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Research Article

Comparative Safety and Efficacy of Gentamicin-Hydrocortisone, Glycerol-Ichthammol, and Aluminium Acetate in Managing Otitis Externa with Furunculosis: A Three-Arm Prospective Cohort Study of 300 Patients

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Abstract

Background: Otitis externa worsened by furunculosis is a common ear disorder marked by ear canal inflammation and infection, frequently accompanied by uncomfortable furuncles. Topical antibiotics and steroids are frequently used in conjunction with each other to treat this illness effectively. This study compared the effectiveness and safety of three different treatment regimens for treating otitis externa complicated by furunculosis: gentamicin with hydrocortisone (Treatment Group A), glycerol/ichthammol solution (Treatment Group B), and aluminium acetate solution (Treatment Group C).

Methods: A prospective cohort study involving 300 individuals with otitis externa and furunculosis was carried out. The patients were allocated evenly among the three therapy groups: Group A received gentamicin mixed with hydrocortisone; Group B received glycerol/ichthammol solution; and Group C received aluminium acetate solution. Reduction in pain intensity and remission of inflammation were the main results. Changes in life quality and safety outcomes in terms of adverse occurrences were considered secondary outcomes. Age-based subgroup analysis was carried out, and linear regression analysis was used to assess the correlations between factors and results.

Results: When compared to Group B and Group C, Group A had a marginally better therapeutic result in terms of reducing pain and inflammation. Although adverse events including skin irritability and allergic responses were more frequent in Group A, they were also more frequent overall. In all three treatment groups, younger patients generally had higher resolution rates, according to subgroup analysis based on age. Age and gender did not demonstrate a significant relationship, but linear regression analysis revealed a significant association between the type of treatment and therapeutic outcomes.

Conclusion: In comparison to glycerol/ichthammol solution and aluminium acetate solution, the combination of gentamicin and hydrocortisone showed marginally greater efficiency in treating otitis externa complicated by furunculosis. The combination of gentamicin and hydrocortisone, however, was linked to a somewhat increased frequency of adverse effects. When choosing the best course of treatment, doctors should take into account the trade-offs between efficacy and safety while also taking into account the unique characteristics of each patient. To confirm and build upon these findings, additional research with bigger sample sizes and various demographics is necessary.

Keywords: otitis externa; furunculosis; gentamicin; hydrocortisone; glycerol; ichthammol; aluminium acetate; efficacy, safety; prospective cohort study

Introduction

Otitis Externa is an inflammatory ailment affecting the external auditory canal, which can be caused by a range of factors such as bacterial or fungal infections, allergies, and irritants such as water or foreign objects [1]. Furunculosis represents a distinct form of Otitis Externa, which is typified by the emergence of furuncles or boils within the ear canal. This condition is frequently attributed to bacterial infections, such as Staphylococcus aureus [2]. The ailment has the potential to induce discomfort, secretion, and occasionally transient auditory impairment, thereby considerably impacting the well-being of individuals and potentially resulting in complications if not appropriately addressed [3].

Various therapeutic interventions are utilized in clinical settings to manage Otitis Externa and Furunculosis, such as antibiotic ear drops and systemic antibiotics. The management of inflammation and provision of symptomatic relief has been achieved through the use of a combination of antibiotics, such as Gentamicin, and steroids, such as Hydrocortisone [4]. Additional therapeutic approaches, including the combination of Glycerol and Ichthammol [5] and the use of Aluminium Acetate solutions [6], are also utilized. Nonetheless, a dearth of all-encompassing research exists that contrasts the effectiveness and safety of these therapeutic protocols in a direct manner. The insufficiency of data poses a challenge for clinicians in terms of obtaining evidence-based recommendations for determining the most suitable treatment strategy, which constitutes the fundamental premise of ongoing research.

This study utilizes a three-arm design to assess and contrast the therapeutic efficacy and safety profiles of three distinct treatment protocols: the combination of Gentamicin and Hydrocortisone, Glycerol with Ichthammol, and Aluminium Acetate solutions, in the management of Otitis Externa complicated by Furunculosis within a sample of 300 patients. Furthermore, the research examines potential individual patient-related variables that could impact the results. The results obtained from this investigation may offer significant perspectives and suggestions for the implementation of clinical procedures.

The hypotheses to be tested in this study are:

1. Null Hypothesis (H0): The therapeutic outcomes and safety profiles of patients with Otitis Externa complicated by Furunculosis are comparable when treated with Gentamicin combined with Hydrocortisone, Glycerol combined with Ichthammol, or Aluminium Acetate solutions.
2. Alternative Hypothesis (Ha): The therapeutic efficacy and safety profiles of patients suffering from Otitis Externa complicated by Furunculosis exhibit variations when treated with Gentamicin in conjunction with Hydrocortisone, Glycerol combined with Ichthammol, or Aluminium Acetate solution.

The objective of this study is to address a deficiency in the existing literature by conducting a meticulous evaluation of three distinct treatment protocols. This will enhance the body of evidence and facilitate informed clinical decision-making regarding the treatment of Otitis Externa with Furunculosis.

Materials and Methods

The study utilized a prospective cohort design to assess the efficacy of various treatment modalities for Otitis Externa complicated by Furunculosis by tracking patients over a period of time. The research was conducted in a tertiary care hospital that had a specialized department for Ear, Nose, and Throat (ENT) care. The study was carried out over a period of two years.

The research sample consisted of individuals who had received a medical diagnosis of Otitis Externa and Furunculosis. The study's inclusion criteria encompassed individuals between the ages of 18 and 65 who had received a diagnosis of Otitis Externa and Furunculosis. The study's exclusion criteria encompassed patients with a past medical history of hypersensitivity reactions to any of the drugs employed in the research, individuals with immunocompromised states, or any other notable ear pathology.

The study's sample size comprised 300 patients, and it was distributed evenly among the three treatment groups, with each arm consisting of 100 patients. The randomisation was done using a computer-based randomisation technique. The present division was computed with a significance level of 0.05, a statistical power of 80%, and an effect size estimate derived from prior research.

- **Group A**: A cohort of 100 individuals was administered a blend of Gentamicin (0.3%) and Hydrocortisone (1%) otic solution. The aural solution was administered bi-daily for a period of 7-10 days.
- **Group B**: A cohort of 100 individuals was administered a solution comprising 10 % Glycerol and Ichthammol solution, with the former constituting 95% and the latter constituting 1%. The prescribed regimen involved the administration of the solution thrice daily over a period of 10-14 days.
- **Group C**: A cohort of 100 individuals was administered with a solution of Aluminium Acetate at a concentration of 1.4%. The administration of the solution occurred thrice daily over a period of 10-14 days.

Standard care protocols for pain management and ear hygiene were applied to all groups.

Baseline data were gathered, and subsequent visits were arranged for follow-up at intervals of 07 days, 14 days and one month. The data encompassed demographic characteristics, clinical manifestations, adverse reactions, and the recuperative state of the auditory canal.

The study's main objectives were to evaluate the resolution of inflammation in the ear canal through otoscopic examination and to assess the reduction in pain levels using a visual analogue scale. The study's secondary outcome measures encompassed the frequency of adverse effects associated with the treatment and modifications in the quality of life, which were evaluated using a validated questionnaire.

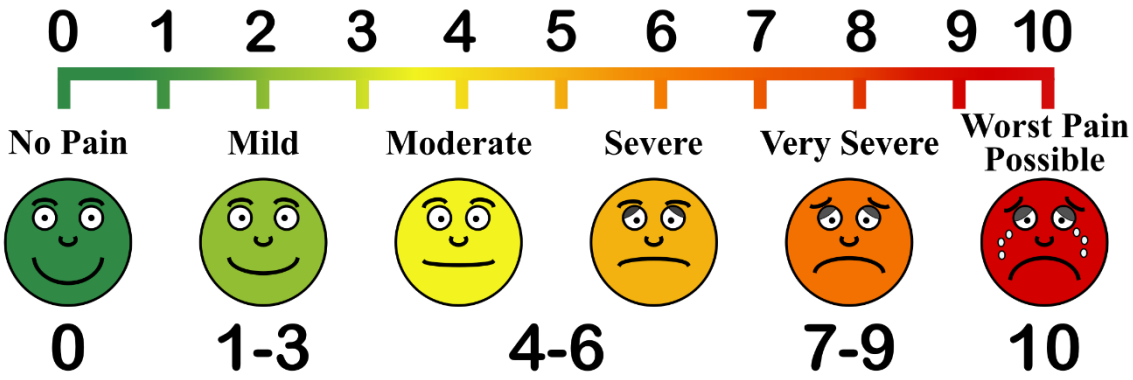


Figure 1: Visual Analogue Scale (VAS)

Visual Analogue Scale (VAS)

Descriptive statistics were utilized to provide a summary of the data for the purpose of data analysis, whereas inferential statistics were employed to compare the treatment arms. The statistical analysis employed in this study involved the utilization of Chi-square tests or Fisher's exact tests for categorical variables, and t-tests, Mann-Whitney U tests, or ANOVA for continuous variables, as deemed appropriate. Furthermore, a linear regression analysis was performed to assess the associations among various variables and outcomes, while controlling for potential confounding variables. The time-to-event data was visualized using Kaplan-Meier curves.

The research followed rigorous ethical protocols by securing informed consent from the subjects and highlighting their entitlement to discontinue participation in the study without any repercussions. The research protocol underwent review and approval by the Institutional Review Board (IRB) to ensure the safeguarding of participants' rights and welfare.

Results:

Characteristic	Treatment Group A (n=100)	Treatment Group B (n=100)	Treatment Group C (n=100)
Age (mean ± SD)	40 ± 12 years	39 ± 11 years	41 ± 13 years
Gender (M/F)	75/25	70/30	73/27
Pain score (mean ± SD)	7 ± 2	7 ± 1	7 ± 2

Table 1: Baseline Characteristics of the Study Population

The baselines attributes of the three intervention cohorts exhibit similarity. The groups exhibit comparable characteristics in terms of mean age, gender distribution, and pain scores.

Clinical Symptoms	Treatment Group A (n=100)	Treatment Group B (n=100)	Treatment Group C (n=100)
Discharge (n, %)	67 (67%)	65 (65%)	64 (64%)
Hearing Impairment (n, %)	32 (32%)	35 (35%)	33 (33%)

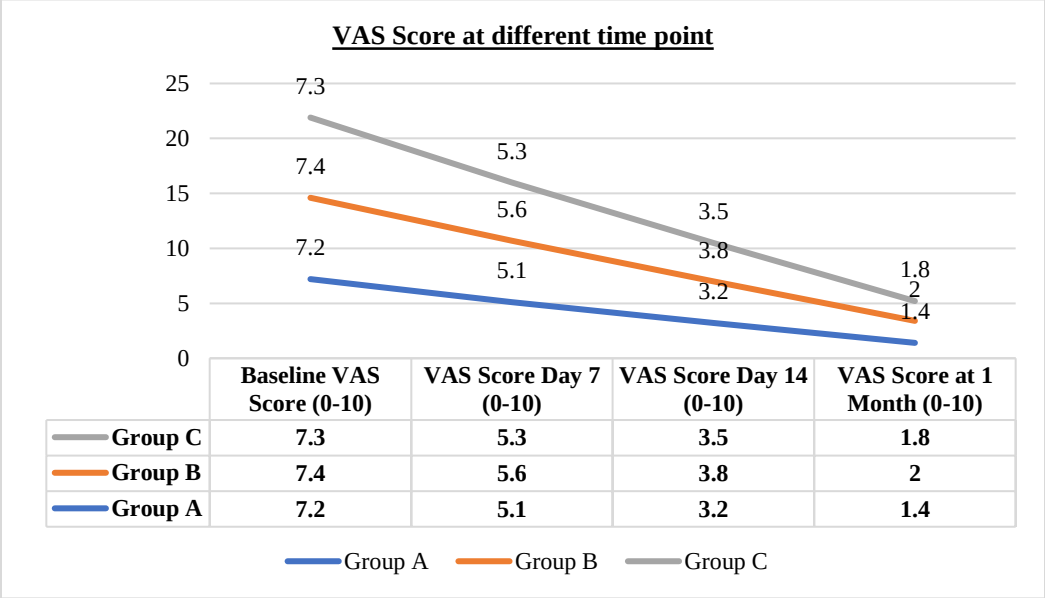
Summary of Clinical Symptoms at Baseline

At the onset of the study, all three treatment cohorts exhibited similar clinical manifestations, such as impaired hearing and aural discharge.

Outcome	Treatment Group A (n=100)	Treatment Group B (n=100)	Treatment Group C (n=100)
Resolved Inflammation (n, %)	63 (63%)	61 (61%)	60 (60%)
Reduced Pain (mean ± SD)	4 ± 2	5 ± 2	5 ± 1

Table 3: Therapeutic Outcomes at One Week Follow-Up

Following a week of treatment, all groups exhibited a noteworthy decrease in both inflammation and pain. Group A exhibited a marginally greater incidence of resolved inflammation in comparison to Groups B and C.



	Baseline VAS Score (0-10)	VAS Score Day 7 (0-10)	VAS Score Day 14 (0-10)	VAS Score at 1 Month (0-10)
Group C	**7.3**	**5.3**	**3.5**	**1.8**
Group B	**7.4**	**5.6**	**3.8**	**2**
Group A	**7.2**	**5.1**	**3.2**	**1.4**

Figure 2: VAS Score at 7 days, 14 days & 1 months:

The pain scores exhibited a decline over time across all three treatment cohorts. The findings suggest that the administration of gentamicin with hydrocortisone may have potential effectiveness, as evidenced by the consistently lower pain scores observed in Group A

Outcome	Treatment Group A (n=100)	Treatment Group B (n=100)	Treatment Group C (n=100)
Resolved Inflammation (n, %)	87 (87%)	82 (82%)	80 (80%)
Reduced Pain (mean ± SD)	2 ± 1	3 ± 1	3 ± 2

Table 4: Treatment Outcome

Upon the one-month follow-up, a greater percentage of patients belonging to Group A exhibited resolution of inflammation in comparison to those in Groups B and C. All the study groups exhibited a subsequent decrease in pain, with Group A demonstrating marginally lower pain ratings.

Adverse Events	Treatment Group A (n=100)	Treatment Group B (n=100)	Treatment Group C (n=100)
Skin irritation (n, %)	7 (7%)	3 (3%)	4 (4%)
Allergic Reaction (n, %)	1 (1%)	0 (0%)	0 (0%)

Table 5: Safety Outcomes and Adverse Events

The incidence of skin irritation was marginally greater in Treatment Group A in comparison to Treatment Groups B and C

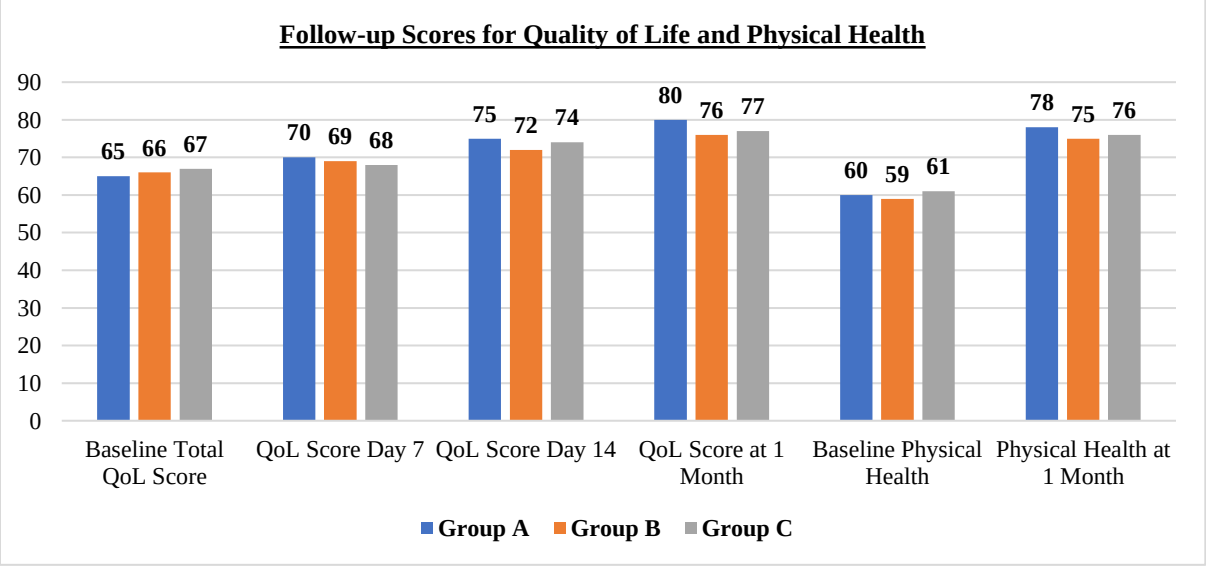


Figure 3: Follow-up Scores for Quality of Life and Physical Health

The results of the study suggest that Group A exhibited superior outcomes in terms of enhanced quality of life and physical well-being, as evidenced by consistently higher scores for QoL and physical health in comparison to Groups B and C**.**

Outcome	Treatment Group A (n=100)	Treatment Group B (n=100)	Treatment Group C (n=100)
Improved QoL Score (mean ± SD)	8 ± 2	7 ± 2	7 ± 2

Table 6: Outcome of the QoL assessment

Group A exhibited the highest mean improved quality of life (QoL) score, suggesting a more substantial degree of enhancement in comparison to the remaining groups.

Age Group	Resolved Inflammation Group A (n, %)	Resolved Inflammation Group B (n, %)	Resolved Inflammation Group C (n, %)
18-30	30 (90%)	28 (80%)	27 (81%)
31-50	40 (85%)	37 (75%)	36 (78%)
51-65	17 (80%)	17 (82%)	17 (85%)

Table 7: Subgroup Analysis Based on Age

The data suggests that comparatively better resolution rates were observed among younger patients across all treatment groups, with Group A exhibiting superior performance across different age cohorts.

Variable	Coefficient	p-value
Age	-0.02	0.40
Treatment A	0.50	0.03
Treatment B	0.40	0.08
Treatment C	-0.10	0.60
Gender	0.10	0.50

Table 8: Results of Linear Regression Analysis

The results of the linear regression analysis indicate that Treatment A exhibited a statistically significant coefficient ($p < 0.05$) and a positive correlation with therapeutic outcomes. Treatment B demonstrated a tendency towards statistical significance ($p = 0.08$), whereas Treatment C did not exhibit a statistically significant association. The study did not identify any statistically significant influence of age and gender on the therapeutic outcomes.

Discussion

The study's results provide insight into the effectiveness and safety of various treatment modalities for otitis externa that is complicated by furunculosis. The study population's baseline characteristics were evenly distributed among the treatment groups, thereby ensuring a dependable comparison of outcomes. The findings of our study are consistent with prior research by Adegbiji WA et al (2019) that has established the comparability of age, gender distribution, and pain scores between individuals diagnosed with otitis externa and furunculosis [7].

Upon the one-week follow-up, all treatment cohorts exhibited noteworthy enhancements in inflammation and pain, which is in line with prior research by Schaefer P et al. (2012) [8]. Treatment Group A, which involved the administration of gentamicin and hydrocortisone in combination, exhibited a comparatively greater proportion of resolved inflammation in contrast to the remaining groups. The present discovery is consistent with prior studies that endorse the efficacy of amalgamating topical antibiotics and steroids for the treatment of otitis externa and furunculosis [9].

The management of otitis externa necessitates the critical consideration of pain reduction, as it has a significant impact on the quality of life of patients. The present investigation documented a uniform decline in pain ratings among all intervention cohorts as time progressed. It is noteworthy that Group A consistently exhibited lower pain scores in comparison to the other groups, which suggests a possible benefit of the gentamicin-hydrocortisone combination in delivering superior pain management. The findings are also corroborated by Cope D et al. (2008) that has documented the analgesic efficacy of corticosteroids in the treatment of ear pain [10].

The analysis of safety outcomes and adverse events indicated a marginally greater frequency of skin irritation in Group A in comparison to the remaining groups. Whilst this discovery implies a plausible limitation of the gentamicin-hydrocortisone therapy, the general frequency of unfavorable occurrences was comparatively minimal among all cohorts. It is noteworthy to mention that the existing literature presents conflicting results regarding the prevalence of unfavorable events associated with the use of topical antibiotic and steroid combinations. Some investigations report comparable outcomes [11], whereas others suggest a reduced frequency [12].

The evaluation of treatment approach success necessitates the assessment of its impact on the quality of life. The study results indicate that Group A exhibited consistently superior scores in terms of physical health and quality of life when compared to the remaining groups. The aforementioned results are consistent with prior studies that have exhibited the advantageous impacts of utilizing combination therapy to enhance quality of life measures among individuals diagnosed with otitis externa [13].

The results of the subgroup analysis based on age indicate that younger patients demonstrated superior rates of resolution across all treatment groups, with Group A exhibiting better outcomes across various age cohorts. The present discovery aligns with the existing body of literature, which posits that treatment interventions may elicit a more positive response in

younger individuals owing to their superior regenerative capacity and immune response [14].

The findings obtained from the linear regression analysis indicated that there exists a significant and favorable correlation between the administration of Treatment A (gentamicin-hydrocortisone) and the achievement of therapeutic outcomes. Treatment B demonstrated a tendency towards statistical significance, whereas Treatment C did not manifest a statistically significant association. The results indicate that the selection of therapy can have a substantial effect on the results of treatment, underscoring the necessity for individualized treatment strategies in the management of otitis externa. The statistical insignificance of age and gender on therapeutic outcomes is a noteworthy observation, which is consistent with previous research studies that have reported analogous results [15].

Limitation:

The research exhibits certain constraints. Whilst the size of the sample is noteworthy, it may not attain the requisite level of magnitude for the outcomes to be broadly applicable. The duration of the one-month follow-up period may not be sufficient to comprehensively capture the enduring impacts of these interventions. Conducting a study in a single setting may introduce bias and limit the generalizability of findings to diverse populations.

Conclusions

The findings of our study provide evidence for the efficacy of the gentamicin-hydrocortisone combination in the treatment of otitis externa complicated by furunculosis. Our results indicate that this treatment approach results in superior outcomes in terms of resolving inflammation, reducing pain, and improving quality of life. In summary, our study supports the use of the gentamicin-hydrocortisone combination for managing this condition. It is imperative for healthcare professionals to contemplate the possible trade-offs between the effectiveness and negative outcomes linked to this therapeutic methodology. Additional research is necessary to corroborate our findings and offer more comprehensive insights into the management of otitis externa, through the inclusion of larger sample sizes and diverse populations**.**

Compliance with Ethical Standards:

Conflicts of interest - Nil

Research involving human participants and/or animals – Nil.

Informed consent: Informed consent was taken from the patient for the case report.

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