

A COMPARATIVE STUDY BETWEEN CLOTRIMAZOLE DROPS AND ACETIC ACID WASH AS A TREATMENT FOR OTOMYCOSIS

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ABSTRACT

Background: Otomycosis is infection caused by fungi in the external auditory canal and is frequently diagnosed by clinical presentation. There was no common agent in treating otomycosis even though many studies were conducted to conclude the effective antifungal agent. **Aim:** This study was conducted to compare rate of improvement of otomycosis treatment with topical medications such as clotrimazole and acetic acid wash. **Materials and Methods:** This study was conducted in 100 patients during the period of June 2022 to June 2023. After receiving the ethical committee approval, this study was initiated. All the patients were included in the study who were referred to ENT Department Malla Reddy Institute of Medical Sciences Hyderabad. A group (Group A) of patients were treated after cleaning the ear canal with suction with 8 drops of 1% clotrimazole (ear drop) each 8 h. Other group (Group B) of patients were treated with acetic acid wash. **Results:**

Males (56) were more than females (44) in the present study. *Aspergillus* Spp were observed in 60 patients and *Candida* Spp were observed in 40 patients. Recurrence after 14 days in group B was 4% and in group A was 6%. Between two groups, no significant difference was observed in rate of recurrence ($P=0.71$). Recurrence after 21 days in group B was 8% and in group A was 6%. Between two groups, no significant difference was observed in rate of recurrence ($P=0.76$). Duration of treatment in group-B is significant when compared to others. **Conclusion:** Both clotrimazole and acetic acid have shown similar therapeutic efficacy in otomycosis treatment however, acetic acid is better suggested to be opted due to its significantly shorter duration of treatment and to reduce the indiscriminate use of antibiotics.

Keywords: Otomycosis, Antifungal agents.

INTRODUCTION:

Otomycosis is the infection of external auditory canal and is common superficial fungal infection. Etiologic agent presence mainly depends on the geographical climatic conditions such as hot and moist climates and predisposing factors such as humidity and temperature¹. Otomycosis has been observed in 30–90% of otitis external cases. It is more common in adults than in kids and in females than in males^{2,3}. The causative organism of otomycosis is wide range of fungi. *Aspergillus* and *Candida* genera were the major causative organisms for otomycosis. Dermatophytes were the next causative organism for otomycosis. The other saprophytic fungi in rare cases were *Fusarium* spp., *Penicillium* spp., *Mucor* spp. And *Geotrichum* spp. Were isolated from otitis discharge^{4,5}.

The associated several risk factors such as traumatic inoculation of sharp objects, cerumen presence, dry and dusty environment, humidity, moisture, the pH of the external ear, swimming, genetic factors and surgery of ear. Despite the need for long term treatment process and treatment of otomycosis come with challenges both for patients and physicians and relapse possibility⁶. Debridement consistently of fungal agents from the ear canal combined with local and systemic antifungal application were the treatment recommendations. Clotrimazole, bifonazole, miconazole, and tolnaftate were the most common anti-fungals used currently for otomycosis, though the exact proper treatment has still remained unknown. Anti-fungals like clotrimazole or nystatin are efficient against *Candida*, but *Aspergillus* is not covered in treatment.⁷

The selection of treatment for otomycosis related to the discernment of fungal species and its antifungal susceptibility is complex. The appropriate treatment regimen should be selected because of increased prevalence of resistance of drug among *Aspergillus* spp. As an otomycosis agent. Excessive organism growth in the external canal ear is caused by overdose of antifungals. Various

in-vivo and in-vitro studies have been conducted on many antifungal agents as an alternative to conventional therapeutics. With uncertain effectiveness rate, various other agents have been used. No study has been conducted to reveal the effect of acetic acid wash in treatment of otomycosis. Acetic acid is usually used to decrease the ear canal inflammation. This study was conducted to compare rate of improvement of otomycosis treatment with topical medications such as clotrimazole and acetic acid wash.

MATERIALS AND METHODS:

This study was conducted in 100 patients during the period of June 2022 to June 2023. After receiving the ethical committee approval, this study was initiated. All the patients were included in the study who were referred to ENT Department Malla Reddy Institute of Medical Sciences Hyderabad. The patients who had complaints of inflammatory puritis, deafness, pain, itching and persistent discharge were included in the study. Patients who had undergone ear surgery, antibiotic therapy, otitis media with restriction of external ear canal, chronic mucus from ear, and who were on corticosteroids and external ear anomaly were excluded from the study. All the research targets were explained to all patients and an informed consent form was taken from all patients before their enrollment into study. After obtaining the informed consent, recording of their age, gender etc were obtained from all patients involved.

A microscopic examination was used to identify otomycosis based on the observation of fungal components in portions of the samples that were generated using the KOH procedure. Additional samples were grown on two Sabouraud Dextrose Agar plates with chloramphenicol and they were incubated for two weeks at 25°C and 37°C. Additionally, yeasts were detected with production of germ tubes in serum and formation of chlamydospores on corn meal agar mixed with tween 80 (Merck, Germany & Sigma-Aldrich, Germany).

All patients had to undergo external auditory canal cleaning and debridement. A group (Group A) of patients were treated after cleaning the ear canal with suction with 8 drops of 1% clotrimazole (ear drop) each 8 h. Other group (Group B) of patients were requested to report to the OPD every alternate day for aural toilet and acetic acid wash. ENT specialist evaluated the amount of response to therapy on 7, 14, and 21 days. Good response (dry ear canal and TM and decrease of discharge), partial response (slight discharge but not dry), and no response (hypersecretion in the EAC) were the response rate to treatment which was graded into three groups associated with the clinical presentation. The treatment process was discontinued, if certain recovery was not taken and

otherwise therapy was continued. After 21st day, non- treatment was considered as resistance cases, and therapy regimen was done by tolnaftate and violet de gentian.

SPSS (V.18) software was used for statistical analysis of the data. For the inferential portion and the examination of distribution frequency, descriptive statistics, the Chi-square test, and the t-test were used . P-value less than 0.050was considered to be significant.

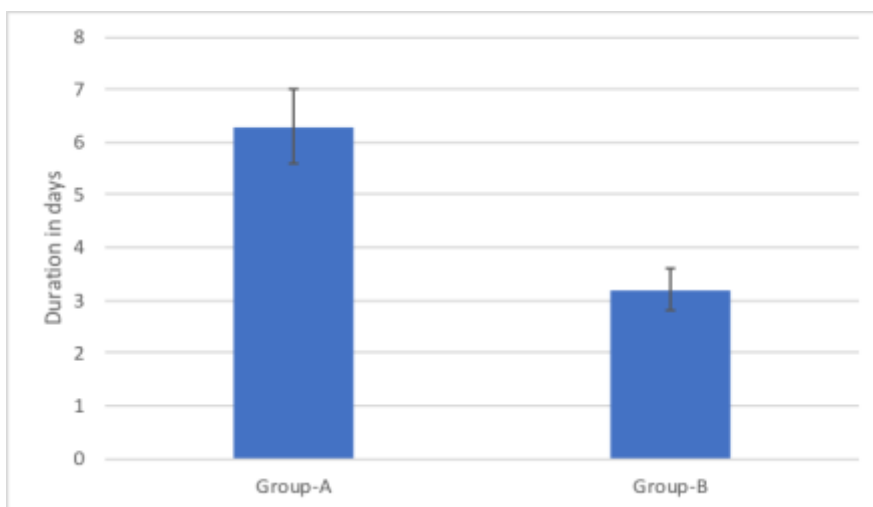
RESULTS:

Table 1: Demographic distribution

Demographics	Group A (%)	Group B (%)	P value
Age	36.32±15.68	38.02±19.89	0.35
Sex			
Males	32 (64)	24 (48)	0.30
Females	18 (36)	26 (52)	
Fungal Agent			
Aspergillus Spp	30 (60)	30 (60)	1.0
Candida Spp	20 (40)	20 (40)	

Table 1 shows that males (56) were more than females (44) in the present study. Aspergillus Spp were observed in 60 patients and Candida Spp were observed in 40 patients. Co-infection or double infection was not observed in present study. There was no significant difference between age (P=0.35), gender (P=0.30) and fungal causative organism (P=1.0) between two groups.

Figure-1: Duration of treatment in present study



Duration of treatment in group-B is significant when compared to others.

Table 2: Comparison of treatment response after specified periods

Period	Groups	Good Response (%)	Partial Response (%)	No Response (%)	P value
7 days	Group B	35(70)	10 (20)	5 (10)	0.32
	Group A	6 (12)	28 (56)	16 (32)	
14 days	Group B	40 (90)	7 (14)	3 (6)	0.48
	Group A	29 (58)	14 (28)	7 (14)	
21 days	Group B	50 (100)	0 (0)	0 (0)	0.23
	Group A	33 (66)	11 (22)	6 (12)	

Table 2 shows that in group B, the recovery rate after 7 days showed 70% of patients detected good response and in group A, 12% showed good response which was dry ear canal and no discharge. In group B, the recovery rate after 14 days showed 90% of patients detected good response and in group A, 58% showed good response. In group B, the recovery rate after 21 days showed 100% of patients detected good response and in group A, 66% showed good response. Between both the groups, there was no significant difference on 7th, 14th and 21st days.

Figure-1: Bar diagram showing of treatment response after specified periods.

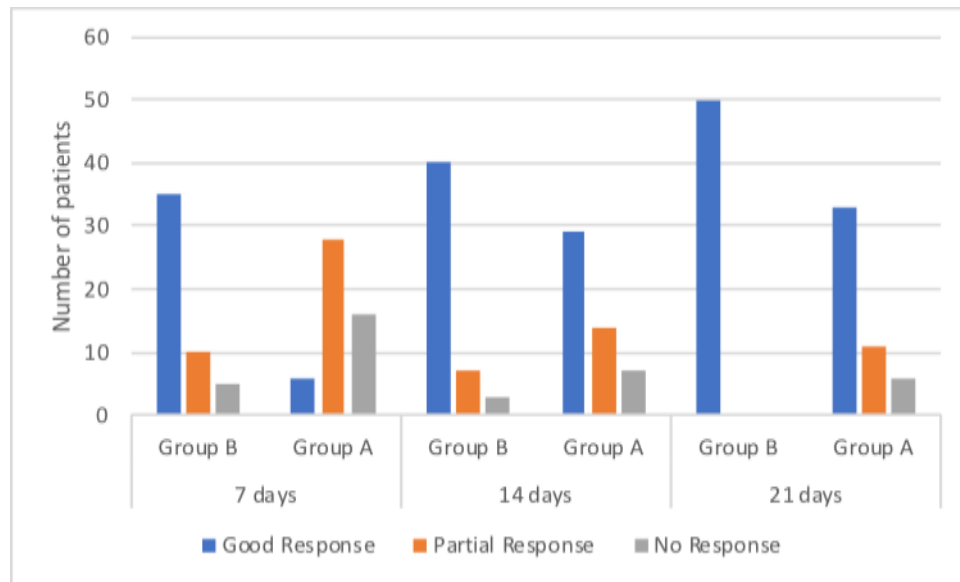


Table 3: Comparison of relapse rates on 14th and 21st days

Treatment Group	Recurrence after 14 days		Recurrence after 21 days	
	Positive (%)	Negative (%)	Positive (%)	Negative (%)
Group A	3 (6)	47 (94)	3 (6)	47 (94)
Group B	2 (4)	48 (96)	4 (8)	46 (92)

Table 3 shows that recurrence after 14 days in group B was 4% and in group A was 6%. Between two groups, no significant difference was observed in rate of recurrence (P=0.71). Recurrence after 21 days in group B was 8% and in group A was 6%. Between two groups, no significant difference was observed in rate of recurrence (P=0.76).

DISCUSSION:

Otomycosis is infection caused by fungi in the external auditory canal and is frequently diagnosed by clinical presentation. The pathogenic saprophytes were identified as *Aspergillus* spp. And *Candida* spp. Which were the most common fungi involved in causing otomycosis. *Aspergillus* Spp were observed in 60 patients and *Candida* Spp were observed in 40 patients in the present study. In study done by Reza M M *et al*.⁸ similar results were observed such as *Aspergillus* spp 72.5% (n=116/160) and *Candida albicans* 27.5% (n=44/160) were the most common agents causing otomycosis. *Aspergillus* 41.1% (*A. niger* 36.9%) and *C. albicans* 8.2% were isolated from 72 patients were reported in Kour *et al*.⁹ study which were similar to the present study results. Common fungal species which were frequent isolated, are *Aspergillus* and *Candida* in studies conducted by Pardhan *et al*.¹⁰ (2003) and Kiakujori *et al*.¹¹ (2014). *Aspergillus* and *C. albicans* were isolated from 75% and 70% of twenty patients suffering external ear fungal infection in study conducted by Kenneth *et al*.¹² In all the above studies, the common result that *Aspergillus* spp was the most common causative agent of otomycosis was observed.

In the present study, acetic acid was used in group B, the recovery rate after 7 days showed 70% of patients detected good response and in group A, 12% showed good response which was dry ear canal and no discharge. In group B, the recovery rate after 14 days showed 90% of patients detected good response and in group A, 58% showed good response. In group B, the recovery rate after 21 days showed 100% of patients detected good response and in group A, 66% showed good response. Between both the groups, there was no significant difference on 5th, 10th and 21st days. Similar results with the present study was conducted by Malik AA *et al*.¹⁴ but with 3% salicylic acid, 3% Salicylic Acid better controlled itching and ear blockade (p=0.000) as compared to clotrimazole. In Reza MM *et al*.⁸ study, in three courses, the recovery rate was monitored on four, ten, and twenty days. The fourth day following tincture and clotrimazole treatment showed partial responses of 51.2% and 58.7%, respectively. Ten days later, 41.2% of patients had an excellent reaction to clotrimazole, while 53.7% of patients had a partial response to the tincture. Ultimately, good responses of 67.5% and 62.5% for the tincture and clotrimazole arms were seen on the twentieth day. The study carried out by Philip *et al*.¹⁵ (2013) assessed the efficacy of povidone-iodine 7.5% in treating otomycosis in

comparison to topical application of clotrimazole 1% solution (17). Their findings indicated that povidone-iodine can be utilized as an effective antifungal agent in the treatment of otomycosis, and they also showed improvements in both therapy arms.

In the present study, recurrence after 14 days in group B was 4% and in group A was 6%. Between two groups, no significant difference was observed in rate of recurrence ($P=0.71$). Recurrence after 21 days in group B was 8% and in group A was 6%. Between two groups, no significant difference was observed in rate of recurrence ($P=0.76$).

Two topical therapy regimens for otomycosis were applied namely clotrimazole and acetic acid wash. One commonazole group medication used to treat mycosis is clotrimazole. Acetic acid is another well-known antiseptic that is readily accessible and has been shown to be effective against external otitis externa infections. Because it is affordable and has the lowest amount of cytotoxicity, acetic acid can be utilized as an additional antifungal alternative for the treatment of otomycosis, particularly in developing countries.

There were some limitations in present study such as treatment response was categorized based on clinical evidence and after the treatment period, culture of debris was not performed. Morphological and phenotypic diagnostic methods were used in detection of fungal agents isolated from patients samples.

In addition to this, the study duration of treatment in group-B is significant when compared to the other group. In study done by Moghadam *et al* confirmed most of the patients were cured perfectly after therapy with the mixture of alcohol and acetic acid. However, the need to come to the OPD every alternate day for cleaning and acetic acid administration does become cumbersome to the patient. Various aspects like treatment length, ease of treatment, economic issues must be considered in searching for an effective agent in treating otomycosis. There was no common agent in treating otomycosis even though many in-vitro studies were conducted to conclude the effective antifungal agent. Salicylic acid, boric acid, isopropyl alcohol, tolnaftate, iodine were the agents which were applied with variable success rate.

CONCLUSION

This study concluded that acetic acid is an inexpensive and readily available antifungal agent and has been proven to be effective in treatment of otomycosis. Duration of treatment in group-B is significant albeit with more number of OPD visits with no bacterial and fungal resistance unlike that caused by using indiscriminately antibiotics. So, regular aural toilet with acetic acid washes can be definitely considered as an alternative option in the treatment of otomycosis.

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