**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 otolaryngological practice, it is mainly bacterial in origin.AOE can cause severe otalgia and can interrupt the daily activeties, 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***: Aprospective 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 through October 2021. A sixty eight immunocompetent patients (39 females & 29 males), diagnosed as cases of uncomplicated AOE which is limited to the ear canal, were included in this study. The patients were allocated in two groups. Patients in group A were treated with topical tobramycin 0.3% -dexamethasone 0.1% drops, while patients in group B were recieved the same treatment as group A patients plus oral ciprofloxacin tabletes 500 mg twice daily . The patients were followed upfrom day to day until complete resolution of pain and odema. Pain was assessed by visual analogue scali (VAS) scores, while odema was graded by dividing the ear canal by imaginary horizontal and vertical lines into 4 quarters. The post-treatment pain VAS scores and odema grades of both groups were compared. Statistical analysis using T-test was done to calculate P value in orded to find if there is significant difference regarding the resolution of pain and odema 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 odema (P value more than 0.05).

***Conclusion***: 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.

***Key words***: Acute otitis externa, Visual analogue scale, Topical tubramycin-hydrocortisone drops, Ciprofloxacin tablets.

**Introduction**

 Acute otitis externa (AOE), also called swimmer,s ear, is defined as diffuse inflammation of the external ear canal (1).. AOE ocurrs in all age groups, Fortunately, it is uncommon in children under 2 years old. It affects male and female 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 (3,4,5,6).

 Bacterial infection is the commonest cause of AOE (5,7,8). Pseudomonas aeruginosa and staphylococcus aereus are the most commonly involved organisms in AOE (9).

 Acute otitis externa diagnosis requires a rapid onset (within 48 hours) 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 lead to the occurrence of side effects and increased bacterial resistance to antibiotics, therefore this study was conducted to assess whether there is a benefit in adding an oral antibiotic with the topical antibiotic-steroid in treatment of uncomplicated AOE which is limited to the ear canal in immunocompetent patients.

**Patients and methods**

 Approval of Ethics Committee and written consents from the patients were achieved, 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 through October 2021.

 After routine history and otolaryngological examination, a sixty eight immunocompetent patients (39 females, 29 males) diagnosed as cases of uncomplicated AOE which is limited tothe ear canalwere included in this study. Acode number was given to each patient, patients with odd numbers (34 patients) were allocated in group A, while patients with double numbers (34 patients) were allocated in group B. The patients in group A were treated by topical tobramycin 0.3% -dexamethasone 0.1% drops, diclofenac tablets 50 mg three times dialy. Group B patients were treated by the same treatment as group A plus oral ciprofloxacine tabletes 500 mg twice daily. In the first visit, wicks imprignated 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 4 drops of tobramycine 0.3% -dexamethasone 0.1% drops onto the wick 3 times daily. In the seconed visit, 48 hours later, the wicks were removed and instructions were given to the patients to drip 4 drops of tobramycin 0.3% -dexamethasone 0.1% drops onto the ear canal. The patients were educated how to administer the drops properly into the ear canal (the patient should lie down and the affected side facing upward, instillation of 4 drops of tobramycin 0.3% -dexamethasone 0.1% drops into the ear canal, and should remain in this position for 5 minutes). After the seconed visit, the patients were followed up every other day until complete recovery. Also, the patients have been instructed to avoid water entering the ear canal. Cleaning of the ear canal by mopping or suction was done as much as possible during the follow up period.

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

 Regarding odema, 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 odema was as follow: grade 0 = no odema, grade 1 = odema obscure less than 25% of the ear canal, grade 2 = odema obscure 25% - 50% of the ear canal, grade 3 – odema obscure 50%- 75% of the ear canal, and grade 4 = odema obscure 75%- 100% of the ear canal. Pain and odema had been evaluated in the morning before taking the medications by the patients.

***Statistical analysis***

 The post-operative data (pain VAS scores and odema graes) in both groups were compared and analysed with computer soft ware SPSS version 24, T-test was used to define the association between the categorial variables ; a confidence level of 95% with P value less than 0.05 was considered significant.

**Results**

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

**Table (1): Age distribution.**

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

**Table (2): Gender distribution.**

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

 Tables (3) and (4) show the pre and post-treatment VAS pain scores and odema grades respectively.

**Table (3): Patients distribution according to pre and post-treatment VAS scores until complete pain relieve.**

|  |  |  |
| --- | --- | --- |
| ***Post-treatment ( days )*** | ***Pre-treatment*** | ***VAS scores*** |
| ***Group B*** | ***Group A*** | ***Group B*** | ***Group A*** |
| ***12*** | ***10*** | ***8*** | ***6*** | ***4*** | ***2*** | ***12*** | ***10*** | ***8*** | ***6*** | ***4*** | ***2*** |
| **34** | **33** | **23** | **17** | **1** | **0** | **34** | **32** | **25** | **16** | **1** | **0** | **0** | **0** | ***0*** |
| **0** | **1** | **10** | **11** | **18** | **10** | **0** | **2** | **8** | **9** | **16** | **8** | **2** | **4** | ***1-3*** |
| **0** | **0** | **1** | **4** | **8** | **12** | **0** | **0** | **1** | **5** | **7** | **11** | **13** | **10** | ***4-6*** |
| **0** | **0** | **0** | **2** | **7** | **9** | **0** | **0** | **0** | **4** | **10** | **13** | **15** | **17** | ***7-9*** |
| **0** | **0** | **0** | **0** | **0** | **3** | **0** | **0** | **0** | **0** | **0** | **2** | **4** | **3** | ***10*** |
| **0.05<P value** |

**Table (4): Patients distribution according to pre and post-treatment odema grades until complete resolution.**

|  |  |  |
| --- | --- | --- |
| ***Post-treatment ( days )*** | ***Pre-treatment*** | ***Odema grades*** |
| ***Group B*** | ***Group A*** | ***Group B*** | ***Group A*** |
| ***10*** | ***8*** | ***6*** | ***4*** | ***2*** | ***10*** | ***8*** | ***6*** | ***4*** | ***2*** |
| **34** | **30** | **22** | **3** | **2** | **34** | **28** | **19** | **2** | **1** | **0** | **0** | ***0*** |
| **0** | **4** | **8** | **19** | **14** | **0** | **6** | **10** | **17** | **12** | **4** | **3** | ***1*** |
| **0** | **0** | **3** | **9** | **13** | **0** | **0** | **4** | **11** | **14** | **11** | **15** | ***2*** |
| **0** | **0** | **1** | **3** | **5** | **0** | **0** | **1** | **4** | **7** | **14** | **13** | ***3*** |
| **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **5** | **3** | ***4*** |
|  **0.05<P value**  |

 Comparison of VAS pain scores and odema grades between both groups, using T-test, had shown that there were no significant differences , P values were more than 0.05 during the whole follow up period as shown in table (5).

**Table (5):Inter-groups comparison (using t-test) P values.**

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

**Discussion**

 Oral antibiotics are used in about 20-40% of the patients with AOE (8,10,11,12). Oral antibiotics are distributed through out the body which can lead to many side effects and increased bacterial resistance to antibiotics, for these reasons, this study was cnducted to find out if there is any benifit of adding asystemic antibiotic to a topical antibiotic- steroid in treatment of AOE.

 Statistical analysis , in the current study, had shown that there was no significant advantages in adding an oral antibiotic (ciprofloxacine) 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 is unhelpful.

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

 Rosenfeld et al., 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 (15). In a study done by Pottumar , the patients were randomized into a topical antibiotic plus oral antibiotic versus topical antibiotic plus placebo, they found no significant difference between the two groups in cure rate of AOE (16). Likewise, in a randomized multicenter trial conducted by Roland , there was no differences regarding otalgia duration or bacteriological efficacy between topical ciprofloxacin-hydrocortisone versus oral amoxicillin plus topical neomycin /polymyxin-hydrocortisone (17). In a study done by Wiegand et al., they concluded that uncomplicated AOE can be treated effectively with cleansing of the ear canal and antibiotic eardrops with or without corticosteroid (18).

 The usage of systemic antibiotics in treatment of AOE can be associated with increased side effects, appearance of resistent bacteria, and recurrance. Also the outcomes and cure rates will not improve in comparison to the use of topical antibiotic alone in 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 that do not include systemic antibiotic (2). However, the appropriate use of topical antibiotic-steroid in treatment of AOE can eliminate the need for systemic antibiotics which can unnecessarily decrease the patient compliance and increase the likelihood of adverse effects and cost (11).

**Conclusion**

 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 benifit. Thus, the side effects and the increased bacterial resistence which are associated with the use of oral antibiotics can be avoided.

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