

## A Comparative Study on the Effectiveness of Glycerine MgSO<sub>4</sub> vs Gentamicin+Dexamethasone in the Management of Otitis Externa and a Study on Symptomatology and Demographics of Otitis Externa

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Conflict of interest: Nil

### Abstract:

**Background:** Otitis externa is a common inflammatory condition of the external auditory canal, frequently associated with pain, swelling, and discharge. Various treatment modalities are available, including antibiotic-steroid combinations and conservative osmotic agents; however, comparative evidence regarding their efficacy remains limited.

**Aim:** To compare the efficacy of glycerine magnesium sulfate (MgSO<sub>4</sub>) with gentamicin-dexamethasone in the medical management of otitis externa.

### Objectives:

- To determine and compare the time taken for symptomatic relief in patients treated with glycerine MgSO<sub>4</sub> and gentamicin-dexamethasone.
- To compare the proportion of patients developing complications despite treatment in both modalities.
- To study the age-wise and sex-wise distribution of patients with otitis externa.
- To identify the common predisposing factors associated with otitis externa.
- To analyze the most common presenting signs and symptoms among patients with otitis externa.
- To determine the proportion of patients presenting with localized versus diffuse otitis externa.

**Methods:** A prospective randomized controlled trial was conducted on 200 patients diagnosed with otitis externa. Patients were randomly divided into two groups: Group A (n=100) treated with glycerine MgSO<sub>4</sub> and Group B (n=100) treated with gentamicin-dexamethasone. Clinical evaluation and follow-up were performed at 1 week, 2 weeks, and 1 month. Treatment outcomes were assessed using pain score, edema, redness, and overall clinical improvement. Statistical analysis was done using appropriate tests with p<0.05 considered significant.

**Results:** Among 200 participants, the majority were aged 31–45 years (45%), followed by 18–30 years (30%) and 46–60 years (25%), with male predominance (55%). Earache was the most common symptom (90%), followed by ear swelling (70%) and ear fullness (50%). Predisposing factors included hot and humid climate (60%), frequent bathing/swimming (50%), self-cleaning (40%), and poor hygiene (35%). Diffuse otitis externa (60%) was more common than localized (40%). Pain reduction ≥75% was achieved in 95% of patients in the gentamicin-dexamethasone group compared to 85% in the glycerine MgSO<sub>4</sub> group. Treatment failure was lower in the gentamicin group (5%) compared to the glycerine group (10%), and complications were absent in the gentamicin group but observed in 5% of the glycerine group. Greater improvement in pain, edema, and redness scores was seen in the gentamicin group. Mean clinical scores reduced from 21.7 ± 0.7 to 3.2 ± 0.6 in the gentamicin group compared to 22.3 ± 0.8 to 4.3 ± 0.5 in the glycerine group at 1 month, with statistically significant differences (p < 0.05). Complications such as secondary fungal infection (25% vs 15%), necrotizing otitis externa (5% vs 3%), and malignant otitis externa (2% vs 1%) were higher in the glycerine group.

**Conclusion:** Gentamicin with dexamethasone is more effective than glycerine magnesium sulfate in the management of otitis externa, providing faster symptom relief, better clinical improvement, and fewer complications. It can be considered a more reliable treatment modality in clinical practice.

**Keywords:** Otitis Externa, Glycerine Magnesium Sulfate, Gentamicin, Dexamethasone, Ear Infection, Randomized Controlled Trial, Topical Therapy.

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## Introduction

Otitis externa (OE), commonly referred to as “swimmer’s ear,” is an inflammatory disorder of the external auditory canal characterized by erythema, edema, and varying degrees of otalgia and discharge. It is a frequently encountered condition in clinical practice, affecting individuals across all age groups, with a higher incidence in humid climates and among individuals with increased exposure to water or mechanical trauma to the ear canal [1]. The condition may arise due to bacterial, fungal, or mixed infections, with *Pseudomonas aeruginosa* and *Staphylococcus aureus* being the most commonly implicated bacterial pathogens [2].

The pathophysiology of otitis externa involves disruption of the normal protective barriers of the external auditory canal, including cerumen and epithelial integrity, leading to maceration, altered pH, and microbial proliferation [3]. Clinically, patients present with symptoms such as ear pain, itching, a sense of fullness, and discharge, which may range from serous to purulent. If inadequately treated, the condition may progress to complications such as cellulitis, abscess formation, or, rarely, malignant otitis externa, particularly in elderly or immunocompromised individuals [4].

Management of otitis externa is primarily topical and aims at reducing inflammation, eradicating infection, relieving symptoms, and restoring the normal canal environment [5]. Common therapeutic agents include antibiotics, corticosteroids, and antiseptic or hyperosmolar preparations. Among these, the combination of gentamicin and dexamethasone is widely used due to its dual action of antimicrobial activity and anti-inflammatory effects [6]. Gentamicin, an aminoglycoside antibiotic, is particularly effective against gram-negative organisms, including *Pseudomonas aeruginosa*, while dexamethasone helps in reducing inflammation and associated symptoms [6].

Alternatively, glycerine combined with magnesium sulfate ( $MgSO_4$ ) is frequently used as a conservative treatment modality. Glycerine acts as a hygroscopic agent that reduces edema by drawing out fluid, while magnesium sulfate enhances the osmotic effect, aiding in the reduction of inflammation and canal congestion [7]. This combination is especially useful in early or non-severe cases where inflammation predominates without significant bacterial infection [8].

The widespread use of both treatment modalities, there is limited direct comparative evidence evaluating their relative efficacy in the management of otitis externa. Current treatment practices are often guided by clinical judgment rather than strong

comparative data, leading to variability in therapeutic approaches [9].

Therefore, this study aims to compare the effectiveness of glycerine  $MgSO_4$  and gentamicin-dexamethasone in the management of otitis externa, along with an evaluation of symptomatology and demographic characteristics. The findings of this study are expected to contribute to evidence-based clinical decision-making and improve patient outcomes.

**Aim:** To compare the efficacy of glycerine magnesium sulfate ( $MgSO_4$ ) with gentamicin-dexamethasone in the medical management of otitis externa.

## Objectives

1. To determine and compare the time taken for symptomatic relief in patients treated with glycerine  $MgSO_4$  and gentamicin-dexamethasone.
2. To compare the proportion of patients developing complications despite treatment in both modalities.
3. To study the age-wise and sex-wise distribution of patients with otitis externa.
4. To identify the common predisposing factors associated with otitis externa.
5. To analyze the most common presenting signs and symptoms among patients with otitis externa.
6. To determine the proportion of patients presenting with localized versus diffuse otitis externa.

## Methodology

This study was conducted as a prospective randomized controlled trial in the Department of Otorhinolaryngology and Head and Neck Surgery at Sir Takhtsinhji (Sir T) Hospital, Bhavnagar, Gujarat, India, over a period of 12 months. A total of 200 patients diagnosed with otitis externa were included in the study. The study population comprised patients attending the ENT outpatient department (OPD) with complaints such as ear pain, swelling, itching, and a sensation of ear fullness. A detailed clinical evaluation was performed in all cases, and the diagnosis of otitis externa was confirmed by headlamp examination.

Patients aged between 18 and 60 years, clinically diagnosed with otitis externa, and willing to provide written informed consent were included in the study. Patients with chronic suppurative otitis media, perforated tympanic membrane, and those outside the specified age group were excluded. After applying the inclusion and exclusion criteria,

eligible patients were randomly assigned into two groups using a computer-generated randomization method to ensure unbiased allocation.

Group A consisted of 100 patients who were treated with a glycerine magnesium sulfate (MgSO<sub>4</sub>) aural wick, while Group B consisted of 100 patients who received topical gentamicin and dexamethasone ear drops. In Group A, a sterile aural wick soaked in glycerine MgSO<sub>4</sub> was inserted into the affected ear canal. The hyperosmolar property of glycerine along with magnesium sulfate helped reduce edema and inflammation, thereby providing symptomatic relief. In Group B, patients were treated with topical ear drops containing gentamicin, an aminoglycoside antibiotic, and dexamethasone, a corticosteroid, which together provided antimicrobial and anti-inflammatory effects. All patients were advised to avoid water exposure and refrain from self-cleaning of the ears during the treatment period.

A detailed history was obtained from all patients, including demographic data such as age and sex, presenting complaints, and predisposing factors such as recent swimming or history of self-ear cleaning. Clinical examination was performed using a headlamp to assess the severity of the disease, including the degree of pain, edema, and erythema of the external auditory canal.

Patients were followed up at 1 week, 2 weeks, and 1 month after initiation of treatment. The effectiveness of treatment was assessed using predefined scoring criteria based on three parameters: pain reduction, ear canal edema, and ear redness. Pain reduction was evaluated using the Visual Analog Scale (VAS), where a score of 1 indicated  $\geq 75\%$  reduction in pain, score 2 indicated 50–75% reduction, and score 3 indicated  $< 50\%$  reduction. Reduction in ear canal

edema was assessed based on visualization of the tympanic membrane, with score 1 indicating full visibility, score 2 indicating partial (approximately 50%) visibility, and score 3 indicating non-visibility. Reduction in ear redness was graded according to the extent of canal involvement, with score 1 representing involvement of less than one-third of the canal, score 2 representing one-third to two-thirds involvement, and score 3 representing more than two-thirds involvement. Lower scores indicated better clinical improvement.

Treatment outcome was defined based on the total score obtained during follow-up. Treatment success was defined as a total score of  $\leq 3$  at the first follow-up visit, while treatment failure was defined as a total score of  $\geq 6$  at the second follow-up visit.

Data were collected using structured case record forms and entered into a computerized database for analysis. Demographic variables, clinical features, predisposing factors, and treatment outcomes were recorded and analyzed. Statistical analysis was performed using appropriate statistical methods. Categorical variables were compared using the Chi-square test, while continuous variables were analyzed using Student's t-test or analysis of variance (ANOVA) as applicable. A p-value of less than 0.05 was considered statistically significant.

Ethical approval for the study was obtained from the Institutional Ethics Committee prior to commencement. Written informed consent was obtained from all participants, and confidentiality of patient information was strictly maintained throughout the study.

## Result

**Table 1: Demographic Profile of Study Participants (n = 200)**

Variable	Category	n	%
Age (years)	18–30	60	30
	31–45	90	45
	46–60	50	25
Gender	Male	110	55
	Female	90	45

In the present study, a total of 200 participants were included. The majority of patients belonged to the 31–45 years age group, accounting for 90 cases (45%), followed by 18–30 years with 60 cases (30%) and 46–60 years with 50 cases (25%). Regarding gender distribution, males constituted a

slightly higher proportion with 110 participants (55%), while females accounted for 90 participants (45%). This indicates a male predominance and a higher burden of disease in the middle-aged population.

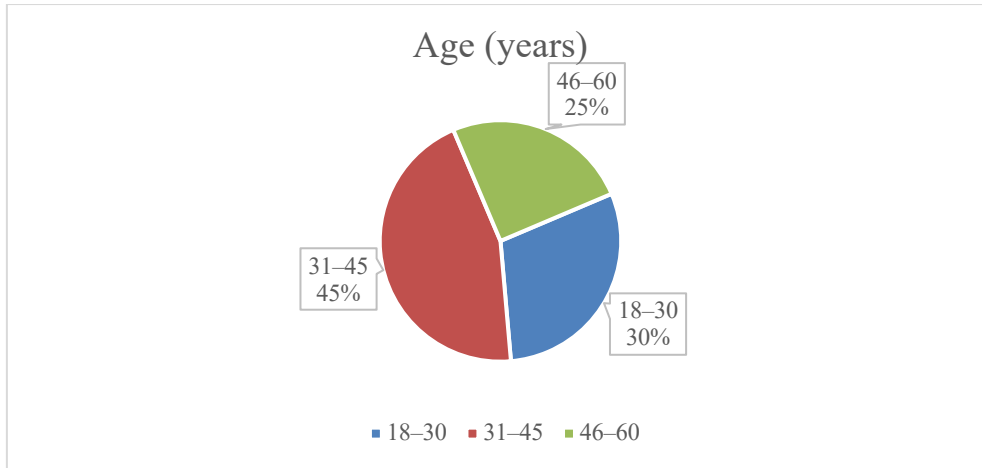


Figure 1: Demographic Profile of Study Participants (Age)

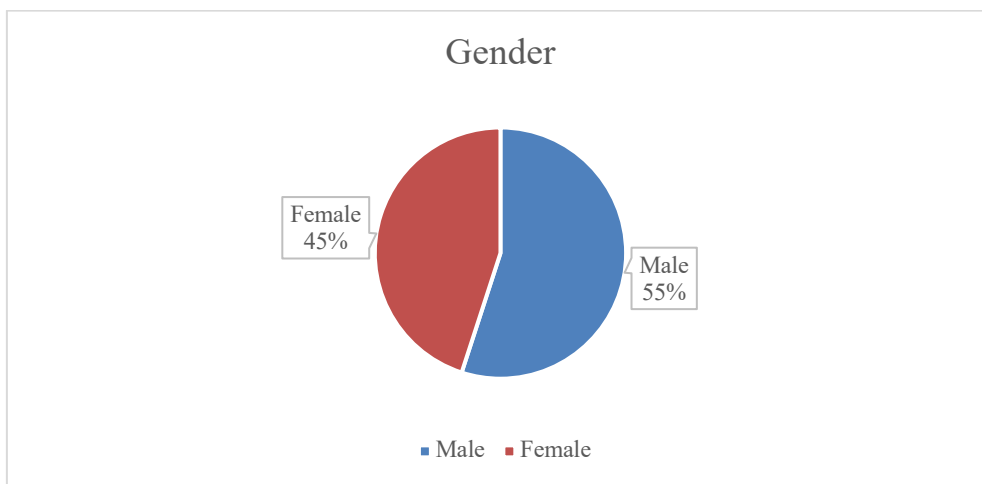


Figure 2: Demographic Profile of Study Participants (Gender)

Table 2: Clinical Presentation and Predisposing Factors (n = 200)

Variable	Category	n	%
<b>Common Symptoms</b>	Earache	180	90
	Ear swelling	140	70
	Ear fullness	100	50
<b>Predisposing Factors</b>	Exposure to hot & humid climate	120	60
	Frequent bathing/swimming	100	50
	Self-cleaning of ear	80	40
	Poor hygiene	70	35
<b>Laterality</b>	Right ear	76	38
	Left ear	112	56
	Bilateral	12	6
<b>Type of Otitis Externa</b>	Diffuse infection	120	60
	Localized infection	80	40

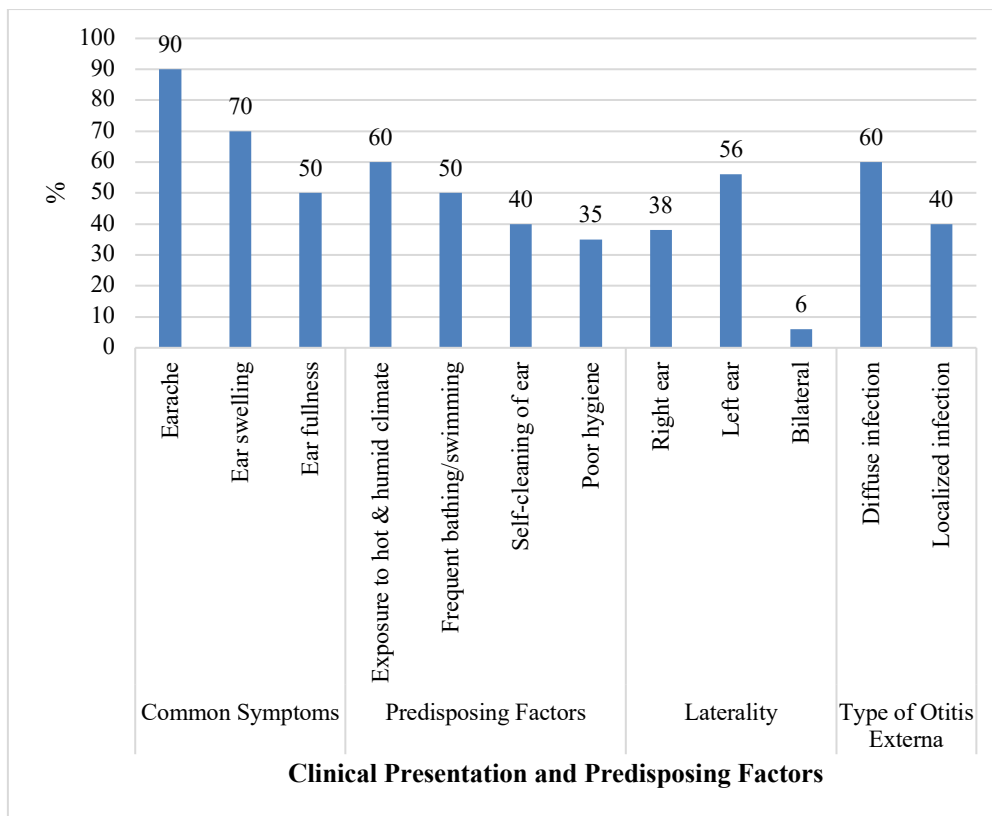


Figure 3: Clinical Presentation and Predisposing Factors

Among the clinical presentations, earache was the most common symptom observed in 180 patients (90%), followed by ear swelling in 140 patients (70%) and ear fullness in 100 patients (50%). Regarding predisposing factors, exposure to hot and humid climate was the most frequent, reported in 120 patients (60%), followed by frequent bathing or swimming in 100 patients (50%), self-cleaning of the ear in 80 patients (40%), and poor hygiene in 70

patients (35%). In terms of laterality, the left ear was more commonly affected in 112 cases (56%), followed by the right ear in 76 cases (38%), while bilateral involvement was seen in 12 cases (6%). Regarding the type of otitis externa, diffuse infection was more prevalent, observed in 120 patients (60%), whereas localized infection was noted in 80 patients (40%).

Table 3: Treatment Outcomes and Symptom Score Improvement in Both Groups (n = 200)

Parameter	Category / Score	Glycerine + MgSO <sub>4</sub> (n = 100)	Gentamicin + Dexamethasone (n = 100)
Overall Treatment Outcome	Pain reduction ≥75%	85%	95%
	Treatment failure	10%	5%
	Complications	5%	0%
Pain Reduction Score	Score 1	85%	95%
	Score 2	10%	5%
	Score 3	5%	0%
Reduction in Ear Canal Edema	Score 1	80%	90%
	Score 2	15%	10%
	Score 3	5%	0%
Reduction in Ear Redness	Score 1	75%	88%
	Score 2	20%	10%
	Score 3	5%	2%
Average Clinical Score	At presentation	22.3 ± 0.8	21.7 ± 0.7
	1-week follow-up	19.2 ± 1.3	18.4 ± 0.4
	2-week follow-up	16.3 ± 1.2	13.5 ± 0.3
	1-month follow-up	4.3 ± 0.5	3.2 ± 0.6
p-value (Independent t-test)	—	—	0.0031 / 0.0021 / 0.00001 / 0.00001*

\*p-values correspond to presentation, 1 week, 2 weeks, and 1-month follow-up respectively.

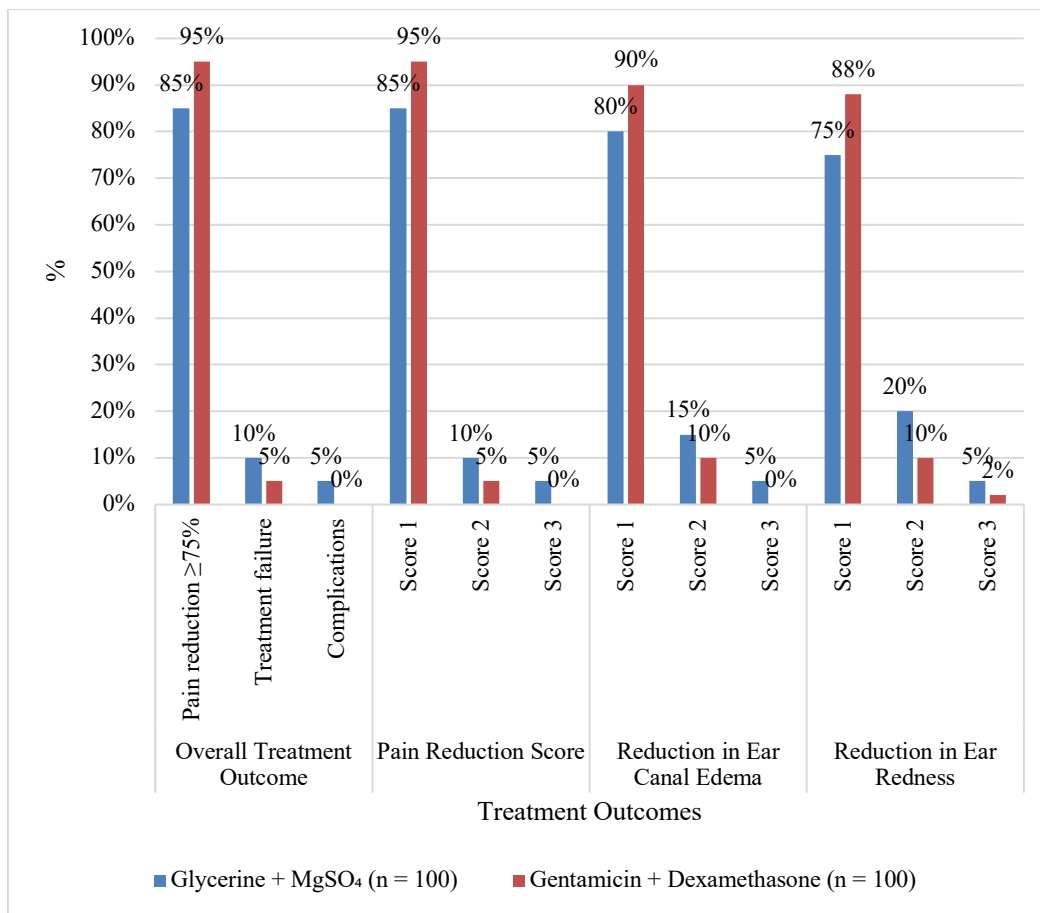


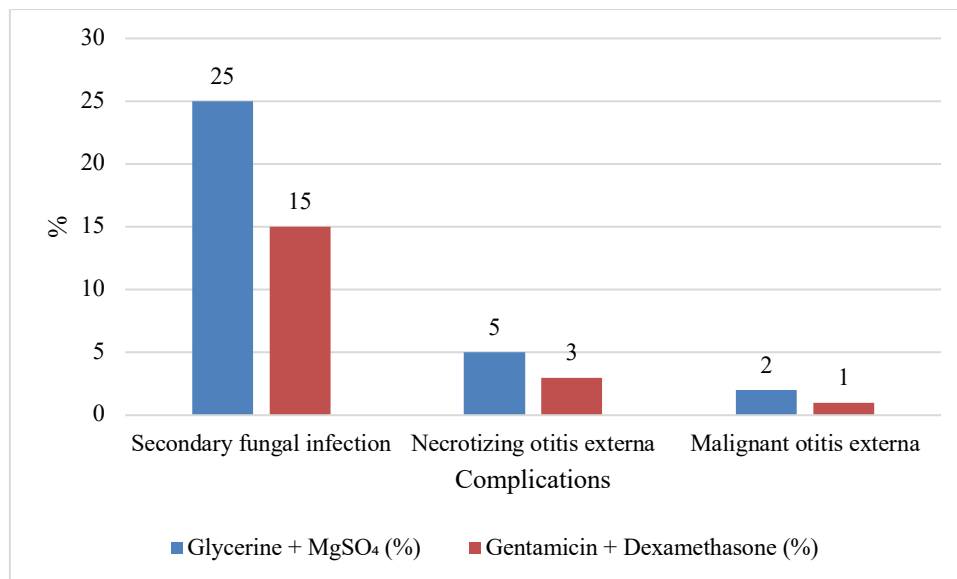
Figure 4: Treatment Outcomes and Symptom Score Improvement in Both Groups

The comparison of treatment outcomes between the two groups showed that pain reduction of  $\geq 75\%$  was achieved in 85% of patients in the glycerine + magnesium sulfate group and 95% in the gentamicin + dexamethasone group. Treatment failure was observed in 10% and 5% of patients, respectively, while complications occurred in 5% of patients in the glycerine group and none in the gentamicin group. Regarding pain reduction scores, score 1 (maximum improvement) was seen in 85% of patients in the glycerine group and 95% in the gentamicin group, whereas score 2 was noted in 10% and 5%, and score 3 in 5% and 0%, respectively. Reduction in ear canal edema showed score 1 in 80% of patients in the glycerine group and 90% in the gentamicin group, score 2 in 15% and 10%, and score 3 in 5% and 0%, respectively.

Similarly, reduction in ear redness revealed score 1 in 75% of patients in the glycerine group and 88% in the gentamicin group, score 2 in 20% and 10%, and score 3 in 5% and 2%, respectively. The average clinical score showed progressive improvement in both groups. In the glycerine group, the mean score reduced from  $22.3 \pm 0.8$  at presentation to  $19.2 \pm 1.3$  at 1 week,  $16.3 \pm 1.2$  at 2 weeks, and  $4.3 \pm 0.5$  at 1 month. In the gentamicin group, it decreased from  $21.7 \pm 0.7$  at presentation to  $18.4 \pm 0.4$  at 1 week,  $13.5 \pm 0.3$  at 2 weeks, and  $3.2 \pm 0.6$  at 1 month. The difference between the groups was statistically significant at all follow-up intervals, with p-values of 0.0031, 0.0021, and  $<0.00001$ , indicating better efficacy of gentamicin with dexamethasone.

Table 4: Complications in Both Treatment Groups (n = 200)

Complication	Glycerine + MgSO <sub>4</sub> (%)	Gentamicin + Dexamethasone (%)
Secondary fungal infection	25	15
Necrotizing otitis externa	5	3
Malignant otitis externa	2	1



**Figure 5: Complications in Both Treatment Groups**

The incidence of complications was higher in the glycerine + magnesium sulfate group compared to the gentamicin + dexamethasone group. Secondary fungal infection was observed in 25% of patients in the glycerine group and 15% in the gentamicin group. Necrotizing otitis externa occurred in 5% and 3% of patients, respectively, while malignant otitis externa was reported in 2% of patients in the glycerine group and 1% in the gentamicin group. These findings suggest a comparatively lower complication rate in patients treated with gentamicin and dexamethasone.

### Discussion

The present study evaluated the clinical profile and comparative effectiveness of glycerine with magnesium sulfate versus gentamicin with dexamethasone in the management of otitis externa. The findings of the present study are broadly consistent with previously published literature and provide additional insight into treatment outcomes in a tertiary care setting.

In the present study, the majority of patients belonged to the 31–45 years age group (45%), with a male predominance (55%). In contrast, Poornima Kabadar et al. reported a relatively younger age group with female predominance [10]. However, both studies emphasize that otitis externa commonly affects young to middle-aged individuals. Clinically, earache (90%) was the most common presenting symptom in our study, followed by ear swelling (70%) and ear fullness (50%). These findings are consistent with standard literature, where otalgia is the predominant symptom due to inflammation of the external auditory canal [11].

In the present study, pain reduction of  $\geq 75\%$  was achieved in 85% of patients treated with glycerine plus MgSO<sub>4</sub> and 95% of those treated with

gentamicin plus dexamethasone, indicating superior efficacy of the antibiotic-steroid combination. These findings are comparable with those reported by Bishnu Lal Shrestha et al., who demonstrated that steroid-antibiotic therapy provides faster and more effective symptom relief compared to glycerine-based packing [12]. Similarly, Richard Hornigold et al. in a randomized controlled trial reported better symptom control with antibiotic-steroid ear drops compared to glycerol-based treatment [13].

Treatment failure in our study was higher in the glycerine group (10%) compared to the gentamicin group (5%), and complications were absent in the gentamicin group. These findings are supported by studies such as that by Ralph Mösges et al., which reported better clinical efficacy and safety profiles with antibiotic ear drops compared to non-antibiotic treatments [14].

Furthermore, our study demonstrated greater improvement in pain, edema, and redness scores in the gentamicin plus dexamethasone group compared to the glycerine group. The mean clinical score reduced from  $21.7 \pm 0.7$  to  $3.2 \pm 0.6$  at 1 month in the gentamicin group, compared to  $22.3 \pm 0.8$  to  $4.3 \pm 0.5$  in the glycerine group. Similar observations were made by Poornima Kabadar et al., who noted earlier symptom resolution in patients treated with antibiotic-steroid combinations [10]. However, a systematic review and meta-analysis by Raffaele Di Traglia et al. suggested that although individual studies favor antibiotic-steroid combinations, pooled data did not demonstrate a statistically significant difference in overall cure rates [15].

In terms of complications, our study found that secondary fungal infection (25% vs 15%), necrotizing otitis externa (5% vs 3%), and malignant otitis externa (2% vs 1%) were more common in the glycerine group compared to the gentamicin group.

These findings further support the superior clinical efficacy and safety profile of antibiotic-steroid therapy in managing otitis externa.

Overall, the findings of the present study suggest that gentamicin with dexamethasone is more effective than glycerine with magnesium sulfate in terms of faster symptom relief, lower treatment failure rates, and fewer complications. These results reinforce the role of antibiotic-steroid combinations as a preferred treatment modality in the management of otitis externa, particularly in cases with significant inflammation and suspected bacterial etiology.

### Summary

A total of 200 patients with otitis externa were included in the study. The majority of participants belonged to the 31–45 years age group (45%), followed by 18–30 years (30%) and 46–60 years (25%), with a slight male predominance (55%).

Earache was the most common presenting symptom, observed in 90% of patients, followed by ear swelling (70%) and ear fullness (50%). Among predisposing factors, exposure to hot and humid climate (60%) and frequent bathing or swimming (50%) were most common, followed by self-cleaning of the ear (40%) and poor hygiene (35%). The left ear was more frequently involved (56%) compared to the right ear (38%), while bilateral involvement was seen in 6% of cases. Diffuse otitis externa (60%) was more common than localized infection (40%).

In terms of treatment outcomes, the gentamicin with dexamethasone group demonstrated superior efficacy compared to the glycerine with magnesium sulfate group. Pain reduction of  $\geq 75\%$  was achieved in 95% of patients in the gentamicin group compared to 85% in the glycerine group. Treatment failure was lower in the gentamicin group (5%) than in the glycerine group (10%), and no complications were reported in the gentamicin group, whereas 5% of patients in the glycerine group developed complications.

Symptom score analysis showed greater improvement in the gentamicin group, with higher proportions of patients achieving the best scores for pain relief, reduction in ear canal edema, and redness. The mean clinical scores also showed a more rapid and significant decline in the gentamicin group across all follow-up periods, from baseline to one month ( $21.7 \pm 0.7$  to  $3.2 \pm 0.6$ ), compared to the glycerine group ( $22.3 \pm 0.8$  to  $4.3 \pm 0.5$ ), with statistically significant differences ( $p < 0.05$ ).

Complication rates were higher in the glycerine group, with secondary fungal infection (25% vs 15%), necrotizing otitis externa (5% vs 3%), and

malignant otitis externa (2% vs 1%) compared to the gentamicin group.

Overall, gentamicin with dexamethasone demonstrated better clinical outcomes, faster symptom resolution, and fewer complications compared to glycerine with magnesium sulfate in the management of otitis externa.

### Conclusion

The present study concludes that otitis externa is more commonly seen in young to middle-aged individuals, with earache being the predominant symptom and environmental as well as behavioral factors playing a significant predisposing role. Comparative evaluation of treatment modalities demonstrated that gentamicin combined with dexamethasone is more effective than glycerine with magnesium sulfate in the management of otitis externa. The antibiotic-steroid combination provided faster and greater symptomatic relief, better improvement in clinical scores, lower treatment failure rates, and fewer complications. Thus, topical gentamicin with dexamethasone can be considered a more efficacious and reliable treatment option for otitis externa, particularly in achieving rapid symptom resolution and minimizing disease-related complications.

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