

Efficacy of Acetic Acid Irrigation in Management of Chronic Suppurative Otitis Media “A Prospective Study

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ABSTRACT

Background: Prior to surgical management of chronic suppurative otitis media (CSOM) for the dry ear medical management is necessary. CSOM is a biofilm disease and due to this has antibiotic resistance. The pillar of its treatment included aural cleaning according to standard protocols, application of topical germ free antiseptic and use of antimicrobials. Acetic acid due to its ability in reducing the pH may be effective in reducing the growth of microorganisms.

Objective: The aim of the study was to compare the efficacy of irrigation with acetic acid versus systemic antibiotics in CSOM patients.

Materials & Methods: A total of 134 patients, who came to the ENT department of Sheikh Zayed Hospital, Lahore between 1st April 2020 to 30th September 2020, who had CSOM, of age 15 to 55 years and both genders were included in the study. The patients were divided randomly into two groups. Group A patients received aural toilets and irrigation with acetic acid and Group B received 500 mg of ciprofloxacin twice a day for 2 weeks.

Results: The mean age (in years) of the patients in Group A was 37.45 ± 7.32 and in Group B, it was 37.96 ± 7.57 . The efficacy of irrigation with acetic acid versus systemic antibiotics was 89.55% and 68.66% respectively and this difference between the two groups was found to be statistically significant ($p=0.003$).

Conclusion: Irrigation with acetic acid was better than systemic antibiotics in managing patients with CSOM.

Key words: Acetic acid, CSOM, Middle ear

INTRODUCTION

Chronic suppurative otitis media (CSOM) is a middle ear disease that has a duration of more than two weeks. CSOM is associated with perforation of tympanic membrane and discharge from the ear. CSOM prevalence is specifically high in developing countries and has been found to be more in rural areas i.e. 46/1000 compared to urban areas i.e. 16/1000 and has a global prevalence rate ranging from 1% to 46%. It begins usually in childhood in the form of spontaneous perforation of tympanic membrane that occurs as a result of acute middle ear infection, which is known as acute otitis media, or as a result of less severe type of otitis media (secretory otitis media). It is still under debate as to when acute otitis media is converted into CSOM.

Generally, CSOM cases are labeled when there is perforation of tympanic membrane that results in continuous discharge of mucoid material despite being treated medically, for a duration of 6 weeks to 3 months. According to WHO, for defining such cases otorrhoea should only be present for a period of 2 weeks, however, a longer duration is adopted by otolaryngologists for defining it i.e. more than 3 months. The disease process related to CSOM may cause dreadful complications as a result of destruction of bones that overlie and underlie.

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. Prior to surgical management of chronic suppurative otitis media (CSOM) for the dry ear, medical management is necessary. The most prevalent form of microbes in the biological environment is biofilms, which plays a central part in

chronic infections. CSOM is a biofilm disease and for this reason has been found to have antibiotic resistance. The mainstay of treatment in it includes aural cleaning according to standard protocols, application of topical germ free antiseptic, use of antimicrobials, both topical and systemic. For topical application, various options such as steroids, antibacterials and acid media ear drops are readily used either alone or in combination to have a disease control. Acetic acid efficacy depends on its ability to reduce the pH in the ear that leads to a decline in the growth of microorganisms. In a study it was found that acetic acid irrigation of CSOM patients was found to be effective in 86% of patients compared to 68% of patients who received systemic antibiotics.

The current study aimed at determining the efficacy of irrigation with acetic acid by comparing it with systemic antibiotics in management of CSOM patients in the local population. The article would guide about an intervention which can lead to improvement and management of persistent discharge from the ear and would affect disease related outcomes in terms of better efficacy and reduced morbidity.

MATERIAL AND METHODS

It was a randomized controlled trial conducted at the ENT department of Sheikh Zayed hospital, from 1st April 2020 to 30th September 2020. Patients with CSOM, of age 15 to 55 years and both genders were included in the study. Patients with a prior history of treatment with antibiotic, with frank cholesteatoma, perforation either attic or marginal, diabetics, pregnant and lactating females, those who had known hypersensitivity to acetic acid and those in whom culture sensitivity showed resistance to either acetic acid or

ciprofloxacin were excluded from the study. CSOM was defined as presence of an ear discharge (on otoscopic examination; presence of thin or thick, seromucoid or purulent secretions in the external auditory canal coming out from the middle ear) and on otoscopic examination, presence of chronically inflamed middle ear cleft with tympanic membrane perforation on otoscopic examination after a treatment for two weeks. The intervention was considered efficacious if there was an absence of otorrhoea (dry ear) and no tympanic membrane perforation as assessed by otoscopic examination following treatment for two weeks.

A sample size of 134 patients (67 in each group) was calculated, keeping 5% margin of error, 80% power of study and expected percentage of efficacy of acetic acid irrigation as 86% compared to systemic antibiotics i.e. 68%⁹. Non-probability consecutive sampling technique was used.

A total of 134 patients were enrolled in the study who fulfilled the inclusion criteria after taking informed verbal consent from all the patients. Patients were randomized into two groups of equal number by the draw for the selection of specific medical group. A box that contained 134 tags (67 tags for acetic acid irrigation and other 67 for ciprofloxacin) was offered to the selected individuals. In this way, two groups A and B were created for a period of two weeks. In Group A, aural toilet along with acetic acid irrigation was given, whereas in Group B 500mg tablet of ciprofloxacin was given twice a day. Before carrying out a swab from the middle ear for microscopic and culture examination, thorough cleaning of the ear was done with dry mopping. Patients in group A were advised to come for follow up on every other day. At every visit, with the help of a suction tube, thorough cleaning of the external auditory canal and middle ear cavity was done and irrigation was done with diluted acetic acid (2 ml) with the help of 1ml syringe. Self-irrigation of the ear was advised to the patients in Group-A, to be carried out once a day at home. Treatment was discontinued if the criteria of no morning discharge, clean and dry external canal and non-edematous mucosa of the ear was met.

The external auditory canal and middle ear cavity were both cleaned thoroughly in group B as well with the help of dry mopping and suction. Topical antibiotics were given together with the systemic antibiotics i.e. tablet ciprofloxacin 500 mg twice a day for two weeks.

At the end of 2 weeks, efficacy of both interventions was noted down on a pre-designed proforma (as per operational definition). Patients' age, gender and duration of CSOM was also noted down on the proforma and all findings were subjected to statistical analysis.

Data was analyzed using SPSS version 25.0. Quantitative data such as age and duration of CSOM was presented as mean and standard deviations. Qualitative data such as gender and efficacy of treatment was presented as frequency and percentages. Data was stratified for age, gender and duration of CSOM. Post-stratification Chi-square test was applied and a p value of ≤ 0.05 was considered as significant. Comparison of efficacy between the two treatment groups was made using Chi square test and a p value of ≤ 0.05 was considered as significant.

RESULTS

The mean age (in years) of the patients in Group A was 37.45 ± 7.32 and in Group B, it was 37.96 ± 7.57 . Most of the patients in the study were of age range 36 to 55 years i.e. 55.97% (table I). Distribution of patients according to duration of disease and gender is shown in table II and III respectively. The efficacy of irrigation with acetic acid versus systemic antibiotics was 89.55% and 68.66% respectively and this difference between the two groups was found to be statistically significant ($p=0.003$) (Table IV). Data was stratified for age, duration of disease and gender and the results are shown in table V, VI and VII, respectively.

Table 1: Age distribution for both groups.

Age (years)	Group A (n=67)		Group B (n=67)		Total (n=134)	
	No. of Patients	%age	No. of Patients	%age	No. of Patients	%age
15-35	31	46.27	28	41.79	59	44.03
36-55	36	53.73	39	58.21	75	55.97
Mean \pm SD	36.33 \pm 7.20		36.36 \pm 7.52		36.36 \pm 7.31	

Table 2: Distribution of patients according to duration of disease.

Duration (MTH)	Group A (n=67)		Group B (n=67)		Total (n=134)	
	No. of Patients	%age	No. of Patients	%age	No. of Patients	%age
<6	46	68.66	45	67.16	91	67.91
≥ 6	21	31.34	22	32.84	43	32.09
Mean \pm SD	5.58 \pm 1.72		5.54 \pm 1.84		5.55 \pm 1.77	

Table 3: Distribution of patients according to gender.

Sex	Group A (n=67)		Group B (n=67)		Total (n=134)	
	No. of Patients	%age	No. of Patients	%age	No. of Patients	%age
Male	47	68.66	43	64.18	90	67.16
Female	20	29.85	24	35.82	44	32.84

Table 4: Comparison of efficacy between both groups (n = 134).

		Group A (n=67)		Group B (n=67)	
		No. of Patients	%age	No. of Patients	%age
Efficacy	Yes	60	89.55	46	68.66
	No	07	10.45	21	31.34

Table 5: Stratification of Efficacy of both groups according to age groups.

Age of patients (group)	Group A (n=67)		Group B (n=67)		p-value
	Efficacy		Efficacy		
15-35	30	01	21	07	0.015
36-55	30	06	25	14	0.060

Table 6: Stratification of efficacy of both age groups according to duration.

Duration (Months)	Group A (n=67)		Group B (n=67)		p-value
	Efficacy		Efficacy		
	Yes	No	Yes	No	
≤ 6	42	04	30	15	0.004
> 6	18	03	16	06	0.295

Table 7: Stratification of efficacy of both groups according to gender.

Gender	Group A (n=67)		Group B (n=67)		p-value
	Efficacy		Efficacy		
	Yes	No	Yes	No	
Male	43	03	26	17	0.0001
Female	17	04	20	04	0.835

DISCUSSION

CSOM traditionally has two subtypes i.e. atticofurcal (unsafe) and tubotympanic (safe) type. It is a well-established fact that individuals who have tubotympanic type can be managed medically in order to have infection control and reduce discharge from the ear. The mainstay of treatment in it includes aural cleaning according to standard protocols, application of topical germ free antiseptic, use of antimicrobials, both topical and systemic. For topical application, various options such as steroids, antibacterials and corrosive media ear drops are readily used either alone or in combination to have a disease control. Several trials conducted previously reported that topical antiseptics are as effective as antibiotics applied topically for otorrhea resolution. In terms of acetic acid, studies conducted previously revealed that it was used widely in numerous fields as antimicrobial in order to kill pathogenic bacteria which are food borne, inhibit growth of *E. coli* and for treating infections of ear. The effectiveness of acetic acid is because of its ability to decrease pH in the ear and limit microorganisms growth. Keeping this in view, the current study was conducted to compare the effectiveness of irrigation with acetic acid for managing CSOM with antibiotics given systemically.

The efficacy of irrigation with acetic acid in managing CSOM was 89.55% compared to systemic antibiotics which was 68.66% and the difference between the two treatments was statistically significant ($p=0.003$). In a study conducted previously on patients with CSOM, similar efficacy of acetic acid irrigation was yielded i.e. 86% and that of systemic antibiotics it was 68%. Aminifarshidmehr et al. used 2% acetic acid for irrigation of ear three times in a week and revealed that 55 out of 96 patients had dry ear at 3 weeks follow up i.e. 57.29%. Loock et al. (2010) revealed that in patients who received eardrops of ciprofloxacin, 73% cases achieved dry ears and in the acetic acid group, dry ears were achieved in 24% patients who had active CSOM. The Clinical practice guidelines of the Philippine Society revealed that in terms of persistent activity on otoscopy, no difference was significantly found between topical antibiotic and topical antiseptic i.e. 83% vs 65% respectively (OR 0.40). The difference was also not significant in patients who were on oral antibiotics and topical antiseptics in terms of persistent activity on otoscopy i.e. 62% vs 65% and with topical antibiotics it was 83%. These results differ from the results of the current study as our study showed that there was a significant statistical difference between acetic acid irrigation and systemic antibiotics and acetic acid irrigation was more effective. The effectiveness of acetic acid as shown by the current study is also supported by Eason et al. who revealed that in terms of effectiveness topical antiseptic and topical antibiotics were comparable however, ciprofloxacin/ofloxacin yielded high rates of cure.

The current study had certain limitations. Firstly, it was carried out at a single center and the sample size was small, so the results cannot be generalized. Secondly,

comparison with only systemic antibiotic was done and not with the topical one, so the results cannot be considered for those.

CONCLUSION

The study concluded that acetic acid irrigation in management of CSOM is better as compared to systemic antibiotics. So, it is recommended that acetic acid irrigation should be used routinely in management of CSOM in order to reduce the morbidity and mortality of the community.

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