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ORIGINAL ARTICLE

Safety and efficacy of intraurethral alprostadil in patients with erectile dysfunction refractory to treatment using phosphodiesterase-5 inhibitors☆

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KEYWORDS
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Abstract

Introduction: Phosphodiesterase-5 inhibitors (PDE5i) are the first choice for treating erectile dysfunction (ED) but are not always effective. The aim of this study was to present our experience in treating patients with ED, refractory to treatment with PDE5i, using intraurethral alprostadil (MUSE).

Material and methods: We conducted a review of 82 patients with ED and no response to PDE5i, from March 2013 to October 2014. Forty-seven patients (57%) had hypertension (AHT), 24 (29%) had diabetes (DM) and 20 (24%) had AHT and DM. Additionally, 19 (23%) had undergone radical prostatic (RP) surgery. The patients were evaluated after the treatment was applied and at 4 weeks using the following validated questionnaires: International Index of Erectile Function (IIEF-5/SHIM), Global Assessment Questionnaire (GAQ), Sexual Encounter Profile (SEP) and Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS).

Results: The mean patient age was 60.5 years (40–80), and the mean follow-up was 11.3 months (1–20). Sixty-eight percent of the treated patients responded to MUSE® (74% in the AHT group, 65% in the AHT + DM group, 62.5% in the DM group and 58% in the RP group). The mean IIEF-5 score was 11.7 ± 4.7, which increased to 18.6 ± 4.9 after MUSE was administered ($P = .027$). The mean EDITS score at 4 weeks was 61.6 (6–81.9). The most common adverse effect was urethral burning, which occurred in 24 patients (29%). There were no cases of urinary tract infection, syncope or priapism.

Conclusions: Intraurethral alprostadil is an effective treatment and has a broad safety profile for treating patients with erectile dysfunction refractory to oral treatment with PDE5i.

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PALABRAS CLAVE
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Eficacia y seguridad del alprostadil intrauretral en pacientes con disfunción eréctil refractarios al tratamiento mediante inhibidores de la 5-fosfodiesterasa

Resumen
Introducción: Los inhibidores de la 5-fosfodiesterasa (IPDE5) son de primera elección para el tratamiento de la disfunción eréctil (DE), pero no siempre son efectivos. El objetivo es presentar nuestra experiencia en el tratamiento de pacientes con DE, refractaria al tratamiento con IPDE5, mediante alprostadil intrauretral.
Material y métodos: Revisión de 82 pacientes con DE, sin respuesta a IPDE5, desde marzo de 2013 hasta octubre de 2014. De ellos, 47 (57%) presentaban hipertensión (HTA), 24 (29%) diabetes (DM), y 20 (24%) HTA y DM. Además, 19 (23%) habían sido tratados mediante cirugía radical prostática (PR). Fueron evaluados en la consulta tras la aplicación del tratamiento y a las 4 semanas mediante los cuestionarios validados: International Index of Erectile Function (IIEF-5/SHIM), Global Assessment Questionnaire (GAQ), Sexual Encounter Profile (SEP) y Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS).
Resultados: La edad media fue de 60,5 años (40-80), con seguimiento medio de 11,3 meses (1-20). El 68% de los pacientes tratados respondieron a MUSE® (74% en el grupo de HTA, 65% en el de HTA + DM, 62,5% en el de DM y 58% en el de PR). La media del IIEF-5 era de $11,7 \pm 4,7$, y ascendió hasta $18,6 \pm 4,9$ tras MUSE® ($p = 0,027$). La media de la puntuación del EDITS a las 4 semanas fue de 61,6 (6-81,9). El efecto adverso más frecuente fue el escozor uretral, que ocurrió en 24 pacientes (29%). No se observó ningún caso de infección del tracto urinario, síncope ni priapismo.
Conclusiones: El alprostadil intrauretral es un tratamiento efectivo y con un amplio perfil de seguridad para tratar a aquellos pacientes con disfunción eréctil refractaria al tratamiento oral con IPDE5.

Introduction

Erectile dysfunction (ED) is a very common disease in our society with a prevalence ranging between 19.2 and 52%.[1]

The etiology of ED is diverse and often associated with risk factors such as age, cardiovascular disease, diabetes mellitus (DM), neurodegenerative disorders, pelvic surgery, trauma, stress, lifestyle or it may arise as a side effect of medications.[2]

Although there are numerous treatments for ED, inhibiting drugs of phosphodiesterase type 5 (PDE5 inhibitors) still represent the first choice. However, they are not exempt from a moderate percentage of non-response, which can reach 25% or even 50%, especially in patients with risk factors such as DM, arterial hypertension or have been treated with radical prostatectomy (RP).[3–6]

Our goal is to present the efficacy and safety of intraurethral (MUSE®: *Medicated Urethral System for Erection*, MEDA Pharma, Solna, Sweden) Alprostadil (synthetic analog of PGE1) in the treatment of ED patients who have not responded to previous treatment with PDE5 inhibitors.

Materials and methods

This study presents a retrospective review of 82 patients treated for ED in the Andrology consultation in our hospital, between March 2013 and October 2014 by applying Intraurethral MUSE®. The primary objective was the erectile response by *Erection-Assessment Scale* (EAS) of the patient in consultation and its subsequent correlation with the score of the *Sexual Health Inventory of Men* (IIEF-5/SHIM) after home delivery. Secondary objectives included the evaluation of the response and patient satisfaction by the values of the *Global Assessment Question* (GAQ), *Sexual Encounter Profile* (SEP) and *Erectile Dysfunction Inventory of Treatment Satisfaction* (EDITS).

ED was defined as the inability to perform a vaginal penetration and having a score of <22 in the IIEF-5 (SHIM). It was considered as non-responsive to PDE5 inhibitors if a patient would lack response in at least four attempts.

The selection criteria established were: >18 year-old males, sexually active, heterosexuals, in a stable relationship and with ED, who had not responded to treatment with PDE5 inhibitors, accept treatment with MUSE® as well as their pre- and post-assessment to their treatment using validated questionnaires. Patients who had previously been treated for ED with intracavernous injections (IC) with alprostadil were not excluded. Within the group of patients treated with RP, those who were once treated by external radiotherapy were not excluded, but those under the influence of hormonal blockade were excluded.

All patients underwent a complete medical history, focusing on the sexual aspect as well as a physical examination and blood tests with a hormonal profile (average total testosterone: 3.82 ± 1.9).

Alprostadil was administered according to the manufacturer's instructions. The first application was made by nurses in the clinic of our hospital to confirm its proper performance, and doing so in successive home applications. In general, we recommended our patients to urinate before the application in order to humidify the urethra, facilitating