Original Research Paper

Volume - 12 | Issue - 11 | November - 2022 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

ENT

# COMPARISON OF THE RECOVERY RATE OF OTOMYCOSIS USING CLOTRIMAZOLE DROPS, CLOTRIMAZOLE CREAM AND 10% POVIDONE IODINE SOLUTION (BETADINE) IRRIGATION.

**Dr. Shafkat Ahmad Lone** Professor, Department of E.N.T, Government Medical College, Kanth Bagh Baramulla, J&K, India.

**Haris Manzoor Qadri** Lecturer, Department Of ENT and Head and Neck Surgery, Government Medical College, Karan Nagar Srinagar, J&K, India.

**Dr. Shakil U Rehman*** Assistant Professor, Department of Pharmacology, Government Medical College Baramulla, J&K India. *Corresponding Author

**ABSTRACT** Otomycosis is one of the common conditions encountered in ENT practice. Difference of opinion does exist regarding ideal treatment modality. **Aim:** Compare the efficacy of 1% clotrimazole drops, 1% clotrimazole cream and 10% betadine irrigation in the treatment of otomycosis. **Method:** Randomized control study conducted in the department of ENT and Head and Neck surgery of Government Medical College Baramulla. The study was conducted on 80 patients over a period of 6 months, clinically diagnosed with otomycosis. Patients were randomly allotted to three groups. Improvement in symptoms of pruritis, pain and blocked sensation on 1st, 2nd, 3rd and 4th follow up visits was recorded. All patients were asked the opinion about preferred treatment modality. **Results:** When compared the symptoms on day one and subsequent follow ups, the change in symptoms in all the groups was significant. Group 2 with 1% clotrimazole cream had significant improvement on first visit only. By 4th visit all the groups had significant improvement.

**KEYWORDS :** Otomycosis, antifungal, external auditory canal (EAC)

## INTRODUCTION

Otomycosis is a fungal infection of the external auditory canal (EAC) that can involve the middle ear in case of tympanic membrane perforation and also extend to the auricle. Fungi cause 9-25% of external otitis [1]. Diagnosing otomycosis is often based entirely on non-specific clinical signs and symptoms. Otomycosis is one of the relatively common diseases in the world, claiming around 30% of ear infections [2]. Among the contributing and stimulating factors for development of otomycosis are manipulating the ears, humidity, heat, age, predisposing primary bacterial infection, and immune system disorders [2]. The main causative agent of otomycosis among saprophytes and yeasts are Aspergillus niger and C. albicans, respectively [3]. The other critical species including A. flavus and A. fumigatus are gradually finding a progressive role in development of otomycosis [2]. The other causative agents are Cladosporium spp., Alternaria spp., Mucor spp., and Rhizopus spp. [2].

Several treatment procedures are used according to the need of the patient with otomycosis. In the treatment of otomycosis, usually first fungal elements are removed from the ear (by suction or washing) and then dried.Topical medications recommended for the control of this condition include steroids, antiseptics, acidic solutions, antifungal agents and driers. Antifungal medications of otomycosis do not always cure the disease and in addition treatment should improve the physiological signs of external ear canal [4, 5]. Using boric acid in an alcohol solution for the treatment of disease is associated with 23% recurrence rate. Furthermore, using antifungal solutions, such as clotrimazole or nystatin, may be effective for the treatment of Candida infections, but Aspergillus infections respond poorly to treatment.[6,7].This is while a wide range of fungi have been reported to cause otomycosis and the most common species is Aspergillus. Therefore, an appropriate treatment regimen is necessary for treatment. On the other hand, widespread and unnecessary use of antibacterial treatment for middle and external otitis may cause fungal overgrowth in this area, so the adverse effects of using wide-spectrum antibiotics are the secondary overgrowth of fungus and increasing prevalence of otomycosis. [8]

Given the importance of otomycosis treatment as one of the challenges facing ENT specialists, the study was conceived with an aim to compare the recovery rate of otomycosis using topical betadine and clotrimazole (drops as well as cream).

## MATERIALAND METHODS:

This study was conducted in the department of ENT and Head and Neck Surgery Government Medical College Baramulla Kashmir over a period of 6 months. Patients were diagnosed on the basis of symptoms and otoscopy findings of matted hyphae, spores, or curdy precipitate in the external auditory canal. Consented diagnosed cases of otomycosis were included in the study between 15 to 85years of age. Patients excluded from study were diagnosed cases of CSOM, post-operative mastoid cavities, regular swimmers, uncontrolled diabetes, patients using hearing aids and those who did not cooperative well with endoscopic cleaning of ear. It was a randomized control study in which patients were allocated to three treatment arms after endoscopic assisted suction cleaning.

**Group 1:** In this group patients were asked to instill 1% clotrimazole drops 2 drops thrice a day.
**Group 2:** In this group endoscopic assisted 1% clotrimazole cream was applied thoroughly in EAC.
**Group 3:** In this group patients EAC was washed with 10ml of 10% povidone iodine solution.

Follow up visits for all patients were kept after every 5 days. Patient was considered cured if patient was asymptomatic and otoscopy revealed a normal EAC.

## RESULTS:

1. A total of 80 patients were included in the study, who were randomly allocated to three treatment arms.
2. 52 patients (65%) were male and 32 patients (35%) were female.
3. The maximum no. of patients belonged to the middle aged groups and a substantial decline on either sides was observed. (Fig. 1)
4. Pain and pruritis were the most common complaints. (Table 1)
5. Out of the total 80 patients, 29 patients (36.25%) were allocated to treatment group 1, 26patients (32.50%) to treatment group 2, 25 patients (31.25%) to treatment group 3. (Fig. 2)
6. Treatment Group 1 contributed to the total of 58 visits out of total 121 visits i.e 47.93% of visits alone.

Out of the 58 visits corresponding to treatment 1, 13.79% had single follow up visits, 48.28% had two follow up visits, 31.03% had three follow up visits and only 6.90% had fourth follow up visits. Thus we may conclude that most of the patients needed second and third follow up visits to cure and assuming the treatment was not so effective to cure the disease. (Fig. 3)

**Treatment Group 2 contributed to the total of 26 visits out of total 121 visits i.e 21.48%.**

Out of the 26 visits attributed to the treatment 2 we had 100% of patients cured on visit first. No patient needed second follow up visit. Thus we assume that this treatment is most effective to cure the disease. (Fig. 3)

**Treatment Group 3 contributed to the total of 37 visit out of total**

**121 visits i.e 30.57% .**

Out of the 37 visits attributed to the treatment type 3 we had 35.14% of single follow up visits and 64.86% of them had second follow up visits and none needed third follow up visits. Thus the patients receiving the treatment 3 we can say most of them needed the second visit to get cured assuming the treatment was effective than treatment 1 to cure the disease. (Fig. 3)

## DISCUSSION

Otomycosis, a superficial fungal infection of the external auditory meatus, is generally seen in hot and moist climates worldwide. [9]. The predisposing factors of otomycosis are the use of wide-spectrum antibiotics, trauma to the external ear canal, and close contact with water [9]. The commonest isolated fungi from the external ear canal are Aspergillus spp. and Candida spp. Several studies have reported that Aspergillus spp. (A. niger, A. flavus, A. fumigatus) were found in the majority of cases, and Candida spp. (C. albicans, C. parapsilosis, C. tropicalis) were seen less frequently [10, 11, 12].

Otomycosis affects primarily the squamous epithelium of the external ear canal, causing epithelial damage which results in symptoms of itching, aural fullness, and pain. In the present study, pain and pruritis are commonest symptoms. Study done by Pradhan et al suggested pruritis only as main symptom of otomycosis [13]. Khurshid Anwar et all suggested most common symptom as hearing loss (77.7%) followed by pruritis (68.8%) and otalgia (40%) [14].

There is no proper agreement regarding the effect of various antifungal agents used for otomycosis and various agents have been used for the same. The use of appropriate antifungal agent along with mechanical debridement remains the mainstay of treatment. Amongst antifungals topical clotrimazole remains widely used agent [14]. 1% Clotrimazole cream has been used for treatment of this condition with good efficacy [15]. Mohammad Reza Mofatteh et al suggested that efficacy of betadine and clotrimazole regimens are same [16].

In this study we compared three different modalities of treatment of otomycosis. Research has been done comparing two modalities, hardly there is a research comparing all 3 together.

We found that patients instilling 1%clotrimazole in ear, only 13.79% patients recovered on first follow up, maximum patients recovered after 2nd and 3rd follow up visits (48.28% and 31.03% respectively). There were patients who even recovered after 4th follow up visit, (6.90%). In comparison to this, treatment 3 i:e washing EAC with 10% povidone iodine seemed much effective, 35.14% were cured after 1st follow up and 64.86% of them were cured after 2nd follow up visit and none needed third follow up visit. But applying clotrimazole cream in EAC was most efficient treatment. 100% patients were cured when seen on 1st follow up.

Patient using 1% clotrimazole drops thrice a day can become a cumbersome job for office going person. Some studies even suggest that instillation of anti fungal solution causes burning sensations and especially in perforated drum. Few patients experienced vasovagal syncope while washing EAC with 10ml of 10% povidone iodine, which can make patients anxious. Even there are reports of getting EAC blocked by applying cream, after applying cream by using otoendoscope. Only 2 of our patients complained of blocking sensation. Applying cream just once makes this treatment very popular among patients.

## CONCLUSION

In our study we conclude that applying clotrimazole cream in cases of otomycosis after cleaning of EAC is most efficient modality of treatment.

**Statements and Declarations:**

1. The authors have no competing interests to declare that are relevant to the contents of this article. No funding was received by any of the authors to assist with the preparation of this manuscript.
2. All the procedures performed in the study were in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study was approved by the institutional ethics committee of GMC Baramulla.
3. Informed written consent to participate in the study and publish the data was obtained from all the Participants.
4. All the authors have contributed significantly for the successful completion of the study.

**Acknowledgments:-**

The authors would like to acknowledge all the participants of the study for consenting to participate and all the supporting staff of the Department of E.N.T, GMC Baramulla for their valuable support without which the study could never have been completed.

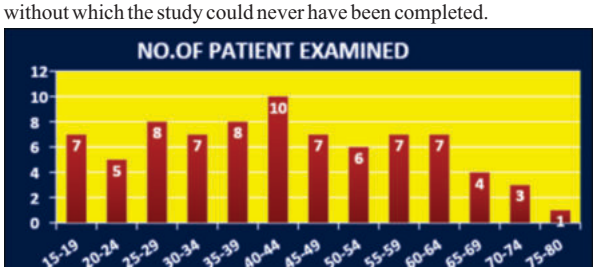


**Figure 1:- Total number of patients according to age groups.**

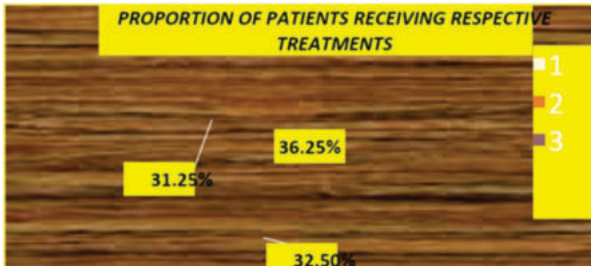


**Figure 2: Out of the total 80 patients enrolled; 29 patients (36.25%) were allocated to treatment group 1, 26 patients (32.50%) to treatment group 2, 25 patients (31.25%) to treatment group 3.**

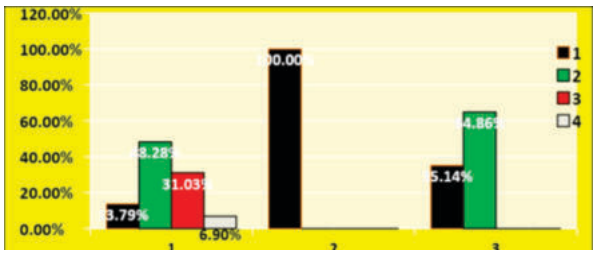


**Figure 3: Number of patients cured on the corresponding follow up visit in the three treatment groups.**

**Table 1: Showing patients with pain and pruritis.**

| Age Group | No.of Persons With Pruritus | No.of Persons Experiencing Pain |
|---|---|---|
| 15-19 | 7 | 7 |
| 20-24 | 5 | 5 |
| 25-29 | 8 | 8 |
| 30-34 | 7 | 7 |
| 35-39 | 8 | 8 |
| 40-44 | 10 | 10 |
| 45-49 | 7 | 7 |
| 50-54 | 6 | 6 |
| 55-59 | 7 | 7 |
| 60-64 | 7 | 7 |
| 65-69 | 4 | 4 |
| 70-74 | 3 | 3 |
| 75-80 | 1 | 1 |
| Grand Total | 80 | 80 |

## REFERENCES

1. Pontes ZB, Silva AD, Lima Ede O, Guerra Mde H, Oliveira NM, Carvalho Mde F, Guerra FS. Otomycosis: a retrospective study. Braz J Otorhinolaryngol. 2009 May-Jun;75(3):367-70. English, Portuguese. PMID: 19649486.
2. Kiakojuri K, Rajabnia R, Mahdavi Omran S, Pournajaf A, Karami M, Taghizadeh Armaki M. Role of Clotrimazole in Prevention of Recurrent Otomycosis. Biomed Res Int. 2019 Dec 26;2019:5269535. doi: 10.1155/2019/5269535. PMID: 31950041; PMCID: PMC6944967.
3. M R Moffateh, Z N Yazdi, M Yousefi, M H Namaei. Comparison of recovery rate of otomycosis using betadine and clotrimazole topical treatment. Brazilian journal of otorhinolaryngology, vol. 84, no 4, pp 404-409, 2018.
4. S Forgie, G Zhanel, J.Robinson. Management of acute otitis media. Paediatr child health, 14(2009), pp. 457-464.
5. K. Kiakojuri, M.R.H. Roushan, S.A.A. Sepidgar. Suction clearance and 2% topical miconazole versus the same combination with acidic drops in the treatment of

otomycosis. Southeast Asian J Trop Med Public Health, 38(2007), pp. 749-753.
6. K.M Ozcan, M. Ozcan, AKaraarslan, F. Karaarslan. Otomycosis in Turkey: Predisposing factors, aetiology and therapy. J laryngolOtol, 117(2003), pp. 39-42.
7. J. Brant, M. Ruckenstein. Infection of external ear. Cummings otolaryngology: head and neck surgery (6th ed), Elsevier Saunders, Philadelphia(PA) (2015), pp. 2115-2122.
8. A Jackman, R. Ward, M.April, J.Bent. Topical antibiotic induced otomycosis. Int J Pediatrotorhinolaryngol, 69(2005), pp. 857-860
9. Mugliston T, O Donoghue. Otomycosis- a continuing problem. J Laryngol Otol. 1985;99:327-33 [PubMed]
10. Kaur R, Mittal N, Kakkar M, agarwal AK, Mathur MD. Otomycosis: a clinicomycologic study. Ear Nose Throat J. 2000;79:606-9.[PubMed]
11. Yehia MM, al-Habib HM, Shehab NM. Otomycosis: a common problem in north Iraq. J Laryngol Otol. 1990;104: 387-9.[PubMed]
12. Enweani IB, Igumbor H. prevelance of otomycosis in malnourished children in Edo state, Nigeria. Mycopathologia. 1997-1998;140:85-7.[PubMed]
13. Pradhan B, Tuladhar NR, Amatya RM (2003). Prevelance of otomycosis in outpatient department of otolaryngology in Tribhuvan university teaching hospital, katmandu Nepal. Ann OtolRhinolLaryngol 112: 384-387.
14. Anwar K, Gohar MS (2014). Otomycosis; clinical features, predisposing factors and treatment implications. Pakistan Journal of Medical Sciences 30:564-567
15. Ologe FE1, Nwabuisi C (2002). Treatment outcome of otomycosis in Ilorin, Nigeria. West Afr J Med 21: 34-36.
16. Moffatteh MR et al. Comparison of the recovery rate of otomycosis using betadine and clotrimazole topical treatment. Braz J Otorhinolaryngol.2018 Jul-Aug;84(4):404-409.