

# Treatment of premature ejaculation: a new combined approach

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## Background

Selective serotonin reuptake inhibitors (SSRIs) are utilized to treat premature ejaculation (PE). However, their effect is moderate, with no universally adopted schedule. A possible role for pelvic floor dysfunction in the pathogenesis of PE was reported previously.

## Objective

The aim of this study was to compare the efficacy of combined sertraline and pelvic floor rehabilitation with either line in patients with an unsatisfactory response to SSRIs.

## Design, setting, and participants

From June 2009 to December 2012, 74 PE patients with an unsatisfactory response to sertraline 50 mg were enrolled and subjected to pelvic floor rehabilitation as an alternative therapy, and then a combination of both was tested on the same group.

## Outcome measurements and statistical analysis

Relationships with outcome were analyzed using the Student *t*-test, Pearson's correlation, and linear regression.

## Results and limitations

The baseline intravaginal ejaculatory latency time (IELT) was 20–110 s (mean  $\pm$  SD = 56.35  $\pm$  21.67). With sertraline 50 mg therapy alone, IELT reached 90–180 s (mean  $\pm$  SD = 121.69  $\pm$  21.76,  $P$  = 0.0001). Of them, 44 (59.46%) patients failed to exceed an IELT of 120 s. With pelvic floor rehabilitation alone, IELT reached 90–270 s (mean  $\pm$  SD = 174.73  $\pm$  45.79,  $P$  = 0.0001). Of them, 13 (17.56%) patients failed to exceed an IELT of 120 s. Using a combination therapy of both, IELT reached 180–420 s (mean  $\pm$  SD = 297.57  $\pm$  59.19,  $P$  = 0.0001). This response was significantly higher than the baseline IELT and that of either lines alone ( $P$  = 0.0001, for all tests).

## Conclusion

Pelvic floor rehabilitation is an important addition when treating PE, particularly in patients with pelvic floor dysfunction. We recommend this combination in patients with an unsatisfactory response to SSRIs.

## Patient summary

Causes of PE differ considerably. In this paper, we compared the outcomes of two single treatment lines together with a combination of both. The combination therapy was more effective than either line alone.

## Keywords:

male sexual dysfunction, pelvic floor rehabilitation, premature ejaculation, selective serotonin reuptake inhibitors

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## Introduction

Premature ejaculation (PE) is the most common male sexual disorder [1]. The prevalence of PE has been ranging in literature between 5 and 30% [2–7]. This wide range is due to the fact that there was no universally accepted standard definition for PE [1]. The most recent definition of PE from the International Society for Sexual Medicine (ISSM) in 2008 is 'a male sexual dysfunction characterized by ejaculation which always or nearly always occurs before or within about 1 min of vaginal penetration; and inability to delay ejaculation on all or nearly all vaginal penetrations; and negative personal consequences, such as distress, bother, frustration and/or the avoidance of sexual intimacy' [8].

Another definition that is frequently utilized in the literature is the definition of PE in the *Diagnostic and Statistical Manual of Mental Disorders*, 4th ed., text revision criteria, for PE for at least 6 months, with an intravaginal ejaculatory latency time (IELT) of 2 min or less in at least 75% of intercourse episodes at baseline [9].

Historically, PE was thought of as a psychological problem and was treated by behavioral treatment and psychotherapy. However, there is increasing evidence from pharmacological studies suggesting that PE may be related to decreased serotonergic neurotransmission [10]. Selective serotonin reuptake

inhibitors (SSRIs), for example, dapoxetine, fluoxetine, paroxetine, and sertraline, are among the recommended pharmacological treatment lines currently used for treating PE [1,9]. However, their effects can be best described as moderate. In addition, there is no universal agreement regarding the type, the dose, the administration protocol, and the duration of therapy [11]. Dapoxetine may alter this situation, showing preliminary promising results [9].

Several reports in the literature suggest an important role for pelvic floor dysfunction as a subtle confounding factor that may account for pharmacological treatment failure in many instances. These studies have utilized many techniques for rehabilitation, such as electrostimulation, physiotherapy and biofeedback therapy, with promising results. These reports refer to pelvic floor rehabilitation as a successful treatment for PE, particularly in patients with pelvic floor dysfunction, with a success rate approaching 57–61% [12–15].

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### Study objective

The objective of this study was to compare the value of a combination therapy of both sertraline and pelvic floor rehabilitation over either of them as a single therapy in patients with an unsatisfactory response to SSRI treatment alone.

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### Patients and methods

During the period from June 2009 to December 2012, 74 patients having PE (according to the PE definition adopted from the *Diagnostic and Statistical Manual of Mental Disorders*) were treated using on-demand sertraline single therapy with a 50 mg dose 3 h before sexual intercourse for 8 weeks, and exhibited an unsatisfactory treatment response. In all patients, the baseline IELT was recorded before therapy, and remeasured after stopping the treatment to assure the return to the pretreatment baseline. Similarly, IELT was recorded during sertraline therapy in each intercourse, and the average IELT for each patient was calculated. All patients gave their formal consent and the protocol was approved by the Ethical committee.

After return to the baseline, all the patients were subjected to a pelvic floor rehabilitation course for 8 weeks and the IELT was measured at the end of the course for each patient; then, 50 mg on-demand sertraline was readministered together with continuing pelvic floor exercise and the average IELT was measured again.

With respect to pelvic floor rehabilitation, all patients received three weekly sessions of electrical stimulation and pelvic floor exercise in addition to a daily exercise at home for 1 month. Electrical stimulation was performed using the interferential current therapy by MEDECT model 3060 interferential therapy unit (EMS). The frequency of the apparatus ranges from 0 to 50 Hz (rhythmic) and the current ranges from 0 to 100 mA.

The technical details of the procedure were as follows: the swing was 50 Hz of 100 mA intensity and the swing pattern was 6/6. The frequency of treatment sessions was three sessions per week, the time of each session was 20 min, for a total of 12 sessions over a period of 1 month, using four electrodes measuring 7.5 × 5.5 cm, with two electrodes placed on the lower abdomen and two electrodes on the inner thigh.

Regarding the pelvic floor exercise, the Kegel exercise program was adopted as follows: the therapist ensured at first that the patient recognized the pubococcygeus muscle (PC) by trying to stop the flow of urine during micturition (and then was acquainted that the muscle that contracts to stop the flow of urine is the PC muscle).

Two forms of exercise were performed for both slow-twitching and fast-twitching muscle fibers respectively: a long-cycle exercise, which comprised sustained submaximal contraction of the PC muscle for 10 s and then relaxation for 10 s. The patient was instructed to repeat the test 15 times, and rest for 30 s for slow-twitching muscle fibers thereafter, and then start over again. The short-cycle exercise comprised contracting the PC muscle maximally for 1 s, and then relaxation for 1 s for fast-twitching muscle fibers. The test was repeated 10 times, with a 30-s relaxation period thereafter before starting over again. Patients were instructed to breath normally to avoid tensing other muscles. Both short-cycle and long-cycle exercises were repeated daily, eventually reaching 15 episodes of each cycle per day.

The response of the patients to different treatment was measured both subjectively and objectively. Objective satisfaction with treatment was categorized into four categories after asking both the patient and his partner to put their results on a visual analog similar to that of the pain analog, where a score from 0 to 3 implies no satisfaction (N), a score of 4–7 implies modest satisfaction (M) (associated interpersonal distress and one partner dissatisfied), and a score of 8–10 implies good satisfaction (S) (both partners).

Statistical analysis and graphical illustrations were performed using SPSS program (version 19; SPSS

Inc., Chicago, Illinois, USA) and Microsoft Excel 2010 professional plus SPSS (version 14; SPSS Inc., Chicago, Illinois, USA). All tests were performed at a confidence level (CL) of 95%, and tests proven to be significant at a higher CL were reported separately. The *P* value was considered significant if 0.05 or less.

### Results

The patient's age range was 23–56 years (mean ± SD = 37.53 ± 8.8). Of these 74 patients, 35 (47.3%) had primary PE, whereas 39 (52.7%) had secondary PE. The duration of PE in these patients was 1–10 years (mean ± SD = 4.27 ± 2.14). The frequency of intercourse episodes per week was one to three episodes (mean ± SD = 2.04 ± 0.67). The patients were instructed to use a stopwatch to record the IELT, and also not to change the frequency of intercourse episodes per week all over the study period. A summary of treatment results of all groups is shown in Table 1.

Side effects reported with sertraline therapy were nausea in 17 (22.97%) patients, vomiting in eight (10.8%), dyspepsia in 13 (17.57%), insomnia in seven (9.46%), somnolence in nine (12.16%), weak scanty ejaculation in 13 (17.57%), and postmicturition dribbling in 11 (14.86%). Both weak scanty ejaculation and postmicturition dribbling improved with pelvic floor exercise. Improvement started after the first week, with complete improvement of symptoms after 1 month of pelvic floor exercise.

Intervariable correlations were performed. The age of the patients correlated significantly and inversely with both the IELT after pelvic floor rehabilitation monotherapy [(IELT<sub>pf</sub>): *P* = 0.0001, *r* = -0.7, CL 99%] and the IELT after combined therapy [(IELT<sub>pfser</sub>): *P* = 0.0001, *r* = -0.8, CL 99%] (Figs 1 and 2). In addition, secondary PE was significantly correlated with a higher patient age (*P* = 0.0001,  $\rho$  = 0.7, CL 99%).

Similarly, the duration of PE in years, that is, PE<sub>dury</sub>, correlated significantly and inversely with both the IELT after pelvic floor rehabilitation monotherapy, that

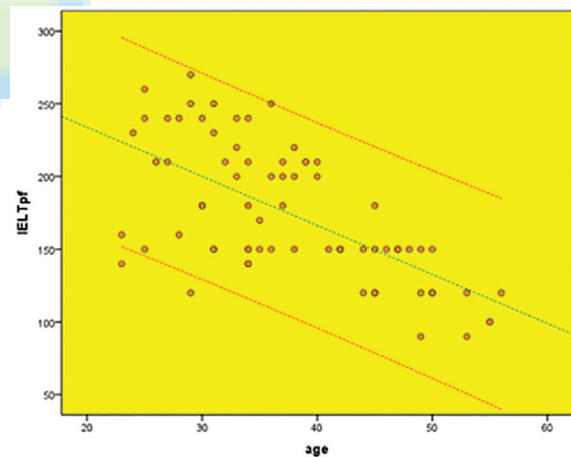
is, IELT<sub>pf</sub> (*P* = 0.0001, *r* = -0.6, CL 99%), and the IELT after combined therapy, that is, IELT<sub>pfser</sub> (*P* = 0.0001, *r* = -0.6, CL 99%) (Figs 3 and 4). In addition, secondary PE was significantly correlated with a longer PE duration (*P* = 0.0001,  $\rho$  = 0.5, CL 99%).

In contrast, the baseline IELT, that is, IELT<sub>b</sub>, correlated significantly and positively with the IELT after sertraline monotherapy (*P* = 0.0001, *r* = 0.6, CL 99%) (Fig. 5).

Moreover, primary PE exhibited a significant positive correlation with a longer IELT with pelvic floor rehabilitation monotherapy (*P* = 0.0001,  $\rho$  = 0.5, CL 99%) and a longer IELT with combined therapy (*P* = 0.0001,  $\rho$  = 0.6, CL 99%).

Lastly, a multivariate regression analysis model was applied to determine as to which variables had a significant impact on the treatment response with both monotherapy and combined therapy lines. With sertraline monotherapy, patients' baseline IELT was the only variable having a significant impact on the IELT (*P* = 0.0001). With pelvic floor rehabilitation monotherapy, however, both the patient age and the baseline IELT were found to have a significant impact on the IELT (*P* = 0.002 and 0.04, respectively). Finally,

Figure 1



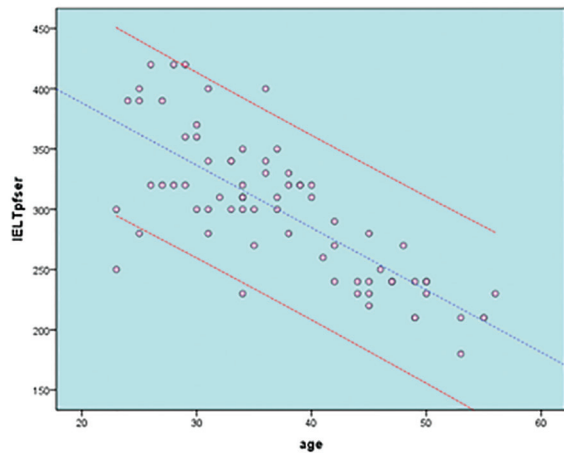
The correlation between age and intravaginal ejaculatory latency time (IELT) after pelvic floor exercise monotherapy.

Table 1 Treatment results among different treatment approaches

Treatment types	Baseline IELT	IELT after treatment	Patients' response	<i>P</i> (CL = 95%)	SS	OS
Sertraline 50 mg		90–180 s (121.69 ± 21.76 SD)	44 (59.46%) <120 s 73 (98.65%) <180 s	0.0001	N	N
PFE	20–110 s (56.35 ± 21.67 SD)	90–270 s (174.73 ± 45.79 SD)	13 (17.56%) <120 s 40 (54%) <180 s	0.0001	M	S
Combined		180–240 s (297.57 ± 59.19 SD)	0 (0%) <180 s 62 (83.78%) ≥240 s	0.0001	S	S

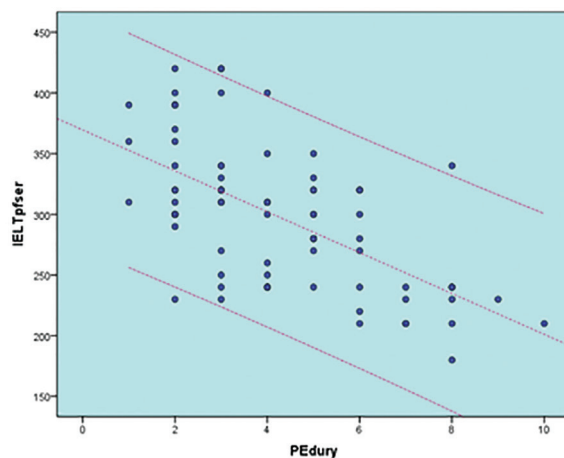
CL, confidence level; IELT, intravaginal ejaculatory latency time; M, modest satisfaction (associated interpersonal distress and one partner dissatisfied); N, no satisfaction; OS, objective satisfaction with treatment; PFE, pelvic floor exercise; S, good satisfaction; SS, subjective satisfaction with treatment (both partners).

Figure 2



The correlation between age and intravaginal ejaculatory latency time (IELT) after combined therapy.

Figure 4



The correlation between the premature ejaculation (PE) duration and intravaginal ejaculatory latency time (IELT) after combined therapy.

only patients' age had a significant impact on the IELT with combined therapy ( $P = 0.0001$ ).

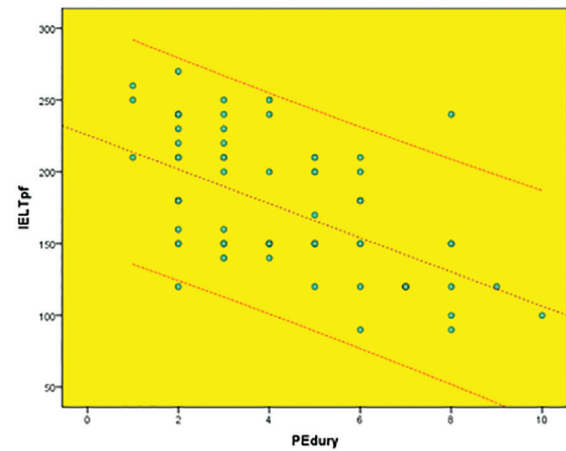
### Discussion

PE is a common male sexual disorder [2,10,16–18]. Moreover, it is associated with sexual dissatisfaction during intercourse for both sexual partners, interpersonal distress, and a negative impact on the male partner's self-esteem [19–21].

The exact etiology of PE is not yet well-understood and is believed to be due to neurobiological, psychological, or penile hypersensitivity issues [1,10,22,23]. This is one of the most important obstacles that hinders the development of a definitive therapy for PE.

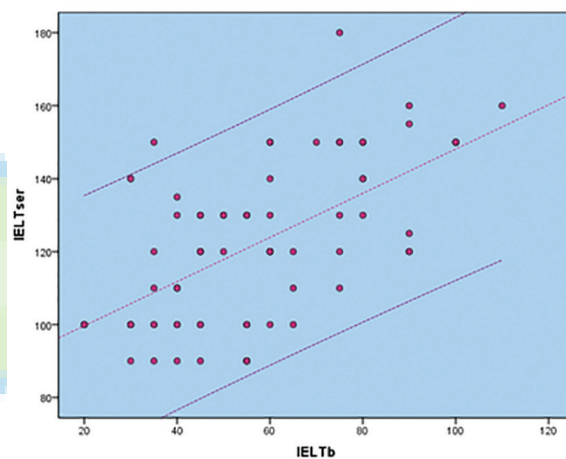
To our knowledge, this is the first study to compare SSRI therapy with pelvic floor rehabilitation and a

Figure 3



The correlation between the premature ejaculation (PE) duration and intravaginal ejaculatory latency time (IELT) after pelvic floor exercise monotherapy.

Figure 5



The correlation between the baseline intravaginal ejaculatory latency time (IELT) and the IELT after sertraline monotherapy.

combination therapy of both. In this study, we utilized mainly the definition of PE in the *Diagnostic and Statistical Manual of Mental Disorders*, 4<sup>th</sup> ed., text revision criteria for PE [9]. However, we did not ignore the subjective issues included in the ISSM definition, that is, bother, frustration, interpersonal distress, and/or the avoidance of sexual intimacy [8], and we found that at the level of an IELT of 2 min or less, the amount of interpersonal distress and psychosocial bother was considerable.

Both medical and psychological perspectives focus mainly on the mere establishment of normal sexual function, but fail to consider the patient himself, his social perspectives, and the anxiety of accomplishing his sex-determined role performance, in addition to overlooking subjective erotic desire, intimacy, and embodiment [24]. In our study, on a subjective basis,



these problems tended to be more important to the patient than a mere statistical or objective definition-based improvement.

Despite a statistically significant improvement of IELT with sertraline 50 mg on-demand monotherapy, the amount of patient-related distress and bother did not improve sufficiently, and further analysis of the results revealed that in reality, only about 40% of the patients achieved an actual, yet marginal, improvement. We assumed that another subtle cause may account for such an unsatisfactory result in this patient population. Our results with sertraline 50 mg on-demand monotherapy are more or less similar to those reported by Tuncel *et al.* [25], but are obviously lower than those reported in the literature [1,16,26], which might be attributed to the variation of the baseline IELT or the underlying etiology of the PE in these studies.

We applied pelvic floor rehabilitation monotherapy at first to determine whether it is sufficient alone for curing these patients or, in case of unsatisfactory response, to denote a mixed etiology of PE in this group of patients; we made sure that the baseline IELT was subjectively restored to its pretreatment values on an individual level with a sufficient silent 'no-treatment' interval between the various treatment strategies to avoid overlapping of therapeutic effects. We also applied the various therapeutic lines to the same patient group so as to avoid any confounding differences among groups such as etiological and demographic factors.

With pelvic floor exercise monotherapy, the IELT improvement was significantly higher than that of sertraline monotherapy. Similarly, on objective definition-based assessment, the results were deemed rather satisfactory. However, on a subjective basis, the amount of distress remained remarkable, taking into consideration that about 18% of the patients remained below an IELT of 120 s and that about 60% of the patients achieved just one minute, that is, 180 s, higher than the cutoff limit for PE in this study. Pastore *et al.* [14] reported a lower success rate with pelvic floor rehabilitation than ours, and a lower success rate than dapoxetine monotherapy, but no previous studies in the literature have compared sertraline with pelvic floor rehabilitation monotherapy. Similarly, La Pera [12] reported a lower success rate with pelvic floor rehabilitation monotherapy, but their report concentrated on the ability of the patients to control the ejaculation reflex with no reference to the cutoff limit for improvement they relied on.

The findings from correlation and multivariate analyses denote that the efficacy of either of the monotherapies alone depend, at least in part, on a better baseline IELT.

In contrast, patients' age played a significant negative impact on pelvic floor muscle function. The negative correlation between the duration of PE duration and IELT improvement in the pelvic floor rehabilitation monotherapy group could be attributed to an overshadowing effect of a higher patient age, which might parallel a longer PE duration and/or possible deterioration of baseline IELT with longer PE periods.

With combined therapy, that is, both sertraline on-demand therapy plus pelvic floor exercises, the amount of statistical, objective, and subjective improvement was significantly higher than either of the treatment lines in the monotherapy approach. These findings denote a definitive mixed etiology of PE in this patient group and highlight the importance of understanding the underlying factors in each individual PE patient.

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## Conclusion

Pelvic floor muscle rehabilitation is an important addition to the treatment options of PE, whether as a monotherapy or combined to SSRIs, particularly in patients in whom pelvic floor dysfunction represents an integral part of the etiology of PE. A better understanding of the underlying mixed etiology of PE plays a key role in definitive treatment.

Currently, we recommend investigating pelvic floor dysfunction in patients with an unsatisfactory preliminary response to SSRI monotherapy, and using the aforementioned combined approach for treating this patient subgroup.

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## Acknowledgements

### Conflicts of interest

None declared.

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