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patients with lifelong premature ejaculation:

Pelvic floor muscle rehabilitation for

a novel therapeutic approach

Abstract

Objectives: Premature ejaculation is the most common male sexual disorder. The aim of the study was to evaluate the possible therapeutic role of pelvic floor muscle rehabilitation in patients affected by lifelong premature ejaculation.

Methods: We treated 40 men with lifelong premature ejaculation, reporting, a baseline intravaginal ejaculatory latency time (IELT) \leq 1 min, with 12-week pelvic floor muscle rehabilitation.

Results: At the end of the rehabilitation, mean IELTs were calculated to evaluate the effectiveness of the therapy. At the end of the treatment, 33 (82.5%) of the 40 patients gained control of their ejaculatory reflex, with a mean IELT of 146.2 s (range: 123.6–152.4 s). A total of 13 out of 33 (39%) patients were evaluated at 6 months follow up, and they maintained a significant IELT (112.6 s) compared with their initial IELT (mean 39.8 s).

Conclusions: The results obtained in our subjects treated with pelvic floor rehabilitation are promising. This therapy represents an important cost reduction compared with the standard treatment (selective serotonin reuptake inhibitors). Based on the present data, we propose pelvic floor muscle rehabilitation as a new, viable therapeutic option for the treatment of premature ejaculation.

Keywords: biofeedback, electro-stimulation, intravaginal ejaculatory latency time, premature ejaculation

Introduction

Premature ejaculation (PE) is the most common male sexual disorder, which has a serious impact on the quality of life of the patient and his partner [Althof, 2006; Carson and Gunn, 2006; Porst *et al.* 2007]. Over the years, the definition of PE has undergone several changes. Kinsey believed that PE is the norm in all mammals, including humans [Kinsey, 1948], whereas Kaplan considered PE to be a condition in which the subject lacks voluntary control over the muscles that regulate the ejaculation reflex [Kaplan, 1974].

The International Society for Sexual Medicine (ISSM) recommends the following definition of PE: 'a male sexual dysfunction characterized by ejaculation which always or nearly always occurs before or within about 1 min of vaginal

penetration, and the inability to delay ejaculation on all or nearly all vaginal penetrations, and negative personal consequences, such as stress, bother, frustration and/or the avoidance of sexual intimacy' [McMahon *et al.* 2008].

Intravaginal ejaculatory latency time (IELT) is defined as the time from vaginal intromission to intravaginal ejaculation [Waldinger *et al.* 2005]. It is often used as a parameter to quantify clinical response to therapy and as a standardized method to compare different treatment modalities in clinical trials.

In the present study, men with lifelong PE underwent pelvic floor muscle (PFM) rehabilitation by using modifications of the techniques used in the treatment of urinary and faecal incontinence

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Elisabetta Costantini, MD Department of Urology, University of Perugia, Italy [Hay-Smith *et al.* 2007], including physio-kinesiotherapy, electro-stimulation and biofeedback. The primary objective of our study was to evaluate the effectiveness of PFM rehabilitation by measuring changes in IELT after 12 weeks of therapy. We also evaluated its effectiveness for training the patient to recognize how and when to control the muscles involved in ejaculation control and for strengthening the muscles of the perineal floor.

Materials and methods

Patients

Between July 2010 and August 2012, 40 male patients were enrolled in this study after undergoing assessment and providing informed consent. The study was conducted in accordance with the Declaration of Helsinki and approved by the local medical ethical committee. PE was diagnosed by applying the ISSM definition of PE. All of the subjects had lifelong PE with a baseline IELT \leq 60 s (mean: 31.7 s, range: 16.6–57.4 s). For inclusion in the study, each patient had to be in a stable relationship with a partner for at least 6 months and to engage in sexual intercourse once a week or more often. At the first visit, the patients and their partners were interviewed individually and each was requested to give an independent estimation of IELT. Pretreatment IELT was measured during a 4-week baseline period; the patients were provided with a stopwatch and instructions on how to measure IELT, and were requested to experience coitus at least four times. Couples were instructed not to use condoms or any topical anaesthetic cream, and not to pause during intercourse or have interrupted intromission. Furthermore, the patients were instructed that if intercourse took place more than once in a single session, only the first intercourse was to be measured.

All of the patients reported having lifelong PE and had tried different types of therapy, such as anaesthetic creams, serotonergic antidepressants and phosphodiesterase type 5 (PDE5) inhibitors, without a substantial response in terms of a significant change in IELT. In particular, 19 patients reported the use of local anaesthetic cream (EMLA 2.5 g, AstraZeneca, London, UK) applied to the glans penis and penile shaft 30 min before sexual intercourse without any significant benefit in IELT, and numbness of penis reported as a most frequent adverse event. A total of 18 patients were previously treated with serotonergic antidepressants, nine of these with a daily treatment of paroxetine (all patients reported decreased libido and anorgasmia as the cause of discontinuation), and the other nine patients with the on-demand selective serotonin reuptake inhibitor (SSRI) dapoxetine (nausea and cost of the drug more important causes of treatment dropout). The last three patients were treated with PDE5i (sildenafil 50 mg 1 h before sexual intercourse) without achieving significant increase in IELT [Jannini *et al.* 2011].

The patients were all treated with PFM rehabilitation. To evaluate the effectiveness of PFM rehabilitation, we compared the mean IELT values of the patients after 12 weeks of treatment. The rehabilitation treatment group comprised 40 patients aged 19-46 years (mean age: 30 years) with a mean baseline IELT of 31.7 ± 14.8 s (range: 16.6-57.4 s). On physical examination, none of the patients presented with phimosis (nine patients were circumcised), frenulum breve, erectile dysfunction or a history of chronic prostatitis. Before treatment commenced, all of the patients underwent a urological screening, which included the Meares-Stamey test to exclude the presence of bacterial prostatitis, and a digital rectal examination [Shamloul and El-Nashaar, 2006]. The baseline characteristics of the enrolled subjects are summarized in Table 1.

The PFM rehabilitation protocol consisted of: (a) physio-kinesiotherapy to achieve a muscle contraction that allowed the patient to be aware of motor activity; (b) electro-stimulation of the perineal floor to stimulate directly the pudendal nerve, resulting in stimulation of the puborectalis muscle, which causes the urethral sphincter to contract; and (c) biofeedback, in which the patient learns to control the muscle contractions of the perineal floor and the genitourinary sphincter. The patients had three 60-min therapy sessions each week, during which the three techniques were applied for 20 min each. The results were measured after the first 20 sessions (6 weeks) and then again at the end of therapy (12 weeks). Physio-kinesiotherapy and biofeedback were used to train patients to recognize the muscular structures involved in pelvic floor contraction. The patients performed personalized physical exercises, during which they conducted isometric and isotonic contractions of the PFMs. During each session, after execution of the physical exercises, the patients underwent electro-stimulation to

Table 1. Baseline characteristics of enrolled patients.

Characteristics	
Mean age	30 years (range 19–48 years)
International Index of Erectile Function – erectile function score	28 (range 26–30)
Nocturnal penile tumescence	4–6 episodes of nocturnal tumescence in all patients (lasting at least 10 min and with greater than 70% rigidity)
Meares-Stamey test	Negative
Digital rectal examination	No pathological findings
Baseline intravaginal ejaculatory latency time)	31.7 ± 14.8 s (range: 16.67–57.41 s)

help strengthen the PFMs. A cylindrical anal probe was positioned in the anal canal. Contact between electrodes in the anal probe and the anterior portion of the sphincter system stimulated the pubovisceral muscles (puborectal and pubourethral); mild, painless electrical pulses were then sent to these muscles *via* the electrodes.

Statistical analysis

Statistical analysis was performed by using the computer statistical package SPSS version 10.0 (SPSS Inc., Chicago, IL, USA) and SAS version 6.4 (SAS Institute Inc., Cary, NC, USA). A p < 0.05 was considered statistically significant.

The independent sample two-tailed *t*-test with associated 95% confidence intervals was used to compare the geometric mean IELTs.

Results

In the PFM rehabilitation group, at the end of 12 weeks of treatment, 33 (82.5%) of the 40 patients gained control of their ejaculation reflex, optimizing the latency time to ejaculation from the start of intravaginal intercourse (IELT before therapy: \leq 60 s). Five patients were nonresponsive to the treatment, whereas two improved their ejaculation after the first 20 sessions and opted to drop out of the study. For the 33 patients who responded favourably to the PFM rehabilitation, the results were maintained throughout the follow-up time (until 6 months after the 12-week treatment). None of the patients reported adverse effects that could have led to discontinuation of the treatment. At the first evaluation after 6 weeks of rehabilitation, the patients achieved a mean IELT of 124.6 ± 18.4 s (range: 122.7–143.1 s).

At the end of week 12 of the PFM rehabilitation, the mean IELT was 146.2 ± 38.3 s (range: 129.6–184.5 s) (Figure 1).

A total of 13 out of 33 (39%) patients reached 6 months follow up and the mean reported IELT was 112.6 \pm 16.4 s (range: 108.7–121.1 s) (Figure 2), which was significant when compared with their initial IELT (mean 39.8 s; range: 24.6–56.3 s).

Discussion

Ejaculation is neuromodulated by the spinal control centre, which coordinates sympathetic, parasympathetic and somatic activities, leading to emission and expulsion. The spinal control centre is influenced by the supraspinal centres [McKenna, 1999], with the control mechanisms responsible for inhibition of ejaculation descending from the supraspinal level and involving a number of regulatory neurotransmitters, of which the most widely studied is 5-hydroxytryptamine, or serotonin.



Figure 1. Mean IELT values (s) at baseline, after 6 weeks, and after 12 weeks of pelvic floor muscle rehabilitation; p < 0.0001 at the 12-week endpoint. IELT, intravaginal ejaculatory latency time.



Figure 2. Mean IELT values (s) at baseline, and after 6 months of follow up by the end of the pelvic floor muscle rehabilitation; p < 0.0001 at the 6 months follow up. IELT, intravaginal ejaculatory latency time.

The pelvic floor undoubtedly plays an important role in sexual function; evidence suggests active roles of the ischiocavernous and bulbocavernous muscles, and sphincters, with a significant increase in electromyographic activity during the entire ejaculatory period [Pischedda *et al.* 2013]. Shafik demonstrated rhythmic contractions of the external striated urethral sphincter during expulsion, which may act like a suction-ejection pump, sucking the seminal fluid into the posterior urethra while relaxed and ejecting it into the bulbous urethra upon contraction [Shafik, 2000].

The PFM rehabilitation protocol used in the present study addresses both of these possibilities; physio-kinesiotherapy and electro-stimulation are designed to improve the contractile strength of the perineal muscles, whereas biofeedback trains the patient to recognize and contract the muscles to increase the closing strength of the urethral sphincter. Only a few studies have reported pelvic floor exercises as a possible treatment option for PE, and no rehabilitation protocol has been standardized yet [Piediferro et al. 2004]. La Pera and Nicastro reported a study of 18 patients with PE, 11 (61%) of whom reported improved control of the ejaculatory reflex after the first 20 sessions of PFM rehabilitation [La Pera and Nicastro, 1996]. After the end of the treatment, 61% of the patients learned to control their ejaculatory reflex, maintaining it at 6-14 months follow up. In our study, we performed the same rehabilitation protocol and achieved a similar percentage of treatment success; 33 (82.5%) of our 40 patients were able to gain control of their ejaculation reflex, optimizing the latency time to ejaculation from the start of intravaginal intercourse. PFM exercises as therapy for patients with PE have been studied only minimally, specific and

exercise protocols have not yet been established. The exercise instructions provided vary, including the type and amount of exercise required, and it is still unclear whether the focus should be on relaxation, strength, support or control. Therefore, further studies are necessary to validate the efficacy of PFM rehabilitation and to elucidate fully the role of physical therapy interventions in the treatment of ejaculatory disorders.

All our enrolled patients had lifelong PE and did not report any significant improvements after previously undergoing other therapeutic treatments such as local anaesthetic creams, behavioural therapy (including the squeeze and stop-and-start techniques), and psychological treatment of various types. In the present study, the pelvic floor exercises led to an improvement in body and, especially, pelvic floor awareness in all of the enrolled subjects, which helped them improve their self-confidence and sense of control of their ejaculatory reflex. In addition, we demonstrated that active perineal muscle control inhibits the ejaculation reflex through intentional relaxation of the bulbocavernous and ischiocavernous muscles, which are active during arousal and should be intentionally relaxed during this phase of sexual intercourse. This is an easily learned technique that can be mastered by using pelvic floor biofeedback.

In our previous study [Pastore *et al.* 2012], we compared dapoxetine therapy with PFM rehabilitation. Dapoxetine is a short-acting SSRI with peak plasma concentrations at 1.01 h and 1.27 h after administration. It has been shown to significantly increase IELT compared with baseline measurements and placebo; IELTs of 1.66 min, 3.03 min and 3.15 min were reported with placebo, 30 mg of dapoxetine and 60 mg of dapoxetine, respectively, when the drug was taken 30–60 min before intercourse [Modi *et al.* 2006]. Dapoxetine was also shown to be effective from the first dose when taken 1–3 h before intercourse [Shabsigh *et al.* 2008; Buvat *et al.* 2009].

In our previous prospective randomized study, we concluded that by 12 weeks, statistical analyses indicated that administration of either dose (30 mg or 60 mg) of dapoxetine achieved significantly greater increases in mean IELT than those achieved with PFM rehabilitation (p < 0.001 for both).

In the present study, the patients achieved a mean 12-week IELT of 146.2 s and 12 (36.4%) of the

33 subjects reported a final IELT of longer than 150 s, three of whom achieved an IELT longer than 180 s.

The PFM rehabilitation protocol is easy to perform, with no reported adverse effects. Although it has not yet been standardized, the results obtained in our patients with lifelong PE suggest that it may be considered as a therapeutic option for patients with PE.

The results of the subgroup, which reached the 6 months evaluation after the end of PFM rehabilitation, confirm the good efficacy of this treatment even at a longer follow up.

The limitations of our study include the small sample of patients enrolled, the relatively large number of patients who did not report for followup evaluations, the short follow-up time, and the lack of another self-administered questionnaire such as the premature ejaculation diagnostic tool. Therefore, further studies are needed to compare treatment of PE by using physical therapy and by using other therapies (e.g. SSRIs, local creams, tramadol, PDE5 inhibitors and behavioural techniques).

In conclusion, the results we obtained with PFM rehabilitation are promising. Furthermore, this treatment option could represent an important cost reduction in comparison with other commonly used treatments (e.g. SSRIs, local anaes-thetic creams and PDE5 inhibitors). Thus, we propose PFM rehabilitation as a new type of physical treatment that may be a viable treatment option for PE.

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Conflict of interest statement

The authors have no conflicts of interest to disclose. All of the authors contributed equally to the design and data analysis of this research study, as well as the drafting of the manuscript.

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