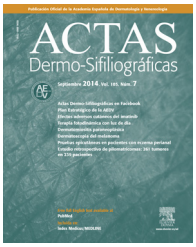
Actas Dermosifiliogr. 2015;**106(2)**:126–132

ACTAS Dermo-Sifiliográficas

Full English text available at www.actasdermo.org



ORIGINAL ARTICLE

Assessment of the Efficacy and Safety of a Combination of 2 Topical Retinoids (RetinSphere) in Maintaining Post-Treatment Response of Acne to Oral Isotretinoin

M.T. Truchuelo[a,*], **N. Jiménez**[a], **D. Mavura**[b], **P. Jaén**[a]

[a] *University Ramón y Cajal Hospital, Madrid, Spain*
[b] *Regional Dermatology Training Centre Kilimanjaro Christion Medical Center, Moshi, Tanzania*

Received 22 March 2014; accepted 1 September 2014

KEYWORDS
Acne;
Recurrences;
Relapses;
Maintenance therapy;
Topical retinoids;
Oral isotretinoin

Abstract
Introduction: The high rate of relapse of acne lesions following oral isotretinoin treatment is a common problem which remains unsolved. To avoid or minimize relapses, topical retinoids have been used for many years as maintenance treatment. However, adverse effects frequently occur.
Aims: To determine the efficacy and safety of a new retinoid combination (Retinsphere technology) in maintaining post-treatment response to oral isotretinoin.
Patients and methods: Prospective, randomized, double-blind and vehicle-controlled study of 30 patients with acne previously treated with isotretinoin. Treatment with the retinoid combination was applied to one side of the face and vehicle was applied to the other, once daily, for 3 months. Standardized photographs were taken using RBX technology at baseline, 1.5 months and 3 months. The primary efficacy endpoint was the appearance of relapse on the treated side compared to the vehicle-treated side. Other endpoints included lesion count, investigator-reported improvement, patient-reported improvement, impact on quality-of-life, and side effects.
Results: Although the majority of patients did not reach the total target dose of oral isotretinoin, the relapse rate was significantly lower on the retinoid-treated side compared to the vehicle-treated side. Likewise, improved lesion count and excellent tolerance were observed.
Conclusions: This new retinoid combination (Retinsphere technology) were effective and safe as maintenance therapy after post-treatment response to oral isotretinoin in patients with acne.

* Corresponding author.
E-mail address: maytetd@yahoo.es (M.T. Truchuelo).

1578-2190/$ – see front matter

PALABRAS CLAVE
Acné;
Recurrencias;
Recaídas;
Terapia de mantenimiento;
Retinoides tópicos;
Isotretinoína oral

Eficacia y seguridad del uso combinado de 2 retinoides tópicos (Retinsphere®) para el mantenimiento de la respuesta obtenida tras el tratamiento con isotretinoína oral

Resumen

Introducción: Existe un alto porcentaje de pacientes que presentan reidivas de acné tras el uso de isotretinoína oral. Para evitar o minimizar dichas recidivas el uso de retinoides tópicos se ha utilizado en ocasiones, aunque con mala tolerancia dada la sensibilidad de la piel tras los tratamientos con isotretinoína oral.

Objetivos: Determinar la eficacia y seguridad de una nueva combinación de retinoides (tecnología Retinsphere®) en el mantenimiento de la respuesta postratamiento con isotretinoína oral.

Pacientes y Métodos: Estudio prospectivo, aleatorizado, doble ciego controlado con vehículo en 30 pacientes con acné tratado previamente con isotretinoína oral. El tratamiento con la combinación de retinoides se aplicó en una hemicara, mientras que en la otra hemicara se aplicó vehículo, durante 3 meses. Se tomaron fotografías estandarizadas con tecnología RBX en el momento basal, al mes y medio y a los 3 meses. La variable principal para determinar la eficacia fue la aparición de recidivas en el área tratada con retinoides vs lado tratado con vehículo. Otras variables estudiadas fueron recuento de lesiones, mejoría percibida por el investigador y el paciente, impacto en la calidad de vida y efectos adversos.

Resultados: La mayoría de los pacientes no habían alcanzado la dosis diana de isotretinoína oral, y sin embargo el porcentaje de recidivas fue significativamente menor en el lado tratado con retinoides frente al lado tratado con vehículo. Además se objetivó una disminución en el recuento de lesiones y una excelente tolerancia.

Conclusiones: Esta nueva combinación de retinoides (tecnología Retinsphere®) demostró eficacia y seguridad en el mantenimiento de respuesta postratamiento con isotreinoína oral en pacientes con acné.

Introduction

Acne is a common complaint among adolescents, although onset can occur at other stages of life. In fact, acne affects to a greater or lesser extent between 80 and 85% of individuals aged between 12 and 25 years[1] and in addition to the potential physical discomfort (for example, pain, itching, superinfection, and scarring), serious psychological repercussions may occur as the face is often targeted by this disease.

We can classify acne into different types according to the predominant lesion, with classic forms including papulopustular, comedonal, and nodulocystic acne.[1] There are several classes of therapeutic drugs used to tackle different types of acne. One of the most widely used medications is oral isotretinoin as it targets all levels of acne pathogenesis. According to expert consensus, the recommended dose is 0.3–0.5 mg/kg/d for moderate papulopustular or nodular acne and more than 0.5 mg/kg/d for at least 6 months (with a mean total cumulative dose of 120–150 mg/kg) for acne conglobata. Other authors, however, recommend lower or pulsed doses for longer periods in cases of moderate acne.[2–4]

Regardless of the dosage regimen used, at the end of treatment most patients show substantial improvement in acne lesions, although this is coupled with erythema and deterioration in the quality of skin due to the extreme cutaneous dryness induced by the treatment. Moreover, recurrence of acne lesions following isotretinoin treatment remains an unsolved problem. According to recent studies, the percentage of patients with relapses is very variable and ranges between 10 and 61% depending on the cumulative dose,[5] population characteristics, and duration of follow-up.[6] There is some debate as to whether failure to reach the target dose leads to the early onset of acne relapse.[7,8] To establish a basis for comparison of the mean relapse rate, the study with the greatest number of patients (17 351), which described a mean relapse rate of 41%, can be taken as a reference.[8] However, there are no specific data on relapse percentages over short periods of time after discontinuing isotretinoin administered at the standard dose of 120–150 mg/kg.

To avoid relapses after isotretinoin administration, topical retinoids have been used for many years in patients with acne due to their capacity to reduce hyperseborrhea (by inhibiting the proliferation and differentiation of sebocytes) and normalize keratinization.[3] Some authors have suggested that their use at the end of treatment with oral isotretinoin may help prevent future relapses.[3,9–12] Consequently, the main objective of the present study is to demonstrate that a new product, whose main component is Retinsphere technology, is effective for reducing acne relapses or maintaining the results obtained by acne patients after treatment with oral isotretinoin. Furthermore, we will determine tolerance to the new product in these patients, without the usual adverse events seen with other retinoids.