

## Acetic Acid Versus Ciprofloxacin Ear Drops In Treating Chronic Otitis Media: A Comparative Study

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### Abstract

**Background:** Chronic suppurative otitis media (CSOM), which is now presently referred to as chronic otitis media (COM), is a chronic inflammation of the middle ear cleft including the eustachian tube, middle ear proper, aditus, antrum, and mastoid air cells. Since its effects are prolonged or repeated, a chronic middle ear infection is often more destructive than an acute middle ear infection. It's recently been classified as mucosal type (active/inactive), squamous (active/inactive), and healed chronic otitis media. Ear discharge and hearing loss are the common symptoms of COM. In developing countries, COM is a leading cause of acquired hearing loss. Topical antibiotics are the foremost commonly used for treating COM which usually act by killing or inhibiting the development of micro-organisms responsible for the infection. For COM, antibiotics alone or in addition to other treatments can be used, like ear cleaning (aural toileting).

**Methods:** This prospective study involved all the patients with chronic otitis media mucosal type who abide by inclusion and exclusion criteria treated with diluted acetic acid ear drops in one group and ciprofloxacin ear drops in another group. A total of 100 patients were selected in a period of 10 months from January 2021 to October 2021 who visited the otorhinolaryngology outpatient department of Navodaya medical college, and were divided into two groups. 50 patients of Group A were treated with diluted acetic acid ear drops and 50 patients of group B were treated with ciprofloxacin ear drops. The pretreatment and post-treatment findings were assessed.

**Results:** Using diluted acetic acid ear drops in treating chronic otitis media gave better results for the absence of discharge, mucosa of the middle ear, and perforation healing when compared to ciprofloxacin ear drops. **Conclusion:** Medical management of active COM mucosal type by irrigation with dilute acetic acid could be more effective in comparison to topical antibiotics. Acetic acid preparation can be used as preferred medical management before surgical management for obtaining a dry ear, however patient compliance is an crucial factor for a better outcome. Use of acetic acid drops is the better alternative to topical antibiotics in terms of cost-effectiveness and fewer side effects.

**Keywords:** Chronic otitis media mucosal type, acetic acid, ciprofloxacin, topical antibiotics, COM.

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### Introduction

Chronic otitis media (COM) defined as "chronic inflammation of the middle ear cleft, which presents with recurrent ear discharge or otorrhoea through a tympanic membrane perforation" [1]. WHO currently defines it as chronic inflammation of the middle ear cavity with repeated discharge through tympanic perforation for three months or more, although the precise definition of COM continues to be under debate [3]. The disease usually tends to start in childhood, which results in tympanic membrane perforation due to middle ear acute infection, also known as acute otitis media (AOM), or as a result of less severe forms of otitis media like otitis media with effusion (OME) [1,3]. Risk factors include poor hygiene, overcrowding, lack of breastfeeding, inadequate housing, poor nutrition, eustachian tube disorders, and lacking or inaccessible health care. In developing countries, poverty seems to be a major risk factor. Most commonly isolated pathogen is *Pseudomonas*

*aeruginosa* [4].

Before surgical treatment, medical management of COM for attaining dry ear is necessary, COM which is a biofilm disease and also justifies the impending resistance towards antibiotics [5]. Mechanical separation or interruption of micro-organism (bacterial) biofilm is found efficacious in treatment of chronic infection which is usually not possible clinically [6]. There are in and of itself no published guidelines for the management of COM. The disadvantage of treatment with antibiotics (orally and parentally) includes adverse effects, costs, and inconvenience for patients. The commonly prescribed medicines for COM are topical antibiotics like ciprofloxacin, ofloxacin, and neosporin [7]. Nevertheless, ear toileting should be a part of the medical management for COM [8].

In our present study, we evaluated the efficacy of diluted acetic acid drops in treating COM when compared to topical antibiotics.

### Methods

The prospective study here involved all the patients with chronic otitis media who comply with inclusion and exclusion criteria treated with diluted acetic acid ear drops in one group and ciprofloxacin ear drops in another group. A total of 100 patients were selected in a period of 10 months from January 2021 to October 2021 who visited the

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otorhinolaryngology outpatient department of Navodaya medical college, into the study who were divided into two groups.  
 Group A – 50 Patients who were treated with diluted acetic acid ear drops.  
 Group B – 50 Patients who were treated with ciprofloxacin ear drops.

**Statistical methods used**

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean±standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square ( $\chi^2$ ) test was used for the association between two categorical variables. If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analyzed using SPSS software v.23 (IBM Statistics, Chicago, USA) and Microsoft office 2007.

**Inclusion criteria:**

- 1) Chronic otitis media mucosal type -active with central perforation (ranging from small to subtotal ) since minimum 1 year duration
- 2) Patient age group 15-65yrs

**Exclusion criteria:**

- 1) Patients with less than 15 or more than 65 years of age
- 2) COM otitis externa.
- 3) COM with cholesteatoma.
- 4) COM with otomycosis.
- 5) COM with vertigo.
- 6) Patient with a previous history of ear surgeries.
- 7) Patient on systemic antibiotics.
- 8) HbsAg, HIV-positive patients and other chronic inflammatory diseases.

- 9) Patients with history of hypertension, Diabetes mellitus, cardiac diseases, renal disease, and malignancies.

**Methodology**

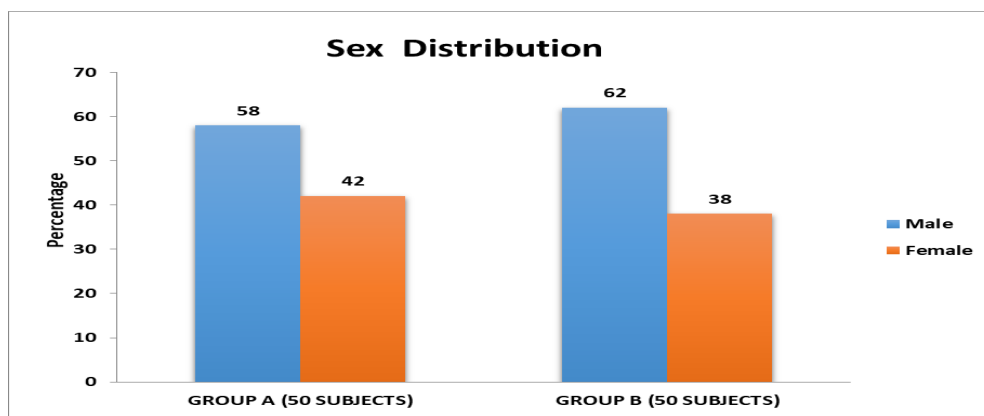
1. History of ear discharges its duration, amount, character, presence or absence of odor, hearing loss, tinnitus, otalgia, vertigo was noted.
2. Microscopic examination of the tympanic membrane, extent of inflammation of middle ear mucosa, and presence of granulation or polyp were noted.
3. Nasopharynx examination, vestibular function test, eustachian tube function test, and tuning fork tests with 256, 512, and 1024 tuning forks were done.
4. Patients were randomly distributed into two groups group A and group B. In group A patients were treated with aural toileting and irrigation with 2% acetic acid and group B was treated with aural toileting and topical antibiotic (Ciprofloxacin ear drops).
5. Aural toileting followed by diluted 2 % acetic acid (1:2) irrigation 1ml using insulin syringe in group A and ciprofloxacin 5 drops in group B on alternate days up to 4 weeks with patient advised for self instillation 3drops of solution thrice daily.
6. After 4weeks, they advised to continue 3 drops thrice daily up to 3 months and the patient followed up for signs of active disease like the absence of discharge, mucosa of the middle ear, and perforation healing.

**Results**

A total of 100 patients were included in this study of age range 15-65 years, 60 were male and 40 were female. Bilateral ear disease was found in 37 patients, left ear in 28 patients, and right ear in 35 patients. Distribution of 137 ears 45 had small central perforation, 61 had medium central perforation, 21 had large central perforation and 10 had subtotal perforation.

**Table 1: Sex Distribution**

Parameters	Male		Female		p-value
	N	%	N	%	
Group A (50 subjects)	29	58	21	42	0.683
Group B (50 subjects)	31	62	19	38	
Total	60	60	40	40	



**Figure 1: Sex Distribution**

Interpretation: It is clear from the above table that the gender distribution of cases among both groups was random. The percentage

of males was higher compared to females in group A as well as in group B.

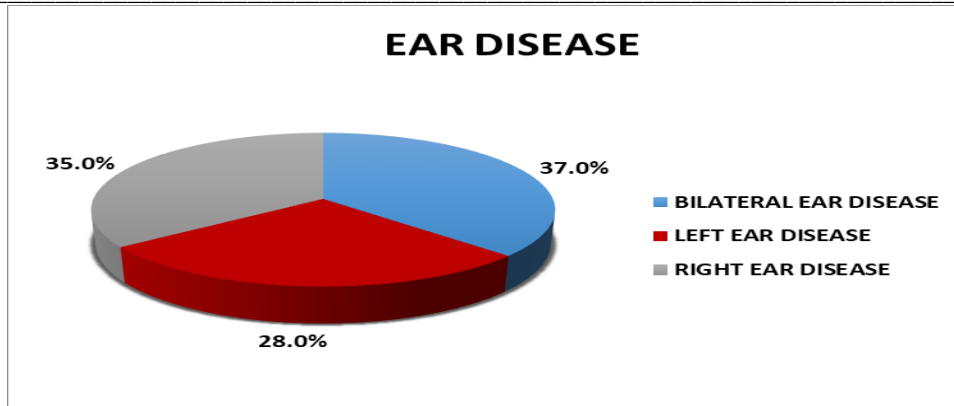


Figure 2: Diseased Ear

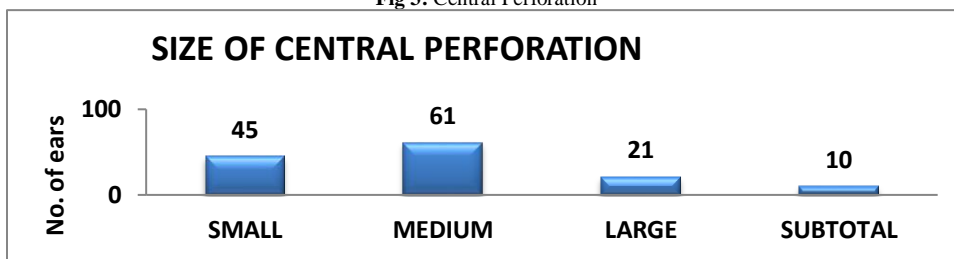


Fig 3: Central Perforation

Table 2: Results

Groups	Number of Ears	Follow up				p-value (0-months)
		4 weeks		3 months		
		N	%	N	%	
Group A	With discharge absent	43	86	48	96	<0.001*
	With healthy middle ear mucosa	45	90	49	98	<0.001*
	With healed perforation	8	16	13	26	<0.001*
Group B	With discharge absent	34	68	40	80	<0.001*
	With healthy middle ear mucosa	36	72	41	82	<0.001*
	With healed perforation	2	4	4	8	0.041*

Note: p value\* significant at 5% level of significance (p<0.05)

Interpretation: It is clear from the above table that there is a statistically significant improvement in the number of cases with dry ears, with healthy middle ear mucosa, and with healed perforation at 3 months from baseline. But this improvement is seen more in Group A compared to Group B. Among more than 80% of cases, dry ears and healthy middle ear mucosa were observed in both groups.

In our study we found 86% of subjects had dry ear, 90% had healthy middle ear mucosa and 16 % had healed perforation in group A at

4weeks post-treatment when compared to 68% subjects who had dry ear, 72% had healthy middle ear mucosa and 4% had healed perforation in group B at 4weeks post-treatment. Also, we found 96 % of subjects had dry ear, 98% had healthy middle ear mucosa and 26 % had healed perforation in group A at 3months post-treatment when compared to 80% subjects who had dry ear, 82% had healthy middle ear mucosa and 8% had healed perforation in group B at 3months post-treatment.



Figure 4: Group A -4 weeks post-treatment

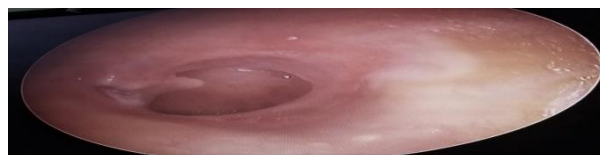


Figure 5: Group B -4 weeks post-treatment

Discussion

The mechanism of aural toileting and irrigation with acetic acid seems

to be:

- 1) Removal of inflammatory debris.
- 2) Destructive effect on biofilm
- 3) Bacterial growth is interrupted with change in the pH media of the auditory canal by affecting the amino acid which causes a change within the three-dimensional structure of bacterial enzymes. Protein denaturation usually occurs at extreme pH changes [5].

In 2002, Roland proposed stating that biofilms are likely the reason of CSOM, and this would explain the resistance to antibiotic therapy[9]. Hyeog Gi Choi et al. study showed 79.5 % achieved dry ear and no healing was noticed and a study done by Chhavi Gupta et al. explained that the resolution of otorrhoea by Acetic acid was 84% and healing of tympanic membrane perforation was 26% with failure rate was 16% [5]. In our study we followed up to patients upto 3 months and found 92 % of subjects had dry ear, 96% had healthy middle ear mucosa and 22 % had healed perforation in the group treated with diluted acetic acid ear drops in comparison to 78% subjects who had dry ear, 84% had healthy middle ear mucosa and 8% had healed perforation in the group treated with ciprofloxacin ear drops.

We had a failure of treatment in 12% of patients in maintaining dry ear, 10% had unhealthy middle ear mucosa whereas 17% had healed perforation ( 12 small central perforations and 5 medium central perforations), these patients were started with oral antibiotics after culture and sensitivity of discharge. Assessment of treatment failure was done and showed that patients lacking compliance (not following water precautions and hygiene) together with the longer duration of the disease proved difficulty in resolving and improvement of symptoms. The degree of inflammation and size of perforation showed no effect on the outcome. The advantage was cost-effectiveness to patients with low socioeconomic status. COM is a persistent and insidious disease and also the mainstay of medical management for the dry ear is necessary before surgical treatment.

Ludman and Nelson used similar approaches and demonstrated possible ototoxic effects as a major disadvantage of topical antibiotics[10]. The risk of ototoxicity is a major disadvantage in the widespread use of topical antibiotics. Our findings of attaining dry ear in 92% patients combined with aural toileting, the Cochrane review observed 50% of otorrhoea resolution, Fradis et al. Demonstrated similar results with 47.4% and 55 % of otorrhoea resolution rates in his study while Supiyaphun et al. found that the resolution of ear discharge (76.9% and 37 %, respectively) was higher with topical together with systemic antibiotics[11,12].

The definitive treatment of tubotympanic COM is surgical treatment by tympanoplasty when the ear is free of discharge. In our opinion, there's no necessity for the long-term use of antibiotics for tubotympanic COM. The main aim of such treatment is to prepare the patient for surgical management by eradicating the infection.

### Conclusions

Medical management of active COM mucosal type by irrigation with dilute acetic acid can be more effective when compared to topical antibiotics. Acetic acid preparation can be used as preferred medical management before surgical management for obtaining a dry ear, however patient compliance is an important factor for a better outcome. Use of acetic acid drops is the better alternative to topical antibiotics in terms of cost-effectiveness and fewer side effects.

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