Study of rationality and utilization pattern of antimicrobials in ear, nose, throat outpatient department of Tertiary Care Hospital, Nanded

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INTRODUCTION

Discovery of antibiotics was one of the important landmarks of 20th century in medicine. These antimicrobial drugs changed the course of medicine over a period of time. Nowadays, antimicrobials are among the most frequently prescribed therapeutic drugs on a worldwide basis. Use of antimicrobial drugs for the treatment of infectious diseases rendered healthy life to individuals resulting in increased lifespan. Though antimicrobial drugs are responsible for dramatic improvements in medical therapy, these medicines tend to lose their efficacy with their frequent use. This may be attributed to resistance acquired by microorganisms to various antimicrobial drugs. So, it is imperative to find out problems with antimicrobial use and developing strategies to overcome it. Antimicrobials are used to treat both life-threatening and trivial infections. The prevalence of the use of antimicrobial agents (AMAs) varies from 24% to

ABSTRACT

Background: Antimicrobials are most commonly prescribed drugs worldwide. Around 50% of the prescriptions of antimicrobial drugs are either not needed, inappropriate or in wrong doses. With the widespread use of antimicrobial agents (AMAs), the prevalence of resistance has increased. To evaluate the prescription pattern and utilization of AMA in ear, nose, throat (ENT) outpatient department (OPD) of Tertiary Care Hospital, Nanded.

Methods: This prospective study was conducted in ENT OPD of Dr. Shankarrao Chavan Government Medical College, Nanded over a period of 3 months. During this period, approximately 1100 patients visited ENT OPD and 600 prescriptions were evaluated. The excluded patients were of post-operative follow-up and of patients undergoing medical examination for fitness and handicap certificate. Data were collected by using specially designed case report form. Appropriateness of AMA was assessed by Kunin’s modified criteria.

Results: Total 600 prescriptions were analyzed out of which (91%) consist of AMA. Most of them reported with upper respiratory tract infections (URTI) (30.4%), chronic suppurative otitis media (21.4%), acute suppurative otitis media (10.4%), tonsillitis (3.3%), sinusitis (2.7%), and others (15%). Amoxicillin (43.9%) was preferred AMA followed by ciprofloxacin (30.6%), cotrimoxazole (5.8%), azithromycin (3.2%), doxycycline (3.2%) cefixime + clavulanate (3.2%), and amoxicillin + clavulanate (1.8%). Single antibiotic was preferred in all prescriptions. In the concomitant medications, antihistaminics were prescribed in 97.22% of patients, non-steroidal anti-inflammatory drugs in 94.96% of patients, and antacids in 87.76% of patients. Fixed-dose combinations were used in 10% of prescriptions. Brand names of AMA were used in 10% of prescriptions. As per the Kunin’s modified criteria, 83% of patients received AMA therapy appropriately, while 17% patients inappropriately.

Conclusions: Amoxicillin is the most common AMA prescribed and URTI is the most common diagnosis made. All AMAs should be prescribed only when needed and should be used in proper dose and for proper duration. Institution wise antibiotic policy should be used to contain resistance. Proper training and regular orientation programs of the juniors’ doctors for judicial use of AMAs will foster the habit of rational prescribing of AMA.

Keywords: Antimicrobial agents, Kunin’s criteria, Rationality
67% in India, and about 64% of the total antibiotics which are prescribed are either not indicated or are prescribed in incorrect dosages or are inappropriately prescribed. The inappropriate use of antimicrobials in hospitals contributes to the emergence and spread of drug-resistant microorganisms and increased treatment expenditures. Besides uses of antimicrobials for inadequate duration and over the counter use by patient himself are other concerns. Antimicrobials account for more than 50% of the drugs which are sold, which puts an excessive strain on the limited health care budget. The overuse and/or misuse of antibiotics can lead to significant consequences like increased costs, bacterial resistance, therapeutic failures, drug toxicities, and drug interactions. Nowadays, there is an alarming increase in AMAs prescribing, raising concerns for antibiotic resistance, and development of superbugs. In addition, this is leading to increased morbidity, mortality, length of hospital stay, and excessive financial burden on patients and institutions. Thus, development of resistance to AMAs and increase of cost as the result of unnecessary and inappropriate use of antibiotics has become a global health problem. Many studies have implicated that the antibiotics are among the major group of drugs, which cause adverse drug reactions.

According to a recent study, acute respiratory infections are the reason for 75% of the antibiotic prescriptions each year and are the most frequent reason for seeking medical attention. This occurs despite the fact that in most cases of upper respiratory tract infections (URTI), antibiotics confer little, or no benefit. Viruses are found to be most common cause for URTIs, with rhinovirus, parainfluenza virus, coronavirus, adenovirus, respiratory syncytial virus, Coxsackie virus, human metapneumovirus, and influenza virus accounting for most cases. Though viral etiology is a most common for respiratory infections, antimicrobials are used rampantly in its management. Thus, the irrational use of antimicrobials in ear, nose, throat (ENT) and respiratory infections is prevalent. There are concerns to treat the patient as well limiting the use of antimicrobials to prevent insurgence of resistant microbes. Surveillance of drug use by the doctors, within the institution as well as in the community is assuming an increasingly important role in therapeutics. The continuous monitoring of prescriptions may help to identify the problems involved in therapeutic decisions and promote the rational prescribing. Thus, it is extremely imperative to evaluate and monitor the drug utilization patterns from time to time, to enable suitable modifications in prescribing patterns to increase the therapeutic benefit, and decrease the adverse effects to optimize the medical services for the patient. Therefore, monitoring and evaluation of prescribing patterns of AMAs are one of the recommended strategies to contain and control resistance also to improve the prescribing practices. The rational use of antibiotics would help to limit as much as possible the appearance and spread of resistant strains. Otherwise, we may head to a post-antibiotic era where trivial infections once treatable can cause mortality. Antibiotic restriction policies are must for hospital setups. Antimicrobial prescription studies may help in devising strategies for antibiotic policy. Hence, the present prospective study was aimed to evaluate drug utilization pattern of antibacterials used in ENT infections in patients of the outpatient department (OPD), Nanded. The aim of this study was to evaluate the rational antibiotic use. This descriptive cross-sectional prospective study was therefore designed to evaluate the prescription pattern.

**Aims and objectives**

1. To study utilization of AMA in ENT OPD
2. To evaluate prescription pattern of AMA used
3. To evaluate rationality of AMA used.

**METHODS**

According to the WHO document “how to investigate drug use in health facilities” at least 600 encounters should be included in a cross-sectional survey to describe the current prescribing practices, with a greater number, if possible. Institutional Ethical Committee approval was taken and this prospective study was conducted in ENT OPD of Dr. Shankarrao Chavan Government Medical College, Nanded for 3 months. During this period, approximately 1100 patients visited ENT OPD. Out of these, 600 prescriptions were evaluated. The excluded patients were of post-operative follow-up cases and of patients undergoing medical examination for fitness and handicap certificate.

Data collection was done in a predesigned, pretested, case report form containing:

i. Demographic profile
ii. Diagnostic information (like complaints for which the consultation was sought, provisional/confirmed diagnosis, investigations)
iii. Drug information (like name of AMAs [generic/brand name], dosage form, dose, frequency, route of administration, duration of treatment, refill instructions).

Data analysis was done by using SPSS 16.0, proportion and percentage using MS Excel.

Following basic drug use indicators were used in the study:

1. The appropriateness of antibiotic therapy was determined using the modified criteria described by Kunin et al. The appropriateness of antibiotic therapy was determined using the modified criteria described by Kunin et al. [15]
2. Total numbers of the AMAs prescribed per prescription
3. Mean numbers of the AMAs per prescription: percentage of antibiotic prescribed was determined by dividing the number of antibiotics prescribed by the total number of drugs prescribed, multiplied by 100
4. Average duration of therapy
5. Numbers of AMAs prescribed by generic versus trade name: percentage of drugs prescribed by generic name was determined by number of drugs prescribed by generic name by the total number of drugs prescribed, multiplied by 100
6. Numbers of prescription with one or more than one AMAs
7. Number of fixed dose combination prescribed: the ratio of fixed dose combinations to single agents was evaluated.

Analysis of rationality of administration of AMA was done by modified Kunin’s criteria as following: 15
I. Agree with the use of therapy given as in the prescription. The treatment is appropriate in terms of choice of drug, dose, dosage regimen, and duration of therapy.
II. Agree with the use of therapy but a potentially fatal infection cannot be ruled out.
III. Agree with the use of therapy but a different (usually less expensive and toxic) combination of therapy is preferred.
IV. Agree with the use of therapy but a modified dose, dosage regimen, and duration would be recommended.
V. Disagree with the use of therapy; administration is unjustified or unnecessary use of drugs.

Category I and II essentially indicate “appropriate” therapy. Category III and IV indicate that there is some major deficiency in the choice or use of drugs by the doctor managing the problem. These indicators are highly standardized in terms of their definition and facilitate the quick and reliable assessment of drug use in health care.

RESULTS
Total 600 prescriptions were analyzed out of which 91% consist of AMA. Gender distribution shows 64% of males and 36% of females (Figure 1). Most of the patients were reported with upper respiratory People of age group 21-40 years were prominent in attending OPD. (Figure 2) tract infections (URTI) (30.4%), chronic suppurative otitis media (CSOM) (21.4%), acute suppurative otitis media (10.4%), tonsillitis (3.3%), sinusitis (2.7%), and others (15%) (like foreign body, vertigo, neurodegenerative dyspepsia, allergic tombo pharynx, otomycosis, epistaxis, furuncle, etc.) (Figure 3). Amoxicillin (43.9%) was preferred AMA followed by ciprofloxacin (30.6%), cotrimoxazole (5.8%), azithromycin (3.2%), doxycycline (3.2%), cefixime + clavulanate (3.2%) and amoxicillin + clavulanate (1.8%), levofloxacin (3.2), metronidazole (1.1), tetracycline (0.4) (Figure 4). Average number of AMAs prescribed was 1.03 in patients with AMA. Average 3.57 drugs were used per prescription. Average duration of prescribed medicines was 3.87 days. In the concomitant medications, In the concomitant medications, antihistaminics were prescribed in 97.22% of patients, non-steroidal anti-infl ammatory drugs in 94.96% of patients, and antacids in 87.76% of patients (Table 1). Fixed-dose combinations were used in 10% prescription. Brand names of AMA were used in 10% of prescriptions. As per the Kunin’s modified criteria, 83% of patients received AMA therapy appropriately, while 17% patients received inappropriately (Table 2).
Table 1: Frequency of administration of other drugs with AMAs.

| Antibiotics & concomitant drugs | Number of patients | Percentage |
|---------------------------------|--------------------|------------|
| Antibiotics                     | 556                | 100        |
| Antibiotics+Antihistamines      | 540                | 97.22      |
| Antibiotics+NSAID               | 528                | 94.96      |
| Antibiotics+Antacids            | 488                | 87.76      |
| Antibiotics+Others              | 288                | 51.79      |

AMAs: Antimicrobial agents, NSAID: Non-steroidal anti-inflammatory drugs

Table 2: Appropriateness of AMA was assessed by Kunin’s modified criteria.

| Appropriate (%) | Non-appropriate (%) |
|-----------------|---------------------|
| 83              | 17                  |

AMA: Antimicrobial agents

Table 3: Pattern of AMA used according to their type of action on microbes.

| Type of Action       | Number of patients |
|----------------------|--------------------|
| Bactericidal (93.2%) | 261                |
| Bacteriostatic (6.8%)| 44                 |
| Amoxicillin capsule (43.9%)+ | 241 |
| Azithromycin (3.2%) |                     |
| Ciprofloxacin (30.6%)| 115                |
| Doxycycline (3.2%)  |                     |
| Cotrimoxazole (5.8%)| 37                 |
| Tetracycline (0.4%) |                     |
| Cefixime+clavulanate (3.2%)| 19 |
| Amoxicillin+clavulanate (1.8%)| 15 |
| Levofloxacin (1.8%) |                     |
| Metronidazole (1.1%)| 13                 |

DISCUSSION

Several influential factors do exist when prescribing the antibiotics. Prescriber’s factors influencing prescriptions are a lack of information, excessive and unnecessary antibiotic prescribing, incorrect dosage or route of administration, antibiotic prescribing for non-bacterial infections, and patient demands. However, inappropriate prescribing of antibiotics by the physicians was the most important recognized factor. The use of antibiotics for a short period of time is also an irrational practice that is done in most countries. In developing countries over the counter, practice is also present for antibiotics which should be strictly prohibited. Recently, Government of India has introduced schedule H1 for antimicrobials and made it mandatory to dispense antimicrobials only with prescription by Registered Medical Practitioner. Manufacturers create artificial demands of unwanted drugs and drug combination through competitive sale promotions. Moreover, the prescribing behavior of clinicians depends upon information from sources like commercial publicities. This may be a one of the determinants for irrational drug use. As with the clinicians, poor adherence by patient and self-prescribing are also causes for irrational drug use.

The study shows that there was male predominance in the patient group. People of age group 21-40 years were prominent in attending OPD. Drug prescriptions were mostly for throat infections followed (Figure 2) by ear infections. This was also found in a study done by Das et al., most of the patients reported with URTI - 32.56%.

In our study, amoxicillin was the most common AMA used. In a study done by Sridevi et al., it was found that the antibacterials commonly used were beta lactams-amoxicillin (56%) followed by macrolides (14%). Among the penicillin group, the most common drug prescribed was a combination of amoxicillin and clavulanic acid (27%), in cephalosporin’s was cefixime + clavulanic acid (19%). In a study done by Das et al., ciprofloxacin (23.85%) was preferred followed by followed by amoxicillin (20.06%). In a study done by Goud et al., chloramphenicol + polymyxin-B sulfate + dexamethasone was found to be most common AMA used. In a study done by Sridevi et al., we found the average number of drugs used in each prescription was 3.20. All the drugs were prescribed with brand names. It is preferable to keep the mean number of drugs per prescription as low as possible since higher figures always lead to increased risk of drug interactions, development of bacterial resistance, and increased cost.

According to Hersh et al., azithromycin is not a first line antibiotic for any pediatric URTI and is the most likely to be used appropriately (inadequate coverage for the most common pathogens causing acute otitis media and sinusitis). In our study, we found that azithromycin is used in only 3% patients including adults.

Many strategies have been proposed for the use of antibiotics, like a formulary replacement or restriction, health care provider education, feedback activities, approval requirement from an infectious disease specialist for the drug prescription, and a more rational use of AMAs all over the world. Our study may have some limitations. Since our study was conducted at government hospital, drugs are mostly prescribed from available formulary. Again study was conducted for a shorter period of 3 months. Hence, seasonal variations in the pattern of diseases may be different. But, nonetheless, such studies are more important to know the sensitivity pattern of microbes in the local area as well prescribers’ choices. This information may help in devising antibiotic policy.

CONCLUSION

Inappropriate use of antibiotics to treat all URTI needs to be avoided. All AMAs should be prescribed only when needed and should be used in proper dose and for proper duration.
Institution wise antibiotic policy should be used to contain resistance. Proper training and regular orientation programs of the juniors’ doctors for the judicial use of AMAs will foster the habit of rational prescribing of AMA.

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