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COMPARATIVE EFFICACY OF TOPICAL CIPROFLOXACIN EAR DROPS VS COMBINATION OF TOPICAL AND ORAL CIPROFLOXACIN IN THE FIRST LINE MANAGEMENT OF DISCHARGING CHRONIC SUPPURATIVE OTITIS MEDIA IN POPULATION VISITING IN TERTIATRY CARE HOSPITAL WESTERN UTTAR PRADESH

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ABSTRACT

Introduction:- Chronic Suppurative Otitis Media (CSOM) is a persistent inflammatory disease of the middle ear mucoperiosteum, influenced by socio-economic factors like poor hygiene and malnutrition. It presents in non-cholesteatomatous (central perforation) and cholesteatomatous (marginal/attic perforation) forms, with the latter posing a higher risk of complications. CSOM management is challenging due to antibiotic misuse, leading to masked infections and resistant strains. Regular microbial evaluation is essential for effective treatment. This study aims to identify causative organisms through culture and sensitivity testing and assess the therapeutic response to ciprofloxacin. **Aim:-** Comparative efficacy of topical ciprofloxacin ear drops vs combination of topical and oral ciprofloxacin in the first line management of discharging chronic suppurative otitis media in population visiting in tertiatry care hospital western Uttar Pradesh. **Materials And Methods:-** This prospective randomized clinical trial includes 100 patients (≥18 years) with bacterial otorrhea and chronic tympanic membrane perforation persisting >21 days. They are randomly assigned to Group A (ciprofloxacin ear drops) or Group B (topical + oral ciprofloxacin) for 14 days. Compliance is assessed at two weeks, and non-compliant patients are replaced. Cure is defined as the absence of otorrhea or negative bacterial culture, with non-responders reassessed at three weeks. Persistent cases in Group A receive systemic antibiotics, while Group B continues or adjusts therapy based on culture. Clinical failures at three weeks are managed accordingly, and unresolved cases are monitored at eight weeks. Outcomes are analyzed statistically, and non-compliant patients are excluded. **Results:** This study on active-stage safe-type CSOM found Pseudomonas aeruginosa (34%) as the most common organism, followed by Staphylococcus aureus (23%) and Klebsiella (17%). Topical ciprofloxacin was as effective as the combination therapy, but recurrence was higher with ear drops alone. Thus, while effective, topical ciprofloxacin alone may increase the risk of recurrence in CSOM without cholesteatoma.

KEYWORDS

INTRODUCTION :-

Chronic Suppurative Otitis Media (CSOM) is a multifactorial disease recognized for its persistent and recurrent nature despite medical intervention. It is a chronic inflammatory condition affecting the mucoperiosteal lining of the middle ear cleft[1].

The incidence of CSOM is influenced by various factors, including racial predisposition and socio-economic conditions. Poor hygiene, overcrowding, malnutrition, and inadequate living conditions have been identified as key contributors to its widespread prevalence[2]. The state of an affected ear represents a balance between disease progression and the healing response of the middle ear cleft. Consequently, CSOM manifestations vary widely, ranging from minor healed tympanic membrane deformities to extensive cholesteatoma infiltration of the temporal bone[3]. As a destructive and persistent condition, CSOM can lead to irreversible sequelae and severe intra- or extra-cranial complications[1].

CSOM is broadly categorized based on the presence or absence of cholesteatoma. The non-cholesteatomatous type typically results from inadequately treated or recurrent acute suppurative otitis media and is characterized by central perforation. In contrast, the cholesteatomatous type is distinguished by marginal or attic perforation and presents a higher risk of severe complications[3].

The assessment and management of CSOM pose significant challenges, especially with the widespread use of antibiotics. The indiscriminate administration of antimicrobial agents has led to masked infections, increased complications, and the emergence of antibiotic-resistant bacterial strains[4]. With the evolving microbiological landscape, regular evaluation of the pathogenic organisms and their antibiotic sensitivity patterns is crucial. Understanding these patterns aids clinicians in formulating effective treatment strategies for patients with chronic ear discharge[1].

This study aims to identify the microbial agents responsible for CSOM through culture and sensitivity testing and evaluate the therapeutic response to topical or combination ciprofloxacin treatment.

AIM:

Comparative efficacy of topical ciprofloxacin ear drops vs combination of topical and oral ciprofloxacin in the first line management of discharging chronic suppurative otitis media in population visiting in tertiatry care hospital western Uttar Pradesh.

MATERIALS AND METHODS

This is an prospective randomized clinical trial in which 100 patients are randomly divided among 2 groups (Group A and group B) and each group have 50 patients. The study includes patients above 18 years of age, comprising males and non-pregnant, non-lactating females, who attended the ENT outpatient department with mucopurulent or purulent otorrhea of bacterial origin. These patients exhibited a chronic tympanic membrane perforation persisting for more than 21 days in the infected ear and had antibiogram results confirming sensitivity to ciprofloxacin.

Patients randomly assigned to either Group A, receiving ciprofloxacin ear drops (3 drops, thrice daily) for 14 days, or Group B, receiving both topical ciprofloxacin (3 drops, thrice daily) and oral ciprofloxacin (500 mg, twice daily) for 14 days. They advised to prevent water entry, dry the ear before instilling drops, and apply tragal pressure for better absorption.

At the two-week follow-up, compliance assessed as good (0–3 missed doses), moderate (4–7 missed doses), or poor (>7 missed doses). Non-compliant patients replaced to maintain the sample size. Ear discharge evaluated clinically, and repeat culture and sensitivity testing conducted if drainage persists.

Cure defined as the absence of otorrhea, otoscopically inactive disease, or serous mucous otorrhea with a negative bacterial culture. Non-responders continue the treatment for one additional week and be reassessed at the third week. If symptoms persist, Group A patients switched to systemic antibiotics if resistant to ciprofloxacin, while Group B patients either continued the combination therapy or shifted to systemic antibiotics based on culture results. Persistent cases at the third visit classified as "clinical failure" and managed accordingly.

Patients not cured or requiring surgery followed up at the eighth week to monitor recurrence. Clinical and bacteriological outcomes analyzed using statistical methods (χ^2 test and Z test for proportions). Patients failing to follow up or intolerant to the medication removed from the study.

OBSERVATION AND RESULTS:

The present study of “Comparative efficacy of topical ciprofloxacin ear drops Vs combination of topical and oral ciprofloxacin in the first line management of discharging chronic suppurative otitis media in population visiting in tertiatry care hospital western Uttar Pradesh” was conducted during a period 2 years and 100 cases were randomly selected and statistically analyzed for various factors as described.

EAR DISCHARGE :
The following table shows the features of ear discharge in our study population.

Table-1 : Ear Discharge

Ear Discharge	No. of patients	Percentage
Duration (years)		
1-5	66	66
6-10	19	19
>10	15	15
Amount		
Scanty	13	13
Moderate	23	23
Profuse	64	64
Character		
Mucoid	96	96
Purulent	4	4

Bacteria Isolated In Csom Without Cholesteotoma :
In the study population Pseudomonas aeruginosa is the most most common orgasim isloated in 45 patients followed by klebsiella in 30 patients the oragansim were all sensitive to ciprofloxacin.

Table-2 : Bacterial Isolated In Ear Discharge

Bacteria isolated	No. of patients	Percentage
Pseudomonas aeruginosa	45	34
Staphylococcus aureus	30	23
Klebsiella	22	17
Coagulase negative Staphylococcus	14	11
Proteus	10	7
E-coli	7	5
Enterococci	4	3
Total	**132**	

2 Week Followings Treatment :

Table-3 : Otorrhea

	Group A	Group B
Absent	18 (36%)	20 (40%)
Present	32 (64%)	30 (60%)

Ch.-sq. 0.17, P-value 0.91, NS

Table-4 : Culture On Repeat Swab

Culture	Group A	Group B
Klebsiella	9 (18%)	5 (10%)
Staphylococcus aureus	3 (6%)	4 (8%)
Pseudomonas	2 (4%)	1 (2%)
Proteus	2 (4%)	0
E-coli	1 (2%)	0
No growth	15 (30%)	20 (40%)
Not done	18 (36%)	20 (40%)

Table-5 : Sensitivity

Sensitivity	Group A	Group B
Positive	10 (20%)	5 (10%)
Negative	7 (14%)	5 (10%)

Table-6 : Result After 2 Weeks Of Treatment

	Group A	Group B
Cured	18 (36%)	20 (40%)
Improved	25 (50%)	25 (50%)
Failed	7 (14%)	5 (10%)

Chi-square : 0.44, P-value 0.80, NS

Table –7 : Plan After Two Weeks Of Treatment

	Group A	Group B
One more week of antibiotics	10 (20%)	4 (8%)
Supportive treatment	15 (30%)	21 (42%)
Change to higher antibiotics	7 (14%)	5 (10%)

3 Weeks After Treatment :
Table-8 : Otorrhoea

	Group A	Group B
Present	7	5
Absent	25	25

Chi-square : 2.17, P-value 0.14, NS

8 Weeks After Treatment :
Table- 9 : Follow Up Visit

	Group A	Group B
Non recurrent	31 (62%)	46 (92%)
Recurrent	19 (38%)	4 (8%)

Chi-square : 12.71, P-value 0.00, HS

DISCUSSION:-

CSOM WITOUT CHOLESTEAOMA AND COMMONEST BACTERIAL MICROORGANISMS:

The commonest organism isolated on culture in the present study was Pseudomonas aeruginosa (34%). Pseudomonas aeruginosa was also the commonest organism isolated in the studies conducted by Itzhak Brook et al[5](72%), Grewal et al[6](37.5%). The second most common organism in the present study was Staphylococcus aureus which was in accordance with Loy et al[7](33.3%), Asif Gul et al[8](15%).

Both Gram-positive and Gram-negative bacteria contribute to middle ear infections, with Gram-negative rods, particularly Pseudomonas aeruginosa, being more prevalent in CSOM. P. aeruginosa thrives without special nutrients, proliferates at room temperature, and exhibits high antibiotic resistance, making treatment challenging. Its ubiquity in moist environments aids infection, as it adheres to epithelial cells via pili and fimbriae, particularly in injured tissues. Additionally, P. aeruginosa forms biofilms, enhancing its resistance to host defenses. Along with Staphylococcus aureus, it is part of the normal external auditory canal flora, and water entry into an ear with a dry perforation can introduce these bacteria into the middle ear, triggering infection.

CSOM WITHOUT CHOLESTEATOMA AND EFFICACY OF ANTIBIOTICS:

In the present study the number of patients with dry ears following use of topical ciprofloxacin is 18/50 (64%) and following combination of topical and oral ciprofloxacin was 20/50 (60%). Hence topical antibiotics were found to be as effective as combination of topical and oral antibiotics.

Ciprofloxacin, a fluoroquinolone with broad-spectrum activity against Gram-negative bacteria and a lower risk of complications, was chosen for both topical and oral use in this study.

The topical antibiotics were also found to be as effective as systemic antibiotics in accordance to Eposito et al[9] (ciprofloxacin oral 40% compared to ciprofloxacin car drops 85%).

Topical antibiotics were found to be as effective as oral antibiotics, delivering a much higher concentration directly to the infection site. A 0.3% ciprofloxacin solution provides 3000 mcg/ml of the drug, ensuring levels well above the minimum inhibitory concentration (MIC), which enhances bacterial eradication and reduces resistance development. Unlike systemic antibiotics, topical application minimizes side effects, avoids disrupting normal flora, and lowers treatment costs.

Maintaining an optimal environment, such as clearing the ear canal before instillation and ensuring proper pH balance, improves efficacy. However, topical drugs may be less effective if canal edema prevents penetration. Fluoroquinolone ear drops, which lack ototoxicity, are preferred for localized treatment, while systemic antibiotics are beneficial for associated respiratory infections. In our study, topical ciprofloxacin was as effective as the combination therapy, though recurrence rates were slightly higher in the topical group.

CONCLUSION :-

This study on the first-line management of active-stage safe-type CSOM found that Pseudomonas aeruginosa (34%) was the most common organism, followed by Staphylococcus aureus (23%) and Klebsiella (17%). Comparison of treatment modalities showed that topical ciprofloxacin was as effective as the combination of oral and topical ciprofloxacin. However, follow-up analysis revealed a higher recurrence rate in patients treated solely with topical ear drops. Thus, while topical ciprofloxacin is effective, its use alone may lead to a higher risk of recurrence in CSOM without cholesteatoma.

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