

Old is Gold. Topical Clotrimazole Remains an Effective Treatment of Otomycosis

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ABSTRACT

Introduction: Otomycosis also known as fungal otitis externa has typically been described as fungal infection of the external auditory canal. The prevalence of otomycosis has been reported to be as low as 9% of cases of otitis externa and as high as 30.4% in patients presenting with symptoms of otitis or inflammatory conditions of the ear. The most common fungal agents causing otomycosis are aspergillus niger (80%), candida albicans (second most common), actinomyces, trichophyton, aspergillus fumigatus and candida tropicalis. **Methods:** It was descriptive case series of six months duration done at department of ENT, Islamabad Medical and Dental College Islamabad. Sample size was 119, using 50%⁸ efficacy of topical clotrimazole, 95% confidence level and 9% margin of error under WHO software for sample size determination. **Results:** A total of 119 patients of otomycosis were included in the study. Male to female ratio was 0.61:1. Average age of the patients was 32.94 years \pm 5.24 SD with range 20-40 years. The efficacy of clotrimazole in treatment of otomycosis was observed in 112 (94.12%) while in 7 (5.88%) patients show no efficacy. Age and gender have no role in efficacy of clotrimazol in treatment of otomycosis.

Conclusion: Topical clotrimazole is effective in the treatment of otomycosis.

Key words: Efficacy, clotrimazol, otomycosis, otitis externa.

INTRODUCTION

Otomycosis also known as fungal otitis externa has typically been described as fungal infection of the external auditory canal.¹ The prevalence of otomycosis has been reported to be as low as 9% of cases of otitis externa, and as high as 30.4% in patients presenting with symptoms of otitis or inflammatory conditions of the ear. Prevalence is also influenced by the geographical area, as otomycosis is most commonly present in tropical and subtropical humid climates.² Otomycosis occur more commonly in female than in male. Moreover it usually occurs most frequently in adults, and less in children.³

The most common fungal agents causing otomycosis are aspergillus niger (80% of case),

candida albicans (second most common), actinomyces, trichophyton, aspergillus fumigatus and candida tropicalis.⁴ Several factors have been reported predisposing otomycosis which include; bacterial infections, use of hearing aid or a hearing prosthesis, self inflicted trauma, swimming in contaminated pools, broad spectrum antibiotic therapy, steroids and cytostatic medication, neoplasia and immune disorders.⁵

It is seen more frequent in immunocompromised patients and recurrence rate and complications are higher in otomycosis patients requiring longer duration of treatment and complications. The infection is usually unilateral and characterized by inflammation, pruritus, scaling and severe discomfort such as pain and supuration.⁶ Treatment options for otomycosis

include predisposing factor elimination, thorough canal cleaning and antifungal agents. Topical antifungals are specific (clotrimazole, miconazole, econazole, nystatin, tolnaftate, potassium sorbate) and non-specific (acetic acid, alcohol, boric acid, m-cresyl acetate and gentian violet).⁷

Efficacy of clotrimazole has been reported to be 50% in one study while in another study it is reported to be 83%.^{8,9} Otomycosis is common clinical problem which require a prompt treatment and has a recurrence tendency. This study will provide us with regional statistics of efficacy of clotrimazole in the treatment of otomycosis. This study was designed keeping in view the difference in efficacy rates as mentioned above and if controversy persists after the results of this study than further research work can be advised in similar regards and further research work into additional treatment options can be carried out locally and internationally to come to a single consensus.

MATERIALS AND METHODS

Study was conducted at the department of ENT, Islamabad Medical and Dental College Islamabad from (30th August 2011 to 1st March 2012). The main aim was to determine the efficacy of topical clotrimazole in treatment of otomycosis. Sample size was 119, using 50%⁸ efficacy of topical clotrimazole, 95% confidence level and 9% margin of error under WHO software for sample size determination. It was descriptive case series with non probability consecutive sampling. Included were all patients of both genders presenting with otomycosis having ages between 20-40 years. Exclusion criteria consisted of non consenting individuals, bacterial infection of external ear (were excluded by absence of masses of white, grey or black debris invading the external auditory meatus on physical examination) and patients with history of trauma to external auditory canal. All patients meeting the inclusion criteria were included in the study through OPD. The diagnosis of otomycosis was based upon patients presenting with ear discharge green/grey or black in color and microscopic examination showing fungal hyphae. The purpose and benefits of the study were being explained to all patients and a written informed

consent was obtained. A detailed history followed by detailed physical examination was conducted in all patients. All patients were put upon clotrimazole lotion twice a day for 2 weeks. Patients were followed at the end of 2 weeks to assess the efficacy of treatment in terms of total absence of fungal hyphae on microscopic examination. All the above mentioned information including name, age, gender and address were recorded in a pre designed proforma. All the microscopic examinations were conducted by single expert microbiologist having minimum of 5 years of experience. Strict exclusion criteria were followed to control confounders and bias in the study results.

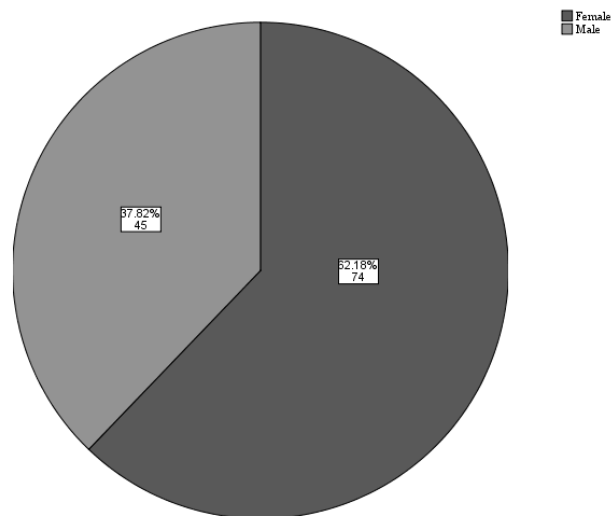


Fig. 1: Gender wise distribution of the patients.

RESULTS

A total of 91 patients of otomycosis were included in the study. There were 45 (37.82%) males and 74 (62.18%) females. Male to female ratio was 0.61:1 (Fig. 1). Average age of the patients was 32.94 years \pm 5.24 SD with range 20-40 years. Patient's age was divided in four categories, out of which most common age group for otomycosis was above 35 years. There were 12 (10.1%) patients of age less than 25 years. Twenty nine (24.4%) patients were in the age range of 26-30 years, 27 (22.7%) were of age range 31-35 years, 51 (42.9%) presented at age more than 36 years of age (Table 1). The efficacy of clotrimazole in treatment of

otomycosis was observed in 112 (94.12%) while in 7 (5.88%) patients it showed no efficacy (Fig. 2).

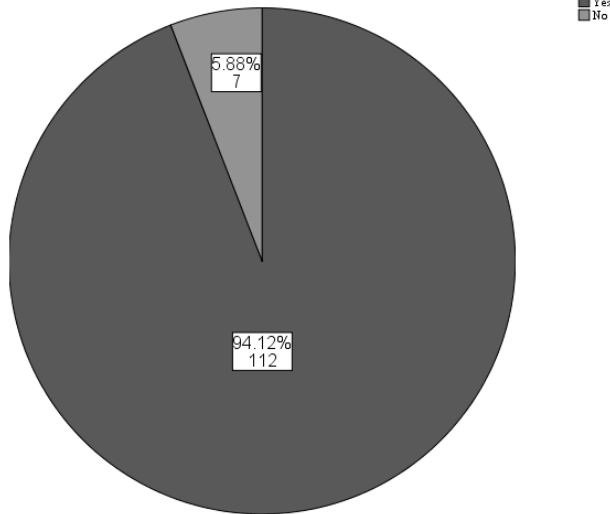


Fig. 2: Efficacy of clotrimazole.

Table 1: Age wise distribution of the patients.

	Frequency	Percent	Cumulative percent
≤ 25.00	12	10.1	10.1
26.00 - 30.00	29	24.4	34.5
31.00 - 35.00	27	22.7	57.1
≥ 36.00	51	42.9	100.0
Total	119	100.0	

Age wise distribution of otomycosis showed that efficacy of clotrimazole in old age was little bit high as that of younger age. The patients having age less than or equal to 25 years had efficacy of 83.3% while no efficacy was in 16.7%, age group 26-30 years had 93.1% efficacy and 6.9% showed no efficacy, 31-35 years age groups gave 96.3% efficacy with 7.3% no efficacy and patients having more than 35 years of age had 96.1% efficacy while 3.9% had non efficacy of clotrimazole in treatment of otomycosis (Table 2).

Gender wise efficacy of clotrimazole in treatment of otomycosis showed no significant difference. The efficacy was 93.3% in males while almost equal efficacy of 94.6% was observed across female participants (Table 3).

Table 2: Age wise distribution of efficacy.

Age (Years)	Efficacy		Total
	Yes	No	
≤ 25.00	10 (83.3%)	2 (16.7%)	12 (100.0%)
26.00 - 30.00	27 (93.1%)	2 (6.9%)	29 (100.0%)
31.00 - 35.00	26 (96.3%)	1 (3.7%)	27 (100.0%)
≥ 36.00	49 (96.1%)	2 (3.9%)	51 (100.0%)
Total	112 (94.1%)	7 (5.9%)	119 (100.0%)

Table 3: Gender wise distribution of efficacy.

Sex	Efficacy		Total
	Yes	No	
Female	70 (94.6%)	4 (5.4%)	74 (100.0%)
Male	42 (93.3%)	3 (6.7%)	45 (100.0%)
Total	112 (94.1%)	7 (5.9%)	119 (100.0%)

DISCUSSION

Otomycosis is an entity frequently encountered by otolaryngologists and can usually be diagnosed by clinical examination. Hearing loss, pain and aural fullness are frequent symptoms as a result of accumulation of fungal debris in the canal. Although pruritis has been frequently cited as one of the hallmark symptoms, up to 93% in one study, it was reported among the chief complaints in only 23% of the current study population.¹⁰ Otomycosis occur more commonly in females and our finding confirmed the results other researchers have reported.¹¹

Otomycosis usually occurs more frequently in adults, and less in children.^{12,13} In our study, we found that otomycosis was more common in young men which is similar to the findings of the other researchers.¹⁴ The women (60.9%) in the present study were more often affected by otomycosis, and such figures were closer to those observed by Zaror et al (65%).¹⁵ Otomycosis was seen in patients aged between 20 and 40 years. Nonetheless, 30% of the cases were diagnosed in patients between 26 and 30 years of age. Kaur et al. reported the occurrence of 41.1% was seen in patients within the age range of 16 to 30 years.¹⁶ Studies found a greater prevalence of *Aspergillus* (*A. niger*, *A. fumigatus*, *A. flavus*

and/or *Aspergillus* spp.) as otomycosis agents Jaiswal et al and Navarrete et al found 46% and 35% of *Candida* spp., respectively.¹⁷

Treatment recommendations have included local debridement, discontinuation of topical antibiotics, and local/systemic antifungal agents.¹⁸ In our study, all patients were put upon clotrimazole lotion twice a day for 2 weeks. Patients were followed at the end of 2 weeks to assess the efficacy of treatment in terms of total absence of fungal hyphae on microscopic examination.

Some studies showed that clotrimazole was one of most effective agents for management of otomycosis, with reported rate of effectiveness that varies from 95% to 100%.¹⁹ Clotrimazole is the most widely used topical azole.²⁰ It is available as powder, a lotion, and a solution and is considered free of ototoxic effects.²¹

Some studies have shown that certain fungal species like *Candida albicans* are more susceptible to 3% salicylic acid (SA).²² This finding is based on meta-analysis of various studies from tropical areas on the globe. There are studies which do not agree with our results.²³ The results of this study cannot be validated as it only had fifteen cases and has studied more than five treatment protocols. Azole group has shown to be quite effective in treating otomycosis.²⁴ Anti fungals like 3% SA and 3% acetic acid solutions have dual effect, firstly causing separation of fungi from external auditory canal to which they are anchored and secondly they cause disturbance of acid base balance within the fungal cells thereby causing cell death and inhibition of fungal proliferation as opposed to inhibition of fungal proliferation only by antifungals like clotrimazole.²⁵ In our study, the results are same. It also decreased the ear blockade better than clotrimazole. As far as the clearance of fungal debris/discharge is concerned, clotrimazole had better result.²⁶

CONCLUSION

Otomycosis is common in females than males. Treatment regimens such as ketoconazole and cresylate coupled with mechanical debridement are generally effective. However, recurrence is not uncommon and eradication of disease can be particularly difficult in postmastoidectomy patients.

Clotrimazole is quite effective in the treatment of otomycosis. Clotrimazole cream after toileting is a better choice due to its lower cost and better compliance.

REFERENCES

1. Pontes SVZ, Silva FDA, Lima OE, Guerra HM, Oliveira CMN, Carvalho PFM. Otomycosis. *Braz J Otorhinolaryngol.* 2009; 75:367-70.
2. Munguia R, Daniel JS. Otological antifungals and otomycosis. *International J Pediatric Otorhinolaryngol.* 2008;7;2:453-9.
3. Mahmoudabadi AZ. Mycological studies in 15 cases of otomycosis. *Pak J Med Sci.* 2006; 22:486-8.
4. Pakshir K, Sabayan B, Javan H, Karamifar K. Mycoflora of human external auditory canal in Shiraz. *Iranian Red Crescent Med J.* 2008;10:27-9.
5. Moghadam YA, Asadi AM, Dehghani R, Mahmoudabadi ZA, Rayegan F, Hooshyar H. Evaluating the effect of a mixture of alcohol and acetic acid for otomycosis. *Jundishapur J Microbiol.* 2010;3:66-70
6. Viswanatha B, Naseeruddin K. Fungal infections of the ear in immunocompromised host. *Medit J Hemat Infect Dis.* 2011;3:10-13.
7. Chalabi EY, Ahmed TS. The role of various out patients aural toileting procedures in the treatment of otomycosis. *J Zankoy Sulaimani.* 2010;13:39-48.
8. Jackman AR, April WM, Bent J. Topical antibiotic induced otomycosis. *Int J Pediatr Otorhinolaryngol.* 2005;69:857-60.
9. Ahmed Z, Hafeez A, Zahid T, Jawaid AM, Matiullah S, Marfani SM. Otomycosis: Clinical presentation and management. *Pak J Otolaryngol.* 2010;26:78-80.
10. Stern JC, Lucente FE. Otomycosis. *Ear Nose Throat J* 1988;67:804-10.
11. Pradhan B, Tuladhar NR, Amatya RM. Prevalence of otomycosis in outpatient department of otolaryngology in Tribhuvan University Teaching Hospital, Kathmandu, Nepal. *Ann Otol Rhinol Laryngol.* 2003;112:384-7.

12. Kaur R, Mittal N, Kakkar M, Aggarwal AK, Mathur MD. Otomycosis: a clinicomycologic study. *ENT J.* 2000;79:606-9.
13. Zaror L, Fischman O, Suzuki FA, Felipe RG. Otomycosis in São Paulo. *Rev Inst Med Trop São Paulo.* 1991;33:169-73.
14. Kaur RK, Mittal N, Kakkar M, Aggarwal AK, Mathur MD. Otomycosis: a clinico mycologic study. *Ear Nose Throat J.* 2000;79:606-9.
15. Yassin A, Maher A, Moawad MK. Otomycosis: a survey in the eastern province of Saudi Arabia. *J Laryngol Otol.* 1978;92:869-76.
16. Paulose KO, Al-Khalifa S, Shenoy P. Mycotic infection of the ear (otomycosis): a prospective study. *J Laryngol Otol.* 1989;103:3-5.
17. Mgbor N, Gugnani HC. Otomycosis in Nigéria: treatment with mercurochrome. *Mycoses.* 2001;44:395-7.
18. Ho T, Vrabec J, Yoo D. Otomycosis: clinical features and treatment implications. *Otolaryngology- Head and Neck Surgery.* 2006;135:787-91.
19. Youssef YA, Abdou MH. Studies on fungus infection of the external ear, mycological and clinical observation. *J Laryngol Otol.* 1967;81:401-12.
20. Pradhan B, Tuladhar NR, Amatya RM. Prevalence of otomycosis in outpatient department of otolaryngology in Tribhuvan University Teaching Hospital, Kathmandu, Nepal. *Ann Otol Rhinol Laryngol.* 2003;112:384-7.
21. Ologe FE, Nwabuisi C. Treatment outcome of otomycosis in Ilorin, Nigeria. *West Afr J Med.* 2002;21:34-36.
22. Kurnatowski P, Filipiak A. Otomycosis: prevalence, clinical symptoms, therapeutic procedure. *Mycosis.* 2001;44:472-9.
23. Ismail HK. Otomycosis. *J Laryngol Otol.* 1962;76:713-9.
24. Stern JC, Shah MK, Lucente FE. In vitro effectiveness of 13 agents in otomycosis and review of the literature. *Laryngoscope.* 1988;98:1173-7.
25. Munguia R, Daniel SJ. Otological antifungals and otomycosis: A Review. *Int J Pediatr Otorhinolaryngol.* 2008;72:453-9.
26. Malik AA, Malik SN, Aslam MA. Comparative efficacy of topical clotrimazole and 3% salicylic acid in otomycosis. *Rawal Med J.* 2012;13:46-9.

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