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RESEARCH ARTICLE
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"A COMPARATIVE STUDY OF ACETIC ACID V/S CIPROFLOXACIN TOPICAL EAR DROPS IN ACHIEVING DRY EAR IN TUBOTYMPANIC CSOM PATIENTS."

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Abstract
Aim: To study the effect of topical instillation of ACETIC ACID V/S CIPROFLOXACIN EAR DROPS in medical management of tubotympanic CSOM.
Materials and Methods: 100 patients including Male and Female above 15 years attending ENT OPD, at Index Medical College and having perforation in pars tensa (tubotympanic CSOM) will be evaluated. These patients underwent ENT examination. Oto-endoscopic examination was done. Further, patient were advised to undergo X-ray bilateral mastoid and pure tone audiometry.
Results: The results of the present study showed that dry ear was significantly achieved in patients using acetic acid (92% patients) than ciprofloxacin (66% patients) ear drops.
Conclusion: Medical management of tubotympanic type of CSOM is better achieved using 2% acetic acid ear drops rather than 0.3% ciprofloxacin ear drops.

INTRODUCTION

CHRONIC SUPPURATIVE OTITIS MEDIA - is defined as chronic mucoperiosteal inflammation of middle car cleft and mastoid cavity which presents with recurrent ear discharge or otorrhoea through a tympanic membrane perforation for a period of more than 3 months.
Bacteriology- In CSOM, bacteria reaches the middle ear either from the nasopharynx or through the external auditory canal. (1,2,3)
Pseudomonas aeruginosa and Staphylococcus aureus being the most commonly reported pathogens.161,
Bacteria preferentially exist in biofilms. Biofilm bacteria have greater antimicrobial resistance and host defences and can best be thought of as 'self-assembling multicellular communities. Biofilms, which are communities of sessile bacteria, resistant to disruption and with a low metabolic rate, are embedded in a matrix of extracellular polymeric substances of their own synthesis. These

communities may adhere to a foreign body or a mucosal surface with impaired host defence. Biofilms thought to play a key role in chronic infections. CSOM is considered a biofilm disease and thus, it also explains the observed resistance to antibiotics [4,5,6]

TREATMENT - Patients with tubo-tympanic type of CSOM can be managed with empirical medical therapy to control the infection and eliminate ear discharge

Medical therapy includes aural toilet; administration of topical and/or systemic antibiotics. After excluding specific causes for CSOM (cholesteatoma and TB) the management starts by converting active CSOM inactive Topical therapies, being able to deliver a much higher dose locally, work better than systemic therapies.

CIPROFLOXACIN is a Fluoroquinolone class antibiotic.

Mechanism of action- It inhibits DNA replication by inhibiting bacterial DNA topoisomerase and DNA-gyrase.

Ciprofloxacin is available in 0.3% ear drops formulation and in oral preparation. [7]

ACETIC ACID EAR DROPS - It is a weak acid and a relatively weak anti-septic.

It is available as 2% acetic acid drops formulation and has anti-bacterial and anti-fungal properties.

Mechanism of action- It acts by:- Creating change in pH of ear canal thereby providing adverse environment for bacterial growth, destructing biofilm and removal of inflammatory debris

The rationale for using acetic acid is, 2% acetic acid being a weak acid, when instilled into the EAC, helps to lower the pH of the discharging car. And thus creates an unfavourable environment for the bacteria and biofilms to survive.[8]

Medical management of CSOM without cholesteatoma by frequent aural cleaning and topical instillation using dilute acetic acid can be more desirable choice as compared to the intravenous and oral antibiotics. It is safe without producing any side effects. Alteration of pH of ear canal is one of the main factors for healing, in addition to mechanical disruption of biofilm and removal of debris from ossicles.

Topical quinolone drops with their wide antimicrobial activity and safety profile are regarded as the gold standard. However, they rely on patient compliance and with widespread use, run the risk of developing bacterial resistance. With CSOM being more prevalent in developing nations, a cheaper yet effective alternative is required. Nonantibiotic, topical, inexpensive antiseptics are therefore an attractive possibility.

AIM: To study the effect of topical instillation of ACETIC ACID V/S CIPROFLOXACIN EAR DROPS in medical management of tubotympanic CSOM.

MATERIALS & METHODS

Study design: Hospital based observational study.

Study area: Index Medical College Hospital and Research Centre, Indore

Sample size: 100 patients were taken for the study. 50 in Group-A (Acetic acid ear drops) & 50 in Group B (Ciprofloxacin ear drops).

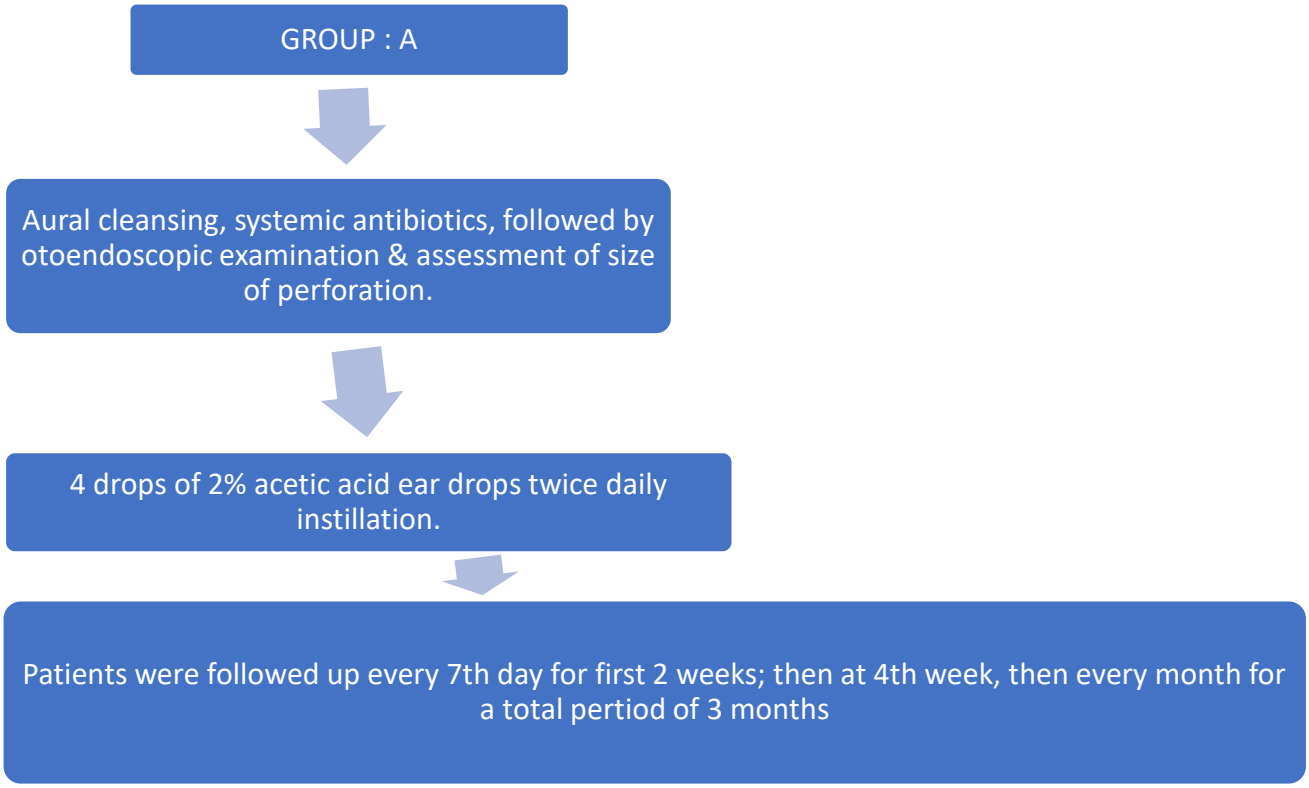
Study duration: January 2021 to July 2022 – 18 months.

INCLUSION CRITERIA:

- Patients with age 15 years and above.
- All patients of either sex having perforation in pars tensa (Tubotympanic CSOM).
- Patients giving consent to be a part of the study.

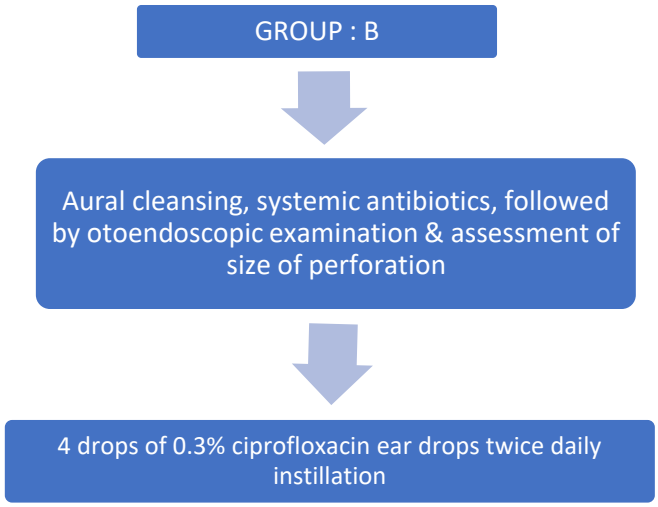
EXCLUSION CRITERIA:

- Patients of CSOM with atticoantral disease.
- Patients of CSOM with otomycosis.
- Patients of CSOM with vertigo.
- Patients <15 years of age.



PROCEDURE:

100 patients including male and female above 15years attending the ENT OPD at index medical college having complaint of Chronic ear discharge were evaluated & included in the study after obtaining informed consent and were randomly divided into 2 groups, A and B.



STATISTICAL ANALYSIS:

Data was entered into the excel sheet. Data was analysed using SPSS (Statistical Package for Social Sciences) 21.0 version, IBM, Chicago. Comparison of categorical variables was done using Chi-square test. P value <0.5 was considered statistically significant.

OBSERVATIONS & RESULTS

Table 1: Comparison of distribution of participants based on amount of otorrhoea

		Group A	Group B	Total	Chi square test	P value
Profuse	Number	42	37	79	1.507	0.220
	Percentage	84.0	74.0	79.0		
Moderate	Number	8	13	21		
	Percentage	16.0	26.0	21.0		
Scanty	Number	0	0	0		
	Percentage	0.0	0.0	0.0		
Total	Number	50	50	100		
	Percentage	100.0	100.0	100.0		

Table 2: Comparison of distribution of study participants based on resolution of otorrhea.

		Group A	Group B	Total	Chi square test	P value
Yes	Number	46	33	79	10.187	0.001
	Percentage	92.0	66.0	79.0		
No	Number	4	17	21		
	Percentage	8.0	34.0	21.0		
Total	Number	50	50	100		
	Percentage	100.0	100.0	100.0		

Table 3: Comparison of distribution of participants based on time taken archive dry ear.

	Group A	Group B	Z value	P value
Median	14.50	27.0	-3.010	0.003
Inter-quartile range	7.0-34.0	11.75-87.5		

RESULT:
A total of 100 patients were observed. It was observed that dry ear was achieved in 46 patients (92%) being treated with ACETIC ACID ear drops. While those patients being treated with CIPROFLOXACIN ear drops, dry ear was achieved in 33 patients (66%).

DISCUSSION:
In group A, 74% of the participants were having profuse otorrhea. In group B, comparatively lesser number of participants were having profuse otorrhea (74%). None of the participants were having scanty otorrhoea. However, the number of participants with history of profuse or moderate otorrhea was non-significantly different between the groups (p value >.05).
In the both groups majority of the participants otorrhea resolved. However, the number of participants showing resolution of otorrhea was significantly more in group A as compared to that in group B (p value<.05).
The duration till dry ear was significantly less in group A participants as compared to that in group B participants [14.50 (7.0-34.0) vs 27.0 (11.75-87.5) days].
The findings of present study are comparable to the study conducted by Gupta et al. in 2014, Where 100 patients were included in their study. In group A (patient treated with acetic acid), they found dry ear in 42 patients (84%), while Perforation healed in 13 patients (26%). In group B (patients treated with Ciprofloxacin), they found dry ear in 29 patients (69.04%). Perforation healed in 7 patients (14%).

CONCLUSION
In the present study, after observing the results following conclusions can be drawn:

Medical management of tubotympanic type of CSOM by frequent aural cleansing and instillation of 2% acetic acid ear drops can be a more desirable choice compared to 0.3% Ciprofloxacin ear drops. It is a safe modality of treatment.

Topical acetic acid ear drops can prove to be an effective drug for treating smaller perforations in tubotympanic type of CSOM especially in patients refusing for surgical management.

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