



DISCERNING THE EFFICACY OF TOPICAL 2% ACETIC ACID IN CHRONIC SUPPURATIVE OTITIS MEDIA USING OTOLOGICAL SYMPTOMS SCORE: A PROSPECTIVE STUDY.

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ABSTRACT

BACKGROUND: Chronic suppurative otitis media (CSOM)- mucosal type 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.” Acetic acid demonstrates antimicrobial, antipersister and antibiofilm potential. The objective of our study is to find out the efficacy of medical treatment using acetic acid for patients of CSOM. **RESULTS:** This prospective study comprised of 100 patients suffering from CSOM who presented to the Department of ENT, HSK Hospital, Bagalkot from July 2021 to December 2022. The patients with chronic otitis media mucosal type with active discharge were enrolled in our study as per the inclusion and exclusion criteria. They underwent complete evaluation including otomicroscopy and pure tone audiometry to determine the nature of disease and its severity. Otological symptom score was calculated in all patients at the time of presentation. They were treated conservatively with topical 2% Acetic acid ear drops. Scores were assessed based on clinical findings at day 7, day 14, day 21 and day 30 follow-up visit. Patients were segregated into those with clinical cure (<3), clinical improvement (3-5) and treatment failure (>5) as per their score. Achieving “treatment success” at the end of the study was considered as an effective parameter to measure effectiveness of topical acetic acid ear drops. “Treatment success” i.e. either clinical cure or clinical improvement was seen in 95% patients after using acetic acid, whereas “treatment failure” was seen in 5% patients at the end of 1 month. **CONCLUSION:** In the present study using topical preparation of 2% acetic acid, the resolution of CSOM was shown with success rate in 95% patients. This shows that acetic acid was effective in reducing the symptoms of CSOM.

KEYWORDS : Topical acetic acid, Chronic suppurative otitis media, Otological symptom score.

BACKGROUND:

Chronic suppurative otitis media (CSOM) - mucosal type 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.”¹ Antibiotics are usually the choice of treatment for infections and can be used to either kill or inhibit the growth of the microbes.² However, the worldwide increase in antibiotic-resistant microbes has limited the effect of traditional treatments making it very difficult to treat infections that were once treatable.²

Biofilms are known to be involved in many chronic infections such as in chronic otitis media.² Both aerobic (such as *E. coli*, *P. aeruginosa*, *S. aureus*, *S. pyogenes*, *P. mirabilis*, *Klebsiella*) or anaerobic (*Bacteroides*, *Peptostreptococcus*, *Propionibacterium*) bacteria may be found in patients with CSOM.³

Various previous studies showed that acetic acid 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.⁴ The efficacy of acetic acid is based on their ability to reduce the pH in the ear and restrict the growth of microorganisms.⁴ Acetic acid demonstrates antimicrobial, antipersister and antibiofilm potential.⁵

Medical management of persistent CSOM with tubotympanic type by 2% acetic acid topical therapy can be the more desirable choice than the topical and oral antibiotics.⁶ It is safe and economical, without producing any side effects.⁷

The objective of our study is to find out the efficacy of medical treatment using acetic acid in patients of CSOM mucosal type.

OBJECTIVES OF THE STUDY:

- To assess efficacy of topical 2% Acetic acid (antiseptic) ear drops in CSOM mucosal type (tubotympanic) with active discharge.

METHODS:

A. DESIGN OF THE STUDY:

Prospective study.

Sample size and its calculation:

Sample size estimation done using OPENEPi software version 2. With 95% Confidence level,

And 80% Power of the study,

Sample size was estimated and it was 100.

Inclusion criteria:

- Patients with chronic otitis media mucosal type with active discharge presenting to the outpatient department of otorhinolaryngology at HSK Hospital, Bagalkot.
- History of ear discharge for more than 3 months.
- Not on antibiotics in past 2 weeks.
- Patients between the age group of 15-75 years of both the genders.

Exclusion criteria:

- Patients below the age of 15 and above 75 years.
- Patients with aural polyp, external auditory canal pathology, ear malignancy, having mastoid surgery in preceding 12 months.
- Patients with squamous (atticoantral) type.
- Severe cases of CSOM for which hospitalization or parenteral antibiotic treatment is required and patients with otological symptom score of ≤5 and >8 were also excluded from the study.
- Patients found to have intracranial complications of chronic otitis media.

Collection of data:

- Patients attending outpatient Department of ENT, HSK Hospital, Bagalkot with chronic otitis media- mucosal type.
- Otological symptom score was analyzed and the disease condition was monitored.

Investigations:

- Otomicroscopy
- Pure tone audiometry

B. MATERIALS AND METHODS:

This was a prospective study conducted in Department of ENT, HSK Hospital, Bagalkot from July 2021 to December 2022 for a period of one and half years. It was carried out in 100 patients suffering from chronic otitis media, mucosal type. They belonged to the age group of 15-75 years. This study was approved by the Ethical Review Committee of SNMC-Institutional ethics committee on human subjects research recognized by Medical council of India and affiliated to RGUHS, Bangalore. Informed consent for participating in the study was obtained from all the patients.

Detailed history was taken from all cases followed by general and systemic examination. Patients were also subjected to ear, nose and throat examination. They underwent otological evaluation namely otomicroscopy and pure tone audiometry (PTA). The nature of disease, presence was established using Otological symptom score.⁸

Factors such as age, sex, presence of systemic diseases, duration of wet period of ear and prior ear surgery were recorded. Patients with discharging ear were treated conservatively with topical 2% Acetic acid ear drops, which was available as pre-prepared over the counter formulation. Otic ear drops (10), with 10 minutes of soak were repeated 6 times per day. They were evaluated at day 7, day 14, day 21 and day 30 follow-up visit and data was collected through scoring and clinical examination.

Table 1: Otological symptom score⁸

Signs/symptoms	Score 0	Score 1	Score 2	Score 3
Tinnitus	Absent	Mild	Moderate	Severe
Amount of discharge	Absent	Mild (confined to middle ear)	Moderate (entering into external auditory meatus)	Severe (completely filling external auditory meatus)
Type of discharge	Absent	Mucoid	Mucopurulent	Purulent
Mucosal edema/Congestion	Absent	Mild	Moderate	Severe

Treatment success was based on changes in the otological symptom scores.¹ It was subdivided into two categories based on the improvement in tinnitus, discharge and congestion: (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 at the end of treatment.¹

Thus, treatment outcome in terms of otorrhoea resolution and reduction of score were evaluated. Their statistical significance was studied to determine the efficacy of topical 2% Acetic acid ear drops in medical management of CSOM.

STATISTICAL ANALYSIS:

Data was entered in the Microsoft excel and analysed using SPSS software version 19. Percentages & proportions was used for qualitative data and mean and standard deviation for quantitative data. Appropriate statistical tests such as ANOVA test, Paired t-test and Chi-square test were applied. $p < 0.05$ was considered as statistically significant.

RESULTS:

Only those patients diagnosed with tubotympanic (safe) type of CSOM based upon detailed history, otomicroscopic examination and PTA were included in the study done at the Department of ENT, HSK Hospital, Bagalkot from July 2021 to September 2022. On the basis of inclusion and exclusion criteria, 100 patients were enrolled in our study.

Most of the patients were from age groups 31-39 years (38%) with the age range of 15-75 years. The mean age of patients was 35.8 years. There was male predominance with male patients comprising 69% and females 31% of participants (Table 1).

Table 1: Gender distribution.

Gender(n=100)	Percentage
Female	69%
Male	31%

All cases presented with ear discharge. Complaints of hearing loss and tinnitus was recorded in 71 and 18 patients respectively. Some of the patients had co-morbidities including hypertension (33%) and diabetes mellitus (10%). None of the patients had complications of CSOM or cholesteatoma.

Out of the 100 patients evaluated, 55 patients had bilateral ear

involvement and 45 had unilateral disease. Among those with unilateral disease, right-side was affected in 29, while left ear was involved in 16 patients. The mean duration of otorrhoea was 4.35 months.

In the 3 months prior to enrolment, 48 patients had not received any treatment for CSOM while 52 had previously been treated but not in the recent 2 weeks. We were unable to document the class of antibiotic used since most of the patients did not usually know which treatment was used.

Regarding the tympanic membrane perforations found in all these individuals, 34% were small central perforations, 59% were medium sized central perforations and 7% were large central perforations. The middle ear mucosa was oedematous in all ears and appeared inflamed on examination prior to treatment. The nature of ear discharge (mucoid, mucopurulent or purulent) as well as amount of discharge (mild- confined to middle ear, moderate- entering into external auditory meatus or severe-completely filling external auditory meatus) was noted during otomicroscopy. A baseline otological symptom score was recorded before prescribing the patients on acetic acid ear drops and mean score on Day 0 was 6.91 (Table 2). They also underwent audiological testing and median PTA was found to be 42 dB HL in ears where there was a complaint of hearing loss, compared with 26 dB HL in ears where there was no such complaint.

Table 2: Mean of otological symptom score at each visit.

Visit	Score
Day 0	6.91
Day 7	5.83
Day 14	5.09
Day 21	1.65
Day 30	1.43

The efficacy of the drug was assessed on the basis of otological symptom score assessed at base line (day 0), day 7, day 14, day 21 and on day 30 (Table 2). Number of subjects achieving "treatment success" at the end of the study was considered as an effective parameter to measure effectiveness of topical acetic acid ear drops (Table 3).

Table 3: Treatment outcome rates based on scores (n=100):

Outcome	Score	Day 7	Day 14	Day 21	Day 30
TREATMENT SUCCESS					
• Clinical cure	<3	1	8	71	87
• Clinical improvement	3-5	61	74	24	8
TREATMENT FAILURE	>5	38	18	5	5

Our analysis showed that the improvement of components of otological symptom score at day 7 and day 14 from baseline (day 0) in the participants were not significant ($p = 0.189, 0.183$ respectively) and only very few achieved clinical cure in terms of improvement in tinnitus, discharge and congestion. However, during these visits marked reduction in symptom scores were noted in majority of patients which was in favour of clinical improvement. When they were reassessed later, our data recorded at day 21 and day 30 from baseline (day 0) were significant ($p = 0.049, 0.05$ respectively). Ninety-five (95%) subjects of the 100 enrolled in this study on topical acetic acid, achieved "treatment success," i.e. either clinical cure or clinical improvement, and the remaining five (5%) subjects were categorized as treatment failure (Table 3). Subjects that were categorized as treatment failure had to be put on other antibiotics after the day 30 evaluation. Tinnitus persisted in 6 patients.

95% patients showed signs of resolution of CSOM and none of the patients had any kind of ear damage or toxicity. The 'dry ears' with complete absence of discharge as well as congestion was achieved in 46 patients with 2% acetic acid at end of 3 weeks and in 56 patients after 1 month treatment. The efficacy of 2% acetic acid was significant (p -value <0.00001) in achieving dry ears in chronic suppurative otitis media.

In the present study using topical preparation of 2% acetic acid, the resolution of CSOM was shown with success rate in 95% patients while failure rate was 5%. Also, acetic acid was found to be cost-effective. This suggested that acetic acid was effective in reducing the symptoms of CSOM which is a chronic burden borne by the patients both in terms of health and financial issues.

DISCUSSION:

Chronic suppurative otitis media (CSOM) is defined as long-standing chronic suppurative of the middle ear cleft and its mucoperiosteal lining resulting in discharging ear and deafness.⁸ Bacterial pathogens in the tubo-tympanic type CSOM vary considerably, and can be a combination of both aerobic and anaerobic bacteria.⁸ The prevalence rate of CSOM is particularly high in developing countries like India; higher in rural area and lesser in urban area.⁹

CSOM is a disease of multiple etiology and is well-known for its persistence and recurrence inspite of treatment.¹⁰ Nowadays, because of the excessive and unconventional use of broad-spectrum antibiotics, corticosteroids, and cytotoxic chemotherapy, the emergence of resistance has increased in recent years.¹⁰ The cost of long term treatment being an important factor in developing countries, it has become a difficult task to treat for ENT specialists.¹⁰ There was a long delay between the onset of symptoms and accessing specialist ENT services.¹¹

The study by Patel found that Acetic acid was found to be equally effective to Gentamicin sulphate suggesting that it is the best choice when infection is caused by multiple antibiotic resistant strains and at an affordable cost.¹²

In a study done by Eason et al, topical antiseptics were found to be just as effective as topical antibiotics; however, ofloxacin/ciprofloxacin produced high cure rates.¹³

In another study using 2% acetic acid solution by Aminifarshidmehr¹⁴, who used ear irrigation with 2% acetic acid solution three times per week; he found dry ear in 55/96 (57.29%) at three weeks follow up.

Gupta et al⁷ in their study showed otorrhoea resolution in 84% (42/50) cases of CSOM (tubotympanic type) using 2% acetic acid versus 58% (29/50) using ciprofloxacin eardrops for 3 months and ciprofloxacin 500 mg twice daily for 15 days at 3 months follow up. Here efficacy of antiseptic was superior to ciprofloxacin eardrops.

In a randomized controlled trial by Loock JW¹⁵, data showed that ciprofloxacin eardrops achieved dry ears in 73% cases while 1% acetic acid eardrops achieved it in 24% cases of active chronic otitis media.

Our study was conducted to explore the efficacy of 2% acetic acid in achieving dry ears and resolution of symptoms in chronic suppurative otitis media in our study population. The present study demonstrated that there is a noteworthy reduction in otological symptom score with topical acetic acid following one week of the treatment and continued till the finish of the study. We discovered treatment success rate in 95% patients while failure rate was 5%. This study confirmed the notion that acetic acid is effective in the treatment of CSOM.

Treatment failure may be due to failure to combine ear toilet with medical treatment, the use of ineffective treatment or the result of re-infection related to poor hygienic conditions. Removal of pus and debris improves the quality of the examination and the efficacy of topical agents in eradicating infections in ear. We failed to get an accurate estimate of the duration for which the patients maintained their clinical state of treatment success and status of perforation since few cases were lost to follow up after the study period. Another limitation of our study was absence of a control group to compare the effectiveness of acetic acid with currently used antibiotic drops in CSOM. Failure to record the microorganisms cultured in all patients is another fact, that could have further supported the rationale in using acetic acid drops in face of multidrug resistance.

Keeping in mind the numerous clinical aspects such as treatment success rate, symptomatic relief of discharge and congestion; topical acetic acid ear drops was found to be an effective means to treat CSOM. It can also be considered as one of the best alternative when infection is caused by multiple antibiotic resistant strains. It also has an added benefit to patient by being available at an affordable cost.

CONCLUSION:

The study of the effect of topical acetic acid in mucosal type of CSOM has sparked the interest of numerous otorhinolaryngologists who wish to offer an effective, affordable antidote to their patients without any adverse aftermath such as ototoxicity. Through our study, we found a treatment success rate of 95% in resolving chronic discharging ears in patients who were managed with 2% acetic acid ear drops.

Abbreviations

CSOM: Chronic suppurative otitis media.

REFERENCES:

1. Thomas I, Nagle S, Chavan S, Potdukhe K, Mody S. A comparative study to evaluate the efficacy of topical 1.5% acetic acid versus 0.3% ciprofloxacin in chronic suppurative otitis media. *International Journal of Scientific Research*. Apr 2022;11(4):77-9.
2. Bjarnsholt T, Alhede M, Jensen PO, Nielsen AK, Johansen HK, Homøe P, Høiby N, et al. Antibiofilm properties of acetic acid. *A*. 2015;4(7):363-72.
3. Riaz N, Faiz S, Hassnain D, Fayyaz A, Khan T, Shaikh SI. Efficacy of acetic acid irrigation in management of chronic suppurative otitis media: a prospective study. *Pak J Med Health Sci* 2021;15(10):3300-3.
4. Vishwakarma K, Khan FA, Nizamuddin S, Yadav L. Role of topical acetic acid in comparison to gentamicin for the management of chronic suppurative otitis media. *Int Arch BioMed Clin Res* 2015 Aug;1(1):13-6.
5. Tawre MS, Kamble EE, Kumkar SN, Mulani MS, Pardesi KR. Antibiofilm and antipersister activity of acetic acid against extensively drug resistant *Pseudomonas aeruginosa* PAW1. *PLoS ONE* 2021;16(2):1-16.
6. Kanakarajulu B, Sowmya L, Teja. Role of 1.5% acetic acid irrigation and medical management in chronic persistent suppurative otitis media. *Int J Otorhinolaryngol Head Neck Surg* 2021;7:1010-4.
7. Gupta C, Agarwal A, Gargav ND. Role of acetic acid irrigation in medical management of chronic suppurative otitis media: a comparative study. *Indian J Otolaryngol Head Neck Surg* 2015 Jul-Sep;67(3):314-8.
8. Ghosh A, Jana U, Khaowas A, Das S, Mandal A, Das N. Comparison of the effectiveness and safety of cefpodoxime and ciprofloxacin in acute exacerbation of chronic suppurative otitis media: a randomized, open-labeled, phase IV clinical trial. *J Pharmacol Pharmacother* 2012;3:320-4.
9. Akhtar A, Ali SM, Naqi SA, Aziz T, Shinwari W, Shah SFH. Efficacy of acetic acid versus ciprofloxacin eardrops in achieving dry ears in chronic suppurative otitis media in adult population of Islamabad, Pakistan: a non-randomized control trial. *Gomal J Med Sci* 2019 Jul-Sep;17(3):90-4.
10. Yogi V, Vyas P, Trivedi B., Chhabra B. To compare the efficacy of topically acetic acid irrigation with topical antibiotics in medical management of tubotympanic chronic suppurative otitis media (CSOM). *Int.J.Med.Sci.Educ* 2020;7(1):41-50.
11. N J Tiedt NJ, Butler IRT, Hallbauer UM, Atkins MD, Elliott E, Pieters M, Joubert G, et al. Paediatric chronic suppurative otitis media in the free state province: clinical and audiological features. *S Afr Med J* 2013;103(7):467-70.
12. Patel S. Effectiveness of topical acetic and gentamicin in patients of chronic suppurative otitis media using otological symptoms score in a tertiary care teaching hospital. *Indian Journal of Basic and Applied Medical Research*; Dec 2014;4(1):554-8.
13. Eason R, Harding F, Nicholson R, Nicholson D, Pada J, Gathercole J. Chronic suppurative otitis media in the Solomon Islands: a prospective microbiological, audiometric and therapeutic survey. *N Z Med J*. 1986; 99:812-5.
14. Aminifarshidmehr N. The management of chronic suppurative otitis media with acid media solution. *Am J Otol*. 1996 Jan 1;17(1):24-5.
15. Loock JW. A randomized controlled trial of active chronic otitis media comparing courses of eardrops versus one- off topical treatments suitable for primary, secondary and tertiary health care settings. *Clin Otolaryngol* 2012 Aug;37(4):261-70.