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Original Article

Empirical Treatment Approach for Itchy Ear Syndrome: Topical Steroids or Antifungals?

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Abstract

Background: "Itchy ear syndrome", defined as ear itching after exclusion of related pathologies with a thorough physical examination, is common in otolaryngology practice. Despite the fact that it is frequent, high quality evidence regarding its etiology and treatment is lacking. We aimed to investigate whether empirical antifungal therapy is effective in this situation in comparison with corticosteroid therapy and the effectiveness of topical mometasone furoate lotion.

Methods: This retrospective observational study included 57 patients who applied with recurrent ear pruritus, were treated with mometasone or ciclopirox olamine, and who did not have any pathological findings on examination. The patients were retrospectively scanned through the hospital database, called, and asked to fill out a modified form of the 5D itching questionnaire to assess the degree of itching before and after treatment. The results were compared statistically.

Results: Of the 57 patients included, 25 (43.8%) were male and 32 (56.1%) were female. The mean age of the two groups was similar (p=0.915). Twenty-eight (49.1%) patients were treated with ciclopirox olamine, and 29 (50.9%) patients with mometasone. When the scores before and after treatment were compared, the decrease in scores was significant (p<0.001). There was no significant difference between the two cohorts regarding pre-treatment and post-treatment scores (p=0,26 and p=0.22, respectively).

Conclusion: Our findings indicate that topical antifungal treatment with ciclopirox olamine and topical steroid treatment with lotion form mometasone furoate are both effective in the treatment of itchy ear syndrome.

Keywords: Pruritis, Ear Canal, Memetasone Furoate, Ciclopirox/pharmacology

INTRODUCTION

Ear itching is one of the most common complaints in otolaryngology practice. Ear itching, as in other dermatological causes, can be caused by inflammatory skin diseases, exogenous trigger factors (e.g. mites, fungi, viruses, etc.), or systemic diseases (e.g. renal insufficiency, liver diseases, diabetes mellitus) (1-4). Although this is a common symptom, the underlying systemic or local cause can not be detected in most patients and this condition is also called " itchy ear syndrome" (5).

Despite the fact that ear itching is a common symptom, there are not enough studies on its etiology and treatment (6,11). It has been reported in previous studies that topical corticosteroid agents, local moisturizers, topical immunomodulators, antihistaminics, and Castellani's paint has been used for treatment, but the treatment of choice, as well as the best empirical treatment approach, remains unclear (3,5). Although the effectiveness of topical steroid therapy is reported in the literature, there are not enough studies on this subject and the choice of the topical agent and pharmaceutical form (lotion, cream, etc.) to use is unclear. It should also be emphasized that before the initiation of empirical treatment with steroids, a thorough physical examination is essential, for absence of funghal infection findings is necessary, in

which steroids may have deleterious effects.

In this study, we aimed to investigate whether empirical antifungal therapy is effective in the itchy ear syndrome in comparison with corticosteroid therapy, the effect of which has already been reported. We also aimed to investigate the effectiveness of the lotion form of topical mometasone furoate on itchy ear.

METHODS

This study was conducted in compliance with the principles outlined in the "Declaration of Helsinki". The institutional ethics committee approved the study protocol (E.Kurul-E2-22-2304). Given the retrospective nature of the study and the use of anonymized data, the requirement for informed consent was waived by the ethics committee. All patient data were anonymized and securely stored in an electronic database to ensure confidentiality. Written informed consent to participate was obtained from the patients participated in this study. Personal data privacy has been protected. Patients signed informed consent regarding publishing their data.

Study Design

This study was designed as a retrospective observational study in our otorhinolaryngology clinic. Twenty-eight patients who were treated with topical mometasone and twenty-nine patients who were treated with topical ciclopirox olamine were randomly selected. Mometasone was applied as 5 drops, 3 times a day and the ciclopirox olamine was applied as 5 drops, 3 times a day. The patients who were treated with these agents and were eligible were retrospectively scanned and called. Patients were asked to fill out a 5-D pruritus scale to assess the degree of itching before and after treatment7. The results of the questionnaire were compared between the two groups.

Data Source

By scanning the outpatient clinic data through hospital data-base, 57 patients who applied to the otorhinolaryngology outpatient clinic within 1 week with recurrent bilateral external ear canal pruritus and were treated with mometasone or ciclopirox olamine were included.

Case Selection

During the study period, we identified a total of 232 patients who presented to our otorhinolaryngology outpatient clinic with recurrent bilateral external ear canal pruritus and received either mometasone or ciclopirox olamine treatment. From this initial cohort, 127 patients met our inclusion criteria after exclusion of those with pathological examination findings, recent medication use, or comorbid conditions. Of the 127 eligible patients, 86 were successfully contacted by telephone, and 57 agreed to participate and completed the 5-D pruritus questionnaire. Reasons for non-participation included: inability to reach (41 patients) refusal to participate (14 patients), and incomplete questionnaire responses (15 patients). The patients who did not have any pathological findings that would cause itching on otolaryngological examination were included in the study.

Exclusion Criteria

Patients with abnormal physical examination findings were excluded. Long-term use of topical or systemic steroids and. antibiotics, as well as usage of these agents within one week prior to study enrollment date were also determined as exclusion criteria. Patients who had earwax or showed signs of otological diseases such as otomycosis, external otitis, or chronic otitis media on otoscopic examination, a history of ear surgery, any history of systemic diseases including diabetes mellitus, renal failure, hepatic disorders or dermatological diseases such as psoriasis or atopic dermatitis were also excluded.

STATISTICAL ANALYSIS

Statistical analyzes were performed using SPSS version 26 software. The conformity of the variables to the normal distribution was examined using visual (histogram and probability graphs) and analytical methods (Kolmogorov-Smirnov). Descriptive analyzes were given using the mean and standard deviations for normally distributed variables, and the median and interquartile range for non-normally distributed variables. Pre-treatment scores were compared with the Independent Groups T-test since this variable showed a normal distribution. Post-treatment scores that did not show normal distribution were compared using the Mann-Whitney U test. Since it was determined that the post-treatment scores did not comply with the parametric test assumptions, the statistical significance of the change over time for these parameters was examined using the Friedman test. Pairwise comparisons were made using the Wilcoxon test and evaluated using Bonferroni correction. Within-group changes from pre- to post-treatment were analyzed using the Wilcoxon signed-rank test for each group separately. A p-value below 0.05 were considered statistically significant.

RESULTS

Of the 57 patients included in the study, 25 (43.8%) were male and 32 (56.1%) were female. The mean age of the patients who were treated with mometasone was 43.1 ± 10.4. The mean age of the patients who were treated with ciclopirox olamine was 47.4 ± 12.2 years. The mean age of the two groups was similar (p=0.915).

Twenty-eight (49.1%) patients were treated with ciclopirox olamine and 29 (50.9%) patients with mometasone. When the scores before and after treatment were compared, it was found that the decrease in scores was significant (p<0.001). When the cicloprox olamine

and mometasone treatments were evaluated separately, the decrease in scores was statistically significant (p<0.001) (Table 1 and Figure 1).

Forty-nine of 57 patients (86%) achieved the minimum itch score of 5, with the highest post-treatment score being 8. For pre-treatment scores, the mean of the ciclopirox olamine group was 15.89 (SD±2.94) and the mean of the mometasone group was 16.97 (SD±4.21). There were no significant difference between two groups (p=0.26). There was no significant difference in post-treatment scores in the ciclopirox olamine and mometasone groups (p=0.22). No statistically significant difference in magnitude of itch reduction was found between the two groups (Table 2).

In the ciclopirox group, itch scores improved from a mean of 15.89 (95% CI: 14.76-17.02) to a median of 5, representing a reduction of 10.89 points (paired Cohen's d = 3.70, p<0.001). In the mometasone group, scores improved from a mean of 16.97 (95% CI: 15.37-18.57) to a median of 5, representing a reduction of 11.97 points (paired Cohen's d = 2.84, p<0.001). For pre-treatment scores, there was no significant difference between the ciclopirox group (mean: 15.89, SD: 2.94) and mometasone group (mean: 16.97, SD: 4.21), with a between-group difference of 1.08 points (Cohen's d = 0.30, p=0.26). Similarly, post-treatment scores showed no significant difference between groups (p=0.22), with both groups achieving similar median scores of 5.

Table 1. The 5-D itch scale scores of all patients before and after treatment

	Mean (SD)	Median (Min-Max)
Score Before Treatment	16.44 (3.65)	17 (9-24)
Score After Treatment	5.51 (0.73)	5 (5-8)

*p<0.001, Friedman test for overall comparison. SD: standard deviation
Note: 5-D itch scale total score ranges from 5 (minimum, no itch) to 25 (maximum, worst itch)

DISCUSSION

The "itchy ear syndrome", which is defined as itching in the ear for no apparent reason after a thorough physical examination is a common condition6. Vallur et al. reported the prevalence of ear itching as 9.8% in a series of 2143 cases (2). The same study reported that the predominant etiologies were otomycosis 30%, wax deposition 25.2%, otitis externa 30%, and use of a hearing aid 7.6%2.

Although ear itching can be caused by many dermatological or systemic diseases and its treatment

Table 2. Comparison of ciclopirox olamine and mometasone treatment by means of 5-D itch scale scores before and after treatment

	Ciclopirox Olamine	Mometasone	p
Mean Scores of the Patients Before Treatment (SS)	15.89 (2.94)	16.97 (4.21)	0.26*
Median of the Scores After Treatment (Interquartile Range)	5 (2)	5 (1)	0.22**
Score Reduction	10.89	11.97	-
Within Group p-value	<0.001***	<0.001***	-

*Independent T Test **Mann-Whitney U Test ***Wilcoxon signed-rank test
Note: 5-D itch scale total score ranges from 5 (minimum, no itch) to 25 (maximum, worst itch)

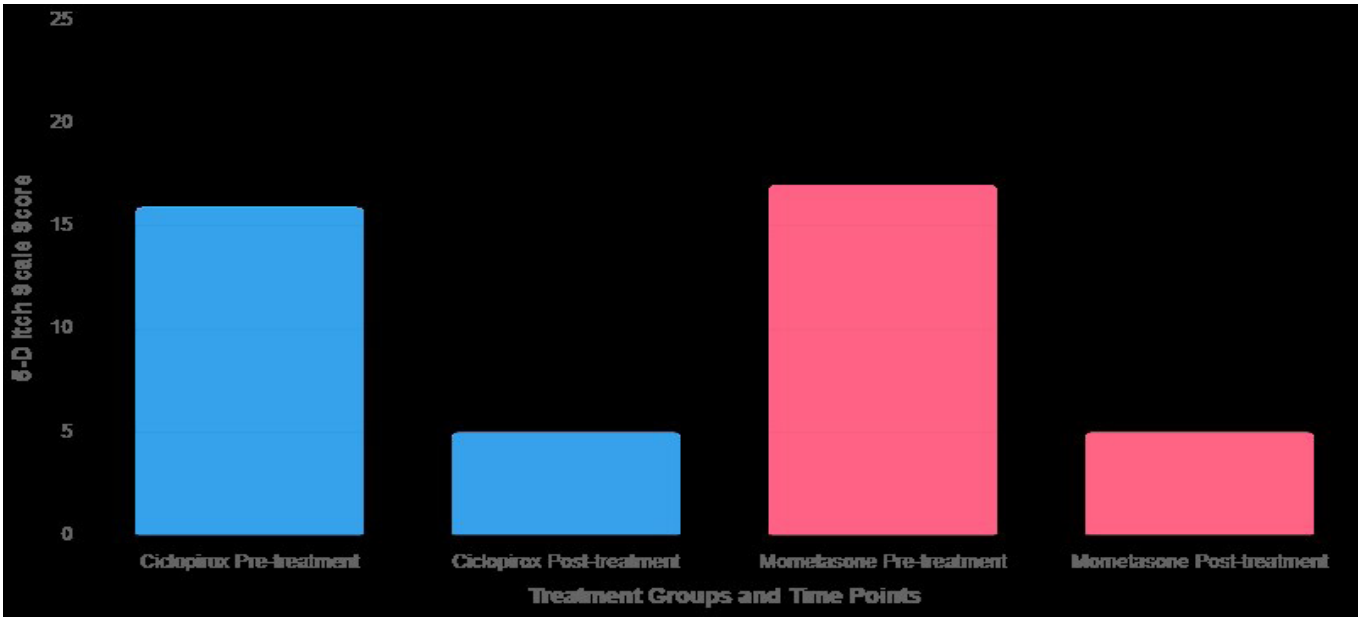

Figure 1. Pre- and Post-Treatment Itch Scores by Treatment Group, basic flowchart

depends on the underlying cause, it may be challenging to identify the cause in daily practice. Moreover, prior studies outlined that the underlying cause of isolated ear itching could not be revealed in a substantial proportion of the patients (6). These findings have led to the ideal empirical treatment for symptom relief being a subject of research. Among these, the most frequently recommended treatment is topical corticosteroids, in the absence of strong evidence.

Although there are several studies in the literature on what this ideal empirical treatment might be, as we have noted before, large randomized controlled trials are lacking. Lea SY et al. compared the effects of a topical calcineurin inhibitor and a moisturizing cream. They suggested that chronic low-level inflammation associated with aging (termed "inflaming") may play a role in ear itching (5). They reported a similar result in both groups and concluded that using moisturizers, especially in elderly patients, provides adequate symptomatic relief and protection from the side effects of other pharmacological agents. Babakurban ST et al. stated that Castellani paint is a well-known antiseptic,and is frequently used in otolaryngology to treat external otitis and otomycosis (3). Their study with Castellani paint reported that it can be administered safely, effectively, and easily without affecting normal skin flora in the treatment of itchy ear syndrome (3).

In another study, Svisthuskin VM et al. reported effective symptomatic improvement with a topical empirical treatment containing beclomethasone, gentamycin, and clotrimazole in the treatment of pruritic dermatoses of the external auditory canal (10).

In our study, we found that the topical lotion form of mometasone (a moderately potent corticosteroid) is effective in the symptomatic treatment of itchy ears, in almost all patients. This finding is consistent with other studies in the literature. We also determined that all patients completed the treatment without reporting any side effects.Topical anti-fungals were also found to be safe and were generally well tolerated, without any documented adverse effects. An important point to note is that fungal infections are one of the common causes of ear itching, and may cause itching even when physical examination reveals no apparent findings. Morinaka et al. reported that dermatophyte infections were detected in the normal appearing ears in 8 of 34 patients with ear itching (8,9). This may partially explain the effectiveness of empirical antifungal treatment, and it also suggests that further diagnostic tests are needed to be developed. From a daily practice perspective, there are no specific treatment recommendations for fungal infections in the absence of fungal infection findings on physical examination. Clinical significance of this, in the absence of supporting physical examination findings, remains unclear, and it is possible that this finding may predict response to empirical antifungal treatment. Currently, it is not known whether steroid or antifungal treatment is superior to each other in these occult fungal infections, and these findings indicate that this should be investigated with randomized clinical trials.

Despite the limitations, our investigation offers a contribution to the literature by demonstrating that a new empirical treatment approach may be beneficial for a symptom that commonly seen in daily practice. It also provides new research topics related to better defining populations that may benefit from empirical antifungal therapy.

Limitations of the Study

Our study has several limitations inherent to its retrospective design, which is prone to data incompleteness. Another limitation is that since the disease has no measurable physical examination, laboratory or imaging findings, symptomatic evaluation must be made via a questionnaire. Because no baseline itch scores were recorded prospectively, we relied on patient recall using a modified 5-D Itch Scale. We recognize this introduces recall bias and

that the 5-D scale is validated for current itch severity, not past recall. An important methodological consideration is the potential floor effect observed with the 5-D itch scale in our study. With 86% of patients achieving the minimum possible score of 5, the scale may have limited sensitivity to detect mild residual symptoms or subtle differences between treatments in patients with excellent responses. Future studies might benefit from using more sensitive outcome measures or additional scales that can better discriminate between different levels of minimal symptoms. Furthermore, in a small subset of patients, it is not possible to make definitive statements, as our findings need to be confirmed in larger, prospective studies. Finally, although large within-group effect sizes demonstrate substantial clinical improvement, this study had limited statistical power to detect small-to-moderate differences between treatments.

CONCLUSION

Topical ciclopirox olamine appears to relieve itchy ear symptoms about as effectively as mometasone furoate lotion in our sample, with both treatments leading to significant itch reduction. However, given the study's limitations (small sample, retrospective design), we cannot conclusively establish equivalence; further randomized trials are warranted.

DECLERATIONS

Ethics Approval: This study was approved by Ankara City Hospital No. 2 Clinical Research Ethics Committee (E.Kurul-E2-22-2304).

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