

EFFECT OF ANTIBIOTIC-STEROID EAR PACK V/S ANTIBIOTIC-STEROID EAR DROPS FOR ACUTE OTITIS EXTERNA

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Abstract

Background: Otitis externa is a generalized condition of the skin of the external auditory canal that is characterized by edema and erythema. It is one of the commonest presentations in ENT OPD. The main complaints of the patient will be ear pain and edema. Most of the studies done in this regard have taken only use of different antibiotic-steroid combination into account, while only few have considered comparing the same drugs in two different preparations. Hence an attempt is made in this study to objectively and symptomatically compare the effectiveness of antibiotic-steroid ointment ear packing with that of antibiotic-steroid ear drops. The aim is to compare the effect of antibiotic-steroid ear pack over steroid-antibiotic ear drops in pain relief in acute otitis externa, to compare the effect of antibiotic-steroid ear pack over steroid-antibiotic ear drops in edema score in acute otitis externa. settings and design is Randomized case control study. **Materials and Methods:** Those patients who fulfill the inclusion and exclusion criteria will be enrolled and pain scoring and edema score will be divided into 2 groups. The affected ear of patients in group 1 will be packed with medicated wick (antibiotic steroid ointment). This medicated ear wick will be replaced regularly for 5 days. Those in group 2 will be receiving same antibiotic-steroid combination ear drops three times daily for 5 days. The patients will be assessed on day 0 and day 5. Pain was assessed by Numerical Rating Scale (NRS), Edema was assessed by dividing the external auditory canal (EAC) in four quadrants giving score of 25% for each on the day of presentation and subsequent visits. Statistical analysis used the study parameters will be entered in Microsoft Excel Worksheet and will be analyzed using Program R, version 3.0.0. Wilkcoxon Signed Rank Test. **Result:** Perception Both groups showed significant improvement in pain and external auditory canal edema following 5 days treatment (p-value < 0.0001, ANOVA) but however, the improvement in the scores among patients in Group 1 was significantly more than observed in Group 2. No significant adverse events were noted. **Conclusion:** On statistically analysing the scores. There is reduction in Pain with both modalities of treatment with a higher degree of reduction with antibiotic-steroid ear packing. There is reduction in edema of the external auditory canal with both modalities of treatment, but the group with antibiotic-steroid ear packing showed a higher degree of reduction in the edema score.

INTRODUCTION

Otitis externa is a generalized condition of the skin of the external auditory canal that is characterized by edema and erythema. It is a common and painful condition presenting as inflammation of outer ear canal.^[1] It may occur as diffuse or localized form of inflammation of external ear canal. Skin present in

the external auditory canal is adherent to the cartilage so edema resulting from inflammation will cause stretching of the nerve fibers which results in severe pain in the ear.^[2] Diagnosis of acute otitis externa is mainly clinical, the presenting complaints being that of severe earache, itching, discharge and hearing loss.^[3] A complete history and physical examination are required which includes evaluation of the auricle,

surrounding skin, lymph nodes and otoscopic examination.^[4]

The key physical finding of acute otitis externa is pain upon palpation of the tragus or application of traction to the pinna (which is one of the hallmark of acute otitis externa).^[5]

It is a very commonly encountered condition in day to day outpatient services. Conditions causing disturbance in the lipid/acid balance of the ear will predispose an individual to Otitis externa.^[6] The severity of pain is attributed to the disruption of the periosteal lining of the bony canal caused by the edema and inflammation.^[7] On examination, ear canal looks narrow, edematous and erythematous. Tragal tenderness will be present in acute otitis externa.

The major predisposing factors are warm humid environment, vigorous ear cleansing and swimming but only swimming has been proven as a risk factor.^[8] Commonly encountered pathogens in this condition are staphylococcal aureus, pseudomonas, anaerobes and gram negative organisms.^[9] According to Russel et al only 40% cases of otitis externa are associated with microbes.^[10]

So treatment includes not only antibiotics and analgesics systemically but also aural packing. It acts by its chemical ingredients and also mechanically by splinting action pressing the soft tissues towards the non-distended position. Traditionally these packs were impregnated with 10% Ichthammol glycerine. Ichthammol has antiseptic action while glycerine is hygroscopic in nature. The combination has a specific antistaphylococcal action.^[11,12] Steroid-antibiotic combination can serve both functions. Steroid reduces edema by its action over capillary wall tone and antibiotic controls infection.

Various studies about comparison of different antibiotics and steroid combinations have been done.^[13-18] For symptomatic control of otitis externa topical antibiotic-steroid combination therapy is superior to steroid therapy alone.^[19,20]

Acute inflammation of the external auditory canal for less than 6 weeks is called acute otitis externa, while in cases when the inflammation lasts beyond three months, the condition is called chronic otitis externa. We performed this study to observe the effectiveness of treatment for relieving pain and edema by comparing antibiotic-steroid ear pack with that of antibiotic-steroid ear drops.

MATERIALS AND METHODS

Study design: Randomized double arm prospective study

Number of Groups Studied: Two groups

Detailed description of the groups:

Group 1: Patients with Acute otitis externa, who fulfill the criteria of inclusion and exclusion are included in the study. Those enrolled patients who receives Antibiotic-steroid ear packing

Group 2: Patients with Acute otitis externa, who fulfill the criteria of inclusion and exclusion are included in the study. Those enrolled patients who receives Antibiotic-steroid ear drops

Inclusion criteria:

- Patients with acute otitis externa.
- Patients who are between the age group of 18 and 80.

Exclusion criteria:

- Those who were using ear drops in the past 4 weeks
- Those who are on any regular drugs.
- Those with otomycosis
- Pregnant women
- Those who have not given consent
- Patients below 18 years of age
- Patients above 80 years of age
- Patients with other co-existing ear disease.

Formulation of the drug used:

- Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone ophthalmic ointment.
- Neomycin and Polymyxin B Sulfates and Hydrocortisone ear drops
- Paracetamol

Dose of the drug used:

- Ointment
- Neomycin Sulphate IP 3400 units
- Polymyxin B Sulfates USP 5000 units
- Bacitracin Zinc 400 units
- Hydrocortisone IP 10 mg
- Ear drops
- Neomycin Sulphate IP 3400 units
- Polymyxin B Sulfates USP 10000 units
- Hydrocortisone IP 10 mg
- Paracetamol 650 mg tablet

Frequency of the drug used:

For Group 1 medicated pack will be placed (antibiotic steroid ointment) and it will be changed at a frequent interval of 24 hrs for five days.

For Group 2 patients antibiotic-steroid ear drops, 3 drops three times daily for five days.

Tablet Paracetamol 650 mg will be given for both group on SOS basis

Route of the drug used:

- Topical application of ear drops and ointment
- Tablet Paracetamol 650 mg orally

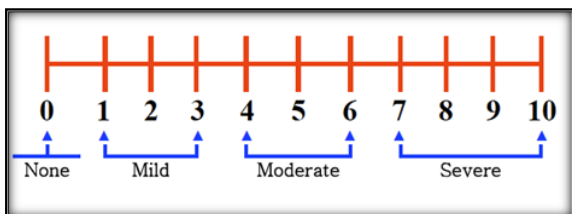
Duration of the drug used: 5 days

Parameters to be studied:

- Pain
- Edema of the external auditory canal

Method(s)/technique(s)/instrument(s)/reagent(s)/kit(s) etc used to measure the quantitative parameters along with their manufacturing source details:

Pain was assessed by Numerical Rating Scale (NRS)



Edema was assessed by dividing the external auditory canal in four quadrant giving score of 25% for each on the day of presentation and subsequent visits

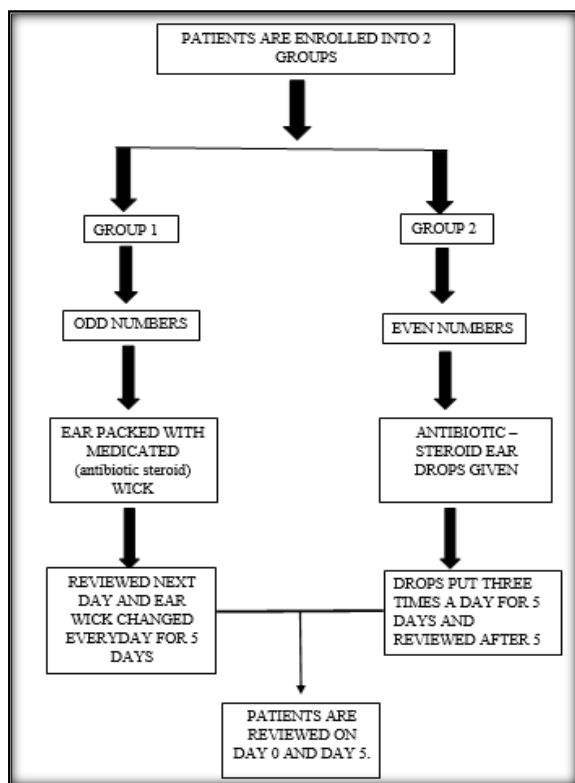
Procedure in brief:

Those patients who fulfill the inclusion and exclusion criteria will be enrolled and pain scoring and edema score will be taken. The patients will be randomized based on simple randomization (odd number and even number).

Those who are in odd number will be enrolled to Group 1 and those with even number to Group 2. Those patients in group 1's ear will be packed with medicated wick (antibiotic steroid ointment) and will be asked to review on the next day. This medicated ear wick will be replaced regularly for 5 days.

Those in group 2 will be receiving antibiotic-steroid ear drops and they will be asked to put the ear drops three times daily for 5 days and asked to come next day for review. The patients will be assessed on day 0 and day 5.

The Principal Investigator will reserve the right to initiate rescue therapy at any treatment visit where the disease state worsens such that either the subject requests additional therapy and/or the Principal Investigator feels that additional therapy is needed to protect the overall health of the subject/ for the treatment of the prevailing condition.



Statistical methods of analysis: The study parameters will be entered in Microsoft Excel Worksheet and will be analyzed using Wilcoxon signed ranks test.

RESULTS

In this prospective study a total of 85 patients were studied out of which 43 were assigned to Group I and 42 in Group II. There was a lost follow up of 3 patients who were excluded from the study. Patients of age group 19 to 74 years were included in the study with mean age of 43.07.

Group I patients were receiving antibiotic steroid ear packing and those in Group II were receiving antibiotic steroid ear drops. 49% & 48% were males in group I & group II respectively, where as females were 51% & 52% respectively in group I & II.

FREQUENCY TABLES:

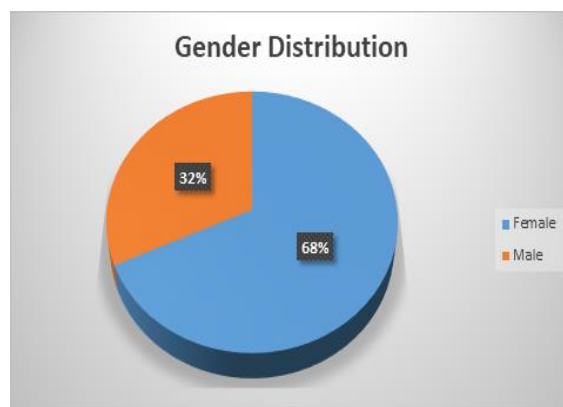


Figure 1: Distribution of patients according to sex

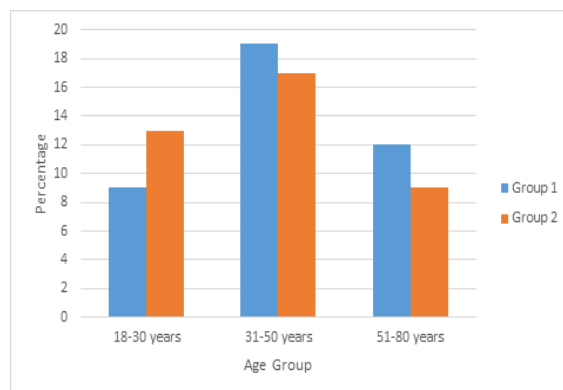


Figure 2: Distribution of patients according to age in group-I and group-II

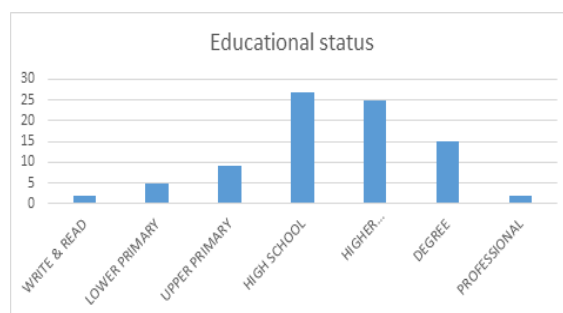


Figure 3: Distribution of patients based on education

Table 1: Distribution of patients according to group (ear wick and ear drops)

	Frequency	Percentage
Group I (Ear wick)	41	48.2
Group II (Ear drops)	44	51.8
Total	85	100.0

Table 2: Pre and post treatment edema score

Edema score	Pre-treatment frequency	Post-treatment frequency
1	4	38
2	6	33
3	41	13
4	34	1
Total	85	85

Table 3: PRE AND POST TREATMENT PAIN SCORE

Pain score	Pre treatment frequency	Post treatment frequency
0		42
1		28
2		11
3	2	2
4	9	1
5	21	1
6	24	
7	10	
8	11	
9	6	
10	2	
Total	85	85

Table 4: wilcoxon signed rank test for the whole study group

		N	MEAN RANK
POST TREATMENT EDEMA SCORE – PRE TREATMENT EDEMA SCORE	NEGATIVE RANK	83a	42
	POSITIVE RANK	0b	0
	TIES OR ZERO	2c	
POST TREATMENT PAIN SCORE – PRE TREATMENT PAIN SCORE	NEGATIVE RANK	85d	43
	POSITIVE RANK	0e	0
	TIES OR ZERO	0f	

- Post treatment edema score < Pre treatment edema score
- Post treatment edema score > Pre treatment edema score
- Post treatment edema score = Pre treatment edema score
- Post treatment pain score < Pre treatment pain score
- Post treatment pain score > Pre treatment pain score
- Post treatment pain score > Pre treatment pain score

Wilcoxon signed rank test was done based on positive ranks and it was statistically significant $p < 0.0005$ which showed both the treatment modalities were beneficial for the patient and they showed significant clinical improvement in symptoms and disease

NPar test was done on each groups:

Table 5: Mann – Whitney Test

	GROUP	N	MEAN RANK
PRE TREATMENT EDEMA SCORE	1	41	46.66
	2	44	39.59
POST TREATMENT EDEMA SCORE	1	41	51.82
	2	44	34.78
PRE TREATMENT PAIN SCORE	1	41	42.43
	2	44	43.53
POST TREATMENT PAIN SCORE	1	41	49.12
	2	44	37.30

Mann Whitney U test showed a p value < 0.05 for both edema and pain score which shows highly significant difference in post edema and pain score of subjects in group 1 and group 2.

NPar TESTS

WILCOXON SIGNED RANKS TEST

Table 6: group 1 (ear wick)

GROUP 1		N	MEAN RANK	Z SCORE
POST TREATMENT EDEMA SCORE – PRE TREATMENT EDEMA SCORE	NEGATIVE RANK	39a	20	-5.528
	POSSITIVE RANK	0b	0	
POST TREATMENT PAIN SCORE – PRE TREATMENT PAIN SCORE	NEGATIVE RANK	41c	21	-5.622
	POSSITIVE RANK	0d	0	

- Post treatment edema score < Pre treatment edema score
- Post treatment edema score > Pre treatment edema score
- Post treatment pain score < Pre treatment pain score
- Post treatment pain score > Pre treatment pain score

Table 7: GROUP 2 (ear drops)

GROUP 2		N	MEAN RANK	Z SCORE
POST TREATMENT EDEMA SCORE – PRE TREATMENT EDEMA SCORE	NEGATIVE RANK	44a	22	-5.872
	POSSITIVE RANK	0b	0	
POST TREATMENT PAIN SCORE – PRE TREATMENT PAIN SCORE	NEGATIVE RANK	44c	22.50	-5.821
	POSSITIVE RANK	0d	0	

- Post treatment edema score < Pre treatment edema score
- Post treatment edema score > Pre treatment edema score
- Post treatment pain score < Pre treatment pain score
- Post treatment pain score > Pre treatment pain score

Wilcoxon signed rank test was done and based on negative ranks it showed clinical improvement in patients in group 1 more than group 2. Test statistics showed that the p value <0.0005 thus making it statistically significant.

Thus on statistically analysing the scores using Wilcoxon signed ranks test:

- There is reduction in Pain with both modalities of treatment with a higher degree of reduction with antibiotic-steroid ear packing
- There is reduction in edema of the EAC with both modalities of treatment, but the group with antibiotic-steroid ear packing showed a higher degree of reduction in the edema score

DISCUSSION

Otitis externa is one of the most common otolaryngological emergency which results in disturbance of daily life activities as it causes severe pain. So the treatment basically aims at relieving the pain and edema with clearing the infection. Topical antibiotics with or without steroid and analgesics are used mainly. Topical steroid antibiotic combination therapy is considered more superior to topical steroid therapy given alone.^[19] Topical treatment is regarded as treatment of choice in acute otitis externa.^[21] Topical antibiotics works very effectively in acute otitis externa.^[16] The great advantage of using topical antibacterial drugs is that they achieve a higher therapeutic concentration at the site of infection than when administered orally, but also to a lesser extent lead to drug resistance. Also complications reported with topical treatment are rare. Steroid drug like hydrocortisone when applied topically reduce swelling and have anti-inflammatory properties, thus relieving pain. The use of combined preparations, i.e. containing an antibiotic and steroid, appears to be the optimal solution due to their properties.^[22-23]

In our study group the topical antibiotic used was Neomycin, Polymyxin B and Bacitracin combination with steroid. In our study for the treatment of AOE, we tried to compare the effectiveness of steroid-antibiotic ear pack versus ear drops. The use of an ointment pack instead of ear drops to manage acute otitis externa could be of greater advantage for the following two reasons. One being the occlusive effect of an ointment will help to increase the humidity in the affected ear.^[24] Secondly fewer hypersensitivity reactions will be seen in ointment packs due to no preservatives, whereas eardrops usually contain preservatives that may cause allergic reactions. Ear drops if used for a prolonged period in perforated tympanic membrane can permeate to inner ear and be ototoxic. So, aural packing which is soaked with topical preparation of antibiotic steroid could be used to decrease pain and edema in perforated tympanic membrane cases.

Also it is difficult for ear drops to penetrate through an edematous ear canal, which can be overcome by the insertion of an ear wick.^[25] Thus insertion of an ear wick is better therapy to treat otitis externa than to instill ear drops into the ear.^[26]

In this study we found out that there was complete reduction in the pain scores by the fifth day in group 1 patients compared to group 2 patients.

Edema reduction was also compared in our study between the two groups that is steroid antibiotic ear wick versus drops. We found out that there was complete resolution of edema by 5th day in steroid antibiotic ear wick group compared to the ear drops group.

Thus it is seen that in our study more effective relief of pain and control of edema was seen in patients treated with steroid antibiotic ear wick than steroid antibiotic ear drops.

There are few studies which compared the single topical agent with topical and oral antibiotic. Whereas we performed the studies using same

antibiotic steroid ear drop and ointment combination with same analgesic (paracetamol) in all included patients to avoid bias.

In a randomized control trial conducted by Masood et al,^[27] steroid pack was used and statistically significant improvement in pain parameters was found when compared with 10% ichthammol glycerine pack. Similar prospective study was performed by Hornigold et al,^[28] which used topical steroid ear drops but failed to show any difference. Study performed by Bhatt et al,^[29] showed statistically significant decrease in pain and number of visits in steroid-antibiotic group as compared to 10% ichthammol glycerine pack.

So in our study, there was statistically significant reduction in pain and edema in steroid-antibiotic ear wick group as compared to ear drop group which is similar to the comparison studies performed by Masood et al. and Bhatta et al. We did not find any side effects so far in the both groups

CONCLUSION

Since the control of pain and edema is much better in steroid-antibiotic ear packing group compared to the steroid antibiotic ear drop group, so it is more advantageous to use steroid-antibiotic pack for effective treatment and control of acute otitis externa cases.

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