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Original Article

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Effectiveness of topical vs. combination ciprofloxacin for the treatment of chronic suppurative otitis media

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ABSTRACT

BACKGROUND & OBJECTIVE: Topical antibiotics are a popular choice for treating chronic suppurative otitis media (CSOM), but there is no consensus on their penetration ability in the middle ear, mastoid cavities, and effectiveness against the causative pathogens. Hence, the present study aimed to compare the efficacy of empirical treatment of Chronic Suppurative Otitis Media (CSOM) with topical ciprofloxacin alone and in combination with oral ciprofloxacin.

METHODOLOGY: In this prospective study, 98 consecutive patients presented with diagnosed CSOM of tubotympanic type were recruited from the ENT Department of Bahawal Victoria Hospital. The enrolled patients were randomly subjected to the treatment groups (49 in each group), i.e., topical ciprofloxacin drops alone or oral and topical ciprofloxacin in combination; the therapy continued for 1 week. After 7 days of treatment, patients were assessed to observe the resolution of discharge and adverse effects of the drugs.

RESULTS: It was observed that 95.9% of the patients had complete resolution of discharge after 7 days of treatment; the outcomes were comparable in both treatment groups (p=1.00). There was no statistically significant difference between the patients of both treatment groups concerning gender, age, and discharge duration (p>0.05). There were minimal side effects but apparently, they were more frequent among group B patients than in group A.

CONCLUSION: It is concluded from the study that topical ciprofloxacin alone is as efficacious as oral and topical combination therapy for the treatment of CSOM.

KEYWORDS: Chronic Suppurative Otitis Media, Adverse Effects, Patient Discharge, Ciprofloxacin, Anti-Bacterial Agents.

INTRODUCTION

Chronic suppurative otitis media (CSOM) is characterized as a stage of ear disease associated with chronic middle ear cleft infection, non-intact tympanic membrane, and discharge, for at least the preceding two weeks, by the World Health Organization (WHO)[1,2]. Gram-negative microorganisms such as Bacillus, Proteus, and Pseudomonas aeruginosa are the commonest pathogen causing CSOM[3]. Younger age, overpopulation, insufficient housing, bad hygiene, poor breastfeeding, lack of nutrition, poverty, Eustachian tube dysfunction, and unavailability of proper healthcare are some known risk factors for CSOM [1,4,5].

The global prevalence of CSOM ranges between 1% to 46%. While 65 to 330 million people have been estimated to have discharging ears, out of which 60% suffer serious hearing impairments [6]. As per the WHO report, Western pacific countries share the highest disease burden (2% to 43%), followed by Southeast Asian countries (1% to 8%), African countries (0.4% to 4%), and South and Central American Countries (3%). In comparison, it is the least prevalent in Europe (0.4%)[7,8].

Dry mopping, topical antiseptics, and antibiotics (sometimes with added steroids and systemic antibiotics) are the most frequently used treatment modalities [2]. Topical antibiotics are a popular choice, but local data are scarce on their penetration ability in the middle ear, mastoid cavities, and effectiveness against causative pathogens. Furthermore, the ototoxic effects of these antibiotics, especially topical aminoglycoside, remain a controversial issue. Therefore, systemic treatments, either monotherapy or combination therapy with topical antibiotics, have been endorsed.

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Preferably quinolones are widely used compared to aminoglycosides due to the ototoxic and nephrotoxic adverse effects caused by aminoglycosides [9].

Furthermore, an increased risk has been reported among pregnant women and children using systemic quinolones due to associated arthralgia and gastrointestinal (GI) disturbances [10]. Hence, topical quinolones, with good efficacy and fewer adverse effects, have gained great attention recently for the management of CSOM. Various trials have shown that the drug sensitivity patterns of quinolones, especially ciprofloxacin, are very active against the most common isolates involved. Amikacin, gentamicin, penicillins, and cephalosporins are also considered effective among CSOM patients [11,12].

There is a lack of agreement locally and internationally as to whether use topical therapy alone or in combination with oral therapy in terms of safety and efficacy. Therefore, the study aims to assess the safety and efficacy of topical vs. combination ciprofloxacin for the treatment of CSOM. Results of this study will provide guidelines for using either topical vs combination ciprofloxacin therapy for treating the chronic otitis media.

METHODOLOGY

This prospective study was conducted at the ENT Department of Bahawal Victoria Hospital, Bahawalpur-Pakistan, from April 1st, 2020, to September 31st, 2020. The sample size of 98 was calculated using the WHO sample size calculator, taking a 95% confidence interval, desire of power as 0.8, having 2-tailed hypotheses [13]. The ethical approval was obtained from the institutional ethical review committee (Reference no 281/DME/QAMC Bahawalpur; Date 2nd March 2020). Study objectives were explained to the participants, and written informed consents were obtained before inclusion. The patient data, including demographic details and CSOM-associated information like discharge duration and resolution after 7 days of treatment, was obtained and recorded in the pre-designed questionnaire. Adverse effects of studied drugs were also assessed and reported.

Patients aged 18 to 50 years presenting with a diagnosis of CSOM of tubotympanic type were included in this study. While pregnant women, patients with diabetes mellitus or immune suppression disorder, those with any sort of ear pathologies other than CSOM, patients with external/middle ear anatomical abnormalities, or received any kind of treatment for the same or any other complaints within the last 2 weeks were excluded. Furthermore, those identified with attic perforation or cholesteatoma/granulations during the examination were also kept under exclusion criteria.

The recruited patients were randomly divided into two groups; randomization was done using the lottery method. Patients of both treatment groups were given 3 to 4 drops of topical ciprofloxacin, 8 hourly. Group A patients received topical ciprofloxacin drops, while patients of group B were given a combination of ciprofloxacin (oral plus topical), an oral dose of ciprofloxacin (200 mg) was given 12 hourly for 7 days. The patients were recommended to adopt aural hygiene and water prevention. After 7 days of treatment, patients were re-assessed in the OPD; an Ear examination was done to observe the discharge rate, perforation, resolution, and adverse effects of the treatment.

The statistical analysis was carried out on SPSS version 20.0. A Chi-square test was used to compare gender, discharge resolution, and treatment adverse effects between the treatment groups. While the continuous variables like age and discharge duration were compared using an independent sample t-test. A p-value < 0.05 was considered statistically significant.

RESULTS

Out of 98 patients, there were 63 males and 35 females with a mean age of 35.48 ± 5.93 years. The mean duration of discharge was found to be 58.4 ± 28.2 days. The left ear was affected in 52.0% of patients and the right ear in 48.0%. After 7 days of treatment, overall, 95.9% of patients had complete resolution of discharge, i.e., 46(93.9%) patients from group A and 47(95.9%) patients from group B (p=0.646). No significant statistical difference was found between the patients of both treatment groups concerning gender, age, and discharge duration (p>0.05).

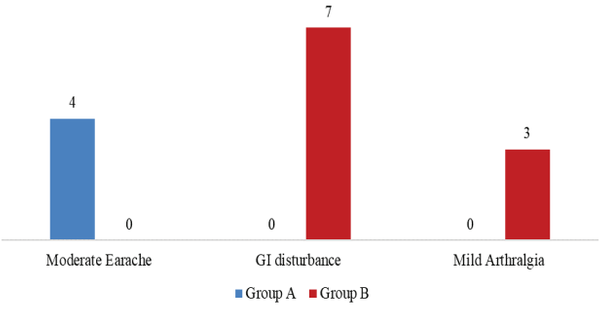

Figure-I: Comparison of adverse effects between the treatment groups.

Table-I: Characteristics of the studied population (n=98).

Characteristics		Group A (n=49)	Group B (n=49)	p-value
Gender	Male	30(61.22)	33(67.34)	0.527
	Female	19(38.77)	16(32.65)	
Age (years)		34.87±4.28	36.4±5.64	0.134
Duration of discharge (days)		60.57±25.48	55.14±30.47	0.341
Resolution of discharge	Yes	46(93.9)	47(95.9)	0.646
	No	3(6.1)	2(4.1)	

*p<0.05 is considered statistically significant.

A total of 14 patients complained of adverse effects related to the given treatment; of these, 4(8.16%) patients from group A and 10(20.40%) from group B reported adverse effects. All the 4 patients of group A had a moderate earache. In group B, 7 patients reported GI disturbance and 3 reported mild arthralgia (Figure-I).

DISCUSSION

In Pakistan, there is a scarcity of data and investigation regarding the tendencies of middle ear infections and treatment outcomes. There is no consensus on the most reliable and effective medical approach to CSOM; clinicians mostly prescribe antibiotics and quinolone drops [11,12]. A local study compared quinolones with aminoglycosides for the medical management of CSOM and found encouraging results [14]. Similarly, Manolidis and colleagues in an evidence-based review, noted fluoroquinolones to exhibit better effectiveness than aminoglycosides for treating middle ear infections [15]. The quinolones have been prescribed widely for treating middle ear infections since the 1980s, but the selection of treatment methods remains controversial [16,17]. A recent systematic review including six randomized controlled trials suggested that the topical treatment may be more effective than the systemic administration of antibiotics for CSOM but based on the scarcity of evidence regarding the comparative efficacy of different antibiotics, it isn't appropriate to approve topical quinolones over systemic aminoglycosides [18].

A preliminary study compared the efficacy of oral or topical ciprofloxacin for CSOM, it was found that the patients treated with topical drops of ciprofloxacin presented better outcomes than other treatment arms [19]. A success rate of 85% with ciprofloxacin drops without additional oral treatment was reported. Similarly, a Cochrane database review, including 24 randomized trials concerning the treatment modalities of CSOM, concluded that a combination of topical and systemic antibiotics was as efficacious as the topical antibiotic drops alone [20]. In the present study, after 7 days of treatment, overall, 95.9% of patients had complete resolution of discharge. The resolution rate was comparable in both treatment groups, i.e., 93.9% in group A vs. 95.9% in group B. A local study from Jinnah Medical College Hospital reported a comparatively high-resolution rate with treatment approaches; topical ciprofloxacin resulted in complete resolution of discharge among 96% of the patients, while the topical and oral ciprofloxacin combination therapy resulted in resolution of discharge among 98% of patients [13].

Hence, additional oral ciprofloxacin with topical drops had no significant advantage in terms of efficacy in CSOM. Furthermore, the oral and topical therapy only added adverse effects in the present set of patients, which is consistently reported in the previous literature [13,21]. Fourteen included patients had treatment-related adverse effects (4 from group A vs. 10 from group B). GI disturbance was the most frequently reported adverse effect by the patients of group B (n=7), followed by mild arthralgia (n=3), while none reported from group A. Onali et al., in their study, reported exactly alike, 15 of their patients were observed having adverse effects. Of them, 4 were given topical ciprofloxacin ear drops alone, whereas 11 patients took oral and topical in combination [13].

Only surgical treatment is the most authentic management option for tubotympanic CSOM when the ear is discharge-free [22]. But most trials, specifically from low to middle-income countries (with restricted healthcare facilities), discuss only short-term treatment options for CSOM [13,21]. Being a government healthcare facility, most of our patient inflow is from low socioeconomic statuses. The prescription of combination drugs with no firm evidence and added adversities where a single treatment approach could work alone could induce a financial burden on the patients.

Like all the previous studies, the present study also focused on the short treatment duration and follow-up. Furthermore, we only focused on the complete discharge resolution, whereas the hearing outcomes following treatment weren't observed. Randomized controlled trials assessing both short and long-term outcomes of various treatment approaches are required to affirm the study findings.

CONCLUSION

Empirical treatment with topical ciprofloxacin drops alone was as efficacious as oral and topical ciprofloxacin combination therapy. Furthermore, the patients who used additional oral and topical ciprofloxacin only experienced more adverse effects than ciprofloxacin drops. Hence, it is concluded that topical ciprofloxacin alone is sufficient for treating tubotympanic CSOM.

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CONFLICT OF INTEREST: None.

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Author's Contribution:

Nasir Wakeel: Substantial contributions to the conception and design of the work.
Aasma Tariq: Acquisition, analysis, and interpretation of data for the work.
Iqra Gull: Drafting the work and revising it critically.
Hamna Hafeez: Final approval of the version to be published.

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