Section: Ear, Nose and Throat (ENT)

Original Research Article

A COMPARATIVE PROSPECTIVE STUDY BETWEEN TOPICAL APPLICATION OF 1 PERCENT GENTIAN VIOLET VS 1 PERCENT CLOTRIMAZOLE IN TREATING OTOMYCOSIS

Paras Singhal[1], Shivam Narang[2], Shatakshi Dubey[3]

[1]Junior Resident, Department of ENT, Index Medical College Hospital & Research Centre, Indore, Madhya Pradesh, India.
[2]Consultant, Jain ENT Hospital, Jaipur, Rajasthan, India.
[3]Junior Resident, Department of ENT, Index Medical College Hospital & Research Centre, Indore, Madhya Pradesh, India.

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Corresponding Author:
Dr. Shivam Narang,
Consultant, Jain ENT Hospital, Jaipur, Rajasthan, India.
Email: shivamnarang1605@gmail.com

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ABSTRACT

Background: Otomycosis is a superficial fungal infection of the external auditory canal, commonly seen in tropical and subtropical climates. While clotrimazole is a widely accepted treatment, increasing resistance and cost-related concerns have prompted interest in alternative therapies such as gentian violet (GV). This study aims to compare the clinical efficacy and safety of 1% clotrimazole versus 1% gentian violet in the treatment of otomycosis.

Materials and Methods: A prospective, randomized, cross-sectional study was conducted at Jain ENT Hospital, involving 100 patients clinically and mycologically diagnosed with otomycosis. Patients were randomized into two groups: Group A received 1% clotrimazole ear drops (TDS for 2 weeks), while Group B received topical 1% gentian violet on Day 0 and Day 7. Clinical evaluation was performed at baseline, 1 week, and 2 weeks to assess symptom resolution, recurrence, and adverse events. Statistical analyses were conducted using Chi- square and unpaired t-tests, with a significance threshold of $p < 0.05$.

Results: By the end of two weeks, 92% of patients in the clotrimazole group achieved complete symptom resolution compared to 84% in the GV group ($p = 0.21$). Clotrimazole showed statistically superior improvement in aural fullness ($p = 0.0012$), otalgia ($p = 0.014$), and clearance of fungal debris ($p = 0.047$). Both treatments were well-tolerated; mild local irritation was reported in 6% of GV patients and 2% of clotrimazole patients.

Conclusion: Both clotrimazole and gentian violet are effective topical treatments for otomycosis. Clotrimazole demonstrated higher clinical efficacy, while GV remains a viable, low-cost alternative, especially in resource-limited settings.

Keywords: Otomycosis, Clotrimazole, Gentian violet, Antifungal therapy, External auditory canal.

INTRODUCTION

Otomycosis is a common superficial fungal infection of the external auditory canal, characterized by symptoms such as pruritus, otorrhea, ear discomfort, and occasionally hearing loss. The global prevalence of otomycosis varies between 9% and 30%, with a significantly higher incidence in tropical and subtropical regions where hot and humid climates facilitate fungal growth.[1] It is estimated to account for approximately 30–90% of otitis externa cases, with adults being more frequently affected than children, and a higher prevalence in females compared to males.[2,3]

A wide range of fungal pathogens have been implicated in otomycosis, with Aspergillus and Candida species being the predominant etiologic agents. Other less common causative fungi include Dermatophytes, Fusarium spp., Penicillium spp., Mucor spp., and Geotrichum spp.[4,5] Multiple predisposing factors contribute to the development of otomycosis, including mechanical trauma to the ear

canal, accumulation of cerumen, excessive moisture or humidity, swimming, prolonged antibiotic or steroid use, and history of ear surgeries.[6,7]

The management of otomycosis remains a clinical challenge due to high relapse rates, persistent symptoms, and rising antifungal resistance. Current therapeutic approaches focus on elimination of predisposing factors, mechanical debridement of fungal debris, and topical or systemic antifungal administration.[8,9] Among the antifungals used, clotrimazole, bifonazole, miconazole, and tolnaftate have been reported as effective options, although there is no consensus on a universally superior treatment.[10-13] Notably, clotrimazole demonstrates high efficacy (95–100%) against Candida species but shows variable activity against Aspergillus [14].

Due to increasing antifungal resistance, particularly among Aspergillus spp., and concerns about the overuse of conventional agents disrupting the microbial flora of the ear canal, there is a growing interest in evaluating alternative therapies. Numerous in vivo and in vitro studies have assessed various antifungal agents as alternatives to standard therapeutics.[15-17] While several agents have been tested clinically, their efficacy remains uncertain. Gentian violet, an aniline dye with known antibacterial and antifungal properties, has demonstrated promising antifungal activity in existing literature, with some reports citing effectiveness of up to 80% in otomycosis cases [18-20]. Despite its historical use, there is limited comparative clinical evidence evaluating its efficacy against widely accepted agents such as clotrimazole.

In light of this gap, the present study is designed to prospectively compare the clinical effectiveness of topical 1% gentian violet and 1% clotrimazole in the treatment of otomycosis. The aim is to assess outcomes including symptom resolution, recurrence rates, and overall therapeutic advantage, thereby providing a more evidence-based approach to selecting optimal treatment strategies for otomycosis.

MATERIALS AND METHODS

This prospective, randomized, cross-sectional study was conducted in the Department of Otorhinolaryngology, Jain ENT Hospital over a period of 12 months, after obtaining ethical approval from the Institutional Ethics Committee. Written informed consent was obtained from all patients enrolled in the study.

A total of 100 patients clinically diagnosed with otomycosis were included in the study. Diagnosis was confirmed using 10% potassium hydroxide (KOH) mount microscopy of ear discharge, demonstrating fungal elements such as septate or aseptate hyphae, spores, or yeast-like cells. Patients were randomized using block randomization into two equal groups of 50 patients each.

Inclusion and Exclusion Criteria

Patients of age above 5 years presenting with clinical symptoms of otomycosis—such as otorrhea, pruritus, otalgia, aural fullness—and confirmed by 10% potassium hydroxide (KOH) mount microscopy showing fungal elements (septate/aseptate hyphae, yeast cells, or conidia), were included.

Exclusion criteria included: patients with coexistent bacterial otitis externa/media, chronic suppurative otitis media (CSOM) with tympanic membrane perforation, immunocompromised status (e.g., uncontrolled diabetes, chemotherapy, radiotherapy, HIV), history of external ear anomaly, ongoing antifungal therapy, or fungal infections elsewhere in the body.

Sample Size Calculation

Based on preliminary prevalence data and therapeutic outcome variability, the minimum sample size was initially calculated to be 35 per group. Accounting for a 10% follow-up loss and 90% compliance, the sample size was adjusted to 45 patients per group, making a total of 90 patients. However, to enhance statistical power and account for real-world clinical variability, the final sample size was rounded and extended to 100 patients, with 50 patients in each treatment group.

Study Design and Allocation

After enrollment, patients were randomly assigned into two groups using block randomization:

- Group A (Clotrimazole group): Received 1% clotrimazole ear drops (in a propylene glycol and lignocaine base) with instructions to instill three drops in the affected ear three times daily (TDS) for two weeks.
- Group B (Gentian Violet group): Received a single topical application of 1% gentian violet solution to the external auditory canal using a sterile cotton swab, followed by a reapplication on the seventh day.

All patients underwent thorough aural toileting (dry mopping/suctioning) and elimination of predisposing factors. Follow-up assessments were scheduled at 1 week and 2 weeks. At each visit, clinical evaluation was done for symptom resolution, compliance, side effects, and need for repeat application.

At each follow-up, clinical assessment was performed for resolution of symptoms, repeat aural toileting was carried out, medication compliance was evaluated, and any adverse reactions (e.g., burning sensation, irritation, or hypersensitivity) were documented. Patients who developed side effects prior to their scheduled visits were advised to report to the ENT clinic or emergency department immediately.

Treatment response was categorized as

- Complete resolution: Absence of all presenting symptoms by Day 14.
- Partial resolution: Improvement in some but not all presenting symptoms.
- No resolution: Persistence or worsening of initial symptoms.

Outcome Measures

- Effectiveness was assessed based on clinical improvement in presenting symptoms (ear discharge, itching, aural fullness, otalgia, debris) and complete clinical recovery, defined as the absence of all presenting features by the end of 2 weeks.
- Patients were instructed to report to the ENT outpatient clinic or emergency services if they developed any side effects such as local irritation, burning sensation, or allergic reactions.

Statistical Analysis

All collected data were entered into Microsoft Excel and analyzed using SPSS software 25.0. Categorical variables were analyzed using the Chi-square test, and continuous variables were compared using the unpaired t-test. A p-value of <0.05 was considered statistically significant for all comparisons.

RESULTS

A total of 100 patients diagnosed with otomycosis were enrolled and analyzed, with 50 patients in each group: Group A (1% Clotrimazole) and Group B (1% Gentian Violet). There were no follow-up losses, and all participants completed the study through the two-week follow-up period.

The comparative analysis of patient demographics and clinical responses in both treatment groups yielded several important observations. Based on Table 1, the mean age of patients in the clotrimazole group was 37.2 ± 17.8 years, while that in the gentian violet group was 36.5 ± 16.4 years. This difference was not statistically significant (p = 0.685), suggesting age-wise comparability between groups. Gender distribution was nearly identical, with 50% males and 50% females in the gentian violet, group and 48% males and 52% females in the clotrimazole group (p = 0.873), confirming a balanced sex distribution. The side of ear involvement was also comparable between the groups, with right-sided cases slightly more common in the clotrimazole group (56%) and left-sided cases more frequent in the gentian violet group (48%). Bilateral involvement was rare in both groups. The lack of statistical significance (p = 0.312) in laterality affirms that the baseline characteristics of both groups were well matched.

Table 1: Demographic Characteristics of Study Participants (N=100)

Demographic Variable	Clotrimazole Group (n=50)	Gentian Violet Group (n=50)	p-value
Age (Mean ± SD)	37.2 ± 17.8	36.5 ± 16.4	0.685 *
Gender			0.873 **
Male (%)	26 (52.0%)	25 (50.0%)	
Female (%)	24 (48.0%)	25 (50.0%)	
Side of Involvement			0.312 **
Right Ear (%)	28 (56.0%)	21 (42.0%)	
Left Ear (%)	18 (36.0%)	24 (48.0%)	
Bilateral (%)	4 (8.0%)	5 (10.0%)	

Statistical tests used: *Unpaired t-test for age; *Chi-square test for categorical variables

Table 2 reflects the clinical response of patients after two weeks of treatment. Aural fullness, a key symptom of otomycosis, was completely resolved in all patients receiving clotrimazole, while it persisted in 22% of the gentian violet group. This difference was statistically significant (p = 0.0012), demonstrating the superior efficacy of clotrimazole in relieving this symptom. Similarly, otalgia was significantly lower in the clotrimazole group (4%) compared to the gentian violet group (20%) with a p-value of 0.014, indicating better pain relief in the clotrimazole-treated patients. Fungal debris in the external auditory canal was present in only 12% of patients in the clotrimazole group versus 28% in the gentian violet group, a statistically significant difference (p = 0.047), highlighting more effective fungal clearance with clotrimazole. Although not statistically significant, trends also favored clotrimazole in other parameters. Ear itching persisted in 24% of the gentian violet group versus 10% in the clotrimazole group (p = 0.084), while otorrhea was seen in 10% of gentian violet cases and none in the clotrimazole group (p = 0.052). These trends, although not reaching statistical significance, consistently pointed toward better clinical outcomes in the clotrimazole group.

Table 2: Clinical Features Two Weeks Post-Treatment (N = 100)

Clinical Feature	Clotrimazole Group (n=50)	Gentian Violet Group (n=50)	p- value
Ear Itching			0.084
Present (%)	5 (10.0%)	12 (24.0%)	
Absent (%)	45 (90.0%)	38 (76.0%)	
Aural Fullness			**0.0012**
Present (%)	0 (0.0%)	11 (22.0%)	
Absent (%)	50 (100%)	39 (78.0%)	
Otorrhoea			0.052
Present (%)	0 (0.0%)	5 (10.0%)	
Absent (%)	50 (100%)	45 (90.0%)	
Otalgia (Ear Pain)			**0.014**

Present (%)	2 (4.0%)	10 (20.0%)	
Absent (%)	48 (96.0%)	40 (80.0%)	
Fungal Debris in External Ear Canal			0.047
Present (%)	6 (12.0%)	14 (28.0%)	
Absent (%)	44 (88.0%)	36 (72.0%)	

Statistical Test Used: Chi-square test; Note: Values in bold denote statistical significance (p < 0.05)

An assessment of overall clinical recovery revealed that at the end of the first week, complete symptom resolution was achieved in 10 patients (20%) from the clotrimazole group and 14 patients (28%) from the gentian violet (GV) group. Although this early recovery rate was slightly higher in the GV group, the difference was not statistically significant (p = 0.33). By the end of the second week, a marked improvement was noted in both groups. Complete clinical recovery was observed in 46 patients (92%) in the clotrimazole group compared to 42 patients (84%) in the GV group. While this trend favored clotrimazole in terms of final treatment outcome, the difference again did not reach statistical significance (p = 0.21), indicating that both treatments were largely effective.

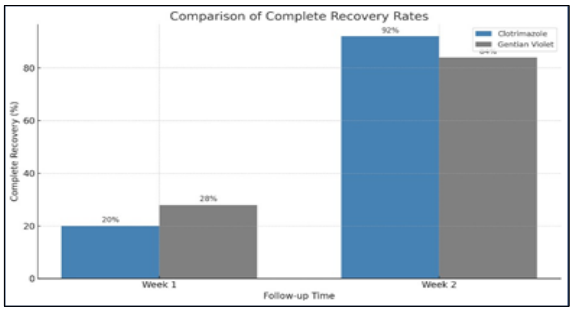

Figure 1: Comparison of Complete Recovery Rates

In terms of safety and tolerability, no major adverse effects were reported in either treatment group. However, mild local irritation was noted in a small number of patients—3 cases (6%) in the GV group and 1 case (2%) in the clotrimazole group. These episodes of irritation were transient and did not necessitate discontinuation of treatment. Thus, both agents were found to be safe and well-tolerated throughout the treatment course.

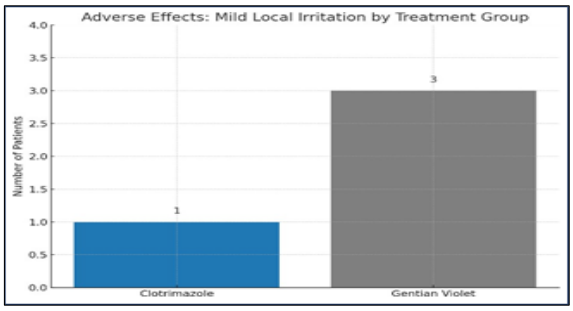

Figure 2: Adverse Effects: Mild Local Irritation by Treatment Group

DISCUSSION

Otomycosis is a superficial fungal infection of the external auditory canal that is particularly prevalent in warm and humid climates. Environmental factors such as moisture, heat, poor ear hygiene, trauma to the external ear, and the use of topical antibiotics or steroids predispose individuals to this condition.[2,21] The most frequently implicated fungal species include Aspergillus and Candida, though microbiological identification was not conducted in our study, which is a limitation.[2,22-27]

In our prospective comparative study, we assessed the efficacy of 1% clotrimazole versus 1% gentian violet (GV) in treating otomycosis among 100 patients, with 50 patients in each treatment group. Both groups were well matched for baseline demographics and laterality, eliminating potential confounding biases. The most commonly affected age group was 25–35 years (32%), consistent with previous studies by Dhakal S et al,[18] Gupta S et al,[21] Prasad et al,[2] and Mofatteh et al,[28] likely reflecting greater exposure to predisposing environmental and occupational factors. Gender distribution was equal, similar to findings reported by Hamza et al,[27] Beaney GP et al,[29] and Malik et al.[30]

It is widely reported that otomycosis is more common in adults than in children, which has been supported by studies including those by Prasad et al,[2] Kaur et al,[26] and Philip et al.[17] The increased prevalence among adults may be due to higher environmental exposure, frequent use of topical medications, or predisposing behaviors such as the use of earbuds and oil instillation.

There was no statistically significant difference in baseline demographic characteristics between the two treatment groups, ensuring comparability. Our findings are consistent with other demographic analyses conducted in similar hospital-based studies such as those by Lageju et al,[24] and Kaur et al,[26]

In the present study, aural fullness and otalgia were the most frequently reported symptoms, found in over 84% of patients, closely mirroring the findings of Khan et al,[22] Navaneethan et al,[9] and Kaur et al.[26] Although pruritus has been cited as the most common symptom in several other studies—including those by Gregson AE et al,[31] Cheraghsahar et al,[23] and Lageju et al,[24] in our cohort, it was reported in 78% of patients, making it the second most frequent complaint.

Various predisposing factors have been associated with otomycosis, such as hot, humid weather, poor ear hygiene, self-inflicted trauma, and overuse of antibiotic/steroid ear drops. These factors were not exhaustively analyzed in our study but are extensively documented in literature by Prasad et al,[2] Rao and Rao,[25] and Malik et al.[30]

The clinical response at two weeks strongly favored clotrimazole in terms of resolution of aural fullness

(100% vs 78%, p = 0.0012), otalgia (96% vs 80%, p = 0.014), and clearance of fungal debris (88% vs 72%, p = 0.047). Although differences in otorrhea and ear itching did not reach statistical significance, they still trended toward greater symptom resolution in the clotrimazole group. These findings are in line with earlier reports by Navaneethan N et al,[9] Dhakal S et al,[18] and Teharia RK et al,[31] demonstrating high efficacy of clotrimazole in otomycosis, often ranging from 90% to 100%.

Interestingly, at the one-week follow-up, a higher proportion of patients in the gentian violet group (28%) reported complete recovery compared to the clotrimazole group (20%), though this difference was not statistically significant. This suggests that GV may have a slightly more rapid onset of symptomatic relief. However, by the end of two weeks, clotrimazole showed a higher complete recovery rate (92% vs 84%), affirming its overall superior effectiveness, albeit not statistically significant (p = 0.21). Similar findings were reported by Dhakal S et al,[18] with higher trend in complete recovery was observed in GV group at first week while recovery was better in clotrimazole group at second week.

Adverse effects were minimal and self-limiting in both groups. Mild local irritation was more commonly reported in the GV group (6%) than the clotrimazole group (2%), but no treatment discontinuation was required. This highlights the favorable safety profile of both agents, making them suitable for routine outpatient use.

Our findings resonate with existing literature. Edward et al. reported the effective use of GV in a single patient,[33] while other studies have consistently highlighted clotrimazole's strong antifungal profile. However, unlike clotrimazole, gentian violet is inexpensive, widely available, and may serve as an effective alternative, especially in resource-constrained settings.

This study has certain limitations. Firstly, fungal species identification was not performed, which might have further explained differential responses to antifungal agents. Secondly, the short two-week follow- up did not allow assessment of recurrence or long-term outcomes. Finally, being a single-center study, generalizability is limited.

In conclusion, both 1% clotrimazole and 1% gentian violet are effective in treating otomycosis, with clotrimazole demonstrating slightly better overall efficacy and symptom resolution by the end of two weeks. Gentian violet, however, remains a viable and cost-effective alternative, especially in settings with limited resources. Future studies with longer follow-up and species identification may help refine therapeutic strategies further.

CONCLUSION

It can be concluded that both 1% clotrimazole and 1% gentian violet are effective and well-tolerated topical treatments for otomycosis. Clotrimazole demonstrated superior efficacy in achieving complete symptom resolution, particularly in addressing aural fullness, otalgia, and fungal debris, by the end of two weeks. However, gentian violet showed a comparatively faster early clinical response and holds promise as a cost-effective and accessible alternative, especially in low-resource settings. Given the favorable safety profiles of both agents and their utility in outpatient management, they remain viable first-line options. To strengthen these findings and guide clinical decision-making, further large-scale, multicentric studies with longer follow-up periods and fungal species identification are recommended.

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