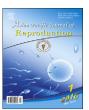
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Asian Pacific Journal of Reproduction

journal homepage: www.apjr.net



Original research

http://dx.doi.org/10.1016/j.apjr.2015.12.015

Male masturbation device for the treatment of premature ejaculation

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ARTICLE INFO

Article history:
Received 27 Mar 2015
Received in revised form 10 Sep 2015
Accepted 15 Sep 2015
Available online 18 Dec 2015

Keywords:
Premature ejaculation
Masturbation
Treatment
Device
Premature ejaculation profile
questionnaire

ABSTRACT

Objective: To determine the efficiency as a treatment of the first line masturbator aid device for patients with premature ejaculation (PE).

Methods: A whole of 18 cases with lifelong PE used a masturbator TENGA, 5 times per week for 6 weeks and a minimum of 5 min for every use. Premature Ejaculation Profile (PEP) was used to measure the effects of its use. As a main outcome measure was used the proportion of patients who achieved criteria for clinical benefit, defined as achieving a two-category or greater increase in the change in control over ejaculation and level of satisfaction with intercourse, and a one-category or greater increase in the change in ejaculation-related distress and degree of interpersonal difficulty.

Results: The proportion of man who achieved the criteria for clinical benefit were 83% in control over ejaculation during sexual intercourse, 72% in ejaculation distress and interpersonal difficulties and men's lower proportion met criteria was in satisfaction with sexual intercourse (33%).

Conclusions: The patients who used the device Flip Hole increased of significant form the control grade on the ejaculation, and its interpersonal ejaculation distress and they reduced difficulties. To further evaluate the validity of these claims, randomized controlled trials should occur.

1. Introduction

The premature ejaculation is the most frequent sexual malfunction in the world, the predominance valuations has changed a lot, nevertheless it is believed that 15% of men would present symptoms compatible with PE [1–5].

Different subtypes have been postulated and aetiologist for the PE, from the first explanations of psychological cut based on inadequate learning associated at high levels of anxiety, up to the last hypotheses neurobiological that postulate a possible hyposensibility of the recipients 5-HT2C and hypersensitivity of 5-HT1A like cause of the PE. The true thing is that there is today none of these explanations has assembled sufficiently empirical support.

As for the available treatments it is undoubtedly the pharmacotherapy that I support empirically has until now emphasizing the use of selective serotonin reuptake inhibitors (SSRI's) [6,7], and tramadol [8], and in a background the use of topical

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Peer review under responsibility of Hainan Medical College.

local anaesthetics [9], phosphodiesterase type 5 inhibitors (PDE5i) [10], and alpha-adrenergic blockers [11]. For his part the psychological treatments of cognitive cut — behavioural keep on being used and turn out to be effective in spite of the scarce empirical support [12–14].

In general, the patients with PE would obtain the biggest clinical benefit with the combination of ISRS and a cognitive—behavioural therapy [7,15]. This combination corrects certain limitations that present both treatments separately. Nevertheless the accessibility to this treatment is very limited, also, the cost, the side effects and the need for collaboration on the part of the couple does that many men could not benefit from the same one. New treatment lines are necessary therefore for these men that they complement the arsenal therapeutic available.

In this sense, at least two independent groups in Japan have put TENGA products to clinical usage. One of them has applied TENGA for ejaculatory disorders [16] and the other has used TENGA on to number of patients suffering from intravaginal anejaculation or post-prostatectomy dysfunction [17].

TENGA is a Japanese brand of masturbation aids produced by the company of the same name. Masturbation aids (masturbators), personal lubricants, and other related products are sold under this brand. The hypothesis is that, if an organ is hypersensitive, an increase rather than a decrease in the intensity and frequency of stimulation should result in habituation. This cases series examines the possible clinical benefit of using device Flip Hole in PE patients in the absence of therapeutic contact and couple collaboration.

In Spain, concretely in the Region of Murcia, we have found studies that use a device masturbation aid as treatment for the PE. The aim of this study was to assess the efficacy of a masturbator aid device for the treatment of patients with PE in an individual format and answer Jan Wise, Watson's study [18] and J.E. Rodríguez, A. López study [19].

2. Material and methods

After several weeks of announcements in press, radio and social networks, we had received 30 requests of participation in the study. After the first interview in which there was applied to them Premature Ejaculation Diagnostic Tool (PEDT), 10 patients were pushed back because they were not fulfilling the criteria (to come at least to a punctuation of 11), to the rest they were called for the second time and I request them a battery of analytical tests, after they are examined the same an autorecord of the estimated intravaginal ejaculatory latency was delivered to him steal (IELT) that they had to refill for two weeks, also the MCMI-III is administered to them and they signed an informed assent.

The inclusion criteria were: participants must be heterosexual males and in a stable monogamous, sexual relationship with a female partner for at least 6 months, must score = 11 in the Premature Ejaculation Diagnostic Tool (PEDT), must have a self-estimated average intravaginal ejaculatory latency time (IELT) of <2 min, must be in good general health with no clinically significant abnormalities as determined by medical history, and clinical lab results.

The exclusion criteria were: to suffer an alteration or mental disorder according to the criteria of the DSM-IV, history of alcohol abuse and dependence, do not to consume medication, drugs of recreative use or alcohol (except for caffeine or nicotine/tobacco).

Spent two weeks there was a third interview in which the averages of the IELT were verified, 20 patients were fulfilling

the criteria established for the IELT, then they completed the Premature Ejaculation Profile (PEP), then, it was time when device Flip Hole is delivered to them (Figure 1) and to high quality lubricant called TENGA hole lotion really, after realizing a demonstration of how it was used, one gave them the following use rules for 6 weeks. "During the next six weeks you will use this devices without partner and at least 5 times per week, in every use you will be at least 5 min masturbating with the lubricated device, if you see that you are going to ejaculate earlier, for and one waits moments until you could continue up to 5 min". In this moment, they signed a new informed assent.

During the following 6 weeks there was maintained contact by e-mail and by phone, at least once for week to verify that the instructions were following and to solve doubts or any incidence with the use of the device.

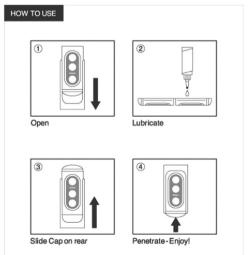
Spent 6 weeks they were called for another interview, of 20 patients 18 had used the device a minimum of 5 occasions per week and they respected the minimal use times, 2 patients did not come at the interview. Is applied to them again Premature Ejaculation Profile (PEP).

The PEP is a validated self-report questionnaire used to assess the four measures of PE defined by the DSM-IV-TR: satisfaction with sexual intercourse, control over ejaculation, ejaculation-related distress, and interpersonal difficulty. Each measure regarding ejaculation is scored on a 5-point scale.

As a main outcome measure was used the proportion of patients who achieved criteria for clinical benefit. Criteria for clinical benefit were defined as achieving a two-category or greater increase in the change in control over ejaculation and level of satisfaction with intercourse, and a one-category or greater increase in the change in ejaculation-related distress and degree of interpersonal difficulty, at the study end point compared with baseline values [20–22].

3. Results

Of the whole of 20 patients that overcame the first phase only 18 patients completed the study. The median age at the study end point was 27 (range 20–42). Lifelong PE was diagnosed in 18 men (100%). Men who had been in a stable, monogamous, heterosexual relationship with the same partner for at least 6



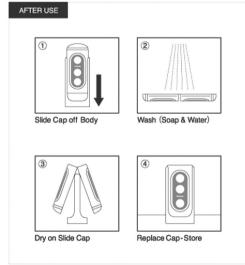


Figure 1. Flip Hole device. Size $85 \times 68 \times 175$ mm/558 g. The Flip Hole features a hard case with flexible front face and buttons. Inside soft elastomer shapes hypoallergenic.

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