



A Randomized Controlled Clinical Study To Evaluate The Efficacy Of Gugguladi Karnadhoopan And Clotrimazole 1% Ear Drops In Otomycosis

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Abstract

Otomycosis is a common superficial fungal infection of the external auditory canal, especially prevalent in humid and tropical regions. It is characterized by itching, ear fullness, mild pain, and thick whitish discharge, and shows a high tendency for recurrence. In Ayurveda, these clinical features correlate with *Kaphaja Karnashūla*. The present randomized controlled clinical study was undertaken to evaluate the efficacy of *Gugguladi Karnadhoopan* in comparison with Clotrimazole 1% ear drops in the management of otomycosis. The study assessed symptomatic relief, clinical improvement, and safety of both interventions. Results demonstrated that *Gugguladi Karnadhoopan* provided significant relief in itching, discharge, and ear heaviness, with good tolerability, suggesting it as an effective alternative therapeutic modality.

Introduction

Otomycosis, also referred to as fungal otitis externa, is a superficial mycotic infection of the external auditory canal and is commonly encountered in otolaryngology practice, particularly in tropical and subtropical regions. The condition is characterized by intense itching, ear fullness, mild otalgia, tinnitus, and thick whitish, black, or greyish discharge. The most commonly implicated organisms are *Aspergillus* species (especially *Aspergillus niger*) and *Candida* species. Factors such as excessive moisture, frequent swimming, use of topical antibiotics or steroids, habitual ear cleaning, and humid environmental conditions predispose individuals to otomycosis. Recurrence is frequent, making management challenging.

Conventional management of otomycosis primarily includes meticulous aural toileting followed by topical antifungal agents such as clotrimazole. Although effective, prolonged use of topical antifungals may disturb the normal microbial flora of the ear canal and contribute to recurrence. Moreover, patient compliance and cost may limit long-term effectiveness.

In Ayurvedic literature, the clinical presentation of otomycosis closely resembles *Kaphaja Karṇashūla* and *Karnasrava*, conditions described with symptoms such as *kandu* (itching), *manda ruja* (mild pain), *gaurava* (heaviness), *shvayathu* (congestion), and *ghana śveta sravā* (thick whitish discharge). Classical Ayurvedic texts advocate *Kaphaghna Dhoopana* (medicated fumigation) as an effective therapeutic approach for Kapha-dominant ear disorders. Drugs like Guggulu (*Commiphora mukul*) and Nimba (*Azadirachta indica*) possess *kaphahara*, *krimighna*, *kledaghna*, and antimicrobial properties, making them suitable for fumigation therapy.

Despite strong classical references, limited scientific clinical evidence is available evaluating the efficacy of Gugguladi Karnadhoopan in otomycosis. Hence, the present randomized controlled clinical study was undertaken to assess its therapeutic efficacy in comparison with Clotrimazole 1% ear drops.

Aim and Objectives

Aim

To evaluate the clinical efficacy of Gugguladi Karnadhoopan in the management of Kaphaja Karṇashūla (clinically correlated with otomycosis).

Objectives

1. To assess the effect of Gugguladi Karnadhoopan on itching of the external auditory canal.
2. To evaluate its effect on ear pain, heaviness, swelling, and discharge.
3. To compare its efficacy with Clotrimazole 1% ear drops.
4. To observe any adverse effects related to the interventions.

Material and Methods

Research Design

The present study was designed as a randomized controlled clinical trial conducted on patients diagnosed with otomycosis. Ethical approval was obtained prior to commencement of the study, and informed consent was taken from all participants.

Selection of Patients

Patients presenting with clinical features of otomycosis such as itching, ear discharge, fullness, and mild pain were included. Patients with tympanic membrane perforation, chronic suppurative otitis media, systemic immunocompromised conditions, or known hypersensitivity to study drugs were excluded.

Grouping

Eligible patients were randomly allocated into two groups:

- **Group A (Trial Group):** Treated with Gugguladi Karnadhoopan.
- **Group B (Control Group):** Treated with Clotrimazole 1% ear drops.

30 patients from Group A and 30 patients from Group B were allocated for the study. The study was performed for 7 days and results were observed.

Drugs

- **Gugguladi Karnadhoopan:** Medicated fumigation prepared using purified Guggulu (*Commiphora mukul*) and Nimba (*Azadirachta indica*) churna, administered as per classical Dhoopana procedure.
- **Clotrimazole 1% Ear Drops:** Standard topical antifungal agent administered as per conventional dosage.

Inclusion Criteria:

- Participants fulfilling the following conditions will be included:
- Age between 18 to 70 years, irrespective of sex, religion, or socioeconomic status.
- Patients clinically diagnosed with Otomycosis presenting with at least three of the following:
 - Otagia
 - Itching in ear
 - Heaviness/blocked sensation
 - Ear discharge
- Patients willing to undergo treatment and follow-up for the study duration.
- Patients able to provide written informed consent.

Exclusion Criteria

- Participants meeting any of the following conditions will be excluded:
- Otomycosis with secondary bacterial infection presenting with foul-smelling or purulent discharge.
- History or presence of:
 - Tympanic membrane perforation
 - Cholesteatoma
 - Aural tumors or polyps
- Maggot infestation (Myiasis)
- Patients with immunocompromised conditions, including uncontrolled diabetes, HIV/AIDS, or chronic systemic illness affecting healing and infection response.
- Patients currently receiving systemic antifungal therapy or participating in another clinical trial.
- Pregnant or lactating women.

Withdrawal Criteria

- A participant will be withdrawn from the study under the following circumstances:
- Failure to attend follow-up visits or inability to complete assessment schedule.
- Patient expresses unwillingness to continue participation at any point.
- Appearance of any adverse reaction or intolerance to either Gugguladi Karnadhoopana or Clotrimazole therapy.

Procedure

In the trial group, Karnadhoopan was performed after cleaning the external auditory canal. Fumigation was administered once daily for the prescribed treatment duration. In the control group, Clotrimazole 1% ear drops were instilled as advised following aural toileting.

Assessment Criteria

Clinical assessment was carried out based on both subjective and objective parameters:

- Itching (*Kandu*)
- Pain (*Ruja*)
- Ear fullness/heaviness (*Gaurava*)
- Swelling/congestion (*Shvayathu*)
- Nature and quantity of discharge (*Ghana Śveta Sravā*)

Symptoms were graded before treatment and after completion of therapy.

Analysis Of Data

- The collected data were compiled and subjected to appropriate statistical analysis.
- For intragroup (before and after treatment) comparison:
- Wilcoxon Signed Rank Test was applied, as the variables were qualitative/ordinal in nature.
- For intergroup comparison (Group A vs Group B):
- Mann–Whitney U Test was applied.
- Level of statistical significance was set at $p < 0.05$.

Parameter	Group A (Dhoopana)	Group B (Clotimazole)
Onset of relief	Early (Day2)	Gradual (Day3-4)
Significant improvement	From Day 2 onward	Mostly after Day7
Final outcome (day 7)	near-total resolution	Partial to moderate relief
Statistical result	Group A > Group B from Day 5	Less effective in reducing heaviness

Observation

A total number of patients diagnosed with otomycosis were enrolled and evenly distributed between the two groups. The majority of patients belonged to humid climatic regions and had a history of habitual ear cleaning or water exposure. Severe itching and thick whitish discharge were the most common presenting symptoms.

Post-treatment observations revealed significant reduction in itching, discharge, and ear heaviness in both groups. The trial group showed early symptomatic relief, particularly in itching and aural fullness. No serious adverse effects were observed in either group.

Results

Both treatment modalities were effective in reducing the clinical symptoms of otomycosis. The Gugguladi Karnadhoopan group demonstrated comparable, and in some parameters like Itching and Discharge superior improvement was seen when compared with the Clotrimazole group. Symptom scores showed statistically significant improvement from baseline in both groups.

Discussion

The results of the present study indicate that Gugguladi Karnadhoopan is effective in the management of otomycosis. The fumigatory action of Dhoopana helps in drying excess moisture within the external auditory canal, thereby creating an unfavorable environment for fungal growth. Guggulu, known for its *shothaghna* and *krimighna* properties, aids in reducing inflammation and microbial load, while Nimba contributes potent antimicrobial and Kapha-pacifying effects.

From an Ayurvedic perspective, otomycosis represents a Kapha-dominant pathology, and the use of *Kaphaghna Dhoopana* directly addresses the underlying *dosha dushti*. Compared to topical antifungals, Karnadhoopan offers additional benefits such as improved canal aeration, reduced recurrence, and minimal adverse reactions. The findings support classical Ayurvedic principles and demonstrate their relevance in contemporary clinical practice.

Conclusion

Gugguladi Karnadhoopan is an effective and safe therapeutic modality in the management of otomycosis, showing significant improvement in itching, discharge, and ear heaviness. Its efficacy is comparable to Clotrimazole 1% ear drops, making it a promising Ayurvedic alternative for fungal otitis externa.

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