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RESEARCH ARTICLE
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Is adding an oral antibiotic with the topical antibiotic steroid useful in treatment of uncomplicated acute otitis externa in immunocompetent patients?

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ABSTRACT

Background: Acute otitis externa (AOE) is a common disease encountered in otolaryngology practice, it is mainly bacterial in origin. AOE can cause severe otalgia and can interrupt the daily activities; however, bed rest is required in about 20% of the patients.

Aim: To evaluate the usefulness of adding an oral antibiotic with the topical antibiotic steroid in the treatment of uncomplicated AOE which is limited to the ear canal in immunocompetent patients.

Patients and methods: A prospective comparative clinical study was conducted in the department of otolaryngology at Al-Jerrahat Teaching Hospital and Private Clinic, Baghdad, Iraq, during the period from April 2020 to October 2021. A total of 68 immunocompetent patients (39 females and 29 males), diagnosed as cases of uncomplicated AOE which is limited to the ear canal, were included in this study. The patients were categorized into two groups. Patients in group A were treated with topical tobramycin 0.3%-dexamethasone 0.1% drops, while patients in group B received the same treatment as group A patients plus oral Ciprofloxacin tablets 500 mg twice daily. The patients were followed up on day-to–day basis until complete resolution of pain and edema. The severity of pain was assessed by visual analogue scale (VAS) scores, while edema was graded by dividing the ear canal by imaginary horizontal and vertical lines into four quarters. The post-treatment pain VAS scores and edema grades of both groups were compared. Statistical analysis using t-test was done to calculate P-value in order to find if there is a significant difference regarding the resolution of pain and edema between group A and group B.

Results: During the whole follow-up period there was no significant difference between group A and group B patients regarding the resolution of pain and edema (P-value was more than 0.05).

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Conclusions: There is no significant benefit of adding an oral antibiotic with the topical antibiotic steroid in the treatment of uncomplicated AOE limited to the ear canal in immunocompetent patients.

Keywords: *acute otitis externa; Ciprofloxacin tablets; topical tobramycin-hydrocortisone drops; visual analogue scale*

INTRODUCTION

Acute otitis externa (AOE), also called swimmer's ear, is defined as diffuse inflammation of the external ear canal.[1] AOE occurs in all age groups, fortunately, it is uncommon in children under 2 years old. It affects males and females with no gender predominance. It is unilateral in about 90% of cases. The increased humidity during summer and in tropical climates may predispose to AOE.[2] Other predisposing factors include warm swimming pools, local trauma, ear canal narrowing, cerumen obstruction, foreign body, and wearing hearing aids.[3–6]

Bacterial infection is the most common cause of AOE.[5,7,8] *Pseudomonas aeruginosa* and *Staphylococcus aureus* are the most commonly involved organisms in AOE.[9]

The diagnosis AOE requires a rapid onset (within 48 h) of the signs and symptoms of external ear canal inflammation in the past 3 weeks.[2,3] The symptoms and signs of AOE include otalgia, hearing impairment, tenderness of the tragus, diffuse external ear canal erythema, and otorrhea.[2]

Since the use of systemic antibiotics leads to the occurrence of side effects and increased bacterial resistance to antibiotics, this study was conducted to assess whether there is a benefit in adding an oral antibiotic with the topical antibiotic steroid in the treatment of uncomplicated AOE which is limited to the ear canal in immunocompetent patients.

PATIENTS AND METHODS

Approval of the Ethics Committee and written consent from the patients were taken. This study was conducted at the Department of Otolaryngology at Al-gerrahat Teaching Hospital and the Private Clinic, Baghdad, Iraq, during the period from April 2020 to October 2021.

After routine history and otolaryngological examination, 68 immunocompetent patients (39 females and 29 males) were diagnosed and included as cases of uncomplicated AOE which is limited to the ear canal. A code number was given to each patient, patients with odd numbers (34 patients) were allocated to group A, while patients with double numbers (34 patients) were allocated to group B. The patients in group A were treated with topical tobramycin 0.3%-dexamethasone 0.1% drops and diclofenac tablets 50 mg three times daily. Group B patients were treated with the same treatment as group A plus oral Ciprofloxacin tablets 500 mg twice daily. In the first visit, wicks impregnated with tobramycin 0.3%-dexamethasone 0.1% drops were inserted in the ear canals of the patients in both groups, the patients were instructed to drip four drops of tobramycin 0.3%-dexamethasone 0.1% drops onto the wick three times daily. In the second visit, 48 h later, the wicks were removed and instructions were given to the patients to drip four drops of tobramycin 0.3%-dexamethasone 0.1% drops onto the ear canal. The patients were educated on how to administer the drops properly into the ear canal (the patient should lie down and the affected side facing upward, instillation of four drops of tobramycin 0.3%-dexamethasone 0.1% drops into the ear canal, and should remain in this position for 5 min). After the second visit, the patients were followed up every other day until complete recovery. Also, the patients were instructed to avoid water entering the ear canal. Cleaning of the ear canal by mopping or the suction was done as much as possible during the follow-up period.

Pain and edema have been assessed in the first (pre-treatment) visit and during the subsequent visits. The severity of pain was assessed by using a visual analogue scale (VAS). Scoring of pain was as follows: 0 = no pain, 1–3 = mild pain, 4–6 = moderate pain, 7–9 = severe pain, and 10 = worst pain.

Regarding edema, it was graded by dividing the ear canal by imaginary horizontal and vertical lines perpendicular to each other into four quarters, each quarter representing 25% of the ear canal. The grading of edema was as follows: grade 0 = no edema, grade 1 = edema obscure less than 25% of the ear canal, grade 2 = edema obscure 25%–50% of the ear canal, grade 3 = edema obscure 50%–75% of the ear canal, and grade 4 = edema obscure 75%–100% of the ear canal. Pain and edema have been evaluated in the morning before patients take their medications.

Statistical analysis

The postoperative data (pain VAS scores and edema grades), in both groups, were compared and analyzed with computer software SPSS version 24, t-test was used to define the association between the categorical variables; a confidence level of 95% with a P-value less than 0.05 was considered significant.

RESULTS

The total number of patients included in the current study was 68 patients, 39 females and 29 males, with their age ranging between 12 and 60 years (mean age = 29.6 and standard deviation = +/- 8.53). Tables 1 and 2 show the age and gender distribution of the patients, respectively.

Tables 3 and 4 show the pre and post-treatment VAS pain scores and edema grades, respectively.

A comparison of VAS pain scores and edema grades between both groups, using t-test, had showed that there were no significant differences. P-values were more than 0.05 during the follow-up period as shown in Table 5.

TABLE 1. Age distribution.

Age	Group A	Group B	Total
12–20	5 (7%)	6 (9%)	11 (16%)
21–30	12 (18%)	11 (16%)	23 (34%)
31–40	9 (13%)	10 (15%)	19 (28%)
41–50	6 (9%)	4 (6%)	10 (15%)
51–60	2 (3%)	3 (45%)	5 (7%)
Total	34 (50%)	34 (50%)	68 (100%)

TABLE 2. Gender distribution.

Group	Female	Male	Total
A	18 (26.5%)	16 (23.5%)	34 (50%)
B	21 (31%)	13 (19%)	34 (50%)
Total	39 (57.4%)	29 (42.6%)	68 (100%)

TABLE 3. Patients distributed according to pre and post-treatment VAS scores until complete pain relief.

VAS scores	Pre-treatment		Post-treatment (days)											
	Group A	Group B	Group A						Group B					
			2	4	6	8	10	12	2	4	6	8	10	12
0	0	0	0	1	16	25	32	34	0	1	17	23	33	34
1–3	4	2	8	16	9	8	2	0	10	18	11	10	1	0
4–6	10	13	11	7	5	1	0	0	12	8	4	1	0	0
7–9	17	15	13	10	4	0	0	0	9	7	2	0	0	0
10	3	4	2	0	0	0	0	0	3	0	0	0	0	0

P–value>0.05.

TABLE 4. Patients distributed according to pre and post-treatment edema grades until complete resolution.

Odema grades	Pre-treatment		Post-treatment (days)									
	Group A	Group B	Group A					Group B				
			2	4	6	8	10	2	4	6	8	10
0	0	0	1	2	19	28	34	2	3	22	30	34
1	3	4	12	17	10	6	0	14	19	8	4	0
2	15	11	14	11	4	0	0	13	9	3	0	0
3	13	14	7	4	1	0	0	5	3	1	0	0
4	3	5	0	0	0	0	0	0	0	0	0	0

P–value>0.05.

TABLE 5. Inter-group comparison of P–values using t-test.

Days of follow up	VAS pain scores (P-value)	Edema grades (P-value)
2nd day	0.18	0.11
4th day	0.21	0.28
6th day	0.33	0.42
8th day	0.45	0.51
10th day	0.57	0.62
12th day	0.62	

DISCUSSION

Oral antibiotics are used in about 20%–40% of the patients with AOE.[8,10–12] Oral antibiotics are distributed throughout the body which can lead to many side effects and increased bacterial resistance to antibiotics. For these reasons, this study was conducted to find out if there is any benefit of adding a systemic antibiotic to a topical antibiotic steroid in the treatment of AOE.

Statistical analysis, in the current study, had shown that there was no significant advantages in adding an oral antibiotic (Ciprofloxacin) with the topical antibiotic steroid (tobramycin 0.3%-dexamethasone 0.1% drops) in the treatment of uncomplicated AOE in immunocompetent patients. Perhaps, the very high concentration of the topical antibiotic steroid that can reach the infected tissue makes the oral antibiotic addition unhelpful.

Possibly the addition of steroids with the topical antibiotic drops can decrease the edema of the ear canal and lead to a faster resolution of symptoms. Furthermore, a local steroid may act as a topical sensitizer.[13,14]

Rosenfeld et al.,[15] in their random meta-analysis, mentioned that the cure rate of AOE which had been treated by local antibiotics is 65%–80% during 10 days of treatment. In a study by Pottumarthy,[16] patients were randomized into a topical antibiotic plus oral antibiotic versus topical antibiotic plus placebo and found no significant difference between the two groups in the cure rate of AOE. Likewise, in a randomized multicenter trial conducted by Roland,[17] there were no differences regarding otalgia duration or bacteriological efficacy between topical Ciprofloxacin-hydrocortisone versus oral amoxicillin plus topical neomycin/polymyxin-hydrocortisone. In another study by Wiegand et al.,[18] they concluded that uncomplicated AOE can be treated effectively by cleaning the ear canal using antibiotic eardrops with or without corticosteroid.

The usage of systemic antibiotics in the treatment of AOE can be associated with increased side effects, the appearance of resistant bacteria, and recurrence. Also, the outcomes and cure rates will not improve in comparison to the use of topical antibiotics alone in the treatment of uncomplicated AOE.[9,17,19,20] However, systemic antibiotics must be

used when the infection has spread outside the ear canal, when complications occur, when there are immunocompromised diseases, or when it is not possible to administer the topical antibiotics.[15,21]

The argument against the use of oral antibiotics for AOE limited to the ear canal is the efficacy of topical treatment that do not include systemic antibiotics.[2] However, the appropriate use of topical antibiotic steroids in the treatment of AOE can eliminate the need for systemic antibiotics which can unnecessarily decrease patient compliance and increase the likelihood of adverse effects and cost.[11]

CONCLUSIONS

Uncomplicated AOE which is limited to the ear canal in immunocompetent patients can be treated effectively by topical antibiotic steroid, which makes the addition of an oral antibiotic of no significant benefit. Thus, the side effects and the increased bacterial resistance which are associated with the use of oral antibiotics can be avoided.

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