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# OTOMYCOSIS;
## A CLINICOMYCOLOGICAL STUDY AND EFFICACY OF TINCTURE MERTHEOLATE IN IT'S TREATMENT

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**ABSTRACT...** **Objectives** : To determine the efficacy of tincture mertheolate in otomycosis. **Design**: An experimental study. **Setting**: Department of ENT Allama Iqbal Medical College/ Jinnah Hospital, Lahore. **Period:** From Dec. 2007 to April 2008. **Patients & Methods** A total of 60 patients of symptomatic otomycosis were investigated prospectively. Aural swabs were collected on first, 7th and 14th day and examined, by direct microscopy of external auditory canal and culture for fungi. Of these 60 patients found to be having pure fungal infection were taken up for mycological and therapeutic study. **Results** Fungi belonging to Aspergillus were isolated in 57(95%) patients of which Aspergillus niger was the commonest isolated in 34(56.6%) patients followed by Aspergillus flavus in 21(35%) and Aspergillus fumigates in 2(3.33). Candida species in 2(3.3%) and Mucor in 1(1.6%) of patients. The patients were of all age groups but majority were between 21 and 30 years and the male to female ratio was equal. No patient had fungal infection elsewhere in the body. The patients were called for regular follow-up for three weeks. In 30 cases tincture mertheolate was applied as topical antifungal agent after cleaning the external auditory canal, in 17 patient's clotrimazole and in rest of the 13 patients miconazole was used. On 7th day, only 8 (13.3%) patients grew fungi in culture. They became symptom free on 14th day and no fungal material could be seen on otoscopy, direct microscopy or culture. Tincture mertheolate was found to be most effective in these patients.

**Key words:** Otomycosis, Tincture Mertheolate, Clotrimazol Miconazole.

## INTRODUCTION

Otomycosis is a superficial sub acute or chronic fungal infection of the external auditory canal and tympanic membrane[1]. A discharging ear is more characteristic of bacterial infection but also seen in the mixed bacterial and fungal infections[2]. Most of the fungi responsible for this infection are saprophytic in nature[2]. Sometimes, there may be simple colonization of these nonpathogenic fungi[3]. Very rarely, the established pathogens are recovered from these patients[4]. The commonest causative agents belong to the genus Aspergillus. The fungi are usually the secondary invaders of the tissue rendered abnormal by prior bacterial infections, eczema, physical injury or excessive accumulation of cerumen[5].

The disease is worldwide in distribution. About 5 to 25% of all the cases of otitis externa are due to fungi. Similarly, Erkan et al reported 16.48%[7] and than et al found 54% incidence of otomycosis[8].

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There is an alarming increase in incidence due to wide spread use of broad spectrum antibiotics, steroids and other chemotherapeutic agents. It has been postulated that indiscriminate use of topical ear drops has increased the incidence of fungal infection of external auditory canal[9]. An immunocompromised host is more vulnerable to otomycosis. Patient suffering from diabetes mellitus, lymphoma, transplantation, patient receiving chemotherapy, radiotherapy and AIDS patients, are also at increased risk for potential complications from otomycosis[2].

Hormonal changes can flare up the infection as seen during menstruation[10]. Otomycosis is more prevalent in warm, humid climate than in arid or cold climates [11].Greater frequency in the tropics is probably due to change in the composition of cerumen that result from increased sweating and can actually promote the growth of fungi. It is more common in low socioeconomic strata with poor hygienic conditions[12-13]. No age group is immune to this disease[14], but it is commonly seen in the 2nd and 3rd decade of life.

Many topical anti-fungal agents are available for the treatment of otomycosis, but there is still need of better and broad spectrum antifungal agent since microscopy and culture for fungus identification are not routinely done in otomycosis patients.

Tincture Mertheolate, an odoreless compound is commonly used as a Keratolytic agent as 1-2% solution. It has got antifungal and antibacterial Properties. Its antifungal properties after topical application have not been widely studied. More over cost factor in developing country like Pakistan is also relatively important. Other topical antifungal agents like clotrimazole and miconazole are very expensive.

Therefore, this study was carried out to know the incidence, etiology and predisposing factors of otomycosis and to explore the role of tincture mertheolate as an antifungal agent and also to compare its efficacy with other commonly used topical antifungal agents.

## PATIENTS & METHODS

All the clinically suspected cases of otomycosis presenting to the ENT outpatient department of Allama Iqbal Medical College Jinnah Hospital, Lahore from December 2007 to April 2008 were investigated prospectively. Clinical details like name, age, gender, occupation, address, history, predisposing factors and chief complaints etc., were noted. The criteria for clinical diagnosis were noted. The criteria for clinical diagnosis were history and characteristic findings on otoscopic examination. The classical appearance looked like “blotting paper” or “wet newspaper”, covering the ear canal and sometimes the tympanic membrane also. Once the clinical diagnosis was established, debris from the external auditory canal were collected by means of sterile cotton swabs and processed in the department of microbiology for direct microscopy and fungal cultures.

Out of 100 cases of otomycosis, 35 patients having co-existent bacterial otitis externa and or otitis media, were not included in the study. Five cases negative for direct microscopy for fungi were also excluded from this study. So isolation of the causative fungal organisms by culture was conducted on 60 out of 100 patients.

The clinical diagnosis was confirmed by microscopy of the debris to see septate hyphae, psudohyphae or yeast cell in 10% potassium hydroxide. The specimens were cultured on two sets of Sabourad’s dextrose agar (SDA)with antibiotics chloramphenicol 50 micro gram/ml and gentamicin 20 micro gram/ml and were incubated at $25^0$C and $37^0$C, separately, over a period of three weeks and were checked every day during first week and twice a week during the next 2 weeks. The mycelia and yeast isolates were indentified by their colony characteristics and microscopic appearance in the Lactophenol Cotton blue (LCB) stained mounts.

All the affected ears were thoroughly cleaned manually by dry mopping. Patients were instructed not to allow water to enter into the ear. A comparative clinical trial of different topical agents was done using tincture mertheolate in 30, clotrimazole in 17 and miconazole in 13 patients . Irrespective of the culture, all the patients were instructed to put 4 drops of topical agents twice

daily. Weekly the aural swabs were collected on 1st day, 7th day and 14th day of visit of the patients.

## RESULTS

The patients belonged to all age groups but maximum were between 21 and 30 years, and majority of them were from low socioeconomic status with poor personal hygiene. The male and female ratio was equal. Sixteen (26.6%) of the male patients were wearing turbans . before developing symptoms, 33(55%) patients had used different types of ear drops like oil by 3(5.0%) mixtures of oil and some unknown herbal medicine by 11(18.3%) , antibiotics by 9(15%) . Wax solvent by 6(10.0%), antiseptics by 2(3.3%) or unknown types of ear drops by 2(3.3%).

All the patients had itching (100%) followed by aural fullness in 22(36.6%) ear discharge in 15(25%) , earache in 8(13.3%) , left ear was involved in 28(46.6%) patients , right ear in 26 (43.3%) and bilateral involvement was seen in 6(10%).

Wax was present in 3 patients (5%) and only 2 patients (3.3%) were diabetic. No patient had fungal infection elsewhere in the body. None had history of taking any systemic steroids, immunosuppressant drugs etc.

The different fungi isolated are shown in Table-I The commonest isolated was Aspergillus nigar in 34(56.6%) patients followed by Aspergillus flavus in 21(35%) and A.fumigatus in 2(3.3%). Candida tropicalis in 2(3.3%) and Mucor species in 1(1.6%) in the culture inoculated on the 1st day. Six (10%) patients had bilateral disease and same pathogens were isolated from both the ears i.e. A nigar in 4(66.6%) and a flavus in 2(33.3%) patients. The number of isolates decreased on the 7th day as A niger in 4(6.6%) A flavus in 3(5%) and rest 53(88.3%) patients revealed sterile cultures.

All the specimens were sterile on the 14th day of visit. On 7th day, culture was positive in 3(5%) patients using tincture mertheolate, 2(3.3%) using clotrimazol and 3(5%) in case of miconazole. No patient showed inteolerance or allergic reaction to any topical agents used. None of the patients returned with recurrence during follow up period of six months. Results obtained after using different anti fungal agents are shown in Table-II.

**Table-I. Fungi responsible for otomycosis before & after treatment**

| Fungi Isolated | 1st day | 7th days | 14 days |
|---|---|---|---|
| A-Niger | 34(56.6%) | 4(6.6%) | - |
| A-Flavus | 21(35%) | 3(5%) | - |
| A-Fungigtus | 2(3.3%) | - | - |
| Candida | 2(3.3%) | - | - |
| Mucor | 1(1.6%) | - | - |
| Sterile | - | 53(88.3%) | 60(100%) |

**Table-II. Results obtained after using different anti-fungal agents.**

| Antifungal Agent | No of positive cases | | |
|---|---|---|---|
| | 1st day | 7th days | 14 days |
| Tincture mrtheolate | 30(50%) | 3(5%) | - |
| Clotrimazole | 17(28%) | 2(3.3%) | - |
| Miconazole | 13(21.6%) | 3(5%) | - |

## DISCUSSION

Otitis externa, the infection of external auditory canal is worldwide in distribution. Though not a life threatening disease but occasionally can be very frustrating for both the patients and the treating physicians.

In the present study , we have found that fungal species belonging to Aspergillus genus were commonest (95%) cause of otomycosis , and A. niger was found to be the most frequent isolate (56.6%). however, the isolates of yeasts from these cases have been scanty. This study corresponds to the findings of other workers, carried out in different countries. Yehia et al, found that Aspergillus species were maximum (92%) and yeast isolates very few in otomycosis cases[3].

Similarly Paulise et al, found more infection with

Aspergillus specimen (79.5%) and Candida Species (17.0%).

This date is supported by the findings of Pahwa et al who have reported that all the species (56.3%) belonging to a niger group[9]. Pencillium was the 2nd most common agent in otomyosis study carried out by Erkan et al in Turkey[7]. But in our study no species of this genus was isolated.

Yehia et al, and Paulose et al, correlated the incidence of fungal infection with the gender. Yehia et al found more incidence in female (65.4%), mainly among the housewives, than in males[3].

Paulose et al found more incidence in male (58.5%) as compared to female (41.5%) in contrary to these findings . this study shows equal incidence in the male and females. However, age was found to influence the incidence of infection since maximum incidence was observed among age group 21-30 years i.e. most active phase of the life and this collaborates the findings of Paulose et al and yehia et al who have shown maximum incidence among the age group 20-30 years and 16-30 years , respectively. Children have been found less commonly affected[3,4].

This study reveals more incidence in the left ear 38(47.5%) than right ear 34(42.5%) and both ears 8(10%).

All patients of bilateral otomycosis had similar findings in both the ears and same findings in isolates and culture from each ear. Contrary to the Paulose et al who found more infection of right ear (46.0%) the left ear (41.1%) and in both ears (13%) Mugliston et al, found 11.0%in both ears[4,5].

The study reveals that most of the patient who reported were with poor hygienic condition and bad ear cleaning habits belonging to low socio-economic status in addition to this, 33 of them were using one or the other type of ear drops. Moreover it was observed that otomycosis is more common in males accustomed to wearing turbans, this factor along with prevailing human conditions on account of total occlusion of external auditory canal by the Tubran , could have result in otomycosis . Hence it can be concluded that once the integrity of ear canal was compromised or lost due to any of the reasons mentioned above the resultant exudates provided a humid atmosphere encouraging fungal growth.

In this study all patients had itching (100%), followed by aural fullness in 30 (50%) watery ear discharge in 16(26.6%), earache in 9(15%) whereas Pahwa et al reported itching in (78.0%) , aural fullness (35%) , ear discharge in (14%), deafness in (14%) tinnitus in (28%)[9] . However no patient complained of tinnitus in our study.

Many antifungal agent are used for the treatment of otomycosis mainly belonging to polyene antibiotics and the azole groups. Nystatin is particularly known to be effective against Candida species whereas econazole nitrate, a broad spectrum antifungal agent is effective against Aspergillus species Paulose et al, reported clotrimazole and tolnaftate as the better antigungal agents as compared to miconazole[10]. It also has been reported that fungal infection of external auditory canal can be treated with frequent aural hygiene and instillation of acetic acid and boric acid[11]. However no study regarding the efficacy of tincture mertheolate, as antifungal agent is available till date.

In the present study, the efficacy of tincture mertheolate, clotrimazole and miconazole was compared. On 7th day it was found that only 3(5%) patient treated with tincture mertheolate for fungal elements wheras 2 out of 17 patients (3.3%) and 3 out of 13 patients (5%) were positive for the fungi who were treated with clotrimazole and miconazole respectively.

Stern et al reported cure rate between 80% to 100 % with different antifungal agents[2]. In our study tincture mertheolate was found to be most effective followed by miconazole and clotrimazole in that order. If we consider the cost factor also, tincture mertheolate is the most economical of all the topical agents used in this study.

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