Section: ENT & HNS

Original Research Article

THERAPEUTIC COMPARISON OF HYDROCORTISONE–NEOSPORIN AND HYDROCORTISONE–ACETIC ACID EAR DROPS IN PATIENTS WITH OTITIS EXTERNA

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ABSTRACT

Background: Otitis externa is defined as a diffuse inflammation of the skin of the external auditory canal with or without involvement of the pinna and the tympanic membrane. It is common with a prevalence rate of 1% of ENT practice. There are many evidence-based treatment guidelines leading to variation in its management. **Aim & Objectives:** The aim of this study is to compare the efficacy of Group A (hydrocortisone-Neosporin) eardrops in patients with otitis externa with Group B (hydrocortisone-acetic acid) ear drops. **Materials and Methods:** A total of 100 patients were divided into two treatment groups with AOE, according to severity of signs and symptoms. Clinical response to treatment is assessed by resolution of infection and Briton grading system. By calculating P-value, Standard statistical analysis is performed. Treatment protocols showing $P<0.05$ is considered as significant. **Result:** On day 7, 48% of participants in Group A and 47.92% in Group B were cured. By the end of 14th day, Group A, 81.63% of participants were cured, while in Group B, it was 77.08%. After 21 days, 85.71% of participants in Group A and 89.58% were cured. **Conclusion:** Local treatment (external auditory meatus) plays a pivotal role in controlling, preventing and recurrence of AOE. The results of this study clearly indicate that there was no significant difference in treatment results between the two treatment groups. Both treatments were safe and effective in treating the signs and symptoms of AOE as proved by the assessments performed throughout the treatment period.

INTRODUCTION

Otitis externa is an infection of the cutis and sub-cutis of the external auditory canal possibly involving the ear drum and pinna as well. Otitis externa is typically associated with pain, swelling and erythema of the external auditory canal and if systemic symptoms such as fever and malaise occur in the context of otitis externa, they may suggest more severe infection or spread beyond the confines of the external ear canal.[1]

Multiple agents are being used for treatment of otitis externa as multiple studies have been done to evaluate the effectiveness of different agents.

A systemic review comparing topical antimicrobial drugs to placebo in otitis externa was done which shows improved clinical efficacy with topical antimicrobial drugs. Topical antimicrobials are effective in relieving symptoms as well as eliminating the causative pathogens responsible for the infection.[5]

Cochrane meta-analysis of randomized controlled trials provides equal efficacy of antiseptic agents and antibiotics.[4]

Combination of topical drugs containing an aminoglycoside (neomycin), polymyxin B, and a corticosteroid were once the only antibiotic treatments for otitis externa approved by the US Food and Drug Administration for otitis externa.[6]

Off label use of ophthalmic preparations containing corticosteroids or aminoglycosides like gentamicin or tobramycin are being used for the treatment of otitis externa. This suggests a versatile approach in managing the condition, albeit within the bounds of off-label usage and individual patient considerations.[7,8]

As there are different regimes for treatment of otitis externa, topical antibiotics and corticosteroid is one of the most used combinations in otitis externa. Neomycin, Polymyxin B are being the most effective antibiotics. Role of Acetic acid in otitis externa was not seen in many studies. Acid preparations like 2%

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acetic acid work by lowering the pH of the affected area. This acidic environment inhibits bacterial growth, as many bacteria thrive in a neutral pH environment. By creating an inhospitable environment for bacteria, acid preparations can help prevent the spread and recurrence of infection.[2,3]

MATERIALS AND METHODS

Study Design

Hospital based prospective observational study was conducted in Department of ENT & HNS, Muzaffarnagar Medical College & Hospital, Muzaffarnagar, Uttar Pradesh India for a period of 18 months. A total of 100 patients visiting the outpatient department were taken up for the study and randomized into two groups: Group A and Group B alternatively. Group A Hydrocortisone-Neosporin ear drops while Group B patients received Hydrocortisone-Acetic acid ear drops. The patients were called for follow up after 7,14 & 21 days to assess the improvement. Every case was assessed for improvement on the basis of Briton grading system. A decrease in the clinical signs and symptoms was observed.

Statistical Data Analysis & Software

Suitable statistical significance test that will be used for statistical analysis along with SPSS version17/20 software. The P-Value < 0.05 will be considered for statistical significance.

Inclusion Criteria

- Age 12-70 years
- Patients of both sexes
- Patient with no severe co-morbidities (Diabetes, Tuberculosis, HIV, Hypertension).

Exclusion Criteria

- Patients who are refusing to give an informed written consent.
- Pregnant and breast-feeding women.
- A Furuncle in the EAC.
- AOM
- Tympanic membrane Perforation
- Past treatment of Otitis Externa (Within 30days of the treatment).
- Patients allergic to any of the study drugs.
- Known case of immune-deficiency like Diabetes mellitus, tuberculosis, HIV etc.
- Age < 12years

Brighton grading system: Quantify the severity of otitis externa:[9]

- Grade 1: Localized canal inflammation with mild pain, No hearing loss and tympanic membrane visible.
- Grade II: Debris in ear canal (Not completely occluded) and erythematous ear canal, tympanic membrane may be partially obscured
- Grade III: The ear canal is edematous, erythematous and occluded (Often completely closed) and the tympanic membrane cannot be seen.

Grade IV: The tympanic membrane is obscured, perichondritis and pinna cellulitis and signs of systemic involvement.[9]

RESULTS

The distribution of participants across different age groups in two treatment groups for otitis externa: Group A, receiving Hydrocortisone- Neosporin Eardrops, and Group B, receiving Hydrocortisone-Acetic acid Eardrops. Group A and B consist of 50 participants each with middle age group with the mean age is 32.16 years in group A and 36.44 years in group B. In Group A: 48% of participants are male and 52% are female, while in Group B: 46% are male and 54% are female.

Table 1: Presents data on tympanic membrane bulging, erythema, middle ear effusion (BGS) Grading within two treatment groups

BGS		Group A		Group B		P value
		N	%	N	%	
Day 0	Normal	0	0.00	0	0.00	-
	Abnormal	50	100.00	50	100.00	
Day 7	Normal	24	48.00	23	47.92	0.993
	Abnormal	26	52.00	25	52.08	
Day 14	Normal	40	81.63	37	77.08	0.579
	Abnormal	9	18.37	11	22.92	
Day 21	Normal	42	85.71	43	89.58	0.562
	Abnormal	7	14.29	5	10.42	

At the beginning of study Day 0, all participants in both Group A and Group B had abnormal BGS findings.

On Day 7, there was decrease in abnormal findings and 48% in Group A and 47.92% in Group B shows improvement.

On Day 21, the proportion of normal findings slightly increased in both groups, with 85.71% of participants in Group A and 89.58% in Group B showing normal BGS findings.

The difference between the two groups remained statistically insignificant as p>0.05.

DISCUSSION

Present study includes 100 patients of Acute otitis externa, who attended OPD of ENT &HNS of Muzaffarnagar Medical College.

These patients were examined, and the findings were recorded on pre-filled forms and analyzed. More than

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95% of patients completed the treatment with 1 patient withdrawal due to adverse effects and 2 patients were LTFU.

In Present study in two treatment groups for otitis externa: Group A: receiving Hydrocortisone-Neosporin Eardrops, and Group B: receiving Hydrocortisone- Acetic acid Eardrops. Group A consists of 50 participants, with the highest representation in the 21-30 and 31-40 age groups, while Group B also comprises 50 participants, with a more evenly distributed representation across age groups. In Group A, the mean age is 32.16 years. In Group B, mean age is 36.44 years. In Group A and Group B, the p-value of 0.142 indicates that there is no statistically significant difference in age between two groups. This suggests that age was not a significant confounding factor in comparing the outcomes of the two treatment groups in the study. In a similar study done by Frank AM Balen et al in 2003, the mean age of patients in Group A (Steroid-Antibiotic) was 41.1 and 48.7 in Group B (Steroid-Acetic acid).[10]

In a study done by E. Abelardo in March 2008, Mean age was 52 in Betamethasone group and 49 in Betamethasone-neomycin group.[11] The decrease in mean age in our study might be due to selected population group of adolescent and adult population.

In our study in Group A: 48% are male and 52% are female while in Group B: 46% are male and 54% are female. In a study done by B.L. Shrestha in 2010, out of 82 patients 40 were Male; 42 were Female.[12] In a study done by Peter S. Ronald in 2007, out of 206 patients, 84 were Male; 122 were Female.[13] So our study is an agreement with other studies conducted by Shrestha and Ronald that AOE affects females more than the males.

In the present study, none of the participants in Group A reported a burning sensation, while 2% of participants in Group B experienced it. However, this difference was not statistically significant (p=1.000). Similarly, for itching, none of the participants in Group A reported it, while 2% in Group B did, with no significant difference observed (p=1.000). In 2016, a study by Amani S. et al,[14] reported a higher incidence of side effects in the group treated with polymxin NH Ear drops (Group B) than patients treating with Boric acid (Group A).[14]

Itching was more on the first(p=0.011) and third day of examination(p=0.007) and swelling was more on the third and seventh day of examination in Group B.

In Present study at the beginning of the study (Day 0), all participants in both Group A and Group B had abnormal BGS findings. After 7 days follow up, 48% were cured in Group A and 47.92% were cured in Group B and cure rate was found statistically insignificant. After 21 days follow up,85.71% in Group A and 89.58% were cured and cure rate was statistically found insignificant even after 21 days as p-value is >0.05. This shows that both drugs are equally effective and efficient in treating patients of otitis externa. A study done by Mosges et al,[15] in 2007 showed the efficacy of Polymyxin B sulphate + neomycin + hydrocortisone was better than that of bacitracin alone and cured AOE patients within 10 days of topical therapy.[15] Similarly, Shrestha et al,[16] revealed that steroid antibiotics (neomycin and betamethasone valerate) produced statistically significant reduction in pain and edema as compared to 10% ichthammol glycerin on 7th day. The finding of these studies supports the result obtained in the present study that polymyxin+ neomycin + hydrocortisone is significantly effective than other antimicrobials. Similarly, multiple studies have evaluated the efficacy of Polymyxin B + Neomycin to other antimicrobials, with mixed findings. Mosges et al,[17] conducted a study that compared the polymyxin B + neomycin + gramicidin (PS) group to glycerol (non-pharmacologic treatment). This study proved that PS was substantially more effective than glycerol. Tempera et al,[17] compared polymyxin B + neomycin to the ciprofloxacin group. The study found that combining neomycin and polymyxin B yields the best results in the shortest timeframe. These studies confirm the current study's results that polymyxin B + neomycin is more effective in AOE than other antimicrobials".[17]

CONCLUSION

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