ORIGINAL ARTICLE

Comparison of Topical Acetic Acid and Gentamicin in Achieving Dry Ear in Chronic Suppurative Otitis Media

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ABSTRACT

Objective: To compare efficacy of topical acetic acid with topical gentamycin ear drops in achieving dry ear in patients with Chronic Suppurative Otitis Media (CSOM).

Study Design: Randomized control trial.

Place and Duration of Study: ENT Department, Fauji Foundation Hospital, Rawalpindi, from July 2021 to June 2022.

Materials and Methods: A total of 80 patients were included in this study through nonprobability consecutive sampling. Patients fulfilling the inclusion and exclusion criteria were divided into two groups of 40 each, by lottery method. Informed consent was obtained from all the patients and approval of the study was taken from the Hospital Ethical Committee. The patients in Group A received topical 1.5% Acetic acid and the other 40 in Group B received topical 0.3% Gentamicin sulphate. Patients were advised to cover their ear canals with ear plugs or cotton balls covered by Vaseline to prevent entry of water in the ear. Effectiveness was assessed by observing resolution of ear discharge, in term of achieving a dry ear on day 14.

Results: Average (±SD) age of cases in Group-A was 32.7 (±17.3) years and in Group-B was 26.2 (±15.4) years. In Group-A, ear discharge (Otorrhoea) resolution was achieved in 36 (90%) cases and in Group-B in 32 (80%). The efficacy was found better in the Group-A receiving topical Acetic Acid, but statistically the efficacy of both groups was similar.

Conclusion: The results of this study suggest that Acetic acid was equally effective to Gentamicin sulphate in achieving ear discharge control (dry ear) in CSOM.

Key Words: *Suppurative Otitis Media, Tympanic Cavity, Topical Anti-Infective Agents, Instillation.*

Introduction

Chronic Suppurative Otitis Media (CSOM) is an on-going intermittent or persisting ear discharge over 3–6 weeks through a perforated tympanic membrane secondary to chronic inflammation of the middle ear and mastoid cavity leading to a certain degree of hearing loss.[1] CSOM is categorized into two types, tubotympanic and atticoantral depending on whether the disease process affects the pars tensa or pars flaccida of tympanic membrane. CSOM is associated with persistent or recurrent ear discharge and conductive hearing loss.[2] Sometimes the hearing loss is disproportionately greater due to necrosis of the ossicles, and there is a definite risk of sensorineural hearing loss and complications too. The most common aerobic bacterial isolates in CSOM are Pseudomonas aeruginosa and Staphylococcus aureus. Other common organisms include Escherichia coli, Proteus mirabilis, Klebsiella spp., Streptococcus pyogenes, Candida spp. and Aspergillus spp.[3] However, this may vary according to topographical and other factors. Treatment for CSOM consists of topical antibiotics (administered into the ear) with or without steroids, systemic antibiotics (given either orally or parenterally), topical antiseptics and regular aural toilet, all of which can be used on their own or in several combinations. Patients respond better to topical therapy than to systemic therapy. Successful topical therapy is based upon proper use of an antimicrobial ear drops and meticulous ear toilet.[4] Broad-spectrum antibiotics such as second-generation quinolones and aminoglycosides, which are often active against the most frequently cultured micro-organisms (Pseudomonas aeruginosa and Staphylococcus aureus), are therefore frequently used.[5] These include gentamycin, tobramycin,

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neomycin, ciprofloxacin alone or combined with dexamethasone. All the aminoglycosides have a potential for ototoxicity. Popular prescriptions like Neomycin and Polymyxin B have lost their reliability against Gram negative bacteria due to drug resistance.[6] Topical antiseptics may be as effective as topical antibiotics in resolving otorrhoea (ear discharge) as found in several trials.[7] These inhibit the growth of bacteria by lowering the pH of the environment and interfere with the growth of bacteria. These alone with regular aural toilet is the cornerstone of a successful medical therapy. It has been observed that combination of topical and systemic therapy has no benefit over topical therapy alone.[8] Many antiseptics such as boric acid,[9] citric acid,[10] acetic acid, povidone iodine, alcohol and hydrogen peroxide have been used with mixed results. But these may cause irritation of the skin, and mucosa and sometimes as in case of alcohol, may be vestibulotoxic.[11] Due to irrational use of antibiotic ear drops that has resulted in antibiotic resistance and a certain amount of ototoxicity too, it was considered to switch over to a relatively safe alternative. Hence the use of acetic acid ear drops was considered for this study, as acetic acid has been proved to be an effective antiseptic. Furthermore, acetic acid is a household item and has shown to give good results in treating CSOM without causing any side effects or any drug resistance. Since much work has not been done in Pakistan on this topic, we carried out a study in ENT Department Fauji Foundation Hospital Rawalpindi from July 2021 to June 2022 to compare efficacy of topical acetic acid with topical gentamycin ear drops in achieving dry ear in patients with CSOM and hence using it as an alternative.

Materials and Methods

This randomized control study was carried out on a total number of 80 patients. The sample size was determined by WHO calculator.[12] Sampling was done by Nonprobability consecutive sampling technique. The inclusion criteria were: Any gender within the age bracket of 10 -70 years having CSOM tubotympanic type active disease, with mucopurulent ear discharge of more than 4 weeks duration. The patients having CSOM tubotympanic type with dry ear, CSOM atticoantral type, otomycosis, otitis externa, CSOM with complications, hypersensitivity to acetic acid and aminoglycosides, or immunocompromised individuals, pregnant and lactating females were excluded from the study.

After approval from the Hospital Ethical Committee, written informed consent was taken from the patients included in the study. Patients fulfilling the inclusion and exclusion criteria were divided into two groups by lottery method. In Group-A, 40 patients received topical 1.5% Acetic acid and in Group-B, the other 40 received topical 0.3% Gentamicin sulphate. In both the groups, the patients were advised to instill two drops three times a day in the affected ear, and to hold these for 30 seconds by tilting their head to one side in a dependent position.

All the cases were followed up weekly for a total period of two weeks. Patients were advised to ensure prevention of water entry in ears while taking bath, either by blocking their ear canals with ear plugs or cotton balls covered by Vaseline. Effectiveness was assessed by observing otorrhoea resolution (dry ear) on day 14.

Data was analyzed through SPSS version 24. Descriptive statistics were calculated for qualitative and quantitative variables. Quantitative variables like age were measured as mean ±SD. Qualitative variables like gender were measured as frequency percentage. The Chi square test was applied for comparison of efficacy between the two groups. Stratification was done for age and gender to avoid effect modifier and post Stratification chi square test was done. All the results were presented in tables or charts.

Results

Gender distribution in both the groups is shown in Figure-1. The average (±SD) age of patients in Group-A was 32.7 (±17.3) years with an age range of 11 – 70 years, while in Group-B it was 26.2 (±15.4) years with an age range of 10 – 65 years. Age distribution in both the groups is shown in Table-I. It was statistically similar in both the groups (p-value=0.195).

The effectiveness of both groups was assessed by observing otorrhoea resolution (dry ear) on day 14. As shown in Table-II, the efficacy was better in Group-A (p-value=0.21), but statistically it was not significant.

Stratification was done according to gender and age. In both males and females, the efficacy (otorrhoea

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resolution) was statistically similar in Group-A & B (p-values=0.29 & 0.49 respectively) as shown in Table-III.

Similar results were found in all age groups, no significant difference was found between two groups in all age groups (p-values=0.49, 0.23 & 0.61 respectively) as shown in Table-IV.

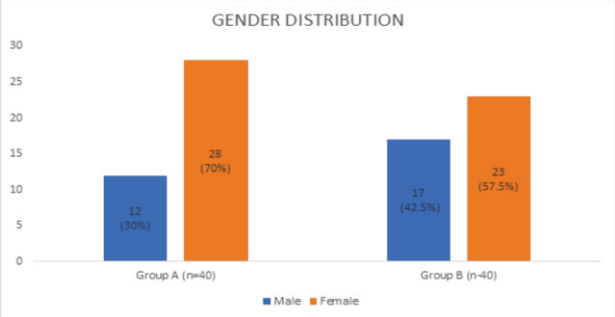

Figure 1: Gender Distribution (N = 80)

Table I: Age Distribution (N = 80)

Age (Years)	Group-A n = 40	Group-B n = 40	p-value
≤ 20	16 (40%)	24 (60%)	0.195
21 - 40	8 (20%)	6 (15%)	
> 40	16 (40%)	10 (25%)	

Table II: Otorrhoea Resolution (N = 80)

Dry Ear	Group-A n = 40	Group-B n = 40	p-value
Yes	36 (90%)	32 (80%)	0.21
No	4 (10%)	8 (20%)	

Table III: Otorrhoea Resolution According to Gender (N = 80)

Gender	Group	Dry Ear		p-values
		Yes	No	
Male	Group-A n = 12	11 (91.7%)	1 (8.3%)	0.29
	Group-B n = 17	13 (76.5%)	4 (23.5%)	
Female	Group-A n = 28	25 (89.3%)	3 (10.7%)	0.49
	Group-B n = 23	19 (82.6%)	4 (17.4%)	

Table-IV: Otorrhoea Resolution According to Age (N = 80)

Age (years)	Group	Dry Ear		p-values
		Yes	No	
≤ 20	Group-A n = 16	14 (87.5%)	2 (12.5%)	0.49
	Group-B n = 24	19 (79.2%)	5 (20.8%)	
21 - 40	Group-A n = 8	8 (100%)	0 (0%)	0.23
	Group-B n = 6	5 (83.3%)	1 (16.7%)	
> 40	Group-A n = 16	14 (87.5%)	2 (12.5%)	0.61
	Group-B n = 10	8 (80%)	2 (20%)	

Discussion

Chronic Suppurative Otitis Media (CSOM) worldwide, especially in developing countries, is a serious and avoidable healthcare concern. It not only causes a social embarrassment due to persistent or recurrent otorrhoea, but also causes a variable amount of hearing loss as well. It is one of the ENT diseases known for the increased incidence of resistance to antibiotics used in otitis media treatment. Among medical therapy, regular aural toilet, topical antiseptics, topical and/or systemic antibiotics form the whole spectrum of medical therapy. Topical quinolones are considered as the most effective medical therapy along with regular aural toilet in achieving dry ear.[13] Topical antiseptics may be as effective as topical antibiotics in resolving otorrhoea as found in several studies. For Acetic acid, various previous studies showed that it was widely used as an antimicrobial agent in different fields; for killing food-borne pathogenic bacteria, to inhibit Escherichia coli growth, and to treat ear infections.[14] The efficacy of acetic acid is based on their ability to reduce the pH in the ear and restrict the growth of microorganisms.[15]

In our study, the efficacy of Acetic acid group was found to be better, though statistically like genticyn sulphate group. Similar results were observed by Yogi et al (2020) in a study that showed otorrhoea resolution in 92% of the patients receiving acetic acid ear drops as compared to 88% in the group receiving topical antibiotic ear drops.[16] Akhtar et al (2019) in their study observed 2% acetic acid ear drops as significantly better than 0.3% ciprofloxacin ear drops in achieving dry ears.[17] Our observations were also supported by another study done by Vishwakarma et al (2015) where the efficacy of ototopical Acetic acid was found to be slightly better (92%) than its comparative Gentamicin sulfate group (88%).[18] In yet another study 1.5% topical acetic acid caused otorrhoea resolution in 88% of the patients as compared to 52% success in the patients who received topical antibiotic ear drops.[19]

The study done by Gupta et al (2015) showed that the resolution of otorrhoea by Acetic acid was 84% as compared to 58% otorrhoea resolution in the group receiving antibiotic ear drops.[20] In yet another study Joshi (2019) also observed acetic acid ear drops to be significantly better than gentamicin ear drops in

achieving dry ear.[21] In yet another study Goyal et al (2022) observed similar results with acetic acid ear drops (94%) as compared to 88% in topical antibiotic ear drops.[22]

However, there are studies that show better results with topical antibiotics as compared to topical antiseptics in terms of getting a dry ear in CSOM. In a study Macfadyen et al (2005) have shown better results with antibiotic ear drops as compared to topical antiseptics in achieving dry ears in cases of CSOM.[23]

As we see that most of these studies observe that topical acetic acid ear drops are better or equally effective in achieving otorrhoea resolution and hence can be used as an alternative to antibiotic ear drops. Since these are easily available, economical, and cost effective, it is recommended that topical acetic acid ear drops may be used as an alternate to antibiotic ear drops to achieve dry ear as first step towards management of tubotympanic type of CSOM. Besides these advantages, acetic acid ear drops do not cause any drug resistance and have no evidence of any ototoxicity. Although there is a study carried out on Guinea pigs that shows its ototoxicity at a higher concentration (4%).[24] But further studies need to be carried out to confirm its ototoxic potential. The limitation of our study was that it was performed on a small scale, so it is recommended that further studies may be carried out on larger scale to confirm better efficacy of topical acetic acid in comparison to other antimicrobial agents in achieving dry ears without causing any side effects or drug resistance.

Conclusion

The results of this study suggest that topical Acetic acid is equally effective to topical Gentamicin sulphate in achieving dry ear in CSOM (tubotympanic).

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CONFLICT OF INTEREST

Authors declared no conflicts of Interest.

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DATA SHARING STATMENT

The data that support the findings of this study are available from the corresponding author upon request.