Original Research Paper

Volume - 16 | Issue - 07 | July - 2026 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Otorhinolaryngology

EFFICACY OF ORAL CIPROFLOXACIN COMBINED WITH TOPICAL CIPROFLOXACIN EAR DROPS VERSUS TOPICAL CIPROFLOXACIN EAR DROPS ALONE IN THE EMPIRICAL MANAGEMENT OF MUCOSAL TYPE OF CHRONIC OTITIS MEDIA: A DOUBLE-BLINDED RANDOMISED CONTROL TRIAL

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ABSTRACT

Introduction: Chronic otitis media (COM) is a chronic inflammatory disease of the middle ear cleft characterized by recurrent or persistent ear discharge through a perforated tympanic membrane. Topical antibiotics remain the mainstay of treatment; however, systemic antibiotics are often added in resistant or severe cases. The comparative efficacy of topical ciprofloxacin alone versus combination therapy with oral ciprofloxacin remains uncertain. **Aim:** To compare the efficacy of oral ciprofloxacin combined with topical ciprofloxacin ear drops versus topical ciprofloxacin ear drops alone in the empirical management of mucosal type of chronic otitis media. **Methodology:** This prospective double-blinded randomized controlled trial was conducted in the Department of Otorhinolaryngology at a tertiary care centre in Puducherry. A total of 200 patients aged above 18 years diagnosed with mucosal type of chronic otitis media were included. Patients were randomized into two groups using sealed envelope method. Group A received oral ciprofloxacin along with topical ciprofloxacin ear drops, while Group B received topical ciprofloxacin ear drops with oral placebo for seven days. Patients were assessed clinically before and after treatment for improvement in symptoms and signs. **Results:** Among the 200 participants, the majority belonged to the age group of 18–30 years (32%), with males constituting 57% of the study population. Otorrhea was the most common presenting complaint, and Pseudomonas aeruginosa was the most commonly isolated organism. There was no statistically significant difference between the two groups in improvement of otorrhea (p=0.096), hard of hearing (p=0.963), pruritis (p=0.331), ear pain (p=0.071), tinnitus (p=0.165), vertigo (p=0.728), tympanic membrane granulation (p=0.107), or tympanic membrane congestion (p=0.058). No significant difference in adverse effects was observed between the groups. **Conclusion:** Topical ciprofloxacin ear drops alone are effective in the management of mucosal type chronic otitis media and may safely be used without routine addition of oral ciprofloxacin. Combination therapy may be reserved for selected patients at increased risk of complications.

KEYWORDS : Chronic Otitis Media, Ciprofloxacin, Topical Antibiotics, Oral Antibiotics, Otorrhea, Randomized Controlled Trial

INTRODUCTION

Chronic otitis media (COM) is defined as chronic inflammation of the middle ear cleft associated with persistent or recurrent ear discharge through a non-intact tympanic membrane. It is one of the most common otological disorders encountered in clinical practice and continues to be a major cause of preventable hearing loss, particularly in developing countries.[1]

The prevalence of COM is significantly higher among populations with poor socioeconomic status, overcrowding, malnutrition, inadequate hygiene, and limited healthcare access.[2] Eustachian tube dysfunction plays a major role in the pathogenesis of the disease. Pseudomonas aeruginosa and Staphylococcus aureus are the most commonly isolated organisms in patients with chronic otitis media.[4]

Management of COM includes both medical and surgical approaches. Medical treatment primarily consists of aural toileting and topical antibiotic therapy. Topical quinolone antibiotics, especially ciprofloxacin, are preferred because of their broad-spectrum activity, effectiveness against common pathogens, and favourable safety profile.[5] Although systemic antibiotics are frequently prescribed in combination with topical therapy, their additional benefit remains controversial.[7]

Several studies have suggested that topical antibiotics achieve higher local concentrations in the middle ear with fewer systemic adverse effects when compared to oral antibiotics.[8],[9] However, evidence directly comparing topical ciprofloxacin alone with combined oral and topical ciprofloxacin therapy remains limited. Hence, the present study was undertaken to compare the efficacy and safety of oral ciprofloxacin combined with topical ciprofloxacin ear drops versus toical ciprofloxacin ear drops alone in the empirical management of mucosal type chronic otitis media.

MATERIALS AND METHODS

Study Design

Prospective double-blinded randomized controlled trial.

Study Setting

Department of Otorhinolaryngology, Sri Venkateshwaraa Medical College Hospital & Research Centre, Puducherry.

Study Duration

Study conducted over the period approved by the Institutional Ethics Committee.

Study Population

Patients aged more than 18 years diagnosed with mucosal type chronic otitis media attending the ENT outpatient department.

Sample Size

A total of 200 patients were included in the study.

Inclusion Criteria

- Patients aged above 18 years.
- Patients diagnosed with mucosal type chronic otitis media.
- Patients willing to participate in the study.

Exclusion Criteria

- Patients with squamosal type COM.
- Patients with complications of COM.
- Patients with known hypersensitivity to ciprofloxacin.
- Pregnant and lactating women.
- Patients with severe systemic illness.

Methodology

After obtaining informed consent, patients underwent detailed clinical examination including otoscopic examination and relevant investigations. Patients were randomized into two groups using sealed envelope method.

Group A: Received oral ciprofloxacin along with topical ciprofloxacin ear drops.

Group B: Received topical ciprofloxacin ear drops with oral placebo.

Treatment was administered for seven days. Patients were assessed before and after treatment for improvement in symptoms including otorrhea, hard of hearing, pruritis, ear pain, tinnitus, and vertigo, as well as signs such as tympanic membrane granulation and congestion.

Statistical Analysis

Data were entered and analysed using appropriate statistical methods. Chi-square test and relevant statistical tests were used for comparison between groups. A p-value less than 0.05 was considered statistically significant.

RESULTS

A total of 200 patients were included in the study and equally divided into two groups.

The majority of patients belonged to the age group of 18–30 years (32%). Male patients constituted 57% of the study population, while females constituted 43%.

Otorrhea was the most common presenting complaint among the patients. Most patients presented with profuse ear discharge. Pseudomonas aeruginosa was identified as the most common bacterial isolate.

Comparison of symptoms before and after treatment showed no statistically significant difference between the two groups in the improvement of:
Otorrhea (p=0.096)
Hard of hearing (p=0.963)
Pruritis (p=0.331)
Ear pain (p=0.071)
Tinnitus (p=0.165)
Vertigo (p=0.728)

Table 1. Baseline Characteristics of Study Participants (N = 200)

Variable	Frequency (n)	Percentage (%)
Total participants	200	100
Group A (Oral + Topical Ciprofloxacin)	100	50.0
Group B (Topical Ciprofloxacin + Placebo)	100	50.0
Age 18–30 years	64	32.0
Male	114	57.0
Female	86	43.0
Most common presenting complaint	Otorrhea	—
Predominant discharge type	Profuse discharge	—
Most common bacterial isolate	Pseudomonas aeruginosa	—

Similarly, no statistically significant difference was noted between the groups in the improvement of tympanic membrane granulation (p=0.107) and tympanic membrane congestion (p=0.058).

There was no significant difference in adverse effects or complications between the two treatment groups.

DISCUSSION

Chronic otitis media remains one of the most common chronic infectious diseases encountered in otorhinolaryngology practice, particularly in developing countries where poor socioeconomic conditions, overcrowding, malnutrition, and limited healthcare accessibility continue to contribute significantly to disease burden.[2]

In the present study, younger adults were more commonly affected, with the majority of patients belonging to the age group of 18–30 years. Similar observations have been reported in previous studies, suggesting increased susceptibility among young adults due to recurrent upper respiratory tract infections, increased environmental exposure, and poor socioeconomic conditions.[11] A slight male predominance was observed in this study. This finding is comparable with other Indian studies on chronic otitis media.[12]

Most patients in this study belonged to lower socioeconomic status and rural background. Poor hygiene, overcrowding, inadequate nutrition, and limited healthcare facilities in rural populations play an important role in the persistence and recurrence of middle ear infections.[2]

Otorrhea was found to be the most common presenting symptom among the study population, which is consistent with the classical clinical presentation of mucosal type chronic otitis media.[3] Hard of hearing was the second most common symptom observed in the patients. Chronic inflammation and tympanic membrane perforation contribute significantly to conductive hearing loss in these patients.[5]

The microbiological profile in the present study demonstrated Pseudomonas aeruginosa as the predominant bacterial isolate. This finding correlates with multiple previous studies which have identified Pseudomonas aeruginosa as the most common pathogen responsible for chronic otitis media because of its ability to survive in moist environments and form biofilms.[4],[12],[13]

The present study demonstrated significant clinical improvement in symptoms and signs within both treatment groups following therapy. However, no statistically significant difference was observed between patients receiving topical ciprofloxacin alone and those receiving combined oral and topical ciprofloxacin therapy. Similar findings were reported by Fliss et al.[7] and Macfadyen et al.[9]

The absence of additional benefit from oral ciprofloxacin observed in this study supports the concept that topical antibiotics are sufficient in the majority of uncomplicated mucosal type chronic otitis media cases. Topical ciprofloxacin achieves higher local drug concentration directly at the site of infection while minimizing systemic exposure and adverse effects.[8]

Systemic antibiotics often fail to achieve adequate middle ear concentration due to poor vascularity and chronic inflammatory changes in the diseased mucosa. Furthermore, prolonged and unnecessary use of systemic antibiotics contributes to increasing antimicrobial resistance, higher treatment costs, and drug-related side effects.[14]

The study also found no statistically significant difference in adverse effects between the groups. However, minor gastrointestinal discomfort was more commonly observed among patients receiving oral ciprofloxacin. This further emphasizes the advantage of topical therapy in reducing systemic complications. The findings of this study are in agreement with previous clinical studies which reported that topical quinolone therapy alone is highly effective in controlling infection and achieving dry ear in patients with chronic otitis media.[8],[9]

The strengths of the present study include its randomized controlled design and adequate sample size. However, certain limitations should be considered. The study duration was relatively short, long-term follow-up was not performed, and bacteriological culture sensitivity-guided therapy was not assessed for all patients.

Despite these limitations, the present study provides valuable evidence supporting the use of topical ciprofloxacin ear drops alone as an effective treatment modality in uncomplicated mucosal type chronic otitis media.

CONCLUSION

Topical ciprofloxacin ear drops alone are effective in the empirical management of mucosal type chronic otitis media. Addition of oral ciprofloxacin does not provide significant additional clinical benefit in routine cases.

Topical therapy can therefore be safely recommended as the primary treatment modality to minimize systemic adverse effects and reduce unnecessary antibiotic exposure. Combination therapy may be considered in selected high-risk patients.

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