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Comparison of 3% Ciprofloxacin-1% Dexamethasone and 10% Ichthammol Glycerin for Control of Pain due to Acute Otitis Externa

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ABSTRACT

Objective: To compare the efficacy of 10% Icthammol glycerin and 3% ciprofloxacin-1% Dexamethasone for controlling pain associated with acute otitis externa.

Patients and Methods: This cross-sectional study conducted at the ENT department of Railway Hospital, Rawalpindi from 1st March to 1st December 2017. Sixty (n=60) patients of both gender between age 12-60 years, diagnosed with moderate to severe acute otitis externa were enrolled and were randomly divided into two groups using lottery method. Group A patients were administered 3% ciprofloxacin-1% Dexamethasone wick in auditory canal and Group B patients were administered 10% Icthammol Glycerin wick. The treatment was considered efficacious if there was marked reduction in pain (pain score decreased to ≤ 4 points from baseline on Visual Analog Score on day 3).

Results: Baseline characteristics were similar in both groups. Mean VAS was 6.67 ± 1.18SD in group A and 6.57 ± 1.16SD in group B (*P*=0.743) at baseline and was 2.43 ± 1.16SD and 3.50 ± 2.16SD, respectively on day 3 (*P*=0.028). Efficacy was significantly better in Group A patients as compared to Group B (76.7%, n=23/30 versus 43.3%, n=13/30; P =0.008).

Conclusion: Treatment with 3% ciprofloxacin-1% Dexamethasone was found to be significantly better than 10% Icthammol glycerin in patients with acute otitis externa in terms of associated pain control.

Key words: % Ciprofloxacin-1% dexamethasone, 10% Ichthammol glycerin

Author`s Contribution
[1] *Conception, synthesis, planning of research and manuscript writing Interpretation and discussion, Data analysis, interpretation and manuscript writing, Active participation in data collection.*

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Introduction

Otitis externa is a common ear condition that affects individuals of all ages.[1] It occurs in approximately 10% of the population, especially in warm and damp climates or in swimmers (swimmer's ear). Other predisposing factors include, local trauma, maceration, external devices, anatomic abnormalities, dermatitides and canal obstruction, which might make the canal epithelium susceptible to infections.[2] Both external auditory canals are affected in approximately 10% of cases. Otitis Externa can be secondary to dermatitis (eczema) only, with no microbial infection or can be caused by active bacterial or rarely fungal/viral infection. Pseudomonas aeruginosa and Staphylococcus aureus are the two most commonly isolated organisms.[3] Management depends on severity of disease. Mild disease is characterized by minor discomfort and pruritus with minimal canal edema and is usually treated with an acidifying agent and a glucocorticoid (acetic acid with hydrocortisone). Topical antibiotic are usually not recommended. Moderate disease is characterized by an intermediate degree of pain and pruritus with canal may be partially occluded and treatement by a topical preparation combination that is

acidic and contains an antibiotic, an antiseptic, and a glucocorticoid is usually preferred. The antibiotic should have coverage against *Staphylococcus aureus* and *Pseudomonas aeruginosa*. Cipro HC (ciprofloxacin and hydrocortisone) and Cortisporin (neomycin, polymyxin, and hydrocortisone) are good first-line agents. Severe disease is characterized by intense pain, and canal is completely occluded due to edema. Fever, peri-auricular erythema, and regional lymphadenopathy may be present. For patients with severe disease, management includes topical therapy, wick placement, and, if there is evidence of deep tissue infection, oral antibiotics are recommended.[4] Various studies reported the use of topicalGlycerol/Ichthammolwick, eomycin/Betamethasone wick,[5] 3% Ciprofloxacin - 1% Dexamethasone[6] oral ciprofloxacin 500 mg [7] for the treatment of bacterial otitis externa in terms of relief of pain.

There is still no agreement upon the use of prescribed drugs in the treatment of acute otitis externa and no drug is considered as the drug of choice. Present study is designed to evaluate two different kinds of treatments in our local population. This will help the ENT surgeons in offering the better one in those patients. Patients will be benefited in terms of better pain control which is quite disturbing and effects the overall quality of life. The primary aim of present study was to compare efficacy of 10% Ichthammol glycerin and 3% ciprofloxacin - 1% Dexamethasone in treatment of moderate to severe acute otitis externa in terms of Pain reduction.

Patients and Methods

It was a randomized controlled trial cross-sectional descriptive study conducted at the ENT department of Railway Hospital, Rawalpindi. Study was conducted for a period of nine months from 1st March 2017 to 1st December 2017. Sample size was calculated by taking level of significance as 5%, power of test as 80%, anticipated Population proportion 1 as 76%, anticipated Population proportion 2 as 38%.[6] Patients of both gender between ages 12 to 60 years, who were diagnosed with moderate to severe acute otitis externa were enrolled in the study. Otitis externa was diagnosed on history and clinical examination, a characteristic history of excruciatingly severe pain, ≥ 5 on visual analogue scale in the ear, which was exacerbated by tragal pressure and when the auricle was pulled superiorly. On Otoscopy, the tympanic membrane was only partially visible due to edema of external auditory canal. Ottitis media was excluded by otoscopy, no fluid was seen and tympanic membrane was normally moving on gentle puffing of air. Patients with a history of acute/chronic suppurative otitis media, patients suffering from local allergic conditions like eczema and psoriasis, patients with bilateral otitis externa and patients using hearing aids were excluded from the study. Severity of pain was recorded twice, baseline pain score on the first day and follow up pain score three days after intervention by using Visual analog score 0-10.

Patients needing aural packing were randomly divided into two groups using lottery method. Group-A patients were administered 3% ciprofloxacin-1% Dexamethasone and Group-B patients were administered 10% Icthammol Glycerin. All the enrolled patients were inquired about history for pain, discharge, use of hearing aid, diabetes and nay sort of allergy. Patients were then examined for tragal tenderness and presence of discharge/debris. After necessary suction clearance topical 3%Ciprofloxacin-1%dexamethasone wick was placed in auditory canal of group-A patients and Icthammol Glycerine wick was placed in group-B. Same dose of analgesics was given to both groups of patients (mefenamic acid 500mg TDS). The baseline Pain score was determined using VAS. As per the treatment protocol Oral antibiotic (Co-Amoxiclav) was also prescribed to patients in both groups, Follow up visits was made on 3rd day after starting the treatment. On first follow up visit (3rd day) after necessary suction clearance new wicks were placed and patients were inquired about the severity of pain which was scored using VAS.

The treatment was considered efficacious if there was marked reduction in pain (pain score decreased to ≤ 4 points from baseline on Visual Analog Score (VAS) on day 3). All the demographic data recorded on the predesigned proforma and statistical analysis of data was performed using statistical software SPSS-version 22. Descriptive statistics were used to calculate mean and standard deviation for quantitative variables like age and pain scores at baseline and at day 3 after treatment. Frequencies and percentages were presented for qualitative variable like gender and efficacy. Efficacy in both groups was compared using the chi-square test and

P ≤0.05 was considered statistically significant. Mean VAS at baseline and at day 3 was also compared in both groups by applying student t-test for independent samples *P*-value ≤0.05 considered as significant.

Results

A total of sixty (n=60, 30 in each group) patients were included in the study. Baseline characteristics were similar in both groups. Age and gender distribution is presented in table 1. Mean baseline VAS was also similar in both groups with 6.67 ± 1.18SD in group A and 6.57 ± 1.16SD in group B (*P*=0.743). After three days of intervention significance difference was noted in VAS with group-A showing mean score of 2.43 ± 1.16SD and Group-B showing a mean score of 3.50 ± 2.16SD (*P*=0.028). VAS results are tabulated in table 2. Efficacy as per our operational definition (pain score decreased to ≤ 4 points from baseline VAS on day 3) was significantly better in patients treated with 3% Ciprofloxacin-1% dexamethasone (Group A). A total of 76.7% (n=23/30) patients in group A reported treatment was efficacious as compared to 43.3% (n=13/30) in group B (P=0.008). Efficacy results are tabulated in table 3.

Table1: Age and Gender distribution in both groups

	Group	
Gender	**3% cipro-1% dexa**	**10% icthammol Glycerin**
Males	21(70%)	20(66.7%)
Females	9(30%)	10(33.3%)
Total	30(100%)	30(100%)
Mean age (years±sd)	42.5±12.1	41.2±12.1

Table 2: VAS in both groups (baseline and at day 3)

VAS	Group	Mean±SD	P-Value
Baseline	3% cipro1%-dexa	6.67± 1.184	0.743
	10% icthammol-glycerin	6.57±1.165	
Day-3	3% cipro1%-dexa	2.43±1.43	0.028
	10% icthammol-glycerin	3.50±2.16	

Table 3: Efficacy of treatment in both groups

Efficacy	Group		P-value
	3% cipro-1% dexa	10% icthammol Glycerin	
Present	23976.7%)	13(43.3%)	0.008
Absent	7(23.3%)	17(56.7%)	
Total	30(100.0%)	30(100.0%)	

Discussion

Acute otitis externa (infection of external ear) is most often infectious in origin, and can be easily treated with a combination of topical antibiotic and steroid preparations.[8] There is no definite agreement upon the use of prescribed drugs.[9] Cleaning of the meatus by an ENT specialist and local application of a broad-spectrum antibiotic or an antiseptic is all what required for treating an uncomplicated infection.[10] Pain associated with acute ottitis externa is bothersome for patients. Different therapies are being used for pain control. Present study results showed that pain control was significantly better in patients treated with 3% ciprofloxacin-1% Dexamethasone as compared to patients treated with 10% Icthammol glycerin (*P*<0.743). Our results are similar with a recent study in local population. Abid et al compared the efficacy of topical Glycerol/Ichthammol wick (group A) with Neomycin/Betamethasone wick (group B) in treatment of bacterial otitis externa in terms of relief of pain. They demonstrated that pain relief was better in group A (19.8% no pain, 48.1% mild pain) as compared to Group B (15.4% no pain, 24.7% mild pain) patients on the third day of treatment (P<0.05).[5] In another recent study, Jamalullah et al compared the efficacies of 3% Ciprofloxacin - 1% Dexamethasone (group A) and 10% Icthammol glycerine (Group B) in treatment of otitis externa in terms of pain relief. They reported that on third day in group A, 76% (n=38) patients had marked, 14% (n=7) had moderate and 10% (n= 5) had mild reduction of pain. On the other hand, group B patients reported marked pain reduction in 38% (n=19) moderate reduction in 30% (n= 15) and mild pain in reduction 32% (n=16).[6] Adhikari et al compared 10% Icthammol glycerin wick with steroid antibiotic wick in treatment of otitis externa in

children. They reported that use of steroid antibiotic pack resulted in earlier relief of pain as well as significantly lesser number of visits (P<0.05).[10] Masood and colleagues studied Triadcortyl with Icthammol glycerin in treatment of otitis externa. They demonstrated that both treatment modalities were efficacious in the treatment of severe acute otitis externa and there was a statistically significant improvement of pain parameters in the Triadcortyl group.[11] The lower efficacy of Icthymol glycerin is attributed to its lower antimicrobial activity against gram negative organisms. Ahmed et al studied antimicrobial activity of Icthammol against otitis externa pathogens measured by a growth inhibition test and a modified cidal assay. They reported that inhibition of selected gram positive organisms (Streptococcus pyogenes and Staphylococcus aureus) by Icthammol and Glycerine-Icthammol combination, but only negligible antibacterial activity against Pseudomonas aeruginosa and Escherichia coli.[12] Candida albicans was also weakly inhibited. Authors suggested that due to minimal activity against gram negative organisms, incorporation of an anti-gram negative antibiotic such as Gentamicin in the Glycerine-ichthammol compound to enhance its antibacterial spectrum. Mösges et al compared the efficacy of treatment using a Ciprofloxacin 0.2% solution with other therapeutic options. The research groups consistently observed high in vitro activity of Ciprofloxacin against Pseudomonas aeruginosa, confirms the hypothesis of superior efficacy of Ciprofloxacin in the treatment of otitis externa, in terms of the cure rate and microbial eradication.[13]

In a comprehensive systematic review of literature, Rosenfeld et al compared antimicrobial versus placebo; antiseptic versus antimicrobial; quinolone antibiotic versus nonquinolone antibiotic; steroid-antimicrobial combination versus antimicrobial alone and antimicrobial-steroid combination versus steroid alone for controlling pain due to acute ottitis externa. They found that compared with placebo, antimicrobials (neomycin/methylprednisolone and acetic acid/glyceryl triacetate) were associated with a significant increase in clinical cure rate at 3 to 10 days (RD 0.46, 95% CI: 0.29, 0.63, p<0.001; 2 RCTs, n=89) and bacteriological cure rate (RD 0.61, 95% CI: 0.46, 0.76, p<0.001; 2 RCTs, n=112). They also highlighted that quinolone antibiotics (ofloxacin, ciprofloxacin with and without dexamethasone or hydrocortisone) were associated with a significant increase in bacteriological cure rate compared with nonquinolone antibiotics (gentamicin, tobramycin, polymyxin/hydrocortisone plus neomycin and oxytetracycline), (RD 0.08, 95% CI: 0.006, 0.16, p=0.035; 6 RCTs, n=980).[14] In our study we did not evaluate bacteriological cure rate yet clinical cure rate was significantly better with3% ciprofloxacin-1% Dexamethasone.

Kaushik V, et al in another systematic review assessed the effectiveness of different interventions for acute otitis externa. Nineteen randomized controlled trials with a total of 3382 participants were included. Authors summarized that topical treatments alone, as distinct from systemic ones, are effective for uncomplicated acute otitis externa. In most cases the choice of topical intervention does not appear to influence the therapeutic outcome significantly. Given that most topical treatments are equally effective, it would appear that in most cases the preferred choice of topical treatment may be determined by other factors, such as risk of ototoxicity, risk of contact sensitivity, risk of developing resistance, availability, cost and dosing schedule. Patients who are prescribed with antibiotic/ steroid drops can expect their symptoms to last for approximately six days after treatment has begun. Patients with persisting symptoms beyond two weeks should be considered treatment failures and alternative management should be initiated.[15]

In summary, based on present study results and on the relevant literature review the evidence is convincing that steroid-antibiotic wick is better in pain control associated with acute ottitis externa when compared to antiseptic wick alone. Outcomes of the study serve as an understanding of two different treatment options for the management of pain associated with acute otitis externa in our population. We recommend further randomized controlled trials with larger sample size to extend the validity of results to the general population.

Conclusion

Treatment with 3% ciprofloxacin-1% Dexamethasone was found to be significantly better than 10% Icthammol glycerin in patients with acute otitis externa in terms of associated pain control. Outcomes of the study do serve as an understanding of two different treatment options for

the management of pain associated with acute otitis externa. We recommend further randomized controlled trials with larger sample size to extend the validity of results to general population.

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