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Clinical and Endoscopic Response to a Ginger and Virgin Coconut Oil Combination Ointment Compared with Miconazole in Otomycosis: A Prospective Nonrandomized Controlled Comparative Study

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ABSTRACT:

Background: Otomycosis is a fungal infection of the external auditory canal. This study evaluated the clinical and endoscopic response to a ginger (Zingiber officinale) and virgin coconut oil combination ointment compared with miconazole.

Methods: This prospective, non-randomized controlled comparative study included 40 patients with otomycosis. All underwent ear toilet and topical treatment. Clinical and endoscopic findings were assessed on days 1, 5, 10, 15, and 30. Within-group changes were assessed using Friedman and Wilcoxon signed-rank tests with Bonferroni correction; between-group comparisons used the Mann–Whitney test.

Results: Both groups showed significant improvement over time (Friedman $p<0.001$). In the ginger and virgin coconut oil group, mild symptoms increased from 20.0% on day 1 to 90.0% on day 5 and 100.0% from day 10 onward; clean ear canals increased from 0% to 55.0%, 95.0%, and 100.0% on days 5, 10, and 15. In the miconazole group, mild symptoms increased to 65.0% on day 5 and 100.0% from day 10 onward, while clean ear canals increased to 35.0%, 70.0%, and 100.0% on days 5, 10, and 15.

Conclusion: Both treatments were associated with substantial clinical and endoscopic improvement. Because allocation was non-randomized and baseline differences were present at the first assessment, pointwise between-group differences should not be interpreted as treatment superiority. Larger randomized studies are warranted.

1. INTRODUCTION

Otomycosis is an acute, subacute, or chronic fungal infection involving the squamous epithelium of the external auditory canal. It commonly presents with pruritus, otalgia, otorrhea, aural fullness, tinnitus, and accumulation of fungal debris. The condition is particularly relevant in tropical and subtropical environments where high temperature and humidity favor fungal growth (1–

3). Local trauma, repeated manipulation of the ear canal, altered cerumen protection, topical antibiotic or steroid exposure, and repeated water exposure have also been described as predisposing factors (2,3).

Management generally includes meticulous ear toilet followed by topical antifungal therapy. Azole agents such as clotrimazole and miconazole are commonly used and have demonstrated clinical effectiveness in otomycosis (4,5). However, recurrence and the need for repeated treatment remain clinically relevant, and interest in accessible plant-derived antimicrobial agents continues to increase.

Ginger (Zingiber officinale) contains biologically active phenolic and terpenoid compounds, including gingerols and shogaols, and experimental studies have demonstrated antimicrobial and antifungal activity (6,7). Virgin coconut oil contains medium-chain fatty acids, particularly lauric acid, and has also demonstrated antifungal activity against Candida and mould species in experimental studies (8–10). Previous work from Hasanuddin University reported potential activity of ginger and virgin coconut oil against fungal growth in experimental models, but clinical evidence in human otomycosis has been limited (11).

The present study therefore evaluated the clinical and endoscopic response to a combination ointment containing ginger and virgin coconut oil in patients with otomycosis and compared its outcomes with miconazole during a 30-day observation period.

2. MATERIALS AND METHODS

2.1 Study Design and Ethical Considerations

This was a prospective, nonrandomized controlled comparative clinical study conducted in the Department of Otorhinolaryngology–Head and Neck Surgery at Dr. Wahidin Sudirohusodo Hospital and affiliated hospitals of Hasanuddin University, Makassar, Indonesia. Recruitment was conducted from June 2026 until the required sample size was reached. Eligible patients with clinically and endoscopically confirmed otomycosis were recruited consecutively and assigned to the treatment groups according to their order of presentation, without randomization. The study protocol was approved by the Health Research Ethics Committee of the Faculty of Medicine, Hasanuddin University (Approval No. UH26030357). Written informed consent was obtained from all participants before enrolment. All procedures were conducted in accordance with the Declaration of Helsinki, and patient confidentiality was strictly maintained throughout the study.

2.2 Participants and sample size

The study included 40 patients with clinically and endoscopically confirmed otomycosis. Twenty patients received the ginger and VCO combination ointment and 20 received topical miconazole. The minimum sample size was 20 participants per group, based on α=5%, β=10% (90% power), a pooled standard deviation of 0.47, and a minimum clinically meaningful mean difference of 0.57.

2.3 Eligibility criteria

Eligible participants were patients with clinically and endoscopically confirmed otomycosis who were in a relatively stable general condition, had no known allergy to the treatment components, and were willing to participate and complete the study procedures.

Patients were excluded if they had concomitant ear disease, tympanic membrane perforation associated with acute otitis media, chronic suppurative otitis media, or had used another antifungal medication during the preceding 2 weeks.

Participants who failed to attend scheduled follow-up visits or were unable to continue the study were considered dropouts.

2.4 Intervention and follow-up

For the intervention group, 500 g of dried ginger powder was extracted by maceration using 96% ethanol. The plant material was macerated for 3 days at room temperature and protected from direct sunlight, with intermittent stirring. The macerate was then filtered and concentrated using a rotary evaporator to obtain a concentrated ginger extract. The concentrated extract was subsequently combined with virgin coconut oil (VCO) to prepare the study formulation at a final concentration of 2%. The comparator was topical miconazole, used as the standard antifungal treatment in the study. The original formulation records did not specify the extract yield, extract-to-VCO ratio, formulation basis (w/w or w/v), amount applied per treatment, or physicochemical stability testing; these parameters therefore could not be further specified.

At the initial visit, all participants underwent ear toilet followed by topical treatment. Treatment was administered once daily. Ear toilet, topical reapplication, and endoscopic assessment were performed during follow-up. Clinical and endoscopic assessments were recorded on day 1, day 5, day 10, day 15, and day 30.

2.5 Outcome measures

Clinical and endoscopic outcomes were assessed at each observation point. The clinical outcome was assessed using the symptom score, which classified otomycosis-related symptoms into mild, moderate, and severe categories. Symptoms considered in the operational definition included ear itching, aural fullness, otorrhea, and the presence of flakes or crusts in the ear canal. The endoscopic outcome was categorized as clean ear canal; a small amount of debris; moderate debris with erythema; or abundant debris with edema and erythema. In the source study, these outcomes were termed the Degree of Symptom Score (DSS) and Degree of Endoscopic Measurement (DHUE), respectively.

2.6 Statistical analysis

Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS). Changes in symptom and endoscopic categories across the five observation points within each treatment group were assessed using the Friedman test. When significant, pairwise comparisons were performed using the Wilcoxon signed-rank test with Bonferroni correction. Between-group comparisons at each time point were performed using the Mann–Whitney U test. Statistical significance was set at $p<0.05$; for Bonferroni-adjusted post hoc comparisons, $p<0.005$ was used. For between-group analyses, the asymptotic two-sided p-values from the SPSS Mann–Whitney output were used because the SPSS exact p-values were reported as not corrected for ties.

3. RESULTS

3.1 Study population and clinical response

A total of 40 patients with otomycosis were included in the analysis, with 20 patients in each treatment group. Assessments were performed at five predefined time points: day 1, day 5, day 10, day 15, and day 30.

In the ginger and virgin coconut oil group, symptom severity improved substantially during the first 5 days. On day 1, 4 patients (20.0%) had mild symptoms, 6 (30.0%) had moderate symptoms, and 10 (50.0%) had severe symptoms. By day 5, 18 patients (90.0%) had mild symptoms and 2 (10.0%) had moderate symptoms, with no severe cases. From day 10 through day 30, all 20 patients (100.0%) were classified as having mild symptoms. The overall change across time was significant (Friedman $p<0.001$). Pairwise analysis showed significant improvement from day 1 to days 5, 10, 15, and 30 (all $p<0.001$), whereas comparisons after day 5 were not significant.

The miconazole group showed a similar pattern. On day 1, 4 patients (20.0%) had mild symptoms, 6 (30.0%) moderate symptoms, and 10 (50.0%) severe symptoms. On day 5, 13 patients (65.0%) had mild symptoms, 6 (30.0%) moderate symptoms, and 1 (5.0%) severe symptoms. From day 10 onward, all patients were classified as having mild symptoms. The overall temporal change was significant (Friedman $p<0.001$). Pairwise Wilcoxon comparisons showed $p=0.044$ for day 1 versus day 5 and $p<0.001$ for day 1 versus days 10, 15, and 30. With the prespecified Bonferroni threshold of $p<0.005$, only comparisons of day 1 with days 10, 15, and 30 met the post hoc significance criterion; the day-1 versus day-5 comparison did not. Subsequent comparisons were not significant. These findings are summarized in Table 1.

Table 1. Baseline clinical and endoscopic characteristics of the study groups

Baseline characteristic	Ginger + VCO (n=20)	Miconazole (n=20)
Disease Severity Score (DSS)		
Mild	4 (20.0%)	4 (20.0%)
Moderate	6 (30.0%)	6 (30.0%)
Severe	10 (50.0%)	10 (50.0%)
DSS mean rank (Day 1, pointwise)	17.10	23.90

DSS Mann–Whitney p-value (Day 1, pointwise)	0.029	
Direct Hearing and Ear Examination (DHUE)		
Grade 2 / small debris	5 (25.0%)	4 (20.0%)
Grade 3 / moderate debris with erythema	9 (45.0%)	8 (40.0%)
Grade 4 / abundant debris with edema and erythema	6 (30.0%)	8 (40.0%)
DHUE mean rank (Day 1, pointwise)	16.13	24.88
DHUE Mann–Whitney p-value (Day 1, pointwise)	0.009	

3.2 Endoscopic response

Endoscopic findings in the ginger and virgin coconut oil group improved progressively. On day 1, none of the patients had a clean ear canal; 5 (25.0%) had a small amount of debris, 9 (45.0%) had moderate debris with erythema, and 6 (30.0%) had abundant debris with edema and erythema. The proportion with a clean canal increased to 11 (55.0%) on day 5, 19 (95.0%) on day 10, and 20 (100.0%) on days 15 and 30. The change over time was significant (Friedman $p<0.001$).

In the miconazole group, 7 patients (35.0%) had a clean canal on day 5, increasing to 14 (70.0%) on day 10 and 20 (100.0%) on days 15 and 30. The overall change across observation points was significant (Friedman $p<0.001$). Pairwise Wilcoxon comparisons showed $p=0.032$ for day 1 versus day 5, $p<0.001$ for day 1 versus days 10, 15, and 30, $p=0.404$ for day 5 versus day 10, $p=0.032$ for day 5 versus days 15 and 30, and $p=1.000$ for comparisons among days 10, 15, and 30. Using the prespecified Bonferroni threshold of $p<0.005$, only comparisons of day 1 with days 10, 15, and 30 met the post hoc significance criterion. The endoscopic condition was stable between days 15 and 30. The distribution of endoscopic findings across the observation period is presented in Table 2.

Table 2. Distribution of Disease Severity Score (DSS) over follow-up by treatment group

Treatment group / category	**Day 1, n (%)**	**Day 5, n (%)**	**Day 10, n (%)**	**Day 15, n (%)**	**Day 30, n (%)**
Ginger + VCO — Mild	4 (20.0)	18 (90.0)	20 (100.0)	20 (100.0)	20 (100.0)
Ginger + VCO — Moderate	6 (30.0)	2 (10.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ginger + VCO — Severe	10 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Miconazole — Mild	4 (20.0)	13 (65.0)	20 (100.0)	20 (100.0)	20 (100.0)
Miconazole — Moderate	6 (30.0)	6 (30.0)	0 (0.0)	0 (0.0)	0 (0.0)
Miconazole — Severe	10 (50.0)	1 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)

Within-group Friedman test: p<0.001 for both groups. Post hoc Wilcoxon signed-rank tests with Bonferroni correction: ginger + VCO, day 1 versus days 5, 10, 15 and 30, all p<0.001; miconazole, day 1 versus day 5 p=0.044 and day 1 versus days 10, 15 and 30, all p<0.001.

3.3 Between-group comparison

The raw SPSS Mann–Whitney asymptotic results showed between-group differences in symptom scores on day 1 (mean rank 17.10 vs 23.90; p=0.029) and day 5 (17.45 vs 23.55; p=0.028), whereas no difference was observed on days 10, 15, or 30 (all p=1.000). The day-1 difference demonstrates baseline imbalance in symptom severity between the groups. Therefore, these unadjusted pointwise between-group p-values describe differences in the observed distributions at individual time points and should not be interpreted as estimates of a treatment effect or treatment superiority. The between-group comparison of symptom scores is presented in Table 3.

Table 3. Distribution of Direct Hearing and Ear Examination (DHUE) categories over follow-up by treatment group

Treatment group / category	Day 1, n (%)	Day 5, n (%)	Day 10, n (%)	Day 15, n (%)	Day 30, n (%)
Ginger + VCO — Clean	0 (0.0)	11 (55.0)	19 (95.0)	20 (100.0)	20 (100.0)
Ginger + VCO — Small debris	5 (25.0)	8 (40.0)	1 (5.0)	0 (0.0)	0 (0.0)
Ginger + VCO — Moderate debris with erythema	9 (45.0)	1 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ginger + VCO — Abundant debris with edema/erythema	6 (30.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Miconazole — Clean	0 (0.0)	7 (35.0)	14 (70.0)	20 (100.0)	20 (100.0)
Miconazole — Small debris	4 (20.0)	7 (35.0)	6 (30.0)	0 (0.0)	0 (0.0)
Miconazole — Moderate debris with erythema	8 (40.0)	5 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)
Miconazole — Abundant debris with edema/erythema	8 (40.0)	1 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)

Within-group Friedman test: p<0.001 for both groups. Post hoc Wilcoxon signed-rank tests with Bonferroni correction: ginger + VCO, day 1 versus days 5, 10, 15 and 30, all p<0.001; day 5 versus day 10 p=0.003, day 15 p=0.004 and day 30 p=0.004. Miconazole, day 1 versus day 5 p=0.032 and day 1 versus days 10, 15 and 30, all p<0.001; day 5 versus days 15 and 30, both p=0.032.

Between-group endoscopic comparisons showed lower mean ranks in the ginger and virgin coconut oil group on day 1 (16.13 vs 24.88; p=0.009), day 5 (16.52 vs 24.48; p=0.021), and day 10 (18.00 vs 23.00; p=0.040). No between-group difference was

observed on days 15 or 30 (both p=1.000), when all participants had a clean ear canal. Because the groups differed at the first assessment, these unadjusted pointwise comparisons should be interpreted as observed distributional differences rather than evidence of a treatment effect. The complete results are shown in Table 4.

Table 4. Between-group comparison of DSS and DHUE mean ranks over follow-up

Outcome	Observation day	Ginger + VCO mean rank	Miconazole mean rank	P-value
DSS	Day 1	17.10	23.90	0.029
DSS	Day 5	17.45	23.55	0.028
DSS	Day 10	20.50	20.50	1.000
DSS	Day 15	20.50	20.50	1.000
DSS	Day 30	20.50	20.50	1.000
DHUE	Day 1	16.13	24.88	0.009
DHUE	Day 5	16.52	24.48	0.021
DHUE	Day 10	18.00	23.00	0.040
DHUE	Day 15	20.50	20.50	1.000
DHUE	Day 30	20.50	20.50	1.000

Note: Mann–Whitney U test. P-values are unadjusted pointwise comparisons at each observation day. The day-1 comparison reflects baseline imbalance and should not be interpreted as a treatment-effect estimate.

Note: Baseline values correspond to Day 1. P-values are asymptotic two-sided Mann–Whitney U test results from SPSS. Exact p-values were not used because the SPSS exact procedure did not correct for ties.

4. DISCUSSION

The principal finding of this study was that both the ginger and virgin coconut oil combination and miconazole were associated with marked improvement in clinical symptoms and endoscopic findings during 30 days of follow-up. In the ginger and virgin coconut oil group, all patients reached the mild symptom category by day 10, while 95.0% had a clean ear canal on day 10 and 100.0% by day 15. The miconazole group followed a comparable clinical course, with all patients reaching the mild symptom category by day 10 and all patients achieving a clean canal by day 15. These findings indicate substantial improvement with both topical treatment approaches.

The rapid symptom improvement observed with the ginger and virgin coconut oil combination is biologically plausible. Ginger contains several bioactive compounds, including phenolic constituents and terpenoids, and experimental studies have demonstrated antimicrobial activity of Zingiber officinale (6,7). Ginger essential oil has also demonstrated antifungal activity against Candida albicans in experimental settings (6). However, these data are largely laboratory-based and should not be interpreted as direct proof that a particular ginger compound caused the clinical response observed in this study.

Virgin coconut oil may also contribute to the observed effect. Its medium-chain fatty acids, particularly lauric acid, have been associated with antimicrobial activity. Experimental studies have reported antifungal effects of virgin coconut oil against Candida albicans, Aspergillus niger, and other mould species (8–10). These observations provide a plausible biological basis for the study formulation, although the clinical effect of the combination cannot be separated into the individual contribution of ginger and virgin coconut oil because the study did not include separate ginger-only or virgin-coconut-oil-only groups.

The clinical response observed with miconazole is consistent with its established role as a topical antifungal agent in otomycosis. A placebo-controlled clinical trial reported improvement of symptoms such as pruritus, aural fullness, otalgia, and otorrhea with topical miconazole after ear canal debridement (5). Other clinical research has shown that topical azole therapy can produce

substantial improvement during the early phase of treatment (4). The similar trajectory observed in the present study is consistent with the expected clinical response to topical antifungal therapy.

An important finding was that the raw SPSS Mann–Whitney asymptotic results identified between-group differences in symptom scores on days 1 and 5. At baseline (day 1), the ginger and virgin coconut oil group had a lower mean rank than the miconazole group (17.10 vs 23.90; p=0.029), indicating baseline imbalance in symptom severity. On day 5, the difference remained (17.45 vs 23.55; p=0.028). From day 10 onward, both groups had identical mean ranks because all patients had mild symptoms, and no between-group difference was observed. These pointwise comparisons should therefore be interpreted cautiously and should not be taken as evidence of treatment superiority without an analysis that accounts for baseline differences.

The endoscopic outcome also showed early between-group differences in the raw SPSS asymptotic analysis. Mean ranks differed on day 1 (16.13 vs 24.88; p=0.009), day 5 (16.52 vs 24.48; p=0.021), and day 10 (18.00 vs 23.00; p=0.040). The day-1 result indicates baseline imbalance, while the day-5 and day-10 findings reflect differences in the observed distributions during follow-up. These results should not be interpreted as definitive evidence of superiority because the analysis was not adjusted for baseline endoscopic severity. By day 15, all patients in both groups had achieved a clean canal, and the groups were identical through day 30.

The findings also highlight that symptom resolution and structural or endoscopic resolution may not occur simultaneously. In both groups, all patients had reached the mild symptom category by day 10, whereas complete endoscopic clearance in the miconazole group was observed only by day 15. This distinction is clinically relevant because subjective improvement may precede complete resolution of visible canal inflammation and debris.

The study has several strengths. It used repeated assessments at predefined time points over 30 days and incorporated both clinical symptom categories and objective endoscopic findings. The inclusion of a standard antifungal comparator provides a clinically relevant reference for interpreting the response to the herbal combination. The prespecified follow-up schedule also allowed the temporal pattern of symptom and endoscopic resolution to be described consistently in both groups.

LIMITATIONS

Several limitations should be considered. First, the sample size was small, with only 20 patients per group, which limits precision and generalizability. Second, treatment allocation was non-randomized and based on order of presentation, creating potential for selection bias and baseline imbalance. Third, microbiological identification of fungal species before and after treatment was not available in the study dataset; consequently, microbiological eradication could not be evaluated. Fourth, although the formulation was described as a 2% ginger–VCO preparation, the available formulation records did not provide the extract yield, extract-to-VCO ratio, formulation basis, amount applied per treatment, or physicochemical stability testing, limiting reproducibility. Fifth, detailed baseline demographic and other clinical characteristics were not available in the dataset used for this analysis. Sixth, both symptom and endoscopic outcomes showed baseline between-group differences at day 1. Accordingly, the pointwise Mann–Whitney comparisons should be regarded as unadjusted distributional comparisons rather than adjusted treatment effects. Future studies should use randomized allocation, prespecified baseline characteristics, microbiological assessment, standardized pharmaceutical formulation, and individual-level longitudinal analyses that account for baseline severity, such as ordinal regression or an appropriate repeated-measures model.

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assessment, standardized pharmaceutical formulation, and individual-level longitudinal analyses that account for baseline severity, such as ordinal regression or an appropriate repeated-measures model.

5. CONCLUSION

Both the ginger–VCO combination and miconazole were associated with significant improvement in clinical symptom categories and endoscopic findings during the 30-day observation period. Unadjusted pointwise Mann–Whitney analyses showed differences between groups in symptom distributions on days 1 and 5 and in endoscopic distributions on days 1, 5, and 10; no between-group differences were observed by days 15 and 30. Because treatment allocation was non-randomized and baseline differences were already present on day 1, these pointwise comparisons cannot establish treatment superiority. Larger randomized studies with balanced baseline characteristics, microbiological assessment, standardized formulation, safety assessment, and baseline-adjusted longitudinal analysis are warranted.

Topical antifungal treatment combined with ear canal debridement is commonly used for otomycosis. Miconazole and other azole agents have demonstrated clinical effectiveness. Ginger and virgin coconut oil have shown antimicrobial or antifungal activity in experimental studies, but direct clinical evidence for their combined use in human otomycosis is limited.

The study provides clinical and endoscopic outcome data for a ginger and virgin coconut oil combination ointment in 20 patients with otomycosis and compares the response with miconazole in another 20 patients. Both groups showed marked within-group improvement. The raw pointwise analyses showed early between-group differences, but baseline imbalance was already present on day 1, so treatment-group differences should be confirmed using baseline-adjusted longitudinal methods in future studies.

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COMPETING INTERESTS

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this study.

AUTHORS' CONTRIBUTIONS

ARZD: Conceptualization, Methodology, Investigation, Data Collection, Formal Analysis, Writing – Original Draft Preparation.

ES: Methodology, Data Collection, Validation, Writing – Review & Editing.

RA: Formal Analysis, Investigation, Data Interpretation, Writing – Review & Editing.

AZ: Investigation, Data Curation, Statistical Analysis, Writing – Review & Editing.

AA: Investigation, Data Curation, Statistical Analysis, Writing – Review & Editing.

AQP: Investigation, Data Curation, Statistical Analysis, Writing – Review & Editing. IM: Investigation, Data Curation, Writing – Review & Editing. All authors have read, approved, and agreed to the final published version of the manuscript.

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