Actas Dermosifiliogr. 2016;xxx(xx):xxx–xxx

ACTAS Dermo-Sifiliográficas

Full English text available at www.actasdermo.org

ORIGINAL ARTICLE

Preliminary Experience With Transdermal Oxybutynin Patches for Hyperhidrosis☆

M. Bergón-Sendín,* A. Pulido-Pérez, L.C. Sáez-Martín, R. Suárez-Fernández

Servicio de Dermatología, Hospital General Universitario Gregorio Marañón, Madrid, España

Received 12 March 2016; accepted 5 July 2016

KEYWORDS
Hyperhidrosis;
Oxybutynin;
Treatment

Abstract

Background and objective: Hyperhidrosis is very common and has a considerable impact on patients' quality of life. While oral oxybutynin is associated with good response rates, adverse effects are common and frequently cause patients to stop treatment. Following the recent launch of oxybutynin in a transdermal patch formulation in Spain, we undertook a preliminary study to assess treatment response and adverse effects in patients with hyperhidrosis.

Material and methods: This prospective study of 25 patients treated twice weekly with transdermal oxybutynin patches over 10 weeks assessed treatment response on 2 subjective scales: the Hyperhidrosis Disease Severity Scale (HDSS) and a visual analog scale (VAS) for sweating.

Results: Sixty percent of patients showed an improvement in HDSS scores. VAS scores improved in all cases, and 68% of patients achieved a reduction of 3 points or more. Just 2 patients (8%) experienced treatment-related adverse effects (irritant dermatitis at the patch application site in both cases).

Conclusions: Although our results are based on a small sample, they suggest that transdermal oxybutynin could be a useful option for the treatment of hyperhidrosis and that it has an excellent safety and tolerability profile.

PALABRAS CLAVE
Hiperhidrosis;
Oxibutinina;
Tratamiento

Experiencia inicial con oxibutinina transdérmica en el tratamiento de la hiperhidrosis

Resumen

Introducción: La hiperhidrosis (HH) es una condición muy prevalente que supone una repercusión importante en la calidad de vida. Entre las opciones terapéuticas disponibles, la oxibutinina oral consigue buenas tasas de respuesta aunque con frecuentes efectos secundarios que condicionan en muchas ocasiones el abandono del tratamiento. Tras la comercialización en

☆ Please cite this article as: Bergón-Sendín M, Pulido-Pérez A, Sáez-Martín LC, Suárez-Fernández R. Experiencia inicial con oxibutinina transdérmica en el tratamiento de la hiperhidrosis. http://dx.doi.org/10.1016/j.ad.2016.07.003

* Corresponding author.
E-mail address: Mbergon1@yahoo.es (M. Bergón-Sendín).

nuestro país de la oxibutinina en presentación transdérmica, realizamos un estudio preliminar para valorar el control de la HH y el perfil de efectos secundarios de este tratamiento.
Material y métodos: Se realizó un estudio prospectivo con 25 pacientes que recibieron tratamiento con 2 parches semanales de oxibutinina transdérmica durante 10 semanas. La respuesta terapéutica se valoró mediante 2 escalas subjetivas: *Hyperhidrosis Disease Severity Scale* (HDSS) y escala analógica visual (EAV).
Resultados: Un 60% de los pacientes consiguieron una reducción en la puntuación de la HDSS. Todos los casos obtuvieron una disminución en la puntuación de la EAV, siendo esta de 3 puntos o superior en el 68% de los pacientes. Solo 2 pacientes (8%) presentaron efectos adversos relacionados con el tratamiento, en ambos casos en forma de dermatitis irritativa en la zona de aplicación del parche.
Conclusiones: Aunque se trata de una experiencia limitada, los resultados de nuestro estudio sugieren que la oxibutinina transdérmica podría tener utilidad en el manejo de la HH, con un excelente perfil de seguridad y tolerancia.

Introduction

Hyperhidrosis (HH) is a condition in which the patient sweats more than is necessary to regulate body temperature. HH can be classed as primary and secondary. In primary HH (PHH), there is no underlying disease that accounts for the excessive sweating, whereas in the secondary form, excessive sweating can be attributed to various causes (eg, abnormalities of the endocrine and nervous systems, cancer, and treatment with drugs).[1]

PHH is defined as the presence of excessive sweating for at least 6 months with no justifiable cause (major criterion) and 2 or more of the following minor criteria: (*1*) bilateral and symmetrical distribution; (*2*) at least 1 episode of excessive sweating per week; (*3*) interference with daily activities; (*4*) cessation of sweating during sleep; (*5*) onset before age 25 years; and (*6*) family history of PHH.[2] The most frequently involved sites are the axillas and palms, followed by the soles and facial region. PHH often affects various sites in the same patient (multifocal) and may even be generalized.[3]

PHH is thought to affect approximately 2%-3% of the population, and even though it is not considered a severe disease, its effect on the patient's quality of life is very significant. According to various quality of life rating scales, its effect is equivalent to that of much more severe conditions, such as diabetes.[4]

PHH can be managed using various therapeutic options, including drugs (topical and systemic), nonsurgical interventions (eg, iontophoresis and botulinum toxin), and surgery (selective sympathectomy and excisional surgery).[5]

Oxybutynin is an anticholinergic drug whose efficacy in the control of PHH is well-documented, although its use in this disease is off-label.[6–9] It is important to note that none of the systemic options used for PHH are currently authorized for treatment of the disease in Spain. HH responds well to treatment with oral oxybutynin; however, adverse effects are common (mainly dry mouth and throat), prove uncomfortable for the patient, and can lead to discontinuation of treatment.

In 2014, a transdermal patch formulation of oxybutynin was marketed in Spain. According to the summary of product characteristics, it was indicated for the treatment of overactive bladder (as with the oral formulation). The transdermal patch avoids the first stage of liver metabolism, thus—in theory—reducing adverse effects and the possibility of drug interactions.[10]

Our hypothesis was that PHH could be improved by minimizing the adverse effects of oral oxybutynin. Therefore, we proposed a pilot study in which we applied transdermal oxybutynin patches in patients with PHH. The primary objective of this study was to evaluate the effectiveness of the transdermal patch; the secondary objective was to describe its tolerance profile.

Material and Methods

We performed a prospective study from February to September 2015. We included 25 patients whose PHH could not be suitably controlled with topical treatments and excluded patients who had received botulinum toxin during the previous 2 years or who had undergone surgery for PHH (selective sympathectomy or excisional surgery). All patients were given exhaustive information about the transdermal oxybutynin patch and alternative treatments and about the conditions of the study. They all gave their written informed consent. The effectiveness of treatment was measured using 2 subjective scales: a visual analog scale (VAS), in which sweating was graded from 1 to 10 (with 10 as the maximum degree of sweating and 1 the minimum); and the validated Hyperhidrosis Disease Severity Scale (HDSS)[11] (Table 1).

Treatment with transdermal oxybutynin patches (Kentera, Gebro Pharma) was administered for 10 weeks. Patients applied 2 patches (36 mg each) per week, rotating between the thighs, hips, and abdomen. The interval of 10 weeks was based on findings for long-term oral oxybutynin, in which a lack of response at 6 weeks of treatment is considered therapeutic failure.[6]

The study comprised 3 visits. At the initial visit (visit 1), patients were informed about the study and gave their