



A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF TOPICAL 1.5% ACETIC ACID VERSUS 0.3% CIPROFLOXACIN IN CHRONIC SUPPURATIVE OTITIS MEDIA

Otorhinolaryngology

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ABSTRACT

Objective : To compare efficacy of topical 1.5% acetic acid with topical 0.3% ciprofloxacin ear drops in achieving dry ears in chronic otitis media with discharge.

Study design: Prospective study

Setting: Department of ENT, Grant Medical College And Sir JJ Group Of Hospitals, Mumbai during the year 2018 to 2020

Materials and Methods: 100 patients of CSOM were randomly distributed in two groups. 50 patients were in each group. Group A was started on topical acetic acid and Group B on topical ciprofloxacin for a period of 28 days. Otoscopic assessment was done on day 0, day 14 and day 28 in each group and observed for dryness of ear on the basis of otologic symptom score.

Results: The topical acetic acid group showed a success rate of 92 % at the end of 28 days when compared to ciprofloxacin group with 88%. The efficacy of 1.5% acetic acid was significantly higher than 0.3% ciprofloxacin eardrops in achieving dry ears ($p < 0.05$).

Conclusion: The efficacy of topical 1.5% acetic acid was significantly higher than 0.3% ciprofloxacin eardrops in achieving dry ears in chronic suppurative otitis media.

KEYWORDS

Chronic suppurative otitis media; Tympanic membrane perforation; middle ear mucosa, Ciprofloxacin; Acetic Acid

INTRODUCTION

Chronic suppurative otitis media (CSOM) is "defined as a chronic inflammation of the middle ear and mastoid cavity, which presents with recurrent ear discharges or otorrhoea through a tympanic perforation." It usually follows one or more attacks of acute otitis media and is considered an important cause of preventable hearing loss.

These infections affect the normal daily functioning of both adults and children and are the frequent cause of absenteeism from work and school among school aged children¹. As with other infections of the upper respiratory tract (URT), ear infections such as chronic suppurative otitis media are of great concern especially in developing countries^{2,3}.

The burden of CSOM varies. Global prevalence rates estimates a range between 1% and 46%; it has been estimated that 65–330 million individuals have discharging ears, 60% of whom suffer from significant hearing impairment.⁴

It is one of the most common bacterial infections in the field of otolaryngology having significant economic and individual repercussion⁵. Medical management of chronic suppurative otitis media (CSOM) for dry ear is essential before surgical treatment. Biofilms are most prevalent microbial form in biological environment⁶ and thought to play a central role in chronic infections.

Among medical therapy, regular aural toilet; insufflation of topical antiseptic, administration of topical and/or systemic antibiotics is the mainstay of the therapy. 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}.

The main objective of this study is to find out the efficacy of topical 1.5% Acetic acid (antiseptics) ear drops in comparison to topical 0.3% Ciprofloxacin ear drops and prevent the patients from antibiotic resistance requiring adjustment and improvement in the overall interest of the patient and the health care system.

MATERIALS AND METHODS

A prospective clinical study was performed at Department of ENT, Grant Medical College And Sir JJ Group Of Hospitals during the period 2018 to 2020 and was approved by the Institutional Ethics committee.

Patients were included in study based on selection criteria

INCLUSION CRITERIA:

- CSOM mucosal type (tubotympanic) with active discharge.
- History of ear discharge more than 3 months
- Age group 15-65yrs
- Not on antibiotics in past 2 weeks
- Giving consent for study

EXCLUSION CRITERIA:

- a. CSOM with dry ear
- b. CSOM squamousal (atticoantral) type
- c. Pregnant and lactating mothers
- d. CSOM with vertigo
- e. Below 15yrs and above 65yrs
- f. Patients who were on antibiotics within past 2weeks
- g. Patients Not giving consent
- h. Patients with aural polyp, external auditory canal pathology, ear malignancy, having mastoid surgery in preceding 12 months.

Patient details including demographics, history and examination findings were collected and recorded using a proforma.

Patients included in the present study were randomly distributed into two groups. In one (group A) patients treated with 1.5% topical acetic acid and in other (group B) patients were treated with 0.3% topical Ciprofloxacin with three otic drops thrice daily in both the groups. Initial evaluation for the otological symptom score (shown in table 1) were done at baseline (at day 0) before treatment. The effectiveness of topical 1.5% acetic acid was compared with that of topical 0.3% ciprofloxacin on the basis of reduction in otological symptom score as in figure 1 involving middle ear and external auditory meatus (EAM) at day 14 and day 28. Patients were monitored continuously throughout the study for any adverse effects.

Figure1-Otological symptom score

Signs/ symptoms	Score 0	Score 1	Score 2	Score 3
Amount of discharge	No discharge	Confined to the middle ear	Entering into EAM	Completely filling EAM

Type of discharge	Absent	Mucoid	Mucopurulent	Purulent
Types of congestion	No congestion	Mild/moderate congestion	Marked	

Treatment success was based on changes in the otological symptom scores. It was subdivided into two categories: (a) "clinical cure" if the otological symptom score was <3 at end of 1 month or (b) "clinical improvement" if the otological symptom score was between 3 and 5 after 1 month. "Treatment failure" was declared if there was no change or increase in the baseline otological symptom score or >5 otological symptom score on day 14 and was excluded from study. Data were presented as mean $\pm$ standard deviation (SD) using an SPSS version 27.0. Chi square test was applied for the comparison of different variables between the groups.

RESULTS

In our study, a total of 100 patients with active mucosal type of CSOM who fulfilled the criteria were selected and randomly divided into two groups, group-I (n=50) for Acetic acid and group-II (n=50) for Ciprofloxacin group. All were observed in prospective manner including their age, sex, presenting complains, clinical features, examination using a preformed proforma.

In our study, the group A (1.5% acetic acid) included 48% (24/50) men and 52% (26/50) women and the ciprofloxacin included 44% (22/50) men and 28% (28/50) women which were matching with male female ratio of 1:1.17. Maximum patients fall within the age group between 10-30 years and among them the most common age group of presentation was 2nd decade.

In our study majority of patients with CSOM were normal (74%) without any significant history of previous illness and there is no evidence suggestive of genetic susceptibility in CSOM. 26% patients had comorbidities like Diabetes Mellitus (DM), Hypertension (HTN) and Human Immunodeficiency Virus (HIV) and were on medications.

39 % of patients had addictions either smoking or tobacco or both, but no significant association seen in dryness of ear noted among those with and without addictions.

96% patients belonged to low socioeconomic status and 39 % of patients had addictions but no significant association seen in dryness of ear noted among those with and without addictions.

Discharge and hearing loss were the most common presenting complaints in this study group.

68% patients had decreased hearing along with ear discharge as there complaints while 32% had only discharge as their complaints. Bilateral ear disease was found in 14 patients, right ear in 30 patients, and left ear in 56 patients.

60% of the study population had associated nasal pathology with 35 % being symptomatic.

Otorrhea was evaluated on day 0, day 14 and day 28. Amongst 50 patients in topical acetic acid group, otorrhea resolution was seen in 31 patients by day 14 and in 15 patients by day 28. 4 patients had no otorrhea resolution even after 1 month and was considered to be a failure. Amongst 50 patients in topical ciprofloxacin group otorrhea resolution was seen in 20 patients by 14 days and 24 patients by 28 days. 6 patients had no otorrhea resolution even after 1 month and was considered to be a failure as shown in table 1.

Table 1-Intergroup comparison of resolution of otorrhea based on otological symptom score

Visit	Acetic acid group A (n=46)	Ciprofloxacin group B (n=44)	P-value
Day 14	31	20	0.0357
Day 28	15	24	

In our study reduction in otological symptom score was seen in both groups at end of day 14 and 28 which was 92% in acetic acid group and 88% in ciprofloxacin group as in table 2. However, the response with acetic acid was somewhat earlier as compared to Ciprofloxacin group. The effectiveness of 1.5% acetic acid was significantly higher than 0.3% ciprofloxacin eardrops (p-value <0.05) in achieving dry ears in

chronic suppurative otitis media with active discharge.

Table 2-Comparison of treatment success rates

Scores	Acetic acid group A (n=50)	Ciprofloxacin group B (n=50)	P-value
Treatment success	46	44	0.049
Clinical cure			
Clinical improvement	46 0	40 4	
Treatment failure	4	6	

Table 2 shows the number and the percentage of patients categorized as "treatment success" or "treatment failure" at the day 28 visit. Forty six (92%) subjects of the 50 enrolled in the Acetic acid group achieved "treatment success," i.e. either clinical improvement or clinical cure, and the remaining four (8%) subject were categorized as treatment failure. Similarly, in the Ciprofloxacin group, 44 (88%) subjects of the 50 evaluated showed "treatment success," i.e. either clinical improvement or clinical cure, and the remaining six (12%) were categorized as treatment failure. Intergroup comparison of the percentage of subjects who were categorized as treatment success showed statistically significant difference (P = 0.049). There were four patients in the acetic acid group and six patients in the Ciprofloxacin group who were categorized as treatment failure and had to be put on other antibiotics after the day 28 evaluation.

DISCUSSION

CSOM is a multifactorial disease resulting from a series of interactions between environmental and host factors. Microbial, immunological, and genetically determined factors, Eustachian tube characteristics, are supposed to be involved in the pathogenesis of CSOM. The deep seated infections in poorly vascularized sites like ear is difficult to treat with conventional systemic antibiotic therapy and now-a-days biofilms play role in these chronic infections with resistance to antibiotic therapy which in turn has increased the disease burden. As such there are no published guidelines for patient presenting with persistent otorrhea. CSOM being a persistent and insidious disease and the mainstay of medical management of CSOM for dry ear is essential before surgical treatment. Hence here is need for some alternate option other than antibiotics to combat the issue. This study was conducted to compare the efficacy of topical acetic acid vs ciprofloxacin ear drops in the medical management of tubotympanic-type CSOM.

In our study of 100 patients, 46% were males and 54 % females with sex ratio M:F of 1: 1.17 showing female preponderance which was similar to study conducted by Basak et al¹¹. In our study, the group A (1.5% acetic acid) was matching to the group B (0.3% ciprofloxacin eardrops) by sex; the Acetic acid group included 48% (24/50) men and 52% (26/50) women and the ciprofloxacin included 44% (22/50) men and 28% (28/50) women. Also the mean age of the acetic acid group 36 $\pm$ 2.14 years was matching to the mean age of the ciprofloxacin group 36 $\pm$ 2.59 years.

Maximum patients fall within the age group between 10-30 years and among them the most common age group of presentation was 2nd decade which were similar to study by Basak et al¹¹. This suggest that CSOM tends to occur more in early decades of life and leads to permanent defect in tympanic membrane with hearing loss.

In our study 96 % of csom patients belonged to low socioeconomic status which is similar to a study conducted by Arunabha et al, where 60% of their patients were from low socio-economic class¹². Poor living conditions, poor access to medical care, inadequate medical treatment, recurrent upper respiratory tract infections and nasal diseases have been recognized as risk factors for CSOM¹³.

Overcrowding, poor hygiene and nutrition and poor living conditions have been suggested as a basis for the widespread prevalence of CSOM in developing countries^{14,15,16}.

In our study 68% patients had decreased hearing along with ear discharge as their complaints while 32% had only discharge as their complaints. Present study shows that, majority of patient with CSOM were normal (64%) without any significant history of previous illness and there is no evidence suggestive of genetic susceptibility in CSOM similar to the study by Rajendran et al.¹⁷

39 % of patients had addictions either smoking or tobacco or both, but

no significant association seen in dryness of ear noted among those with and without addictions which was against the study done by Gaur et al wherein addictions are associated with greater prevalence of middle ear and inner ear diseases.¹⁸

This study found left ear disease to account for the majority of the cases (56%) with bilateral involvement accounting for the least (14%) number of cases which is similar to what was found by Olowookere et al.¹⁹. Predominance of the left ear may be due to random selection of the study cases but no genetic or structural differences have been identified between the right and left ear.

In our study 60 patients were found having one or other nasal pathology that might be the culprit for ear disease of the total nasal pathologies. Maximum cases were of DNS alone or with Allergic rhinitis. The involvement of Eustachian tube in patients with sinonasal pathology might be attributed to the greater proportion of suppuration in cases having sinonasal pathology. Sinonasal pathology interrupts the passage to Eustachian tube thus showing higher prevalence of blockage leading to CSOM. Yeolekar et al (2011)²⁰ reported presence of sinonasal pathology in 90% patients. Poorey and Iyer (2002)²¹ reported presence of pharyngeal and sinonasal pathology in 93% patients. Sinonasal pathologies are the major risk factor for CSOM and in order to treat the CSOM, first the sino nasal pathologies should be ruled out and should be addressed first followed by ear pathology.²²

In our study reduction in otological symptom score was seen in both groups at end of day 14 and 28 in about 92% in acetic acid group and 88% in ciprofloxacin group. However the response with acetic acid was somewhat earlier as compared to Ciprofloxacin group. The effectiveness of 1.5% acetic acid was significantly higher than 0.3% ciprofloxacin eardrops (p-value <0.05) in achieving dry ears in chronic suppurative otitis media with active discharge. This was similar to results obtained by Yadav et al (2020)²³. In a similar study by Ali et al.²⁴ 'dry ears' were achieved in 74.47% (35/47) (90% CL 64.01-84.93) patients in acetic acid group and in 23.40% (11/47) (90% CL 14.01-34.59) patients in 0.3% ciprofloxacin group. The efficacy of 2% acetic acid was significantly higher than 0.3% ciprofloxacin eardrops (p-value <0.0001) in achieving dry ears in chronic suppurative otitis media in adult population of Islamabad, Pakistan.²⁴

The mechanism of action of acetic acid appears to be:

1. Removal of inflammatory debris.
2. Destructive effect on biofilm and.
3. Change in the pH media of ear canal interrupts the growth of bacteria by affecting the amino acid which causes alteration in the three dimensional structure of bacterial enzymes. Extreme changes in pH cause protein denaturation.²⁵

However, study done by Macfadyen, et al. in a trial in 2002 in Kenya, using ciprofloxacin (Ciloxan 0.3%; Alcon) eardrops and antiseptic eardrops (2% boric acid in 45% alcohol) in school children twice daily had opposing results.²⁶ At two weeks follow up, dry ear was achieved in 123/207 (59.42%) cases with ciprofloxacin eardrops while it was 65/204 (31.86%) in antiseptic eardrops. Here efficacy of ciprofloxacin was superior to antiseptic eardrops.

Another study by Onali et al proved that the addition of oral ciprofloxacin had no significant effect in treating CSOM and only added to the systemic side effects.²⁷ This emphasis that acetic acid can be more desirable and initial choice as topical agent as compared to the topical and oral antibiotics. It is safe and economical without producing any side effects. Acetic acid acts by alteration of pH of ear canal which is one of the main factors for healing, in addition to mechanical disruption of biofilm and removal of deep seated debris in poorly vascularized sites such as bones and ear.

CONCLUSION

Topical 1.5% acetic acid solution is clinically effective and better option than topical 0.3% Ciprofloxacin in the treatment of active tubotympanic chronic suppurative otitis media. Irrational use of antibiotics are leading to emergence of antibiotic resistance; in addition Acetic acid is cheaper with lesser side effects than topical Ciprofloxacin. The study has shown the topical Acetic acid is better than the topical Ciprofloxacin in CSOM and hence should be considered as an initial choice for topical treatment.

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