

EMPIRICAL TOPICAL, ORAL AND COMBINATION OF TOPICAL AND ORAL ANTIBIOTICS IN TREATMENT OF CHRONIC OTITIS MEDIA MUCOSAL ACTIVE: A COMPARATIVE STUDY

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Date of Submission : April 10, 2024

Date of Acceptance : April 22, 2024

Date of Publication : June 25, 2024

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Citation:

Khatri S, Chettri ST, Shah SP, Shrestha SD, Paneru M. Empirical Topical, Oral and Combination of Topical and Oral Antibiotics in Treatment of Chronic Otitis Media Mucosal Active: A Comparative Study. Medphoenix. 2024;9(1):3-6

DOI: <https://doi.org/10.3126/medphoenix.v9i1.67177>

Conflict of interest: None, **Funding:** None

Publisher: National Medical College Pvt. Ltd. MedPhoenix - Journal of National Medical College (JNMC); 2024,9(1), available at www.jnmc.com.np

ISSN:2631-1992 (Online); ISSN:2392-425X (Print)



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ABSTRACT

Introduction: Chronic otitis media is a common problem in Nepal. Due to overzealous use of expensive oral antibiotics there arise possibilities of severe systemic side effects. Such comparative study has not been done in the context of Nepal. This study will help to find the effective and better treatment modality for treatment of chronic otitis media.

Materials and Methods: Among 300 patients above 14 years of age diagnosed with COM mucosal active were divided into 3 treatment groups randomly (100 in each group): Topical chloramphenicol (Group A), Oral Amoxicillin (Group B) and Combination of both oral Amoxicillin and topical chloramphenicol (Group C). Patients were followed up after two weeks and reassessment was done.

Result: Out of 100 patients of each groups 77% following treatment with topical antibiotic, 80% following treatment with combination of oral and topical antibiotics and 69% following treatment with oral antibiotic only had resolution of ear discharge. This shows that there is no statistical significant difference in the outcome of treatment of patient with COM mucosal active with above three different antibiotic categories ($p = 0.176$).

Conclusion: : There is no significant difference in outcome of treatment of COM mucosal active disease with topical chloramphenicol ear drop or oral amoxicillin or combination of both topical chloramphenicol and oral amoxicillin.

Keywords: COM, Oral Amoxicillin, Topical Chloramphenicol

INTRODUCTION

The World Health Organization (WHO) defines CSOM as “a stage of ear disease in which there is chronic infection of the middle ear cleft, a non-intact tympanic membrane (i.e. perforated eardrum) and discharge (otorrhea), for at least the preceding two weeks.”^{1,2} Chronic otitis media is common in developing and underdeveloped countries affecting 0.5 – 30% of any community. The prevalence of COM in Nepal is 3.5%.³

In developing countries like Nepal, there are still people who are using oral antibiotic for management of COM and there are others who advice combination of oral and topical antibiotics. There seems confusion among

medical professionals regarding use of oral antibiotic alone, topical antibiotic alone or combination of oral and topical antibiotics.

The main objective of our study is to find out the best modality of medical management of COM by comparing the outcomes of topical antibiotic alone, oral antibiotic alone and combination of topical and oral antibiotic. Such type of study has not been done in our setup.

MATERIALS AND METHODS

Prospective, comparative longitudinal study was conducted in outpatient Department of

Otorhinolaryngology and Head & Neck Surgery of BPKIHS from 1st September 2018-31st August 2019. All patients of age more than 14 years presented to OPD with uncomplicated COM mucosal active were included in the study. Patients with COM squamous type, otomycosis, COM mucosal with complication or impending complications, aural polyp in the middle ear, history of antibiotic therapy in last month, immunodeficiency status, craniofacial anomalies, syndromic patient and those on steroid or immunosuppressant therapy, otological surgery within last 1 year, presence of tympanostomy tube, acute traumatic perforation, pregnant or lactating mother, symptomatic conditions such as otitis externa, chronic sinusitis, chronic pharyngitis requiring systemic antibiotic therapy that could interfere with the outcome of the study were excluded from the study.

A detailed clinical history, thorough general and ENT and Head and Neck examinations were carried out. Otoscopic examination was done and diagnosis was confirmed after verifying with the faculty in OPD.

Three hundred identical pieces of coupons, each 100 pieces written with alphabet A, B and C was folded and kept in a box in a locker in the OPD. During the time of prescription to each patient a coupon was withdrawn by the doctor him/herself and the patient were allocated and treated according to the alphabet in the coupon. Patients were allocated in one of the following groups:

Group A (Topical chloramphenicol): Ear drop 5% chloramphenicol 2 drops topically three times a day for 2 weeks

Group B (Oral Amoxicillin): Tab Amoxicillin 50mg/kg/day orally in three divided doses 8 hourly for 7 days.

Group C (Combination of both oral Amoxicillin and topical chloramphenicol): Combination of above two in same dose and duration.

Patients were called for the follow up after 2 weeks and on follow up otoscopic examination was done again. A dry mop was used and the ear with or without discharge was verified with the help of faculty. The purpose of the study and procedures was explained to the patients or legal guardians and informed consent was gained before commencing the data collection. All information was kept confidential and consent forms were number coded for identification. Ethical clearance was obtained from institutional review committee (IRC-1363/018).

Data handling and Coding Data was entered in Microsoft Excel, and converted into Statistical Package for Social Sciences for statistical analysis (11.5). Alpha numerical codes were used.

Data was entered after every day's work. The data has been presented in percentage, mean and standard deviation. Data has been summarized using frequency distribution tables and graphical methods of presentation of data (Bar diagram, Multiple bar diagram, pie charts, etc. as appropriate). Bi-variate analysis was done using appropriate test of significance (chi-square test). Statistical significance was tested with 95% confidence interval and p value less than 0.05 was considered as significant.

The outcome measure of the study is resolution of ear discharge following administration of topical antibiotic or oral antibiotic or combination of topical and oral antibiotics in patients with COM mucosal active.

RESULTS

This study included 300 patients from age 15 years to 74 years with mean age of 32.98±13.29 years. Most of the patients were below 35 years of age (60.3%) and 139 (46.3%) were male and 161 (53.7%) were female as shown in table 1. The mean age of male was 33.55 years and that of female was 32.49 years.

Table 1: Distribution of patients according to age group

Age	Frequency	Percent
15-24	87	29.0
25-34	94	31.3
35-44	57	19.0
45-54	36	12.0
55-64	21	7.0
≥65	5	1.7
Total	300	100.0

It was seen that in those who were treated with topical chloramphenicol (n=100), 77 had resolution of ear discharge and in 23 there was persistence of discharge in Group A. Similarly, among 100 patients who were treated with oral amoxicillin alone 69 patients had complete resolution of ear discharge and 31 failed to have complete resolution of ear discharge (Group B). Out of 100 patients who were treated with combination of topical chloramphenicol and oral amoxicillin, 80 patients had complete resolution of ear discharge whereas 20 patients did not have resolution of ear discharge (Group C). Applying Chi-Square test there is no statistical significance in the outcome of treatment of patient with COM mucosal active with either topical chloramphenicol alone or oral amoxicillin alone or combination of topical chloramphenicol and oral amoxicillin. (Chi-Square=3.480, p = 0.176, p > 0.05) (Table.2, Fig.1)

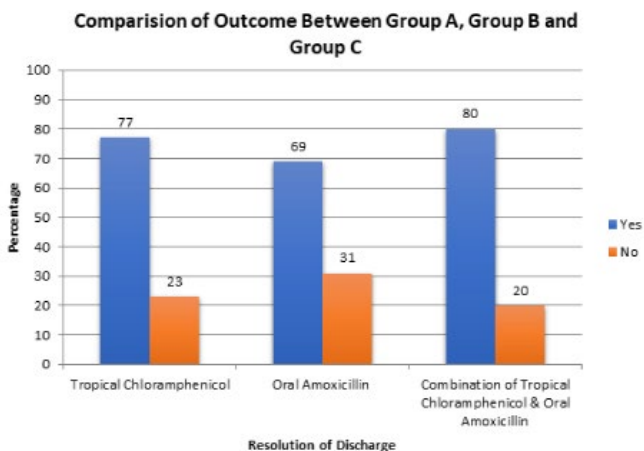


Figure 1: Comparison of outcome between Group A, Group B and Group C.

Table 2: Comparison of outcome of Group A, Group B, and Group C

Treatment given	Resolution of ear discharge		Total
	Yes	No	
Topical Chloramphenicol (Group A)	77	23	100
Oral amoxicillin (Group B)	69	31	100
Combination of topical chloramphenicol and oral amoxicillin (Group C)	80	20	100
Total	226	74	300

Chi-square test, $p=0.176$, $p>0.05$ not significant

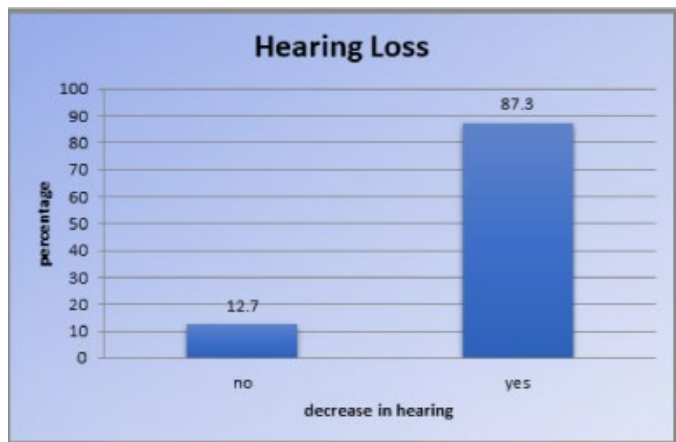


Figure 2: Distribution of patient on the basis of hearing loss.

DISCUSSION

This study showed the prevalence of COM mucosal was more in age group below 35 years of age which is similar to the finding of the study done by Shrestha BL et al in 2010 in which more than 60% of cases were less than 35 years of age .⁴

This study showed the prevalence of COM was more

in female than in male (54% and 46%, respectively).A community based prospective study done by Prakash et al in 2013 showed similar prevalence rate of COM ,which found female prevalence of 53.92% and male prevalence of 46.08%.⁵This study showed that the prevalence of COM was comparatively more among those who are still studying in high school and college level (prevalence among student =30.7%).This is probably that they themselves and their parents were more aware and concerned regarding their health. People at the level of high school and college are more involved in social activities, outdoor games like swimming, playing football and other water games. They are more exposed to the environment than the older ones that usually reside in home. The older people do not bother of any ear problems if they have any. They don't get enough care like the younger. Older people are busier in daily activities for earning their livelihood. They hardly get chance to think about their general health. Therefore, they visit to the hospital less frequently. This probably attributes to increase detection of ear disease in young school and college going population. In this study among 300 patients included 45.3% had right ear discharge, 35.3 % had left ear discharge and remaining 19.4% had bilateral ear discharge. In contrast to the findings of this study, a double blinded prospective randomized trial done by Onali et al in 2017 found that among 100 patient enrolled in the study 55 patient had left ear affected ,45 had right ear affected and none of patient had bilateral ear affected.⁶The laterality of ear discharge does not bear any clinical, surgical or prognostic implication and there are no known publications that determine it from the laterality of the ear discharge. The presenting symptom of COM mucosal is ear discharge, decrease hearing, itching, and aural fullness. This study found that 87.3% had associated decrease in hearing while in 12.7% patients the hearing was normal as shown in figure 2. Those who had no associated hearing loss might be due to small size tympanic membrane perforation or high middle ear volume, or dry ear. Our study result shows combination of chloramphenicol and oral amoxicillin is better than topical chloramphenicol and oral amoxicillin alone. Similar result was obtained by study done by Verma Sachin et al on 2017 which showed combination treatment being the best.⁷ Similarly study done by Onali et al also showed there was better response rate on using combination of topical and oral ciprofloxacin in compared to using only topical ciprofloxacin.⁶ A study done by Esposito et al in three groups of 20 patients each affected by chronic otitis media those receiving topical ciprofloxacin and combination of topical and oral ciprofloxacin had better clinical response than those receiving oral ciprofloxacin only.⁸Our study used topical chloramphenicol and oral amoxicillin which is different than antibiotic used by other studies mentioned previously. These are easily available,

over the counter broad spectrum antibiotics and they are equally effective in curing ear infections. However there is no conclusive studies showing one better than other. So the result of above studies are comparable to ours. Although the combination treatment is found out to be more efficacious than others in our study there is however no statistical significance among Group A, Group B and Group C. However due the possibility of systemic side effects and cost involved in oral and combination treatment topical alone is preferable in the treatment of COM mucosal disease.

Patient were advising to dry mop the ear with cotton bud before instilling ear drop and after instilling to apply intermittent tragal pressure. We are not sure whether the patients follow the right technique while instilling the antibiotic drop. This may affect our outcome. Similarly missing of doses of antibiotic as prescribed and concurrent use of medicine for other health problems like cough and fever may affect our study result.

CONCLUSIONS

This study shows there is no difference in outcome of treatment of COM mucosal active disease with topical chloramphenicol ear drop alone or oral amoxicillin alone or combination of both topical chloramphenicol and oral amoxicillin. To get a more convincing result larger sample size should be included. Study has to be done regarding which topical antibiotic to be used among topical chloramphenicol, topical ciprofloxacin and topical ofloxacin.

FUNDING: Not any

CONFLICT OF INTEREST: No

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