

## Treatment of otomycosis with one time application of 1% Clotrimazole cream: An observational study

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### Abstract:

**Introduction and aim:** Otomycosis, a superficial fungal infection, is usually associated with frequent exposure to water, and trauma to the external auditory canal. We aimed to establish that topical application of 1% clotrimazole cream only once is a cost-effective and efficient treatment option for otomycosis.

**Methods:** The external auditory canal of each patient was cleaned by suction under the microscope. Followed by filling with 1% clotrimazole cream using a green cannula and a 10 ml syringe. Patients were followed up a week later.

**Results:** Among the 93 patients enrolled in the study, at the first visit > 81% of patients reported itching or otalgia while 43% reported aural fullness. On examination, 92.5% of patients had fungal hyphae while 58.1% of patients had erythema. At follow-up 1-week later, >90% of patients reported relief from itching, otalgia and aural fullness and had no hyphae. Among patients with erythema, only 9% had not recovered from it completely at follow-up.

**Conclusion:** We report the topical application of 1% clotrimazole cream only once is a cost-effective and efficient treatment for otomycosis. By this method treatment failures of otomycosis due to a patient's unwillingness in applying topical drops routinely for a long time can be avoided

**Keywords:** Clotrimazole; ear; fungal infection; otomycosis; treatment

Running head: Clotrimazole in fungal infections of the ear

### Background

Otomycosis (or fungal otitis externa) is a superficial fungal infection of the external auditory canal. Frequent exposure to water, and trauma to the external auditory canal are some factors associated with the development of otomycosis [1-3]. Fungal species most frequently associated with the development of otomycosis are *Aspergillus* and *Candida* while

Penicillium, Mucor, and Rhizopus are less frequently seen [2-4]. The commonest finding is a black, grey, green, yellow or white discharge with debris that is often said to resemble a wet newspaper. Occasionally, debris is seen with visible fungal hyphae. Although usually not life-threatening, but otomycosis can cause persistent aggravating symptoms such as itching, pain, or fullness of the ear, as well as hearing loss, discharge, and tinnitus [2] Treatment of otomycosis consists of toilet and removal of the debris followed by application of topical antifungal drops (e.g. clotrimazole or flumethasone with clioquinol) for a period of at least 3 weeks [5] Complications may be seen otomycosis but are easily avoided with the use of topical antifungal agents.<sup>6</sup> In the present study we used 1% clotrimazole cream applied only once for the treatment of otomycosis and studied the success of this single-visit application. Our study aimed to establish that topical application of 1% clotrimazole cream only once is a cost-effective and efficient treatment option for otomycosis.

## **MATERIALS AND METHODS**

The study was conducted among patients who presented to the outpatient department of ENT & HNS, SMHS, Srinagar with itching/pain of ear with or without aural fullness and tinnitus and diagnosed with otomycosis. After taking consent in the local language, a total of 93 patients were enrolled in the study.

### **Inclusion criteria -**

- Patients diagnosed with otomycosis based on the history of symptoms and otoscopic findings of fungal hyphae.

### **Exclusion criteria -**

- Patients with concurrent immune suppression, such as in acquired immune deficiency syndrome, after using cytotoxic or immunosuppressive drugs.
- Patients with a concurrent bacterial infection.
- Patients who did not give their consent.

For each patient selected in the study, the external auditory canal was cleaned by suction under the microscope. The external auditory canal was then filled with 1% clotrimazole cream using green cannula and a 10 ml syringe. Patients were followed up a week later.

### Statistical analysis

The data was presented as numbers and percentages in the categorical variables. All the data were analysed using SPSS software.

### RESULTS

Among the 93 patients enrolled in the study, 52(56%) were males and 41(44%) patients were females. Majority of the patients (40%) belonged to the age group of 31 - 50 years. At the first visit 90.3% of patients reported itching, 81.7% reported otalgia while 43% of patients reported aural fullness. On examination, 92.5% of patients had fungal hyphae while 58.1% of patients had erythema at the time of first visit. At follow-up 1 week later, out of 84 patients with itching at first visit 91% of patients reported relief from itching while only 9% of patients reported no relief or minimal relief from itching, out of 76 patients with otalgia at first visit 92% of patients reported relief from otalgia while only 8% of patients reported no relief or minimal relief from otalgia and out of 40 patients with aural fullness at first visit 90% reported relief aural fullness while only 10% reported no relief or minimal relief from aural fullness. Out of 86 patients with fungal hyphae on examination at first visit, 91% had no hyphae while only 9% had residual hyphae/debris on examination at follow up 1 week later. Out of 54 patients with erythema on examination at first visit, 91% had no erythema while only 9% had erythema on examination at follow-up 1 week later.

**Table 1: Sex distribution and age distribution of the subjects**

<b>Demographic feature</b>	<b>No. Of patients (N=93)</b>
<b>Gender</b>	
Males	52
Females	41
<b>Age categories (years)</b>	
<30	20
31 - 50	37
51 - 70	25
>70	11

**Table 2: Clinical features at first visit of the patient.**

Symptom	No. Of patients
Itching	84
Otalgia	76
Aural fullness	40
<b>Sign</b>	
Fungal hyphae	86
Erythema	54

**Table 4 : Clinical features of the patients at the follow up**

Symptom	No. Of patients
Itching	8
Otalgia	6
Aural fullness	4
<b>Sign</b>	
Fungal hyphae	8
Erythema	5

## DISCUSSION

Otomycosis presents many challenges, both for patients and for ENT specialists, and may recur despite the concern for long-term treatment and follow-up [7, 8]. The first step in the treatment of otomycosis is the elimination of predisposing factors. Then, local cleaning and administration of an antifungal agent (local or systemic) are recommended [6, 9, 10]. Sanders suggested the treatment of fungal otitis externa with cleansing followed by the application of acidifying drops and in more resistant cases 1% clotrimazole solution [11] Similarly FE Lucente [12] suggested treatment of otomycosis with cleansing with topical application of antifungal drugs. In another study Vennewald and Klemm [13] reported that after local cleaning, treatment with a topical antifungal is sufficient for non-invasive fungal otitis externa, whereas oral antifungal agents should be reserved treat fungal malignant otitis externa, which can be complicated by meningitis and mastoiditis. Munguia and Daniel [14] in their study found that the most effective agents for treating otomycosis are the azole antifungals. In this study, we used topical 1% clotrimazole cream to fill the external auditory canal (following initial cleaning under the microscope) to the patients diagnosed with otomycosis. Clotrimazole is a broad-spectrum imidazole antimycotic agent. Clotrimazole acts

by inhibiting the synthesis of ergosterol, a major component of the cell membranes of yeast and fungi. Clotrimazole replaces lanosterol which is a precursor for the fungal cytochrome P450 enzyme lanosterol-14-demethylase and alters the permeability of fungal cell walls [15]. This study showed that packing the external auditory canal with 1% clotrimazole cream applied only once is effective and may be used for the treatment of otomycosis. It seems that still larger sample size and comprehensive studies are needed to clarify the sensitivity of otomycosis to topical 1% clotrimazole cream applied only once. This treatment is more effective than prescribing topical drops for long durations.

## CONCLUSION

According to the results of our study topical application of 1% clotrimazole cream only once is a cost-effective and efficient treatment option for otomycosis. By this method treatment failures of otomycosis due to patient's unwillingness in applying topical drops routinely for a long period of time can be avoided

**Ethical clearance** - Ethics Committee, GMC Srinagar

**Conflict of interest** - None declared.

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**Data availability:** all the data is presented in the manuscript.

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