Print ISSN: 2319-2003 | Online ISSN: 2279-0780

IJBCP International Journal of Basic & Clinical Pharmacology

DOI: http://dx.doi.org/10.18203/2319-2003.ijbcp20180652

Original Research Article

Therapeutic guidelines for antimicrobial use in chronic suppurative otitis media for a tertiary care hospital in Sub Himalayan region

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Received: 15 October 2017
Revised: 05 January 2018
Accepted: 09 January 2018

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ABSTRACT

Background: The battle against micro-organisms, in their role as primary cause of the disease and infective complications of medical and surgical techniques, has not decreased in spite of modern antimicrobial therapy. Chronic suppurative otitis media (CSOM) is a disease with worldwide prevalence having potentially serious long term effects. The disease remains an important global public health problem leading to hearing impairment, and due to wide spread irrational use microbial resistance is very common to these antibiotics, thereby leading to treatment failure. Hence it is important to know the type of bacteria and their sensitivity pattern so that appropriate antibiotics may be given for treatment and prevention of complications.
Methods: 428 patients of otitis media were enrolled from ENT OPD of Tertiary Care Hospital. Ear swab was taken from diagnosed cases of CSOM and culture and sensitivity were done.
Results: The microbiology of the swab showed no growth in (25.4%) of samples. Staphylococcus aureus (26%) and Pseudomonas (25%) were the main organisms isolated. Staphylococcus aureus isolated was sensitive to vancomycin, clindamycin, cefixime, gentamicin and cefipime in descending order. *Pseudomonas aeruginosa* was sensitive to ceftazidime, imipenem, piperacillin, gentamicin, cefipime. In the present study Staph. aureus and Pseudomonas were the predominant bacteria, it is suggested to undertake a gram staining in all patients. If gram positive organisms are isolated it is suggested that presumptive treatment should be directed against Staphylococcus aureus and if gram negative then against Pseudomonas aeruginosa. Such a treatment is not only likely to be effective but will also go a long way in preventing emergence of drug resistance.
Conclusions: The antimicrobial therapy should be based on locally determined microbiological isolates and local sensitivity patterns to a particular antimicrobial agent. The presumptive antimicrobial therapy should therefore be directed against these organisms.

Keywords: CSOM, Culture and sensitivity, *Klebsiella*, *Pseudomonas*, *Staphylococcus aureus*, Therapeutic guidelines

INTRODUCTION

Therapeutic Guidelines are designed to support the decision-making process in patient care and help to describe appropriate care, based on the best available scientific evidence, reduce inappropriate variation in practice and promote efficient use of resources. However, formulation of therapeutic guidelines is a continuous process and should be reviewed at regular intervals to monitor the sensitivity and specificity.[1] Rational use of medicine is importance for minimizing unnecessary exposure to antibiotics and even WHO advises to promote

constitution of therapeutic committees in district hospitals to monitor and implement interventions to improve the use of medicines. There is increasing evidence that directly associates antibiotic use with the emergence of resistant bacteria such as Methicillin-Resistant *Staphylococcus aureus* (MRSA), Vancomycin-Resistant *Enterococcus*, and resistant Gram negative bacilli and *Clostridium* difficile.[2-4] Many studies have shown that more judicious use of antibiotics according to preset locally determined guidelines can reduce resistance, independent of traditional infection control measures.[5]

Prescription should be based on pharmacodynamics principles that predict efficacy, bacterial eradication and prevention of resistance emergence. Pharmaco-economic analyses confirm that bacteriologically more effective antibiotics can reduce overall management costs, particularly with respect to consequential morbidity and hospital admission. Application of these guidelines should positively benefit therapeutic outcomes, resistance avoidance and management costs and will more accurately guide antibiotic choices by both individuals and formulary/guideline committees.[6] For rational antibiotic use of medicines and successful treatment of CSOM, an appropriate knowledge of antibacterial susceptibility of causative microorganisms is essential.

Aim of the study was to prepare the therapeutic guidelines for antimicrobial use in chronic suppurative otitis media for a tertiary care hospital in Sub Himalayan region.

Objectives of the study were to know the bacterial spectrum of Chronic Suppurative Otitis Media in a tertiary care hospital in North India and to study the culture and antimicrobial sensitivity pattern of common causative organisms of Chronic Suppurative Otitis Media a tertiary care hospital in North India.

METHODS

It was prospective cross-sectional study.

Study setting

The study was conducted in collaboration with the departments of Pharmacology, Microbiology, Otorhinolaryngology, of Dr. R P. Government Medical College and Hospital Kangra at Tanda for a duration of one year.

Study participants

Patients diagnosed with CSOM in the OPD of Otorhinolaryngology department fulfilling the inclusion and exclusion criterion were enrolled on Monday and Saturday of every week during the study period over a period of one year.

Inclusion criteria

Clinically diagnosed cases of CSOM belonging to all ages and any gender.

Exclusion criteria

- Known Immuno compromised patients
- Patients not willing to participate in the study
- Those already on antibacterial therapy

The study was approved by Protocol Review Board and Institutional Ethical Committee of Dr. RPGMC Kangra at Tanda. The information collected, and individual identity was kept strictly confidential. Results of the study are used only for academic purpose and forming therapeutic guidelines.

Consent

The written informed consent was obtained from all the patients/ guardian (in case of a minor).

Sample collection for culture and sensitivity

Specimen which is used for the study was Ear discharge.

Sterile swab sticks (commercially available single use swab sticks).

The specimen of the discharge was collected on a thin, sterile cotton wool swab. The swab was then placed in a sterile container and stopper was replaced tightly. Utmost care was taken to avoid surface contamination. The specimen was labelled appropriately and sent to the laboratory immediately for further processing. Samples (2 in no.) were collected and labelled accordingly under aseptic precautions.

Sample transportation

Samples were transported immediately to the Department of Microbiology, Dr. R.P. Govt. Medical. College and Hospital Kangra at Tanda.

Processing of samples out of the two specimens collected, Gram staining was used for gram staining by modified Hucker's method and other was used for culture.

Culture

Another swab was used for culture on MacConkey agar incubated at 37^0C for 24-48 hrs. The plates showing no growth at 48 h were recorded as negative cultures i.e no growth. Culture was done only for aerobic organisms. The media for MacConkey agar were procured from HiMedia laboratories Pvt. Ltd. Mumbai, India.

Identification of organisms the isolates obtained on culture were studied and identified by the standard bacteriological techniques based on colony characters and biochemical tests.[7]

The antimicrobial susceptibility test

AST for antibacterial was performed for all pathogenic isolates by modified Kirby-Bauer disk diffusion method on Mueller - Hinton agar plates.[8] All antibiotic disks were procured from HiMedia Pvt Ltd

The zone of inhibition was reported as susceptible (S), Intermediate (I), Resistant(R) as per CLSI guidelines.[9] Drugs used for antibiotic sensitivity testing according to the organism.[10]

Quality control

E. coli ATCC 25922; *S. aureus* ATCC 25923, *Pseudomonas aeruginosa* ATCC 27853 were used as standard strains for quality control as per Clinical and laboratory standards institute guidelines.[9]

Formulation of the therapeutic guidelines

After culture and sensitivity reports, other parameters were taken into consideration. Cost of therapy, Pharmacokinetics properties of antimicrobials and adverse drug reactions were obtained from available literature. The cost of therapy was calculated and based on all the above parameters the therapeutic guidelines were formulated.[11,12]

RESULTS

A total of 428 ear swab samples were collected. Out of which 250 (58.5%) specimens were from males and 178 (41.5%) from females. From total 428 samples, pathogenic bacteria were isolated in 299 (70%), no growth in 105 (24%) and commensals 24 (6%) specimens. The culture of the specimens revealed that *Staphylococcus aureus* including *Methicillin Resistant Staphylococcus aureus (MRSA)* 118, (39%) and *Pseudomonas aeruginosa* 110, (37%) were the main organisms isolated. In addition, a number of other organisms were isolated viz. Non-fermenter Group of organisms (NFGO) 19 (6%), *E. coli* 13 (4%), *Klebsiella spp.* 8 (3%), *Proteus spp.* 4 (1.5%), *Enterobacter spp.* 4 (1.5%), *Enterococcus spp.*4 (1.5%) *β Haemolytic streptococcus* 3 (1%), *Citrobacter* 2 (1%) *Acinetobacter* 1 (0.5%) and 13 (4%) others* non-significant organisms (Figure 1). All the S*taphylococcus aureus* isolated were sensitive to vancomycin 118 (100%); while sensitivity to other antimicrobials was as: clindamycin 84 (71.3%), cefixime 67 (56.8%), gentamicin 62 (52.5%), cefipime 58 (49.1%), amoxy+clav 32 (27.2%), imipenem 30 (25.4%), ofloxacin 27 (22.9%), penicillin 22 (18.6%), ceftazidime 23 (19.5%), piperacillin 19 (16.1%), Cefoperazone 15 (12.7%), ceftriaxone 7 (5.9%), ciprofloxacin 6 (5.1%) and azithromycin 6 (5.1%) (Figure 2). *Pseudomonas aeruginosa* isolated was sensitive to ceftazidime 86 (78.2%), imipenem 79 (71.8%), piperacillin 71 (64.5%), Gentamicin 59 (53.6%), Cefepime 26 (23.6%), Ticarcillin 24 (21.8%), Carbenicillin 18 (16.4%), cotrimoxazole 9 (8.2%), ciprofloxacin 7 (6.4%), Cefoxitin 4 (3.6%), Penicillin 1 (0.9%) (Figure 3).

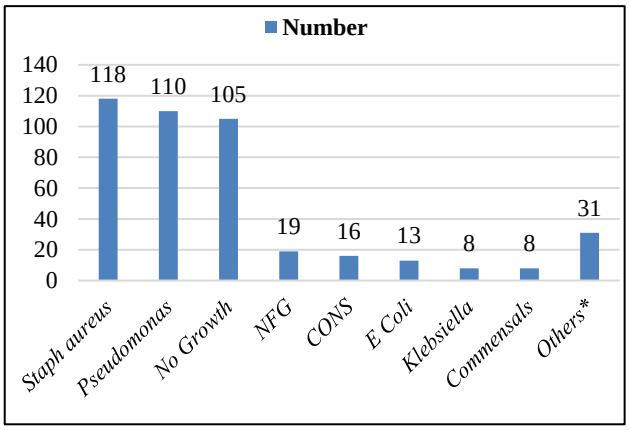

Figure 1: Culture of the ear swab (n=428).

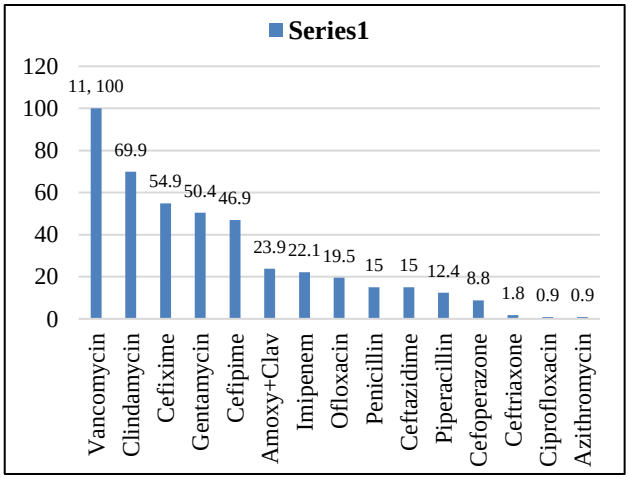

Figure 2: Sensitivity profile of *Staphylococcus aureus* (n=113).

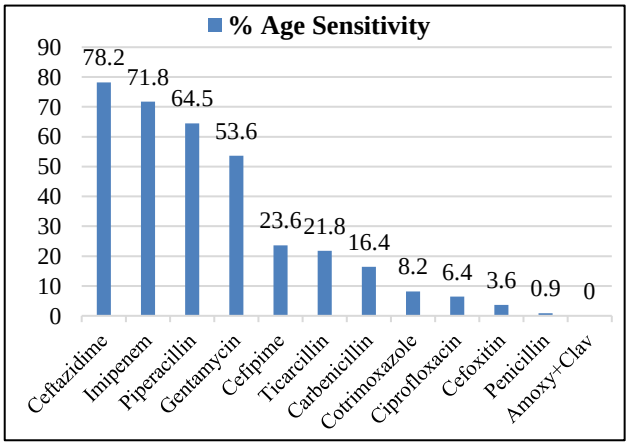

Figure 3: Sensitivity profile of *Pseudomonas aeruginosa* (n=110).

NFGO isolated was sensitive to vancomycin 19 (100%), ceftazidime 13 (68.4%), imipenem 12 (63.1%), gentamicin 11 (57.8%), amoxy+clav 10 (52.6%), ciprofloxacin 9 (47.4%), cefixime 4 (21%), cotrimoxazole 4 (21%), clindamycin 2 (10.5%), azithromycin 2 (10.5%), cefotaxime 2 (10.5%), piperacillin 1 (5.3%), Carbenicillin 1 (5.3%), ticarcillin 1 (5.3%) and Ampicillin+Sulbactam 1 (5.3%) (Figure 4).

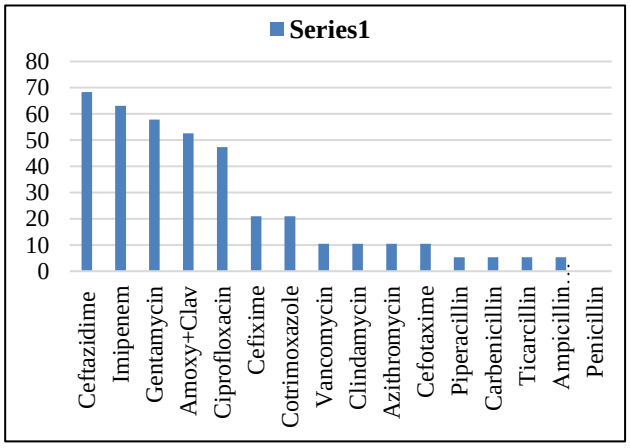

Figure 4: Sensitivity profile of NFGO (n=19).

E. coli isolated showed sensitivity to cefixime 10 (77%), gentamicin 9 (69.2%) piperacillin 4 (30.8%), clindamycin 2(15.4%) and ceftriaxone 1 (7.7%).

Klebsiella spp. isolated were sensitive to gentamicin in 8 (100%), cefixime 7 (87.5%) piperacillin 6 (75%), clindamycin 5 (62.5%), ceftazidime 5 (62.5%), imipenem 4 (50%), ciprofloxacin 1 (12.5%), erythromycin 1 (12.5%) of the specimens (Figure 5).

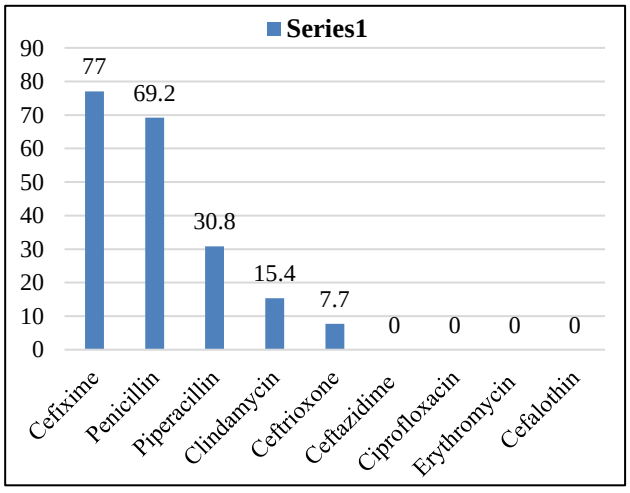

Figure 5: Sensitivity profile of *E. coli* (n=13).

Therapeutic guidelines for CSOM

Therapy is recommended based on the results of gram staining and is as under:

Gram Positive organisms

- Drug of choice Clindamycin 600 mg 8 hourly, orally
- Second line therapy Cefixime 200 mg BD, orally
- Gram Negative organisms:
- Drug of choice Ceftazidime 2 g 8 hourly IV
- Second line therapy Gentamicin 2 mg/ kg then 3-5mg/kg/day in 3 divided doses IM/IV

Notes

- In case of no response to the above therapy, culture and sensitivity should be undertaken and the treatment should be revised accordingly.
- The antibiotics recommended for other organisms isolated are mentioned above.

DISCUSSION

CSOM is a chronic inflammation of middle ear due to various causes. It is one of the common causes of deafness. The disease usually occurs after upper respiratory viral infections followed by invasion of pyogenic organisms. CSOM can cause severe adverse effects like intra and extra cranial complications which can be life threatening. The complications of CSOM have been reduced to a greater extent because of the invention of antibiotics. But irrational use of antibiotics has led to the emergence of resistant organisms to the commonly used drugs. In CSOM knowledge of the local microbiological flora is essential for initiating empirical therapy. Often, the primary care physicians are usually the first to see these patients and mostly rely on empirical antibiotic therapy and only refer to the otolaryngologist when their treatments fail. Due to its recurrent nature and the development of resistant pathogenic organisms, control of infection poses a greatest therapeutic challenge. The challenges of resistance have even been compounded by the activities of self-medication and quacks in this part of the country where they engage in non-judicious use of antibiotics. Now a days, it is rare for an otolaryngologist to encounter bacterial flora of a chronic discharging ear that has not already been modified by previous antibiotic therapy with some of them returning sterile cultures.

In our study, overall, 299 (70%) specimens had a culture positive for pathogenic bacteria, while no growth and commensals were obtained in 105 (24%) patients and 24 (6%) specimens respectively. This is similar to the study conducted by Adoga et al.[13]

In the present study, gram negative organisms were isolated in 164 (54.12%) specimens, and gram positive organisms were isolated in 139 (45.8%) specimens. Adoga, et al and Madana, et al also found similar results. Therefore, these studies show that gram negative bacteria are more commonly isolated in CSOM patients than gram positive bacteria, including our study, however in our study the difference was not as much as in the previous studies.[13,14]

In the present study, the main organisms isolated were *Staphylococcus aureus* (118, 39%) and *Pseudomonas aeruginosa* (110, 37%). This is similar to the study by Prakash, et al, Taneja, et al, Kuchal, et al and Shyamala, et al.[15-18]

The predominant organisms cultured were *Klebsiella spp.* (31, 41.3%), *Escherichia coli* (22, 29.3%) and *Pseudomonas aeruginosa* (6, 8%). The gram-positive isolates were *Streptococcus spp.* (8, 10.8%) and *Staphylococcus aureus* (7, 9.3%). Afolabi et al found that majority of the bacteria isolated from the middle ear of patients with CSOM were *Pseudomonas aeruginosa* and *Klebsiella Spp.* in 31.3% and 23.9%, the least were *Streptococcus Spp., E. coli* and fungal contaminants. Therefore, results of our study were in consonance with previous studies in this regard, as we also found that *Staphylococcus aureus* and *Pseudomonas aeruginosa* to be the predominant pathogenic bacteria among CSOM patients.[13,19]

We found that, drug sensitivity pattern of isolates was more sensitive to vancomycin, clindamycin, cefixime, gentamicin, cefipime, ceftazidime, imipenem and piperacillin, while Adoga, et al reported that in-vitro drug sensitivity pattern of all isolates were more sensitive to ofloxacin, ciprofloxacin and pefloxacin. Prakash, et al found that antimicrobial profile of aerobic isolates revealed maximum sensitivity to amikacin (95.5%), ceftriaxone (83.4%) and gentamicin (82.7%). These differences are not only due to the different bacterial isolates but also reflects varying sensitivity patterns of organisms in different regions as well.[13,15]

In our study all the S*taphylococcus aureus* isolated were sensitive to vancomycin 118, (100%); while sensitivity to other antimicrobials was as: clindamycin 84, (71.3%), cefixime 67, (56.8%), gentamicin 62, (52.5%), cefipime 58, (49.1%). In the study by Prakash *et al Staphylococcus aureus* was found to be highly susceptible to chloramphenicol and piperacillin followed by cephalosporins and quinolones. This is variance to our study, as we found that *Staphylococcus aureus* was sensitive to quinolones (ofloxacin) only in 27 (22.8%) and to piperacillin in 19 (16.1%) specimens.[20]

In the present study, *Staphylococcus aureus* isolated was resistant to Amoxicillin with Clavulanate in almost 73% of the cases. Our results are also in accordance with studies by Chakraborty, et al (95.4%) and Malkappa, et al (90%) in this regard. Prakash, et al found that most of the isolates were found to be susceptible to amikacin. But, almost 85% of the organisms showed resistance to amoxicillin.[20-22]

In our study *Pseudomonas aeruginosa* isolated from the ear was sensitive to ceftazidime (86, 78.2%), imipenem (79, 71.8%), piperacillin (71, 64.5%), gentamicin (59, 53.6%). Afolabi, et al in their study found ciprofloxacin, azithromycin and amoxicillin/clavulanic acid to be effective against *Pseudomonas aeruginosa,* which is different from the sensitivity patterns obtained in our study as *Pseudomonas aeruginosa* was sensitive to ciprofloxacin only in 6.4% cases while no isolate was sensitive to amoxicillin/clavulanic acid.[19]

NFGO isolated was sensitive to vancomycin 19 (100%) ceftazidime 13 (68.4%), imipenem 12 (63.1%) gentamicin 11 (57.8%) Amoxy+clav 10, (52.6%) ciprofloxacin 9 (47.4%).

E. coli isolated showed sensitivity to cefixime 10 (77%), gentamicin 9 (69.2%). No isolate showed sensitivity to ciprofloxacin, erythromycin and cefalothin. *Klebsiella spp.* isolated was sensitive to gentamicin in 8 (100%), cefixime 7 (87.5%) piperacillin 6 (75%), clindamycin 5 (62.5%) ceftazidime 5 (62.5%), imipenem 4 (50%).

Prakash et al, reported that the gram negative isolates were fairly susceptible to ciprofloxacin, third generation cephalosporins and gentamicin. *Klebsiella spp. Escherichia coli* and *Streptococcus spp*. were the leading pathogenic organisms in CSOM in their region and their sensitivity rates were highest to the quinolone antibiotics. However, we did not find similar sensitivity rates to quinolone antibiotics against gram negative organisms isolated in our study, as percentage sensitivities of *Klebsiella spp., Pseudomonas aeruginosa* and *E. coli* were only 12.5%, 6.4% and 0% respectively in our study. This is an indication of an increasing resistance to quinolones among gram negative organisms in our region.[20]

The above discussion highlights the fact that although the organisms isolated in CSOM patients are similar in different studies conducted not only over a varied geographical area but also at different time periods, the sensitivity to antibiotics is entirely different. Therefore, broad guidelines even at national level are not likely to be effective and local guidelines are a must. We also suggest undertaking gram staining in all cases, as it would indicate whether the presumptive therapy should be directed against *Staphylococcus aureus* or *Pseudomonas aeruginosa* as these were the predominant organisms. The antibiotics recommended for our area are mentioned in the guidelines for CSOM. Later, when the culture and sensitivity results become available then the antibiotics should be changed accordingly.

Limitations of this observational study was a center based study and the patient number was limited. It was a profiling study, so all the etiological factors could not be investigated in detail. For such type of research work a large sample size is required. It was a cross sectional study and for this type of study a continuous study is required.

CONCLUSION

Among 428 ear swab specimens of CSOM patients, pathogenic bacteria were 70%. 61% (n=299) pathogenic bacterial isolated from were gram negative and 39% gram positive. The culture revealed that *Staphylococcus aureus*

including *MRSA* (39%, n=118) and *Pseudomonas aeruginosa* (37%, n=110) were the main organisms isolated in most number of cases. All the S*taphylococcus aureus* isolated were sensitive to vancomycin. *Pseudomonas aeruginosa* isolated was mainly sensitive to ceftazidime, imipenem, piperacillin and gentamicin. Based on above observations and taking into consideration other parameters (pharmacokinetic, pharmacodynamics, cost and safety) guidelines were formulated. The first line drug in case of gram positive isolates was clindamycin; while for gram negative isolates ceftazidime was recommended.

The sensitivity pattern of organisms causing CSOM to antimicrobials changes considerably from time to time and this variation is even worsened by misuse or irrational use of antibiotics, which tend to create multidrug resistance among the organisms, thereby making the management of CSOM more difficult. Often, it is common in the ENT practice to see actively discharging ears yielding sterile cultures in view of previous antibiotic therapy which had modified the bacterial making treatment problematic.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee and Protocol Review Board of Dr. RPGMC Kangra, Tanda, India

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Cite this article as: Sawaraj S, Dogra SS, Kansal D, Thakur K, Sharma PK. Therapeutic guidelines for antimicrobial use in chronic suppurative otitis media for a tertiary care hospital in Sub Himalayan region. Int J Basic Clin Pharmacol 2018;7:416-22.