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Active Tubotympanic Chronic Otitis Media: The Role Of Topical Acetic Acid In Comparison With Topical Ciprofloxacin Ear Drops In Achieving Dry Ear

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ABSTRACT

Background: *Chronic suppurative otitis media (COM) is a persistent middle ear infection that often leads to otorrhea and hearing loss. Achieving a dry ear is a crucial therapeutic goal to prevent recurrence, facilitate surgical intervention, and reduce complications. This study aimed to compare the efficacy of aural irrigation with 1% dilute acetic acid followed by 2% acetic acid ear drops versus topical ciprofloxacin ear drops in achieving a dry ear in patients with active tubotympanic COM.*

Methods: *A total of 94 patients with unilateral active tubotympanic COM were randomly assigned to two groups. Group A underwent aural irrigation with 1% dilute acetic acid and continued self-administration of 2% acetic acid ear drops for five days. Group B received topical ciprofloxacin ear drops. Patients were evaluated on days 7 and 14 for clinical improvement based on ear discharge status and otologic symptom scores.*

Results: *The mean ages in Groups A and B were 44.74±16.54 and 40.21±16.77 years, respectively. No significant difference was observed in sex distribution or pretreatment discharge type. By day 14, 77.7% of Group A and 73.4% of Group B achieved a dry ear ($p = 0.519$). Otologic symptom scores improved comparably in both groups ($p = 0.862$).*

Conclusion: *Both acetic acid and ciprofloxacin treatments were effective in achieving dry ear in active tubotympanic COM. Given its comparable efficacy, low cost, and lack of antibiotic resistance risk, acetic acid irrigation is a valuable alternative, especially in resource-limited settings.*

Keywords: *Chronic otitis media, acetic acid, ciprofloxacin, ear discharge, otologic symptom score, tubotympanic COM.*

INTRODUCTION

Chronic otitis media (COM) is a persistent inflammatory middle ear condition marked by recurrent otorrhea and hearing loss, particularly prevalent in developing countries [1,2]. Achieving a dry ear is crucial to prevent complications and enable surgical intervention [3]. Common pathogens include Staphylococcus aureus and Pseudomonas aeruginosa, with ciprofloxacin widely used topically due to its efficacy [4–7]. However, antibiotic resistance and biofilm formation challenge treatment [8–11]. Acetic acid, by lowering pH, disrupts biofilms and offers a cost-effective alternative [12]. This study compares the effectiveness of acetic acid irrigation and ciprofloxacin drops in achieving a dry ear in active tubotympanic COM.

MATERIALS AND METHODS

This Hospital-based observational comparative study was conducted over 1 year at the Department of ENT, in a tertiary care centre in Chennai, involving 188 participants diagnosed with COM mucosal type. The study was initiated after obtaining ethical clearance from the Institutional Ethics Committee. Written informed consent was obtained from all patients.

Inclusion And Exclusion Criteria

Patients between the ages of 15 and 60, both males and females, who have unilateral, active tubotympanic chronic otitis media with symptoms persisting for over four weeks, including both outpatient and inpatient cases. However, individuals with Atticoantral CSOM, cholesteatoma, or marginal tympanic membrane perforation, as well as those who are immunosuppressed, have a dry ear with CSOM, secretory otitis media,

CSOM with otomycosis, or CSOM with vertigo, will be excluded. Additionally, patients who have taken systemic antibiotics or used topical ear drops within the two weeks prior to treatment will not be included in the study.

METHODOLOGY

A detailed patient history, general, and systemic examinations were conducted, followed by an otoendoscopic examination of the tympanic membrane. Under otoendoscopic guidance, ear swabs were collected for microbiological culture and sensitivity testing.

Patients were randomized into two groups:

- **Group A (Acetic Acid Group):** After aural toileting on Day 1, patients received ear irrigation with 1% acetic acid solution (prepared by diluting 100 mL of 5% vinegar with 400 mL of distilled water). They were instructed to self-administer 2% acetic acid ear drops three times daily for five days while maintaining dry ear precautions.
- **Group B (Ciprofloxacin Group):** Following aural toileting on Day 1, patients were prescribed topical ciprofloxacin ear drops to be used as directed for five days.

All patients were reviewed on Day 7 and Day 14. Clinical improvement was assessed using otological symptom scores [24], [Table 1]. Treatment effectiveness was determined based on changes in these scores at each follow-up:

- **Improved:** Score <3 or between 3–5
- **Not improved:** No reduction or increase from baseline score

Patients showing resistance based on clinical findings or culture reports were given appropriate alternative treatment.

Table 1 Otological symptoms score

SIGNS/SYMPTOMS	SCORE 0	SCORE 1	SCORE 2	SCORE 3
Amount of discharge filling EAM	No discharge	Confined to middle ear	Entering in EAM	Completely filling EAM
Type of discharge	No discharge	mucoid	mucopurulent	purulent
Type of congestion	No congestion	Mild/moderate congestion	Marked congestion	

Statistical Analysis

"Data are presented as mean, standard deviation, frequency, and percentage. Continuous variables were compared using independent sample t-tests". "Categorical variables were analysed using Pearson's chi-square test." Statistical significance was set at $p < 0.05$ using a two-tailed test. Data analysis was performed using IBM SPSS version 21.0 software.

RESULTS

In our study, the mean age of groups A and B was 44.74±16.54 and 40.21±16.77 years, with a p-value of 0.064 ."Based on the sex distribution in our study, 51 patients (54.3%) were male and 43 patients (45.7%) were female in group A". "In contrast, 53 (56.4%) and 41 (43.6%) patients were female and male, respectively, in group B, and the p-value was 0.145".Based on socioeconomic status in our study, 49 patients (52.1%) were lower middle class, 45 (47.9%) were upper middle class, and no patients were from lower and middle class in group A. 49 patients (52.1%) were from the upper middle class, 27 patients (28.7%) were from the lower middle class, 9 patients (9.6%) were lower class, and 9 patients (9.6%) were middle class in group B with a p-value < 0.0001.

Based on comorbidities in our study, 64 patients (68.1%) had no comorbidities, 26 patients (27.7%) had type 2 DM, 2 patients (2.1%) had SHTN, and 2 patients (2.1%) had both type 2 DM and SHTN in group A. 76 patients (80.9%) had no comorbidities, 15 patients (16.0%) had type 2 DM, 2 patients (2.1%) had SHTN, and only 1 patient (1%) had both type 2 DM and SHTN in group B, and the p-value was 0.230 .

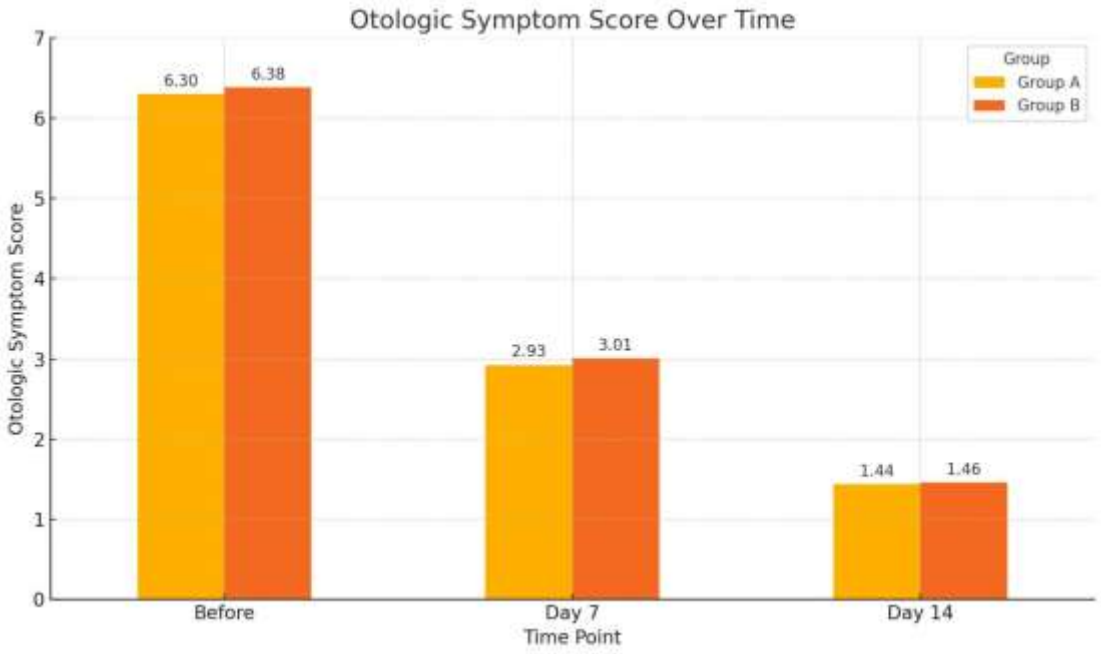
Table 2. Distribution based on the type of discharge before treatment between the groups

	GROUP		P value
	GROUP A	GROUP B	

		Count	Column N	Count	Column N	
Type Of discha	Mucoid	46	48.9%	48	51.1%	0.108
before treatmen	Mucopurulent	48	51.1%	42	44.7%	
	Purulent	0	0.0%	4	4.3%	

Based on the type of ear discharge in our study, 48 patients (51.1%) had mucopurulent discharge, 46 patients (48.9%) had mucoid discharge, and no patient had purulent discharge in group A. In group B, 48 patients (51.1%) had mucoid discharge, 42 (44.7%) had mucopurulent discharge, and 4 patients (4.3%) had purulent discharge in group B and a p-value of 0.108 (Table 2).
Based on the otologic symptom score before treatment in our study, 65 patients (69.1%) had a score of 6 and 29 patients (30.9%) had a score of 7 in group A. 63 (67.0%) had a score of 6 and 31 patients (33.0%) had a score of 7 in group B, and the p-value was 0.754 .Based on the otologic symptom score on the 7th day of treatment in our study, 72 patients (76.6%) had a score of 2, 22 patients (23.4%) had a score of 6, and no patient had a score of 1 in group A. Seventy patients (74.5%) had a score of 2, 22 patients (23.4%) had a score of 6, and 2 patients (2.1%) had a score of 1 in group B, with a p-value of 0.363.Based on the otologic symptom score on the 14th day of treatment in our study, 73 patients (77.7%) had a score of 1, and 21 patients (22.3%) had a score of 3 in group A. 72 patients (76.6%) had a score of 1, and 22 patients (23.4%) had a score of 3 in group B, and the p-value was 0.862 .(Figure 1)

Figure 1: Otologic symptom score before, day 7, and day 14 of treatment



Based on the type of ear discharge after treatment, 73 patients (77.7%) in group A had no discharge, 21 patients (22.3%) had discharge in the external auditory meatus (EAM), and no patient had discharge confined to the middle ear. In group B, 69 patients (73.4%) had no discharge, 24 patients (25.5%) had discharge in the ear, and only one patient (1.1%) had a discharge confined to the middle ear. The p-value was 0.519. Based on the type of middle ear mucosa after treatment in our study, 71 patients (75.5%) had mild congestion, 23 (24.5%) had moderate congestion, and no patient had congestion in the middle ear mucosa in group A. In group B, 71 patients (75.5%) had mild congestion, 22 patients (23.4%) had moderate congestion, and only 1 patient (1.1%) had no congestion, with a p-value of 0.6. Based on treatment effectiveness in our study, 73 patients (77.7%) improved, and 21 patients (22.3%) did not improve in group A. In group B, 72 patients (76.6%) improved and 22 patients (23.4%) did not improve, with a p-value of 0.862.

DISCUSSION

Chronic suppurative otitis media (CSOM) is a persistent inflammation of the middle ear cleft, frequently resulting in tympanic membrane perforation and mucopurulent otorrhea. The tubotympanic type, characterized by perforation of the pars tensa, is typically associated with a less aggressive course [13]. However, when active, it involves inflammation, mucosal edema, and persistent or recurrent discharge, presenting considerable management challenges due to its chronicity, recurrence, and association with biofilm-forming, antibiotic-resistant organisms.

CSOM remains a major public health problem, especially in developing countries, due to its high prevalence, risk of complications such as hearing loss and intracranial infections, and its significant socioeconomic burden [14]. A key clinical objective in CSOM management is achieving a dry ear to enable surgical intervention and minimize complications. However, the emergence of antibiotic resistance and the chronic nature of biofilm-associated infections complicate treatment and necessitate alternative, non-antibiotic approaches[15,16].

In our study, patients were divided into two groups: Group A received diluted acetic acid for irrigation and self-administered 2% acetic acid drops, while Group B received topical ciprofloxacin. Both groups showed clinical improvement, with statistically insignificant differences in treatment outcomes ($p = 0.862$). Most patients achieved significant symptom score reduction by Day 7 and further improvement by Day 14. These findings are consistent with those of Lalendrayadav et al. (2015), who reported a marked decrease in otologic symptom scores with both treatments over a similar time frame [24].

Demographic analysis in our study revealed no statistically significant difference in sex distribution ($p = 0.145$), with Group A being predominantly male and Group B predominantly female. This distribution aligns variably with existing literature; Osma et al. (2000) reported a male-to-female ratio of 2:1[17], while Maharjan et al. (1970) observed more female patients. Such differences may reflect regional or healthcare access variations [18].

Regarding comorbidities, type 2 diabetes mellitus was the most common in our cohort. Diabetes is a known risk factor for persistent infections due to impaired immunity. Comparatively, Yen et al. (2015) reported a lower prevalence of comorbid conditions among CSOM patients[19]. Socioeconomic status analysis revealed a predominance of patients from lower-middle and upper-middle classes, with statistically significant differences between groups ($p < 0.0001$). This contrasts with studies like Lasisi et al. (2007) [20] and Siddartha et al. (2012) [21], which observed higher representation from lower socioeconomic groups. These disparities may be attributed to regional differences in healthcare-seeking behavior and accessibility.

Most patients initially presented with mucopurulent or mucoid discharge, with otologic symptom scores around 6–7. Following treatment, the majority showed marked improvement: scores dropped to around 2 on Day 7 and 1 by Day 14 in both groups. Residual discharge was minimal, and the difference between groups was not statistically significant ($p = 0.519$). Mild middle ear mucosal congestion persisted in a few patients, but without significant intergroup variation ($p = 0.6$).

Our findings are comparable to those of Kanakarajulu B et al. (2021), who reported dry ears in 88% of patients following treatment with diluted acetic acid[22]. Their study highlighted the gradual improvement over weeks to months, supporting the notion that acetic acid, combined with regular aural toileting, can be highly effective. Similarly, Yogi et al. (2020) reported high success rates with acetic acid irrigation, with only a small proportion of patients failing to achieve otorrhea resolution after prolonged treatment[23].

In conclusion, our study demonstrates that both topical ciprofloxacin and acetic acid are effective in managing active tubotympanic-type CSOM. However, acetic acid has several advantages: it is inexpensive, readily available, and avoids the complications associated with antibiotic resistance and sensitization. While no significant difference in efficacy was observed, the simplicity and affordability of acetic acid make it an excellent alternative, particularly in resource-limited settings or in cases where non-antibiotic options are preferred.

Limitation

A key limitation of this study is the relatively short follow-up period of 14 days, which may not be sufficient to assess long-term treatment outcomes, recurrence rates, or delayed complications. Additionally, the sample size was limited, and the study was conducted at a single center, which may affect the generalizability of the findings. Microbiological analysis was limited to initial culture and sensitivity, without evaluating changes in microbial patterns post-treatment. Another important limitation encountered during the study was patient intolerant to acetic acid, a significant number of patients reported experiencing irritation, burning sensations, or discomfort upon instillation. Further multicenter studies with larger populations and extended follow-up

are needed to confirm the long-term effectiveness and safety of acetic acid irrigation in the management of CSOM.

CONCLUSION

This study demonstrated that both acetic acid irrigation and topical ciprofloxacin are effective in achieving a dry ear and improving symptoms in patients with active tubotympanic COM. With no significant difference in treatment outcomes, acetic acid emerges as a cost-effective, accessible, and non-antibiotic alternative. Its ability to alter pH and disrupt biofilms makes it especially valuable in managing COM, where antibiotic resistance is a concern. These findings support the incorporation of acetic acid irrigation into CSOM treatment protocols, particularly in resource-limited settings. Further studies with larger populations and longer follow-up are recommended to validate its long-term efficacy and role in recurrence prevention.

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