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A Study on the Efficacy of Ciprofloxacin Ear Drops Versus Ciprofloxacin with Dexamethasone Ear Drops in Patients with Otitis Externa at a Tertiary Care Hospital

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Abstract: Otitis externa is an inflammatory process in the external auditory canal, mostly due to bacterial infections, and involves signs like pain, discharge, tenderness, and swelling. This study intended to determine the comparative effectiveness of ciprofloxacin alone in relation to the combination of ciprofloxacin and dexamethasone in managing otitis externa. The study involved a prospective observation for six months at the ENT outpatient department of a tertiary care hospital in Tamil Nadu. Fifty patients with otitis externa were selected and randomly assigned to two groups, which included the use of ciprofloxacin alone or in combination with dexamethasone. Clinical results were measured through the Visual Analogue Scale (VAS) on Days 1, 7, and 14. Improvement in all symptoms was noted in both study groups over time. Nevertheless, a better effect was seen in combination therapy, especially in terms of reduction in pain, tenderness, swelling, and discharge after 14 days. Analysis of the data collected suggests that while initial effects were similar, the use of dexamethasone had a more beneficial effect after day seven. In Conclusion it can be said that ciprofloxacin in combination with dexamethasone works more effectively against otitis externa compared to ciprofloxacin alone because of its faster action. The addition of a steroid makes the therapy more effective due to a decrease in inflammation.

Keywords: *Otitis Externa, Ciprofloxacin, Dexamethasone, Treatment Efficacy, Visual Analogue Scale.*

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I. INTRODUCTION

Otitis externa, commonly referred to as “Swimmer’s ear”, is an inflammation of the external auditory canal, auricle, or both and is usually caused by bacterial, fungal or mixed infections. It is one of the most common otic conditions seen by general practitioners and ENT specialists [1]. It affects around 10% of the population during their lifetime. Its predisposing factors include swimming or water exposure, use of hearing aids, compulsive scratching, and foreign body reaction [2]. Both Gram-positive and Gram-negative bacteria are found in the patients [3].

The signs and symptoms of Otitis Externa include otalgia, pruritus, erythema, swelling, discharge-clear or purulent, and at times temporary hearing loss may occur, especially when the canal is occluded. Diagnosis is based on clinical signs and symptoms that include pain, itching due to inflamed tissue, clinical examination, including inspection of the ear canal for redness, swelling, discharge or debris, culture samples may be taken to identify bacterial or fungal pathogens, and imaging is rarely necessary.

Management of Otitis Externa: Topical antibiotics are the most common therapy prescribed for Otitis Externa. Topical application delivers the antibiotic directly to the infected area, reduces the risk of adverse events associated with systemic antibiotic therapy [1]. Topical antibacterial agents used are, Aminoglycosides- Neomycin, Gentamicin, Tobramycin. Polypeptides- Polymyxin B, Colistin. Fluoroquinolones- Ciprofloxacin, Ofloxacin [3]. The topical fluoroquinolone preparations are generally effective against both P. aeruginosa and S. aureus and have few side effects associated with them, so they represent a good first-line option for acute otitis externa [1]. Corticosteroid may be prescribed in severe cases. The topical preparations containing corticosteroid in combination with an antibiotic fasten the recovery of the patients.

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The study aims to compare the efficacy of the ear drops containing antibiotic alone, Ciprofloxacin, against ear drops containing antibiotic with corticosteroid, namely Ciprofloxacin with Dexamethasone, in relieving signs and symptoms in patients with Otitis Externa. Equally important, the study will be able to understand how Dexamethasone may contribute to the therapy outcomes for Otitis Externa.

II. MATERIALS AND METHODS

➢ *Study Site*

This study was done at one center. It took place in the ENT outpatient Department at Government Cuddalore Medical College and Hospital (GCMCH) located in Annamalai Nagar, Chidambaram, Tamil Nadu, with the postal code 608002.

➢ *Study Design*

A comparative, Prospective Observational study.

➢ *Study Period*

The study was conducted for a period of 6 months from November 2024 to April 2025.

➢ *Sample Size*

Since it was a preliminary research, sample size calculation was not done. Number of participants were decided based on the patient's availability and those who met the inclusion and exclusion criteria.

➢ *Study Recruitment*

Target population: Clinically diagnosed Otitis Externa patients attending the ENT department, at Government Cuddalore Medical College and Hospital, a Tertiary care teaching Hospital in Chidambaram.

Study population: The patients recruited for the study were selected on the basis of inclusion and exclusion criteria.

➢ *Inclusion Criteria*

- Patients aged over 18 years of both sexes, diagnosed with Otitis Externa.
- Patients with Otitis externa, who are willing to give informed consent for present study.

➢ *Exclusion Criteria*

- Patients with diseases of middle ear like, Chronic Otitis media are excluded
- Patients currently being treated for Otitis externa with either antibiotics or Corticosteroids are excluded
- Pregnant and lactating women are excluded.

➢ *Data Collection*

The data was collected in a predesigned data collection form containing Visual Analogue Scale (VAS). The data gathered were recorded using Microsoft Excel and statistical analysis was carried out using the JASP (Jeffreys's Amazing Statistics Program) software.

III. RESULTS AND DISCUSSION

❖ *Descriptive Statistics*

➢ *Gender-Wise Distribution*

In this study, 50 patients were enrolled, of which 30 (60%) were males and 20 (40%) were females, as shown in Table 1. The higher incidence in males might be because males are much more exposed to outdoor activities, swimming, and occupational factors that increase the possibility of acquiring an ear canal infection. This agrees with the findings by Haider et al., in 2022, and Adegbiji et al., in 2017, who found a higher incidence of OE among males.

Table 1 Gender-Wise Distribution of Otitis Externa Patients

Gender	Number of Patients	Percentage
Male	30	60%
Female	20	40%

➢ *Age Group Distribution*

The occurrence of OE across various age groups is shown in Table 2.

Table 2 Age Group Distribution of Otitis Externa Patients

Age Group (Years)	Number of Patients	Percentage
18-25	17	34%
26-35	6	12%
36-45	12	24%
46-55	8	16%
56-65	4	8%
66-75	3	6%

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The incidence was most frequent in the 18–25 years group, comprising 34%, followed by 36–45 years, 24%, and declined with age, with the lowest in the 66–75 years group, comprising 6%, indicating higher prevalence among younger and middle-aged individuals. This is usually because of increased outdoor activities and the use of ear devices like ear buds, headphones, all of which are risk factors of OE. Likewise, a higher incidence of OE is found in the 21-30-year age group in the study conducted by Haider et al., in 2022.

➢ *Ear Affected in Otitis Externa – Distribution*

The distribution of patients based on whether the right ear or left ear was affected is shown in Table 3.

Table 3 Ear Affected in OE - Distribution

Ear affected	Number of Patients	Percentage
Right ear	26	52%
Left ear	23	46%
Both ears	1	2%

The issue was limited to one ear and only 2% of patients experienced it in both ears.

➢ *Distribution of Signs and Symptoms*

The distribution of pain, discharge, tenderness and edema observed in the 50 patients is shown in Table 4.

Table 4 Distribution of Signs and Symptoms

Parameters	Number of Patients	Percentage
Pain	49	98%
Discharge	31	62%
Tenderness	47	94%
Edema	44	88%

In this study, we found that pain (98%) and tenderness (94%) were the most frequently reported symptoms, followed closely by edema (88%) and discharge (62%). This aligns with the classic presentation, where pain and tenderness in the canal are the key indicators, while discharge tends to be observed less consistently.

- *Inferential Statistics*

The fifty patients were allocated to two different treatment groups (either Ciprofloxacin ear drop or Ciprofloxacin with Dexamethasone ear drop) by simple randomization. The data on the severity of signs and symptoms (pain, discharge, tenderness, edema) were collected from the patients at Day1, Day7, Day14 using Visual Analogue Scale (VAS). The results were tabulated accordingly and data was analyzed based on the objectives framed, using Jeffery's Amazing Statistics Program (JASP) software. A p-value of <0.05 is considered as statistically significant.

- *Comparison within the Groups*

Friedman test and Post Hoc tests (Pbonf - Bonferroni adjusted p-value) were used to evaluate the statistical significance within the group (between Day1, Day7, Day14).

- *Comparison within the Ciprofloxacin Ear Drop Group*

✓ *Pain*

The Friedman test with a post hoc comparison was done to assess the difference of pain scores in three different time frames, i.e., Day 1, Day 7, and Day 14 is shown in Table 5.

Table 5 Friedman Test and Post-Hoc Comparison for Comparison of Pain Across Day 1, Day 7 and Day 14

Friedman χ^2 (df)	p-Value	Kendall's W
46.645(2)	<0.001	0.933
Post-hoc comparison	**T-stat**	**Pbonf**
Day1 vs Day7	14.415	<0.01
Day1 vs Day14	25.794	<0.01
Day7 vs Day14	11.649	<0.01

$\chi^2(2) = 46.645$, $p < 0.001$, indicates significant changes in pain levels over time. Kendall's W = 0.933, suggests a very strong agreement and large effect size. From the post-hoc comparison it is seen that the pain significantly decreased over time with substantial reductions observed from Day 1 to Day 7 and further to Day 14.

✓ *Discharge*

The Friedman test and post hoc comparison for discharge across the three visits is shown in Table 6.

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Table 6 Friedman Test and Post-Hoc Comparison for Comparison of Discharge Across Day 1, Day 7 and Day 14

Friedman χ^2 (df)	**p-Value**	**Kendall's W**
21.526(2)	<0.01	0.431
Post-hoc comparison	**T-stat**	**Pbonf**
Day1 vs Day7	4.617	<0.01
Day1 vs Day14	5.659	<0.01
Day7 vs Day14	1.043	0.302

$\chi^2(2) = 21.526$, $p < 0.01$; thus there has been a statistically significant change in discharge over time. Kendall's W = 0.431, indicating a moderate effect size. The post-hoc test showed that the discharge was significantly reduced from Day 1 to both Day 7 and Day 14, but there was no significant difference between Day 7 and Day 14, which shows that most of the improvement occurred within the first week.

✓ *Tenderness*

The Friedman test and post hoc comparison for tenderness across the three visits is shown in Table 7.

Table 7 Friedman Test and Post-Hoc Comparison for Comparison of Tenderness Across Day 1, Day 7 and Day 14

Friedman χ^2 (df)	**p-Value**	**Kendall's W**
34.597(2)	<0.01	0.692
Post-hoc comparison	**T-stat**	**Pbonf**
Day1 vs Day7	6.710	<0.01
Day1 vs Day14	10.217	<0.01
Day7 vs Day14	3.507	0.003

$\chi^2(2) = 34.597$, $p < 0.01$; this indicates that there is a statistically significant change in tenderness over time. Kendall's W = 0.692, indicating a strong effect size. In the post-hoc test, it was shown that, over time, tenderness decreased significantly, with clinically relevant changes from Day 1 to Day 7 and further to Day 14.

✓ *Edema*

The Friedman test and post hoc comparison for edema across the three visits is shown in Table 8.

Table 8 Friedman Test and Post-Hoc Comparison for Comparison of Edema Across Day 1, Day 7 and Day 14

Friedman χ^2 (df)	**p-Value**	**Kendall's W**
30.400(2)	<0.01	0.608
Post-hoc comparison	**T-stat**	**Pbonf**
Day1 vs Day7	5.413	<0.01
Day1 vs Day14	8.571	<0.01
Day7 vs Day14	3.429	<0.01

$\chi^2(2) = 30.400$, $p < 0.01$ indicates a statistically significant difference in edema scores over time. Kendall's W = 0.608 suggests a moderate to strong effect size, indicating consistent changes across the time points. The post-hoc test showed that the there was a significant and progressive reduction in the edema from Day 1 to Day 14, thus indicating effective treatment or resolution over time.

- *Comparison within the Ciprofloxacin with Dexamethasone Ear Drop Group*

✓ *Pain*

The Friedman test and post hoc comparison for pain across the three visits is shown in Table 9.

Table 9 Friedman Test and Post-Hoc Comparison for Comparison of Pain Across Day 1, Day 7 and Day 14

Friedman χ^2 (df)	**p-Value**	**Kendall's W**
48.639(2)	<0.01	0.973
Post-hoc comparison	**T-stat**	**Pbonf**
Day1 vs Day7	22.599	<0.01
Day1 vs Day14	41.361	<0.01
Day7 vs Day14	18.762	<0.01

$\chi^2(2) = 48.639$, $p < 0.01$ indicating that there was a statistically significant change in pain across time. Kendall's W = 0.973, indicating a very strong effect size. The post-hoc test showed that pain significantly decreased over time, especially from Day 1 to Day 7 and further to Day 14.

✓ *Discharge*

The Friedman test and post hoc comparison of discharge across the three visits is shown in Table 10.

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Table 10 Friedman Test and Post-Hoc Comparison for Comparison of Discharge Across Day 1, Day 7 and Day 14

Friedman χ^2 (df)	**p-Value**	**Kendall's W**
33.797(2)	<0.01	0.676
Post-hoc comparison	**T-stat**	**Pbonf**
Day1 vs Day7	7.764	<0.01
Day1 vs Day14	9.348	<0.01
Day7 vs Day14	1.584	<0.01

$\chi^2(2) = 33.797$, $p < 0.01$ indicates a statistically significant change in discharge over time. Kendall's W = 0.676, suggests a strong effect size. The post-hoc test revealed that the discharge was significantly reduced from Day 1 to Day 7 and further to Day 14. The reduction between Day 7 and Day 14 was not statistically significant.

✓ *Tenderness*

The Friedman test and post hoc comparison for tenderness across the three visits is shown in Table 11.

Table 11 Friedman Test and Post-Hoc Comparison for Comparison of Tenderness Across Day 1, Day 7 and Day 14

Friedman χ^2 (df)	**p-Value**	**Kendall's W**
42.8837(2)	<0.01	0.858
Post-hoc comparison	**T-stat**	**Pbonf**
Day1 vs Day7	12.766	<0.01
Day1 vs Day14	16.114	<0.01
Day7 vs Day14	3.348	0.005

$\chi^2(2) = 42.883$, $p < 0.01$ suggests that the change in tenderness across time is statistically significant. Kendall's W = 0.858, indicating a very strong effect size. The post-hoc test showed that there was a significant decrease in tenderness over time, as it constantly decreased from Day 1 to Day 7 and even further improved on Day 14.

✓ *Edema*

The Friedman test and post hoc comparison for edema at the three visits is shown in Table 12.

Table 12 Friedman Test and Post-Hoc Comparison for Comparison of Edema Across Day 1, Day 7 and Day 14

Friedman χ^2 (df)	**p-Value**	**Kendall's W**
43.280(2)	<0.01	0.866
Post-hoc comparison	**T-stat**	**Pbonf**
Day1 vs Day7	13.748	<0.01
Day1 vs Day14	16.366	<0.01
Day7 vs Day14	2.619	0.012

$\chi^2(2) = 43.280$, $p < 0.01$ which indicates a statistically significant change in edema over time. Kendall's W = 0.866, indicating a very strong effect size. The post-hoc test revealed that the edema significantly decreased over time, with the most significant improvements between Day 1 and Day 7 and further reduction at Day 14.

- *Comparison between Groups (Ciprofloxacin Ear Drops vs Ciprofloxacin with Dexamethasone Ear Drops)*

The Mann - Whitney U test was employed to assess statistical differences between the two treatment groups as shown in Table 13.

Table 13 Comparative Analysis of the Effectiveness of Ciprofloxacin Ear Drops and Ciprofloxacin with Dexamethasone Ear Drops in the Reduction of Symptoms (Pain, Discharge, Tenderness, Edema) at Day 1, Day 7, Day 14.

Parameters	**Median (C)**	**Median (CD)**	**Mann-Whitney U Statistics**	**p-Value**	**Interpretation**
D1 pain	6.0	6.02	270.0	0.408	NS
D7 pain	3.0	2.0	402.0	0.080	NS
D14 pain	2.0	0.0	521.5	<0.01	S
D1 discharge	1.0	2.0	241.0	0.149	NS
D7 discharge	0.0	0.0	360.5	0.267	NS
D14 discharge	0.0	0.0	389.5	0.033	S
D1 tenderness	2.0	2.0	282.5	0.545	NS
D7 tenderness	1.0	0.0	457.5	0.002	S
D14 tenderness	1.0	0.0	454.5	<0.001	S
D1 edema	2.0	2.0	261.5	0.295	NS
D7 edema	1.0	0.0	478.5	<0.001	S
D14 edema	1.0	0.0	452.0	<0.001	S

Note: C = Ciprofloxacin; CD = Ciprofloxacin + Dexamethasone; S =Significant; NS = non-significant.

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Pain: There was no statistically significant difference between the two groups on both Day 1 and Day 7. By Day 14, there was a significant reduction in pain, with $p < 0.001$ in the combination group, indicating that the addition of Dexamethasone enhances pain relief over time. Median: Ciprofloxacin = 2.0, Ciprofloxacin with Dexamethasone = 0.0

Discharge: There was no significant statistical difference between the groups on Day 1 and Day 7. However, by Day 14, there was a significant reduction in discharge ($p = 0.033$) with the combination, showing that Dexamethasone resulted in better management of discharge. Median of Ciprofloxacin = 0.0, Median of Ciprofloxacin with Dexamethasone = 0.0

Tenderness: At Day 7, $p=0.002$ and Day 14, $p<0.001$, the combination therapy demonstrated significant and increasing reduction in tenderness, which was better than with Ciprofloxacin alone. Day7- Median: Ciprofloxacin = 1.0, Ciprofloxacin with Dexamethasone = 0.0. Day 14- Median (Ciprofloxacin) =1.0, Median (Ciprofloxacin with Dexamethasone) = 0.0

Edema: On Day 1, no statistically significant difference between the two groups was found ($p = 0.295$). From Day 7 onwards, however, a strongly significant reduction of edema ($p < 0.001$) was found in favor of the Dexamethasone combination.

There was a mild, statistically significant symptom-reducing advantage, resulting from the steroid combination that increased between Day 1 and Day 7, continuing to the final visit of Day 14. Results are statistically significant, especially from Day 7 onwards, proving a point that an anti-inflammatory agent like Dexamethasone definitely has a role in otic preparations for quicker and more complete resolution of symptoms.

In the study conducted by Mōsges et.al, though there was no significant change observed, there was a slight advantage in terms of symptom reduction by the final visit in the topical treatment that had steroid combination. In the study conducted by E. Abelardo et.al, steroid alone, namely Betamethasone, was compared with a combination of steroid and antibiotic, namely Betamethasone-Neomycin; there was observed a statistically significant reduction in symptoms in the group receiving the combination therapy. This suggests that a combination of an antibiotic with a steroid is superior to either antibiotic alone or steroid alone therapy in the treatment of Otitis Externa.

IV. CONCLUSION

The addition of Dexamethasone improved the efficacy of Ciprofloxacin ear drops in the resolution of signs and symptoms of Otitis Externa. A consistent reduction in pain over time is seen in both the treatment groups. However, patients receiving the combination treatment showed significant reduction in the pain severity as measured by the Visual Analogue Scale. These findings support the fact that Dexamethasone may enhance the therapeutic results when added to Ciprofloxacin in otitis externa management.

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REFERENCES

[1]. Drehobl, M., Guerrero, J. L., Lacarte, P. R., Goldstein, G., Mata, F. S., & Luber, S. (2008). Comparison of efficacy and safety of ciprofloxacin otic solution 0.2% versus polymyxin B-neomycin-hydrocortisone in the treatment of acute diffuse otitis externa. *Current medical research and opinion* , 24 (12), 3531-3542.

[2]. Abelardo, E., Pope, L., Rajkumar, K., Greenwood, R., & Nunez, D. A. (2009). A double-blind randomised clinical trial of the treatment of otitis externa using topical steroid alone versus topical steroid–antibiotic therapy. *European Archives of Oto-Rhino-Laryngology*, 266(1), 41-45.

[3]. Roland, P. S., Pien, F. D., Schultz, C. C., Henry, D. C., Conroy, P. J., Wall, G. M., ... & Stroman, D. W. (2004). Efficacy and safety of topical ciprofloxacin/dexamethasone versus neomycin/polymyxin B/hydrocortisone for otitis externa. *Current medical research and opinion*, 20(8), 1175-1183.

[4]. Mösges, R., Domröse, C. M., & Löffler, J. (2007). Topical treatment of acute otitis externa: clinical comparison of an antibiotics ointment alone or in combination with hydrocortisone acetate. *European archives of oto-rhino-laryngology*, 264(9), 1087-1094

[5]. Arms, E., & Dibb, W. L. (1993). Otitis externa: clinical comparison of local ciprofloxacin versus local oxytetracycline, polymyxin B, hydrocortisone combination treatment. *Current medical research and opinion* , 13 (3), 182-186.

[6]. Rahman, A., Rizwan, S., Waycaster, C., & Wall, G. M. (2007). Pooled analysis of two clinical trials comparing the clinical outcomes of topical ciprofloxacin/dexamethasone otic suspension and polymyxin B/neomycin/hydrocortisone otic suspension for the treatment of acute otitis externa in adults and children. *Clinical therapeutics*, 29(9), 1950-1956.

[7]. Haider, K. K., Al Robbani, A. M., Sattar, M. A., & Mamim, A. D. (2022). Pattern of otitis externa in ENT outpatient department of BSMMU, Dhaka, Bangladesh. *Integrative Journal of Medical Sciences*, 9, 1-10.

ISSN No: -2456-2165 https://doi.org/10.38124/ijisrt/26may399

[8]. Adegbiji, W. A., Aremu, S. K., Olatoke, F., Olajuyin, A. O., & Ogundipe, K. O. (2017). Epidemiology of otitis externa in developing country. *International Journal of Recent Scientific Research*, 8(6), 18023-18027.

[9]. Wiegand, S., Berner, R., Schneider, A., Lundershausen, E., & Dietz, A. (2019). Otitis externa: investigation and evidence-based treatment. *Deutsches Ärzteblatt International*, 116(13), 224.

[10]. Cassisi, N., Cohn, A., Davidson, T., & Witten, B. R. (1977). Diffuse otitis externa: clinical and microbiologic findings in the course of a multicenter study on a new otic solution. *Annals of Otology, Rhinology & Laryngology*, 86(3_suppl2), 1-16.