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**Research Article** 

# Drug utilization pattern of antimicrobial agents in an outpatient department of otorhinolaryngology in a tertiary care hospital: a prospective, cross-sectional study

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#### **ABSTRACT**

**Background:** Study based on antimicrobial drug utilization pattern and focus on factors related to prescribing, administering and its associated events. The aim of this study is to assess the prescribing patterns of antimicrobials, to assess the appropriateness of prescribed antimicrobials in an ear, nose and throat (ENT) infections.

**Methods:** A prospective observational drug utilization study was carried out in otorhinolaryngology department for a period of 4 months. Patients who attended the ENT outpatient department (OPD) with ENT infections were included in the study and patients who were not willing to participate in the study were excluded and the data were analyzed.

**Results:** Out of 155 patients, the average number of drugs per patient was 1.2. The percentage of drugs prescribed with the generic name was 26.32%. During this study, it was found that the most commonly prescribed groups of antimicrobials were penicillins (34.87%) followed by fluroqinolones (26.32%) and nitroimidazole (25%). During the study, it was observed that 46.71% patients visited for treating ear infections, 12.5% for nasal infections and 40.79% for throat infections. The routes of administration were oral (74.23%) and topical (20.10%).

**Conclusions:** Our study shows some rational prescription patterns like less utilization of antimicrobials in ENT infections and were according to standard treatment guideline. The results of this study will be useful in future for making standard treatment guidelines. It also promotes the rational prescription and rational use of drugs.

**Keywords:** Drug utilization, Antimicrobial agent, ENT infections, WHO indicators, Prescribing pattern

# INTRODUCTION

The routine life of children and adults are disturbed by diseases of ear, nose and throat (ENT) and also cause significant morbidity. Infections remain the major cause of ENT diseases because of increase in the population. Among all the infections of ENT, upper respiratory tract infections (URTIs) are very common. The respiratory tract infections were found the fourth major cause of mortality according to World Health Report of 2004 estimated by the World Health Organization (WHO). In 2002, 6.9% deaths and 94.6 disability adjusted life years (DALY) were lost globally because of respiratory tract infections. Hospital admissions are common because of acute respiratory tract infections which includes

approximately 20-40% of outpatient and 12-35% of inpatient. URTIs include naso-pharyngitis, otitis media, tonsillitis and pharyngitis which account for 87.5% of respiratory tract infections and are responsible for the hearing loss and absenteeism from work.<sup>3</sup>

The acute URTIs are mainly caused by viruses in most cases and resolve spontaneously, hence antimicrobial agents are not necessary until it is complicated and severe.<sup>3</sup> The different studies found that antimicrobials were prescribed in almost 90% cases of pharyngitis. The resistant of antimicrobials is very prominent in the various part of Asia. Resistance is found common against penicillin, nalidixiac acid and chloramphenicol among people of India.<sup>4</sup> The lack of compliance to the

medications is also important and it is associated with deterioration of patient's health, extra medicines, additional costs and hospital admission.<sup>5</sup>

Even though antimicrobials are used since many years, little is known about how antimicrobials should be used. The important question is how it should be prescribed to minimize the resistant without altering the efficacy and safety. International network for the rational use of drugs (INRUD) was started to increase the rational use of the drugs. The WHO and INRUD had developed indicators for the evaluation of drug use.<sup>6</sup> Evaluation of drug utilization is a continuous and systemic process which is designed to review the prescribing patterns, develop standard treatment guideline develop criteria for rational use of drugs and promote appropriate drug use. There are very less information about antimicrobial use. So, it is necessary to look for the pattern of drug utilization by the time and to make necessary modification in prescription to increase efficacy and decrease the adverse effects. With the aim of that, the present study was carried out to evaluate drug utilization pattern of antimicrobials among patients of ENT infections in outpatient (OPD) department at Sir Takhtasinhji General Hospital attached to Government Medical College, Bhavnagar, Gujarat, India.

#### **METHODS**

Ethical approval was obtained from the institutional review board (IRB), Government Medical College, Bhavnagar, Gujarat, India. Patients were thoroughly informed about the study and written informed consent was taken before their enrolment into the study. This was a prospective and cross sectional study. The study was held at the otorhinolaryngology OPD of Sir Takhtasinhji general hospital attached to government medical college, Bhavnagar, Gujarat, India from November 2013 to February 2014. It was based on antimicrobial agents prescribed in ear, nose & throat infections. All the patients who were taking antimicrobial agents were included into the study. The pregnant and lactating mothers were also enrolled into the study. The patients who were not taking antimicrobial agents and those were not able to give consent were excluded. Those patients who did not want to participate into the study were also excluded from the study. All the information was recorded in case record form (CRF) which was designed according to WHO criteria. It includes age, gender, other details of patient, investigations, information related with prescription drug information from the prescriber like the indication, dose, frequency of drug administration, routes of administration, duration of therapy and concomitant disease / condition.

### Outcome measures

The WHO/INRUD indicators were followed in the present study in addition to other indicators. Types of infections, types of antimicrobial used, commonly

prescribed agents, number of antimicrobials per prescription, antimicrobial agents used as a single drug, fixed dose combination therapy and multiple drug therapy, number of antimicrobials prescribed by generic and brand name.

#### Statistical analysis

Data were expressed in percentage and descriptive statistics were used.

#### RESULTS

A total of 152 patients were selected for the study over a period of 4 months. Among 152 patients, 79 (51.98%) were male and 73 (48.02%) were female. The maximum numbers of patients were found in the 19-60 years of age group (adult) while the lowest number was in > 60 years (geriatric) of age group (Table 1).

Table 1: Baseline demographics of ENT patients.

Demographics of ENT patients		
Age	No. (%)	
Pediatric (<18 years)	37 (24.34%)	
Adult (19 to 60 years)	103 (67.76%)	
Geriatrics (>60 years)	12 (7.89%)	
Gender	No. (%)	
Male	79 (51.97%)	
Female	73 (48.02%)	
Religion	No. (%)	
Hindu	125 (82.23%)	
Muslim	27 (17.76%)	
Domicile	No. (%)	
Rural	59 (38.81%)	
Urban	93 (61.18%)	
Socioeconomic status	No. (%)	
Low	90 (59.21%)	
Medium	60 (39.47%)	
High	02 (1.31%)	

The most commonly prescribed groups of antimicrobials in this study were penicillins (34.87%) followed by fluroqinolones (26.32%) and nitroimidazole (25%) (Table 2). The most commonly prescribed agent of these classes was amoxicillin, amoxicillin with clavulanic acid (34.2%), metronidazole (25%) and ciprofloxacin (22.37%) (Table 2). The most commonly prescribed antimicrobials were amoxicillin (29.58%), ciprofloxacin (23.94%) and doxycycline (23.94%) in ear infection; amoxicillin (36.84%), ciprofloxacin (42.10%) and metronidazole (31.58%) in nose infection; amoxicillin (37.1%), metronidazole (35.48%) and azithromycin (16.13%) in throat infections.

Most commonly prescribed antimicrobials were amoxicillin (48.65%) and metronidazole (32.43%) in pediatric patients; amoxicillin (28.16%) and ciprofloxacin (25.24%) in adult patients; metronidazole (33.33%) and amoxicillin (25%) in geriatric patients. In male patients,

Table 2: Most commonly used anti-microbial agents in ear, nose and throat infections.

Drug	Ear N = 71	Nose N = 19	Throat N = 62	<b>Total N = 152</b>
Penicillins 53 (34.87%)				
Amoxicilin	21 (41.17%)	07 (13.73%)	23 (45.1%)	51 (33.55%)
Co-amoxiclav	00	00	01 (100%)	01 (0.65%)
Ampicillin + Cloxacillin	00	00	01 (100%)	01 (0.65%)
Fluroqinolones 40 (26.32%)				
Ciprofloxacin	17 (50%)	08 (23.53%)	09 (26.47%)	34 (22.37%)
Norfloxacin	01 (100%)	00	00	01 (0.65%)
Levofloxacin	00	01 (20%)	04 (80%)	05 (3.29%)
Nitroimidazoles 38 (25%)				
Metronidazole	10 (26.32%)	06 (15.79%)	22 (57.9%)	38 (25%)
Tetracyclines 29 (19.07%)				
Doxycycline	17 (58.62%)	02 (6.9%)	10 (34.48%)	29 (19.07%)
Macrolides 13 (8.55%)				
Azithromicin	01 (9.09%)	00	10 (90.9%)	11 (7.24%)
Erythromycin	00	00	02 (100%)	02 (1.31%)
Cephalosporins 11 (7.24%)				
Cefaclor	02 (100%)	00	00	02 (1.32%)
Cefixime	01 (33.33%)	01 (33.33%)	01 (33.33%)	03 (1.97%)
Cefotaxime	02 (66.66%)	00	01 (33.33%)	03 (1.97%)
Cefadroxil	04 (100%)	00	00	04 (2.63%)
Aminoglycosides 3 (1.97%)				
Gentamicin	00	00	01 (100%)	01 (0.65%)
Neomicin	01 (50%)	01 (50%)	00	02 (1.32%)
Antifungals 2 (1.32%)				
Clotrimazole	02 (100%)	00	00	02 (1.32%)
Chloramphenicol/Beclomethasone Dipropionate/Clotrimazole/Lignocaine	03 (100%)	00	00	03 (1.97%)
Chloramphenicol	02 (100%)	00	00	02 (1.32%)

Table 3: Most commonly found infections and antimicrobial agents in different age groups.

	Diseases (%)	Drugs (%)
Pediatrics	Tonsillitis (32.43%) CSOM (24.32%) ASOM (10.81%)	Amoxicillin (48.65%) Metronidazole (32.43%) Ciprofloxacin (13.51%) Doxycycline (10.81%)
Adult	CSOM (37.86%) Pharyngitis (22.33%) Tonsillitis (15.53%) Nasal vestibulitis (5.83%) ASOM (4.85%)	Amoxicillin (28.16%) Ciprofloxacin (25.24%) Doxycycline (22.33%) Metronidazole (17.48%)
Giriatrics	CSOM (33.33%) Nasal vestibulitis (16.66%)	Metronidazole (33.33%) Amoxicillin (25%) Ciprofloxacin (25%)
Male	CSOM (30.38%) Pharyngitis (21.52%) Tonsillitis (21.52%) Nasal vestibulitis (6.32%) ASOM (5.06%)	Amoxicillin (34.17%) Metronidazole (25.32%) Doxycycline (16.46%) Ciprofloxacin (16.46%)
Female	CSOM (38.36%) Tonsillitis (16.44%) Pharyngitis (13.70%) ASOM (6.85%)	Amoxicillin (32.87%) Ciprofloxacin (31.51%) Doxycycline (21.92%) Metronidazole (17.80%)

most commonly prescribed antimicrobials were amoxicillin (34.17%), metronidazole (25.32%) and in female patients, they were amoxicillin (32.87%) and ciprofloxacin (31.51%) (Table 3).

The ear, nose and throat infections were found in 46.71%, 12.5% and 40.79% of patients during this study (Table 4). Among these, most commonly found infections were tonsillitis (32.43%) and chronic suppurative otitis media (CSOM) (24.32%) in paediatric patients; CSOM (37.86%) and pharyngitis (22.33%) in adult patients; CSOM (33.33%) and nasal vestibulitis (16.66%) in geriatric patients. In males, most commonly found infections were CSOM (30.38%) and pharyngitis (21.52%) while in female they were CSOM (38.36%) and tonsillitis (16.44%). The most frequent associated conditions of the study population were hypertension (7.89%), diabetes (2.63%) and tuberculosis (0.65%) (Table 5).

Table 4: Most commonly found ear, nose and throat infections.

Infections	Diseases	No. (%)
Ear	C.S.O.M.	52 (34.21%)
	A.S.O.M.	09 (5.92%)
	Otto mycosis	04 (2.63%)
	C.S.O.M. + Cholesteatoma	03 (1.97%)
	Ottitis Externa	02 (1.32%)
	Fungal Ottitis media	01 (0.66%)
	Total	71 (46.71%)
Nose	Nasal Vestibulitis	09 (5.92%)
	Allergic Rhinitis + D.N.S.	05 (3.29%)
	Maxillary Sinusitis	03 (1.97%)
	Dacrocystitis	02 (1.32%)
	Total	19 (12.5%)
Throat	Pharyngitis	27 (17.76%)
	Tonsilitis	27 (17.76%)
	Parotitis	04 (2.63%)
	Peritonsilar abccess	01 (0.66%)
	Acute Epiglotitis	01 (0.66%)
	Cervical Abccess	01 (0.66%)
	Submendibular Abscess	01 (0.66%)
	Total	62 (40.79%)

A total no. of antimicrobials prescribed was 194. Their routes of administration were oral (74.23%) and topical (20.10%). The mean number of antimicrobial drugs prescribed per patient was 1.2. Culture sensitivity tests were not performed in any of the patient out of 152. The antimicrobial agents prescribed by their generic names were seen in only 26.32% patients while rests of the prescriptions were by their brand names. In this study, it was observed that a total of 77.63% patients received antimicrobial monotherapy, whereas 22.37% patients received multiple drug therapy. From 152 patients, 12 patients had taken self-medications among them 3 patients had taken Ayurvedic medication, 6 patients had

taken homeopathic medications and 3 patients had taken other medication.

Table 5: Concomitant disease conditions associated with ENT infections.

Concomitant condition	No. of patients (%)
Hypertension	12 (7.89%)
Diabetes mellitus	4 (2.63%)
Tuberculosis	1 (0.65%)
Gastritis	1 (0.65%)
Total	18 (11.84%)

#### DISCUSSION

Prescription by the doctors shows attitude of the doctors towards the patients and diseases. There is much variation in prescription of antimicrobials. Irrational and indiscriminate use of the antimicrobials for the treatment of infections may increase the bacterial resistance.<sup>8</sup> In the present study, prescriptions for male were 52% as compared to females which may be because of males are more travelling. This result is similar with other studies conducted by MR Ain et al, Pradhan et al, Yadav Pramila et al and Shankar et al. 9-12 However, in some other study it was shown that ENT infections were common in females as compared to males which might be because of their exposure to kitchen smoke in the Indian context.<sup>13</sup> Most of the patients in our study were from metropolitan backgrounds which contradict to the other study conducted by Khan et al. It may be because of selfmedications of antimicrobials by urban population.<sup>14</sup>

Our study shows that ear infections (46.71%) were common, followed by throat (40.79%) while nose infections (12.5%) were least common. This is in accordance with other study conducted by Yadav Pramila et al who also shows ear infections (50.8%) were common, followed by throat (31.37%) and nose infections (26.47%) were less common. 11 Among ontological diseases, CSOM was the most commonly found condition which may be due to ignorance about the disease and inadequate medical management at the peripheral level. In present study, most commonly prescribed antimicrobials were penicillin (34.87%), followed by fluroqinolones (26.32%) and nitroimidazole (25%). The most commonly prescribed antimicrobial agents were amoxicillin (33.55%), ciprofloxacin (22.37%) followed by metronidazole (25%). This contradicts to other study conducted by Das et al who shows ciprofloxacin (23.85%) was the most commonly prescribed agent followed by amoxicillin (20.06%), a combination of ampicillin + cloxacillin (9.17%), doxycycline (5.96%), erythromycin (4.58%) and cotrimoxazole (4.58%).<sup>14</sup> The use of broad spectrum antimicrobials like ampicillin and amoxicillin + clavulanic acid as found in our study might be because of increase in antimicrobial resistance which stimulates the surgeons to prescribe broad spectrum and safer antibiotics. In our study, amoxicillin was most commonly

prescribed antimicrobial which may be because of preponderant mixed bacterial infections. The result of the present study is similar to the other study done by MR Ain et al in which amoxicillin was the most common prescribed antimicrobial. Majority of the antimicrobial were prescribed on the basis of clinical experience of the ENT surgeons but it is advisable to go for culture sensitivity before prescribing antimicrobials.

The average number of antimicrobial agents prescribed per patient was 1.2 which was similar to other study by Das et al. in which 1.4 antimicrobial agents were prescribed per patient. 15 Rationality of the prescription is determined by average number of drugs per prescription. Hence, ENT surgeons should prescribe minimum number of drugs per prescription which reduces bacterial resistance, cost of therapy and drug interaction.<sup>8,16</sup> Further, in our study 77.63% patients received single antimicrobial drug whereas 22.36% patients received multi drug therapy which was similar with other study. 9,10 The routes of administration of antimicrobials used in this study according to standard treatment guideline. The major numbers of prescriptions were by their brand names which may be because of drug promotional activities by pharmaceutical industries. Numbers of prescriptions with drugs by generic names were less.<sup>17</sup> Prescribing the antimicrobial agents by brand names may affect some of the features of essential drug concept. The overall health expenditure can be reduced by prescribing the drugs by generic names. However, in spite of all these limitations, our study shows few rational prescribing practices. Prescription of antimicrobials in ear, nose and throat infections were according to standard treatment guideline. Continuous motivation, education monitoring are needed at different levels to encourage rational use of medicines.

#### CONCLUSION

Present study shows some rational practice like less use of antimicrobials in ENT infections and was according to standard treatment guideline. Prescriptions by brand names, prescription of broad spectrum antimicrobial without culture and sensitivity reports are some irrational practices. The results of this study will be useful in future for making and improving standard treatment guidelines. It also promotes the rational prescription and rational use of medicines.

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Institutional Ethics Committee

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