Research Article

Prescription Pattern of Drugs Prescribed in Out Patient Department of ENT and Adverse Drug Reactions Reported from ENT Department in A Tertiary Care Hospital of Bihar

Nidhi Kumari[1], Sarita Kumari Mishra[2], Manish Kumar[3], Adil Ali Shakur*[4], Hitesh Mishra[5], Harihar Dikshit[6]
1.   Junior Resident, Department of Pharmacology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
2.   Additional Professor, Department of ENT, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
3.   Additional Professor, Department of Pharmacology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
4.   Assistant Professor, Department of Pharmacology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
5.   Additional Professor, Department of Pharmacology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
6.   Professor and Head, Department of Pharmacology, Indira Gandhi Institute of Medical Sciences, Patna, Bihar, India.
*Corresponding author's E-mail: adilshakur04@gmail.com

ABSTRACT

Diseases related to Ear, Nose & Throat (ENT) occur very commonly in all age groups. Thus periodic evaluation of prescription pattern and adverse drug reaction (ADR) monitoring will be helpful in enabling appropriate modifications in prescribing pattern. This will also result in improved therapeutic efficacy and better patient compliance. The aim of the study is to evaluate prescription pattern of drugs prescribed in ENT OPD and to analyse the ADRs from ENT Department (IPD & OPD). This was an observational & prospective study, conducted for the duration of six months i.e. from March 2021 to October 2021. Prescription was analysed for demographic details, pattern of prescribed medications, pattern/types of ENT diseases and adequacy of prescription. For monitoring of ADRs active surveillance and spontaneous reporting both were used. In this study, prescription of 251 patients were analysed. It was found that male patients (64.5%) were significantly higher. A total of 850 drugs were prescribed. The most commonly prescribed group of drugs were antimicrobials. Most commonly prescribed FDC was of cefpodoxime and clavulanic acid. Otitis media was the most commonly suffered condition. Dose, frequency, total duration of treatment and instructions in vernacular language was mentioned in all the prescription. The average number of drugs prescribed was 3.3. A total of four ADRs were reported. This study was a sincere attempt to see the prescribing pattern of drugs prescribed in ENT department and its associated ADRs. Antimicrobials were the most commonly prescribed drugs and it could be attributed to increased occurrence of infections. The adequacy of prescription demonstrates good aspects of prescription writing. Since no prescription had more than five drugs; we can say that polypharmacy was avoided. ADR reporting was very low so it strongly suggests the need to spread awareness among health-care workers and patients for reporting.

Keywords: Adverse drug reaction, Antimicrobials, ENT, Prescription pattern.

INTRODUCTION

Diseases related to Ear, Nose & Throat (ENT) occur very commonly in both paediatric as well as adult age groups often leading to significant impairment of accustomed daily pursuits in adult age groups which might lead to work loss and wage loss in them as well as absenteeism from schools in children. This often hampers their academics and normal routine activities. Some of the routinely encountered problems includes upper respiratory tract infection (URTI), otitis media, impacted ear wax, unilateral and bilateral hearing loss of conductive or sensorineural type. [1] URTI commonly includes common cold, pharyngitis, epiglottitis, laryngotracheitis and associated etiologic agents include viruses, bacteria, mycoplasma and fungi. However, overall there is preponderance of RTI which occur mostly due to viruses and these viral infections are usually benign, transitory, self-resolving and require only symptomatic management with no requirement of adding any antibiotics unless and until it is associated with secondary bacterial infections amounting to otitis media, epiglottitis, laryngotracheitis etc. [2-4] However, often indiscriminate and irrational use of antibiotics leads to bacterial resistance, ineffective treatment, economic burden on patients and also adverse drug reactions (ADRs). [5]

The analysis of prescription pattern plays an important role in clinical practice as it forms the basis for making changes in the drug dispensing policies at local and national levels. The end objective of such study is to facilitate rational use of drugs. As this type of study helps in developing strategies to utilize health resources in the appropriate manner, it is particularly needed in a developing countries like India where 72% of all health care burden is borne by the patients. [6] World Health Organization defines drug use as 'The marketing, distribution, prescribing and usage of drug in society, with special emphasis on medical, social and economical consequences. [7] Therefore, it becomes

imperative that periodic monitoring and evaluation of prescription patterns and Pharmacovigilance is done in order to enable appropriate modifications in prescribing patterns which can lead to increased therapeutic efficacy, facilitate rational utilization of drugs, limit unnecessary use of antibiotics which in turn will lead to reduction of cost and also adverse effects so that patients can avail optimized medical services. [8-11] It can also aid in providing proper feedback to prescribers and will be helpful in setting up of hospital formulary depending on geographic profile of the disease and availability of drugs.

MATERIALS AND METHODS

This was an observational & prospective study which was conducted for a duration of six months i.e. from March 2021 to October 2021 in the department of ENT and Adverse Drug Reaction monitoring center (AMC) i.e., Department of Pharmacology of IGIMS, Patna, Bihar. The study was conducted after obtaining approval from Institutional Ethics Committee (Letter No. 98/IEC/IGIMS/2021). All patients who visited ENT OPD during this time period and met the inclusion criteria their prescriptions were collected and studied. Simple random sampling method was employed and three-four prescriptions of new patients were collected on thrice weekly basis. The prescriptions were analysed for demographic details, pattern of prescribed medications, pattern/types of ENT diseases and adequacy of prescription by various prescribing indicators. For monitoring of ADRs active surveillance and spontaneous reporting both the methods were used. Patients in whom at least one ADR developed in both OPD and IPD during this period were included in the study. The ADRs were then screened according to World Health Organization-Uppsala Monitoring Centre (WHO-UMC) assessment system and were consequently reported.

Inclusion Criteria:

1. Patients who consulted ENT OPD during the study period and gave consent to participate in this study.

2. Adverse effect that was encountered in both OPD and IPD during the study period.

Exclusion Criteria:

1. Patients who were seriously ill.

2. Patients who required surgery.

3. Patients who came for follow-up.

4. Patients admitted in indoor departments of ENT

5. Adverse events which were caused due to administration errors, noncompliance or overdose were excluded from the study.

Demographic details of the patient as well as information related to drug, disease and other important parameters were noted and entered in a predesigned excel sheet. After analysis results were made as follows:

1. Age and Gender distribution

2. Total and average number of drugs prescribed

3. Drug prescribing pattern and route of drug administration

4. Commonly prescribed Fixed Dose Combinations and its rationality

5. Types of disease/disorder

6. Adequacy of prescription by various prescribing indicators

7. Analysis of Adverse drug reactions

Descriptive Analysis was used for assessment of collected information. The results were depicted using percentage in pie-charts and tables.

RESULTS

During the study period, prescription of 251 patients were collected. These prescriptions were analyzed for its gender distribution and it was found that 162 (64.5%) were males and 89 (35.4%) were females. The maximum number of patients belonged to age group of 18-40 years and least number of patients were found to be in the age group of more than 60 years. (Table 1)

Table 1: Demographic details

Gender	Number of patients (Total= 251)	Percentage of patients
Male	162	64.5 %
Female	89	35.4 %
Age (years)	**Number of patients (Total= 251)**	**Percentage of patients**
< 18	65	25.8 %
18-40	134	53.3 %
41-60	40	15.9 %
>60	12	4.7 %

On analyzing the drugs prescribed, we found that a total of 850 drugs were prescribed in 251 prescriptions and average drugs prescribed was 3.3. The maximum prescriptions (42.6%) consisted of four drugs and least prescriptions (5.5%) had monotherapy in them. (Table 2)

Table 2: Drugs prescribed per prescription

Number of prescriptions (Total= 251)	Number of drugs per prescriptions	Percentage
14	1	5.5%
40	2	15.9%
62	3	24.7%
107	4	42.6%
28	>4	11.1%

From amongst these drugs, the most commonly prescribed group of drugs were antimicrobials (225) followed by antihistaminics (187), antacids (164), Nonsteroidal Anti-inflammatory Drugs (NSAIDs)/antipyretics-analgesics (140), miscellaneous (83), nasal decongestant (36), vitamins and mineral supplements (10) and corticosteroids (5). (Figure 1)
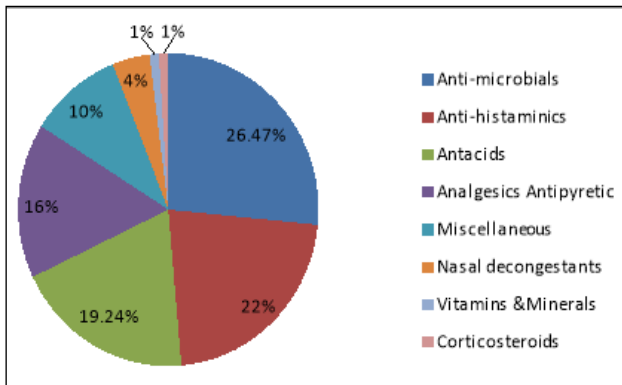

Figure 1: Prescribing pattern

On analyzing the most common group of drugs (antimicrobials and antihistaminics) we found that Beta-lactam antibiotics and Fexofenadine were maximally prescribed (Table 3)

Table 3: Prescribing Pattern of Antimicrobials and Antihistaminic

Antimicrobials	Drug	Number of drugs	Percentage
Beta-Lactams	Cefpodoxime + Clavulanic Acid	121	53.7%
	Amoxicillin + Clavulanic Acid	62	27.5%
Fluroquinolones	Levofloxacin	09	4%
Macrolides	Azithromycin	07	3.1%
Antifungals	Clotrimazole	20	8.8%
	Posuconazole	01	0.4%
Antiprotozoal	Metronidazole	05	2.2%
Antihistaminics	**Drug**	**Number of drugs**	**Percentage**
	Fexofenadine	74	45.12%
	Montelukast+ Fexofenadine	11	6.7%
	Montelukast+ Levocetrizine	56	34.14%
	Levocetrizine	23	14.02%

On analyzing the routes of drug administration it was observed that oral route was most commonly preferred (81.53%), followed by topical (18.37%) and inhalational (0.10%).

The prescriptions were then looked into for the commonly prescribed FDC's and we found that by Cefpodoxime proxetil + potassium clavulanate was most commonly prescribed FDC followed by Amoxicillin + Claulinic acid,

Cefuroxime + clavulinic acid, Cefpodoxime + Ofloxacin, Cefixime + Levofloxacin, Aceclofenac + paracetamol, Beclomethasone + Neomycin + Clotrimazole, Esomeprazole + Domperidone, Pantoprazole + Domperidone, Montelukast + fexofenadine and Montelukast + levocetrizine.

On analyzing the types of disease/disorder from among 251 prescriptions, we found that 101 (40.2%) prescriptions were of ear disease, 76 (30.2%) prescriptions were of throat disease, in 63 (25.09%) of them drug therapy was given for disease related to nose and nasal passage and 10 (3.9%) prescriptions were of combined organ diseases. On further evaluating the diseases of ear, nose and throat we observed that otitis media (unilateral), rhinitis and sore throat was most commonly suffered condition among these patients (Figure 2,3 & 4)
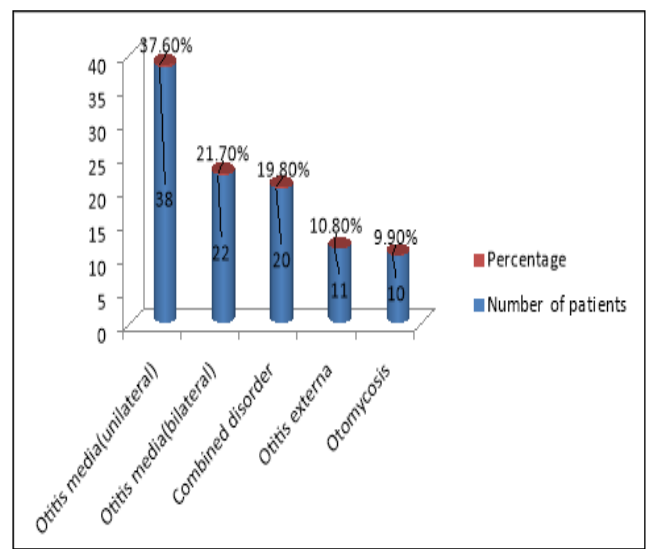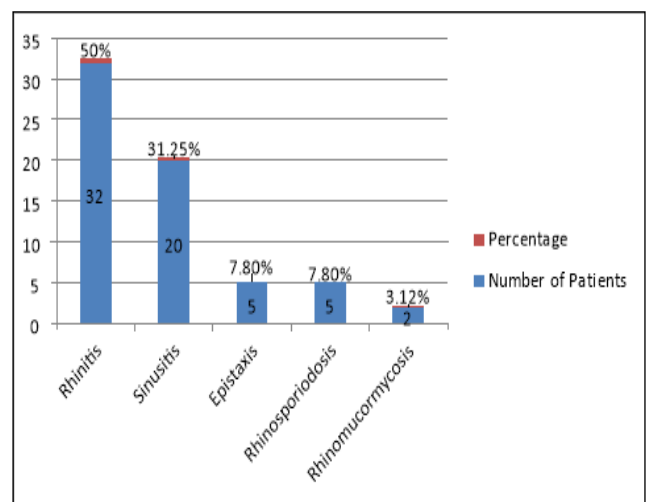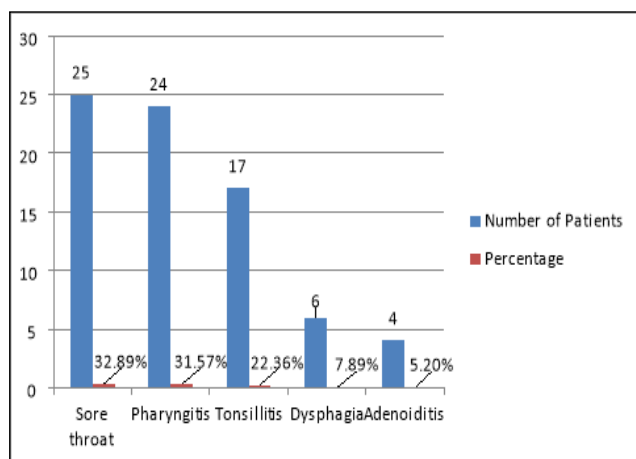

Figure 2: Types and number of patients with disease of ear

Figure 3: Types and number of patients with disease of nose

Figure 4: Types and number of patients with disease of throat

Further, overall assessment of prescription was done by various prescribing indicators to evaluate its adequacy (Table 4).

Table 4: Adequacy of prescription by various prescribing indicators

Prescription parameter	Mentioned%
Presenting complaints	160 (63.74%)
Diagnosis/Provisional diagnosis	200 (79.68%)
Duration of treatment	251 (100%)
Dosage frequency	251(100%)
Dosage form	251 (100%)
Instructions in local language	251(100%)
Generic drugs	68(27%)

A total of four adverse drug reactions were reported from ENT department during the study period among which two cases were from 1-18 years' of age group and two cases were from 31-60 years' of age group. Male preponderance was seen as three out of four ADRs belonged to male patients. Adverse drug reactions were reported both from oral and parenteral route with no reactions from topical route. After causality assessment it was seen that all ADRs belonged to Possible category.

On analyzing the types of ADRs, we found that there was a case of diarrhea post consumption of levosalbutamol syrup (1mg/5ml) for cough, two incidences of hypokalemia & aggravated liver enzymes were seen in which first one occurred after intravenous administration of 300 mg of liposomal amphotericin B with 5% dextrose (500ml) for the treatment of post-covid orbital mucormycosis and in the second case 250 mg I.V. infusion of Liposomal Amphotericin B was given for management of post-covid mucormycosis followed by which the patient developed hypokalemia. The last case reported was of hematemesis which occurred in a patient suffering from otalgia with suppurative infection who was prescribed Cefpodoxime 200 mg with clavulanic acid 125 mg orally twice a day.

DISCUSSION

This was an observational prospective study which was conducted at outpatient department of ENT of a tertiary care hospital of Bihar. This study was done to analyze the prescription in different categories. On analyzing the prescriptions on the basis of gender, we found that number of male patients were markedly higher than that of female patients. The probable reason for this could be higher exposure rate of male population to environmental pollutants and pathogens as males belong to higher ambulatory working population and also gross neglect by women of their health and not accessing health care services due to cost incurred. Similar observation was made in a study done by Kishore Kumar Y et al. [12] It was also observed that majority of the patients belonged to the age-group of 18-40 years which was also observed in a similar study done by Shruti et al. [13] On analyzing the prescribing pattern, we found that antimicrobials were the most commonly prescribed drugs followed by antihistaminics. Among the antimicrobials combination of Cefpodoxime and Clavulinic acid followed by combination of Amoxicillin and Clavulinic acid was maximally prescribed. In a similar study done by Renu et al it was found that among the antimicrobials beta-lactams were most commonly prescribed. [14] However, this was in contrast to the study of Phukan et al where combination of amoxicillin with clavulinic acid was most commonly prescribed. [15] On analyzing the total and average number of drugs prescribed, it was seen that a total of 850 drugs were prescribed in 251 prescriptions so on an average 3.3 drugs were prescribed. This finding in our study was in accordance to the observation of M.H.Sumana et al where average number of drugs prescribed was 3.04. [16] In this study, the most common prescribed route of drug administration was oral route followed by topical and inhalational route and no injectable were prescribed probably because all prescriptions were obtained from OPD of ENT. It amounts to good prescribing pattern as increased and indiscriminate use of injectable increases the cost of health care management. This finding is in accordance to observations made by Joshi et al and Daniel et al. [17,18] The prescriptions were then analyzed for commonly prescribed FDC's and we found fifteen FDC's most commonly advised. Its rationality was assessed from the approved list by DCGI and we found all the combinations to be rational, which again amounts to good prescribing pattern. [19] On analyzing the types of diseases it was observed that a total of 101 patients suffered from ear ailments and maximum cases were of unilateral otitis media. A total of 64 patients had ailments related to nose with maximum cases of rhinitis. A total of 76 patients had throat ailments with maximum patients suffering from sore throat and pharyngitis. On overall assessment of prescribing indicators, it was found that presenting complaints were mentioned in 160 prescriptions, Provisional diagnosis in 200, but all the prescriptions had duration of treatment, dosage frequency, dosage form and instructions in local language mentioned in them.

Mentioning the instructions in vernacular language is beneficial for patients as it ensures better understanding and improved compliance. Only 27% of drugs were prescribed by their generic names and majority of the drugs were prescribed by their brand names which is similar to observation made by Jyotsna et al. [20]

On analysis of adverse drug reactions reported, it was observed that only a cumulative of four adverse drug reactions were reported from both OPD & IPD of ENT department during the six months of study which highlights the need of increased awareness and significance of ADR reporting among the healthcare professionals. The reason for this under-reporting could be attributed to disruption of routine OPD services and decreased IPD admissions of routine cases due to Covid-19 out-break during our study period. However, during our study admissions related to post-covid mucormycosis was quite high but only two adverse drug reactions were reported from such patients which signifies the need to sensitize the health care workers as well as patients for reporting of adverse drug reactions. Awareness in patients as well as health care workers regarding the detection and reporting of ADRs and proper management and prevention of ADRs is of utmost importance for improving patient care and to reduce the cost.

The limitation of this study is that it was performed for a limited duration so, only 251 prescriptions were analyzed and cost of drugs and relation of prescribing to the socio-economic status of the patient was not included in our study. In our study patient's characteristics for example socio-cultural parameters and attitudes towards drugs was not included. In addition, prescriber characteristics like specialty, education and factors which influence therapeutic decisions were not included. Follow-up of the patients for the success or failure of treatment was not done. In few prescriptions diagnosis was not mentioned so it was not possible to make a remark about the rationality of the prescription.

CONCLUSION

This study was a sincere attempt to see the prescribing pattern of drugs prescribed in ENT department and its associated ADRs. We found that antimicrobials were the most commonly prescribed drugs and it could be attributed to increased occurrence of infections related to ear, nose and throat. Dose, frequency, total duration of treatment and instructions in vernacular language was mentioned in all the prescriptions which highlights good aspects of prescription writing. The average number of drugs prescribed was 3.3. Since no prescription had more than five drugs; we can say that polypharmacy was avoided. However, generic drug was significantly much lesser compared to use of brand drugs. As generic prescribing is also an essential element of good prescribing pattern, hence it needs to be improved. ADR reporting was very low during the study period so it strongly suggests the need to spread awareness among health-care workers and patients for reporting of adverse drug reactions.

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