

Comparison of Efficacy of Topical Ofloxacin and Gentamycin in Tubotympanic Type of Chronic Suppurative Otitis Media

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ABSTRACT

Objectives: To compare the efficacy of 0.3% topical ofloxacin 4 drops thrice daily with topical gentamycin 0.3%, 4 drops thrice daily in patients with active tubotympanic type of CSOM.

Study Design: Randomized controlled trial study.

Place and Duration of Study: This study was carried out in the Department of ENT and Head and Neck Surgery, HMC, Peshawar from Jan 2012 to July 2012.

Materials and Methods: This Randomized controlled trial was conducted, consisting of 134 patients with ear discharge for more than three months which were randomly allocated to two groups each consisting of 67 patients. Patients in group A received gentamycin 0.3% in a dosage of four drops thrice daily, while patients in group B received 0.3 % ofloxacin four drops thrice daily for ten days. Patients were followed for two weeks after therapy for ear symptoms assessment, otoscopy and examination under microscopy.

Results: A total of 134 patients of chronic suppurative otitis media were included in the study. Results showed that the rate of resolution of ear discharge (otorrhea) is significantly higher in patients treated with topical Ofloxacin than gentamycin (98.5% vs 89.6%). ($P < 0.05$)

Conclusion: Topical Ofloxacin is a better choice in management of CSOM than topical Gentamycin in terms of resolution of ear discharge.

Key Words: CSOM, Tubotympanic otitis media, Topical Ofloxacin, Topical Gentamycin

INTRODUCTION

Chronic suppurative otitis media (CSOM) is a persistent infection of middle ear cavity presenting as purulent ear discharge extending over a period of 3 months. Chronic Suppurative otitis media is one of the most common ear diseases in South East Asia having a prevalence of approximately 5.2 % in the general population.¹ The disease is slow and insidious that often leads to destructive changes in the middle ear mucosa, ossicles and underlying bone. This local destruction sometimes leads to serious extracranial and intracranial complications.² In CSOM the most common bacterial isolates are *Pseudomonas aeruginosa* followed by *S. aureus*, *Proteus*, *Klebsiella pneumoniae*, *diphtheroides*, fungal isolates such as *Aspergillus* species and *Candida albicans* as well as *Mycobacterium tuberculosis*.³ A variety of treatment modalities, both medical and surgical have been tried for the management of CSOM. More recently there is growing trend in using topical aural therapy as an isolated modality or in conjunction with systemic therapy due its documented advantages. Topical medications are delivered directly to the infected area bypassing the untoward side effects of systemic therapy. The topical antibiotics are less likely to cause microbial resistance than systemic ones.⁴ The antibiotic should have an appropriate spectrum of

activity that includes gram -ve organisms especially *pseudomonas* and gram positive organisms especially *Staph aureus*. The antibiotics that meet this criterion are aminoglycosides and flouroquinolones and both are available for topical use.⁵ Considering the significant advantages and the popular use of available antibiotic ear drops, it is worth mentioning that the quinolones have been proved to be superior to aminoglycosides in terms of overall cure rate, relief of otalgia and otorrhea.^{6,7} There is an intense need to have a modality of treatment which is not only cheaper, easily administrable but also effective in all age groups.^{1,7} The success rate of Ofloxacin in reducing ear discharge has been found to be 90% and that of gentamycin 70%.⁶ While another study shows that Ofloxacin application resulted in dry ear in 80% of cases as compared to 50% in gentamycin group.⁷

MATERIALS AND METHODS

This randomized control study was conducted at the ENT Department, Hayatabad Medical complex (HMC) Peshawar from Jan 2012 to July 2012. All patients who presented to OPD meeting the inclusion criteria were included in the study. The inclusion criteria were patients above 16 years of any gender having active tubotympanic type of chronic suppurative otitis media. Patients who had taken antibiotics in last 2 weeks and

those having marginal perforation, cholesteatoma, aural polyps and history of mastoid surgery were excluded from the study. The diagnosis of tubotympanic chronic suppurative otitis media was made on the basis of detailed history and otoscopic examination. The purpose and benefits of the study were explained to all patients and a written informed consent was obtained. All patients were allocated into two groups by randomization done by lottery method. Patients in group A received gentamycin 0.3%(only preparation available) in a dosage of four drops thrice daily while patients in group B received 0.3% ofloxacin four drops thrice daily. Data were collected at first visit prior to medication and 2nd visit, two weeks after medication. Medication history review, ear symptom assessment and otoscopy was done at each visit. Patients were evaluated for decreased ear discharge. Approval from hospital ethical board was obtained. The data were stored and analyzed in SPSS version 16.

RESULTS

A total of One hundred and thirty four patients were included in this study from Jan to July 2012. Patients in group A received gentamycin while patients in group B received 0.3% ofloxacin four drops thrice daily for ten days. The results were compared and analyzed regarding age, gender, otorrhea before and after treatment and efficacy of drugs. The most common age affected were patients in third decade as shown in Fig 1. In group A, 42 patients were male with the mean age of 27.66 years and 25 were female with mean age of 27.5 years. In group B, 38 patients were male with the mean age of 30.81 years and 29 were female with mean age of 27.67 years as shown in Table 1. The mean ages of group A was 27.52 ± 9.16 years while in group B, mean age was 27.76 ± 7.25 years. In group A, there were 42 patients who presented with severe otorrhea, while 25 patients were having moderate otorrhea while severe and moderated otorrhea were found in 47 and 20 patients in group B respectively before initiating treatment (Table 2). After receiving treatment of ten days both groups were compared by doing otoscopy and rear examination under microscope. Moderate discharge was found only in 16.4% (n-11) patients in group A who received gentamycin eardrops while no patient was having moderate discharge in group B who received Ofloxacin 0.3% eardrops. This means that ofloxacin was more efficacious than gentamycin eardrops. Regarding mild discharge in group A 49.3% (n-33) patients having mild discharge as compared to 34.3% (n-23) patients in group B, favoring efficacy of ofloxacin. Similarly patients having no discharge were compared in both groups after treatment. In group A 34.3% (n-23) patients were having no discharge as compared to 65% (n-44) patients in group B which means that patients in group B were more symptoms free than group A suggestive of better efficacy of

ofloxacin than gentamycin eardrops (Table 3). No severe discharge was found in either group. The p-value was found significant (p value 0.000). Topical Ofloxacin is more efficacious (98.5%) than gentamycin (89.6%) as shown in Table 4.

Fig.1: Age distribution of patients

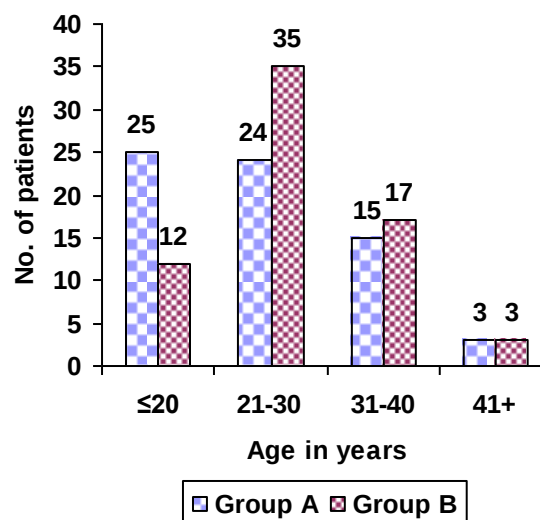


Figure No.1: Age distribution of patients.

Table No.1: Gender distribution between the two groups

Gender	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Male	42	31.3	38	28.4	80	59.7
Female	25	18.7	29	21.6	54	40.3

Table No.2: Status of otorrhea before treatment

Otorrhea	Group A		Group B	
	No.	%	No.	%
Severe	42	62.7	47	70.2
Moderate	25	37.3	20	29.8
Mild	-	-	-	-
No Discharge	-	-	-	-

Table No.3: Status of Otorrhea after treatment

Status of treatment	Group A	Group B	Total
Moderate	11	-	11
Mild	33	23	56
No Discharge	23	44	67

P value = 0.000 (<0.05)

Table No.4: Efficacy in both groups

Efficacy	Group A		Group B		Total	
	No.	%	No.	%	No.	%
Yes	60	89.6	66	98.5	126	94.0
No	7	10.4	1	1.5	8	6.0

DISCUSSION

Chronic suppurative otitis media (CSOM) is the result of an initial episode of acute otitis media and is

characterized by a persistent discharge from the middle ear through a tympanic perforation. Among such patients, medical treatment can be aimed at control of infection and elimination of ear discharge as short-term goals and eventual healing of the tympanic perforation and improvement of hearing as ultimate goals. Medical treatment options include aural toilet, use of antibiotics (topical, systemic, parenteral), topical antiseptics and combination of these. In our study 134 patients were recruited after informed consent from every patient. Results showed that patients who underwent treatment with ofloxacin (group B) showed better results in terms of resolution of the ear discharge after the treatment as compared to those treated with Gentamycin (group A). Results of this study were quite similar to the study of Kadar et al⁶, who recruited 120 patients in a comparative clinical trial and divided into two groups: aminoglycoside group of 60 patients were treated with gentamycin hydrocortisone ear drops and quinolone group of 60 patients were prescribed norfloxacin topical solution with a dose of 6 drops in the affected ear twice daily for two weeks. They concluded that in the medical management of chronic suppurative otitis media, the topical quinolones should be considered first line of treatment as there are no ototoxic effects of quinolones, which can be used safely in the presence of tympanic membrane perforation. Tong et al⁸ conducted a double-blind study compared two antibiotics, namely ofloxacin and neomycin-polymyxin B, with similar in vitro sensitivities to Gram positive and Gram negative organisms. Fifty-two patients were selected randomly and the results show that ofloxacin eardrops have marginal benefits in symptomatic improvement (89 per cent versus 79 per cent, $p = 0.27$) and bacterial eradication (81 per cent versus 75 per cent, $p = 0.81$) in active chronic suppurative otitis media. Significantly fewer patients (seven per cent versus 29 per cent, $p = 0.04$) in the ofloxacin group had active disease at the end of the two-week treatment. They recommended the use of ofloxacin eardrops in managing active chronic suppurative otitis media since it has high clinical efficacy, contains no steroid component and has no demonstrated risk of ototoxicity.

Lorente et al⁹ conducted a multicentric double-blind randomized study to compare topical ciprofloxacin and topical gentamycin in the treatment of simple non-cholesteatomatous purulent chronic otitis media. Three hundred and eight patients were included in the study, 159 treated with ciprofloxacin and 149 treated with gentamycin. The percentage of clinical success (elimination of otorrhea) was 95% with ciprofloxacin and 94% with gentamycin. Likewise, the percentage of bacteriological eradication was 96% with ciprofloxacin and 93% with Gentamycin. In these patients, topical ciprofloxacin shows the same efficacy as topical Gentamycin without any potential ototoxic effects.

Tutkun et al¹⁰ determined and compared the therapeutic efficiency of ciprofloxacin hydrochloride and Gentamycin sulfate in the treatment of chronic ear disease. They recruited 44 patients with chronic suppurative otitis media randomized into two groups. Ciprofloxacin hydrochloride (200 mg/mL) was administered to the first group (composed of 24 patients), while the second group (composed of 20 patients) received Gentamycin sulfate (5 mg/mL) locally, five drops three times a day for 10 days. In the ciprofloxacin group, 21 (88%) of the 24 patients with suppurative chronic otitis media were cured. On the other hand, only six (30%) of the patients in the Gentamycin group were cured. The rest of the patients showed no clinical or bacteriological improvement. They concluded that topical ciprofloxacin preparation is more efficacious and efficient than topical Gentamycin for the treatment of chronic otitis media in the acute stage. Miro et al¹¹ administered otic drops of either ciprofloxacin 0.2% solution or a combination of polymyxin B, neomycin, and hydrocortisone suspension (PNH) for 6 to 12 days to patients (14-71 years old) with chronic suppurative otitis media in a randomized, non-blinded, multicenter clinical trial. Two hundred thirty-two enrolled patients were analyzed for efficacy on a per protocol basis. Clinical success was observed in 91% and 87% of the ciprofloxacin and PNH-treated patients, respectively. In the comparative study of Supiyaphun et al¹² reported that the efficacy and safety of 0.3 per cent Ofloxacin otic solution 6 drops twice daily with those of oral Amoxycillin 500 mg three times daily plus 1 per cent Chloramphenicol ear drop at 3 drops three times daily were compared in a two-week treatment of chronic suppurative otitis media with acute exacerbation. The susceptibility of all the pathogenic isolates to ofloxacin, amoxycillin and chloramphenicol were 96.4, 57.1 and 51.8 per cent respectively.

Cure rate was significantly better in Ofloxacin treated group than in AMOX + CRP-treated groups in terms of painless ($p = 0.05$) and dry ($p < 0.001$) ears. Similarly De Miguel Martínez et al¹³ conducted a randomized study of 125 patients with chronic middle ear infection. In order to study the effectiveness of ciprofloxacin in chronic otitis media, they selected four different treatment groups: oral ciprofloxacin (500 mg/12 h); 0.5 and 0.2% topical solutions of ciprofloxacin (3 drops/8 h), and oral ciprofloxacin plus 0.2% topical solution. Topical polymyxin and neomycin were used as controls. They found that topical ciprofloxacin (0.2%) was the most effective regimen of those tested for the treatment of chronic otitis media. In summary, there are different treatment options for the management of chronic suppurative otitis media. Variety of topical antibiotics has been used and results of their efficacy are reported in the literature. Topical Quinolones have also been used in the treatment. In this study, 0.3%

topical ofloxacin, a flouroquinolone, 4 drops thrice daily was compared with 0.3% topical Gentamycin, an aminoglycoside given in a dosage of 4 drops thrice daily in the management of CSOM. It was found that ofloxacin is a better choice than Gentamycin in terms of resolution of ear discharge (otorrhea).

CONCLUSION

0.3% topical ofloxacin is a better choice in medical management of CSOM than 0.3% topical gentamycin in terms of resolution of ear discharge (otorrhea)

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