

## TO COMPARE THE EFFICACY OF TOPICALLY ACETIC ACID IRRIGATION WITH TOPICAL ANTIBIOTICS IN MEDICAL MANAGEMENT OF TUBOTYMPANIC CHRONIC SUPPURATIVE OTITIS MEDIA (CSOM)

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### ABSTRACT

**Background:** Chronic suppurative otitis media (C.S.O.M.) is a disease of multiple etiology and is well-known for its persistence and recurrence inspite of treatment. Nowadays, because of the excessive and unconventional use of broad-spectrum antibiotics, corticosteroids, and cytotoxic chemotherapy, the resistance emergence has increased in recent years. Due to the cost of long term treatment is an important factor in developing countries. It has become a difficult task to treat for ENT specialists. Acetic acid alters the pH of EAC and the middle ear to treat otorrhea in CSOM that needs to be studied. **Methods:** 200 patients with active CSOM were randomly distributed in two groups. One hundred patients in each acetic acid and topical antibiotic group. Acetic acid and topical antibiotic irrigation were done for 3months in each group. Pus culture and sensitivity was done for each patient. Both groups were followed up for three months and observed for resolution of ear discharge and healed perforation. **Results:** In our study, otorrhea resolution with acetic acid was 92%and of the topical antibiotic group. 88% of patients had successful otorrhea resolution. The mean time of otorrhea resolution was 30.4 days in a topical antibiotic group, whereas 30.9 days in acetic acid group. No statistically significant difference between both the groups in otorrhea resolution was seen in active CSOM ( $p > 0.05$ ). **Conclusions:** Inactive CSO Macetic acid can be used as an alternative treatment method, which is cost-effective and easily available and performed even at a primary health center for the resolution of ear discharge in active CSOM. As long term management of chronic ear discharge may be required in CSOM.

**Keywords:** Chronic Suppurative Otitis media, Acetic acid,

### INTRODUCTION

Chronic suppurative otitis media (CSOM) as a stage of disease in which there is a chronic infection of the middle ear cleft, i.e., Eustachian tube, middle ear and mastoid, and in which a non-intact tympanic membrane and discharge (otorrhea) are present for at least two weeks or more. There are 65-330 million sufferers worldwide, 60% of whom suffer from significant hearing loss with a disproportionate number of children in developing countries(1). There is a differential prevalence of CSOM in developing

countries among the different socio-economic strata of the community, and it varies from 1.3 to 17.6%. In contrast, the prevalence of CSOM is less than 1% in the USA, and India is among the few countries with the highest prevalence rate (prevalence > 40%).

The main aim in cases of treatment of CSOM who are managed conservatively is to control of infection and elimination of ear discharge for a short period. Eventual healing of the tympanic membrane perforation and hearing improvement is the ultimate

goal. The tertiary medical facility is not available to all people in developing countries like India where, an alternative treatment method, which should be cost-effective and easily available and performed even at primary health centers, should be tried. The methods of management of CSOM are regular aural toilet, a topical antiseptic, administration of topical and systemic antibiotics, and tympanoplasty if the drum fails to heal.

Acetic acid, also well known as plain, white household vinegar, is an antiseptic that can be used to treat infections caused by bacteria or fungus and is commonly prescribed home remedy for the treatment of otitis externa. Treatment involves profuse and frequent irrigation of the ear with 1.5%, 2%, or 5% acetic acid. (1,2,3) The antibacterial effectiveness of these preparations is largely due to their acidity, The pH of the external auditory canal in health varies from 5.0 to 7.8, and that of respiratory mucous membrane ranges from 5.5 to 6.5; and both of which being acidic ones are unfavorable to the growth of the pathogens (Fabricant and Perlstein, 1948, 1949)

The most common etiology for CSOM is considered to be bacterial, so physical removal or destruction of biological films is essential in the medical management of CSOM.

Topical antibiotics ear drops are easily available and commonly used as a treatment option for ear discharges. Therefore, the chances of developing resistance against these antibiotics are more.

The most common class used as topical antibiotics ear drops are fluoroquinolones, and aminoglycoside. They are effective against a variety of gram-negative and gram-positive bacteria, most commonly *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and MRSA, etcetera. Mechanism of action for these antibiotics are multiple. E.g., Ciprofloxacin and ofloxacin show bactericidal action results in interference with the enzyme DNA gyrase.

Gentamicin is a bactericidal antibiotic that works by binding the 30S subunit of the bacterial ribosome, negatively impacting protein synthesis. Medical management of CSOM for the dry ear is essential even before operating the patient. With the use of

excessive antibiotics, the emergence of multiple resistant strains of bacteria has been precipitated, which can produce both primary and post-operative infections. Antibiotics haphazard and discriminate use, and patient's poor follow up have resulted in the persistence of low-grade infections. The changes in microbiological flora following the advent of synthetic antibiotics have increased the relevance of the reappraisal of the modern-day.

## MATERIAL & METHODS

This is Tertiary health care Hospital-based randomized observational comparative study conducted in the Department of ENT& Head-Neck Surgery, Mahatma Gandhi medical college, and hospital, Jaipur from 1st January 2018- 30th December 2019. 200 Patients were included in the study and randomly distributed in two groups. In group one (group A), patients will be treated with aural toilet and irrigation with acetic acid, and in second (group B) patients will be treated with topical antibiotics ear drops.

Inclusion criteria: Patients with tubo-tympanic chronic suppurative otitis media in both sexes age 15 to 60 years. Chronic suppurative otitis with the active mucosal disease, not responding to oral antibiotics. Both outpatients and inpatients will be included. Exclusion criteria:

1. The age group below 15 and above 60 of all sexes
2. Serous Otitis Media
3. CSOM with otomycosis
4. CSOM with vertigo
5. CSOM with intracranial complication
6. Cholesteatoma or with marginal perforation of the tympanic membrane Patients with sensorineural hearing loss.

The ear was thoroughly cleaned with dry mopping. Prior to cleaning a swab of the middle ear being taken for microscopy and culture in all patients. The patient was advised to instill three drops acetic acid two times a day using 1 ml syringe and hold it up to 15-30 minutes by tilting their head to one side or by putting a cotton plug. Topical antibiotic ear drops were self-administered by patients three times daily

The efficacy of two groups was compared based on reduction in otological symptoms, involving the

middle ear and external auditory meatus (EAM) at two weeks, 1 month and three months after treatment. Patients were monitored continuously throughout the study for any adverse effects.

## RESULTS

In our study, we have included a total number of 200 cases of an active mucosal type of CSOM who fulfilled the selection criteria were registered. All the patients were randomly categorized into two groups, Group-A (n=100) for Acetic acid and group-B (n=100) for topical antibiotic eardrops group. Patients with mucoid discharge, irrespective of the amount of discharge and duration of discharge, at the time of presentation, were included.

Patients between the age group of 15-60 years were included in this study. Maximum numbers of patients were seen in the age group of 15-30 years total of 81%. In the Acetic acid irrigation group, 45 patients were between the age group of 15-30 years (45%), 33 patients in 31-45 years (33%), and 22 patients in 46-60 years age group (22%). In topical antibiotics, ear drops irrigation group 36 patients were between the age group of 15-30 years (36%), 34 patients in 31-45 years (34%), and 30 patients in 46-60 years age group (30%). The mean age in the acetic acid group was 41.10 years, whereas in the topical antibiotics ear drops group, it was 37.22 years. Thus both groups were matched in age distribution.

Gender wise distribution of patients showed that out of 200 cases, randomly 129 were males, and 71 were females. In the Acetic acid group, among them, 61 were males and 39 females. In the topical antibiotic ear drop group, there were 68 males and 32 females.

All the patients included in the study were classified based on socioeconomic status as per Modified Kuppusswamy classification. In our study maximum number of patients belonged to Upper-lower class 78 patients (39%), including 38 patients who were irrigated with Acetic acid ear drops and 40 patients were irrigated with Topical antibiotics.

58 Patients (29%) belonged to a Lower middle class, including 30 patients in the Acetic acid group and 28 patients in the Topical antibiotic group. 37 (18.5%)

patients belonged to lower socioeconomic groups, including 16 patients in the Acetic acid group and 21 patients in the topical antibiotic group. 16 (8%) patients belonged to the Upper-middle socioeconomic group, including nine patients in the Acetic acid group and 7 patients in the topical antibiotic group. 11 (5.5%) patients belonged to the Upper socioeconomic group, including 7 patients in the Acetic acid group and 4 patients in the topical antibiotic group.

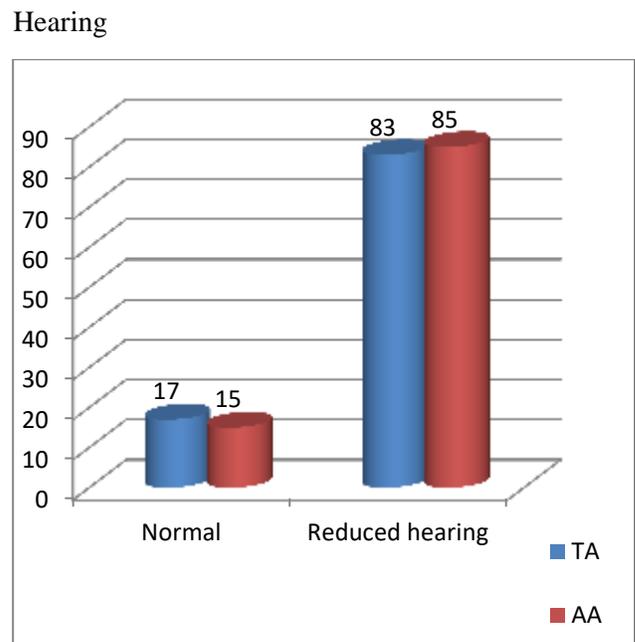
The SES distribution was comparable between both the groups and statistically not significant.

In Acetic acid group 85 patients had decreased hearing, and 15 patients had no hearing loss, whereas in the Topical Antibiotic group, 83 patients had hearing loss, and rest 17 had normal hearing.

**Table 1:-** Associated Presenting complain Hearing in both groups.

	Normal Hearing	Reduced hearing
<b>TA</b>	17	83
<b>AA</b>	15	85

**Figure 1:-** Associated Presenting complain Hearing in both groups



Twenty-five patients in the Topical antibiotic group complained of earache as compared to 24 patients in the Acetic acid group. In the Topical antibiotic group out of 100 patients, only 4 patients complained of headaches, whereas 7 patients out of 100 patients complained of headaches in the Acetic Acid group. 9 patients presented with tinnitus in the Topical Antibiotic group, while 8 patients complained in the Acetic acid group. Remaining 91 and 92 patients had no complaints of tinnitus in the Topical antibiotic and acetic acid group, respectively. Out of the 100 patients, 8 of the patients in the Topical Antibiotic group had a history of allergic rhinitis, whereas 11 out of the 100 patients in the Acetic acid group had a history of allergic rhinitis.

On examination of the nasal cavity, 11 out of 100 patients in the topical antibiotic group had Symptomatic DNS whereas in Acetic acid group 8 out of 100 patients had symptomatic DNS

In the Topical antibiotic group, TM perforation was seen in 61 patients in the right ear and 56 patients in the left ear with B/L TM perforation in 17 patients. Whereas in 100 patients, in Acetic acid group TM perforation was seen in 68 patients in the right ear and 54 patients in the left ear with B/L TM perforation in 22 patients.

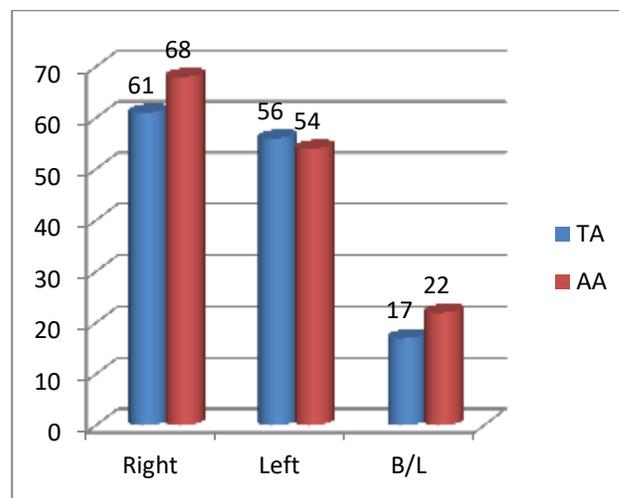
**Table 2** – Perforation status

	Right	Left	B/L
TA	61	56	17
AA	68	54	22

**Table 3** – Pus culture

	Staph aureus	Pseudomonas	Klebsiella	Mixed	CoNS	E. coli	Proteus	Providentia	NGNB
TA	39	30	4	12	5	5	2	1	2
AA	36	30	11	10	7	1	0	1	4

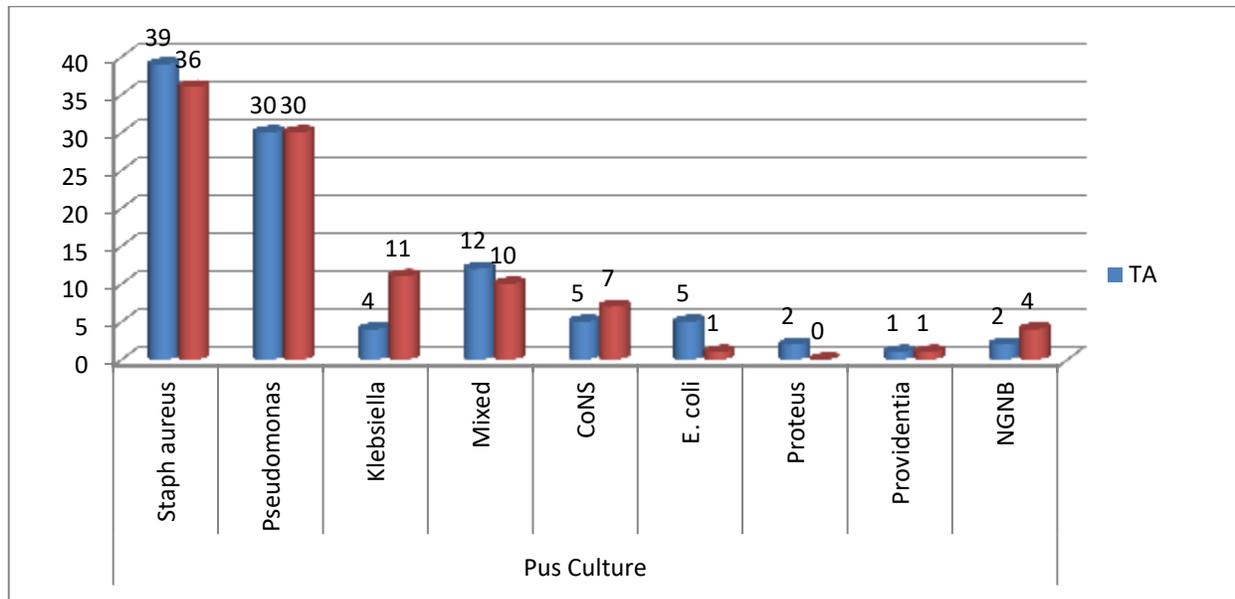
**Figure 2** – Perforation status



In our study of 200 patients, otoscopy showed 25 patients in the Topical antibiotic group had granulations compared to 11 patients in the acetic acid group.

Pus for culture and sensitivity was done in all patients. Amongst 100 patients in the topical antibiotic group, 39% Staph aureus followed by 30 patients, Pseudomonas was the most common organism detected on Culture and sensitivity. 12 % cases had mixed growth, 4% Klebsiella, 5 % CoNS, 5 % E. coli, 2 % Proteus, 1 % Providentia were other organisms cultured, and 2 % NGNB were cultured for which species typing could not be done at our setup. Amongst 100 patients in the acetic acid group, 36% Staph aureus followed by 30 patients, Pseudomonas was the most common organism detected on Culture and sensitivity. 10 % cases had mixed growth, 11% Klebsiella, 7 % CoNS, 1 % E. coli, 1 % Providencia were other organisms cultured, and 4 % NGNB were cultured for which species typing could not be done at our setup.

**Figure 3 – Pus culture**



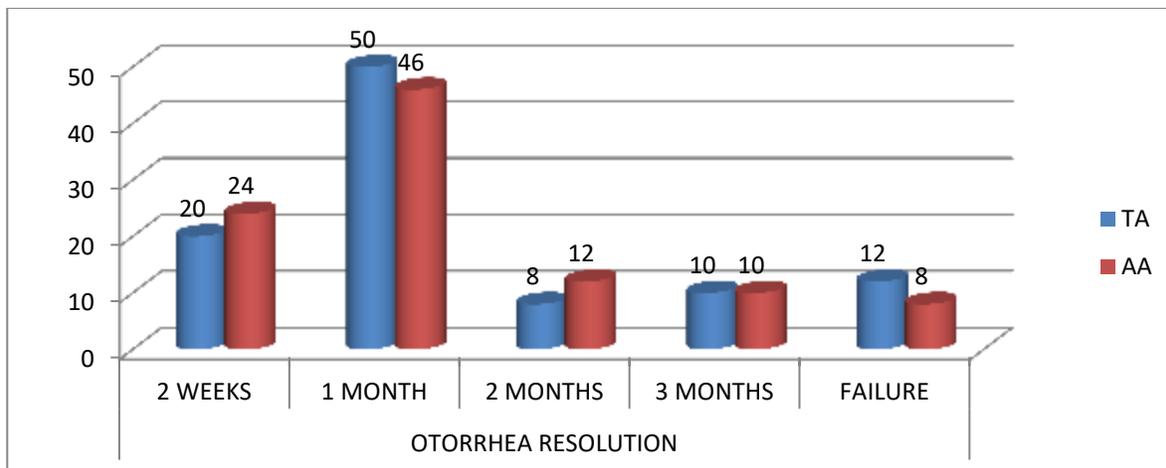
Otorrhea was evaluated on day 0, 2 weeks, 1 month, 2 months, and 3rd month. Amongst 100 patients in topical antibiotic group otorrhea resolution seen of 20 patients in 2 weeks, 50 patients in 1 month, 8 patients in 2 months, 10 patients in 3 months. 12 patients had no otorrhea solution even after 3 months

of irrigation considered to be a failure. Amongst 100 patients in acetic acid group otorrhea resolution seen of 24 patients in 2 weeks, 46 patients in 1 month, 12 patients in 2 months, 10 patients in 3 months. 8 patients had no otorrhea resolution even after 3 months of irrigation considered to be a failure

**Table 4 – Otorrhea resolution**

	2 WEEKS	1 MONTH	2 MONTHS	3 MONTHS	FAILURE
<b>TA</b>	20	50	8	10	12
<b>AA</b>	24	46	12	10	8

**Figure 4 – Otorrhea resolution**

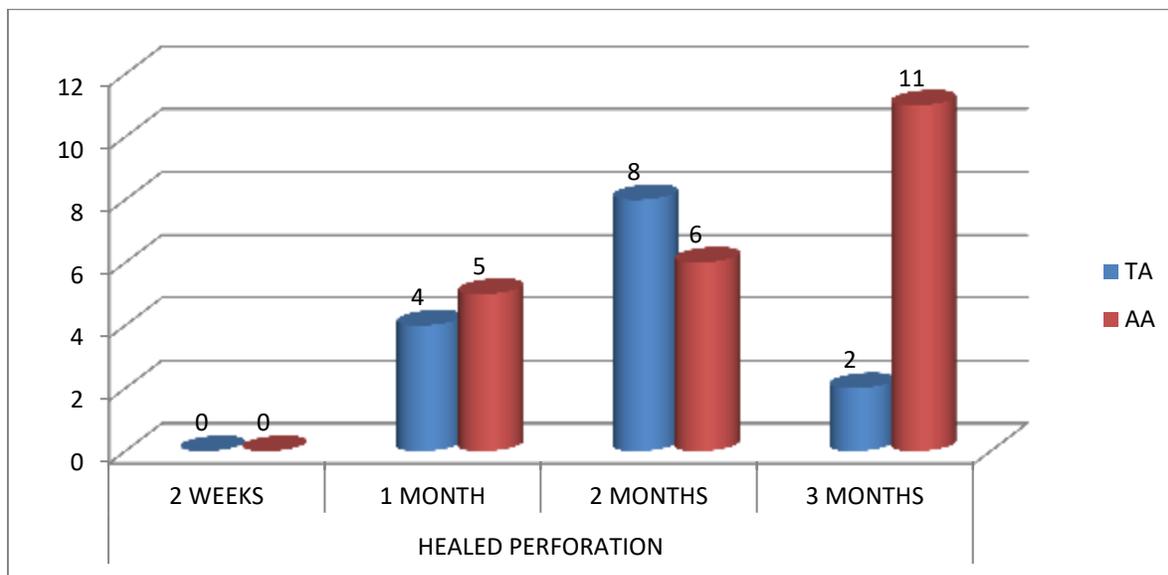


Tympanic membrane perforation was evaluated on day 0, 2 weeks, 1 month, 2nd month, and 3rd month. Amongst 100 patients in topical antibiotic tympanic membrane perforation healed in, 4% patients in 1 month, 8% patients in 2 months, 2 % patients in 3 months%. Amongst 100 patients in acetic acid group healing of perforation seen in 5 patients in 1 month, 6 patients in 2 months, 11 patients in 3 months.

**Table 5 – Healed perforation**

	2 WEEKS	1 MONTH	2 MONTHS	3 MONTHS
<b>TA</b>	0	4	8	2
<b>AA</b>	0	5	6	11

**Figure 5 – Healed perforation**



In an acetic acid group, otorrhea resolution was maximum by 1 month in lower-middle and upper lower class 14 and 15 patients, respectively, with maximum failure in the same group 2 patients in lower-middle and 6 in the upper-lower class. No failure was seen in the upper, upper-middle, and lower class. In our study in topical antibiotics, otorrhea resolution was maximum by 1 month in lower-middle and upper lower class 15 and 20 patients respectively with maximum failure in the same group 3 patients in lower-middle and 7 in the upper-lower class. No failure was seen in the upper class.

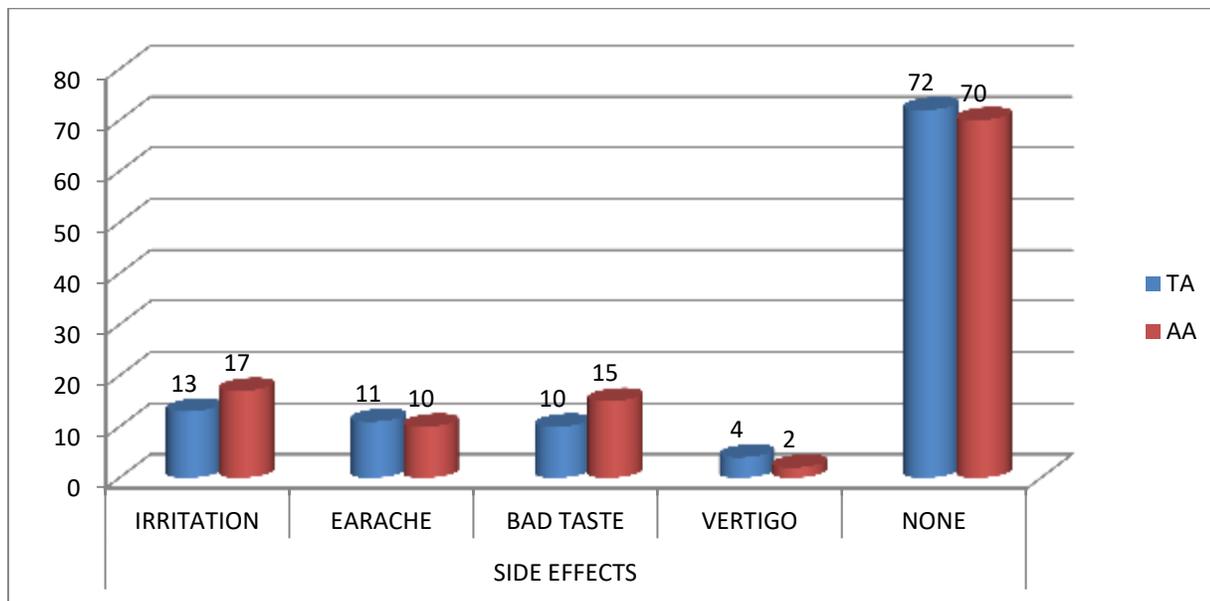
Amongst 100 patients in the topical antibiotic group experienced irritation in 13 patients, ear-ache in 11 patients, bad taste in mouth in 10 patients, and vertigo in 4 patients. 72 patients had no complaint with topical antibiotic ear drops. Whereas amongst 100 patients in acetic acid group experienced

irritation in 17 patients, ear-ache in 10 patients, bad taste in mouth in 15 patients, and vertigo in 2 patients. 70 patients had no complaint with acetic acid ear irrigations

**Table 6 – Side effects**

	SIDE EFFECTS				
	IRRITATION	EARACHE	BAD TASTE	VERTIGO	NO COMPLAINT
<b>TA</b>	13	11	10	4	72
<b>AA</b>	17	10	15	2	70

**Figure 6 – Side effects**



## DISCUSSION

Chronic suppurative otitis media (CSOM) worldwide especially in developing countries, is a serious and avoidable healthcare concern; not only it causes distress to the patient and family, but also because of the substantial economic burden quantifiable and unquantifiable, financial and non-financial imposed on the affected individuals(7). It is one of the ENT diseases known for the increased incidence of resistance to current antibiotics used in otitis media treatment (4). CSOM is capable of causing severe destruction and sequelae of manifestation of Deafness, Discharge, and Perforation of the tympanic membrane (5).

In this study, we have discussed an adjuvant treatment (Acetic acid and Topical antibiotics) in the management of CSOM. Various factors influencing the success rate of this treatment have been discussed in the literature.

Age is a non-mastoid factor that may influence the outcome. We have excluded the patients under 15 years of age, as this group has adenoid hypertrophy in general. Repeated respiratory tract infections are more frequent in this group. In this study, we have found CSOM to be more common in 15-30 years of age group, and due to increased susceptibility of this age, it is considered to be an economic burden.

In our study, the slight male preponderance is seen in both groups.

CSOM is considered to be a disease of a developing country. It has been proven that socioeconomic factors such as poor living conditions, overcrowding, poor hygiene, and poor nutrition are predisposing factors. In our study, we have categorized patients according to socioeconomic status by Modified Kuppuswami classification. Maximum patients were present in upper lower class i.e., 78 patients (39%) and in lower middle class 58 Patients (29%) which was comparable with the study of Aditya Singhal et al. 2017 of 495 patients, 129 patients (26.6%) were in Upper lower class, 102 patients (20.61%) in the lower middle class and 148 patients (29.9%) in the lower class. As the maximum population in a developing country is in this class, this disease is considered a socioeconomic burden. So, a cost-effective method is required for this class for this disease.

All the 200 patients had complained of ear discharge with associated complaints like reduced hearing in 84% patients, earache in 24.5% patients, headache in 5.5% patients, and tinnitus in 8.5% patients making the disease troublesome. None of the patients in our study complained of associated vertigo.

Allergic rhinitis and symptomatic DNS are not commonly present but are considered to increase the episodes of CSOM. It is an influencing factor in otorrhea resolution. In our study, out of 200 patients, 19 patients had a history of allergic rhinitis, and 19 patients had symptomatic DNS.

The mean time of otorrhea resolution was 30.4 days in a topical antibiotic group, whereas 30.9 days in the acetic acid group, which was maximum in cases of small perforations. Healing of perforation in the Topical antibiotic group was 14%, whereas 22 % in acetic acid group.

Various previous studies like that of Supreetha et al. 2015-2016 & Ashok Sharma et al. 2018, showed that most common organisms found in CSOM are *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Proteus mirabilis*, *Klebsiella pneumoniae*, *E.coli*, *Aspergillus* and *Candida* (5,6) which was comparable in our study of 200 patients. Amongst 100 patients in the topical antibiotic group, 39% *Staph aureus* followed by 30 patients, *Pseudomonas* was the most common organism detected on Culture and sensitivity.

Amongst 100 patients in the acetic acid group, 36% *Staph aureus* followed by 30 patients, *Pseudomonas* was the most common organism detected on Culture and sensitivity. With increased and irrational use of wide-spectrum antibiotics on a long term basis, the emergence of multiple resistant strains of bacterial isolates has become very common. The main aim in cases of treatment of CSOM who are managed conservatively is to control of infection and elimination of ear discharge for a short period. Eventual healing of the tympanic membrane perforation and hearing improvement is the ultimate goal (5).

In our present study, the efficacy of both the topical agents are evaluated in their respective group i.e., Group A for antiseptic, Acetic acid & Group B for topical antibiotics according to their sensitivity profile were compared based on patient's treatment succeeding rate. Various clinical aspects are kept in view such as, including overall success rate, symptomatic relief in discharge pain and congestion, according to this study clinically onto topical Acetic

acid was found to be comparatively slightly better with otorrhea resolution in 92% with healed perforation in 22% than its comparative topical antibiotic group with otorrhea resolution in 88% with healed perforation in 14 %, but statistically, both the topical agents are equally effective.

The study was done by Chhavi Gupta et al., 2014 showed that the resolution of otorrhea by Acetic acid was 84%, and healing of tympanic membrane perforation was 26% while failure rate 16% was noted (9). In the present study, 1.5% Acetic acid showed that resolution of CSOM was higher than the study done by C. Gupta et al. as the treatment success rate in 92% patients while failure rate 8% and 2% patients were found to had vestibular toxicity.

Aminifarshidmehr's study in 1996 showed that the acetic acid works on principle on their ability to reduce the pH in the ear, as low pH restricts the growth of bacteria and fungi, which flourish in a basic environment (pH 8-10) (8). The findings of our study are in accordance with Aminifarshidmehr, 1996.

The result of the present study somewhat differed from the result obtained by Clinical Practice Guidelines of the Philippine Society of Otolaryngology-Head and Neck Surgery 1997 & 2002; their study did not find a significant difference between topical acetic acid and topical antibiotics in persistent activity on otoscopy (13/20 [65%] with topical antiseptics v 15/18 [83%] with topical antibiotics; (OR 0.40, 95% CI 0.10 to 1.66).

The present study showed that both the topical antibiotics and Acetic acid groups were equally effective (p-value < 0.05), the difference in effectiveness for otological symptom score between two groups are narrowed after one week of treatment, but remained both the drugs was statistically significant till the end of treatment.

The effectiveness of present study (<0.05) of topical Acetic acid (antiseptic) versus topical antibiotics support the study done by Eason et al. (OR = 0.67, 95% CL = 0.2, 2.25); Topical antiseptics were found to be just as effective as topical antibiotics; however, ofloxacin/ciprofloxacin produced high cure rates (5).

For Acetic acid group: various previous study postulated that Acetic acid was used in different fields widely as an antimicrobial agent, e.g., for killing food-borne pathogenic bacteria (Berry and Cutter, 2000; Rhee et al., 2003), to inhibit *Escherichia coli* growth (Roe et al., 2002); used in combination with boric acid or corticosteroids to treat ear infections (Balen et al., 2003), and to disinfect contaminated wounds (Bowler et al., 2001) (11-13) Acetic acid (2%) was commonly prescribed remedy for fungal otitis externa, in vitro study revealed significant antifungal effect ( $p < 0.05$ ) against examined fungal species, this result support its clinical use in otomycosis (10).

For topical antibiotic group: the various previous studies showed that *Pseudomonas aeruginosa* and anaerobes are the most frequently isolated organisms and aminoglycosides such as tobramycin and Gentamicin, neomycin sulfate, are commonly used in patients with otitis media (14). Topical antibiotics are ototoxic but highly effective against gram Negative & positive bacteria, which was chosen for the study as it is commonly employed in the topical treatment of chronic otitis media (15). Despite their topical ototoxicity, antibiotics eardrops are frequently used in clinical practice for patients with otitis externa, otitis media with or without perforations, and infected mastoid cavities.

Various studies have shown that topical antibiotics eardrops cause ototoxicity when used for longer than 7 days in patients with a tympanic membrane defect. After the discharge has stopped, these eardrops should be discontinued in the presence of healthy middle ear mucosa (16-19).

In the early 1990s, in a survey done on 2235 otolaryngologists, 84% reported using ototopical agents in the presence of a perforated tympanic membrane, and only 3.4% reported having witnessed irreversible ear damage caused by such agents (20).

Since all the patients were not afforded such payment hence the study was based on empirical therapy; because most patients want to be recovered quickly. Thus among such patients who cannot yet afford topical antibiotics, topical antiseptics may offer some benefit. It is the best alternative when the

infection is caused by multiple antibiotic-resistant strains and where there is a shortage of therapeutic options.

Since the study was prospective and observational-based on symptomatic relief of problem caused by the pathogen in CSOM patients by removing or killing the related pathogens and making the ear dry, so the study was successful for the purpose of the study, and the study suggests that the use of Acetic acid is quite better than that of topical antibiotics in CSOM patients for their economic purpose as well as by preventive the patients from antibiotics resistance and toxicity as mentioned in the literature above. So it can be added in the first-line treatment of active CSOM tubo-tympanic cases, especially for *pseudomonas* and *staph aureus*. Oto-toxicity chances are lesser with diluted acetic acid. However, further studies regarding the type, dilution ratio, duration of irrigation, pH, long term sequelae, and standardization of acetic acid treatment has to be conducted yet.

## CONCLUSION

Since the study was prospective and observational-based on symptomatic relief of problem caused by the pathogen in CSOM patients by removing or killing the related pathogens and making the ear dry, so the study was successful for the purpose of the study and the study suggests that use of Acetic acid is better than that of Topical antibiotics in CSOM patients for their economic purpose as well as by preventing the patients from antibiotics resistance and toxicity as mentioned in the literature above.

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