

Original Research Article

Comparison between vinegar wash and culture based oral antibiotic therapy in active chronic suppurative otitis media

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ABSTRACT

Background: Chronic otorrhea in chronic suppurative otitis media (CSOM) has become a difficult task to treat for ENT specialists because of emerging resistance to the available antibiotics and patient's affordability for its cost. Also biofilms have been responsible for the chronicity of disease. Use of vinegar as an antiseptic and altering the pH of middle ear to treat otorrhea in CSOM needs to be studied.

Methods: 120 patients with active CSOM were recruited randomly for either vinegar wash or antibiotic therapy. Vinegar diluted with water in 1:1 ratio at pH 4 was used twice a day for 3 weeks to one group. Oral antibiotics based on culture sensitivity report were given to other group for 3 weeks. Both groups were followed up for a month and observed for resolution of ear discharge.

Results: *Pseudomonas* (40%) and *Staphylococcus aureus* (25%) were the most common organisms detected. 96.2% of *Pseudomonas* and 50% of *Staphylococcus aureus* ears became dry with vinegar wash. 81.67% of antibiotic group and 68.33% of vinegar group ears became dry in 3 weeks. No statistically significant difference between vinegar wash and culture based oral antibiotic therapy in resolution of ear discharge was seen in active CSOM ($p > 0.05$).

Conclusions: Management of otorrhea is long term in CSOM and vinegar can be used as an alternative to costly oral antibiotics for resolution of ear discharge in active CSOM. Two fold dilution of vinegar prevents chance of ototoxicity.

Keywords: Otitis media, Acetic acid, *Pseudomonas*

INTRODUCTION

Chronic suppurative otitis media (CSOM) is one of the most common otological conditions encountered in day to day practice. Incidence of CSOM is high in developing countries because of overcrowding, inadequate health care, poor hygiene, recurrent upper respiratory tract infections, poor nutrition and pollution.¹ CSOM is considered as a biofilm disease and it also explains the observed resistance to antibiotics.²

Medical management for resolution of otorrhea in active chronic suppurative otitis media is essential before surgery. Different treatment options like aural toilet,

topical and systemic antibiotics are available. But the widespread use of antibiotics has precipitated the emergence of multiple resistant strains of bacteria which produce both primary and postoperative ear infections. Drawback of treatment using antibiotic both orally and parenterally includes cost, adverse effects, toxic reaction and inconvenience for patients.

The use of vinegar which is acetic acid as a medicine goes back to ancient times because of its antimicrobial properties. The objective of this study was to acidify the pH of middle ear with vinegar and compare its outcome with oral antibiotic treatment in CSOM to resolve chronic otorrhea.

METHODS

A prospective study on 120 patients of active chronic suppurative otitis media attending the outpatient department of otorhinolaryngology at tertiary care hospital (Karnataka Institute of Medical Sciences, Hubli) in the year 2015-2016 were recruited. Patients who met the inclusion criteria were selected and randomly allotted to vinegar or antibiotic group. Ethical clearance for the study obtained.

Inclusion criteria were patients with active CSOM, age group between 12-60 years, patients who gave informed written consent for both the above treatment and willing for regular follow up.

Exclusion criteria were CSOM cases who have not taken any antibiotics for a minimum duration of two weeks prior, those with symptoms and signs suggesting of complications, systemic illness like diabetes mellitus, chronic renal failure and immunocompromised status, patients with other active focus of infection like acute rhinosinusitis.

Patients with ear discharge more than 3 months with tympanic membrane perforation on examination were selected. Detailed history of ear discharge and associated symptoms taken. Routine ENT examination was done. Diagnosis of CSOM confirmed.

Sample collection of ear discharge done after dry mopping the outer part of external auditory canal, swab was taken with sterile precautions from middle ear and sent to laboratory immediately. Then it was inoculated on chocolate agar and Mac conkey agar at 37°C and aerobically incubated for 48 hours. The antibiogram of each bacterial isolate was performed by Kurby Bauer disc diffusion technique.

Vinegar group of patients underwent bone conduction testing by pure tone audiometry prior to therapy. Diluted vinegar as 2% acetic acid solution was given for ear wash twice a day to this group. Synthetic vinegar of pH 4 was diluted in the ratio of 1:1 with

water at body temperature and instilled as 40ml solution into discharging ear twice a day with 20cc syringe. This was performed in sitting position by the patient attenders. After wash, dry mopping of ear was done with ear buds. Patients were followed up every week for 4 weeks for symptomatic assessment and examination of ear. Bone conduction of the ear repeated after 4 weeks.

Ototoxicity of vinegar was assessed based on the definition and criteria for it established by the American Speech-language-Hearing Association (ASHA) i.e. defined as: (a) 20 db or greater decrease in pure tone threshold at one frequency, (b) 10 db or greater decrease at 2 adjacent frequencies, or (c) loss of response at 3 consecutive test frequencies in which responses were previously obtained.

Based on the culture sensitivity report, oral antibiotic therapy was given to another group for three weeks. Few topical antibiotic preparations have acidic pH hence use of topical antibiotics was not considered in this study.

Patients of both groups were followed up weekly for 4 weeks. After 4 weeks any persistent discharging ear was considered as failure of treatment. Statistical analysis was done with SPSS v20 software. Chi square test was applied.

RESULTS

Age of 60% of the CSOM patients were less than 30 years as given in Table 1. Mean age for antibiotic group found to be 31 with standard deviation of 15.16 years. Vinegar group found to have mean age of 27.97 with standard deviation of 12.43 years. Chi square test was used and value noted as 1.0692 with $p=0.7842$. Since $p > 0.05$, both antibiotic and vinegar groups were comparable. 30 males and 30 females in antibiotic group whereas vinegar group 34 males and 26 females were distributed. Chi square test done and value found to be 0.5364 with p value = 0.46. Hence no statistical difference in gender distribution observed.

Table 1: Age distribution of patients in antibiotic and vinegar groups.

Age group (years)	Antibiotic group		Vinegar group		Total	
	n	%	n	%	n	%
<=20	17	28.33	19	31.67	36	30.00
21-30	17	28.33	20	33.33	37	30.83
31-40	11	18.33	13	21.67	24	20.00
41-50	7	11.67	5	8.33	12	10.00
51-60	8	13.33	3	5.00	11	9.17
Chi-square= 1.0692 p = 0.7842						
Total	60	100.00	60	100.00	120	100.00
Mean age	31.00		27.97		29.48	
SD age	15.16		12.43		13.89	

113 (94.17%) cases were of tubotympanic type (TTD) and 7 cases (5.83%) were of Atticoantral disease (AAD). Among TTD cases, 59 and 54 cases were distributed in antibiotic and vinegar group respectively. Chi square test with Yates correction applied. Chi square value was 2.4227 with p =0.1191. As p value >0.05, effects of two treatments in both types of CSOM were comparable.

40% *Pseudomonas* followed by 25% *Staphylococcus aureus* were the most common organisms detected in culture sensitivity. 10.9% of the CSOM cases had a mixed growth, 6.7% *Klebsiella*, 5.8% coagulase negative *Staphylococcus* (CoNS), 2.5% *E. coli*, 0.8% *Proteus*, 0.8% *Providencia* were other organisms cultured. 2.5% non-fermentative gram negative bacilli were cultured for which species typing could not be done at our set up. 58.33% of the organisms were gram negative and 30.83% were gram positive organisms.

Antibiotic sensitivity of various organisms detected in this study shown in descending order as follows and also given in Table 2.

- *Pseudomonas*: ceftazidime > amikacin > imipenem > gentamicin > ciprofloxacin > levofloxacin > piperacillin+ tazobactam.
- *Staphylococcus aureus*: clindamycin > erythromycin > ciprofloxacin > amoxicillin+clavulanic acid.
- *Klebsiella*: gentamicin > ciprofloxacin > ceftriaxone.
- *Coagulase negative Staphylococcus*: amoxicillin+clavulanic acid = clindamycin = ciprofloxacin.
- *Citrobacter*: gentamicin > ciprofloxacin > cefotaxime and amoxicillin+ clavulanic acid.

Table 2: Antibiotic sensitivity of various organisms in CSOM (in terms of number of cases).

Organism	A m	A v	P i	E r	C l	C t	C x	T x	C u	C p	C z	C d	C i	G n	A k	C x	P x	O x	L x	A z	I m
Pseud	-	-	17	-	-	2	5	2	-	6	42	-	5	34	39	31	4	2	25	1	37
Staph	15	15	1	22	25	13	1	8	1	1	1	1	1	9	1	21	3	1	10	-	-
Kleb	3	2	-	1	-	5	8	1	2	-	1	-	-	8	1	8	2	2	2	-	1
CoNS	2	6	-	3	6	4	-	1	-	-	-	-	-	1	-	6	2	-	-	-	-
Citro	1	4	-	-	-	1	4	5	-	1	1	-	-	6	2	6	3	3	1	-	2
NGNB	1	2	1	-	-	3	2	2	-	-	-	-	-	2	-	3	-	1	1	1	-
Ecoli	2	-	-	-	-	2	3	-	1	-	-	-	-	3	-	3	-	-	-	-	-
Prot	-	1	-	-	-	-	1	1	-	-	-	-	-	1	-	1	1	-	-	-	-
Prov	-	1	-	-	-	1	1	1	-	-	1	-	1	1	-	1	-	-	-	-	-
Total	24	31	19	26	31	31	25	21	4	8	46	1	7	65	43	80	15	9	39	2	40

*Am- Ampicillin, Tx- Cefotaxime, Ak-Amikacin, Av- Amoxicillin+clavulanate, Cu-Cefuroxime, Cx-Ciprofloxacin, Pi-Piperacillin+tazobactam, Cp-Cefoperazone, Px-Pefloxacin, Er-Erythromycin, Cz-Ceftazidime, Ox-Ofloxacin, Cl-Clindamycin, Cd-cefpodoxime, Lx-Levofloxacin, Ct-Cefoxitin, Ci-Cefepime, Az-Azithromycin, Cx-Ceftriaxone, Gn-Gentamicin, Im-Imipenem, Pseud-Pseudomonas, NGNB- Nonfermentative gram negative bacilli, Klebs- Klebsiella, Provi- Providencia, CoNS- Coagulase negative staphylococcus, Citro- Citrobacter.

Table 3: Antibiotic resistance of various organisms in CSOM (in terms of number of cases).

Organism	A m	A v	P i	E r	C l	C t	C x	T x	C u	C p	C z	C d	C i	G n	A k	C x	P x	O x	L x	A z	I m
Pseud	2	-	1	-	-	1	-	3	-	1	6	3	-	6	2	7	2	2	5	1	3
Staph	12	1	1	10	9	6	1	1	1	1	1	1	1	2	1	5	1	-	-	1	1
Kleb	10	1	-	-	-	4	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
CoNS	7	2	-	6	3	3	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Citro	4	3	-	1	1	6	2	2	-	-	-	-	-	1	-	1	1	-	1	-	-
NGNB	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Ecoli	2	-	-	-	-	-	1	1	-	-	-	-	-	-	-	-	-	-	-	-	-
Prot	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Prov	1	-	-	-	-	1	-	-	-	-	1	-	-	-	-	1	-	-	-	-	-
Total	40	7	2	17	13	21	4	7	1	2	7	4	1	8	3	14	4	2	6	2	4

*Am- Ampicillin, Tx- Cefotaxime, Ak-Amikacin, Av- Amoxicillin+clavulanate, Cu-Cefuroxime, Cx-Ciprofloxacin, Pi-Piperacillin+tazobactam, Cp-Cefoperazone, Px-Pefloxacin, Er-Erythromycin, Cz-Ceftazidime, Ox-Ofloxacin, Cl-Clindamycin, Cd-cefpodoxime, Lx-Levofloxacin, Ct-Cefoxitin, Ci-Cefepime, Az-Azithromycin, Cx-Ceftriaxone, Gn-Gentamicin, Im-Imipenem, Pseud-Pseudomonas, NGNB- Nonfermentative gram negative bacilli, Klebs- Klebsiella, Provi- Providencia, CoNS- Coagulase negative staphylococcus, Citro- Citrobacter.

66.7% of organisms were sensitive to ciprofloxacin, followed by gentamicin (54.2%), ceftazidime (38.3%), amikacin (35.8%), imipenem (33.3%), levofloxacin, amoxicillin-clavulanic acid and clindamycin (25.8%). Highest resistance observed to ampicillin (33.3%) followed by cefoxitin (17.5%) and erythromycin (14.2%) as seen in Table 3. 11.67% of cases also showed resistance to ciprofloxacin.

96.2% of the *Pseudomonas* and 50% of the *Staphylococci* detected TTD cases became dry with 3 weeks of vinegar wash as in Table 4. Other organisms were few and hence their results were not significant. Only 3 cases (5%) of active CSOM cases showed worsening of bone conduction at 3 consecutive frequencies after 3 weeks of vinegar wash.

Table 4: Results of vinegar wash in tubotympanic disease.

Organism	Dry ear (%)	Improved (%)	Fail (%)
<i>Pseudomonas</i>	96.2	3.8	0
<i>S. aureus</i>	50	14.3	35.7
<i>Klebsiella</i>	33.3	33.3	33.3
<i>CoNS</i>	66.7	33.3	0
<i>Citrobacter</i>	66.7	33.3	0
<i>NGNB</i>	50	50	0
Mixed	0	33.3	66.7

*CoNS- Coagulase Negative Staphylococcus, NGNB- Nonfermentative gram negative bacilli

Table 5: The final analysis of two groups (antibiotic and vinegar) in active CSOM.

Results	Antibiotic group		Vinegar group		Total	
	n	%	n	%	n	%
Dry	49	81.67	41	68.33	90	75.00
Improved	5	8.33	11	18.33	16	13.33
Fail	6	10.00	8	13.33	14	11.67
Total	60	100.00	60	100.00	120	100.00

Chi-square= 3.2473; P = 0.1972

83% of the active TTD cases became dry when treated with culture based oral antibiotic therapy for 3 weeks. 73.7% of the *Pseudomonas* and 81.3% of the *Staphylococcus* infected ears became dry.

Out of 6 AAD cases, 3 cases became dry following vinegar treatment. One AAD case with mixed growth was treated with antibiotic therapy but ear failed to become dry. Hence vinegar wash has a role in reducing the ear discharge in AAD.

Pseudomonas cases responded better to vinegar when compared to antibiotics. Out of 11 cases with granulation, in 6 cases granulation disappeared after vinegar wash. Chi-square =1.9057; p= 0.1689. No statistically

significant difference was observed in reduction of granulation with vinegar and antibiotic treatment in CSOM (p >0.05).

Two modes of therapy in CSOM were compared. 81.67% of the vinegar wash treated ears and 75% of culture based antibiotic treated ears became dry as given in Table 5. Chi-square value=3.2473 and p =0.1972. As p >0.05, we concluded that no statistically significant difference between antibiotic therapy and vinegar wash seen in active CSOM.

DISCUSSION

Management of otorrhea in chronic suppurative otitis media has become a difficult task to otologists. It is because of the emerging resistance to antibiotics, patient compliance for long term treatment and biofilm formation by organisms. The present study was conducted with an intention to know the role of systemic antibiotics and vinegar wash in the management of chronic otorrhea in CSOM.

Chronic suppurative otitis media found common in age group less than 30 years in this study. Due to increased susceptibility of people in this age group it has become a burden to people and economy of country like India.

Since 1993 *Pseudomonas* is the most common organism detected in CSOM in Indian scenario.³⁻⁸ *Pseudomonas* (40%) followed by *Staphylococcus aureus* (25%) were the most common organisms in our study which is similar to previous studies. Gram negative infections (69.2%) were more common than gram positive infections (30.8%). *Pseudomonas* to ceftazidime, *Staphylococci* to clindamycin, *Klebsiella* and *Citrobacter* to gentamicin and *coagulase negative Staphylococcus* to amoxicillin+clavulanate were the highest sensitivity pattern of organisms detected in our cases.

The present study showed 66.7% of organisms sensitive to ciprofloxacin, followed by gentamicin (54.2%), ceftazidime (38.3%), amikacin (35.8%), imipenem (33.3%), levofloxacin, amoxicillin+clavulanic acid, clindamycin (25.8%). This highest sensitivity to ciprofloxacin was similar to study by Deb et al.⁹ However, 11.67% of cases show emerging resistance to ciprofloxacin which necessitates the need based use of antibiotics. Also few of the organisms were found sensitive to intravenous antibiotics only which was a financial burden and suggested a cost effective alternative treatment for chronic otorrhea in poor socioeconomic conditions.

Acetic acid is present in vinegar at 3–5% concentration, which has been used in medicine for thousands of years. Hippocrates recommended it for food preservation and as a tonic, as well as to treat wounds. It is a weak organic acid and can be inexpensively produced either by fermentation from ethanol or synthetically.¹⁰ Vinegar as

diluted acetic acid has been used since 1961 in the management of otorrhea as aural wash or topical drops.¹¹ The mean pH of external auditory canal is 3.950 ± 1.199 . While in the presence of otorrhea, mean pH of the EAC was 6.412 ± 1.193 and in the absence of otorrhea was 5.227 ± 1.682 .¹² Thus vinegar was tried in this study to acidify pH of middle ear in the form of aural wash for resolving otorrhea of CSOM.

Vinegar diluted with water in the ratio 1:1 was used in

our study. Among the tubotympanic cases, 70.4% of the ears became dry and 14.8% cases failed after 3 weeks of vinegar wash. Percentage of dry ears was less compared to the results of Somayaji¹³ et al, Gupta¹⁴ et al and Choi HG¹⁵ et al. Failures in our study may be attributed to persistent mastoid disease, need for further long term treatment and presence of undetected cholesteatoma in middle ear cleft. However 14.8% of failure detected in the present study compared with results of Gupta¹⁴ et al, Choi HG¹⁵ et al, Malik¹⁶ et al as in Table 6 was less.

Table 6: Results of vinegar wash for tubotympanic CSOM in various studies.

Year	2016	2015	2010	2006	1996	1975
Study	Present study	Gupta ¹⁴ et al	Choi HG ¹⁵ et al	Somayaji ¹³ et al	Aminifarshid ¹⁷ et al	Malik ¹⁶ et al
Dry	70.4%	84%	79.5%	96.7%	57%	40%
Fail	14.8%	16%	15%	3.3%	8%	20.4%

Pseudomonas ears responded better to vinegar wash (96.2%) when compared to oral antibiotics (73.7%) with 3 weeks of treatment. Even 50% of staphylococcus aureus cases ears became dry. Hence acidifying the pH of middle ear prevented the growth of above organisms and plays an important role in the management of otorrhea. Few immediate side effects like ear ache, giddiness noted in the initial week of therapy which was reduced on continuation of treatment.

Worsening of bone conduction was observed in 5% of vinegar washed CSOM ears. However further studies need to be conducted to find whether it was due to disease process or ototoxicity of vinegar. Sugamura et al (2012) explained in his study that diffusion of acetic acid ear drops across the round window is unlikely because in infected middle ear, a mechanical barrier is offered at round window membrane by mucopurulent exudates and is thickened due to mucosal edema. Also the round window membrane in humans is 6 times thicker and has greater collagen density than in rodents.¹⁸ Yamano et al in 2015 studied ototoxicity of acetic acid in guinea pig with various pH and duration. The pH values of the acetic acid solutions were 3.0, 4.0, and 5.0, and the application time was 30 min, 24 h, and 1 week. He found that ototoxicity becomes evident at pH 3.0 after 30 min by altering the compound action potential of eighth nerve.¹⁹ Thus immediate dry mopping of ear after vinegar wash can reduce the contact time and chances of ototoxicity.

Patients need to be counseled about the advantages of vinegar for the management of CSOM. It is also cost effective in treating otorrhea in poor socioeconomic conditions.

In present study culture based antibiotic therapy (83%) showed better results compared to vinegar (70.4%). But there was no statistically significant difference between vinegar wash and culture based antibiotic therapy results in active chronic suppurative otitis media treatment

($p > 0.05$). Hence vinegar wash can be tried as a first line of management in active uncomplicated CSOM.

Culture based oral antibiotic therapy had 83% improvement and 8.5% failures in resolution of otorrhea. In the study by Gupta et al where empirical treatment with topical and systemic antibiotics was used in CSOM, 60.04% of ears became dry and 39.96% failed.¹² This shows culture based oral antibiotic treatment has significant improvement than empirical treatment in CSOM. Hence antibiotics to be advised based on culture sensitivity report, judiciously to avoid future resistant strains.

Vinegar wash can be added in the first line management of active CSOM tubotympanic cases especially with cultures showing *Pseudomonas* and *Staphylococcus aureus*. Vinegar helps in reduction of granulation in CSOM. Chances of ototoxicity are less with diluted vinegar in the ratio 1:1. However, further studies has to be conducted on standardisation of the vinegar treatment in terms of dilution, type of vinegar (synthetic or fruit based), duration of therapy, pH and long term sequelae of vinegar wash like ototoxicity.

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