



# Single Topical Application of 1% Clotrimazole Cream in Otomycosis

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## Abstract

**Aim:** To assess the clinical improvement after single dose topical application of 1% clotrimazole cream in otomycosis and follow up for recurrence at the end of first and the third month. **Materials and Methods:** A prospective observational study was carried out at Government Medical college hospital. Patients with KOH diagnosed fungal infection of external auditory canal were included in the study. After obtaining informed written consent from the participating patients, a detail clinical history was taken. Single topical application of 1% clotrimazole cream in otomycosis. The fungal debris was removed with the help of suction aspiration and dry mopping. A single topical application of 1% clotrimazole cream was applied under all aseptic precautions. On the 3rd day the applied cream was cleaned with help of suction under ear microscope. Patients were advised to follow up after one month and three months. During each follow up patients were assessed clinically and examined for residual fungal debris. **Result:** Otomycosis was seen predominantly in middle aged females, housewives and laborers by occupation. Earache was most common symptom seen in 65.2%. Unilateral involvement was seen in 89.3% cases. The most common organism isolated in otomycosis was *Aspergillus niger*. At the end of one month of treatment with a single dose of 1% clotrimazole cream, 102 (91.0%) patients were recovered and 10 (9.0%) patients were with persistence or recurrence of the symptoms. At the end of third month, the recovery rate was 84.8% and recurrence rate was 6.3%. **Conclusion:** Single topical application of 1% clotrimazole cream is effective in treating otomycosis.

**Keywords** External ear · Fungal infection · Otomycosis · Recurrence rate · *Aspergillus*.

## Introduction

Otomycosis is caused by saprophytic fungi. It is known to contribute 30% of ear infections globally [1]. Though the prevalence varies according to geographical regions, it is widely present in the tropics and also in the subtropical areas.

The clinical manifestations of otomycosis include pruritus, scaling, discharge, and pain [2, 3]. It is known to involve individuals in different age groups ranging from infancy to

old age [4]. The common causative organisms include saprophytic fungi (70%) including *Aspergillus* spp. and *Fusarium* spp., yeasts (20–25%) and dermatophytes (5%) [5]. The majority of the cases report *Aspergillus niger* saprophytes and *Candida albicans* yeasts as the leading causative organisms in cases of otomycosis [6].

Its diagnosis is based on the isolation of fungi mycelium, pseudomycelium and yeasts from ear discharge, wax or the scrapes from the external auditory canal. The perfect investigation for the diagnosis of otomycosis must be a triple confirmation such as positive KOH smear, positive culture and clinical examination [7]. The specificity for culture in diagnosing otomycosis is 84.6% and the sensitivity is 87.5% [8].

The primary line of treatment depends on the type of fungus isolated and includes commonly used, antifungal agents. More recently, azoles in the form of topical ketoconazole, miconazole and clotrimazole have become the mainstay of treatment options for otomycosis. Single-dose topical clotrimazole cream has been largely used to treat otomycosis with variable success rates. Among topical antifungals, single dose topical clotrimazole cream appears to be a good

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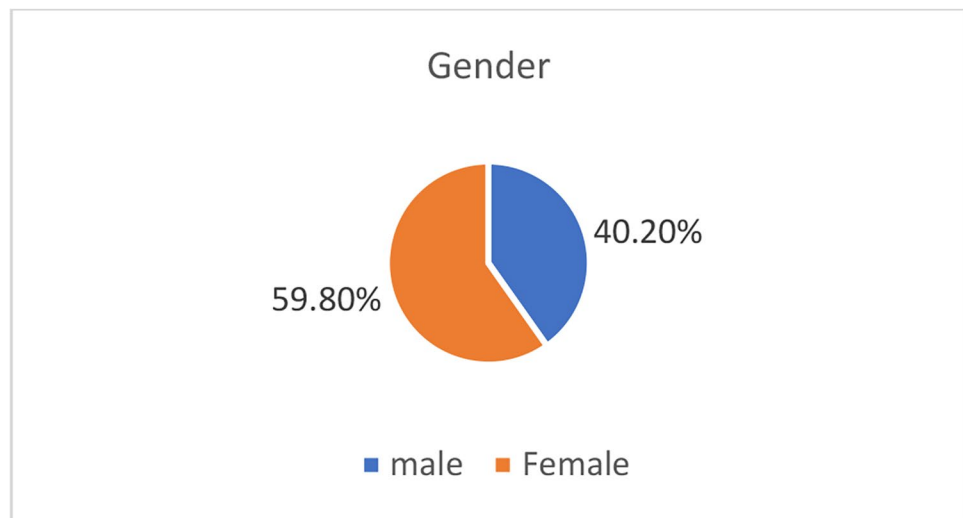
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**Fig. 1** Sex distribution in study group



treatment option [9, 10]. Usually, otomycosis is treated by antifungal drops but to prevent recurrence it should be used for at least three weeks. Patients with otomycosis are not willing for a longer duration of treatment. Additionally, it is convenient to the patient and does not require multiple visits to the hospital.

The purpose of this study is to evaluate the antifungal efficacy of a single application of topical clotrimazole cream for providing symptomatic relief and to assess its effectiveness in the prevention of recurrence of otomycosis.

## Materials and Methods

A prospective observational study was carried out from 1 to 2020 to 30 July 2021 at the Government Medical college hospital. The study was approved by the Institutional Ethical Committee. Patients in 18 to 60 yrs age group with KOH diagnosed fungal infection of the external auditory canal were included in the study. Patients with a history of tympanic membrane perforation, vertigo, giddiness, immunodeficiency and known history of allergy to clotrimazole cream were excluded. After obtaining informed written consent from the participating patients, a detailed clinical history was taken.

A clinical diagnosis of otomycosis was made after visualization of cotton woolly mass, black mycological plug and soft debris in the external auditory canal. Specimen of the aural swab (fungal debris) was collected with a sterile cotton swab. Each sample was divided in to two parts. One part was directly examined under a microscope with 10% KOH whereas the second part was mounted on Sabourad dextrose agar with 0.05 mg/ml of chloramphenicol. After confirmed by fungal culture, patients were thoroughly examined under an ear microscope for fungal debris.

The fungal debris was removed with the help of suction aspiration and dry mopping. A single topical application of 1% clotrimazole cream was applied under all aseptic precautions. Any irritation, redness and swelling in the external auditory canal after application of cream were noted. On the 3rd day, the applied cream was cleaned with help of suction under an ear microscope. Patients were advised to follow up after one month and three months. During each follow-up visit the patients were evaluated for resolution of symptoms. Patients were examined under ear microscope.

Successful treatment outcome was defined as resolution of all symptoms as well as the absence of fungal infection on otoscopic and microscopic examination.

## Results

The present study 112 otomycosis patients were included.

### Age

In the present study, 87 (77.6%) of the patients were below the age of 50 years, 26 (23.3%) cases were among the age group of 31–40 years, 25 (22.3%) were among the age group of 21–30 years and 24 (21.4%) cases were among the age group of  $\leq 20$  years. The mean age of the study participants was 36.1 years.

### Gender

In the present study, 67 (59.8%) were females and 45 (40.2%) were males. (Fig. 1)

**Table 1** Distribution in study group as per presenting complaints

Presenting Complaints	Number	Percentage (%)
Pain in right ear	70	62.5
Itching in left ear	32	28.6
Aural fullness in right ear	32	28.6
Aural fullness in left ear	27	24.1
Itching in right ear	25	22.3
Pain in left ear	23	20.5
Itching in both ear	9	8
Aural fullness in both ear	8	7.1
Pain in both ears	8	7.1
Decreased hearing in in right ear	7	6.3

**Table 2** Distribution in study group according to isolated organisms

Isolated organisms	Number	Percentage
Aspergillus niger	52	46.4
Candida albicans	36	32.1
Aspergillus fumigatus	17	15.2
Aspergillus flavus	7	6.3
Total	112	100

### Occupation

In the present study, 49 (44%) were housewife, 23 (20%) were labourer, 18 (16%) were students, 13(12%) were businessmen and 9 (8%) were farmers by occupation.

### Presenting Complaints

In the present study, the commonest presenting complaint was pain in the right ear in 70 (65.2%) patients (Table 1).

### Wax

In the present study, only 6 (5.4%) patients showed the presence of wax along with fungal infection, 106 (94.60%) showed only of fungal debris in the external ear canal on otoscopic examination.

### Laterality Distribution

In the present study, unilateral involvement of otomycosis was seen in 100 (89.3%) patients. Among them 61 (54.5%) patients were of right side and 39 (34.8%) patients were of left side. Bilateral involvement was seen in 12 (10.7%) of them.

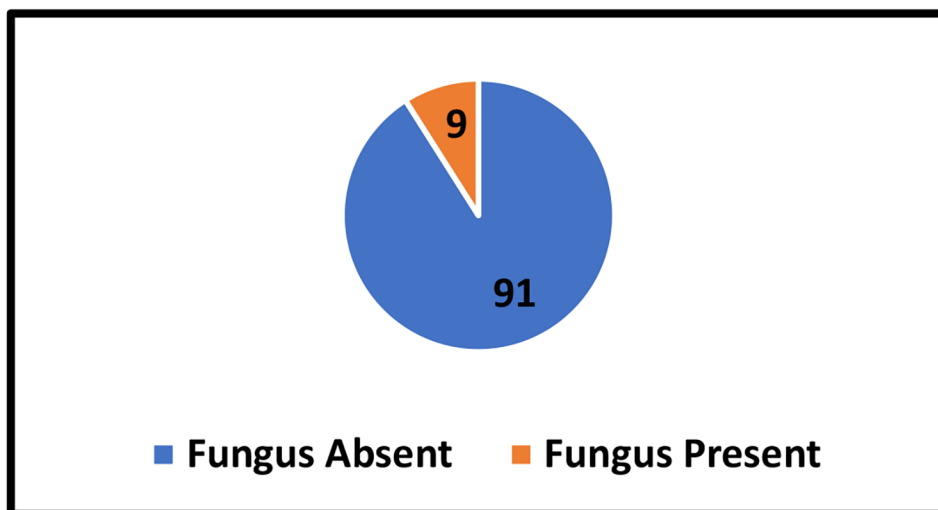
### Fungal Distribution

In the present study, the most common organism isolated was Aspergillus niger, seen in 52 (46.4%), candida albicans in 36 (32.1%), Aspergillus fumigatus in 17 (15.2%) and Aspergillus flavus in 7 (6.3) patients (Table 2).

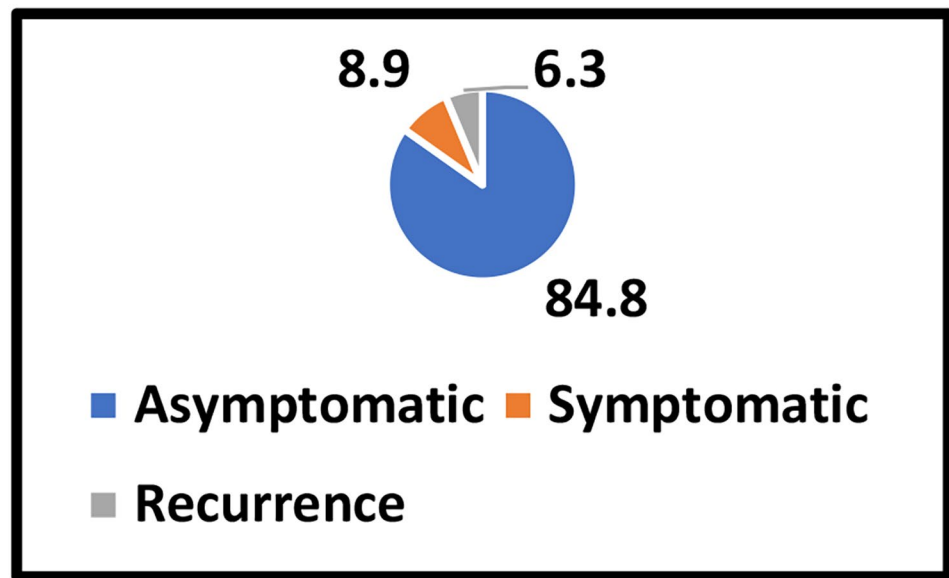
### Symptoms at the end of One Month

In the present study, at the end of one month, patients with persistent symptoms were 10 (9.0%), patients without fungal debris and asymptomatic were 102 (91.0%) (Fig. 2).

**Fig. 2** Distribution of cases according to symptoms at the end of one month



**Fig. 3** Distribution of cases according to symptoms at the end of three months



### Symptoms at the end of Three Months

In the present study, at the end of three months, 10 (8.9%) patients were symptomatic and 95 (84.8%) patients were asymptomatic. Hence the recurrence rate at the end of the third months of treatment was 6.3% (Fig. 3).

### Discussion

Otomycosis is worldwide in distribution with prevalence ranging from 9 to 30% among the patients presenting with signs and symptoms of otitis externa and discharging ear. [1] High incidence can be attributed to a high degree of humidity, heat and a large proportion of the population doing outdoor labour and low socioeconomic status. Other contributing factors might be habits such as cleaning the ear with a match stick, contamination by fingertips and installation of oil in the ear [11].

### Age

Kaur R et al. (2000) and Zaror L et al. (1991) explained in their study that Otomycosis usually occur more frequently in adults and less in children [11].

According to the study by Mgbe R et al. [12], 33.8% of the otomycosis patients were in the 21–30 years age group.

According to Ozcan K.M et al., otomycosis was seen commonly among the 31–60 Year age group, probably due to religious practice of head coverings as a predisposing factor [13]. Studies conducted by Kiakojuri K et al. (2019),

Gharaghani M et al. (2015), Anwar K, and Gohar MS (2014) also showed that incidence of otomycosis was prevalent in the age group 20–40 years [14],[15],[16].

In the present study, fungal infection was more common in the middle age group. 75 (66.7%) cases in the present study were among the 18–40 years age group. This could be explained by the fact that this age group is the active age group in the outdoor environment leads to more exposure to several predisposing factors for otomycosis such as tropical climates with high humidity and high temperatures [13, 17].

### Gender

According to Yehia MM et al. (1990) study, the incidence of otomycosis was found more among females. [18] Ozcan K M et al. study showed a higher incidence of otomycosis in females (80.5%) [13]. A study conducted by Pradhan B et al. (2003) shows that otomycosis occurs more commonly in females [19]. According to Ho T et al. (2006) study, females were more often affected by otomycosis [2]. Female preponderance was observed in studies conducted by Aneja K R et al. (2010) [20] and Fasuola J et al. (2008) [21].

In the present study, 67 (59.8%) females and 45 (40.2%) males were with otomycosis which indicates female predominance. Housewives and fields workers, working in damp, cold conditions in houses and fields lead to exposure to dust and deposition of fungal spores. The unhygienic practice of self-cleaning the ear canal with dirty fingers, hair pins and match sticks hastens the deeper invasion of the fungus.

## Occupation

A study conducted by Yehia MM et al. showed that housewives frequently clean and sweep the floor of their houses [18] and the resulting dust containing fungal spores mixed with the air of the atmosphere to act as predisposing agent for the initiation of the disease.

In the present study, 44% of cases were Housewives living in villages and towns with the cold damp working atmosphere in kaccha houses. The next group of highest cases was labourers (20%) in environments like machinery and moving parts of machines which generate heat and prepare the ground for ideal hot humid and dusty conditions for initiation of the disease. Students who play sports were exposed to a similar environment.

## Presenting Complaints

According to studies conducted by Mohanty JC et al. (1999), 94.4% of patients had pain as the presenting complaint and 92.5% of patients had itching [22]. Also, studies by Nwabuisi C, Ologe FE and Kombilla M et al. showed otalgia and pruritis as the most common symptoms [23, 24]. In the study carried out by Pradhan B et al. (2003), the predominant complaints were itching and ear discharge, followed by earache, ear blockage, hearing loss and tinnitus [19]. In a study conducted by Ho T et al. (2006), otalgia was reported as the major symptom followed by otorrhoea and hearing loss [2]. Studies conducted by Jimenez-Garcia L et al., (2019) [25] also described pruritus, diminished hearing and discharge as the major clinical symptoms in cases of otomycosis. The fungal hyphae cause irritation of the ear canal leading to itching and fullness in the ear. The mechanical blockade caused by the fungal hyphae as well as the debris and wax accumulated in the ear canal in the case of otomycosis was the cause of hearing loss. Nevertheless, typically, these symptoms are also observed with a few differences in other kinds of bacterial infections of the ear as reported in a study by Bineshian F et al. (2006) [26].

In the present study, pain in the ear was commonest presenting complaint. 83% of patients were presented with pain in the ear. 52.7% of patients were presented with aural fullness. 50.9% of patients were presented with itching and 6.3% of patients were presented with decreased hearing.

## Wax

A study conducted by Gutierrez PH et al. (2005) and Oliveri S et al. (1984) showed that Antimycotic and bacteriostatic properties of secretions of the apocrine and sebaceous

glands (cerumen) protect the healthy ear from invading organisms and fungal infections occur after the damage of these glands by bacteria or some other agents. Therefore the absence of cerumen increases the chances of fungal and bacterial infections [27]. According to a study conducted by Kaur R et al. (2000), presence of excessive cerumen in patients with poor personal hygiene favours the germination of spores and conidia [11].

Scratching of the ear canal in order to remove the cerumen and to get relief from itching can cause minor trauma in the skin of EAC which may get deposited by fungal spores that later on germination can cause fungal infection.

In the present study, only 6 (5.4%) patients showed the presence of wax in the external auditory canal on otoscopic examination whereas, all the cases showed the presence of debris in the external ear canal on otoscopic examination. In the present study, the presence of cerumen in the ear canal was seen in 5.4% which was similar to other studies conducted by Adegbiiji, W A, et al. (2014) [28] and Czechowicz JA, et al. (2010) [29].

## Laterality Distribution

Otomycosis is commonly unilateral disease. A study carried out by Anwar et al. (2014), was found that unilateral involvement was commonly seen in otomycosis [30]. According to a study conducted by Nowrozi H et al. (2014), otomycosis was mainly reported as unilateral in immunocompetent patients [31]. A study conducted by Yehia MM et al. (1990) and Aneja KR et al. (2010) reported that a major chunk of unilateral ear involvement with the right side was more common possibly because it was on side of the dominant hand [18],[20] However, Prasad SC et al. (2014) mentioned that 5% of cases were bilateral [32].

In the present study, unilateral involvement of otomycosis was seen in 100 (89.3%) patients. Among them, 61 (54.5%) patients were on the right side and 39 (34.8.0%) patients were on the left side. Bilateral involvement was seen in 12 (10.7%) of them.

## Fungal Distribution

Though otomycosis is multifactorial with several etiological agents responsible for it, the commonest one being fungi. Among the fungi causing otomycosis, *Aspergillus niger* and *Candida albicans* are by far the most common offenders [6]. Aneja KR et al. (2010) observed that *Aspergillus* was a ubiquitous mould identified as the causative organism in various infections and diseases. *Aspergillus* can be found in the form of minute conidia that can be easily propelled into

the air with dust and other particles, making this its primary route of transmission [20]. Beany and Broughton (1967) found that *Aspergillus* species produce antibiotics, which eliminate bacterial competitors. This could be attributed to the fact that *Aspergillus* more common than candida in the isolates [33].

The studies conducted by Chander J et al. (1996), Mohanty JC et al. (1999), and Yassin A et al. (1998) showed that, *Aspergillus spp* were the most common fungi isolated, followed by *C albicans* [22]. In the present study, *Aspergillus niger* was the commonest causative organism observed in 52 patients (46.4%) and *Candida albicans* in 36 patients (32.1%) which is similar to the above studies. *Aspergillus fumigatus* was seen in 17 patients (15.2%) and *Aspergillus flavus* was seen in seven patients (6.3%).

### Treatment of Otomycosis with 1% Topical Clotrimazole Cream

As per Malik AA et al. (2012) and Ologe FE et al. (2002), clotrimazole is the most widely used topical azole [34, 35].

Regarding antifungals, the imidazole group showed an 80% resolution rate in the initial application with a scant probability of recurrence according to the Malik study [34]. According to Jadhav VJ et al. (2003), Malik AA et al. (2012), and Ahmed Z et al. (2010), clotrimazole was considered free of ototoxic effects [34, 36, 37]. Studies by Munguía R (2008), Jadhav VJ et al. (2003), Khan F et al. (2013) and Vega-Nava CT et al. (2015) reported effectiveness rates of clotrimazole between 50–100% [38–40].

According to Dundar R and Iynen I, the efficacy of single dose clotrimazole 1% was good for the treatment of otomycosis [41]. Jackman A also states Clotrimazole as the most popular and effective treatment [42].

In the present study, at the end of the first month after treatment with a single dose of 1% clotrimazole cream, 102 patients (91.0%) and at the end of 3 months 95 patients (84.8%) were relieved of their symptoms. The present study showed significant relief of symptoms with a single dose of 1% clotrimazole cream in otomycosis at the end of first and third months of follow-up.

In the present study, 84.8% of patients had a significant reduction of symptoms at the end of the first month. This is in accordance with a study conducted by Paulose KO, et al. (1989) who found improvement in the range of 89% by using clotrimazole [43]. The study conducted by Jia X et al. (2012), Anwar K (2014), Nemati S et al. (2014) and Naqi S et al. (2014) reported that a treatment failure rate between 9–17% [44–47]. In the present study, the recurrence rate was 6.3% at the end of 3 months of follow up with a single dose of 1% clotrimazole cream application. This failure can

be attributed to factors such as resistance of the causative organism, comorbidities, non-compliance to therapeutic course, genetic variations, surgery or use of hearing aids etc. A study by Kazemi et al. (2015) reported lower relapse rates with a recurrence observed in only 3.1% [48]. This may be due to the factors such as younger populations in studies and a lack of other predisposing factors in study populations. Higher otomycosis relapse rates of 48% were also reported by Anwar K (2014) studies [45]. Majority of the relapses were observed in those with concomitant inflammation and ulceration of the ear canal and tympanum. Therefore, 1% clotrimazole cream for a single local application is highly effective in not only treating otomycosis but is also effective in the prevention of relapse.

### Conclusion

A single dose topical application of 1% clotrimazole cream in patients of otomycosis saves both time and cost, and is effective in treating otomycosis.

### Limitations of the Study

Long term follows up and large number of study population was not possible due to Covid 19 pandemic.

**Supplementary Information** The online version contains supplementary material available at <https://doi.org/10.1007/s12070-022-03206-x>.

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### Declarations

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with ethical standards of the institutional ethical committee as per ICMR guidelines and University protocol by letter. No. GMCM/IEC-C 30 /2019 and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

**Informed consent** Informed consent was obtained from all individual participants included in the study.

**Consent for Publication of data** Informed written consent for publication of data was obtained from all individual participants included in the study.

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