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**ORIGINAL RESEARCH**

# Comparison of outcome of 1 percent clotrimazole against 7.5 percent povidone iodine for treatment of otomycosis

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## ABSTRACT

**Background:** Otomycosis is a common superficial fungal infection of the external auditory canal, primarily caused by *Aspergillus* and *Candida* species. Clinically, it presents with black, grey, yellow, or whitish debris containing fungal hyphae. The standard treatment includes antifungal agents such as 1% clotrimazole. However, povidone-iodine, a widely used antiseptic with proven efficacy against bacterial and fungal pathogens, is emerging as a potential alternative. **Aim:** This study aims to compare the effectiveness of 1% clotrimazole and 7.5% povidone-iodine in the treatment of otomycosis. **Methodology:** A hospital-based, randomized clinical study was conducted in the Department of ENT at our institute over a period of two years. A total of 150 clinically diagnosed otomycosis patients were enrolled and randomly assigned into two groups. Group 1 received 1% clotrimazole ear drops, while Group 2 was treated with 7.5% povidone-iodine ear drops. Both groups underwent treatment for three weeks and were evaluated based on clinical resolution of symptoms such as itching, ear discharge, and blockage. **Results:** Both treatment groups showed comparable symptomatic improvement and resolution of infection. There was no statistically significant difference in treatment outcomes, indicating similar efficacy of both agents in managing otomycosis. **Conclusion:** The findings suggest that 7.5% povidone-iodine is equally effective as 1% clotrimazole in the treatment of otomycosis. Hence, povidone-iodine can be considered a cost-effective and accessible alternative, especially in resource-limited settings.

**Keywords:** Otomycosis, External Auditory Canal, 1% Clotrimazole, 7.5% Povidone-Iodine, Antifungal Treatment.



## INTRODUCTION

Otomycosis is a superficial fungal infection that primarily affects the squamous epithelium lining the external auditory canal. It is characterized by symptoms such as pruritus (itching), otalgia (ear pain), aural fullness, otorrhea (ear discharge), and varying degrees of hearing loss or hypoacusis[1]. The global prevalence of otomycosis varies, but it is estimated that approximately 10% of the general population experiences an external auditory canal infection during their lifetime. Among these cases, nearly 90% are unilateral in presentation, with the right and left ears being equally affected[2].

The etiological agents most commonly implicated in otomycosis are saprophytic fungi, particularly *Aspergillus* species (notably *A. niger*, *A. flavus*) and *Candida albicans*. These organisms thrive in warm, humid environments and are often found in tropical and subtropical regions, making otomycosis more prevalent in such climates. Risk factors include use of topical antibiotics or steroids, hearing aid use, trauma to the ear canal, and poor ear hygiene[3].

Clinically, itching is the most frequently reported symptom, affecting up to 70% of patients. This is often accompanied by discomfort (54%), tinnitus, discharge, and hearing impairment (35%). Diagnosis is primarily clinical, based on symptoms and otoscopic findings, such as the presence of fungal debris—typically black, gray, white, or yellow material with visible hyphae[4].

While clotrimazole 1% remains a widely used topical antifungal for treating otomycosis, alternatives such as povidone-iodine are gaining attention[5]. Povidone-iodine is a broad-spectrum antiseptic commonly used in wound care and surgical preparation due to its bactericidal, fungicidal, and sporicidal properties. Its

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affordability and accessibility make it a potential substitute for antifungal agents, particularly in resource-limited settings.

This study aims to compare the clinical outcomes of 1% clotrimazole versus 7.5% povidone-iodine in the treatment of otomycosis, evaluating their effectiveness in symptom resolution and overall therapeutic efficacy.

## MATERIALS AND METHODOLOGY

### Study Design and Rationale

This study was conducted to compare the clinical efficacy of 7.5% povidone-iodine versus 1% clotrimazole in the treatment of otomycosis. It was designed as a hospital-based, randomized clinical study to objectively evaluate and compare treatment outcomes.

### Study Setting and Duration

The study was conducted in the Department of ENT at our institution over a two-year period, from October 2022 to September 2024. A total of 150 patients who fulfilled the inclusion criteria were enrolled and monitored throughout the study duration.

### Study Population and Sampling

A total of 150 patients aged between 15 and 60 years, of either gender, with clinically diagnosed otomycosis were selected using random sampling and divided equally into two groups (n = 75 each).

### Inclusion Criteria

- Age between 15–60 years
- Both male and female patients
- Willingness to participate with informed consent
- Clinical diagnosis of otomycosis

### Exclusion Criteria

- Age below 15 years or above 65 years
- Use of hearing aids
- Patients with chronic suppurative otitis media
- Uncontrolled diabetes mellitus
- Known cases of immunodeficiency (e.g., HIV, immunosuppressive therapy)

### Allocation and Intervention Strategy

Patients were randomly allocated into two groups:

**Group 1:** Treated with 1% clotrimazole ear drops

**Group 2:** Treated with 7.5% povidone-iodine ear drops

Both groups were advised to instill the drops twice daily for three weeks. Weekly follow-ups were conducted to monitor symptom resolution and compliance.

### Clinical Assessment

A comprehensive clinical history was recorded, including symptoms such as itching, discharge, aural fullness, hearing loss, and tinnitus. Otoscopic examination was performed initially, followed by confirmation using a Karl Zeiss operating microscope. Findings noted included:

Color and consistency of discharge

Presence and morphology of fungal debris

Oedema of the ear canal

Status of tympanic membrane

### Outcome Measures

The primary outcome was complete clinical resolution of symptoms and clearance of fungal infection at the end of the three-week treatment period. Secondary outcomes included recurrence rates and any reported side effects.

### Statistical Analysis

Data were entered and analyzed using SPSS version 25. Descriptive statistics were used to summarize demographic variables. Chi-square test was applied to compare categorical variables, while the independent t-test was used for comparing continuous variables between the two groups. A p-value of $<0.05$ was considered statistically significant.

### Ethical Considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrollment. Patient confidentiality was strictly maintained throughout the study, and all procedures were carried out following the principles outlined in the Declaration of Helsinki.

## RESULTS

A total of 150 patients clinically diagnosed with otomycosis were included in the study. Patients were categorized into two age groups: 15–40 years and 41–65 years. It was observed that females were more commonly affected across both age categories. Regarding laterality, 62% of patients presented with left ear involvement, while 38% had right ear involvement. Seasonal variation in case distribution was noted, with a marked increase during the autumn season (October to December), peaking in October with 23 patients. A notable predisposing factor was the practice of self-cleaning the ears, reported by 104 patients (69.3%).

The most commonly reported symptom was itching (74%), followed by ear pain (60.6%), ear discharge (54.6%), deafness (42%), aural fullness (38%), and tinnitus (28.6%). The most prevalent clinical signs included the presence of fungal debris (76.6%), congestion of the tympanic membrane (62.7%), oedema of the ear canal (56%), ear discharge (40.7%), and tragal tenderness (38.6%).

Pre-treatment microbiological examination of ear swabs revealed *Aspergillus niger* as the most frequent isolate (39.3%), followed by *Aspergillus fumigatus* (21.3%), *Aspergillus flavus* (15.3%), *Candida albicans* (11.3%), *Candida tropicalis* (9.3%), and *Rhizopus* (3.3%) (Table 1).

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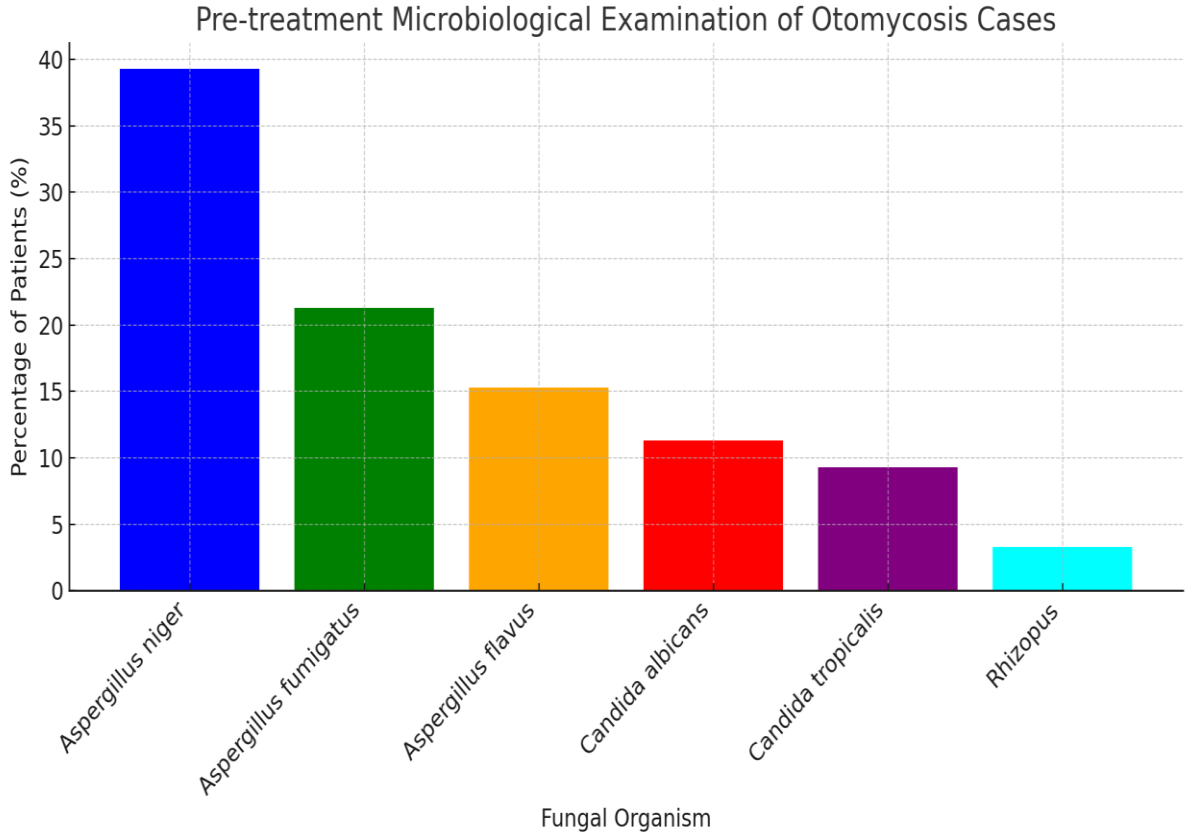
**Table 1: Microbiological Examination – Pre-treatment**

| Organism | Number of Patients | Percentage (%) |
|---|---|---|
| Aspergillus niger | 59 | 39.3 |
| Aspergillus fumigatus | 32 | 21.3 |
| Aspergillus flavus | 23 | 15.3 |
| Candida albicans | 17 | 11.3 |
| Candida tropicalis | 14 | 9.3 |
| Rhizopus | 5 | 3.3 |




After three weeks of treatment, microbiological analysis showed no fungal growth in 91.3% of patients, indicating a high rate of fungal eradication. A small number of residual isolates included *Aspergillus flavus* (3.3%), *Aspergillus fumigatus* (2.7%), *Aspergillus niger* (2.0%), and *Candida albicans* (0.7%) (Table 2).

**Table 2: Microbiological Examination – Post-treatment (After 3 Weeks)**

| Organism | Number of Patients | Percentage (%) |
|---|---|---|
| No growth | 137 | 91.3 |
| Aspergillus niger | 3 | 2.0 |
| Aspergillus fumigatus | 4 | 2.7 |
| Aspergillus flavus | 5 | 3.3 |
| Candida albicans | 1 | 0.7 |

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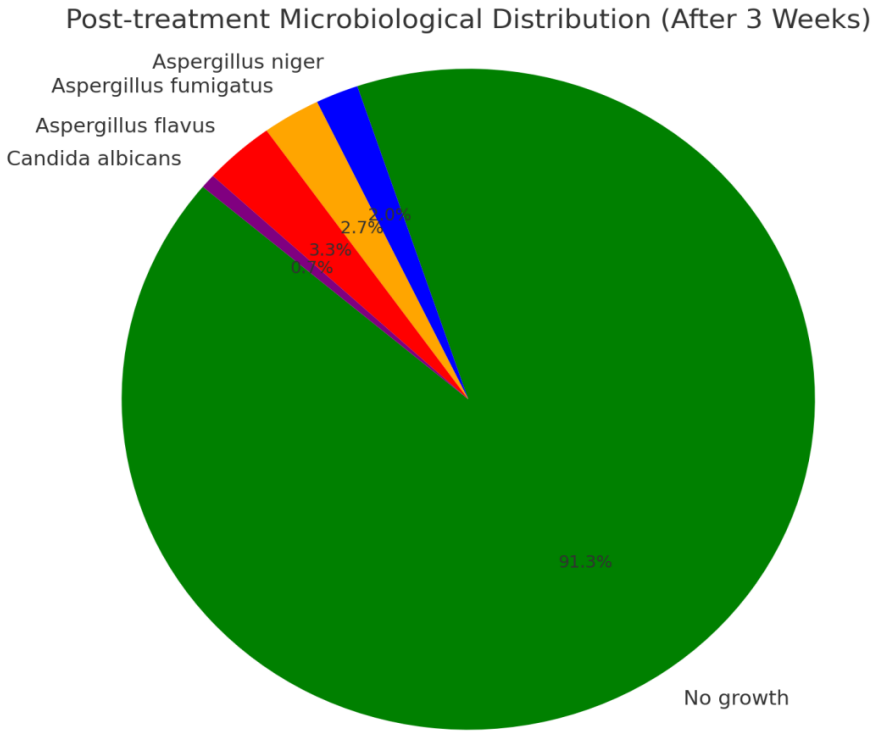
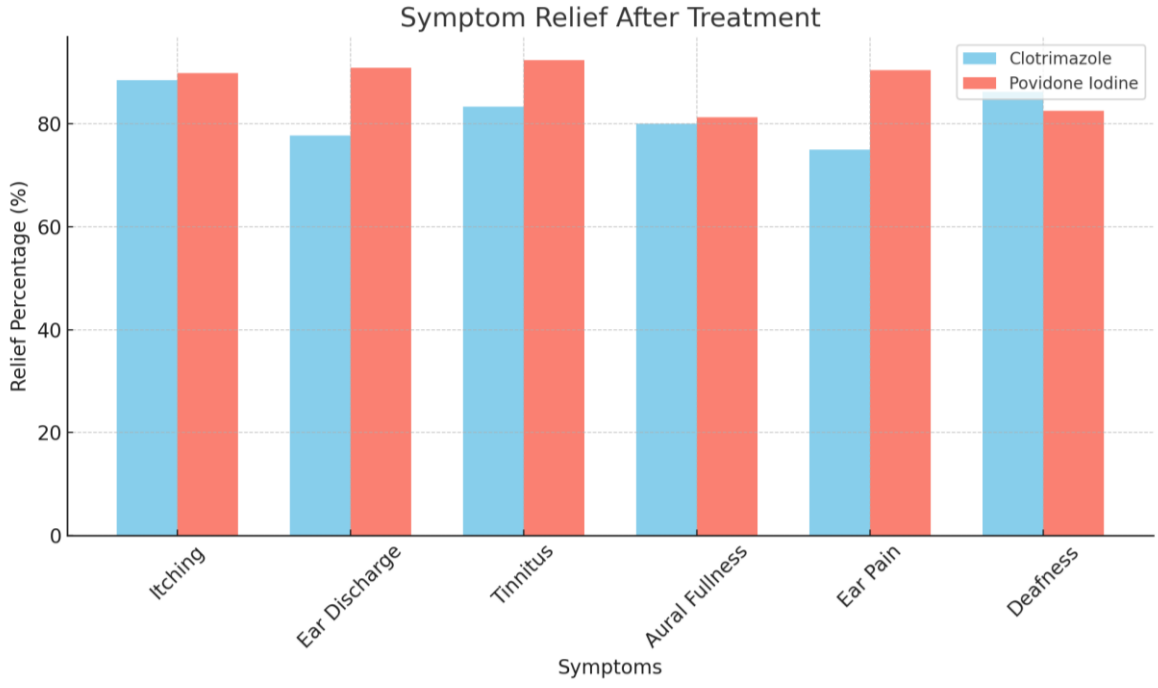



Clinical symptom resolution was noted in both treatment groups. Symptom relief percentages were comparable between clotrimazole and povidone iodine, with povidone iodine showing slightly higher improvement for ear discharge (90.9% vs. 77.8%), tinnitus (92.4% vs. 83.4%), and ear pain (90.5% vs. 75%) (Table 3).

**Table 3: Symptom Relief After Treatment**

| Symptom | Clotrimazole Relief (%) | Povidone Iodine Relief (%) |
|---|---|---|
| Itching | 88.5 | 89.9 |
| Ear Discharge | 77.8 | 90.9 |
| Tinnitus | 83.4 | 92.4 |
| Aural Fullness | 80.0 | 81.3 |
| Ear Pain | 75.0 | 90.5 |
| Deafness | 86.2 | 82.6 |



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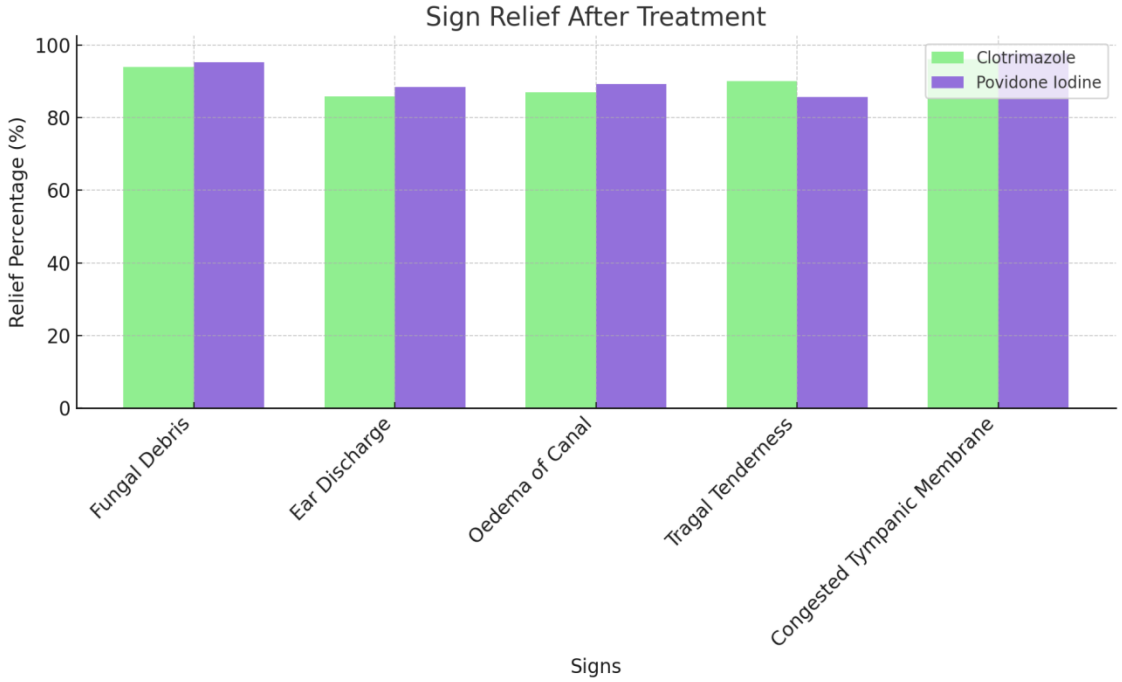
Similarly, signs such as fungal debris and congestion of the tympanic membrane showed slightly better resolution with povidone iodine compared to clotrimazole (Table 4).

**Table 4: Sign Relief After Treatment**

| Sign | Clotrimazole Relief (%) | Povidone Iodine Relief (%) |
|---|---|---|
| Fungal Debris | 94.0 | 95.2 |
| Ear Discharge | 85.8 | 88.4 |
| Oedema of Canal | 86.9 | 89.2 |
| Tragal Tenderness | 90.0 | 85.7 |
| Congested Tympanic Membrane | 96.08 | 97.7 |




Statistical comparison between the two groups revealed no significant differences in symptom resolution for most parameters, although ear discharge ($p = 0.101$), tinnitus ($p = 0.436$), and ear pain ($p = 0.052$) showed a trend toward better outcomes with povidone iodine (Table 5).

**Table 5: P-value Comparison of Symptoms Between Groups**

| Symptom | P-Value |
|---|---|
| Itching | 0.817 |
| Ear Discharge | 0.101 |
| Tinnitus | 0.436 |
| Aural Fullness | 0.906 |
| Ear Pain | 0.052 |
| Deafness | 0.664 |

Sign resolution was also statistically comparable between both groups, with no significant difference observed (Table 6).

**Table 6: P-value Comparison of Signs Between Groups**

| Sign | P-Value |
|---|---|
| Fungal Debris | 0.809 |
| Ear Discharge | 0.753 |
| Oedema of Canal | 0.747 |
| Tragal Tenderness | 0.617 |
| Congested Tympanic Membrane | 0.661 |

Overall, both 1% clotrimazole and 7.5% povidone iodine demonstrated comparable efficacy in treating otomycosis, with slight variations in individual symptom and sign resolution.

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## DISCUSSION

Otomycosis is a frequently encountered ailment in ENT OPD and is Often annoying and demanding for both patient and treating otorhinolaryngologist.This disease reappears often and requires prolonged regimen with supervision. uncontrolled diabetes, proven immune deficiency states, operated mastoid andpersistent middle ear discharge are vulnerability conditions that were exempted from this study. Core principles of management include meticulous aural toileting, using antifungal agents.

Considering socio demographic data all the subjects were divided into two groups 15-40 and 41-65. Among both groups disease was predominant among females and that to age group of 41-65 which is in consonance with study conducted by hasti sarwestani et al [6].

Broadly speaking otomycosis is unilateral disease which is clearly discernible from this study. Predominance of otomycosis in left ear has been noticed in study conducted by Vincent Prasanna et al[7]. In this study vast portion ofpatients had fungal infection in left ear which could be attributed to self-cleaning the ear causing more epithelial damage.

Taking in account of seasonal changes, in this study augmentation of cases was observed during late monsoon season (October to December) which is in consensus with study conducted by Arjun sing Vija sing samorekar et.al[8] on 103 clinically diagnosed patients of otomycosis for seasonal variation of this Clinical entity between 2019 to 2021.

Most of patients in the context of this study presented with complaints of itchingfollowed by ear pain, ear discharge, deafness, aural fullness, tinnitus which are in concordance with the study conducted by shvaib kayode Aremu et al[9] where itching was most primary and common complaint followed by ear pain, auralfulness, ear discharge, tinnitus, hearing impairment.

On analysing the fungal flora growth, a prospective cohort study conducted by S. Chandra Prasad et al[10] showed species of Aspergillus and Candida wereMost pervasive offenders causing otomycosis.In this study Pre-treatment smears revealed predominance of Aspergillus andCandida species and among all the Aspergilli, Niger headed the list followed byfumigatus and flavus and among Candida strains isolates of albicans were morefollowed by tropicalis. This could be ascribed to the pervasive nature ofAspergillus species and its microconidia which are easily catapulted into airwith dust serving as its predominant route of transmission.Various ototopical antifungal preparations have been employed in previous experiences like burrow solution, acetic acid, cresylate drops but these drugs went out of vogue due to their side effects.

Being first in family of azoles clotrimazole is routinely used antifungal either in combination with topical antibiotic or steroid preparation for treatment of otomycosis with proven efficacy of 80% resolution and diminutive recurrence.Povidone iodine on other hand which has versatile antimicrobial properties has been chosen for management of otomycosis due to easy availability, molecular stability, affordability.After treating patients with clotrimazole and povidone iodine both groups had amelioration of manifestations and cues with nearly equal residual rate and there by showing both had equal efficacy in treating otomycosis. In spite of refinements achieved by povidone iodine and clotrimazole in managing otomycosis, there are studies depicting development of significant resistance for azole group of anti-fungal drugs[11].Povidone iodine is an affordable, innocuous substance, effective againstmicrobes with no proven antimicrobial resistance has equal efficacy likeclotrimazole in treating otomycosis.

## CONCLUSION

Otomycosis is a commonly encountered clinical condition in otorhinolaryngology practice, especially in tropical and humid regions. This study evaluated the therapeutic outcomes of 1% clotrimazole and 7.5% povidone-iodine in the management of otomycosis. The results demonstrated that both treatments were comparably effective in resolving clinical symptoms and eradicating fungal infection.However, clotrimazole is associated with certain limitations, including stinging sensation, local erythema, itching, and the potential risk of developing antimicrobial resistance with prolonged use. In contrast, 7.5% povidone-iodine offers several advantages such as broad-spectrum antimicrobial action, low cost, easy availability, better patient compliance, and absence of reported microbial resistance.Based on the findings of this study, 7.5% povidone-iodine can be recommended as an effective, affordable, and practical alternative to conventional antifungal agents in the treatment of otomycosis, particularly in resource-constrained settings.

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