Comparative Study of Combined Steroid-Antibiotic Aural Pack versus Antibiotic Drop in Otitis Externa

Jayanta Saha, Debabrata Biswas, Tithi Debnath, Subhadeep Chowdhury

ABSTRACT

Introduction
Otitis externa is an inflammatory condition of the skin of the external auditory canal that is characterized by generalized edema and erythema. It is a very common condition which is encountered in day to day outpatient services in the life of otolaryngologists. So treatment includes not only antibiotics and analgesics systemically but also aural packing for topical application. This study was performed to observe the effectiveness of treatment for relieving pain and edema by comparing steroid–antibiotic aural pack with antibiotic ear drop.

Materials and Methods
A total of 60 patients were divided into two groups where one group was given steroid–antibiotic pack and the other group was given antibiotic ear drop. NRS was used to assess the pain and edema was assessed by otorhinolaryngologists on subsequent visits. Patients were called every 48 hours for assessment. We also assessed the need for second line antibiotic in both group of patients. Statistical analysis was done using “Z” test of mean to compare average number of score and visits in two different groups.

Results
Patients belonging to the steroid-antibiotic pack group had early subsidence of edema and lesser number of visits as compared to only antibiotic group. Also pain was relieved early in less number of visits in the antibiotic-steroid pack group as compared to only antibiotic group. Also need of second line of antibiotic was also statistically significant in steroid-antibiotic pack group as compared to antibiotic drop group. Age and gender were analyzed and there was no significant differences in these factors on comparison between the two groups.

Conclusion
As control of pain and edema is more and hence the number of visits is significantly less in steroid–antibiotic packing group, so it is therefore suggested to use steroid–antibiotic pack for effective treatment of acute otitis externa.

Keywords
Otitis Externa; Ear Diseases; External Ear; Topical Administration

Otitis externa is an inflammatory condition of the skin of the external auditory canal that is characterized by generalized edema and erythema. It presents as diffuse or localized form of inflammation of external ear canal. It is a very common condition which is encountered in day to day outpatient services in the life of otolaryngologists. Disturbance of the lipid or acid balance of the ear predisposes an individual to Otitis externa.1 Edema caused as a result of inflammation distracts the periosteal lining of bony canal and cause extreme amount of pain.2 So treatment includes not only antibiotics and analgesics systemically but also aural packing for topical application. Its actions is both chemical and mechanical where by it has a splinting action pressing the soft tissues towards the non-edematous position. Traditionally these packs are impregnated with 10% Ichthammol glycerine. Ichthammol...
has antiseptic action while glycerine has its hygroscopic nature.\textsuperscript{3,4} Steroid–antibiotic combination cream can serve both functions. Steroid reduces edema by its action over capillary wall tone and antibiotic acts by controlling infection. Different studies about comparison of different antibiotics and steroid combinations have been done.\textsuperscript{5-8} many studies have shown topical antibiotic–steroid combination therapy is superior to antibiotic therapy alone for symptomatic control of otitis externa.\textsuperscript{9,10} In this study we aim to observe the effectiveness of treatment for relieving pain and edema by comparing steroid–antibiotic aural pack with antibiotic ear drop.

Materials and Methods

Patients of age more than 10 years and both genders presenting in OPD of Otolaryngology department of a tertiary care hospital from July 2021 to December 2021 and diagnosed to have acute otitis externa were included. The total number of patients with acute otitis externa needing aural packing was chosen to be 70. Out of them seven patients were lost to follow up and three had concomitant chronic otitis media with perforated tympanic membrane. These cases were excluded from the study. Hence, 60 patients were included in the study. Patients needing aural packing were randomized and alternatively antibiotic drops and steroid–antibiotic pack were kept. For steroid–antibiotic combination, we used a combination of betamethasone valerate and neomycin and for antibiotic drop we used neomycin. Before packing was carried out, pain was assessed. Since, all our patients were above 10 years of age, we used a ten point Numerical Rating Scale and the score was given by the patient subjectively. Similarly for scoring of edema we divided the external auditory canal in four quadrants and scoring was performed as per the percentage of the involvement of canal by the same otolaryngologist. Score of pain and edema on first visit was recorded. As per therapeutic guidelines all the patients were distributed the same systemic antibiotic and analgesic. Patients were called after 48 h for reassessment. On subsequent visits, they were called in the early morning without taking morning dose of analgesic so that the scoring performed at that time was not influenced by analgesics. Repacking was done if tragal tenderness and canal swelling persisted and asked for follow up again after another 48 hours. Assessment and repacking was done every 48 hours till tragal tenderness disappeared and edema subsided completely. We also assessed the need for second line antibiotic in both group of patients. Statistical analysis was done using “Z” test of mean to compare average number of score and visits in two different groups.

Results

The total number of patients included in the study was 60. Among them 30 (50%) were male and 30 (50%) were female. The age group ranged from 10 to 60 years (mean = 22.5) as shown in Table I. In 30 (50%) patients steroid-antibiotic pack was given whereas in another 30 (50%) patients antibiotic drops were given. The average duration of pain among included patient was 2.45 days (1–7 days) on presentation. Regarding the OPD follow up with antibiotic drop, 1 (3.3%) patient had maximum number of seven visits whereas in steroid–antibiotic group, maximum number of visit was five done by 12 (40%) patients (Table II). Regarding the status of pain there was statistically significant decrease in pain in steroid–antibiotic group as compared to antibiotic only group on third visit (\(P < 0.0001\)) and regarding status of edema, there was statistically significant decrease in edema on the third visit in steroid–antibiotic group as compared to antibiotic drops group (\(P < 0.05\)). The edema was completely subsided on fifth visit in steroid–antibiotic group whereas it was on sixth visit in the antibiotic drops only (Table III). So, the average number of visits in antibiotic drops was 5.5 days whereas in steroid–antibiotic pack it was 3.4 days and this difference was statistically significant (\(P < 0.05\)). Similarly in edema control, there was statistically significant difference between steroid–antibiotic as compared to antibiotic drops only (\(P < 0.05\)). In our study it is seen that out of 30 patients in the steroid antibiotic pack group only 8 (26.67%) patients needed second course of antibiotics after 7 days or 3\textsuperscript{rd} visit where as in the antibiotic drops group 19 (63.33%) patients needed second course of antibiotic after 1 week or 3\textsuperscript{rd} visit (Table IV).
Table I: Distribution of study subjects with respect to age and sex (N = 60) Male = 30; Female = 30

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-20</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>21-30</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>31-40</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>41-50</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>51-60</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>

Table II: Total number of visits till complete pain relief (N = 60)

<table>
<thead>
<tr>
<th>Number of Visits</th>
<th>Antibiotic and Steroid Pack (N = 30)</th>
<th>Antibiotic Only Drops (N = 30)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 (3.3%)</td>
<td>13 (43.3%)</td>
<td>12 (40%)</td>
</tr>
</tbody>
</table>

Table III: Number of visits till complete resolving of Edema (N = 60)

<table>
<thead>
<tr>
<th>Number of Visits</th>
<th>Antibiotic and Steroid Pack (N = 30)</th>
<th>Antibiotic Only Drops (N = 30)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 (10%)</td>
<td>13 (43.3%)</td>
<td>10 (33.3%)</td>
</tr>
</tbody>
</table>
Combined Steroid-Antibiotic Aural Pack versus Antibiotic Drop in Otitis Externa

Discussion

Acute otitis externa is a clinical condition which is mostly caused by bacteria and triggered by moisture. Pathogens are mostly *Staphylococcus aureus* and *Pseudomonas aeruginosa* also in about 10% of cases fungi mainly (*Aspergillus* sp.) are detected. The main aim of treatment in otitis externa is to control pain and edema. In this study we aimed to compare the effectiveness of steroid–antibiotic versus antibiotic drops. In the treatment of otitis externa ointments seems to be more effective than drops as the occlusive effect of an ointment may raise the humidity in the affected ear on one hand. On the other hand, due to lack of preservatives fewer hypersensitivity reactions are to be expected which causes allergic reactions in patients. Water free ointments are better in these cases. Also the drugs present in ear drops are potentially ototoxic, if used for a prolonged period in perforated tympanic membrane. So, aural packing impregnated with topical preparation is preferred to decrease both the pain as well as edema. However packs are more cumbersome and hence patients compliance to treatment is poor as compared to drops. Normally topical medications will not be able to penetrate an edematous canal wall a ear wick is preferred. Hence insertion of wick is undoubtedly a better topical therapy of otitis externa than instilling ear drops in the patients. Broad spectrum antibiotics are required for the treatment as external ear infections are caused by both gram positive as well as gram negative bacteria. Topical preparation is generally the treatment of choice as high concentration of active agents can be delivered to the site of infection with minimal side effects. Many bacterial (including pseudomonas) and fungal species are eradicated by the acidified environment of the ear canal hence topical medications with an acidic pH improves the therapeutic efficacy in cases of otitis externa. Studies using drops also showed significant improvement with steroid and antibiotic combination versus only antibiotic drop. There are few studies which compared the single topical agent with topical and oral antibiotic also. In our study we have used the same antibiotics and analgesics in all patients to avoid bias. In the study by Masood et al. used steroid pack and found statistically significant improvement in pain parameters when compared with 10% IG pack. In our study we found that steroid antibiotic combination pack had significant improvement of pain and reduction of edema as compared to only antibiotic drops. Similar study performed by Hornigold et al. using topical steroid ear drops failed to show any difference. Study by Bhatt et al. showed statistically significant decrease in pain and number of visits in steroid–antibiotic group as compared to 10% ichthammol glycerine pack. In our study, there was complete reduction in pain on the sixth visit in the steroid–antibiotic group whereas in the antibiotic drop group it was only on the seventh visit. We also compared the edema reduction also and it was found that there was complete reduction in edema on the fifth visit in the steroid–antibiotic group whereas it was on sixth visit in the antibiotic group, thereby showing less number of visits and thus early control of pain and edema.

<table>
<thead>
<tr>
<th>NUMBER OF PATIENTS REQUIRING SECOND DOSE OF ORAL ANTIBIOTICS</th>
<th>NOT REQUIRED</th>
<th>REQUIRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>STEROID ANTIBIOTIC PACK (N = 30)</td>
<td>22 (73.33%)</td>
<td>8 (26.67%)</td>
</tr>
<tr>
<td>ANTIBIOTIC DROPS (N = 30)</td>
<td>11 (36.67%)</td>
<td>19 (63.33%)</td>
</tr>
</tbody>
</table>
| **P VALUE**                                                   |              | 0.004 (<0.05)**

Table IV: Number of patients requiring second course of oral antibiotics (N = 60)
in steroid–antibiotic group. So we see our study, there was statistically significant reduction in pain, edema and reduction in number of visits in steroid–antibiotic group which is similar to study performed by Masood et al. and Bhatta et al but they use 10% ichthammol glycerin and we compared to antibiotic drop. Our study is in accordance with Abelardo et al17 where also it was seen that the steroid antibiotic combination was found to be more effective than only antibiotic combination for reduction of pain and edema in patients with acute otitis externa. In our study we found that the frequency of otitis externa is more common in young adults like that of study performed by Bhatt et al. but differs with Neher et al.19 It was also seen to be more common in female which differed from study performed by Bhatt el., may be because the habit of ear pricking using hair pin or bird feather or cloth is more in women. No side effects were noted in both the groups so far.

Conclusion

As control of pain and edema is more and hence the number of visits is significantly less in steroid–antibiotic packing group, so it is therefore suggested to use steroid–antibiotic pack for effective treatment of acute otitis externa.

References

7. Davies S, Guzman A. Ear drops containing steroids were better than acetic acid for otitis externa. *Evid Based Nurs.* 2004;7(2):43