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New therapeutic approach with ozoile® to the EAC eczema, a chronic and annoying pathology

Abstract

The Eczema of the external auditory canal (EAC) is a challenge for the otolaryngologist and it's a pathology that can annoy the patients and, in the most extreme cases, compromise their quality of life. Hence patients with eczema of EAC are exposed to a greater number of bacterial (acute bacterial otitis externa) or fungal (otomycosis) infections. The therapies proposed as of now for chronic eczematous external otitis (more than 3 months) are empirical. The most widely used drugs in this condition are topical corticosteroids which unfortunately can lead to dehydration of the skin, hypotropism with a reduction in their effectiveness over time

Ozoile® (Stable Ozonides with Vitamin E acetate) acts as a biological inducer, regulates the main metabolic pathways, stimulates the endogenous defense system and through the regulation of gene transcription promotes tissue regeneration and damage-injury repair. This biological inducer has anti-inflammatory, anti-itching and anti-microbial action. Based on these results, the author used Ozoile® for the treatment of chronic eczematous external otitis (symptoms lasting more than three months).

Sixty patients suffering from chronic eczematous otitis externa (CEOE) were recruited and given 1 month of treatment with 5 drops per ear in the morning and in the evening. Through a visual analogue scale (minimum score 0 and maximum 10 depending on the severity of the symptoms) the parameters itching, secretions, flaking and complications were evaluated at the beginning of the treatment (time 0) and at one month (time 1). After the treatment the results were as follow: 62.5% itching reduction, desquamation reduction by 72%, reduction of secretions by 80%. Total absence of side effects. We can conclude that Ozoile® (Stable Ozonides with Vitamin E acetate) has an excellent "outcome" in EAC eczema even for prolonged periods and is a manageable and complication-free biological inducer.

Keywords: otitis externa, therapy, ozonides, eczematous dermatitis, corticosteroid

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Abbreviations: CEOE, chronic eczematous otitis externa; EAC, external auditory canal

Introduction

The Eczema of the external auditory canal (EAC) is a challenge for the otolaryngologist and it's a pathology that can annoy the patients and, in the most extreme cases, compromise their quality of life. Excessive desquamation is a very frequent pathology but, considering that the ear canal is lined with skin up to the outer side of the tympanic membrane, it becomes a problem when it occurs here. The material resulting from this de-epithelialization accumulates on the bottom of the EAC, and undergoes a process of maceration, becoming itself a cause of chronic irritation with symptoms such as itching, auricular ovulation and signs such as malodorous otorrhea. When the EAC lacks the most superficial epidermal and lipid barrier it is exposed to bacteria and saprophytic mycetes super infections. Hence patients with eczema of EAC are exposed to a greater number of bacterial (acute bacterial otitis externa) or fungal (otomycosis) infections.

The patients most at risk are:

a. swimmer

b. Hearing aids users

c. Patients with narrow EAC

d. Patients who live in environments with a humid microclimate.

The therapies proposed as of now for chronic eczematous external otitis (more than 3months) are empirical and can thus be divided according to their utility and chemical composition.

Fairly useful: antibiotics + topical corticosteroids, topical corticosteroids, boric acid.

Of unknown utility: Antifungals, acetic acid, antibiotics by oral administration.

Useless: antibiotics and corticosteroids by oral administration.

All the drugs mentioned above are burdened by other limits that affect the following factors.

Indications: drugs do not have specific indications.

Handling and duration of treatment: The use of antibiotics and cortisone drugs have a limit of use beyond which the beneficial effects are reduced and the side effects are increased.

Relapses: with the end of the described topical therapies there is often a recurrence of the pathology.

The most used drugs in the treatment of eczematous external otitis are the topical corticosteroids which unfortunately, as already

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mentioned, can lead to dehydration of the skin, hypotropism with a reduction in their effectiveness over time.

Materials and methods

Ozoile® (Stable Ozonides with Vitamin E acetate) overcomes these obstacles due to its flexibility and multiplicity of functions, thanks to the following features.

a. Anti-inflammatory and anti-itching activity equal to cortisone without the side effects.

b. Contrast of hypoxia.

c. Antimicrobial and antifungal action.

d. Regeneration and tissue re-epithelialization.

Ozoile® (Stable Ozonides with Vitamin E acetate) acts as a biological inducer, regulates the main metabolic pathways, stimulates the endogenous defense system and through the regulation of gene transcription promotes tissue regeneration and damage-injury repair. The molecular mechanisms through which Ozoile® acts can be summarized as follows.

I. Considerable decrease of chemical mediators of inflammation. The Ozoile® by the anti-inflammatory action inhibits the expression of the enzyme COX-2 responsible for the production of prostaglandines, chemical mediators involved in the pain response; by the anti-itching action it increases the action of aminoxidase MAO e DAO. The aminoxidase MAO and DAO are enzymes which degrade serotonine and histamine, decreasing the itching, pain and redness phenomenon's.

II. Significant Reduction Of Levels Of Pro-Inflammatory Cytokines Even In Comparison With Corticosteroids For Topical Use

III. Significant Increase In The Levels Of Anti-Inflammatory Cytokines Compared To Corticosteroids For Topical Use Antimicrobial Action. Ozoile® is a broad-spectrum microbicide due to its high affinity for the lipoprotein components of the bacterial and fungal wall and for the oxidizing action (Table 1).

IV. Activation of the endogenous system of contrast to hypoxia the resistance to oxygen deficiency is expressed through the activation of the follows factor.

a) HIF-1α, that is an inducible transcription factor that mediates cellular responses to hypoxia

b) VEGF that is a vascular endothelial growth factor. The activation of this growth factor lead to tissue regeneration and re-epithelialization.

c) Induction of E-cadherin, a transmembrane adhesion molecule that promotes correct re-epithelialization (Figure 1).

Table 1 Bacterial and fungal wall and for the oxidizing action

Reduction of bacterial and fungal growth (%) University of Pavia

Time (h)	4	12	24	48
Sample	OZOILE	OZOILE	OZOILE	OZOILE
E. coli	99,40	99,99	98,20	98,20
P. aeruginosa	99,99	99,99	98,99	98,99
S. aureus	99,07	99,99	99,70	99,70
C. abicans	99,99	99,99	99,99	99,99
C. glabrata	99,99	99,99	99,99	99,99
A. niger	-	-	-	-
G. vaginalis	87,50	99,99	99,99	99,99
P. mirabilis	96,47	99,99	99,99	99,99
P. acnes	99,99	99,99	99,99	99,99
E. faecalis	82,77	99,99	99,99	99,99
S. epidermidis	99,99	99,99	99,99	99,99
T. mentacrophytes	99,99	99,99	99,99	99,99
S. agalactiae	48,75	99,99	99,99	99,99
E. cloacae	68.60	99,99	99,99	99,99
B. cepacia	90,00	99,99	99,99	99,99
k. oxytoca	99,99	99,99	99,99	99,99
A. baumannii	99,99	99,99	99,99	99,99
C.pseudodiphterticum	99,99	99,99	99,99	99,99

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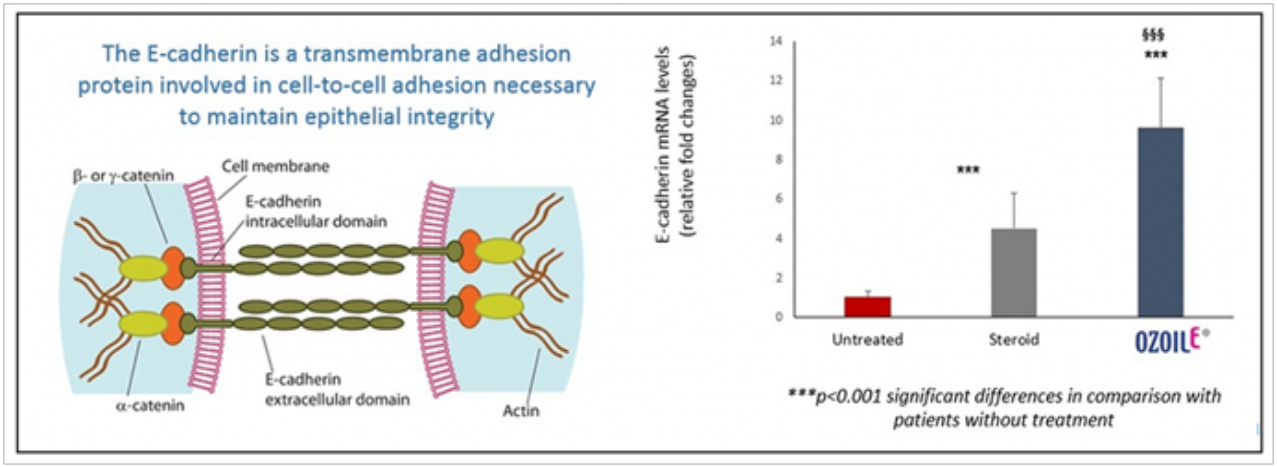


Figure 1 Ozoile® icreases the e-cadherin levels a transmembrane adhesion molecule that promotes correct re-epithelialization.

Results

Sixty patients suffering from chronic eczematous otitis externa (CEOE) were recruited and given 1 month of treatment with 5 drops per ear in the morning and in the evening.

Through a visual analogue scale (minimum score 0 and maximum 10 depending on the severity of the symptoms) the following parameters were evaluated at the beginning of the treatment (time 0) and at one month (time 1).

a) Itching

b) Secretions

c) Flaking

d) Complications.

After the treatment the results were as follow: 62.5% itching reduction, desquamation reduction by 72%, reduction of secretions by 80%. Total absence of side effects (Figure 2).

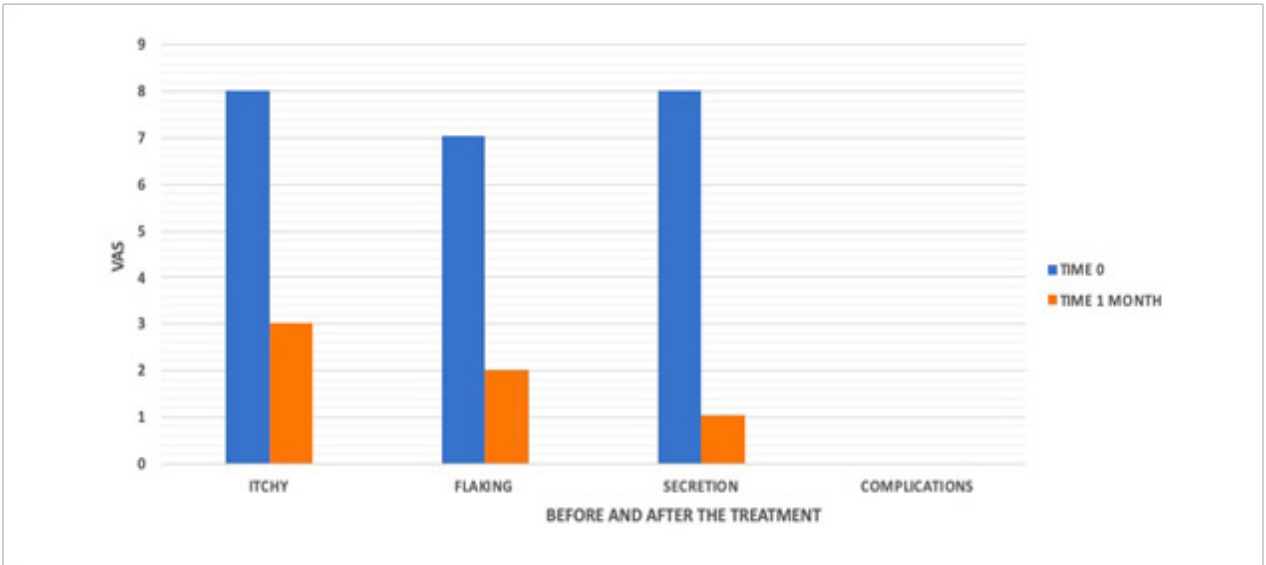


Figure 2 Results after one month treatment by Ozoile® of 60 patients suffering from chronic eczematous otitis externa.

Discussion

Ozoile® (Stable Ozonides with Vitamin E acetate) has been tested in the treatment of sclerotic obliterating balanitis and has been able to stop the chronic inflammatory mechanisms underlying the inflammatory pathology acting like a corticosteroid and to promote tissue regeneration. Based on these results, the author used Ozoile® for the treatment of chronic eczematous external otitis (symptoms lasting more than three months). The most used drugs in the treatment of eczematous external otitis are the topical corticosteroids which unfortunately, as already mentioned, can lead to dehydration of the skin, hypotropism with a reduction in their effectiveness over time.

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We can conclude that Ozoile® (Stable Ozonides with Vitamin E acetate) has an excellent "outcome" in CEOE even for prolonged periods and is a manageable and complication-free biological inducer, useful for relapsing bacterial external otitis not responsive to topical antibiotic therapy and for otomycosis.[1–12]

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Conflicts of interest

There are no conflicts of interest.

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