EFFICACY OF TOPICAL KETOCONAZOLE IN MANAGEMENT OF OTOMYCOSIS AND ITS OUTCOME- A CLINICAL STUDY OF 100 CASES

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ABSTRACT

BACKGROUND

Otomycosis (OM) is one of the common conditions encountered in a general otolaryngology clinic. The disease process is a challenging and frustrating entity for both patients and otolaryngologists for it requires long-term treatment and recurrence rate remains. Otomycosis is called as otitis externa mycotica or mycotic external otitis. Otomycosis is the inflammation of the external auditory canal caused by the invasion of the fungus sometimes affecting middle ear. The fungus grows and affixes on the top most layers of the skin and the exotoxin produced by it acts as an irritant. As the fungus grows, the superficial layers of the epithelial cell are cast off and fill the external auditory canal with a mass of epithelial debris, which looks like a wet blotting paper or wet bread. It occurs because the protective lipid/acid balance of the ear is lost.

The aim of the study is to assess, treat and follow up of otomycosis patients. In this study, an effort is made to describe the efficacy of Ketoconazole (KC) 2% (ointment) local application when used in otomycosis patients after aural toilet.

MATERIAL AND METHODS

A total of 100 outpatients were studied during a period of 2 years from September 2011 to August 2013 in Gandhi Medical College/Hospital.

RESULTS

Otomycosis comprised 2.4% of all new OPD cases. Of all the ear cases, otomycosis was seen in 5.3% of cases. Infection of Aspergillus niger is more common followed by Aspergillus fumigatus and Candida albicans. Otomycosis is rarely associated with other diseases. Response of patients to local application of ketoconazole was good with no side effects. 60% of patients responded within 1 week and 40% more than one week.

CONCLUSION

Response to ketoconazole local application does not change with age, side of the ear and male or female gender. Candida albicans and Aspergillus fumigatus respond faster than Aspergillus niger.

KEYWORDS

OM- Otomycosis, KOH- Potassium Hydroxide, KC- Ketoconazole, AN- Aspergillus niger, AF- Aspergillus fumigatus, CA- Candida Albicans, DM- Diabetes Mellitus, CSOM- Chronic Suppurative Otitis Media.

because of the increasing number of immunocompromised patients.  

**Aims and Objectives**

1. To assess, treat and follow up of otomycosis patients.
2. In this study, an effort is made to describe the efficacy of ketoconazole 2% (ointment) local application when used in otomycosis patients after aural toilet.
3. Collection of debris from affected ear.
4. Debris sent for culture and KOH mount.
5. Aural toilet to the patient and local application of ketoconazole 2% ointment.
6. Follow up.

**MATERIALS AND METHODS**

This study was conducted in our ENT Department, Gandhi Medical College/Hospital, Hyderabad, for two years extending from September 2011 to August 2013. During this period, 47,716 new cases attended our department. Of these, 21,726 cases had ear complaints. Among these, 1164 cases were clinically diagnosed as otomycosis. During this period in all 100 patients were examined in detail.

Two sterile aural swabs were collected from the ear canal of each patient under sterile conditions. One swab was cultured on Sabouraud’s medium to which Chloromycetin and alcohol were added to suppress the growth of bacteria. The swabs were inoculated into the medium within 24 hours. The inoculated plates were cultured at 37 degrees. The other swab was used for direct mycological examination. For direct mycological examination, a small fragment of the debris collected on the sterile swab was mounted on a glass slide in a drop of 10% KOH and then the slide was warmed gently and examined under a microscope to verify the presence of fungus. Diagnosis can be confirmed by identifying fungal elements on a KOH preparation or by culture. The cultured plates were examined after 3 and 10 days of inoculation for fungal growth at the site of inoculation. This is necessary to exclude false positive results due to airborne contaminants. On Sabouraud’s medium, growth was visible in 48 to 72 hours in majority of cases. At this stage, when the growth was examined in KOH preparation showed only mycelium. On fourth day, swollen conidiophores, flask-shaped stigmata and spores were seen.

Aspergillus species are easily identified by the presence of typical conidiophores and candida species as budding yeasts and occasional pseudohyphae. None of the plates were discarded before a minimum period of 3 weeks to allow for the isolation of slowly developing fungus. The mass in the external canal is removed with suction, then antifungal agent is applied to the external auditory canal. The patient was examined every alternate day. In majority of cases, no recurrence of growth was seen after complete removal. The patient is advised to use the antifungal agent at least 7 days after complete cure of the disease.

**Inclusion Criteria**

All the patients suffering with only otomycosis were included in this study.

**Exclusion Criteria**

Patients using other antifungals (like clotrimazole) are not included in the study. Patients with other ear diseases are not included.

**RESULTS**

Otomycosis is a common clinical condition that we came across in ENT practice. The disease produce symptoms and signs, which interfere with regular work of patient, but it never endanger the life of person.

The total numbers of new OP cases treated in our hospital during the period September 2011 to August 2013 were 47,716. During this period, 21,726 ear cases were seen. Among the ear cases treated, 1164 were otomycosis.

<table>
<thead>
<tr>
<th>Duration</th>
<th>Total No. of ENT Cases</th>
<th>Total No. of Otomycosis</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 September to 2013 September</td>
<td>47716</td>
<td>1164</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

**Table 1**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Total No. of ENT Cases</th>
<th>Total No. of Otomycosis</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011 September to 2013 September</td>
<td>21726</td>
<td>1164</td>
<td>5.3%</td>
</tr>
</tbody>
</table>

**Table 2**

Thus, otomycosis comprised 2.4% of all the new cases and 5.3% of all the ear cases treated in our hospital.

**Habits**

Most of the patients give history of putting oil into the ears. Some gave history of putting match sticks, feathers, hair pins or cleaning the ears with cloth after head bath, thereby facilitating the growth of fungus.

**Fungus Isolated and Percentage**

On mycological analysis of the present cases showed the infection of the ear with Aspergillus niger is more common. The next common fungus is Aspergillus fumigatus, less commonly infection is caused by Candida albicans.

<table>
<thead>
<tr>
<th>Type of Fungus</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspergillus niger</td>
<td>58%</td>
</tr>
<tr>
<td>Aspergillus fumigatus</td>
<td>27%</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>15%</td>
</tr>
</tbody>
</table>

**Table 3**

![Figure 1 (a) Aspergillus, (b) Niger](image)
ASSOCIATED CONDITIONS
Otomycosis is rarely associated with other diseases. Otomycosis will not produce that disease, but a mere coexistence of both diseases.

<table>
<thead>
<tr>
<th>Only Otomycosis</th>
<th>Otomycosis + CSOM</th>
<th>Otomycosis + DM</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>82%</td>
<td>11%</td>
</tr>
</tbody>
</table>

The above table shows 82% cases have only otomycosis without associated diseases, while 11% cases are associated with CSOM, 7% cases are associated with Diabetes Mellitus (DM).

Treatment
The underlying principle is to keep the ear clean and dry, hence debris in the external auditory canal is removed with suction clearance and 2% ketoconazole cream is applied in the external auditory canal.

Treatment is continued till there is no formation of debris and until meatal wall is free of irritation in the present study of 100 cases.

<table>
<thead>
<tr>
<th>Number of Cases</th>
<th>Less than 1 Week</th>
<th>More than 1 Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>60</td>
<td>40</td>
</tr>
</tbody>
</table>

From the above table, it is clear that the duration of treatment for the disease to be cured varies from 5 to 10 days.

60% of cases responded within 1 week and 40% cases took more than 1 week to respond.

<table>
<thead>
<tr>
<th></th>
<th>Respond up to 7 Days</th>
<th>Respond &gt;7 Days</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>33 (59%)</td>
<td>23 (41%)</td>
<td>56</td>
</tr>
<tr>
<td>Female</td>
<td>27 (61.4%)</td>
<td>17 (38.6%)</td>
<td>44</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>40</td>
<td>100</td>
</tr>
</tbody>
</table>

DISCUSSION
1). Yan Edward, Dolly Irfandy Otorhinolaryngology Head and Neck Surgery Department, Medical Faculty of Andalas University/Dr. M. Djamil Hospital.

This study showed Aspergillus niger was isolated as an etiologic agent. The ointment form has some advantages than eardrop formula because it is remaining over ear canal skin for longer time. With the treatment of ear toilet and combination of Gentian violet, an improvement was observed. Ketoconazole and fluconazole have a broad-spectrum activity. Efficacy of ketoconazole reported 95-100% against Aspergillus species and Candida albicans. We can find 2% ketoconazole in the cream form. The ointment form has some advantages than eardrop formula, because it is remaining over ear canal skin for longer time. The
Otomycosis is fungal infection of the external ear and infrequently involves the middle ear. It presents with symptoms of itching, ear discharge, blocking sensation, and earache. The disease is predominantly unilateral with bilateral involvement more in the immunocompromised patients. Aspergillus species and Candida are the most commonly isolated fungi among the immunocompetent and immunocompromised patients, respectively. Otomycosis is successfully treated with topical antifungals.

5). Braz J. Otorhinolaryngol. (Impr.) vol.75 no.3 Sao Paulo May/June 2009, Otomycosis (85-89)- A retrospective study.

Usually, otomycosis can be diagnosed by means of a clinical exam. Nonetheless, a high rate of assumption is required and the most frequent symptom is pruritus and otalgia in the most advanced stages, otorrhea and/or hypacusis. However, in this study, the diagnosis was based on symptoms and laboratory workup and pruritus, otalgia, otorrhoea and/or hypacusis were the symptoms more frequently reported by the patients. These symptoms can be attributed to factors such as humidity and heat recorded in Joao Pessoa, as well as lack of cerumen by washing the external auditory canal and/or its manipulation reported by the patients without losing sight of the fact that most of the patients were of low socioeconomical status.

The occurrence of bilateral otomycosis is very low. Ho et al (2006) observed a bilateral involvement in 7% of the patients, while in this study, this figure reached 20%. The women (60%) in the present study were more often affected by otomycosis and such figures were closer to those observed by Zaror et al (1991) (65%). However, these data are in disagreement from the findings by Kaur et al (2000), Ho et al (2006) and Yenia et al (1990) who found 60%, 56% and 52.5%, respectively in males. Otomycosis was seen in patients aged between 2 and 66 years. Nonetheless, 50% of the cases were diagnosed in patients between 2 and 15 years of age. Occurrences of 70% to 41.1% were seen in patients within the age range of 16 to 30 years. Species of Aspergillus and Candida are the most commonly identified germs causing otomycosis. Studies found a greater prevalence of Aspergillus (A. niger, A. fumigatus, A. flavus, and/or Aspergillus spp.) as otomycosis agents. Jaiswal et al (1990) and Navarrete et al (2000) found 46% and 35% of Candida spp., respectively. In Sao Paulo, there were 75% of Aspergillus and 20% of Candida species identified. The data found in the present study were of 55% of isolates of Candida (albicans, C. parapsilosis and C. tropicalis) and 35% of Aspergillus (A. niger, A. flavus and A. fumigatus).

CONCLUSION
1. Otomycosis comprises 2.4% of the cases of the total ENT diseases and 5.3% of ear cases.
2. It is not a life-threatening disease and it is curable.
3. It is usually a unilateral disease. It appears right ear is commonly affected than left ear.
4. It is more common in males.
5. It is commonly seen in low socioeconomic groups and...
people living in unhygienic, unhealthy and overcrowded surroundings.

6. Aspergillus niger is the commonest fungi seen infecting the ear than other fungi.

7. The disease is observed in all age groups, but more common among younger age group (10-30 years).

8. The commonest symptom is itching and irritation of the ear in majority of cases.

9. It is not usually associated with other ear conditions except in few cases, which is mere coexistence.

10. Response of patients to ketoconazole cream, local application was good with no side effects. 60% of patients responded within 1 week and 40% more than 1 week. Earliest response was within 5 days and is seen in Candida albicans infection.

11. All the 100 cases were divided into two groups:

  Group I- Aspergillus niger.
  Group II- Others (Aspergillus fumigatus, Candida albicans).

**Following Parameters were Compared**

1. Response to drug and gender.
   a) % of fast responders in males- 59%.
   b) % of fast responders in females- 61.4%.
   c) The difference was statistically nil significant.

2. Response to drug and fungus.
   a) % of fast responders with Aspergillus niger infection- 51.7%.
   b) % of fast responders with others- 71.4%.
   c) This difference is statistically significant.

3. Response to drug and age.
   a) Mean age of fast responders- 32 years.
   b) Mean age of slow responders- 31 years.
   c) The difference is statistically nil significant.

**REFERENCES**


