Original Article

Use of a single topical agent versus a combination of topical agent and oral antibiotics in the management of otitis externa: A comparative study

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Abstract

Objective: To compare the therapeutic efficacy of topical antibiotic therapy alone versus combined topical and systemic antibiotic therapy in the management of acute otitis externa.

Methods: This quasi-experimental study was conducted at the Department of Otorhinolaryngology, Pak Emirates Military Hospital, Rawalpindi, over a period of 9 months. Visual Analogue Scale score (VAS) for otalgia, canal erythema, oedema, and tenderness were recorded at presentation, 3rd, and 7th day follow-ups. Data were analysed using SPSS 23; categorical variables were expressed as percentages and continuous variables as mean ± SD, with Independent Samples t-test and Mann–Whitney U test applied as appropriate, considering $p < 0.05$ statistically significant.

Results: Both groups showed improvement; however, combined therapy resulted in a greater reduction in pain scores (VAS) at follow-ups ($p < 0.001$). Significantly better improvement was demonstrated in otalgia ($p = 0.019$), itching ($p = 0.001$), canal oedema ($p < 0.001$), and erythema ($p < 0.001$), while no significant difference was observed for otorrhea ($p > 0.05$).

Conclusion: Combined topical and systemic antibiotic therapy provided faster symptomatic relief in cases of acute otitis externa. Microbiological data gathering should be encouraged to facilitate targeted therapy and support antimicrobial stewardship principles.

Keywords: Ciprofloxacin, External auditory canal, Infection, Otitis Externa, Pseudomonas Aeruginosa, Staphylococcus aureus.

Introduction

Acute otitis externa (OE) refers to inflammation of the skin of the outer ear canal and is diagnosed by the presence of pain with or without the presence of ear discharge and/or itching, lasting for a duration of less than 6 weeks. The clinical signs consist of the painful movement of the pinna or tragal tenderness, along with a variable degree of ear canal oedema, erythema, with or without any debris.[2] The outer cartilaginous part of the external auditory canal is lined by cerumen, which maintains its acidic pH and creates a bacteriostatic and fungistatic environment. OE has a 10% lifetime incidence in the adult population;[3] meanwhile, a Pakistani study recorded 12% prevalence of acute otitis externa in their study population. The self-induced manipulations in the ear may disrupt this natural defensive mechanism, leading to overgrowth of microorganisms.[4] A study reported 76.25% cases of OE occur secondary to self-induced trauma.[5] Staphylococcus aureus and Pseudomonas aeruginosa are considered to be commonly isolated disease-causing bacteria.[6] The treatment strategies for this condition involve aural toilet, supportive care, and eliminating the causal agent. The most effective way to administer antibiotics is still debated. A considerable heterogeneity is recorded in the literature; studies point out that oral antibiotics are prescribed for 16%–40% cases and topical antibiotics for 14%–50% cases of OE,[7] reflecting a lack of consensus regarding the optimal mode of antibiotic administration.

To the best of our knowledge, there is a lack of local comparative data on this topic in the last 05years, evaluating the outcomes of topical versus combined antibiotic therapy in

acute otitis externa. This gap may lead to inconsistent treatment practices, unnecessary systemic antibiotic use, and an increased risk of antimicrobial resistance. Therefore, the rationale of this study was to gather local, evidence-based data comparing the efficacy of topical therapy alone versus combined topical and systemic antibiotic therapy in the management of acute otitis externa and promote rational antibiotic use in line with antimicrobial stewardship principles.

Materials And Methods

This quasi-experimental study was conducted at the Department of Otorhinolaryngology, Pak Emirates Military Hospital, Rawalpindi, over a period of 9 months, from 1st January to 30th September 2025, after obtaining approval from the Ethical Review Committee of the hospital. Written consent was obtained from all participants before their recruitment for the study.

The sample size was calculated for the comparison of two proportions ($\alpha = 0.05$, power = 80–90%). Due to significant heterogeneity in the available literature, with variable efficacy reported for topical versus combined therapy, the expected 7-day cure rates were assumed to be 60% for topical and 99% for combined therapy. In the absence of recent local data, these estimates were based on clinical judgment to reflect meaningful differences between the treatment groups.

Allowing for 10% attrition, 24 per group were required; for enhanced precision, 200 (100 per group) were enrolled to improve statistical precision, increase external validity, reduce the margin of error, strengthen subgroup representation, and enhance the reliability and generalisability of treatment effect estimates in the absence of robust local epidemiological data. Adults (≥18 years) with acute otitis externa (<6 weeks) and at least one symptom (otalgia, otorrhea, or itchiness) and two signs (tragal tenderness, canal oedema, erythema, or wet debris) were included. The exclusion criteria were chronic or fungal otitis externa, tympanic membrane perforation, debilitating illnesses, pregnancy, lactation, recent systemic antibiotics, ear surgery in the last 3 months, and immunocompromised states such as uncontrolled diabetes mellitus. A non-probability consecutive sampling technique was used, and participants were allocated alternately to the two groups (first patient to Group A, next to Group B, and so on) to maintain equal group sizes and a systematic approach to group assignment in the study setting while minimising selection discretion. The study variables included demographics, symptom profile (otalgia, otorrhea, itchiness, and duration), and otoscopic findings (canal erythema, oedema, tragal tenderness, and debris), which were recorded on a predesigned proforma. Otalgia was graded using a Visual Analogue Scale (VAS) score (0–10): mild = 1–3, moderate = 4–6, and severe = 7–10. Otorrhea was considered mild when the canal was moist, moderate when it was partially filled, and severe when it overflowed. Itchiness was considered mild if occasional, moderate if it disturbed activities, and severe if persistent or disturbed sleep.[12]

Canal erythema and oedema were graded otoscopically on a 4-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe). Mild erythema was defined as patchy redness, moderate diffuse redness, and severe extension to the pinna. Mild oedema permitted full tympanic membrane (TM) visibility, moderate oedema caused partial TM obstruction, and severe oedema caused near or complete occlusion with no TM visibility. Group A received topical ciprofloxacin, whereas Group B received combined topical and oral ciprofloxacin. Changes were suggested in the case of known allergies. Follow-ups were planned on days 3 and 7. Outcome assessment was performed by an independent ENT specialist who was blinded to group allocation and not involved in treatment administration, thereby reducing assessment bias. This study was reported in accordance with the TREND recommendations for non-randomised interventional studies. Statistical analysis was performed using SPSS 23. Categorical data are presented as percentages, and continuous data are presented as mean ± standard deviation. The Mann–Whitney U test and Independent Samples t-test were employed to assess statistical significance, with $p < 0.05$ considered significant..

Results

In group A, 100 participants (49 men and 51 women) were enrolled with a mean age of 38.0 ± 10.5(range, 18–60) years. The mean duration of symptoms was 3.1 ± 2.0(1–10) days. All patients had varying degrees of pain during the 1st and 2nd follow up. However, 86 patients were completely pain-free at the last follow-up. The symptoms and clinical signs of group A are shown in Table 1.

In Group B (combined therapy), 100 participants (52 men and 48 women) were enrolled with a mean age of 37.0 ± 9.9 (18-60) years and symptom duration of 3.1 ± 1.9 (1-10) days. The clinical features are shown in Table 2.

The mean VAS score in Group A decreased from 4.7 ± 1.6 at presentation to 2.8 ± 1.2 at the first follow-up and 0.59 ± 0.85 at the second. Similarly, in Group B, the mean VAS score improved from 4.8 ± 1.5 at presentation to 2.1 ± 1.0 at the first follow-up and 0.15 ± 0.38 at the second follow-up (Figure 1).

Table 1: Features of Group A (Topical Therapy Group) N=100

Study variables	1st Visit	1st Follow-up	2nd Follow-up
Otalgia	Completely pain-free: Nil Mild: 25 (25%) Moderate: 64 (64%) Severe: 11 (11%)	Completely pain-free: Nil Mild: 71 (71%) Moderate: 29 (29%) Severe: Nil	Completely pain-free: 86 (85%) Mild: 13 (13%) Moderate: 1 (1%) Severe: Nil
Otorrhea	Absent: 80(80%) Mild: 14(14%) Moderate: 6(6%) Profuse: Nil	Absent: 86 (86%) Mild: 14 (14%) Moderate: Nil Profuse: Nil	Absent: 91 (91%) Mild: 9 (9%) Moderate: Nil Profuse: Nil
Itch	Absent: 35(35%) Mild: 50 (50%) Moderate: 10(10%) Severe: 5 (5%)	Absent: 64 (64%) Mild: 36 (36%) Moderate: Nil Severe: Nil	Absent: 100 (100%) Mild: Nil Moderate: Nil Severe: Nil
Tragal Tenderness	Absent: Nil Positive 100(100%)	Absent: 56 (56%) Positive: 44 (44%)	Absent: 95 (95.0%) Positive: 5 (5.0%)
Canal Edema	Absent: Nil Mild: 36 (36%) Moderate: 44 (44%) Severe: 20 (20%)	Absent: 12 (12%) Mild: 81(81%) Moderate: 7 (7%) Severe: Nil	Absent: 93 (93%) Mild: 7(7%) Moderate: Nil Severe: Nil
Canal erythema	Absent: Nil Mild: 31 (31%) Moderate: 43 (43%) Severe: 26 (26%)	Absent:13 (13%) Mild: 70 (70%) Moderate:17 (17%) Severe: Nil	Absent: 91(91%) Mild: 9(9%) Moderate: Nil Severe: Nil
Debris	Absent: 76 (76%) Wet: 17 (17%) Dry: 7(7%)	Absent: 84 (84%) Wet: 15 (15%) Dry: 1(1%)	Absent: 100(100%) Wet: Nil Dry: Nil

Table 2: Features of Group B (Combined Therapy Group) N=100

Study variables	1st Visit	1st Follow-up	2nd Follow-up
Otalgia	Completely pain-free: Nil Mild: 22 (22%) Moderate: 66 (66%) Severe: 12 (12%)	Completely pain-free: Nil Mild: 74 (74%) Moderate: 19(19%) Severe: Nil	Completely pain-free: 86 (86%) Mild: 13 (13%) Moderate: 1 (1%) Severe: Nil
Otorrhea	Absent: 78(80%) Mild: 22(22%) Moderate: Nil Profuse: Nil	Absent: 91(91%) Mild: 9 (9%) Moderate: Nil Profuse: Nil	Absent: 96 (96%) Mild: 4 (4%) Moderate: Nil Profuse: Nil
Itch	Absent: 72(72%) Mild: 11 (11%) Moderate: 14(14%) Severe: 3 (3%)	Absent: 81 (81%) Mild: 15(15%) Moderate: 3(3%) Severe: Nil	Absent: 94 (94%) Mild: 6(6%) Moderate: Nil Severe: Nil
Tragal Tenderness	Absent: Nil Positive 100(100%)	Absent: 79 (79%) Positive: 21(21%)	Absent: 93 (93.0%) Positive: 7 (7.0%)
Canal Edema	Absent: Nil Mild: 34 (34%) Moderate: 33 (33%) Severe: 33 (33%)	Absent: 28 (28%) Mild: 66(66%) Moderate: 6 (6%) Severe: Nil	Absent: 98 (98%) Mild: 27(27%) Moderate: Nil Severe: Nil
Canal erythema	Absent: Nil Mild: 37 (37%) Moderate: 58 (58%) Severe: 5 (5%)	Absent:71 (71%) Mild: 29 (29%) Moderate: Nil Severe: Nil	Absent:98 (98%) Mild: 2(2%) Moderate: Nil Severe: Nil
Debris	Absent: 78(78%) Wet: 12(12%) Dry: 10(10%)	Absent: 81 (81%) Wet: 9 (9%) Dry: 10(10%)	Absent : 97(97%) Wet: 3(3%) Dry: Nil

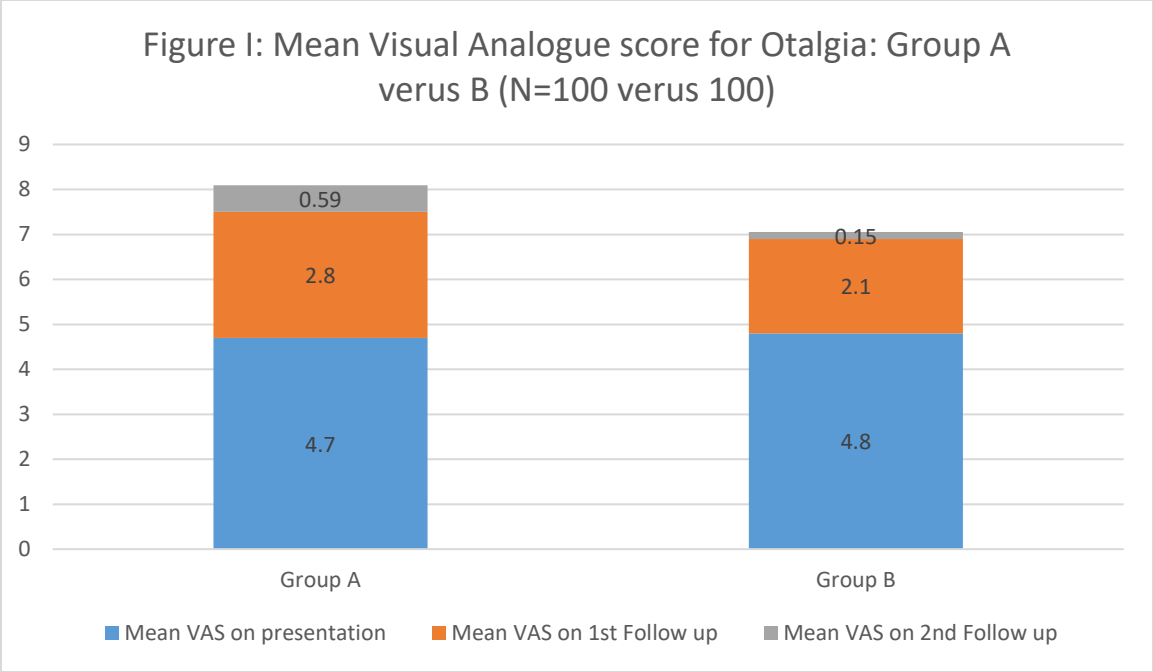

Figure 1: Mean Visual Analogue score for Otalgia: Group A versus B (N=100 versus 100)

Group B showed superior results in terms of symptomatic relief, except for otorrhea (Table 3)

Table 3: Statistical analysis of ordinal variables using the Mann-Whitney U test

Study variables	Recording time	Mann-Whitney U	Z	p-Value (2-sided)
Otalgia	Presentation:	4829.000	-.496	.620
	1st Follow-up	4251.500	-2.351	.019
	2nd Follow-up	5000.000	.000	1.000
Otorrhea	Presentation:	4966.000	-.117	.907
	1st Follow-up	4750.000	-1.105	.269
	2nd Follow-up	4750.000	-1.431	.153
Itching	Presentation:	3472.500	-4.130	.000
	1st Follow-up	3907.000	-3.326	.001
	2nd Follow-up	4900.000	-.827	.408
Canal Edema	Presentation:	4504.000	-1.291	0.197
	1st Follow-up	3375.000	-4.587	0.000
	2nd Follow-up	4500.000	-2.764	0.006
Canal Erythema	Presentation:	4053.500	-2.541	0.011
	1st Follow-up	1737.500	-8.745	0.000
	2nd Follow-up	4250.000	-3.608	0.000

The mean VAS score difference between the two groups is shown in Table IV. Effect size analysis using Cohen's d demonstrated a negligible difference at baseline (d = -0.07), while moderate effect sizes were observed at the 2nd and 3rd follow-ups (d = 0.60 and 0.67, respectively), indicating a clinically meaningful improvement with combined therapy over time.

Discussion

The present study verified the comparable demographic characteristics of both groups, which supports the comparability and internal validity of the outcome comparisons.

The mean symptom duration in both groups (3.1 ± 2.0 vs. 3.1 ± 1.9 days) corresponds with previous studies, in which the offending agents mostly initiate inflammatory changes, including oedema formation, within the first 48 h, leading to early arrival of patients in clinics.[14]

Our results indicated that Group B was superior in controlling otalgia, itching, canal oedema, and canal erythema at the first follow-up ($p < 0.05$) and canal oedema ($p = 0.006$) and canal erythema ($p = 0.000$) at the second follow-up, suggesting a superior anti-inflammatory role of systemic antibiotics.

Thus, systemic antibiotic therapy may offer faster symptomatic improvement when inflammation and canal swelling compromise drug penetration.

Variability in data has been found on this topic. Some researchers suggest that systemic antibiotics are reserved for immunocompromised patients or those who present with severe infection. Hasan et al. proved the efficacy of topical antibiotics ($p=0.01$) along with patient education to keep the ear dry(<0.01).[16]

Some studies have suggested that systemic antibiotics play a significant role in controlling OE, especially when the infection extends beyond the external auditory canal.[17]

An RCT conducted to evaluate different regimens of topical antibiotic therapy for managing otitis externa found that combined therapy showed a significantly higher resolution rate of otorrhea (90.3% vs. 80.2%, $p = 0.046$) and a trend toward better otalgia relief (78.6% vs. 67.0%, $p = 0.069$) compared to monotherapy, while differences in oedema resolution were not statistically significant ($p = 0.436$).[18]

Group B showed faster pain reduction at both follow-up visits ($p < 0.001$), reflecting a statistically significant advantage of oral antibiotics (Table IV).

Table 4: Independent Sample t-test to compare Visual analogue scale (VAS) scores between Group A and B (N=100 versus 100)

Recording time	The t-test for Equality means	t	2 sided p-Value	Mean difference	95% Confidence interval of the difference		Effect Size (Cohen's d)
					Lower	Upper	
1st Visit VAS scores	Equal variances assumed	-.489	.625	-.11000	-.55369	.33369	-0.07
	Equal variances not assumed	-.489	.625	-.11000	-.55369	.33369	0.60
2nd Visit VAS scores	Equal variances assumed	4.216	<0.001	.71000	.37791	1.04209	0.67
	Equal variances not assumed.	4.216	<0.001	.71000	.37786	1.04214	
3rd Visit VAS scores	Equal variances assumed	4.695	<0.001	.44000	.25520	.62480	
	Equal variances not assumed.	4.695	<0.001	.44000	.25470	.62530	

Comparing our results with Sindhuja et al. also reported comparable VAS trends between the combined and topical therapy group, with scores improving from 6.35 ± 1.72 and 6.55 ± 1.67 at baseline to 3.4 ± 1.62 and 4.15 ± 1.69 by day 03, showing statistically meaningful pain relief with combined therapy ($p = 0.044$) by day 07.[19]

In contrast to the above findings, Ronald et al. found that topical therapy was non-inferior to combined therapy (95.71% vs. 89.83%, lower confidence limit, −4.98), with no significant difference in the median time to control pain (6 days for both groups).[20]

Regardless of symptom grading, clinical resolution was recorded in both groups between 5 and 7 days, which is consistent with other studies. In group B, 100% of the cases were debris-free, underscoring the need for targeted therapy, favouring good penetration of the topical preparation.[22]

The single-centre study design may limit the generalisability of our findings. Moreover, with only 02-follow up visits, relapse rates could not be assessed.

Future multicentre studies with larger sample sizes, longer follow-ups, and microbiological profiling are suggested to strengthen evidence-based OE management.

Conclusions

Combined therapy provided earlier symptomatic relief than topical therapy alone, although both showed comparable outcomes at one week. Rational antibiotic use should be guided by clinical severity and supported by microbiological evidence, where available.

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