ORIGINAL ARTICLE

Journal of Otorhinolaryngology and Facial Plastic Surgery 2025;11(1):1-6.
https://doi.org/10.22037/orlfps.v11i1.48281

Comparison between Topical Formulations of Ichthammol Glycerin and Betamethasone Valerate in the Management of Acute Otitis Externa

Saai Ram Thejas[1*], Sindu Mohan[2], Bathula Deepthi[3]

1. Department of Otorhinolaryngology, RVM Institute of Medical Sciences, Laxmakkapally Village, Mulugu Mandal, Siddipet District, Telangana, India.
2. Department of Otorhinolaryngology, Velammal Medical College and Hospital, Anuppanadi, Madurai, Tamil Nadu, India.
3. Department of Otorhinolaryngology, RVM Institute of Medical Sciences, Laxmakkapally Village, Mulugu Mandal, Siddipet District, Telangana, India.

Article Info

Article Note:
Received: December 2025
Accepted: February 2025
Publish Online: April 2025

Corresponding Author:
Dr. Saai Ram Thejas

Email:
21thejas@gmail.com

Keywords:
Ichthammol Glycerin; Betamethasone Valerate; Acute Otitis Externa.

Abstract

Background: Acute Otitis Externa (AOE) is diffuse inflammation of the external auditory canal. Findings show a narrowed, tender and erythematous external auditory canal. There are no concrete methods in the management of AOE. Current methods include aural toileting and application of topical agents. Betamethasone Valerate, a Corticosteroid and 0.1% w/w of drug is used most commonly. The commercially used 10% Ichthammol Glycerine solution is a mixture of pure Glycerol [C3H8O3] in a 9:1 ratio with Ichthammol.

Aim: To compare Betamethasone Valerate & Ichthammol Glycerine in the management of Acute Otitis Externa.

Methods: All patients presenting to the Department of Otorhinolaryngology of a Rural Hospital in South India diagnosed with AOE between were included in study. Thirty were assigned to each group. Group A had IG and Group B had BV placed in their ear canal with the help of a sterile cotton wick at 0, 24 and 48 hours. The Visual Analogue Scale and Edema Erythema Index were used as parameters of assessment.

Results: The EET improvement stood at 51.31% in Group A. The EET improvement stood at 47.96% in Group B. In Group A, VAS had an improvement of 63.85%. In Group B, VAS had an improvement of 49.42%.

Conclusion: The use of IG was found to be superior to BV in the management of AOE. IG provides relief from topical allergy and irritation along with reduction of edema. Since IG is cheaper and easy to procure, it can be used as a first line treatment in the management of AOE..

Conflicts of Interest: The Authors declare no conflicts of interest.
Please cite this article as: Thejas SR, Mohan S, Deepthi B. Comparison between Topical Formulations of Ichthammol Glycerin and Betamethasone Valerate in the Managment of Acute Otitis Externa. J Otorhinolaryngol Facial Plast Surg 2025;11(1):1-6. https://doi.org/10.22037/orlfps.v11i1.48281

Introduction

Acute Otitis Externa (AOE) aka swimmer's ear is diffuse inflammation of the external auditory canal, frequently associated with a bacterial or fungal infection. Other causes include virus, allergy or a dermatological condition like psoriasis and eczema (1). Patients commonly present with a history of earache, itchiness, ear discharge and hearing loss (2).

Examination findings usually show a narrowed, tender and erythematous external auditory canal. The infection may also cause excessive skin desquamation resulting in the accumulation of a large amount of keratin debris in the canal. In severe cases, there may be associated auricular cellulitis and perichondritis (3).

Journal of Otorhinolaryngology and Facial Plastic Surgery 2025;11(1):1-6.
https://doi.org/10.22037/orlfps.v11i1.48281

There are no concrete methods in the management of Acute Otitis Externa. Various modalities have been used in literature which are being tapered case wise. Current methods of management include aural toileting, application of topical antibiotics, with or without corticosteroids and less commonly systemic anti-microbial therapy when there is significant external auditory canal edema. Delivery of topical preparations can be facilitated by placement of an ear wick or ribbon gauze.

Ichthammol is colloquially known by terms like black ointment and bear grease. The chemical compound is Ammonium Bituminosulfonate [C28H36S5O6(NH4)2]. The commercially used 10% Ichthammol Glycerine solution is a mixture of pure Glycerol [C3H8O3] in a 9:1 ratio with Ichthammol. Ichthammol is prepared by the destructive distillation of bituminous shale with ammonium sulphate and contains mainly ammonium salts of sulphuric acid and contains not less than 10% of organically incorporated sulphur.[4] Glycerine is a clear hydroscopic liquid and exerts its effects mainly due to dehydration action. Ichthammol glycerine solution has a specific anti-staphylococcal action (5).

Betamethasone Valerate, a Corticosteroid, is usually used as a topical agent in the management of AOE. 0.1% w/w of drug is used most commonly. Doxycycline belongs to the Tetracycline group of antibiotics and is used in a large scale to manage infections of the skin and soft tissue. The primary aim of this study was to compare the efficacy between Ichthammol Glycerine and Betamethasone Valerate in the management of symptoms of AOE.

Methods

All patients presenting to the Department of Otorhinolaryngology between January and December of 2022 of a Rural Hospital in South India. The Institute Ethical Committee approved the study and the reference number for the same was RVM/2022/23. According to demographics and prevalence, sample size was calculated for the local district and it was found to be 60. Thirty were assigned to each group.

Patients of the age group of 18-60, diagnosed AOE with positive tragal sign with no middle ear involvement and intact Tympanic Membrane were included in the study.

Patients with Diabetes Mellitus and associated Malignant Otitis Externa, Paediatric and Geriatric age group (below 18 and above 60) and with Chronic Suppurative Otitis Media (Mucosal and Squamous) were excluded from the study.

All statistical analyses were performed using SPSS Statistics 19 for Windows (IBM Corp., Armonk, NY, USA). Samples were compared and evaluated by means of a Paired T-test. A P-value of <0.05 was considered statistically significant. The confidence interval was set at 95%. A simple randomised sampling was used. Odd patients (Group A) were given IG (Ichthammol Glycerine) treatment protocol and even patients (Group B) were prescribed the BV (Betamethasone Valerate) protocol.

After diagnosis, all patients signed a consent form to be part of the study. They were then started on Doxycycline, Pantoprazole, Trypsin, Chymotrypsin, Bromelain, Paracetamol and Rutoside via the oral route with adequate dose calculation based on weight of the individual.

Individuals in Group A had 10% IG placed in their ear canal with the help of a sterile cotton wick. Individuals in Group B had BV placed in their ear canal with the help of a cotton wick. 1-2 ml of agent was used based on the volume of the ear canal. Erythema Edema Tragal Index (EET) was used to compare the clinical signs before and after treatment. Table 1 shows a self-tailored score was used to identify the changes seen in the ear canal. A maximum score of 9 could be obtained for each ear under study.

Results

Out of the 60 patients, 38 were male and 22 were female. 20 males were in Group A and 18 in Group B. 10 females were in Group A and 12

Journal of Otorhinolaryngology and Facial Plastic Surgery 2025;11(1):1-6.
https://doi.org/10.22037/orlfps.v11i1.48281

in Group B. The average score on the EET index before the procedure in Group A was 6.86/10. The average score at the end of Days 1, 2, and 3 combined was 3.34. Thus, the improvement stood at 51.31% in 3 days. (Figure 2). The average score on the EET index before the procedure in Group B was 7.13/10. The average score at the end of Days 1, 2, and 3 combined was 3.71. Thus, the improvement stood at 47.96% in 3 days (Figure 1).

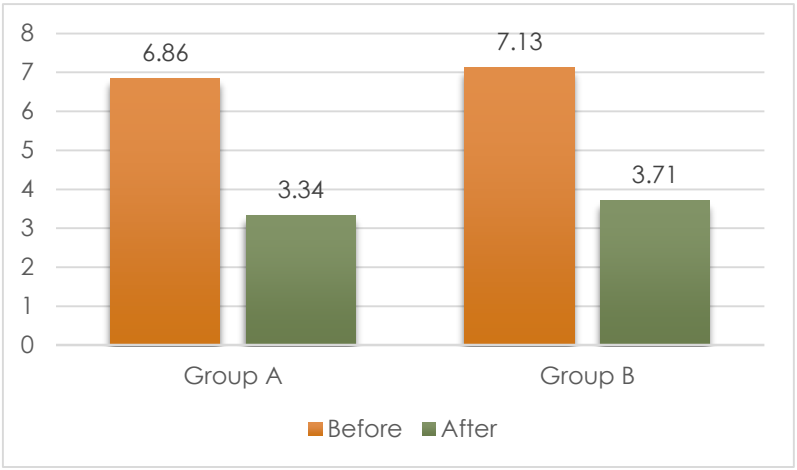

Figure 1. EET scores between groups before and after treatment

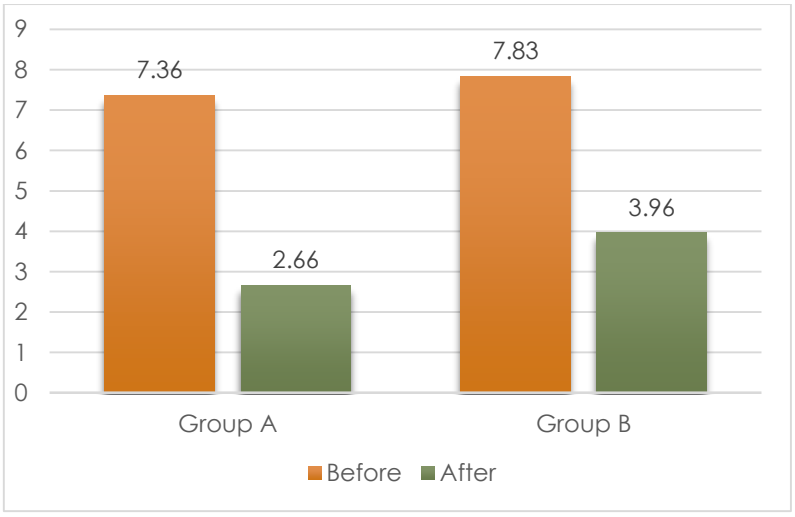

Figure 2.VAS scores between groups before and after treatment

In Group A, the average VAS score was 7.36 before procedure and 2.66 after procedure, an improvement of 63.85%. In Group B, the average VAS score was 7.83 before procedure and 3.96 after procedure, an improvement of 49.42% (Figure 2). As evidenced in Tables 2 and 3, it is clear that the significance is superior in Group A as compared to Group B.

Table 1. EET Index

Score	Erythema	Edema	Tragal Sign
0	No erythema	No Edema	Negative
1	Very slight, barely perceptible	Very slight, barely perceptible	Positive
2	Well defined	Well defined	
3	Moderate to severe	Moderate	
4	Severe with or without eschar	Severe > 1mm thickness	

Journal of Otorhinolaryngology and Facial Plastic Surgery 2025;11(1):1-6.
https://doi.org/10.22037/orlfps.v11i1.48281

Table 2. Paired Samples Correlations in Group A

	Paired Differences					t	Sig.	Corr.
	Mean	S.D.	S.E.Mean	95% confidence interval				
				Lower	Upper			
Before vs After EET	3.52	1.31	0.24	3.03	4.01	14.77	0.01	0.74
Before vs After VAS	4.70	2.25	0.41	3.86	5.54	11.46	0.01	0.58

Table 3. Paired Samples Correlations in Group B

	Paired Differences					t	Sig.	Corr.
	Mean	S.D.	S.E.Mean	95% confidence interval				
				Lower	Upper			
Before vs After EET	3.42	1.75	0.32	2.77	4.08	10.71	0.02	0.70
Before vs After VAS	3.87	2.71	0.50	2.85	4.88	7.81	0.02	0.27

Discussion

AOE is usually precipitated by moisture and triggered by mostly bacteria and sometimes fungi. The most common organisms are Staphylococcus aureus and Pseudomonas aeruginosa with some cases having Aspergillus species of fungi (6).

There are various accepted methods to treat AOE and all of them invariably work on only one aspect i.e. to reduce the moisture content of the External Auditory Canal to prevent aa conducive atmosphere for the growth of organisms. Thus, the instillation of ear drops is effectively ruled out since it does not provide a contact point to all surfaces of the canal and ear drum. It is here that the application of a paste preparation is favorable. Reducing the ear canal humidity could offer treatment for the myriads of symptoms (7).

Many bacterial and fungal organisms are killed by the acidified environment of the ear canal. Thus, topical medications with an acidic pH have been a mainstay of treatment for otitis externa for a long time. Topical preparations will not be able to penetrate an oedematous canal wall and thus, the insertion of an ear wick is useful to facilitate the delivery of the drug to the local surface (8).

Skin conditions such as eczema and seborrheic dermatitis are commonly found in otitis externa and this particular type of epidermal inflammation associated with these skin conditions responds well to Ichthammol application (9).

Older studies have shown that isolated application of Betamethasone has worked in the complete eradication of Otitis Externa without antibiotics. A standardized scoring system was used to evaluate colour, swelling and effusion of the ear canal (10).

A study conducted in 2011 demonstrated that a steroid antibiotic ointment regimen was superior to a 10% ichthammol glycerine ointment regimen in alleviating pain associated

Journal of Otorhinolaryngology and Facial Plastic Surgery 2025;11(1):1-6.
https://doi.org/10.22037/orlfps.v11i1.48281

with acute otitis externa. Notably, the steroid antibiotic group experienced complete pain relief on the fourth visit, whereas the 10% IG group required seven visits to achieve similar results. This suggests that the steroid antibiotic group required fewer visits and demonstrated earlier control of pain and edema compared to the 10% IG group. The specific steroid antibiotic regimen used was betnovate sodium phosphate 0.1% and neomycin sulfate 0.5%.11 This proves that the topical antibiotic has a stronger effect in local improvement. Another study conducted in 2009 also showed similar results (12).

In 2007, a prospective single-blind randomized controlled trial was performed to compare the efficacy of 10% glycerine–ichthammol (GI) solution and Triadcortyl® (TAC) ointment, both applied as ear canal dressings, in the initial management of severe acute otitis externa. They concluded that there were no significant differences in clinical findings between the two groups. The authors recommended that GI dressing can be used instead of an antibiotic dressing as an initial treatment of severe acute otitis externa on the basis of cost, avoidance of resistance and toxicity (13).

Given the limited number of studies and the diverse outcomes obtained, it is imperative to elucidate the mechanism of action of both drugs on the skin's surface. In our study, while the improvements were substantial in both groups, the percentages were more pronounced in Group A. Notably, Ichthammol Glycerine also exhibits astringent properties, which may have contributed to the better results observed in this group.

Conclusion

The VAS score improved by 63.85% in Group A and 49.42% in Group B. The EET score improved by 51.31% in Group A and 47.96% in Group B. Thus, the use of IG was found to be superior to BV in the management of AOE. The various reasons which can be attributed to this are the fact that IG provides relief from topical allergy and irritation along with reduction of edema. Since IG is cheaper and easy to procure, it can be used as a first line treatment in the management of AOE.

Acknowledgements

We would like to thank our Institute which has helped us in doing our study.

Conflicts of Interest

The authors declare no conflicts of interest.

Financial Support

The authors declared that there was no funding support for this study.

Ethics

The Institute Ethical Committee approved the study and the reference number for the same was RVM/2022/23.

Authors ORCIDs

Saai Ram Thejas
https://orcid.org/0000-0003-1854-3938

References

1.Sander R. Otitis externa: a practical guide to treatment and prevention. Am Fam Physician 2001; 63(5):927-936, 941-942.

2.Agius AM, Pickles JM, Burch KL. A prospective study of otitis externa. Clin Otolaryngol 1992 17:150–154.

3.Masood A, Moumoulidis I, Ray S et al. A randomised controlled trial comparing Triadcortyl with 10% glycerine-ichthammol in the initial treatment of severe acute otitis externa. Eur Arch Otorhinolaryngol 2008; 265(8):881-5.

4.Ahmed K, Roberts ML, Mannion PT. Antimicrobial activity of glycerine–ichthammol in otitis externa. Clin. Otolaryngol. Allied Sci 1995; 20:201-3.

5.Nilssen E, Wormald PJ, Oliver S. Glycerol and ichthammol: medicinal solution or mythical potion? J. Laryngol. Otol 1996; 110:319-21.

6.Bojrab DI, Bruderly T, Abdulrazzak Y. Otitis externa. Otolaryngol Clin North Am 1996; 29:761–82.

7.Gray RF, Sharma A, Vowler SL. Relative humidity of the external auditory canal in normal and abnormal ears, and its pathogenic effect. Clin Otolaryngol. 2005 Apr;30(2):105-11.

8.Ruckenstein MJ (2005) Infections of the external ear. In: Cummings CW et al (eds) Otolaryngology head and

Journal of Otorhinolaryngology and Facial Plastic Surgery 2025;11(1):1-6.
https://doi.org/10.22037/orlfps.v11i1.48281

neck surgery, 4th edn, vol 3. Elsevier Mosby, Philadelphia, pp 2979–2987.

9.Nilssen E, Wormald PJ, Oliver S. Glycerol and ichthammol: medicinal solution or mythical potion? J Laryngol Otol. 1996 Apr;110(4):319-21.

10. Emgård P, Hellström S. A topical steroid without an antibiotic cures external otitis efficiently: a study in an animal model. Eur Arch Otorhinolaryngol. 2001 Aug;258(6):287-91.

11. Adhikari P, Bhatta R, Bhandari S, Pyakurel Bhatta M. Comparison of steroid antibiotic pack and 10% ichthammol glycerine pack in relieving pain of acute otitis externa in children. Int J Pediatr Otorhinolaryngol. 2011 Apr;75(4):500-3.

12. Bhatta R, Pokharel R, Adhikari P, Neupane Y. A comparison of 10% Ichthalmmol Glycerine pack with steroid-antibiotic pack for relieving pain in cases of Acute otitis Externa. J Inst Med 2009; 31:7-10.

13.Masood A, Moumoulidis I, Ray S, Chawla O, Panesar J. A randomised controlled trial comparing Triadcortyl with 10% glycerine–ichthammol in the initial treatment of severe acute otitis externa. Eur Arch Otorhinolaryngol 2008; 265, 881–5.