ISSN: 2582-6751
Journal of Clinical Medical Research

ATHENAEUM SCIENTIFIC PUBLISHERS

Case Report

Treatment of Acute External Otitis with Ear Drops of Etamsylate

Pedro Cuevas[1*], Isasa Francisco[2], Angulo Javier[1]

[1]Servicios de Histología, Hospital Universitario Ramón y Cajal, Madrid, Spain

[2]Otorinolaringologia, Hospital Universitario Ramón y Cajal, Madrid, Spain

***Correspondence author:** Pedro Cuevas, Servicios de Histología, Hospital Universitario Ramón y Cajal, Madrid, Spain; Email: pedro.cuevas@gmail.com

Citation: Cuevas P, et al. Treatment of Acute External Otitis with Ear Drops of Etamsylate. Jour Clin Med Res. 2026;7(1):1-3.

https://doi.org/10.46889/JCMR.2026.7109

Received Date: 21-01-2026

Accepted Date: 12-02-2026

Published Date: 20-02-2026

Abstract

Acute otitis externa is an inflammatory condition that causes a negative effect in patients. It is known that fibroblast growth factor participates in the pathophysiology of otitis externa through its pro-inflammatory and pain activities. In anterior studies we have demonstrated that etamsylate, an inhibitor of fibroblast growth factor, showed marked anti-inflammatory and anti-pain activities. The present report demonstrates that etamsylate ear drops application is effective in reducing symptoms and signs in patients with acute otitis externa.

Keywords: Otitis Externa; Ear Drops; Etamsylate; Fibroblast Growth Factor

Introduction

External otitis is an inflammatory process of the external auditory canal. This condition was found to be disabling enough to cause in 36% patients interruption of their daily activities for a median duration of four days with 21% bed rest [1]. The two most characteristic symptoms and signs of external otitis are otalgia (ear discomfort) and otorrhea. The ear discomfort can range from pruritus to severe pain that is exacerbated by motion of the ear, including chewing. If inflammation causes sufficient swelling to occlude the external auditory canal, the patient may also complain of aural fullness and loss of hearing. The use of ear drops steroid has been postulated to decrease the inflammation and oedema of the auditory canal and resolve symptoms, but not all studies have shown a benefit. In addition, a topical steroid can be a topical sensitizer. Furthermore, fungal external otitis (otomycosis) may be aggravated by the use of steroid containing drops [2]. Obviously, novel and safe treatment options for all these diseases are needed and must be considered an unmet medical need. We report here that ear application of etamsylate, a synthetic inhibitor of FGF, improves symptoms and signs in acute external otitis.

Case Presentation

After approval of our Institutional Ethical Committee, patients signed an informed consent form, which includes a comprehensive description of the proposed procedures. Six patients of both sexes with acute external otitis participated in this study. Otoscopic examination was performed at baseline and after treatment. Patients were asked before and during treatment the experienced otitis symptoms. Otitis symptoms and signs (pain, pruritus, hypoacusis and otorrhea) were rated as; 0: none, 1: mild, 2: moderate and 3: severe. Patients applied etamsylate (5 ear drops twice a day) for one week in the affected auditory canal. Mean clinical symptoms scores before and after one week of treatment with etamsylate were compared by paired t-test (Fig. 1). Patients reported that all symptoms improved after the first day of treatment. After one week of treatment all symptoms and signs scores were significantly reduced (Fig. 1). Patients did not show any apparent side-effects that may be attributed to the treatment. The magnitude and consistency of the response contrast with the variety of spontaneous amelioration in untreated patients with acute external otitis. After three months follow-up, patients live free of symptoms and signs.

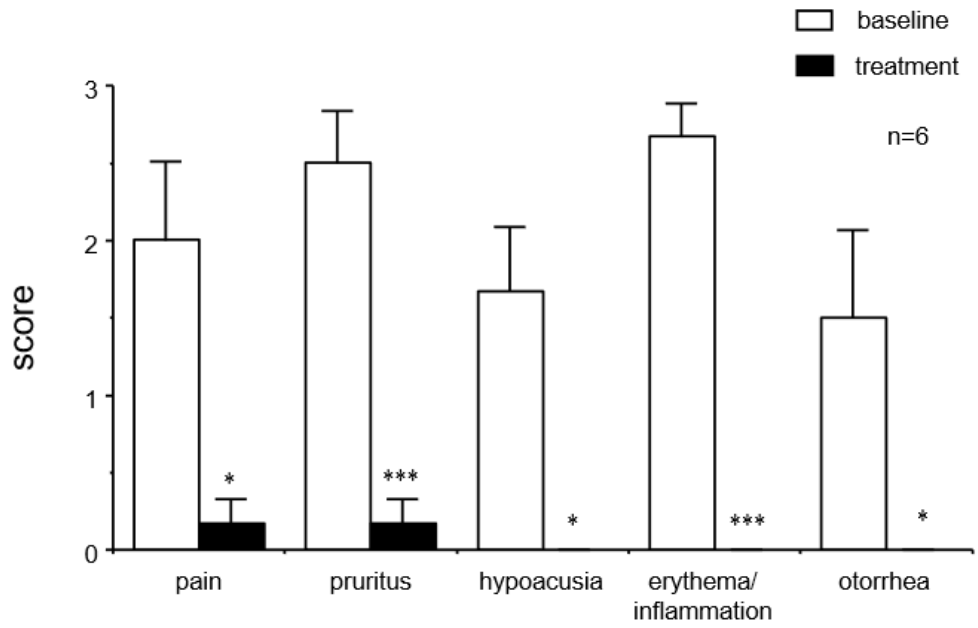

Figure 1: Effect of etamsylate ear drops in acute external otitis symptoms and signs after one week of treatment. Ear drops application of etamsylate improved symptoms and signs in patients. Data from the six patients are expressed as mean ± SEM. * indicates $p<0.05$ and *** $p< 0.001$ vs baseline by paired t-test.

Discussion

External otitis is an inflammation of outer ear and ear canal that may extend distally to the pinna and proximately to the tympanic membrane. It was found to be disabling enough to cause the interruption of daily activities in 36% patients for a median duration of 4 days, with 21% requiring bed rest [1]. Its monthly incidence in USA increases during the summer season from 0.2% to 1,4%. Because Fibroblast Growth Factor (FGF) has been reported to participate in inflammatory and pain pathways, it seems obvious that anti-inflammatory and antalgic activities of etamsylate may contribute to the clinical improvement of patients suffering from acute external otitis [3-8]. Thus, local inhibition of FGF may represent an attractive approach for the treatment of acute external otitis.

Conclusion

In this report we present preliminary assessment of the efficacy of the local administration of etamsylate in patients with acute external otitis. We show that ear drops application of etamsylate relieves the symptoms and signs in patients after one week after treatment. No relevant adverse effects were observed along the study in agreement with the good safety profile of this drug. Large scale therapeutic trials are obviously needed for more definitively establishing the efficacy of this treatment.

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding Statement

This research did not receive any specific grant from funding agencies in the public, commercial or non-profit sectors.

Acknowledgement

None

Data Availability Statement

Not applicable.

Ethical Statement

The project did not meet the definition of human subject research under the purview of the IRB according to federal regulations and therefore, was exempt.

Informed Consent Statement

Informed consent was taken for this study.

Authors' Contributions

All authors contributed equally to this paper.

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