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Comparative Effectiveness of the Oral versus Topical Ofloxacin to Reduce the Discharge in Chronic Suppurative Otitis Media; A Randomized Control Trial

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Author`s Contribution

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ABSTRACT

Objective: To compare the effectiveness of oral versus topical ofloxacin in reducing discharge in patients with chronic suppurative otitis media (CSOM).

Methodology: This randomized controlled trial was conducted in the Department of Otorhinolaryngology–Head and Neck Surgery at PIMS, Islamabad, from June 2019 to December 2019, A non-probability consecutive sampling technique was used. A total of 98 participants, with 49 patients in each group (A and B). Group A received topical ofloxacin, while group B received oral/systemic ofloxacin. The efficacy of both treatments was compared two weeks after the initiation of treatment. Data analysis was performed using SPSS version 23.

Results: In group A, 67.3% (n=33) of participants were male and 32.7% (n=16) were female. In group B, 61.2% (n=30) were male and 38.8% (n=19) were female. The mean age in group A was 27.0 ± 9.4 years, while in group B it was 26.6 ± 10.1 years. The mean disease duration was 2.6 ± 2.1 years in group A and 2.4 ± 1.9 years in group B. In group A, 73.5% (n=36) of patients had pus discharge, 26.5% (n=12) had pus mixed with blood-stained discharge, 89.8% (n=44) had redness, and 12.2% (n=6) presented with edema. In group B, 95.9% (n=47) had pus discharge, 4.1% (n=2) had blood-stained discharge, 46.9% (n=23) had redness, and 6.1% (n=3) had edema. After two weeks of treatment, the reduction in discharge was significantly greater in patients treated with topical ofloxacin compared to those treated with oral ofloxacin ($p<0.05$ for all outcomes).

Conclusion: Topical ofloxacin is more effective than oral ofloxacin in reducing discharge in patients with CSOM. Further multicenter studies with larger sample sizes are recommended to validate these findings.

Keywords: Chronic suppurative otitis media, ofloxacin, oral vs topical, antibiotics, otitis media

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Introduction

Chronic suppurative otitis media is a disease of middle ear effecting people all around the globe.[1] It is defined as a persistent or intermittent ear infection for more than three months and characterized by an ear discharge through perforated tympanic membrane.[2,3] The disease is most commonly found in developing countries whereas, the incidence is negligible in developed regions of the world. The worldwide hearing impairment among the estimated 300 million cases is 60%.[4,5] The disease complication results in 28000 deaths annually.[2] CSOM has two types, Tubotympanic (Pars Tensa) and Attic antral (Pars flaccida). The former types are supposed to be safe whereas the later one is known as dangerous type due to its association with serious complications. Before opting for surgical procedure, medical management to treat CSOM has got prime importance. No particular guidelines are available for its management and treatment because of the involvement of the pathogens.

Chronic ear disease occurs when there is a dysfunction of Eustachian tube, characteristically associated to

impediment (usually due to upper respiratory tract infection or seasonal allergic rhinitis). By divergence, non-standard un-obstruction of the Eustachian tube does not cause infection but results in autophony (hearing one's own voice) and ear fullness.[6,7] Balloon dilatation of the Eustachian tube is a progressing technology used for the treatment of Eustachian tube dysfunction.

The customary quinolone therapy for otitis media typically involves the use of ciprofloxacin or ofloxacin drops administered twice daily for two weeks, although extending treatment to four weeks may provide additional benefit without increasing complication rates. Many sources recommend warming the otic solution in the hands for a few minutes prior to administration, as the instillation of cold drops can cause dizziness. The patient should lie on their side with the affected ear facing upward during and after instillation. Some sources also suggest gently pressing on the tragus several times to help facilitate the movement of the drops into the middle ear.

No robust data is available for the medical management of CSOM, an evidenced based report indicates the efficacy of topical fluoroquinolones in its significant treatment.[8] Topical fluoroquinolones are the only oto-topical agents approved in the US to treat a tympanic membrane perforation.[9] A systematic review found that topical quinolone were better than systemic one in reducing the intensity of the ear discharge after treatment of two weeks.[10] Several studies suggested that topical fluoroquinolone may be superior to topical aminoglycosides agents[11]. In another study, topical quinolone were ominously better than topical antiseptics at 1-4 weeks.[12]

The objective of the study was to assess the reduction rate of discharge in chronic suppurative otitis media with the use of oral vs topical Ofloxacin.

Methodology

The study was commenced after obtaining approval from the ERB. It was a six-month study utilizing a non-probability consecutive sampling technique. The sample size of 98 patients (49 in each group, A and B) was calculated using the WHO calculator. Hypothesis testing for two population proportions (two-sided) was performed with a 5% level of significance (α) and 80% power of the test, using anticipated population proportions of 88% (cure in the topical group) and 72% (cure in the oral group).

All 98 patients who met the inclusion criteria were enrolled in the study. Inclusion was based on symptoms such as active mucosal disease with a defect of the pars tensa, inflamed middle ear mucosa, mucopurulent discharge lasting more than four weeks, history, and clinical findings. Informed consent was obtained from all patients before the initiation of treatment as part of the ethical process. Patients were fully informed about their participation in the study, the treatment or management they would undergo, as well as the associated benefits and risks. Data was collected on a pre-designed proforma, and patient confidentiality was strictly maintained.

The patients were randomized into two groups using a lottery method. Participants in group A received topical ofloxacin, while participants in group B received oral/systemic ofloxacin. Statistics regarding the reduction of ear discharge were gathered from both groups, and the efficacy of the two drugs was compared. Efficacy was assessed two weeks after the start of treatment.

Data analysis was conducted using SPSS version 23. Descriptive statistics were calculated for both qualitative and quantitative variables. Qualitative variables, such as gender and resolution of otorrhoea, were expressed as frequencies and percentages. Quantitative variables, such as age, were measured as means and standard deviations. A chi-square test was used to compare efficacy between the two groups, including the number of days until discharge resolution, as well as discharge resolution at day 7 and day 14. An independent sample t-test was applied to compare the time to discharge resolution between the groups. A p-value ≤ 0.05 was considered statistically significant.

Results

Gender distribution is shown in Figure 1, with group A having 67.3% males and 32.7% females, and group B having 61.2% males and 38.8% females. The mean age and disease duration for both groups are presented in Figure 2.

A pus discharge was recorded in 73.5% (n=36)patients, pus and blood stained discharge in 26.5%, (n=12), 89.8% (n=44) had redness and 12.2% (n=6) had edema on examination. The values for group B were 95.9% (n=47), 4.1% (n=2), 46.9% (n=23) and 6.1% (n=3), respectively. The results are shown in table 1.

The results regarding the efficacy of topical and oral ofloxacin in both the study groups after week 1 and week 2 are generalized in table II.

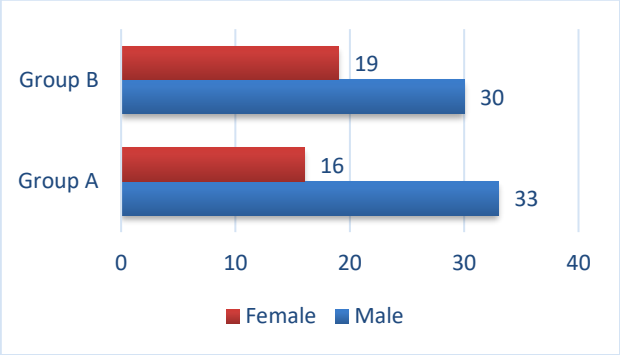

Figure 1. Gender wise distribution among the study groups.

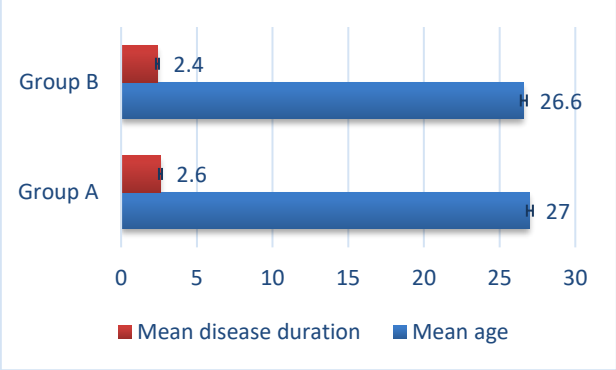

Figure 2. Mean age (in years) and mean disease duration (in years).

Table I: Presence of complications in both the study groups.

Groups	Pus discharge (%)	Pus & blood-stained discharge (%)	Redness (%)	Edema (%)
Group A	73.5	26.5	89.8	12.2
Group B	95.9	4.1	46.9	6.1

Table II: Comparison of the efficacy of topical vs oral ofloxacin after various time duration.

Cure		Groups		Total	*P*-value (Chi-square)
		Group A	Group B		
Week 1	**Present**	17	0	17	0.001
		34.7%	.0%	17.3%	
	Absent	32	49	81	
		65.3%	100.0%	82.7%	
Week 2	**Present**	49	32	81	0.001
		100.0%	65.3%	82.7%	
	Absent	0	17	17	
		.0%	34.7%	17.3%	

After two weeks of treatment, treatment was found efficacious in 100% (n=49/49) patients in group A and it was observed in 40.8% (n=20/49) patients in group B (P=0.001). The efficacy of treatment was significantly better in patients treated with topical ofloxacin when compared with those treated with oral ofloxacin. The results are shown in table III.

Table III. Comparison of the efficacy of topical vs oral ofloxacin in study groups.

Efficacy	Groups		Total	*P*-value (Chi-square)
	Group A	Group B		
Present	49	20	69	0.001
	100.0%	40.8%	70.4%	
Absent	0	29	29	
	.0%	59.2%	29.6%	
Total	49	20	69	
Total	100.0%	40.8%	70.4%	

The results showing overall efficacy with respect to gender distribution in both the study groups are mentioned in table IV.

Table IV: Overall efficacy (stratification with respect to gender) in both the study groups.

Variables	Efficacy	GROUPS		Total	*P*-Value Chi Square
		Topical	Oral		
Male	**Present**	33	11	44	0.001
		100.0%	36.7%	69.8%	
	Absent	0	19	19	
		.0%	63.3%	30.2%	
Female	**Present**	16	9	25	0.001
		100.0%	47.4%	71.4%	
	Absent	0	10	10	
		.0%	52.6%	28.6%	

Discussion

Chronic suppurative otitis media (CSOM) is treated using various regimens across the world. Treatment options include topical antibiotics, with or without steroids, systemic antibiotics, topical antiseptics, and aural toileting.[13] Topical quinolones are the first-line choice for otolaryngologists in managing chronic otitis media. Some reports also support the use of systemic antibiotics in patients with more invasive ear infections or those at higher risk for resistant pathogens.[14] This study aimed to compare the effectiveness of topical versus oral ofloxacin in reducing discharge in patients with CSOM.

In our study, we enrolled 98 patients of either gender, all presenting with active mucosal disease characterized by a defect in the pars tensa, inflamed middle ear mucosa, and mucopurulent discharge lasting for more than four weeks. The participants were randomized into two groups, A and B, using the lottery method. Group A was treated with topical ofloxacin, while group B received oral/systemic

ofloxacin. The efficacy of both treatments was compared two weeks after the start of treatment. After two weeks, patients treated with topical ofloxacin showed significantly greater improvement compared to those treated with oral ofloxacin ($p<0.05$ across all groups).

The enhanced efficacy of topical ofloxacin compared to systemic treatment may be due to the limited penetration of systemic drugs through the devascularized mucosa of the middle ear and mastoid. Additionally, the use of topical agents allows for the modification of the local microenvironment. In an acidic medium, the administration of antibiotics helps restore and stimulate the normal host defense mechanisms.[15]

The findings of our study are in consistent with the results of other similar studies. In a systematic review, a comparison was done between topical vs oral antibiotics for the treatment of chronically discharged ears with an underlying eardrum perforation.[10] The pooled analysis of the data exposed that topical quinolone antibiotics were better than systemic antibiotics with regards to clearance of the discharge at 1-2 weeks of treatment. They also showed that there was no benefit of adding systemic to topical treatment at 1-2 weeks.

In the present study, we however, compared topical and systemic ofloxacin in different groups and did not add systemic therapy to the topical one. The efficacy results at two weeks are similar.

In another review, Brennan-Jones evaluated the effects of topical antibiotics for the treatment of CSOM. The review included 17 RCTs (randomized controlled trials) with a total of 2198 participants with at least a one-week follow-up. Comparisons of different topical antibiotics (Quinolones versus aminoglycosides) revealed that resolution of discharge at one to two weeks was higher in the quinolones group ($P<0.05$). The review further explained the effectiveness of topical antibiotics in comparison to oral one, however, the evidence is unpredictable and indeterminate. The review concluded that topical quinolones are an effective first line therapy for the treatment of CSOM.[16]

In a Pakistani study from Bahawal Victoria Hospital, the researchers compared the effectiveness of topical vs oral ofloxacin and combination of topical and oral ofloxacin as the first line management among patients with CSOM. The researchers concluded that topical ciprofloxacin alone is as efficacious as oral and topical combination therapy for the treatment of CSOM.[17] In a study conducted on a local population in Karachi, researchers compared topical quinolone (ciprofloxacin) with a combination of topical and systemic quinolone (ciprofloxacin) in patients with tubotympanic CSOM. They included 100 patients who were randomly assigned to receive either topical eardrops or a combination of systemic and topical ciprofloxacin following aural toileting. After one week of treatment, 48 out of 50 patients (96%) in the topical group responded, while 49 out of 50 patients (98%) in the combined therapy group showed a response. This difference was not statistically significant ($P>0.05$). Additionally, age, sex, and duration of discharge had no significant effect on treatment outcomes. The authors concluded that combining oral and topical ciprofloxacin did not provide any additional benefit over topical therapy alone and only increased the overall cost.[18]

Conclusion

Topical ofloxacin is a better agent as compared to orally available in resumption of discharge in CSOM. More, multicenter studies with an enlarged sample size are suggested to strengthen the evidence.

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