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Comparison of Efficacy of Topical Cprofloxacin Ear Drops 0.6% Versus Oral Cprofloxacin 500 mg Twice Daily in Achieving Dry Ear in Chronic Suppurative Otitis Media

Muhammad Imran Malik, Aiman Fatima Naqvi*, Zaimal Shahan, Amir Akbar***, Amna Enam****, Mohsin Raza*****

Department of ENT, Fazaia Medical College Pakistan Airforce Hospital Islamabad Pakistan, *Department of ENT, Combined Military Hospital Malir/ National University of Medical Sciences (NUMS) Pakistan, **Department of ENT, THQ Kallar Syedan Pakistan, ***Department of ENT, Rawal Institute of Health Sciences Islamabd Pakistan, ****Department of ENT, Sindh Institute of Urology & Transplantation Karachi Pakistan, *****Department of ENT, Combined Military Hospital Abbottabad/National University of Medical Sciences (NUMS) Pakistan

ABSTRACT

Objective: To compare the efficacy of Cprofloxacin 0.6% ear drops versus oral Cprofloxacin in achieving the dry ears in chronic suppurative otitis media patients presenting at a tertiary care hospital, Islamabad Pakistan.

Study Design: Quasi-experimental study.

Place and Duration of Study: Department of Otorhinolaryngology and Head and Neck Surgery, Pakistan Institute of Medical Sciences, Islamabad Pakistan, from Jun 2022 to Dec 2022.

Methodology: The study recruited 130 patients with unilateral or bilateral chronic ear discharge, of either gender, aged 12-60 years, and divided them into two groups of 65 each. Group-A received topical Cprofloxacin 0.6% in a dose of four drops three times per day, while Group-B, 65 patients received oral Cprofloxacin 500 mg twice daily. Otoscopy was used to monitor patients for two weeks following dry ear treatment.

Results: The mean age of participants was 29.70±9.03 years and most patients were males (60%). Post-treatment results of Group-A revealed that there were 11(16.9%) subjects with ear discharge. The rest 54(83.1%) had no ear discharge. In Group-B, there were 46(70.8%) subjects with ear discharge. The rest 19(29.2%) had no ear discharge. A statistically significant (p=0.001) difference in efficacy was observed between both groups.

Conclusion: Topical Cprofloxacin 0.6% given 6 drops twice daily for two weeks is a better choice in medical management of CSOM than oral Cprofloxacin 500mg twice daily in terms of resolution of ear discharge.

Keywords: Anti-bacterial agents, Cprofloxacin, Suppurative otitis media, Suppuration.

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INTRODUCTION

Chronic otitis media (COM), often referred to as chronic suppurative otitis media (CSOM), is characterized by persistent ear discharge (otorrhoea) caused by a perforated tympanic membrane.[1,2] It is a chronic infection and inflammation of the middle ear and mastoid cavity. Over 31 million episodes of CSOM occur annually on a global scale, or 4.8 new episodes per 1000 persons of any age, with 22% of these episodes affecting children under the age of five.[3,4] Annually, CSOM caused around 28,000 fatalities worldwide.[5] Although it mostly affects citizens of low- and middle-income countries, the prevalence of CSOM varies greatly between nations.[4,6] CSOM prevalence is 3.1% in unilateral and 1% in bilateral disease, whereas, there are no gender variations in CSOM prevalence.[1]

The treatment choices for CSOM consist topical antiseptics, topical antibiotics (ear drops) with or without steroids, systemic antibiotics (oral or injectable) and aural toilet.[7,8] International studies show that topical quinolone antibiotics were better than systemic antibiotics at clearing discharge from chronically discharging ears with CSOM within 1-2 weeks.[9,10]

However, there is currently a dearth of local data comparing the effectiveness of topical Cprofloxacin with oral Cprofloxacin. Hence, in the current study, we compared the efficacy of Cprofloxacin 0.6% ear drops versus oral Cprofloxacin in achieving the dry ears in chronic suppurative otitis media patients presenting at a tertiary care hospital, Islamabad Pakistan.

METHODOLOGY

The Quasi-experimental study was conducted at the Department of Otorhinolaryngology & Head and Neck Surgery, Pakistan Institute of Medical Sciences (PIMS), Islamabad Pakistan, from June 2022 to December 2022. Ethical approval was obtained from Institutional Ethical Review Committee (CMH Atd-ETH-70-ENT-23). The sample size of 130, 65 for each

Correspondence: Dr Mohsin Raza, Department of ENT, Combined Military Hospital, Abbottabad Pakistan

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group, was estimated using OpenEpi sample size calculator, keeping efficacy of oral Moxifloxacin and topical Cprofloxacin eardrops as 90%[1] and topical Cprofloxacin ear drops as 70%.[1]

Inclusion Criteria: Patients of either gender over 12 years of age, presenting with unilateral or bilateral CSOM i.e. chronic inflammation of the mastoid cavity and middle ear presenting with otorrhea through a non-intact tympanic membrane persisting for more than six weeks confirmed by otoscopy were included.

Exclusion Criteria: Patients who had already received antibiotic treatment in another health care facility, pregnant and lactating women, patients with known hypersensitivity to quinolones and those with histologically proven cholesteatoma, allergy, upper respiratory tract infections, patency of Eustachian tube and refraining from water exposure, attic defect and marginal perforation were excluded.

Patients fulfilling the selection criteria were recruited using non-random consecutive sampling from the outdoor department of Otorhinolaryngology, Head & Neck Surgery, PIMS. After obtaining informed consent, and noting patient's data on a predesigned proforma, patients were divided using lottery method and given treatments (Figure-1).

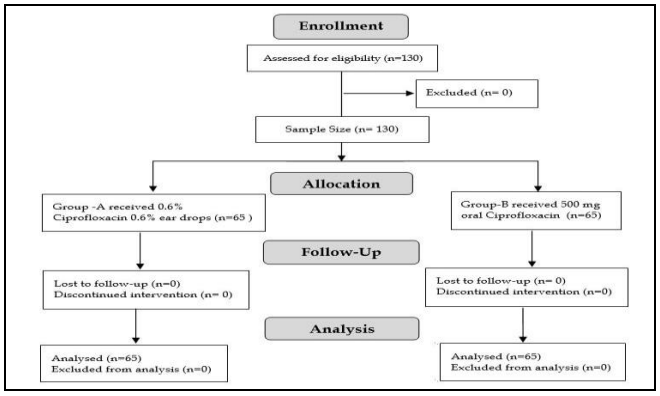

Figure-1: Patient Flow Diagram (n=130)

Group-A (n=65) received topical Cprofloxacin 0.6% ear drops and Group-B (n=65) received oral Cprofloxacin 500 mg twice daily for two weeks. The patients were assessed initially by adequate history of symptoms and otoscopy. Group-A patients receiving topical Cprofloxacin 0.6% ear drops were instructed to do proper aural toilet and put 06 drops twice daily in supine position with the affected ear facing the ceiling followed by tragal rub for 5 minutes. Group-B members receiving oral Cprofloxacin were instructed to take a 500 mg pill twice daily.[1] Follow up was done after 02-week interval. For follow up phone numbers were resorted. Subjective assessment was done by finding out from the patients about the absence, reduction or no change in the discharge and objective assessment was done by otoscopy to assess the presence and nature of the discharge. After two weeks of therapy in CSOM, the treatment was deemed effective if dry ears were obtained. The assessment of dry ears was done after one week of completion of treatment.

Statistical Package for Social Sciences (SPSS) version 23.0 version was used to analyze data. Mean and SD were reported for numeric variables like age and duration of CSOM. Frequency and percentage were reported for categorical variables like gender and efficacy (ear discharge). Comparison between both groups for efficacy was done using Chi-square test. The *p*-value of ≤0.05 was considered as statistically significant.

RESULTS

Study sample revealed a mean age of 29.70±9.03 years (range 12-29 years). Majority of the patients were males (60%) and 40% were females. In most of the patients (85.35%) the duration of discharge was <30 weeks (Table).

Table: Baseline Characteristics of Patients (n=130)

Variables	Overall (n=130)	Study Groups	
		Group-A (n=65)	Group-B (n=65)
Age (years)	29.7±9.03	29.75±2.83	29.75±2.19
Gender			
Male	72(60)	38(58.5)	34(52)
Female	58(40)	27(41.5)	31(48)
Duration of Ear Discharge			
≤30 weeks	111(85.3)	58(89.2)	53(81.5)
>30 weeks	19(14.7)	7(11.8)	12(12.5)

In Group-A, there were 11(16.9%) subjects with ear discharge. The rest 54(83.1%) had no ear discharge. In Group-B, there were 46(70.8%) subjects with ear discharge. The rest 19(29.2%) had no ear discharge. There was a statistically significant difference in efficacy of intervention between both groups with *p*-value=0.001. (Figure-2)

DISCUSSION

Globally, people are becoming more aware of the serious morbidity of ear discharge caused by CSOM.[11,12] The increased understanding of topical antibiotics' function in CSOM has important treatment ramifications.

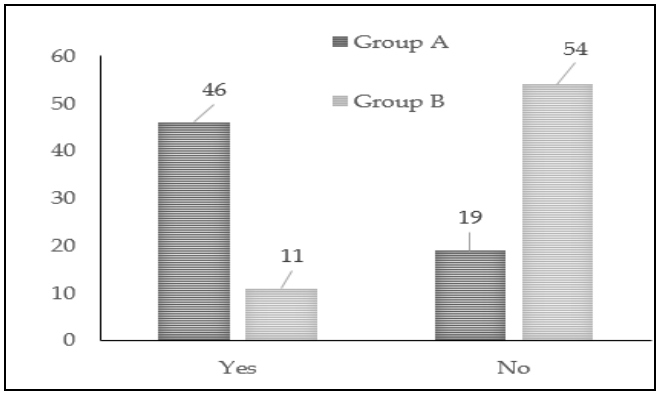

Figure-2: Comparison of Ear Discharge Between Groups (n=130)

Topical Cprofloxacin is effective in treating ear discharge caused due to certain types of bacteria, like Staphylococcus aureus or Pseudomonas aeruginosa.[8,9,13] In the current study, we found topical Cprofloxacin 0.6% ear drops was more efficacious on otoscopic assessment than oral Cprofloxacin 500 mg twice daily after 2 weeks of treatment (83.1% vs 29.2%, p=0.001). In a similar study, Cprofloxacin eardrops had excellent outcome in 52%, while oral Cprofloxacin had excellent outcome in 36% of the patients with CSOM.[14] International research also found that topical quinolone antibiotics could clear ear discharge better than systemic antibiotics. At 2-4 weeks, topical non-quinolone antibiotics (without steroids) or antiseptics had no statistically significant advantage over systemic antibiotics. They also found no advantage in combining a systemic medication with a topical therapy after 1-2 weeks.[15] Syed *et al*. found tab Cprofloxacin 500mg was more effective than Topical Cprofloxacin ear drops (61.3% vs 53.3%), however, this difference was statistically insignificant (p=0.322).[9] In a Cochrane review by Chong *et al*. three studies showed resolution of ear discharge at 1 to 2 weeks and found topical Cprofloxacin administration had better outcomes compared to oral Cprofloxacin.[7] Other studies also highlighted Cprofloxacin ear drops had greater efficacy than oral Cprofloxacin (76% vs 60%) with p-value=0.017.[14] In another study, it was found that topical Cprofloxacin was an effective treatment for acute on chronic otitis media. However, there was a higher recurrence rate in this group compared to those who received combination therapy with both oral and topical antibiotics. Overall, they concluded that systemic antibiotics alone or in combination with topical preparations do not improve outcomes when treating CSOM as much as using only topically applied medications does.[16] In a study by Khan *et al*. moxifloxacin showed positive effect on symptoms of CSOM. Additionally, moxifloxacin in combination with topical Cprofloxacin ear drops had higher efficacy as compared to Cprofloxacin ear drops (alone).[1] Another research project showed topical Cprofloxacin was more effective than neomycin in reducing ear discharge and congestion, with a p-value of less than 0.005. They highlighted topical Cprofloxacin solution has several advantages over neomycin such as its pH level which does not burn on administration and minimal absorption from usage suggesting low possibility inducing toxicity or adverse reactions when used topically.[16] Similarly, Jamalullah *et al*. found that topical Cprofloxacin 0.6% was more effective than gentamycin 0.3%, with 25% of patients in the former group showing a change to moderate otorrhea, 62.5% changing to mild otorrhea and 12.5% having no ear discharge after treatment; compared to 32.5% for the latter group who showed a change from profuse otorrhea status to mild one and 67.5% had no ear discharge post-treatment (p=0.001).[17] In another recent study by Patel *et al*., topical Cprofloxacin showed that it was not effective against Pseudomonas aeruginosa, *Staphylococcus aureus* and other organisms found in ear discharge. Oral Cprofloxacin had better efficacy than the topical form as it was able to inhibit growth of some bacteria like Klebsiella pneumoniae but still could not completely eradicate them from the sample.[18] Onali *et al*. also revealed that topical Cprofloxacin was more effective than oral administration for treating CSOM related ear discharge; however, both treatments were found to be equally successful at eliminating any remaining signs of infection after treatment had been completed.[19]

CONCLUSION

The 0.6% topical Cprofloxacin given 6 drops twice daily for two weeks is a better choice in medical management of CSOM than oral Cprofloxacin 500mg twice daily in terms of resolution of ear discharge.

Conflict of Interest: None.

Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

MIM & AFN: Data acquisition, data analysis, drafting the manuscript, critical review, approval of the final version to be published.

ZS & AA: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

AE & MR: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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