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### ORIGINAL RESEARCH—ED PHARMACOTHERAPY

# Adherence to Phosphodiesterase Type 5 Inhibitors in the Treatment of Erectile Dysfunction in Long-Term Users: How Do Men Use the Inhibitors?

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#### ABSTRACT-

*Introduction.* The high effectiveness of phosphodiesterase type 5 inhibitors (PDE5-i) in the treatment of erectile dysfunction (ED) has been demonstrated. However, previous research shows that PDE5-i treatments have high discontinuation rates.

**Aim.** The main goals of this study were to (i) characterize the way men use PDE5-i and (ii) analyze the adherence to treatment, identifying the factors that influence PDE5-i use.

*Methods.* A total of 148 men with clinical diagnosis for ED who maintained the treatment with PDE5-i for over 3 years were interviewed. Interviews concerning their ongoing treatment were carried out using a standardized questionnaire with quantitative and qualitative items.

*Main Outcome Measures.* Physiological measures included the intracavernous alprostadil injection test, associated with penile rigidometry and penile Doppler ultrasound. The qualitative measure included two questions: "Do you use the drug in every sexual intercourse?" and "How do you use the inhibitor?"

Results. ED causes were classified as venogenic (31%), arteriogenic (23%), psychogenic (18%), iatrogenic (13%), neurogenic (8%), and diabetic (7%). Participation rate was 71.8%. Of the 148 patients studied, 75% claimed not to use PDE5-i in every intercourse. Most used tadalafil (66%), followed by sildenafil (20%), vardenafil (10%), and 4% alternated the type of medicine. Four main categories emerged concerning the factors that determine the intake of PDE5-i in some intercourse situations and not in others: (i) psychological factors; (ii) medication-related factors; (iii) circumstantial factors; and (iv) relational factors.

Conclusion. The analysis of men's narratives revealed a combination of factors that influence the adherence to PDE5-i. The psychological and medication-related factors were the most prevalent. This study highlighted the importance of taking these factors into account, both at the time of prescription and during the follow-up in order to improve adherence. Carvalheira A, Forjaz V, and Pereira NM. Adherence to phosphodiesterase type 5 inhibitors in the treatment of erectile dysfunction in long-term users: How do men use the inhibitors? Sex Med 2014;2:96–102.

Key Words. Erectile Dysfunction; PDE5 Inhibitors; Adherence; ED Causes

#### Introduction

The oral agents for treatment of erectile dysfunction (ED) belonging to the group of phosphodiesterase type-5 inhibitors (PDE5-is) are described in the literature as effective, safe, and easy to administer [1–4]. However, their use is often described by clinicians as involving a pattern of repeated medication intake, often followed by abandonment of the treatment, even when it is effective [5]. These data suggest that the improvement of erectile function is not the only, or even the most important, factor involved in the success of the treatment [6].

Research reveals high discontinuation rates [7–14], suggesting that some of these men may have characteristics specific to their sexual attitude and perception of sexual relationships [6]. A recent study [13] with a sample of 327 men with ED who undertook PDE5-i revealed a discontinuation rate of 48.9%. A qualitative analysis of the reasons for dropout revealed as main reasons the insufficient effectiveness of PDE5-i (36.8%) and psychological factors (e.g., anxiety, negative emotions, fears, concerns, dysfunctional beliefs). It is also known that treatment with PDE5-i among men may follow very irregular patterns [15]. Several studies have attempted to clarify the process of adherence to treatment [5,16–18]. In a qualitative study with 33 men and 27 women [16] evaluating the impact of sildenafil use, the results demonstrated that some participants used a dose lower than prescribed or used the medication intermittently.

Some studies have also shown that a significant percentage of men alternate between several available drugs [19,20]. The spontaneity and naturalness of sexual intercourse, the acceptance of the treatment by the partner, and the speed/duration of the action seem to be decisive in the choice of medication [21]. Variables such as the cost and rationing of medication have also been described as influential in treatment adherence, especially in patients with lower incomes [18,21]. However, these different studies do not address systematically the patients' adherence to PDE5-i and are not consensual regarding the reasons that may influence the medication intake in men.

#### Aim

Two main research questions emerged: "Which factors are responsible for patients' adherence to PDE5-i?" and "How do patients use these drugs?" We sought to (i) characterize the way men use

PDE5-i (inhibitor type, frequency of use, side effects) and (ii) analyze the adherence to treatment, identifying the factors that influence PDE5-i use.

#### Method

#### **Participants**

The study sample consisted of 148 adult male patients at an andrological outpatient's clinic, aged 25–81 years, with clinical diagnosis of ED who initiated and maintained the treatment with PDE5-i for over 3 years, in a regular basis of at least every 3 months. Exclusion criteria included: taking antidepressants, history of alcohol and substance abuse, hypogonadism, Peyronie's disease, and presence of a severe psychopathological disorder.

Although these exclusion criteria would be interesting to include in the sample, they could also contribute to hide the main reasons why patients are not adhering to PDE5-i treatment. Also, antidepressants intake could interfere with sexual desire and arousal, which ultimately could lead the results into inaccurate analysis.

#### Instrument

A comprehensive, detailed questionnaire was developed and piloted for this study, based on the literature review and on the researcher's clinical experience. This was a 29-item questionnaire (see Appendix), which included quantitative and qualitative variables (incorporating sociodemographic, clinical, and adherence-related items). Quantitative variables include demographics, type of PDE5-i and frequency of use, other previous treatments, side effects, expectations regarding the treatment, and partner involvement. Regarding qualitative variables, men were asked if they used the PDE5-i in every intercourse. When the answer was "No", an open-ended question was presented: "How do you take the inhibitor?" When the participants' answers were not clear, the question was reformulated: "Why don't you take the PDE5-i in every single sexual intercourse?"

We chose a phenomenological approach, given our interest in the meanings given by individual men regarding this phenomenon [22].

### Procedure

Patients were contacted by telephone and, after their authorization, they received an informed consent by mail at the discharge address; at this

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