1.031	0.046	0.048	4.397
		Visit 1	0.889	0.559	0.131	-0.291	2.069
		Visit 3	0.889	0.559	0.131	-0.291	2.069
<b>Paroxetine</b>							
Ejaculation control	Visit 1	Visit 2	2.167*	0.283	0.000	1.570	2.764
		Visit 3	3.333*	0.457	0.000	2.368	4.298
Sexual satisfaction	Visit 2	Visit 3	1.167*	0.326	0.002	0.479	1.854
		Visit 1	2.389*	0.472	0.000	1.392	3.385
Distress	Visit 2	Visit 3	4.222*	0.880	0.000	2.365	6.079
		Visit 1	1.833*	0.562	0.005	0.649	3.018
Total score	Visit 1	Visit 2	-0.889*	0.241	0.002	-1.397	-0.380
		Visit 3	-1.778*	0.319	0.000	-2.451	-1.105
		Visit 2	-0.889*	0.241	0.002	-1.397	-0.380
Total score	Visit 2	Visit 3	3.667*	0.583	0.000	2.437	4.897
		Visit 1	5.778*	1.040	0.000	3.583	7.972
Total score	Visit 3	Visit 1	2.111*	0.646	0.005	0.748	3.474
		Visit 2	2.111*	0.646	0.005	0.748	3.474

\*Statistically significant with *p* value 0.042. CI=Confidence interval, SE=Standard error

IELT of all the patients after 7 weeks of treatment. They also conducted a study on 42 patients; prescribed 10 mg paroxetine initially for 4 weeks then 20 mg for 3 weeks; the patients reported improvement. There is no study to our knowledge that has compared these two drugs for the use in premature ejaculation.

### Strengths of the study

It is the first study as per knowledge to have compared these two drugs. It is a follow-up study over 8 weeks' duration.

### Limitations of the study

Small sample size; self-reported calculation of IELT using the stopwatch and telephonically acquired data for baseline visit might have biased the result, stress, and anxiety (although handled by sex education and psychoeducation), noncooperative partner (as the partner did not accompany in majority of the cases) could not be studied during the current research. Given the above limitations, the results of this study cannot be generalized.

## CONCLUSION

We would like to summarize that though PME is less talked about although it is more prevalent and needs management. Paroxetine showed a better result in this study, but levosulpiride is another potentially good option. Levosulpiride does improve the patient and relieves the patient from distress. We want to conclude by saying both agents are efficacious with paroxetine having more efficacy, but levosulpiride needs further research support.

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### Conflicts of interest

There are no conflicts of interest.

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