

Pharmacological/dynamic rehabilitative behavioural therapy for premature ejaculation: Results of a pilot study

Franco Mantovani

Clinica San Giovanni, Milan, Italy.

Summary *Objectives: Premature ejaculation (PE) is a sexual disorder characterised by excessive rapidity of orgasm. It is defined as either primary (60%), present since the onset of sexual activity, or secondary (40%), manifesting later in life. To date, dapoxetine is the only preparation approved for the on-demand treatment of PE. However, side effects, costs associated with the treatment of chronic PE, drug dependence and its variable effectiveness leads to a not insignificant drop-out rate. Dynamic rehabilitative/behavioural therapy may be a viable therapeutic option, working alongside pharmacological treatment, as long as the participation and involvement of both the individual and the couple is optimal. Materials and methods: 18 patients were enrolled, aged between 25 and 55 (mean: 40), all with primary PE, free of comorbidities and with their partners involved. Six patients were prescribed 30 mg dapoxetine two hours before sexual relations for 3 months (group A); 6 patients began the dynamic rehabilitative treatment (group B); 6 other couples were assigned to pharmacological treatment in association with dynamic rehabilitative behavioural treatment for 3 months (group C). Division of subjects was carried out by simple randomisation, excluding patients with a short frenulum, phimosis, ED, chronic prostatitis or experiencing results from previous treatment. Results: Outcomes of treatment were evaluated at the end of the 3 months of treatment and 3 months after discontinuing treatment. In Group A 75% of patients were cured at 3 months and 25% at 6 months. In Group B 25% patients were cured at 3 months and 25% at 6 months. In Group C 75% of patients were cured 3 months and 50% at 6 months. "Cured" means a Premature Ejaculation Diagnostic Tool (PEDT) score reduced from an average of 12 to an average of 6 and Intravaginal Ejaculation Latency Time (IELT) values from < 1 to > 6 minutes. Conclusions: the integration of pharmacological treatment with dynamic behavioural rehabilitation has the specific aim of optimising and stabilising the results, supporting a more efficient recovery of ejaculatory control. The close involvement of the partner is extremely useful for all results.*

KEY WORDS: Premature ejaculation; Dapoxetine; Perineal rehabilitation; Vacuum device; Sex-therapy.

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INTRODUCTION

Premature ejaculation (PE) is a sexual disorder characterised by excessive rapidity of orgasm. On average, from international case studies, it affects 25% of the male population aged 25 to 55. It is defined as either primary (70%), present since the onset of sexual activity, or sec-

ondary (30%), manifesting later in life. They share the symptoms of reduced ejaculation latency times, a lack of control and/or subjective perception of the time of ejaculation. The etiopathogenesis may be somatic and/or neurobiological, which is often associated with a significant psychosexual component and intimate discomfort. Our diagnosis was based mainly on anamnestic-clinical and laboratory data (*hormones, Meares-Stamey tests, semen cultures*). PEDT questionnaires (*Premature Ejaculation Diagnostic Tool*) and IELT tests (*Intravaginal Ejaculation Latency Time*) were very useful during the research, while electrophysiological tests presented more difficulties in terms of execution and interpretation (1, 2). Assuming that the treatment of choice should be causative, the vast majority of patients will be excluded from treatment, because a precise identification of the causes is lacking in most of the patients that often are not able to completely resolve the disease (3). In the pharmacological field Dapoxetine is, to date, the only preparation approved for the on-demand treatment of PE. Unlike conventional selective serotonin reuptake inhibitors (SSRI), it allows for use on an as-needed basis (not requiring a window to take effect), has a good safety profile, and does not present the risk of developing a withdrawal syndrome after discontinuation (4).

However, the side effects (nausea, headaches, dizziness, diarrhoea), the costs associated with the treatment of chronic PE, drug dependence and its variable effectiveness leads to a not insignificant drop-out rate. Although there are no clinical studies of sufficient quality to generate high levels of scientific evidence, dynamic rehabilitative/behavioural therapy may be a viable therapeutic option, working alongside pharmacological treatment, as long as the participation and involvement of both the individual and the couple is optimal following simple, precise and controlled explanations, examples and training (5).

MATERIALS AND METHODS

Eighteen patients were enrolled, aged between 25 and 55 (mean: 40), all with primary PE, free of comorbidities and with their partners involved. Six patients were prescribed 30 mg dapoxetine two hours before sexual relations for 3 months, six patients began dynamic rehabilitative treatment consisting of toning the pubococcygeus (the funda-

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Figure 1.
Dynamic electro-stimulation (FES) associated with use of Vacuum device.

mental perineal muscle for ejaculation control) by means of daily home physiotherapy following outpatient demonstration and by weekly application (for 3 months) in an outpatient clinic of extracorporeal magnetic innervation (*ExMI-Neocontrol*) followed by functional electrical stimulation (FES) and biofeedback (BFB) with rectal probe (*MyoPlus 40Hz*) in a dynamic setup with erection induced and maintained using a Vacuum device (*Rapport-Medis*) (Figure 1). Over the 3 month period the couple was also trained in home behavioural therapy (Sensate - Squeeze - Stop and Start). Six other couples were assigned to pharmacological treatment associated with dynamic rehabilitative behavioural treatment for 3 months. Assignment of subjects to treatment was carried out by simple randomisation, after excluding patients with a short frenulum, phimosis, erectile dysfunction, chronic prostatitis or experiencing results from previous treatment.

The muscle rehabilitation procedure is largely adapted from the established procedure for urinary incontinence, but it is carried out during a vacuum-induced erection for identification with the condition of the penis when ejaculatory control is required. The behavioural therapy, through various dedicated exercises, is targeted at the acquisition of greater control over levels of arousal and ejaculation times, rebuilding their self-esteem, which translates into greater confidence during sexual intercourse, thereby reducing anxiety, causing increased ejaculation latency times and offering the possibility of greater ease of penetration.

RESULTS

PEDT questionnaires were filled and IELT values were evaluated by interviews with the couples at the end of the 3 months of treatment and 3 months after the discontinuation of treatment; fortunately no subjects dropped out or failed to follow-up.

In Group A (pharmacological treatment) 75% of patients were cured at 3 months and 25% at 6 months. In Group

Figure 2.
Changes in PEDT score.

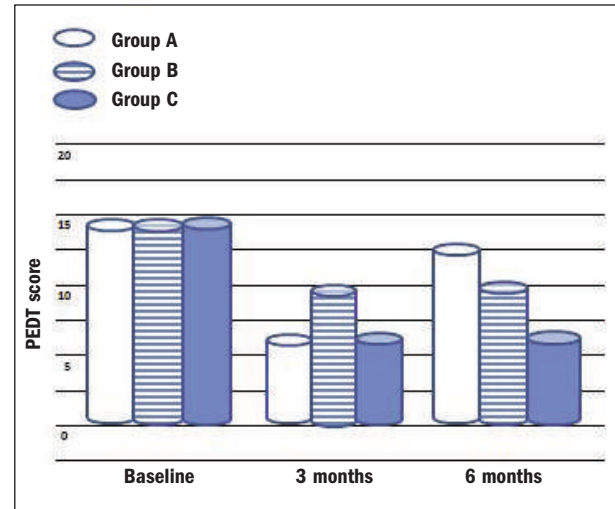
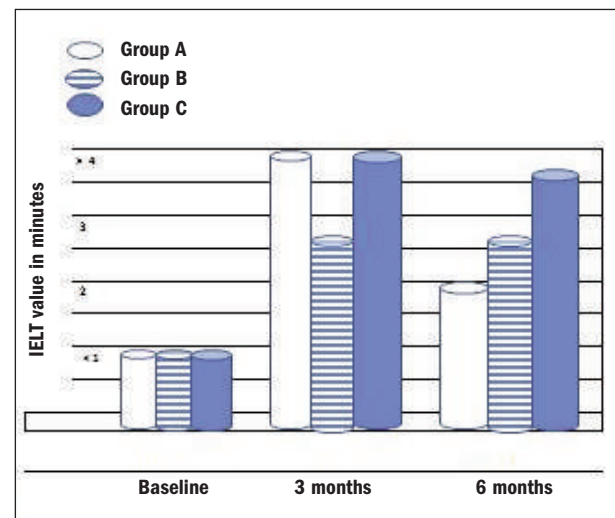


Figure 3.
Changes in IELT values.



B (dynamic rehabilitative behavioural therapy) 25% of patients were cured at 3 months and 25% at 6 months. In Group C (pharmacological associated with dynamic rehabilitative behavioural therapy) 75% of patients were cured at 3 months and 50% at 6 months.

Positive results were considered a reduction in the PEDT score from an average of 12 to an average of 6 (Figure 2) or an increase of IELT from < 1 to > 6 minutes on average (Figure 3). From the baseline to the evaluation at 3 and 6 months, all groups presented a significant ($P < 0.0001$) increase in IELT values and a reduction in PEDT score. The difference between group A and group C is particularly significant.

In group A (dapoxetine alone) the increase in IELT (in seconds) was significantly lower (84.8-170.9-120.7) compared to group C (complete integrated treatment) (86.2-370.7-232.5) and similarly the decrease in the reduction in PEDT scores was lower in group A than in group C (18.16-9.88-14.68) vs (19.56-5.92-8.96).

DISCUSSION

The integration of pharmacological treatment (6) with a dynamic rehabilitative behavioural approach (7) has the specific aim of optimising and stabilising the results, supporting the patient in a more efficient recovery of lasting ejaculatory control (8). To that effect, the involvement of the partner in the therapeutic process is extremely useful, as the establishment of greater involvement in the sexual relationship provides further stimulus for the patient in the recovery of their self-esteem, virility and sense of adequacy of their sexuality. (9) In addition, the involvement of the couple is extremely useful in mitigating the drop-out rate associated with the pharmacological treatment and effectively reducing the difficulty of keeping the patient committed to the integrated treatment plan. The limits of this study, despite the prospective nature of the study and the use of three treatment groups, include the reduced number of patients enrolled in the study and the limited time of the follow-up. Further comparative studies are necessary to assess in more detail the actual significance of the therapeutic approaches to be proposed for PE.

In conclusion, these integrated treatments, alternating concentration and relaxation, create an impression of real control in overcoming this issue. Excluding the cases with comorbidities that have to be resolved first, the administration of dapoxetine is beneficial in terms of immediate results. Its use in conjunction with dynamic perineal rehabilitation and behavioural therapy offers significant advantages and a more appreciable stability along time of the results.

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Correspondence

Franco Mantovani, MD
 mantovanifranco@yahoo.it
 Clinica San Giovanni
 via Civitali 71, Milano, Italy