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## Comparison of Oral Vs Topical Ofloxacin in CSOM (Safe/ Tubotympanic/ Active Mucosal Type)

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### ABSTRACT

Chronic Suppurative otitis media a commonly encountered clinical condition in ENT causing hearing impairment disability social stigma and poor school performance. *The incidence of chronic otitis media (COM) appears to depend on socio-economic factors. The present study compared the efficacy of oral, topical and combined oral plus topical ofloxacin to make discharging ear dry in patients suffering from chronic otitis media (active mucosal type). A total of 150 patients suffering from chronic otitis media selected for the study. Patients with uncomplicated discharging Com who were eligible for the study were explained about their condition and a written consent was obtained for the study baseline audiometry was done in all patients participating in the study. The patients were then divided into 3 groups by random sampling method.*

Group A	-	only topical antibiotic
Group B	-	only Oral antibiotic
Group C	-	Combined oral plus topical antibiotic

*In our study, only topical ofloxacin is better and cost-effective than only oral and combined oral plus topical ofloxacin in controlling discharge in COM cases. We can safely prescribe only topical ofloxacin drops as empirical therapy to control symptoms of com which is cost-effective in comparison to oral ofloxacin and devoid of systemic side effects. In the absence of systemic infection topical ofloxacin alone constitute first-line treatment for most patients with chronic otitis media (active mucosal type) No evidence suggests that systemic ofloxacin alone or in combination with topical preparations improve treatment outcomes compared with topical ofloxacin alone*

**Keywords:** CSOM, oral vs. Topical, Antibiotics, Ofloxacin.

### 1. INTRODUCTION

Chronic supportive otitis media a commonly encountered clinical condition in ENT OPD causing hearing impairment, disability, social stigma and poor scholastic performance, can occasionally lead to fatal intracranial infections and acute mastoiditis, especially in resource-poor countries.

The incidence of chronic otitis media (COM) appears to depend on socio-economic factors. Socio-economic factors such as poor living conditions, overcrowding, poor hygiene, and nutrition have been suggested as a basis for the widespread prevalence of CSOM.<sup>[1]</sup>

Changes in the microbiological flora following the use of synthetic antibiotics and their in-vitro sensitivity pattern is very important for the clinician to plan a general outline of treatment for a patient with a chronically discharging ear.<sup>[2]</sup>

The present study is aimed to find the best mode of administering ofloxacin in controlling symptoms of COM (topical, oral or a combination of topical plus oral).

## **2. MATERIAL AND METHODS**

It was a time-bound study was done on 150 patients who presented to the ENT OPD, JNMCH, AMU, and Aligarh. Between March 2015 to March 2016. Pt. presented with an episode of otorrhoea after taking detail history and clinical examination patient diagnosed with uncomplicated COM (active mucosal type) included in the study.

Following inclusion and exclusion criterias used in our study.

### **2.1 Inclusion Criteria**

- Age-20-40 years of both sex.
- The patient presented with otorrhoea (purulent/mucopurulent) diagnosed as uncomplicated COM i.e. pt. with chronic otitis media with tympanic membrane perforations (active mucosal type)
- Culture sensitivity test shows flora sensitive to ofloxacin (empirical treatment started on the first visit)

### **2.2 Exclusion Criteria**

- Age <19 or >40 years.
- Com other than simple tympanic membrane perforations (presence of chlosteatoma, aural polyp, retraction pocket)
- Complicated COM (any complication extra or intratemporal)
- Underlying systemic disease (any h/o cardiac, renal hepatic or TB)
- Acute otitis media
- Flora resistant to ofloxacin
- Pt used any antibiotic therapy topical (in target ear) or systemic in past one month.
- Otological surgery within the past year.

Patient with uncomplicated discharging COM who were eligible for the study was explained about their condition, and a written consent was obtained for the study. Baseline audiometry was done in all patients participating in the study. The patients were then divided into 3 groups by random sampling method.

**Group-A:** Topical ofloxacin (0.3%) ear drop therapy for 2weeks

**Group-B:** oral ofloxacin (200mg) twice daily for 2weeks

**Group-C:** combined topical (0.3% ear drop) and oral ofloxacin (200mg) **BD** for 2weeks

At the first visit of every patient, a pretested proforma was used to record the relevant information of each individual included in the study. The aural discharge was collected with a conventional sterile swab preventing contact with the external auditory canal using a sterilized aural speculum. The specimens were immediately taken to the microbiology laboratory. The samples were first put into a glucose broth and subsequently inoculated into blood agar (enriched medium) and Mac Conkey agar (differential medium) following which they were cultured for 24hours. The primary colony of the cultured bacteria was identified by Gram stain and biochemical tests. Culture and sensitivity of isolates were determined by the Kirby—Bauer disk diffusion method.

Each patient was then randomly assigned to a study group by means of a lottery system.

Group A- Ofloxacin ear drops (0.3%, 3 drops) was to be used thrice a day for 14 days in the affected ear.

Group B- T.ofloxacin (200mg) twice a day was administered for 14 days

Group C- A combination of topical and oral ofloxacin in same doses and concentrations was used for 14days

All Patients were asked to prevent water entry into affected ear and dry mopping before installing the ear drops. The right technique of installing with intermittent tragal pressure was advised.

On the patient's next visit, two weeks post-treatment, compliance was assessed and defined by the number of times the patient forgot to use the drug within the two weeks. Noncompliant patients and pt who reported resistant for ofloxacin on culture sensitivity report were excluded and were substituted by new cases to meet the

sample size. A detailed assessment of the ear discharge was done subjectively and objectively and repeat ear culture and sensitivity test was performed if drainage was still present.

“CURED”<sup>[3]</sup> was defined as the absence of otorrhea or otoscopically inactive (no pooling of discharge; noninflamed middle ear mucosa) or the presence of a serous mucous otorrhea with negative bacteriological culture after the treatment period.

### 3. RESULTS

Bacterial	No. of pt (total 150)	percentage	Sensitivity to ofloxacin
mixed	78	52%	sensitive
proteus	36	24%	sensitive
pseudomonas	21	14%	sensitive
staph	15	10%	sensitive

symptoms	GroupA (topical)	Group B-oral	Group c oral+topical
Cured <sup>3</sup>	44 (88%)	36 (72%)	45 (90%)
Not cured	6 (12%)	14 (28%)	5 (10%)

Data were analysed with chi square test significance was taken at p value <0.05 i.e 95% confidence limit

On comparing group A and B, Chi-square test= 4 and p=0.045 (i.e.<0.05) it means difference is significant,

On comparing group A and C, Chi-square test =0.1021 and p=0.75 (i.e. >0.05) means difference is not significant.

On comparing group B and C, Chi-square test =5.26 and p=0.02 (i.e. <0.05).means difference is significant

By interpretation of above data, we can safely say topical+oral combination is equivalent to only topical and both the aforementioned are better than only oral in controlling symptoms of COM (active mucosal type)

We can safely prescribe only topical ofloxacin drops as empirical therapy to control symptoms of COM which is cost-effective in comparison to oral ofloxacin and devoid of systemic side effects.

### 4. DISCUSSION

Inactive COM there is Chronic inflammation within the mucosa of middle ear and mastoid which get secondarily infected.<sup>[4]</sup> Continued mucosal Infection and inflammation of middle ear and middle ear cleft plays a major role in persistent otorrhea. Continued infection is a trigger for persistent inflammation, so after controlling infection, inflammation get subsided due to host immune response thus complication can be prevented.

Resorption of bone can be there due to resorptive osteitis, due to triggers such as infection, inflammation, pressure, keratin.<sup>[4]</sup> In mucosal disease pathology is limited to superficial layers or maximum up to periosteum, no deep-seated infection in bone is present, Cholesteatoma is rare entity in mucosal disease so bone necrosis induced by keratin and pressure necrosis are not in picture that's why topical preparations by binding with mucosa works better than systemic therapy in active mucosal COM

Otic drops differ in pH. Drops designed for otic use are often buffered slightly to an acidic pH<sup>[5]</sup> so they work better in an acidic environment which is present in cases of active infection and mucous. Topical agents allow the modification of local microenvironment, administration of an antibiotic in an acidic medium helps to restore and fortify the normal host defense mechanism, the, therefore, better efficacy of antibiotics used<sup>[6]</sup>. In topical delivery, there is the absence of systemic effects. Otological antibiotics are generally less expensive than systemic medications, therefore reduces the cost of treatment. A higher concentration of antibiotic can be delivered to the site of infection by topical administration<sup>[7]</sup>. The possibility for the emergence of resistance is lower in topical routes compared with drugs administered systemically.<sup>[8]</sup>

The susceptibility of microorganisms to ofloxacin and aminoglycosides are similar except that ofloxacin has a higher efficacy for staphylococcal and pseudomonal infections. Hence, we selected ofloxacin instead of other antimicrobials.<sup>[9]</sup>

The antimicrobial response to ofloxacin alone and, ofloxacin + dexamethasone by assessing the bacteriological cure result are same as both medications containing the same antibiotic, the difference in bacteriological cure rates was not expected.<sup>[10]</sup> Using only a topical steroid preparation is not better than placebo<sup>[11]</sup> Spandow<sup>[12]</sup> demonstrated the possibility of ototoxicity by glucocorticoids related to an impaired auditory brainstem response

The topical ofloxacin was found to be more effective than oral ofloxacin in active mucosal COM. Oral antibiotics can be of immense use when the systemic effect of antibiotic is desired like inpatients of CSOM with concomitant acute or chronic rhinosinusitis, adenotonsillitis, pharyngitis and upper respiratory tract infection”.<sup>[13]</sup>

## 5. CONCLUSION

In our study, the most common organisms isolated were mixed infections 52% (aerobic predominantly gram-negative and anaerobic), followed by proteus 24% and *Pseudomonas aeruginosa* 21%.

Topical ofloxacin was found to be more effective and economical compared to oral ofloxacin and equally effective but cheaper to combined oral plus topical ofloxacin treatment.

So in the absence of systemic infection topical ofloxacin alone constitute first-line treatment for most patients with chronic otitis media (active mucosal type) for eradicating mucosal bacterial flora.

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