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Orginal Article

COMPARISON OF EFFICACY OF TOPICAL CIPROFLOXACIN/DEXAMETHASONE WICK WITH ICHTHAMMOL/GLYCERIN WICK IN OTITIS EXTERNA

Asghar Ullah[1], Israr Ud Din[2], Imran Khan[2], Nazneen Liaqat[2], Aafia Afridi[3], Ihtisham ul Haq[2], Shakir Ullah[2]

[1]Department of ENT, Head & Neck Surgery, Pak International Medical College, Peshawar, Pakistan
[2]Department of ENT, Head & Neck Surgery, Khyber Teaching Hospital, Peshawar, Pakistan
[3]Badar Hospital, Peshawar, Pakistan

ABSTRACT

Objectives: *To compare efficacy of 3% Ciprofloxacin/1% Dexamethasone and 10% Ichthammol Glycerin as topical treatment regimen of acute otitis externa.*

Materials and Methods: *This study was a Randomized Control Trial conducted over a six-month period, from May 2022 to November 2022, at the Department of Otorhinolaryngology - Head and Neck Surgery, Khyber Teaching Hospital, Peshawar, Pakistan. A total of seventy patients, both male and female, aged between 12 and 60 years, who were diagnosed with moderate to severe acute otitis externa, were enrolled in the study. These patients were randomly assigned to one of two treatment groups: Group A, which received 3% ciprofloxacin and 1% dexamethasone, or Group B, which received 10% Ichthammol Glycerin. The efficacy of the treatments was evaluated on day 3 by assessing pain control, using the Visual Analogue Scale (VAS).*

Results: *Each group contained 35 subjects each. Regarding baseline characteristics, both the groups were similar. The mean VAS score on day 1 was comparable among the 2 groups, i.e., 6.71± 1.15 in group A, and 6.73 ± 1.13 in group B. At day 3, mean VAS was lower in group A, i.e., 2.43 ± 1.36 SD in group A and 3.63 ± 2.04 SD in group B. The efficacy of treatment was found to be 77.1% (27/35) in group A and 40% (14/35) in group B (p=0.002).*

Conclusion: *The efficacy of Ciprofloxacin/Dexamethasone was significantly higher than Ichthammol Glycerin in terms of pain control in patients with moderate to severe acute otitis externa.*

Key words: *Ciprofloxacin, Ichthammol Glycerin, Otitis externa*

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INTRODUCTION

Otitis externa, also known as inflammation or infection of the external auditory canal, is a common condition that can affect all ages[1]. It has an annual incidence of 1% and a lifetime prevalence of 10%[2]. Various predisposing factors contribute to the development of otitis externa, including local trauma, maceration, anatomical abnormalities, dermatitides, all of which render the external auditory canal's skin susceptible to infections[2]. Although microbial infections especially Pseudomonas aeruginosa and Staphylococcus aureus are the primary cause, fungal and viral infections can also be responsible, albeit rarely[3]. Otitis externa is typically characterized by minor discomfort and itching, accompanied by minimal swelling of the external auditory canal.

Correspondence:
Dr. Israr Ud Din
Chairman
Department of ENT, Head & Neck Surgery, Khyber Teaching Hospital, Peshawar, Pakistan
Email: israr_uddin2000@gmail.com

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Severe otitis externa manifests as intense pain, often accompanied by complete occlusion of the canal due to significant swelling, fever, periauricular erythema, and regional lymphadenopathy[4].

Management generally depends upon the severity of disease. Mild cases are usually treated with an acidifying agent with glucocorticoid, as topical antibiotics have a limited role. In moderate cases of otitis externa, treatment typically involves the use of a topical preparation with an acidic pH. It is preferable for this preparation to contain an antibiotic, an antiseptic, and a glucocorticoid. In instances of severe otitis externa, a comprehensive management approach is necessary. This typically includes topical therapy combined with the placement of a wick to facilitate the delivery of medication deeper into the ear canal. In case of deep tissue infection, oral antibiotics may be added to topical treatment[4,5].

An absence of standardized treatment protocols for acute otitis externa have led to a number of different drugs being prescribed in the treatment of acute otitis externa. However, none of these have been identified as the drug of choice. Previous studies have explored both 3% ciprofloxacin-1% dexamethasone and 10% ichthammol-glycerin wicks for otitis externa, demonstrating each treatment's unique advantages: ciprofloxacin-dexamethasone for its potent antibacterial and anti-inflammatory effects, and ichthammol-glycerin for its antiseptic and hygroscopic properties[6,7]. However, there remains limited comparative research assessing their effectiveness in real-world settings, especially within our specific clinical environment where patient demographics and resource availability may influence treatment outcomes. Addressing this gap, this current study aimed to evaluate and compare the efficacy of these two widely used treatments among our local population.

MATERIALS AND METHODS

AThis randomized single-blind prospective control trial was conducted after approval by the institutional ethics committee with an informed written consent obtained from each of the enrolled patients. A total of 70 patients diagnosed with moderate to severe degrees of acute otitis externa were included into the study through non-probability consecutive sampling, from the outpatient clinic of the Department of Otorhinolaryngology - Head and Neck Surgery, Khyber Teaching Hospital, Peshawar, Pakistan. This study spanned over a duration of 6 months from May 2022 till November 2022. Patients falling within ages 12 to 60 years from both genders were included. Patients with otitis externa of both ears, active or previous use of hearing aids, presence of allergic conditions such as eczema and psoriasis, history of acute/chronic otitis media, history of immunosuppression, presence of diabetes mellitus or poor follow-up compliance were excluded from the study.

The sample size for this study was calculated by WHO sample size calculator (2.2b) using the model for hypothesis testing for two population proportions (two-sided). A sample size of n=70 (35+35) was calculated assuming power of 90%, $\alpha = 5\%$ and anticipated proportions of population 1 taken as efficacy of steroid-antibiotic treatment regimen equaled 76% and population 2 i.e. efficacy of ichthammol glycerin was taken as 38%[6].

Prior to initiating any management, patients would undergo an initial examination to assess for tenderness of tragus and the presence of debris/discharge in the ear canal. Upon clearance of the external auditory canal from discharge or debris, the treatment would be administered to the patients in the form of aural packing soaked in the intended drug and renewed after every 24 hours till day 3. The patients from our study pool were randomly allocated into two groups. A simple randomization method was applied using computer generated random numbers. Patients were either allocated to group A and would take a combination of topical 3% ciprofloxacin – 1% dexamethasone or to group B where they would be given topical 10% Ichthammol glycerin. As per protocol, all patients were provided similar analgesia with mefenamic acid 500 mg TDS and weight-based antibiotic coverage through co-amoxiclav. The primary outcome variable for this study was the severity of pain as measured through the Visual Analogue Scale (VAS) and would be scored 0 through 10 with 0 indicating 'no pain' and 10 indicating 'most severe pain'. The baseline level of pain would be measured on day 0 when treatment was initiated and on day 3. During pain assessment, the assessor was kept strictly blind regarding the treatment group.

The data collected from the study pool was analyzed using SPSS® version 22. Means and

standard deviations were calculated for continuous parametric variables such as age and pain scores. Statistics related to categorical variables such as gender and drug efficacy were presented as frequencies and percentages. Efficacy of the drugs against pain were compared using chi-square test with $p < .05$ was considered as statistically significant. Effect modifiers like age and gender were stratified and post stratification chi-square test was applied.

RESULT

A total of seventy (n=70) patients of any gender or ethnicity, with age between 12 to 60 years, who were diagnosed as unilateral moderate to severe acute otitis externa were included. The study pool comprised of 68.57% (n = 48) male patients and 31.43% (n = 22) female patients [Table 3]. Equal number of patients (n = 35) were present in the early (12 - 40 years) and elderly (41 - 60 years) age groups [Table 5] with a mean age of 40.4±12.5SD years in group A and 39.6±11.4 years in group B.

At day 3 since the commencement of treatment, mean VAS score was 2.43 ± 1.36 SD in group A and it was 3.63 days ± 2.04 SD in group B. Clinical response in a patient can be judged using VAS scores, depicting the change in the pain experienced by the subjects. A significantly lower VAS score in group A showed the advantage of antibiotic-steroid treatment in a real-world setting as compared to ichthammol glycerin regimen in terms of patient satisfaction.The efficacy of treatment was found to be 77.1% (27/35) in group A and 40% (n=14/35) in group B. This indicated a statistically significant higher efficacy in group A as compared to group B (p = 0.002, Table 8).

Similar trends (better efficacy in group A compared to group B) were noted when the data was stratified for gender (table 9) and age (table 10). P value was <0.05 in all cases. None of the patients in any group experienced any allergic reaction or side effects during the treatment.

DISCUSSION

Acute otitis externa refers to the sudden onset of infections in the external ear canal. These infections can be effectively treated using a combination of antibiotic and steroid preparations topically. [5] The treatment of acute otitis externa remains a topic of ongoing debate and lacks consensus among healthcare professionals[6]. For the management of uncomplicated infections, a widely practiced approach involves the cleaning of the meatus followed by the topical antibiotic or antiseptic[7]. In the current study, the authors aimed to assess the effectiveness of two different treatments, namely 3% ciprofloxacin - 1% Dexamethasone and 10% Ichthammol Glycerin, in reducing pain caused by moderate to severe acute otitis externa.

Present study results showed that both the groups were similar regarding baseline characteristics. The mean VAS score on day 1 was comparable among the 2 groups, i.e., 6.71± 1.15 in group A, and 6.73 ± 1.13 in group B. At day 3, mean VAS was lower in group A, i.e., 2.43 ± 1.36 SD in group A and 3.63 ± 2.04 SD in group B. The efficacy of treatment was

Table 3: Gender Distribution among groups

Gender	Group	
	3% Ciprofloxacin – 1% Dexamethasone n(%)	10% Ichthammol Glycerin n(%)
Males	26 (74.3)	22 (62.9)
Females	9 (25.7)	13 (37.1)
Total	35 (100)	35 (100)

Table 4: Age distribution among groups

Group	Gender	Age (Mean ± SD)
3% Ciprofloxacin – 1% Dexamethasone	Males	40.4 ± 13.1
	Females	40.2 ± 11.5
	Total	40.4 ± 12.5
10% Ichthammol Glycerin	Males	40.4 ± 11.2
	Females	38.4 ± 12.1
	Total	39.6 ± 11.4

Table 5: Different age groups among study sample

Age groups	Group		Total n(%)
	3% Ciprofloxacin – 1% Dexamethasone n(%)	10% Ichthammol Glycerin n(%)	
12 – 40 years	18 (51.4)	17 (48.6)	35 (50)
41 – 60 years	17 (48.6)	18 (51.4)	35 (50)
Total	35 (100)	35 (100)	70 (100)

Table 6: VAS scores in both groups (Baseline and Day 3)

Group	VAS Score (Mean ± SD)	
	Baseline	Day 3
3% Ciprofloxacin – 1% Dexamethasone	6.71 ± 1.15	2.43 ± 1.36
10% Ichthammol Glycerin	6.73 ± 1.13	3.63 ± 2.04

found to be 77.1% (27/35) in group A and it was 40% (n=14/35) in group B (P=0.002). Our study found that patients who were treated with 3% ciprofloxacin-1% Dexamethasone experienced significantly better pain control than those treated with 10% Ichthammol glycerin. (P=0.002).

In another study by Mustafa et al, found that ciprofloxacin/Dexamethasone was significantly more effective in reducing pain as compared to 10% Ichthammol glycerin[7]. In a study conducted by Gurov et al, it was reported that oral administration of Ciprofloxacin for 7 to 10 days in patients with otitis externa was both clinically and microbiologically effective[9]. Clinical response in a patient can be judged using VAS scores, depicting the change in the pain experienced by the subjects. A significantly lower VAS score in group A showed the advantage of antibiotic-steroid treatment in a real-world setting as compared to ichthammol glycerin regimen in terms of patient satisfaction.

In a local study by Jamalullah et al, it was found that the Ciprofloxacin-Dexamethasone group had a higher percentage of patients experiencing marked pain reduction (76%) compared to the Ichthammol Glycerin group (38%)[10]. In a study by Adhikari et al, it was shown that the steroid/antibiotic pack provided earlier relief of pain and reduced the number of consultations required for treatment compared to the Ichthammol glycerin wick[6]. The study by Masood et al showed that Triadcortyl and Ichthammol glycerin, both were effective, but the Triadcortyl group provided statistically significant improvement in pain parameters[8]. In another study, the Ichthammol's antimicrobial potential against pathogens of otitis externa was investigated using a modified cidal assay and a growth inhibition test. The study reported that Ichthammol and the Glycerin-Ichthammol combination showed inhibition of selected gram-positive organisms such as Streptococcus pyogenes and Staphylococcus aureus[11]. It was suggested that addition of an anti-gram-negative antibiotic like Gentamicin in the Glycerin-ichthammol can enhance its antibacterial spectrum. Mösges et al compared the efficacy of Ciprofloxacin 0.2% solution to other treatments for otitis externa, and found high in vitro activity of Ciprofloxacin against Pseudomonas aeruginosa, suggesting that Ciprofloxacin may have

Table 7: Efficacy of both the treatments

Efficacy	Group		Total n(%)	p -value
	3% Ciprofloxacin – 1% Dexamethasone n(%)	10% Ichthammol Glycerin n(%)		
Present	27 (77.1)	14 (40.0)	41 (58.6)	0.002
Absent	8 (22.9)	21 (60.0)	29 (41.4)	
Total	35 (100)	35 (100)	70 (100)	

Table 8: Efficacy of treatment in both groups (gender-based stratification)

Gender	Efficacy	Group		Total n(%)	p - value
		3% Ciprofloxacin – 1% Dexamethasone n(%)	10% Ichthammol Glycerin n(%)		
Males	Present	18 (69.2)	8 (36.4)	26 (54.2)	0.023
	Absent	8 (30.8)	14 (63.6)	22 (45.8)	
Females	Present	9 (100)	6 (46.2)	15 (68.2)	0.008
	Absent	0 (0)	7 (53.8)	7 (53.8)	

Table 9: Efficacy of treatment in both groups (age-based stratification)

Age	Efficacy	Group		Total n(%)	p - value
		3% Ciprofloxacin – 1% Dexamethasone n(%)	10% Ichthammol Glycerin n(%)		
12 – 40 years	Present	13 (72.2)	6 (35.3)	19 (54.3)	0.028
	Absent	5 (27.8)	11 (64.7)	16 (45.7)	
41 – 60 years	Present	14 (82.4)	8 (44.4)	22 (62.9)	0.020
	Absent	3 (17.6)	10 (55.6)	13 (37.1)	

superior efficacy regarding cure as well as microbial eradication in the treatment of otitis externa[12]. The superior efficacy of ciprofloxacin-dexamethasone treatment can be attributed to its potent antibacterial and anti-inflammatory effects, respectively.

In a systematic review conducted by Rosenfeld et al, various treatment options were compared for controlling pain associated with acute otitis externa. The findings showed that antimicrobials such as neomycin/methylprednisolone had significantly higher clinical cure rate at 3 to 10 days and bacteriological cure rate[13]. In a systematic review conducted by Kaushik V et al concluded that topical treatments alone are quiet effective for uncomplicated acute otitis externa. Patients prescribed with antibiotic/steroid drops can expect symptom relief within approximately six days of starting treatment. If symptoms persist beyond two weeks, alternative management should be considered as a treatment failure[14].

Despite its randomized controlled design and clinical setting, this study is limited in its scope by a smaller sample size and single-blinded design.

CONCLUSION

The study findings indicate that the efficacy of 3% ciprofloxacin - 1% dexamethasone was significantly superior to 10% ichthammol glycerin in terms of pain control in patients with moderate to severe acute otitis externa. However, further randomized controlled trials with larger sample sizes are needed to validate these results and extend their applicability to the general population.

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CONFLICT OF INTEREST
Authors declare no conflict of interest.
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AUTHORS' CONTRIBUTION

The following authors have made substantial contributions to the manuscript as under:

Conception or Design:	AU, IUD, IK, NL, AA, IUH, SU
Acquisition, Analysis or Interpretation of Data:	AU, IUD, IK, NL, AA, IUH, SU
Manuscript Writing & Approval:	AU, IUD, IK, NL, AA, IUH, SU

All the 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.