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Research Article

Role of Topical Acetic Acid in Comparison to Gentamicin for the Management of Chronic Suppurative Otitis Media

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Abstract

Introduction: Chronic Suppurative Otitis Media (CSOM) is one of the diseases resistant to current antibiotics; persisting for more than two week; and capable of causing severe discharge, tympanic membrane perforation and deafness. This may cause distress and affect their quality of life and productivity.

Aims: To assess the role of topical Acetic Acid in comparison to Gentamycin for management of CSOM.

Methods: It was a Randomized, open label study. Patients diagnosed as CSOM (safe type) were randomly divided into two groups, group I - topical 1.5% Acetic acid and group II - topical 0.3% Gentamicin sulphate in a dose of three otic drops thrice daily. Follow up was done every week for two weeks and was compared on the basis of otological symptoms score.

Results: The mean difference of otological symptom score at day 7 and day 14 from baseline in Group I was 1.90±1.01 and 3.40±1.08; and in Group II 1.96±0.57 and 3.12±0.74; $p<0.05$. Among the study groups, reduction of otological symptom scores at day 7 (Group I =3.22±1, Group II=2.66±1.76; $p=0.14$) and at day 14 (Group I = 1.72±1.76, Group II= 1.50±1.79; $p=0.56$) respectively. Also, "Treatment success" seen in 46 (92%) patients in the Acetic acid group and 44 (88%) patients in Gentamicin sulphate group. Moreover, cost of the treatment for Acetic acid was 102.94 and for Gentamicin sulphate was Rs.160.25 per person.

Conclusion: Topical Acetic acid was found to be equally effective to Gentamicin sulphate for the treatment of CSOM.

Keywords: Chronic Suppurative Otitis Media, Gentamicin, Acetic Acid

Introduction

According to World Health Organization (WHO), Chronic Suppurative Otitis Media (CSOM) is defined as an inflammatory condition of the ear that causes recurrent ear discharge (otorrhoea) through perforation of the ear drum (tympanic membrane). [1] The disease usually begins in childhood, resulting in spontaneous tympanic perforation due to an acute infection of the middle ear, known as acute otitis media (AOM), or as a sequelae of less severe forms of otitis media (otitis media with effusion). [1,2] Later on, if disease persists, it may lead to complications such as, recurrent acute otitis media, persistence of middle ear effusion, hearing impairment, mastoiditis, meningitis, brain abscess and sepsis. [3]

The clinical assessment of the presenting ear in CSOM requires a careful evaluation of the history and examination, both of which are essential in determining the type, state and the extent of the disease process, prior to the management strategy. [4] Traditionally CSOM is divided into two types: Tubotympanic (safe) type of CSOM and Atticoantral (unsafe) type of CSOM. [5] It is well documented that, patients with tubotympanic type of CSOM can be managed with empirical medical therapy to control the infection and eliminate ear discharge. [6] Among medical therapy, regular aural toilet; insufflation of topical antiseptic, administration of topical and/or systemic antibiotics is the mainstay of the therapy.[7,8] Several topical agents such as antibacterial, steroids and acid media ear drops are widely used alone or in combination to control the infection. [7,8]

Various previous studies showed that most common organisms found in CSOM are Staphylococcus aureus, Pseudomonas aeruginosa, Proteus mirabilis, Klebsiella

pneumonia, E.coli, Aspergillus species and Candida. [9,10] Aminoglycosides such as amikacin, gentamicin, tobramycin and fluoroquinolones such as ciprofloxacin are commonly used antibiotics in patients with otitis media. [11] However, due to increased and irrational use of wide-spectrum antibiotics, the resistance in the bacterial isolates has become very common. [10]

Topical antiseptics may be as effective as topical antibiotics in resolving otorrhoea as found in several trial. [12,13] 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. [14-16] The efficacy of acetic acid is based on their ability to reduce the pH in the ear and restrict the growth of microorganisms. [17] In view of this, we aimed to conduct a study to assess the role of topical Acetic acid in comparison to Gentamicin for the management of CSOM.

Method

A Randomized, open label study was carried out in the department of Pharmacology in co-ordination with department of ENT, Teerthanker Mahaveer Medical College and Research Centre, T.M.U. Moradabad, for duration of 10th months (March 2014 - December 2014).

Subjects of any sex, aging 10 years or more, diagnosed with tubotympanic (safe) type of CSOM based upon detailed history and otoscopic examination were included in the study. They were then explained the rationale of the study and requested to participate. The study was approved by the institutional ethics committee and written informed consent was taken from each of the subjects.

Patients with atticoantral types of CSOM; cholesteatoma; known case of hypersensitivity to acetic acid and aminoglycosides; case in which culture and sensitivity showed resistance of bacteria to either Gentamicin or acetic acid or both; immunocompromised individuals; pregnant females and lactating mothers; and patients not willing to participate were excluded from the study.

Patients were then randomly divided in to two groups, group I was given topical 1.5% acetic acid and group II was given topical 0.3% Gentamicin sulphate in a dose of three otic drops three times daily. All the cases were followed up weekly for total period of two weeks.

The efficacy of two drugs were compared on the basis of otological symptoms score assessed at base line (day 0), day 7 and on day 14. Number of subjects achieving "treatment success" in each treatment group at the end of the study was considered to be an effective parameter (Table 1). A difference of 10% in clinical cure rates was assumed to be the largest clinically acceptable effect for which equivalence could be accepted (equivalence limit).

Patients were also monitored for any adverse effects throughout the study period. All ADRs were recorded and casualty analysis was done as per the World Health Organization-Uppsala Monitoring Centre (WHO-UMC) criteria. Cost effectiveness was also calculated as total cost of drugs (in INR) divided by health benefit ratio.

Data were presented as mean ± standard deviation (SD) using an SPSS version 16.0. Students paired T-test was applied for the comparison of different variables between the groups.

Results

A total of 100 patients were randomly divided in two groups, group-I (n=50) for Acetic acid and group-II (n=50) for Gentamicin sulphate group. Most of the patients were from age groups 20-29 years (38%) with the age range of 10-60 years. The mean age (±SD) of patients in the Acetic acid group was 30.42±13.49 years and in Gentamicin sulphate groups were 27.08±10.86 years (Figure1).There was male predominance with male (61%) and female (39%) (Figure 1). The baseline otological symptom score were comparable (Group I=5.12±1.54; Group II=4.62±1.55) and showed no significant difference among the two groups (p=0.12). An intra-group analysis was done, which showed that the mean difference of otological symptom score at day 7 and day 14 from baseline (day 0) in the two study groups were significant (Group I = 1.90±1.01, 3.40±1.08; and Group II= 1.96±0.57 and 3.12±0.74; p<0.05). This suggested that both acetic acid and Gentamicin sulphate are effective in reducing the symptoms of CSOM (Figure2 and Table 2).

Table 1: Otological symptom score

Signs/ symptoms	Score 0	Score 1	Score 2	Score 3
Tinnitus	Absent	Mild	Moderate	Severe
Amount of discharge	Absent	Mild	Moderate	Severe
Type of discharge	Absent	Mucoid	Mucopurulent	Purulent

Table 2: Intragroup comparison of mean difference of otological symptom score.

Visit	Acetic acid group (n=50) Mean ± SD	Gentamicin sulphate group (n=50) Mean ± SD	p value
Day 0	*5.12±1.54*	4.62±1.55	0.12
Day 7	3.22±1.91	2.66±1.76	0.14
Day 14	1.72±1.76	1.50±1.79	0.56

** & ** = significant, p<0.05. Clinical cure if score <3, Clinical improvement if score 3-5 and Treatment failure if score >5.*

Visit	Acetic acid group (n=50) Mean ± SD	Gentamicin sulphate group (n=50) Mean ± SD	p value
Day 0	*5.12±1.54*	4.62±1.55	0.12
Day 7	3.22±1.91	2.66±1.76	0.14
Day 14	1.72±1.76	1.50±1.79	0.56

Table 3: Intergroup comparison of ontological symptom score

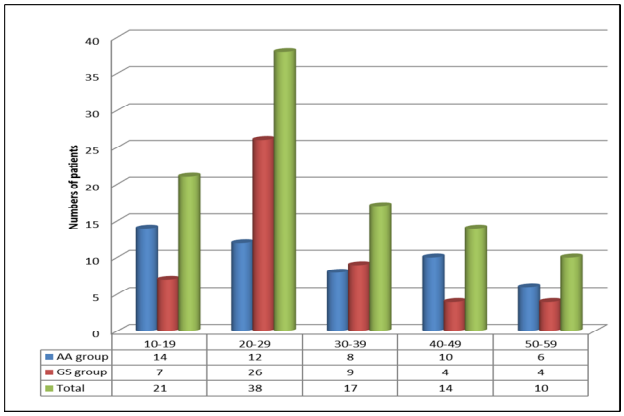

Figure 1: Age wise distribution in both groups

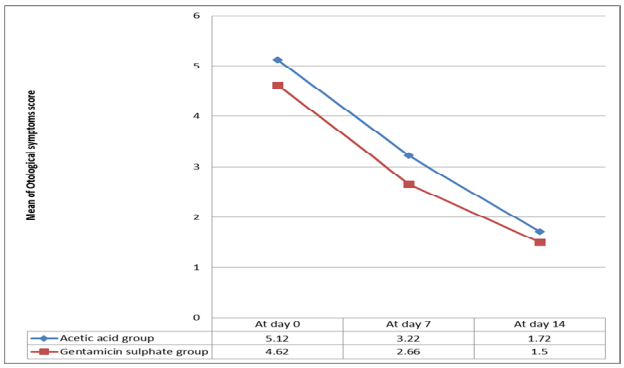

Figure 2: Changes in mean of Otological symptom score in the both the groups.

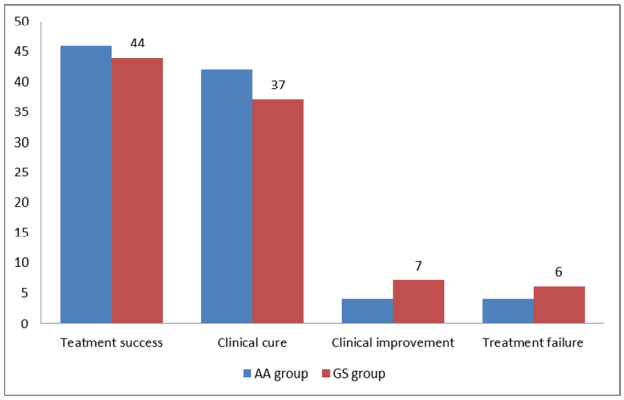

Figure 3: Comparison of treatment success rates in both groups

There was also no significant difference in reduction of otological symptom scores among the study groups at day 7 (Group I =3.22±1, Group II=2.66±1.76; p=0.14) and at day 14 (Group I = 1.72±1.76, Group II= 1.50±1.79; p=0.56) respectively. This suggested that both Acetic acid and Gentamicin sulphate are equally effective in the treatment of CSOM (Table 3).

'Treatment success" i.e. either clinical improvement or clinical cure was seen in 46 (92%) patients in the Acetic acid group and 44 (88%) patients in the Gentamycin sulphate group, whereas "treatment failure" was seen in 4 (8%) and 6 (12%) patients in the Acetic acid group and Gentamycin group respectively (Figure 2).

The safety and tolerability profile of both the study drugs were optimum and none of the patients reported any kind of serious ADRs. Only single patient in the Acetic acid group had mild irritability and 2 patients in the Gentamicin group reported headache. These ADRs were mild in nature and did not require any dose reduction or withdrawal of the study medications. Causality analysis showed that they were in the "possible" category.

The cost of the drug consumed during study period was calculated for each patient in the two study groups. Two weeks treatment incurred an expenditure of Rs.102.94 per patient in the Acetic acid group and Rs.160.25 in the Gentamicin sulphate group. It was found that treatment with Acetic acid was more cost effective than treatment with Gentamycin sulphate.

Discussion

The present study showed that there is a significant reduction in otological symptoms score with both the topical agents, Acetic acid as well as Gentamicin sulphate, Also they were found to be equally effective as there was no significant difference in reduction of otological symptom scores among the study groups after one week of the therapy and persisted till the end of the study. This was supported by a study done by Eason et al (OR = 0.67, 95% CL = 0.2, 2.25); where topical antiseptics were found to be just as effective as topical antibiotics; however, ofloxacin/ciprofloxacin produced high cure rates. [13] It was also similar to the results obtained by Clinical Practice Guidelines of the Philippine Society of Otolaryngology– Head and Neck Surgery 1997 & 2002; where it was found that there is no significant difference between topical antiseptics and topical antibiotics in persistent activity on otoscopy (13/20 [65%] with topical antiseptics, 15/18 [83%] with topical antibiotics; (OR 0.40, 95% CI 0.10 to 1.66). No significant difference was also found between oral antibiotics and topical antiseptics in the rate of persistent activity on otoscopy (8/13 [62%] with oral antibiotics, 13/20 [65%] with topical antiseptics, 15/18 [83%] with topical antibiotics; OR 0.87, 95% CI 0.21 to 3.61).

In a survey of 2235 otolaryngologists in the early 1990s, 84% reported some or the other benefits using topical agents in CSOM and only 3.4% witnessed irreversible ear damage caused by such agents. [18] In the present study, 88% patients showed resolution of CSOM and none of the patients had any kind of ear damage or toxicity. A study done by Chhavi Gupta et al. showed that the resolution of otorrhoea by Acetic acid was 84% and healing of tympanic membrane perforation was 26% while failure rate was 16%. [12] In the present study 1.5% Acetic acid showed that resolution of CSOM was higher with success rate in 92% patients while failure rate 8%. Also Acetic acid was found to be cost-effective than Gentamicin sulphate.

Keeping in view various clinical aspects, including treatment success rate, symptomatic relief of discharge and congestion, topical Acetic acid was found to be equally effective to Gentamicin sulphate suggesting that it is the best alternative when infection is caused by multiple antibiotic resistant strains and at an affordable cost. The limitation of study was that antimicrobial activity was not performed due to time and cost constraints. Also the study was performed on small number of population so it is suggest that further study is required on large numbers of population along with antimicrobial activity of Acetic acid for efficacy of topical acetic acid in comparison to other antimicrobial agents.

Conclusion

Thus, in this study we found that Acetic acid was equally effective to Gentamicin sulphate suggesting that it is the best alternative when infection is caused by multiple antibiotic resistant strains and at an affordable cost.

What this study adds:

Topical antiseptics could be as effective as topical antibiotics in resolving symptoms in safe type of CSOM. The efficacy of acetic acid could be based on their ability to reduce the pH in the ear and restrict the growth of microorganisms.

1. What is known about this subject?

Several topical agents such as antibacterial, steroids and acid media ear drops are widely used alone or in combination to control the infection.

2. What new information is offered in this study?

It could be the best alternative when infection is caused by multiple antibiotic resistant strains and at an affordable cost.

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ETHICS COMMITTEE APPROVAL Approved

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