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Original Research Paper

Comparison of efficacy of neomycin/betamethasone otic solution alone with oral Amoxycillin plus neomycin/betamethasone otic solution in the treatment of chronic suppurative otitis media – Comparison of efficacy of tubotympanic, (SAFE) type during acute exacerbation

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ABSTRACT:
Objective:- Comparison of efficacy of neomycin / betamethasone otic solution alone with oral amoxicillin plus neomycin / betamethasone otic solution in the treatment of chronic Suppurative otitis media- tubotympanic (safe) type during acute exacerbation. **Materials and methods**: - Patients were recruited from the out-patient clinic of the Department of Otorhinolaryngology Head & Neck Surgery from December 2023 to June 2024. Patients with age >12 years and with a diagnosis of CSOM-TT with acute exacerbation wear enrolled in the study and divided into two treatment groups. Group 1 received neomycin / betamethasone otic solution alone for ten days while Group 2 received oral amoxicillin for seven days plus the above otic solution for ten days. The primary outcome measure was attainment of dry ear (responder) evaluated after two weeks of the start of treatment. Non responding ears were subjected to culture of the discharge for bacteriological flora and drug resistant pattern. **Justification**: - Ear discharge is a major factor for CSOM especially amongst the children and poor hygiene people in Nepal. Ear discharge is one of the public health problem in Nepal. For starting preventive measures information on nature and extent of CSOM is required. This studies is intended to find necessary answer about the pattern of CSOM at Bheri Hospital which will guide the local bodies, district and national authorities to take necessary step for CSOM prevention to decrease disease for undeveloped country as Nepal. **Results:** - At two weeks of scheduled follow up, the percentage of ears which was dry in treatment Group 1was 70.6% and in treatment Group 2 it was 78.9% but the p value was not significant. Non responding ears predominantly grew Staphylococcus aureus and Pseudomonas species. **Conclusion**: - The combination of antibiotic / steroid otic solution with systemic antibiotic is not superior to antibiotic / steroid otic solution alone in the treatment of CSOM-TT during active stage.

Keywords: Otic solution, neomycin/betamethasone, chronic suppurative

INTRODUCTION:

Chronic Suppurative otitis media is more common in the lower socioeconomic population and more so in developing countries as compared to developed countries. The prevalence of chronic Suppurative otitis media tubotympanic type in developed countries is less than 2%. The microbiologic flora of the discharge usually consists of Pseudomonas aeruginosa, Staphylococcus aureus, Proteus mirabilis, Escherichia coli and anaerobes in different order in different studies. The management of chronic Suppurative otitis media-tubotympanic type (CSOM- TT) is both surgical; and medical. Surgical treatment, that is, myringoplasty aims at grafting the perforation in the parstensa so as to prevent recurrent infection and to improve hearing provided the ossicular chain is intact and mobile and the cochlear reserve is adequate. Hearing mechanism can be reconstructed when necessary during myringoplasty-ossiculoplasty. On the other hand medical management of CSOM-TT aims at resolving the otorrhoea during the active stage of infection. Sometimes the medical treatment may follow spontaneous closure of the perforation. Many studies have been carried out in the past with regard to the treatment of acute exacerbation of disease. As one of the different treatment arms, people have tried oral antibiotics alone Some Authors have tried oral antibiotics together with topical antimicrobial otic solution while other authors have tried topical antimicrobial otic solution alone. Use of oral antibiotics has to amoxicillin clavulanic acid evolved from Co-trimoxazole to amoxicillin to quinolones. Similarly the use of otic solutions has evolved from aminoglycoside otic solution chloramphenicol to

quinolones to povidone-iodine. When a patient is diagnosed to have CSOM-TT in active stage, the usual practice at the Department of ENT and Head & Surgery, Bheri Hospital is to give oral amoxicillin or oral quinolone (ciprofloxacin or Ofloxacin) for a period of seven days together with topical ciprofloxacin or aminoglycoside otic solution with or without steroid for a maximum period of ten to fourteen days. This study was conducted to compare the efficacy of oral amoxicillin and betamethasone / neomycin otic solution with betamethasone / neomycin otic solution alone in the treatment of chronic Suppurative otitis media-tubotympanic type (CSOM-TT). This will help us to find out whether the use of amoxicillin improves the cure rate significantly or that it is just being unnecessarily used causing additional financial burden to the patient as well as increasing drug resistance.

Aims and Objectives:

1. To evaluate the efficacy of the empirical use of neomycin/betamethasone otic solution alone in the treatment ofCSOM-TT during the active stage.
2. To evaluate the efficacy of the empirical use of oral amoxicillin plus neomycin/betamethasone otic solution in the treatment of CSOM-TT during the active stage.
3. To compare the efficacy between the above-mentioned treatmentmodalities.
4. To study the bacteriological flora and drug resistant pattern of theear discharge in those patients who do not respond to the above treatment modalities.

MATERIALS AND METHODS:

Place of study: Patients for our study were recruited from the out-patient clinic of the Department of Otorhinolaryngology and Head & Neck Surgery, Bheri hospital

Duration of study: The study was conducted for a period of six months starting from December 2023 to June 2024

Study design: An interventional study.

Patient Types: Patients with following characteristics were enrolled in the study.

Inclusion Criteria:

➢ Patients with CSOM-TT disease of more than 3 months durationand which was active.

➢ Patients with age greater than or equal to twelve years, that is by the time when the adenoids, which are thought to harbour upper respiratory tract infections pathogens that may be responsible for ASOM/CSOM, have regressed.

➢ Patients of either sex

➢ Patients with both unilateral and bilateral disease.

Exclusion criteria:

➢ Patients who had atticoantral type of CSOM

➢ Patients who were already taking oral antibiotics or on antibioticotic solution for the last 48 hours.

➢ Patients who had aural polyps.

➢ Patients who had associated otitis externa.

➢ Patients who had other complications of CSOM-TT.

➢ Patients who had co-morbid conditions like diabetes mellitus andknown immunosuppressive disorders.

➢ Patients who were suffering from rhino sinusitis or pharyngitis andrequired systemic antibiotics.

➢ Those who did not turn up for follow up after being enrolled.

➢ Patients who did not complete the treatment for some reasons like adverse effect of the drugs or non-compliance.

Intervention:

Patients who fulfilled the enrolment criteria were divided into one of the two treatment groups after suction and clearance of the discharge in their first visit:

Group I was assigned only neomycin (0.5%w/v)/betamethasone (0.1%w/v) otic solution which was instilled for a period of ten days, three drops thrice a day, the patient lying on the side with the affected ear on top for about at least ten minutes and applying pressure on the tragus intermittently with the index finger after the drops were kept.

Group II was assigned oral amoxicillin at 10mg/kg body weight thrice a day for seven days plus neomycin/betamethasone otic solution like above for a period of ten days.

Sampling Method:

The sampling method employed in this study was a convenient sampling. The first patients was selected for treatment Group 1, and the next consecutive one automatically went into treatment Group Il so that by the end of the study there were equal number of patients in each group when enrolled. As we included both ears from the same patient if both ears were infected and since there was variation in the rate of follow up of the Patients in two different groups, the total number of ears studied at the end of the study period was not equal inboth groups.

Outcome Measure:

Follow up was done at two weeks after starting the treatment. At that time the treatment response in terms of otorrhoea was evaluated. We recorded whether there was

1. Discharge (wet ear) - no response, or
2. No discharge (dry ear) - complete response.

Those patients who did not respond to the above empirical treatment at two weeks of their follow up visit underwent culture and sensitivity of their discharge. This assured that these patients were at least

48 hrs off antibiotics before the discharge was subjected to culture and sensitivity. The discharge material was collected in a sterile swab under a sterile technique and was processed in the Department of Clinical Microbiology, Bheri Hospital. For bacterial isolation the swabs were cultured on blood agar under aerobic condition at 37° C. The culture media were examined after 24 hrs and predominant growth seen was identified and sub cultured to see the drug resistant pattern for commonly used oral antibiotics including ampicillin, ciprofloxacin, erythromycin, cotrimoxazole and Cloxacillin.

Simple size:

To calculate the sample size for our study we calculated the standard error of difference in the outcome between the two different treatment modalities as observed from the first seven months of the study. Since at seven months, there were 65% and 77% of response in treatment Group I and treatment Group II respectively, the stander error was 10.6. If we assume that 77% of response is adequate in treatment Group II, then to have a significant difference between the two treatment modalities, treatment Group I should have 56% response rate (77 minus 1.96Xs.e, for $p<0.05$). If the power of probability of finding a significant result is 75% (u=0.67), then the required sample size is 67 numbers of ears in each treatment group as derived from the following formula:

$(u+v)^2 (p_1q_1+p_2q_2)$ where v=1.96 and u=0.67 $(P1-p2)^2$

We decided to enrol seventy affected ears in each group of treatment as a minimum requirement.

Analysis and Statistics:

Results of our study were analysed in terms of the difference in the outcome of resolution of ear discharge between the two treatment modalities, the rate of isolation of bacteriologic flora and their drug resistant pattern in those ears which did not respond to the empirical treatment, the rate of follow up of patients after treatment, the difference in the rate of follow up between males and females and the difference in the distribution of males and females in each treatment group.

Chi-square tables were used to find out the significant differences between the two measured proportions. The p value of less than or equal to 0.05 was taken as significant in our study. Web Chi-Square calculator was employed to tabulate the data and obtain chi-square and p values.

RESULTS:

There were altogether 174 patients who fulfilled the enrolment criteria. There were 107 males and 67 females: the male: female ratio1.6:1. (Fig.1)

A total of 127 patients came for follow up, out of which 81 were males and 46 were females; the male: female ratio being 1.8:1. This meant that only 75.7% of male and 68.6% of female came for follow up. There was observed difference in the follow up rates between the genders but the chi-square analysis was not significant (chi-sq. =1.04,p value<1) (Table 1).

The demographic profile of the patients in two treatment groups isshown in Table 2.

There were 66 patients in treatment Groups I, out of whom there were 45 males and 21 females; with a male: female ratio of 2.1:1. The age range varied from 12 to 50 years and the mean age of the patients was 25.3 years.

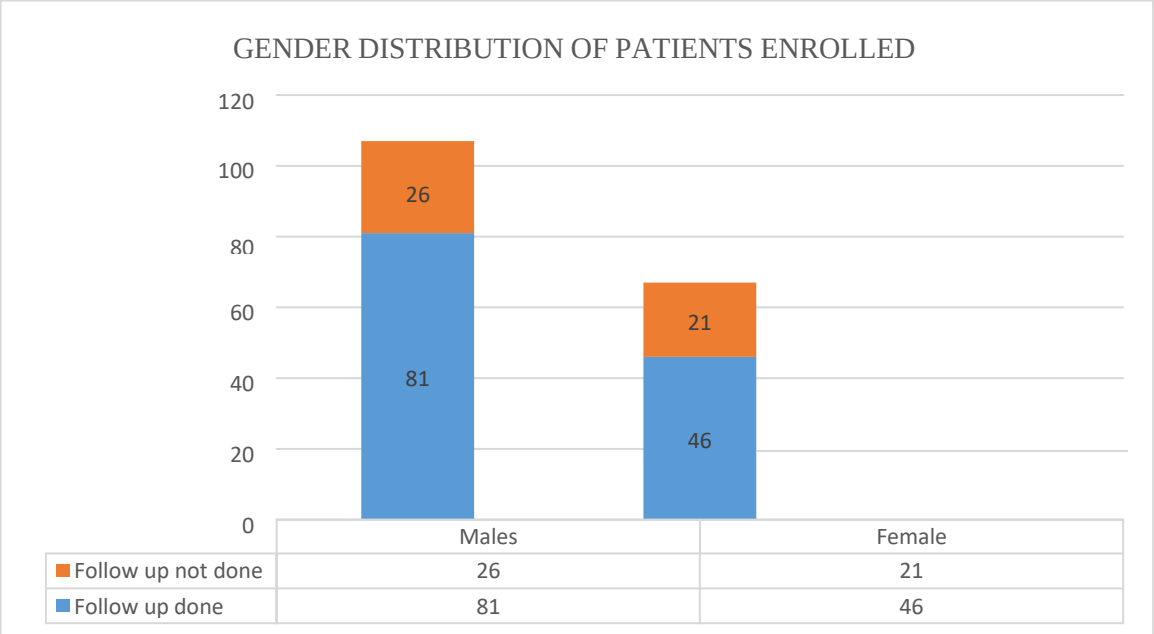

Fig:-1

Table 1. Chi-square table to show the significant difference in thefollow up rates for male and female.

Gender	Follow up done	Follow up not done
Male	**81**	**26**
Female	**46**	**21**

Chi-sq. = 1.04

P value <-Not significant

There were 61 patients in treatment Group II, out of whom there were 36 males and 25 females, with a male: female ratio of 1.4.1. The age of the patients varied from 12 to 56 years and the mean age of the patients was 27 years.

There was uneven distribution of males and females in the two treatment groups but the chi-square analysis showed that the difference was not significant (chi- sq. 1.15, p value < 1) (Table 3).

In our study, both the affected ears of the same patient were included and studied individually although it is obvious that they received the same treatment.

At the end of the study period we found that there were altogether 146 ears that received treatment and were assessed at follow up after two weeks of starting treatment (Fig. 2). Of these, 75 affected ears were treated with neomycin / betamethasone otic solution alone while 71 affected ears were treated with oral amoxicillin plus the above otic solution. The only outcome measure that we assessed at follow up was the dryness of the treated ears. So at two weeks of scheduled follow up, the number of ears that were dry in treatment Group I was 53, which was equivalent to 70.6%. Similarly, in treatment Group II dry ears numbered 56, which was equivalent to 78.9% (Fig.3). When we combined the number of ears which did not respond to the empirical treatment, it was found that in treatment Group I there was 50% non- responders while in treatment Group If there were 41% non-responders (Fig. 4).

Our results showed that when CSOM-TT was treated with both oral amoxicillin and neomycin/betamethasone otic solution during the active stage the outcome is better than when treating the same condition with the above otic solution alone. Although there is an observed difference in the results, chi-square analysis shows that the difference was not significant (chi-sq. =1.30, p value<1) (Table 4).

Table 2. Demographic profile in two treatment groups.

	Treatment Group I	Treatment Group II
Total Patients	66	61
Male	45	36
Female	21	25
Male: Female	2:1:1.	1:4:1.
Age Range	12-50 years	12-56 years
Mean age	25:3 years	27 years

Table 3. Chi-square table to show the significant difference in the division between mall and female in the two treatment groups.

	Male	Female
Treatment Group I	45	21
Treatment Group II	36	25

Chi- Sq. = 1.15

P value < 1 -Not Significant

There were altogether 22 (29.4%) non-responders in treatment Group I while there were 15 (21.1%) non-responders in treatment Group II. The predominant floras identified in the culture after 24 hours of growth were Pseudomonas species and Staphylococcus aureus (Fig.5). There were the only aerobic bacteria Identified.

Among 22 non-responders in treatment Group I, 13 of them showed growth, of which 6 were Staphylococcus aureus and 7 were Pseudomonas species. While in treatment Group II, only 4 out of 15 non-responders showed positive culture, of which 2 were Staphylococcus aureus and 2 were Pseudomonas species. There were altogether 3 non-responder ears which were not subjected to culture for bacteriological flora due to associated otitis externa found at follow up (Table 5).

The drug resistant pattern of isolated organisms is shown in Table 6. It shows that Staph aureus was sensitive to ciprofloxacin, erythromycin, cotrimoxazole and Cloxacillin 100% of the isolates in treatment Group 1. Only one isolate was sensitive to ampicillin.

However in the same treatment group, Pseudomonas species was most of the time resistant to the common oral antibiotics.

Looking at treatment Group II, Staph aureus was sensitive to ciprofloxacin, cotrimoxazole and Cloxacillin in 50% of the isolates only and resistant to other antibiotics in 100% of the isolates.

Pseudomonas species was resistant to all the tested oral antibiotics.

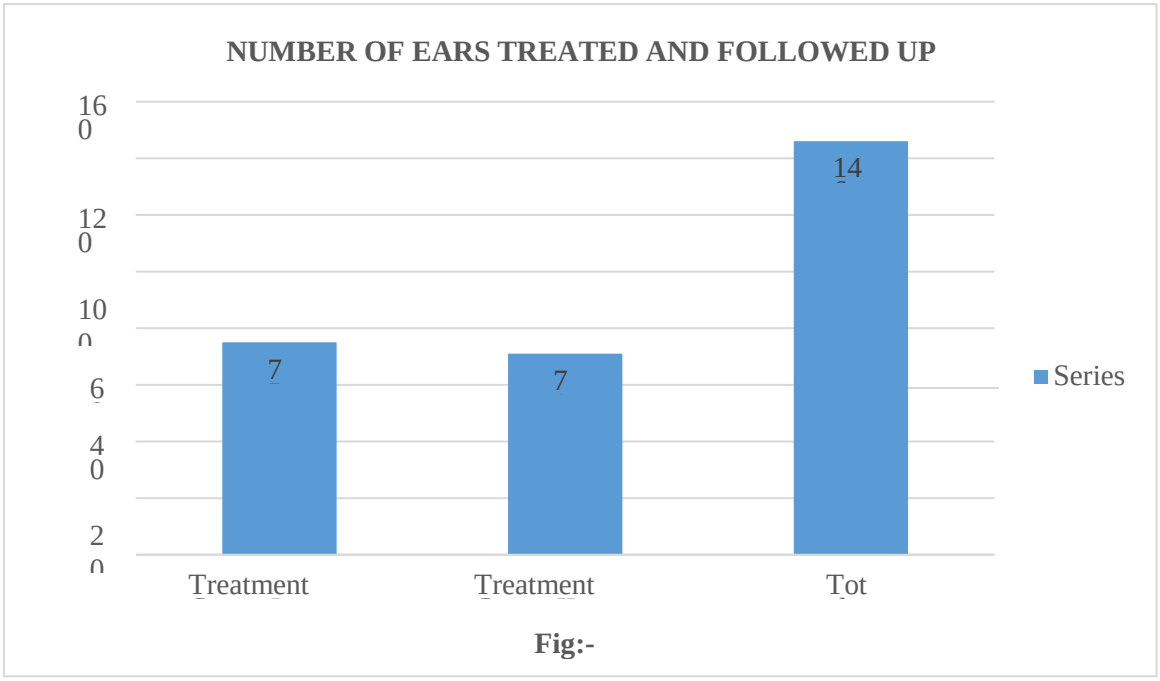

Fig.2. Number of ears treated and followed up.

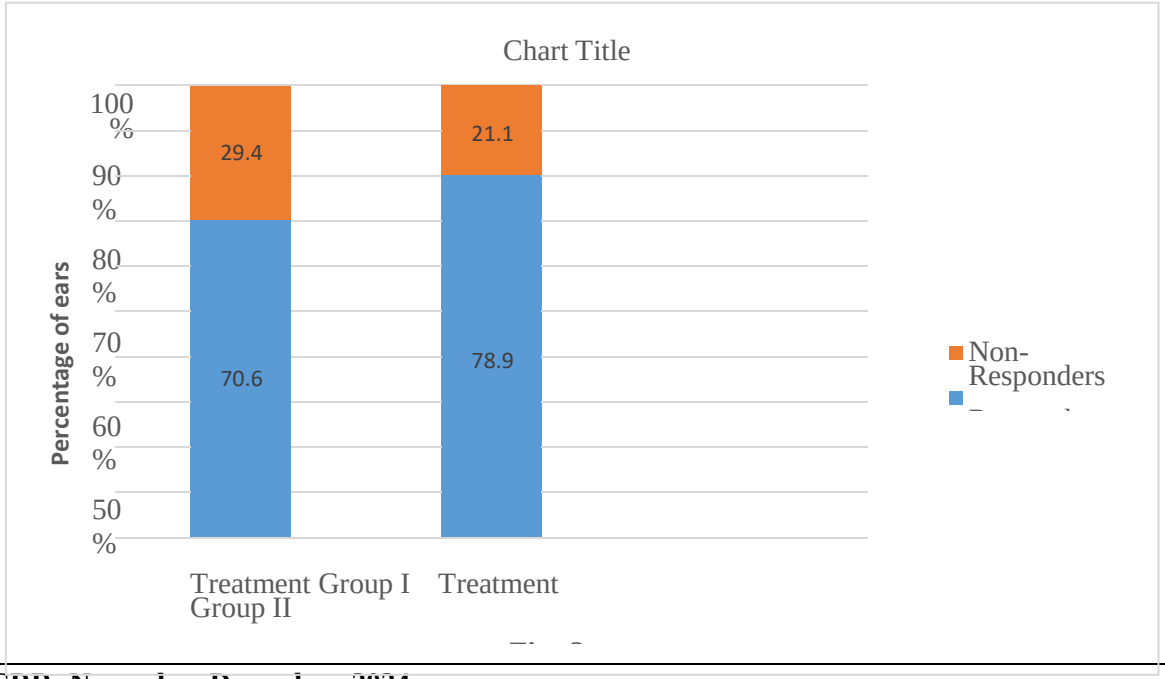

Fig.3. End Result of the treatment at follow up

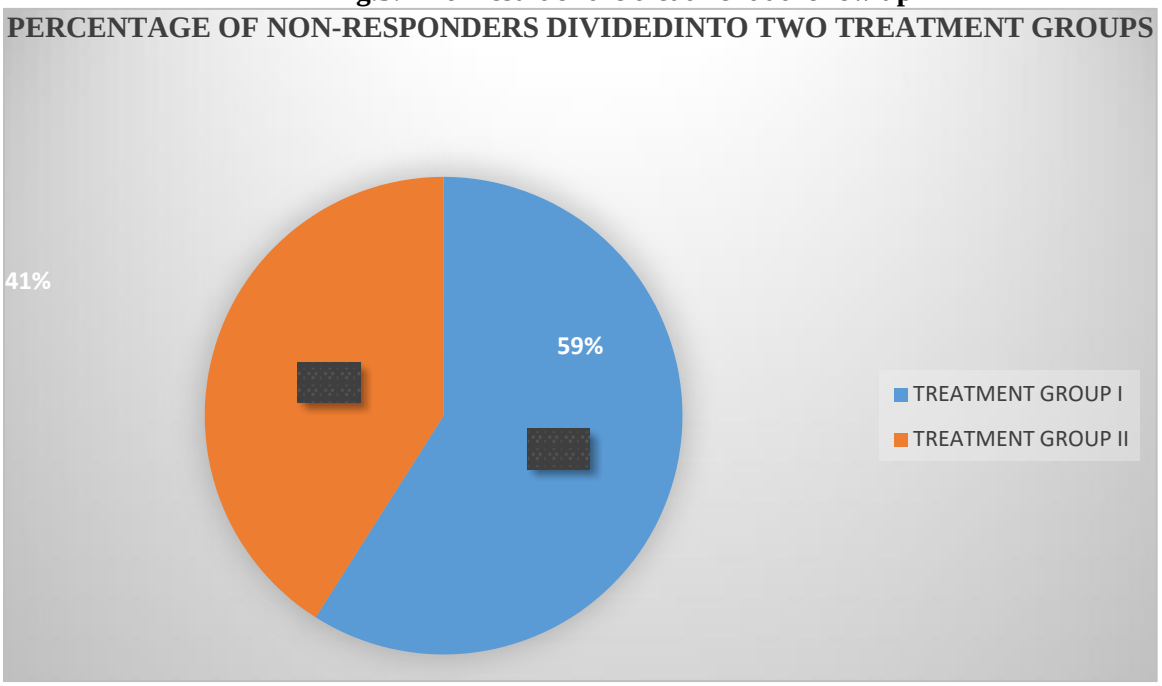

Fig.4. Percentage of non-responders divided into two treatment groups

Table 4. Chi-square table to show the significant difference in the resolution of discharge between the two treatment groups.

	Responders	**Non-Responders**
Treatment Group I	53	22
Treatment Group II	56	15

Chi-Sq. =1.30
P value< -Not Significant

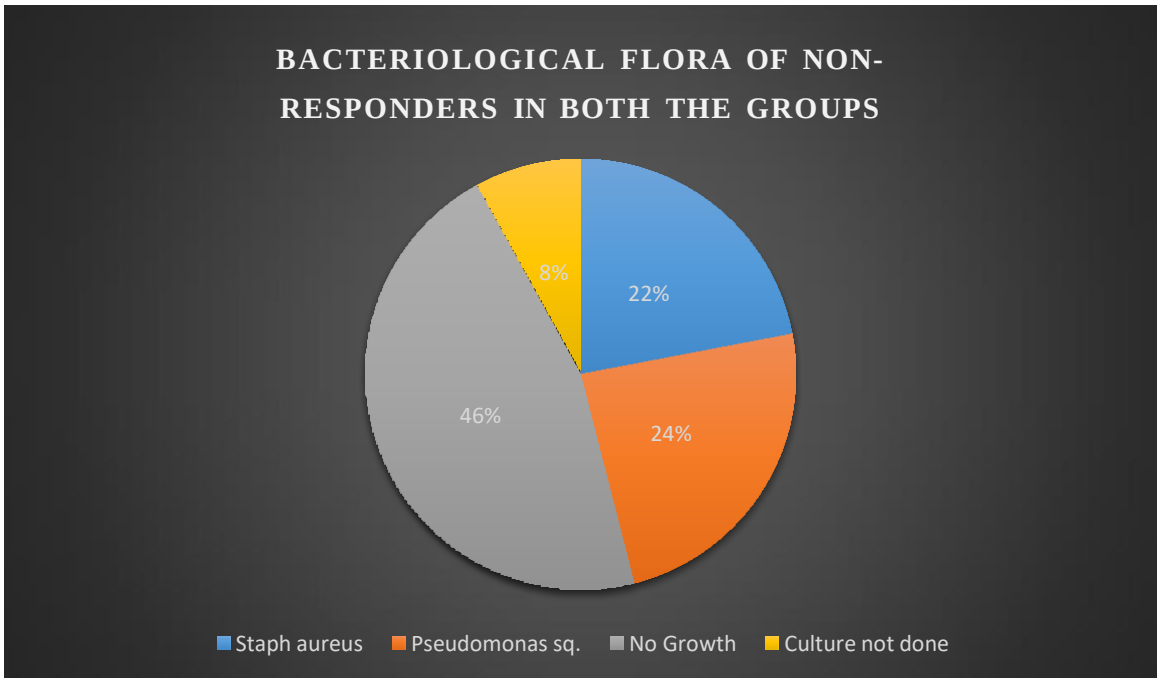

Fig.5. Bacteriological Flora of non-responders in both the group

Table 5. Bacteriological flora of non-responders in individual groups.

Organism	Treatment Group I	Treatment Group II
Staph aureus	6	2
Pseudomonas sq.	7	2
No Growth	8	9
Not Taken (otitis externa, furuncle)	1	2

Table 6. Drug sensitivity pattern of micro-organisms in individualgroups.
Treatment Group I

Antibiotic disc	Staph aureus N=6	Pseudomonas sp. N=7
Ampicillin (10ug)	1	0
Ciprofloxacin (5ug)	6	1
Erythromycin (15ug)	6	1
Cotrimoxazole (25ug)	6	0
Cloxacillin (5ug)	6	0

Treatment Group II

Antibiotic disc	Staph aureus N=2	Pseudomonas sp. N=2
Ampicillin (10ug)	0	0
Ciprofloxacin (5ug)	1	0
Erythromycin (15ug)	0	0
Cotrimoxazole (25ug)	1	0
Cloxacillin (5ug)	1	0

CONCLUSION:

The primary objective of this study was to compare the efficacy of oral amoxicillin and betamethasone/ neomycin otic solution with betamethasone / neomycin otic solution alone in the treatment of chronic Suppurative otitis media-tubotympanic type (CSOM-TT). The only outcome measure that we assessed at follow up was the dryness of the treated ears. At two weeks of the scheduled follow up, the percentage of ears which was dry in the treatment Group I was 70.6% and in the treatment Group II it was 78.9%. Although our results showed that when CSOM-TT was treated with both oral amoxicillin and neomycin / betamethasone otic solution during the active stage the outcome was better than when treating the same condition with the above solution alone, chi-square analysis showed that the difference was not significant (chi-sq. =1.30, p value< 1).

Therefore the conclusion was that combining antibiotic /steroid otic solution with systemic antibiotic is not superior to antibiotic/ steroid otic solution alone in the treatment of CSOM-TT during active stage.

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