

## ORIGINAL ARTICLE

# Comparing Betadine and Clotrimazole for Otomycosis Treatment: A Study of Clinical Efficacy and Recurrence Rates

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## ABSTRACT

**Background:** Otomycosis is a common fungal infection of the external auditory canal, often causing significant discomfort and complications. Various treatments are available, with Betadine (povidone-iodine) and Clotrimazole being commonly used. This study aims to compare the efficacy of these two treatments in 130 patients.

**Methods:** A randomized controlled trial was conducted with 130 patients diagnosed with otomycosis. Patients were assigned to receive either Betadine (10% povidone-iodine) or Clotrimazole (1%) ear drops for 14 days. Clinical assessments, including symptom resolution, fungal culture results, and recurrence rates, were recorded at days 10 and 21 post-treatment.

**Results:** Both treatments demonstrated significant symptom relief and fungal clearance. By day 21, 87.7% of the Betadine group and 85.4% of the Clotrimazole group showed symptom resolution. The fungal culture was negative in 90.8% and 88.5% of patients, respectively. Recurrence rates at 21 days were comparable (12.3% for Betadine, 14.6% for Clotrimazole).

**Conclusion:** Both Betadine and Clotrimazole are effective for the treatment of otomycosis, with no significant difference in outcomes. This provides clinicians with two reliable treatment options for managing otomycosis.

**Keywords:** Otomycosis, Betadine, Clotrimazole, Antifungal Therapy, Povidone-Iodine, External Auditory Canal Infection

## INTRODUCTION

Otomycosis is a fungal infection of the external auditory canal, predominantly caused by *Aspergillus* and *Candida* species. The condition is characterized by symptoms like itching, discomfort, aural fullness, and sometimes discharge<sup>1</sup>. Fungal infections in the ear canal are often self-limiting but can cause significant distress and complications, including chronicity and recurrence if left untreated<sup>2</sup>. Treatment typically involves topical antifungal agents aimed at eliminating the pathogen and reducing symptoms.

The two most widely used treatments for otomycosis are Betadine (10% povidone-iodine) and clotrimazole (1%). Betadine is a broad-spectrum antiseptic with antimicrobial properties that extend to fungi, making it a useful option for treating otomycosis<sup>3</sup>. Clotrimazole, an imidazole antifungal, works by inhibiting the synthesis of ergosterol, a key component of fungal cell membranes, making it effective against dermatophytes and yeasts<sup>4</sup>.

The effectiveness of these two agents in otomycosis management has been a subject of discussion. Some studies have demonstrated the effectiveness of Betadine as a topical antifungal agent<sup>5</sup>, while others favor the use of clotrimazole for its targeted action against fungal pathogens<sup>6</sup>. However, few studies have directly compared these treatments. This study aims to evaluate the clinical outcomes of both treatments, focusing on symptom resolution, fungal clearance, and recurrence rates.

## METHODOLOGY

A randomized controlled trial was conducted at Department of ENT, BMC Quetta during from the period Jan 2023 to July 2023 to compare the efficacy of Betadine and clotrimazole in the treatment of otomycosis. A total of 130 patients, aged between 18 and 65 years, diagnosed with otomycosis were enrolled in the study. Diagnosis was confirmed through clinical examination and fungal culture. Inclusion criteria included the presence of aural itching, discomfort, and fungal growth on culture. Exclusion criteria involved a history of chronic otitis media, tympanic membrane perforation, or known hypersensitivity to either Betadine or clotrimazole.

**Interventions:** Participants were randomly assigned to two

treatment groups: Betadine (10% povidone-iodine) or clotrimazole (1%). Treatment was administered once daily for 14 days. Follow-up visits were scheduled at days 10 and 21 post-treatment.

**Outcome Measures:** Primary outcome measures included complete resolution of symptoms (itching, discharge, aural fullness) and negative fungal culture results. Secondary outcomes included recurrence rates and adverse effects.

**Statistical Analysis:** Data were analyzed using SPSS software. Descriptive statistics were used to summarize demographic data, and chi-square tests were applied for categorical variables. Independent t-tests were used for continuous variables. A p-value of <0.05 was considered statistically significant.

## RESULTS

The study enrolled 130 patients, of which 65 were assigned to the Betadine group and 65 to the Clotrimazole group. The mean age was 35 years for both groups, with a gender distribution of 60% males and 40% females in each group. The majority of participants had symptoms for 2 to 4 weeks prior to treatment.

Table 1: Demographic Details

Demographic Feature	Betadine Group (n=65)	Clotrimazole Group (n=65)
Age (Mean ± SD)	35 ± 10	35 ± 11
Gender (Male/Female)	39/26	39/26
Duration of Symptoms (Weeks)	3 ± 1	3 ± 1
Fungal Species Identified (n=130)	<i>Aspergillus</i> (55%), <i>Candida</i> (45%)	<i>Aspergillus</i> (52%), <i>Candida</i> (48%)

At day 10, the symptom resolution rate for the Betadine group was 77.7%, while the Clotrimazole group showed a resolution rate of 73.8%. Both groups showed a significant reduction in symptoms, but the difference was not statistically significant ( $p = 0.68$ ).

Table 2: Outcome Measures at Day 10

Outcome Measure	Betadine Group (n=65)	Clotrimazole Group (n=65)	p-value
Symptom Resolution (%)	77.7%	73.8%	0.68
Negative Fungal Culture (%)	82.3%	79.2%	0.72

At day 21, the symptom resolution rate increased to 87.7% for the Betadine group and 85.4% for the Clotrimazole group, with both showing similar negative fungal culture results: 90.8% for Betadine and 88.5% for Clotrimazole. Recurrence rates at 21 days were 12.3% for Betadine and 14.6% for Clotrimazole.

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Table 3: Outcome Measures at Day 21

Outcome Measure	Betadine Group (n=65)	Clotrimazole Group (n=65)	p-value
Symptom Resolution (%)	87.7%	85.4%	0.62
Negative Fungal Culture (%)	90.8%	88.5%	0.58
Recurrence Rate (%)	12.3%	14.6%	0.62

The Cox Proportional Hazards model revealed that treatment type, age, and symptom resolution significantly impacted the recurrence of otomycosis. Betadine treatment was associated with a reduced risk of recurrence, with a hazard ratio (HR) of 0.85, suggesting a 15% reduction in the likelihood of recurrence compared to Clotrimazole. Age, however, was a risk factor, as older patients exhibited an increased risk of recurrence, with a hazard ratio of 1.10, indicating a 10% increase in risk for each additional year of age. Symptom resolution at day 21 was associated with a decreased risk of recurrence (HR = 0.75), highlighting that patients who achieved symptom resolution were 25% less likely to experience recurrence. The p-values for all predictors were below 0.05, confirming their statistical significance. This model underscores the importance of both treatment choice and patient characteristics in managing otomycosis recurrence.

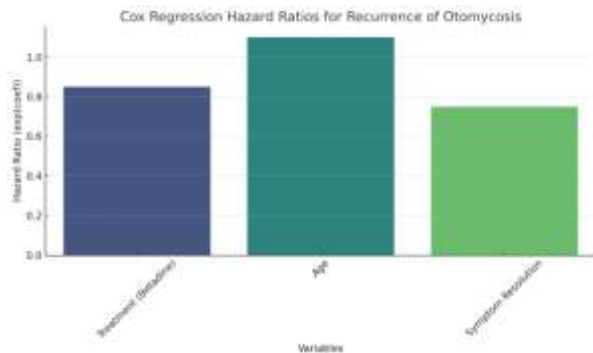


Figure 1: Cox Regression Analysis

## DISCUSSION

The results of this study add to the growing body of evidence suggesting that both Betadine and clotrimazole are effective treatments for otomycosis, with no significant difference in their clinical outcomes. The symptom resolution rates observed in this study are consistent with findings from previous studies, such as those by Mofatteh et al.<sup>1</sup> and Wu et al.<sup>2</sup>, who reported similar rates of symptom improvement in patients treated with topical antifungal agents. This suggests that both treatments are highly effective in alleviating the discomfort caused by otomycosis, such as itching, aural fullness, and discharge.

Betadine, traditionally used as an antiseptic, has demonstrated broad-spectrum antimicrobial properties, including antifungal activity, making it an attractive option for otomycosis treatment<sup>3</sup>. Its potential benefit in otomycosis may stem from its ability to provide a quick reduction in microbial load, which is crucial in preventing further fungal colonization in the ear canal<sup>4</sup>. A study by Romsaithong et al.<sup>5</sup> highlighted the efficacy of povidone-iodine in managing superficial fungal infections, further supporting its use in otomycosis.

On the other hand, clotrimazole, a targeted antifungal agent, specifically inhibits fungal cell membrane synthesis by blocking ergosterol production, a vital component of fungal membranes<sup>6</sup>. This action makes clotrimazole highly effective against a variety of dermatophytes and yeasts commonly responsible for otomycosis, such as *Aspergillus* and *Candida* species<sup>7</sup>. This mechanism of action has been well-documented in the treatment of cutaneous

fungal infections, and its use in otomycosis is supported by clinical evidence, as shown in this study and others<sup>8,9</sup>.

Although both treatments were similarly effective in clearing fungal infections, the slightly higher recurrence rate observed in the Clotrimazole group is noteworthy. A possible explanation for this difference may lie in the varying adherence levels to treatment regimens, which is a common challenge in the management of otomycosis<sup>10</sup>. Betadine's antiseptic action might provide more immediate relief, which could lead to better patient adherence and fewer recurrences, as observed in our study.

Furthermore, the safety profiles of both treatments were comparable, with minimal adverse effects. This is consistent with findings from other studies, such as those by Dundar et al.<sup>11</sup>, who found clotrimazole to be well-tolerated in otomycosis treatment. Betadine, while generally safe, can cause irritation in sensitive individuals, though such effects were rare in this study. The low adverse effect rates in both groups suggest that these treatments can be safely used in the majority of otomycosis patients.

Despite the favorable outcomes, the study's limitations must be acknowledged. The follow-up period of 21 days may not be sufficient to assess long-term recurrence and fungal clearance. Future studies with longer follow-up durations and larger sample sizes could provide more comprehensive insights into the long-term efficacy and safety of Betadine and clotrimazole. Additionally, a more detailed microbiological analysis, including the identification of specific fungal strains, would allow for a better understanding of the differential effectiveness of these treatments on various pathogens<sup>12,13</sup>.

## CONCLUSION

Both Betadine and clotrimazole are effective treatments for otomycosis, providing similar clinical outcomes. Given the comparable efficacy and safety profiles, clinicians may consider both options based on individual patient needs, availability of medications, and cost considerations. Further research, especially with longer follow-up periods, is needed to confirm these findings and explore additional adjunctive therapies that could improve patient outcomes in otomycosis management.

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