

International Journal of Medical Science and Current Research (IJMSCR) Available online at: www.ijmscr.com Volume1, Issue 2, Page No: 177-180 July-August 2018



Prospective comparative study of two topical medications- 10% Ichthammol gycerine pack vs Steroid-Antibiotic pack for the treatment of Acute Otitis Externa

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Type of Publication: Original Research Paper Conflicts of Interest: Nil

ABSTRACT

Background:

Acute Otitis externa, a common clinical entity of the external auditory canal is characterized by pain, erythema and edema. Aural packing using 10% Ichthammol Glycerine or steroid-antibiotic combination is usually done as the initial treatment modality. The aim of this study is to compare the efficacy of 10% Ichthammol Glycerine against steroid-antibiotic (Betamethasone Topical (0.1% w/w), + Neomycin Topical (0.5% w/w)) pack in relieving pain and edema in patients with acute otitis externa.

Materials and Methods:

This prospective comparative study was done on 50 patients with a diagnosis of acute otitis externa who were randomly divided into two groups of 25 each (Group A & B). Group A were treated using 10% Ichthammol Glycerine (IG) pack and Group B with Betamethasone Topical (0.1% w/w), + Neomycin Topical (0.5% w/w)) (Betnovate N) cream.

Pain was assessed using a ten point Numerical Rating Scale (NRS) and scored based on patients response. For edema the severity was graded based on degree of visualization of tympanic membrane into mild, moderate and severe.

NRS score and edema grading were compared on initial presentation and during subsequent follow-up between the two groups. **Results:**

There was a statistically significant (p 0.0001) decrease in pain as well as edema in patients treated with steroid-antibiotic pack when compared with 10% IG pack. The average number of follow up visits needed was also observed to be less in Group-B patients.

Conclusion:

Steroid antibiotic pack does produce rapid relief of pain and edema, decreases the number of follow-up visits needed and hence can be considered as a better alternative over 10% IG pack in the initial treatment of acute otitis externa.

Keywords: NIL

INTRODUCTION

Otitis externa is characterized by edema, erythema and an itchy discomfort of the external auditory canal (1). Its prevalence is 0.4%/year and affects 10% of general population during their life-time (2). The inflammation can be localized or diffuse with the

underlying basic pathology being a disturbance in the lipid/acid balance of the ear canal. Extreme pain is usually observed as edema causes stretch of adjacent nerve fibres and common organisms involved include staphylococcus aureus and pseudomonas. Treatment

modalities available include aural packing, analgesics 3. Immuno-compromised patients and antibiotics.

These packs are generally impregnated with either 5. Pregnant or breast-feeding mothers 10% ichthammol glycerine or steroid-antibiotic preparation. Ichthammol serves as an antiseptic agent whereas glycerine due to its hygroscopic nature acts as anti-edema agent. In addition I+G together has specific anti-staphylococcal action(3,4).

Steroid pack on the other hand is well documented to reduce pain, edema and when combined with antibiotics controls infection. Steroid-antibiotic pack is always considered superior to steroid monotherapy in treating otitis externa(5,6). This study was undertaken to compare the effect of 10% IG pack 1- Mild – Tympanic membrane (TM) completely visible versus steroid-antibiotic pack in managing acute $\frac{1}{2}$ otitis externa(AOE). 3-

III. MATERIALS AND METHODS:

A prospective randomized study was conducted on 50 patients at a tertiary care hospital, department of ENT with the diagnosis of acute otitis externa.

Inclusion Criteria:

- 1. Age 15-60 years with diagnosis of AOE
- 2. Willing to take part in the study
- 3. Unilateral ear involvement

Exclusion Criteria:

- 1. AOE with concurrent middle ear infection
- 2. Diabetes mellitus

IV. RESULTS: Table1: Age and sex distribution

4. Peri-aural abscess

Enrolled patients were randomized into two groups A & B. Pain score based on a numerical rating scale (NRS) 0-10, where 0 represents no pain and 10 worst pain was recorded on first visit before aural packing in all patients. After pain assessment microscopic ear examination done to assess the severity of edema based on the degree of visualization of tympanic membrane.

Edema grading:

Moderate – TM partly visible

Severe – TM not visible

Group A patients received 10% IG pack and group B patients received steroid antibiotic pack (Betamethasone Topical (0.1% w/w), + Neomycin Topical (0.5% w/w)) (Betnovate N) cream).

After aural packing, patients were asked to come for follow-up after 48 hours for re-assessment of pain and edema and findings recorded. If pain or edema persists, re-packing was done and patients were asked to come every 48hours until pain/edema completely subsides. Follow-up data recorded.

	n=50 (%)
<u>Sex</u> Male Female	29 (58%) 21 (42%)
<u>Age</u> (years) 15-30 31-45 26-60	30 (60%) 12 (24%) 8 (16%)

Table 2:

Follow-up visits until complete relief of pain n=50 (%)

Follow-up visits in days after aural packing	2	4	6	8	P value
Group A (10% IG pack)	2 (8%)	9 (36%)	11 (44%)	3 (12%)	
Group B (steroid-antibiotic pack)	4 (16%)	18 (72%)	3 (12%)	0	0.0001

mow-up visits until complete subsidence of edema n=50 (%)								
	Follow-up visits in days until complete subsidence	2	4	6	8	P value		
	of edema							
	Group A (10% IG pack)	1 (4%)	4 (16%)	14 (56%)	6 (24%)			
	Group B (steroid-antibiotic pack)	6 (24%)	11 (44%)	6 (24%)	2 (8%)	0.0001		

Table 3:Follow-up visits until complete subsidence of edema n=50 (%)

A total of 50 patients participated in the study of which 29 were males and 21 were females. Majority were between 15-30 years of age (Table-1). 50% patients randomized under group-A received 10% IG pack and the rest received steroid-antibiotic pack. Regarding pain status, complete relief of pain was observed much earlier in patients who received steroid-antibiotic pack and hence needed less number of follow-up visits, when compared to those who received 10% IG pack and results were found to be highly statistically significant (p value 0.0001) (Table-2).

Edema subsidence was also faster in group B patients (Table 3), which was also found to be statistically significant (p value 0.0001).

V. DISCUSSION:

AOE, an inflammatory condition of the external auditory canal, usually bacterial in origin, presents with excruciating pain and edema, requiring immediate intervention (7,8). Management included topical antibiotics, steroids, aural toilet and rarely systemic antibiotics (9). Commonly used topical agents include 10% IG pack and steroid antibiotic pack.

Many studies have compared the efficacy of 10% IG pack with steroid antibiotic pack in relieving pain and edema in AOE. Results from our study showed rapid relief of pain and edema in patients who received steroid-antibiotic pack and was also found to be statistically significant with a p-value of 0.0001.

Bhatta et al (10) and Shrestha et al (11) in their study also demonstrated similar findings wherein the steroid antibiotic pack offers earlier pain and edema relief and decreases follow-up visits that were needed.

Hornigold et al (12) and Masood et al (13) in their study found no significant difference between the two groups and hence recommended both (IG and steroidantibiotic pack) for the initial treatment of AOE.

VI. CONCLUSION:

In our study, patients who were treated with steroidantibiotic pack had faster pain relief and earlier subsidence of edema, less hospital visits than 10% IG pack with no documented adverse effects and hence recommended as the initial treatment modality in the management of AOE.

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Dr. Jayagar Prabakaran et al. International Journal of Medical Science and Current Research (IJMSCR)

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