



Steroid Antibiotic Pack Versus 10% Ichthammol Glycerol Pack in Management of Acute Otitis Externa: A Comparative Study

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ABSTRACT

Acute otitis externa is a common clinical condition that presents with rapid onset of otalgia, fullness, otorrhea and canal oedema. Moisture in-ear canal appears to be an important predisposing factor. The most common etiological agents include *Pseudomonas aeruginosa* and *Staphylococcus aureus*. Management includes control of otalgia and elimination of infection from the ear. Precipitating factors should be avoided. The main objective of this study is to compare the efficacy of 10% ichthammol glycerol ear pack with steroid antibiotic ear pack in the treatment of acute otitis externa. Institutional Review Board (IRB) clearance was obtained, and a prospective randomised clinical trial was conducted in the ENT outpatient department of Saveetha Medical College & Hospital, Thandalam, from January 2020 to March 2020. Patients were explained about the study in detail, and consent was obtained. The patients were randomised, and 10% ichthammol glycerol pack and steroid antibiotic pack were used in alternate turns for aural packing. Pain rating was done using Numerical rating scale (NRS) before and 48 hours post-treatment and also in each subsequent hospital visit till complete subsidence of symptoms. Among the 85 patients included in the study, 42 (49.4%) were males, and 43 (50.6%) were females. Most of them belonged to the age group 31-40 years (41.2%). In the patients treated with steroid antibiotic pack, only 2.3% of the patients had severe pain, whereas 14% had moderate pain and 83.7% had only mild pain. Whereas among those treated with 10% ichthammol glycerol pack, 9.5% of the patients had severe pain, whereas 35.7% had moderate pain and 54.8% had mild pain. On analysis, the results were statistically significant, and there was considerable pain relief with steroid antibiotic pack. Therefore, our study showed that steroid antibiotic pack is more effective in relieving the symptoms, thereby reducing the number of hospital visits when compared to 10% ichthammol glycerol pack.

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INTRODUCTION

Otitis externa refers to external auditory canal inflammation, which may or may not be associated with infection (Wipperman, 2014). Patients with acute otitis externa usually present with rapid onset of otalgia, aural fullness and ear discharge. Tenderness elicited during movement of the tragus is a classical finding observed on examination (Schaefer and Baugh, 2012). Inflammation of the canal results in oedema. This canal oedema causes severe pain when it distracts the periosteum (Linstrom

and Lucento, 1989). On otoscopy, the canal shows oedema and erythema. Physicians can quickly diagnose acute otitis externa on clinical grounds provided that they have adequate experience and clinical acumen.

The external auditory canal contains sebaceous glands in its outer cartilaginous part. These glands secrete cerumen which serves as a significant lipid-rich barrier. It protects against various insults like moisture that can easily disrupt the canal lining. The slight acidity and lysozymes present in the cerumen inhibit the growth of pathogenic organisms (Lum et al., 2009). Any alteration in the pH of the cerumen, any defect in cerumen synthesis, obstruction of the canal, unskilled instrumentation to remove foreign bodies or any injury to the canal lining can predispose to the development of infection, thereby eliciting an inflammatory response. Swimming, moisture from humidity and excessive sweating are some important factors that can favour the growth of pathogens. Other predisposing factors include anatomical factors like stenosis of the canal, exostoses and dermatological conditions like psoriasis, eczema and seborrhea. (Schaefer and Baugh, 2012).

Commonly implicated etiological agents include *Pseudomonas aeruginosa* and *Staphylococcus aureus* (Mahmood, 2004). Rarely, fungal pathogens like *Aspergillus* and *Candida* are also implicated. Otitis externa lasting for six weeks or less is termed as acute, whereas when its persistence exceeds three months, it is termed as chronic. It is estimated to have a prevalence of 0.4% per year, affecting 10% of the population during their lifetime (Shrestha et al., 2019).

Though being a common condition encountered almost every day in clinical practice, accurate diagnosis is of utmost importance. A detailed history should be taken. Physicians should also carefully examine the pinna, the adjacent skin and regional lymph nodes apart from the routine otoscopic examination. Tympanic membrane intactness should be verified before initiating any treatment (Schaefer and Baugh, 2012). Investigations like pneumatic otoscopy and tympanometry can be done to distinguish it from an acute middle ear infection. It is extremely valuable in the management protocol as oral antibiotics play an essential role in the treatment of otitis media (Wipperman, 2014). The interpretations of these investigations are shown in Table 2.

Other conditions that can mimic acute otitis externa like chronic suppurative otitis media, inflammatory dermatoses, furunculosis, herpes zoster oticus,

malignant otitis externa, seborrheic dermatitis and otomycosis should be ruled out (Rosenfeld et al., 2014).

Management of acute otitis externa includes control of otalgia and elimination of infection from the ear. Precipitating factors, if any, should be avoided. Effective treatment is a must, if not complications like abscesses, cellulitis, tympanic membrane perforation or malignant otitis externa can occur. Ear packs serve a beneficial role in treatment. The 'splinter action' of the ear pack acts on the nerves of the ear canal and reduces stretching. This mechanical function per se provides pain relief (Shrestha et al., 2019). The most common drug used in aural packing is 10% ichthammol glycerol. Ichthammol (ammonium bituminosulfonate) has anti-inflammatory, bactericidal, and fungicidal properties (Gayko et al., 2000) while dehydrating effect of glycerine reduces canal oedema and provides pain relief (Nilssen et al., 1996). This combination also has specific antibacterial activity against staphylococci and streptococci. Steroid antibiotic combination can also serve the above functions. Steroids reduce oedema by acting on the capillary wall while antibiotics control the infection.

The main objective of this study is to compare the efficacy of 10% ichthammol glycerol pack with steroid antibiotic pack for relieving symptoms in acute otitis externa.

MATERIALS AND METHODS

A prospective randomised clinical trial was conducted in the ENT outpatient department of Saveetha Medical College & Hospital, Thandalam, Chennai, for a period of 3 months, i.e., from January 2020 to March 2020. Among the patients diagnosed with acute otitis externa (as mentioned in Table 1), only those above ten years of age were enrolled in the study. Both the sexes were included in the study. Patients with bilateral disease, complications like abscess formation, otitis media, known diabetics and immuno compromised patients and those who had lost follow up were excluded. Permission to conduct the study was obtained from the Institutional Review Board (IRB). The study was performed after getting proper informed consent from the participants. A detailed history was taken regarding the onset & nature of symptoms and associated predisposing factors. Clinical examination was done, and ear findings were noted. In otitis externa, the canal contains necrotic tissue and debris. These hinder the penetration of topical medication into the inflamed canal lining (Monga et al., 2017).

Taking this fact into account, the debris was removed entirely. Patients were then randomised and 10% ichthammol glycerol pack and steroid antibiotic pack were used in alternate turns for aural packing. For a steroid antibiotic pack, Betnovate-N was used. It is a combination which contains betamethasone valerate and neomycin. Patients treated with steroid antibiotic pack were grouped as Group A. Whereas those treated with ichthammol glycerol pack were grouped as Group B. Pain scoring was done using Numerical Rating Scale (NRS) at presentation and after 48 hours of treatment. '0' meant no pain, and '10' meant extreme pain. Score values of 1-3 were considered as mild pain, 4-6 as moderate pain and 7-10 as severe pain. Patients were advised to avoid insertion of cotton buds and foreign objects and also prevent the entry of water into the ear canal. Aural packing was continued on subsequent visits till complete resolution of canal oedema. Statistical analysis was done, and the pain score in both the groups was compared. Efficacy of both the treatment modalities was compared using the chi-square test. For analysis, a p-value less than 0.05 was considered to be statistically significant.

RESULTS

The total number of patients enrolled in the study was 85. Among them, 42 were males, and 43 were females. Table 3 shows the sex distribution of the patients enrolled in the study.

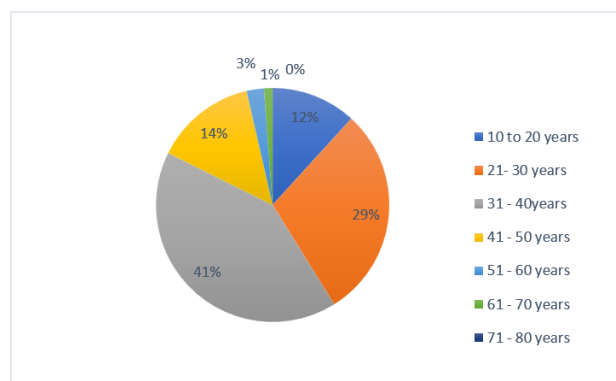


Figure 1: Age Distribution

The highest proportion of patients belonged to the age group 31-40 years (41.2%). Table 4 and Figure 1 show the age distribution of the patients enrolled in the study.

The left ear was involved in 52.9% and right ear in 47.1% of the cases. Based on the inclusion and exclusion criteria mentioned above, patients with acute otitis externa were initially assessed, and the ear findings were noted. All patients had tragal tenderness, while 97.6% of the patients had external

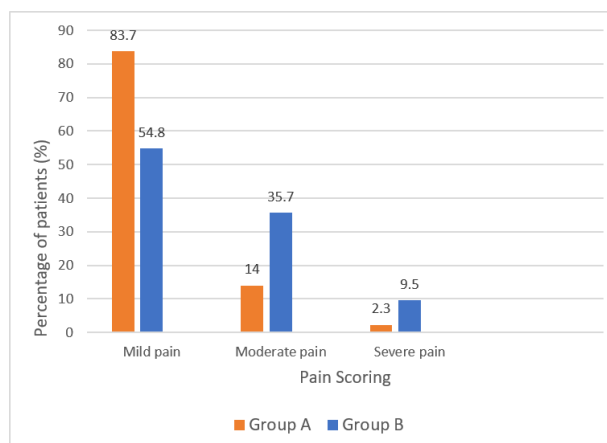


Figure 2: Comparison of pain rating scores after 48 hours of treatment

auditory canal oedema, and 82.4% had pain during jaw movement. Symptoms like lymphadenitis and cellulitis were relatively less common. Table 5 shows the frequency of different ear findings among the patients.

Patients treated with steroid antibiotic pack were included under Group A, whereas those treated with 10% ichthammol glycerol pack were included under Group B. In Group A, only 2.3% of the patients had severe pain, whereas 14% had moderate pain and 83.7% had only mild pain. In Group B, 9.5% of the patients had severe pain, whereas 35.7% had moderate pain and 54.8% had mild pain.

The p-value was calculated to be 0.007563. The results were statistically significant at $p < 0.05$. Table 6 and Figure 2 represent the pain rating after 48 hours in both groups.

In Group A, 44.2% of the patients showed complete resolution of symptoms after three visits, and the maximum number of visits was 5. Whereas in Group B, 42.9% of the patients showed complete resolution only after five visits and 4.8% had to come for up to 7 visits till complete subsidence of symptoms. Table 7 shows the number of hospital visits undertaken by the patients to complete subsidence of symptoms.

DISCUSSION

Acute otitis externa refers to diffuse oedema of the external auditory canal with or without associated infection. It is also known as 'the swimmer's ear'. It is a severe condition encountered almost every day in clinical practice. The bacteriology has remained the same over the past few decades. Commonly implicated etiological agents include *Pseudomonas aeruginosa* and *Staphylococcus aureus* (Patel and Dehadaray, 2018).

Table 1: Diagnosis of acute otitis externa

Presenting complaints	On examination
Rapid occurrence of symptoms (within 48 – 72 hours)	Tragal tenderness, erythema and oedema of the external auditory canal - present
Severe ear pain, aural fullness - present	Ear discharge, tympanic membrane involvement, lymph node involvement, cellulitis of the adjoining skin - may or may not be present
Hard of hearing, pruritus, pain during jaw movement - may or may not be present	

Table 2: Distinguishing acute otitis externa from otitis media

Investigation	Acute Otitis Externa	Acute Otitis Media
Pneumatic otoscopy	Normal	Negligible motion
Tympanometry	Normal tracing (Type A)	Flat (Type B)

Table 3: Sex distribution

Sex	No. of patients	Percent (%)
Male	42	49.4
Female	43	50.6

Table 4: Age distribution

Age	No. of patients	Percent (%)
10 - 20	10	11.8
21- 30	25	29.4
31 - 40	35	41.2
41 - 50	12	14.1
51 - 60	2	2.4
61 - 70	1	1.2
71- 80	0	0

Table 5: Ear findings

Ear findings	Present in	Absent in
Tragal tenderness	85 (100%)	0
External auditory canal oedema	83 (97.6%)	2 (2.4%)
Pain during jaw movement	70 (82.4%)	15 (17.6%)
Regional lymphadenitis	35 (41.2%)	50(58.8%)
Cellulitis of pinna & adjacent skin	5 (5.9%)	80 (94.1%)

Table 6: Pain rating after 48 hours

Pain rating after 48 hours	Mild pain	Moderate pain	Severe pain
Group A Steroid - Antibiotic pack n= 43	36 83.7%	6 14%	1 2.3%
Group B Ichthammol Glycerol pack n = 42	23 54.8%	15 35.7%	4 9.5%
Chi – square value = 9.769		p – value = 0.007563	

Table 7: Number of hospital visits undertaken by patients of groups A and B

Groups	Total number of hospital visits till complete subsidence of symptoms					
	2	3	4	5	6	7
Group A	5	19	12	7	0	0
Steroid - Antibiotic pack (n= 43)	11.6%	44.2%	27.9%	16.3%	-	-
Group B	4	4	11	18	3	2
Ichthammol Glycerol pack (n=42)	9.5%	9.5%	26.2%	42.9%	7.1%	4.8%

Unless treated completely, complications like cellulitis and malignant otitis externa are more likely to occur. Most of the patients in our study were of the age group 31-40 years (41.2%). (Shrestha *et al.*, 2019) observed acute otitis externa to be more common among the age group 21-30 years (37.2%) whereas (Neher *et al.*, 2008) observed it to be more common in the older age group. The gender distribution was almost equal in our study (49.4% males and 50.6% females), and a similar observation was made by (Khalil *et al.*, 2019) (52% males and 48% females) in their study.

The effectiveness of the treatment depends to a great extent on the mode of drug delivery. Topical agents form the mainstay of treatment because they can be delivered directly to the infected area without systemic adverse effects (Sander, 2001; Bojrab *et al.*, 1996). The use of systemic antibiotics is somewhat limited, bearing in mind the risks of adverse effects, drug resistance and recurrence (Schaefer and Baugh, 2012). Hence, they are not used unless there is a spread of infection beyond the external auditory canal, or there are factors like uncontrolled diabetes in the host, which necessitate systemic therapy. One disadvantage of topical medications is that they cannot penetrate an edematous canal wall. Therefore, to provide pain relief and resolution of oedema in acute otitis externa ear packs containing topical medications are used. Medications with acidic pH can kill many microbes, including *Pseudomonas*. Hence, the pH of the medication used also plays an important role. The commonly used antibiotics include aminoglycosides and fluoroquinolones as their spectrum covers both *Pseudomonas* and *Staphylococcal* species. Neomycin can destroy the hair cells in the organ of Corti, thereby resulting in permanent sensorineural hearing loss (Rosenfeld *et al.*, 2014). The risk is more with prolonged use. Neomycin hypersensitivity has been reported in up to 32% of the study population by (Smith *et al.*, 1990), and hence patients receiving neomycin should be under clinical observation.

Providing faster and adequate pain relief in acute

otitis externa is of growing concern and necessitates substantial research among the available treatment options. On comparing the efficacy of the two treatment modalities, namely steroid antibiotic pack and 10% ichthammol glycerol pack, our study showed that steroid-antibiotic pack provided faster pain relief and the results were statistically significant. (Shrestha *et al.*, 2019) also observed similar results in their study with 94 patients that those treated with steroid-antibiotic ointment pack had a considerable reduction in pain after 48 hours of treatment and quoted that 91.4% had only mild pain, 8.5% had moderate pain and none of the patients suffered from severe pain.

On comparing the maximum number of hospital visits until resolution of canal oedema, in the ichthammol glycerol group, the maximum was seven visits done by two patients (4.8%) in our study. Similarly, in the study done by (Shrestha *et al.*, 2010), a maximum of seven visits was done by one patient (2.4%). Whereas comparing the same in the antibiotic steroid group, maximum of five visits were done by seven patients (16.3%) in our study and maximum of five visits were done by 8 (19%) patients in their study (Shrestha *et al.*, 2010). Thus both the studies have shown effective pain relief and subsidence of oedema and hence significantly lesser hospital visits in patients treated with steroid-antibiotic pack compared to those treated with 10% ichthammol glycerol pack.

(Adhikari *et al.*, 2011) observed in their study in children that those treated with steroid antibiotic pack needed fewer hospital visits until complete symptom relief, and their results were statistically significant. (Hornigold *et al.*, 2008) observed both the modalities to be equally efficacious in their study. Still, they concluded that the ichthammol glycerol pack should be used as it was more cost-effective and had better treatment adherence among the patients. (Monga *et al.*, 2017) also conducted a similar prospective randomised study in 60 patients. They found statistically significant reduction (p-value <0.001) in pain score and oedema

score in both the groups at the first follow-up. But they concluded that on the comparison, there was no significant difference in the mean pain score between both the groups. Hence, they recommended the use of 10% ichthammol glycerol pack as it was more cost-effective and carried a lesser risk of antibiotic resistance (Monga *et al.*, 2017).

On the other hand, (Masood *et al.*, 2008) compared the efficacy of 10% ichthammol glycerol solution and Triadacortyl® (TAC) ointment. They found that though both the treatment modalities were equally productive, there was considerable improvement in pain, especially in the TAC group, and they observed it to be statistically significant. All these studies correlate with our observation that steroid antibiotic pack is more effective in relieving pain and provides faster subsidence of symptoms compared to 10% ichthammol glycerol pack. This is attributable to the potent anti-inflammatory activity of steroids. Another critical point to be emphasised is that if the patient does not improve within 48 – 72 hours, physicians should consider checking for sensitivity to medication, misdiagnosis and treatment adherence (Schaefer and Baugh, 2012). Ear swabs can be taken and sent for culture to identify fungi or any drug-resistant species, thereby to modify the regimen used.

CONCLUSIONS

Both steroid antibiotic pack and 10% ichthammol glycerol pack are equally effective in the management of acute otitis externa. But our study showed that steroid antibiotic pack is more effective in relieving the symptoms, thereby reducing the number of hospital visits when compared to 10% ichthammol glycerol pack.

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Conflict of interest

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