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Original Research Article

Determination of the drug utilization patterns of antimicrobial agents used in the department of ear, nose and throat at a tertiary care teaching hospital

Satyashil A. Ingle, Sujeet A. Divhare*, Rajesh S. Hiray, Sujata Shingare

Department of Pharmacology, BJGMC and SGH, Pune, Maharashtra, India

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***Correspondence:** Dr. Sujeet A. Divhare, Email: drsujeet22@gmail.com

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ABSTRACT

Background: Pharmacoepidemiology deals with the epidemiological aspects of clinical use of and effects of drugs over a large population with intentions to have a rationalised prescription practices while using various drugs preferably anti-microbial agents. Objective of the research was to study the prescribing patterns of drugs in ear, nose and throat (ENT) department and to evaluate prescriptions according to World Health Organization (WHO) drug use indicators. **Methods:** A cross sectional, observational study was conducted in the department of ENT. Data was collected from the prescriptions of patients in outpatient (OPD) and inpatient department (IPD) both.

Results: Total number of 250 prescriptions were analysed in which 1038 drugs were prescribed, with average number of drugs prescribed per prescription were 3.6 and 4.6 drugs among OPD and IPD group respectively. Anti-histaminic class of drugs were most prescribed drugs in OPD while in IPD, all anti-microbial agents were most prescribed class of drugs. **There** was a statistically significant difference between drugs prescribed by generic and branded names. When compared statistically, it was found that 1%, 59% and 40% prescribed drugs in OPD were from desirable, essential and vital class respectively. While 3%, 62% and 36% of prescribed drugs in IPD were from desirable, essential and vital class respectively.

Conclusions: It is vital to aware prescribers about the importance of rationalised prescribing and avoid polypharmacy. A need for the development of prescribing guidelines and educational initiatives to encourage the rational and appropriate use of drugs, in order to give the inputs to the prescribing doctors.

Keywords: Drug utilization study, Generic, Branded, WHO drug indicators, Evidence based treatment

INTRODUCTION

The World Health Organization (WHO) has defined drug utilization research as the marketing, distribution, prescription and use of drugs in a society, with special emphasis on the resulting medical, social, and economic consequences.¹ Pharmacoepidemiology refers to the epidemiological methods to study the clinical use and effects/side-effects of drugs in wide range of population with the purpose of supporting the rational and costeffective use of drugs in that population. So, the drug utilization research or studies are the powerful exploratory tools to ensure the role of drugs in the society. That's why drug utilization research has become a vital part of pharmacoepidemiology and together both provide the insights into various aspects of drug prescribing and drug use like pattern of use, quality of use, determinants of use and outcomes of use.² Inappropriate and irrational use of drugs in health care system seen globally is a major concern for all of us.³ In the recent past influx of newer therapeutic agents and tendency to prescribe the newer drugs more often is a concern.⁴ Drug utilization pattern needs to be evaluated from time to time so as to increase therapeutic efficacy and decrease adverse effects. With this background, the present study was undertaken to investigate the patterns of prescriptions and drug utilization by measuring WHO drug use indicators in the department of ear, nose and throat (ENT). There are many studies done for the prescription or drug utilization pattern in various departments including the ENT but most of them are restricted to outpatient department only. No data is available from the inpatient department. Keeping these facts in consideration, the present study was planned with the aim of pharmaco-epidemiological analysis of the drugs to define the pattern of use, their availability in the hospital and to evaluate their cost analysis in each prescription of ENT, outpatient (OPD) and inpatient department (IPD) of a tertiary care hospital attached to study institute.

Aims and objectives

Aim of the study was to determine the utilization of antimicrobial drugs prescribed to patients suffering from ENT disorders attending, ENT OPD as well as patients admitted in ENT wards of a tertiary care teaching hospital.

Objectives of the study were: to find out the pattern and prevalence of common ENT related diseased conditions; to analyse the prescription pattern of drugs being prescribed to patients with ENT disorders; to find out most common antimicrobial class and drugs being prescribed to these patients; to find out the empirical and evidence based prescription patterns among these patients by noting drug sensitivity reports; to find out the drug-drug interactions among the drugs being prescribed to these patients; and to analyse the adverse drug effect profile among these patients.

METHODS

Study type

It is a cross-sectional, observational analysis done at ENT department (both OPD and IPD) of Sassoon General Hospital, Pune, over a period of one year i.e., from January 2019 to January 2020, after obtaining the permission from Institutional ethics committee.

Inclusion criteria

Patients from ENT OPD and IPD (all ages of either sex) receiving ENT medication and patients >18 and <60 years of age were included in the study.

Exclusion criteria

Patients not willing to be a part of study/refusing to sign informed consent form (ICF), and patients <18 and >60 years of age were excluded.

Statistical analysis

Patients were explained about the study design and ICF was taken. The case record form (CRF) was filled and the data obtained was compiled in tabular form and analysed. Statistics were used to present data in tabular and graphical forms and suitable statistical tests were applied. The data was collected for a continuous period of one year from the date of approval of study.

Data was analysed by using statistical package for the social sciences (SPSS) software version 17.0 graphs were depicted using Microsoft excel or open office spreadsheet. Continuous variables were summarized as mean±standard deviation or median with inter quartile range. Categorical variable was summarized in terms of frequency with % and tested using Chi square/Fischer's exact test. Comparison of continuous variable were done using Univariate analysis of variance. For all test p value <0.05 was considered as statistically significant.

The prescriptions were analysed for following parameters.

Demographic details

The variables that were assessed from the prescriptions included the demographic profile. It included: gender, age, locality, and medical history.

WHO drug use indicators

Prescribing indicators

It included total number of prescriptions, average number of drugs per prescription, percentage of dosage forms recorded, number (percentage) of encounters with antibiotics, percentage of encounters with an injection prescribed, percentage of frequency of therapy recorded, percentage of duration of therapy recorded, percentage of drugs prescribed by generic name, percentage of drugs prescribed by brand name, percentage of scheduled drugs actually dispensed from the hospital pharmacy, and percentage of polypharmacy in prescription.

Patient indicators

It included total number of female and male patients, average age of male and female patients, and number of patients receiving monotherapy and multiple drugs respectively.

Adverse drug reaction (ADR) profile

It included: incidence and type of adverse drug reaction, causality relationship of ADR with suspected drug according to Naranjo's ADR probability scale, whether suspected drug was stopped after ADR, whether any treatment was given for ADR, and drug(s) most commonly causing ADR.

RESULTS

In the present study total 250 prescriptions were studied in both the OPD and IPD group. All the prescriptions were studied according to WHO Drug Use Indicators. In the present study total 250 prescriptions were studied containing 125 from each IPD and OPD. And among them total 457 drugs from OPD and 581 drugs from IPD were studied respectively. The average age of all 125 patients, those visited ENT OPD, was 36 years, while that of 125 admitted patients' (i.e., IPD) was 38 years. In the present study, average number of drugs per prescription among OPD and IPD group was 3.6 and 4.6 drugs respectively. 32 (26%) OPD patients were natively from outside of Pune; while 93 (74%) of them were from Pune. 8 (6%) of patients those were admitted to wards were from outside area of Pune; while 117 (94%) were native to Pune, when compared, was found statistically significance (p=0.0001).

Table 1 has brief presentation about the epidemiological data of this study, regarding age, gender-wise distribution, location and other factors among the study population.

The pie diagram shows that majority among enrolled subjects i.e. 51% patients were of acute suppurative otitis media (ASOM), followed by 31% of common cold, followed by otalgia, otitis externa and URTI (Figure 1).

The most commonly prescribed drug in all the three domains was tablet cetirizine, which was given in 82% of encountered patients, followed by tablet ranitidine in 81% of patients, tablet amoxycillin-clavulanic acid was 5th most prescribed tablet, followed by tablet ciprofloxacin (Table 2).

Tablet amoxycillin-clavulanic acid was the preferred antimicrobial of choice in most of the clinical conditions in OPD, except, in otalgia patients tablet ciprofloxacin was preferred (Table 3).

Drug utilisation in ASOM

Proportions of drugs used among various clinical conditions in ENT- in ear related pathologies, ASOM was most common diagnosis, where 96% patients were prescribed tablet ranitidine, irrespective of exposure of the patient to the antimicrobial agent, followed by tablet cetirizine in 80% of the patients, followed by tablet diclofenac and tablet amoxycillin-clavulanic acid.

Drug utilisation in cold

In nose related conditions, tablet cetirizine was prescribed to all 100% cold patients, followed by tablet B-complex in 61%, tablet ranitidine in 55% of the patients.

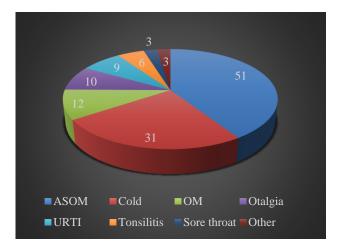
Drug utilisation in URTI

In throat related conditions, URTI was most common presentation, where 89% of patients were prescribed with

tablet ranitidine and tablet amoxycillin-clavulanic acid, followed by tablet cetirizine in 78% of the URTI patients.

In IPD settings, it was observed that 50% of the patients were of mastoidectomy, followed by 18% of tonsillectomy, 17% of ASOM and 13% were of nasal septal abscess (Figure 2).

The median number of drugs prescribed to a patient in OPD was around 14 with range of (7-14) while in IPD the number was 14 ranging from (10-14) (Table 4).





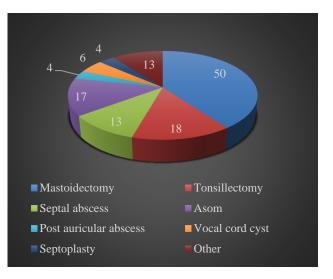


Figure 2: Distribution of diagnosis in IPD.

Duration of management as per diagnosis: The median number of drugs prescribed to a patient in OPD was around 14 with range of (7-14) while in IPD the number was 14 ranging from (10-14). The median duration of management of a patient in OPD set up was of 7 days with range of 5-7 days; while in IPD it as also for 7 days but the range was of 5-9 days which was wider as compared to OPD patients' management. This elongation of treatment was seen to be dependent upon the factors like – diagnosis, age of the patient, underlying conditions like other comorbidities and culture and sensitivity reports (Table 5).

Table 1: Epidemiological data analysis.

Characteristics	OPD	IPD	Total	P value	
Ν	125	125	250		
Age (years)	36 (26 – 47)	38 (29 – 47)	38 (28 - 47)	0.29	
Sex					
Male	69 (55%)	65 (52%)	134 (54%)	0.70	
Female	56 (45%)	60 (48%)	116 (46%)	0.70	
Place: Pune					
No	32 (26%)	7 (6%)	40 (16%)	< 0.0001*	
Yes	93 (74%)	118 (94%)	210 (84%)	<0.0001	
Number of drugs prescribed (median, IQR)	4 (2 – 4)	5 (4 – 5)	4 (4 – 5)	<0.0001#	
Number of dose of drugs prescribed (median, IQR)	41 (22 – 45)	48 (38 - 62)	48 (38 – 45)	<0.0001#	
Duration of treatment (median, IQR)	7 (5 – 7)	7 (5 – 7)	7 (5 – 7)	>0.95	

*Indicates difference between yes and no in combined IPD and OPD patients; and #indicates difference between OPD and IPD patients

Table 2: Various classes of drugs used in ENT OPD.

Drugs (overall)	Dose (mg)	Numbers	Percentages
T. cetirizine	5	103	82
T. ranitidine	150	101	81
T. B-complex	500	69	55
T. diclofenac Na	50	59	47
T. amoxicillin-clavulanic acid	625	55	44
T. ciprofloxacin	500	24	19
T. paracetamol	500	23	18
T. azithromycin	500	8	6
Others	-	15	12

Table 3: Antibiotic utilization in ENT OPD.

Clinical diagnosis	Antibiotic used	Dose (mg)	% use
ASOM	T. amoxicillin-clavulanic acid	625	37 (73)
	T. ciprofloxacin	500	12 (24)
Cold	T. amoxicillin-clavulanic acid	625	1 (3)
Otitis externa	T. amoxicillin-clavulanic acid	625	6 (50)
	T. ciprofloxacin	500	4 (33)
Otalgia (non-specific)	T. ciprofloxacin	500	6 (60)
	T. amoxicillin-clavulanic acid	625	2 (20)
	T. azithromycin	500	1 (10)
URTI	T. amoxicillin-clavulanic acid	625	8 (89)

The bar diagram shows distribution of drugs prescribed to both IPD and OPD in percentages among three categories, i.e. desirable, essential and vital (Figure 3).

Table 4: Number of drugs used per patient.

Clinical diagnosis	Number of drugs prescribed
Mastoidectomy	16 (14 – 16)
Tonsillectomy	14 (10 – 14)
Septal abscess	10 (10 – 10)
ASOM	10 (9 – 10)
Post auricular abscess	9 (8 - 10)
Vocal cord cyst	14 (12 – 16)
Septoplasty	10 (10 – 12)
Other	8 (6 - 8)

Table 5: Duration of management as per diagnosis.

Duration of treatment	Median, IQR
Mastoidectomy	8 (7 – 8)
Tonsillectomy	7 (5 – 7)
Septal abscess	5 (5 – 5)
ASOM	5 (5 – 5)
Post auricular abscess	5 (4 – 5)
Vocal cord cyst	7 (6 – 8)
Septoplasty	5 (5 - 6)
Other	4 (3 – 4)

VED analysis is based on critical values and shortage cost of the relative material. Based on their criticality, the materials could be classified into three categories: vital, essential and desirable. When compared statistically, it was found that there was a significant statistical difference as p value was 0.01 (less than 0.05) between the drugs

prescribed based on the names i.e. generic versus branded (Table 7).

Clinical condition (IPD)	Antibiotic used	Doses (gm)	Drug utilization (%) (125)	Clinical condition (IPD)	Antibiotic used
Mastoidectomy	Inj. cefotaxime	1	50 (100)	Mastoidectomy	Inj. cefotaxime
Tonsillectomy	Inj. cefotaxime	1	18 (100)	Tonsillectomy	Inj. cefotaxime
Septal abscess	Inj. amoxicillin- clavulanic acid	1.2	1 (8)	Septal abscess	Inj. amoxicillin- clavulanic acid
	Inj. cefotaxime	1	12 (92)		Inj. cefotaxime
ASOM	Inj. amoxicillin- clavulanic acid	1.2	2 (12)	ASOM	Inj. amoxicillin- clavulanic acid
	Inj. cefotaxime	1	15 (88)		Inj. cefotaxime
Post auricular abscess	Inj. amoxicillin- clavulanic acid	1.2	2 (50)	Post auricular abscess	Inj. amoxicillin- clavulanic acid
abscess	Inj. cefotaxime	1	2 (50)	abscess	Inj. cefotaxime
Vocal cord cyst	Inj. cefotaxime	1	6 (100)	Vocal cord cyst	Inj. cefotaxime
Septoplasty	Inj. cefotaxime	1	4 (100)	Septoplasty	Inj. cefotaxime

Table 6: IPD drug utilization.

Drug utilization (antibiotic) in ENT IPD (diagnosis wise)

Table 7: Generic versus branded drugs.

Generic/brand (G/B)	OPD (%)	IPD (%)	P value
В	5 (1)	234 (40)	<0.001*
G	452 (98)	347 (60)	<0.001*

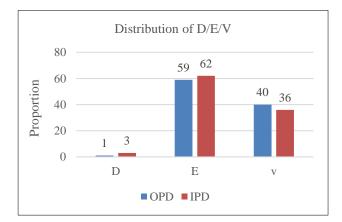


Figure 3: Classification of drugs utilized as per hospital policy.

DISCUSSION

It was seen that majority of the patients attending ENT OPD, i.e., 41% were suffering from ASOM while 25% were presented with cold, while in IPD, 27% patients were admitted for mastoidectomy, followed by 14% were admitted for tonsillectomy while 13% were for tympanoplasty. In study by Kumar et al, it was observed that, the most common disease reported was CSOM in 31 (15.5%) patients followed by otitis externa 25 (12.5%) patients, pharyngitis patients 21 (10.5%), URTI patients 20 (10.0%), again which was similar to the incidences those

were found in our study.⁵ While analysing the prescriptions from OPD, it was found that 79.5% of the prescriptions were with 4-5 drugs, followed by 12% of the prescriptions with more than 5 drugs while only 8% were with 2-3 drugs.

In this case there is a major trend of polypharmacy, which in turn can have many issues, like adverse drug reactions, drug-drug interactions etc. In present study, it was found that, the most commonly prescribed group of drugs was antihistaminic (cetirizine -82%), followed by H-2 blocker (ranitidine -81%) followed by multivitamins (55%) followed by analgesic (NSAIDS- diclofenac Na- 47%), followed by anti-microbial agents (69%), followed by antipyretic (18%).The use of tablet ranitidine is however, seems to be inappropriate as most of the time the drug was given irrespective in the connection with tablet diclofenac Na or any anti-microbial agent. It should be only prescribed along with those drugs which can enhance the gastric acid secretions, in order to avoid GERD like conditions.

So, here we need to create awareness among the medical practitioners in order to prescribe tablet ranitidine in a rational way. In a study by Rehan, it was found that most common group of drugs used was of anti-microbial agents (31.81%) followed by analgesics and antipyretic (20.7%) followed by anti-histaminic (19.19%).⁶

In this study, the use of antacid agent was in an adequate proportion and irrational use was avoided. In present study, in OPD section on ENT, the anti-microbials agents used were – tablet amoxicillin-clavulanic acid (55%), followed by tablet ciprofloxacin (24%), tablet azithromycin (8%) while other agents were used in traces like anti-fungal agents (clotrimazole), anti-viral agents (tablet acyclovir) (5% and 2% respectively).

While in study done by Daniel et al, the drug utilization in ENT OPD was found slightly different.⁷ In concerned study, it was found that the highest prescribed antimicrobials agent was azithromycin (98/177), followed by amoxicillin-clavulanic acid (49/177), followed by gentamycin, amikacin and metronidazole (each 10/177). In a study done by Begum, it was seen that there were at least 80.67% prescriptions with 2 anti-microbial agents in them, while rest 19.33% were with single anti-microbial agent in them.⁸ While in current study, it was noticed that, out of those anti-microbial agents containing prescriptions, 87% had single antimicrobial agent prescribed, while rest 13% were having 2 anti-microbial agents. While 13 prescriptions overall were without any anti-microbial agent.

In present study, it was found that most of the antimicrobial agents prescribed were- evidence based, empirical drugs – as per hospital policy, and were preferably broad-spectrum which would provide cover to maximum number of causative micro-organisms, and giving satisfying relief to the patients. Similar trends of prescription were found in study done by Isaac, most of drugs were prescribed by its generic name.⁹ It also highlighted good adherence to the formulary listed drugs by the physicians.

The most common micro-organisms that were seen grown were – S. aureus, Klebsiella, and Pseudomonas. In a study done by Joel, the causative micro-organisms found were similar to those microbes which have been grown in present study.¹⁰ As their study also stated that, Pseudomonas aeruginosa and Staphylococcus were the most isolated organisms. In a study done by a Seid et al, the main isolates in AOM in this study were S. the *Proteus* spp. aureus (4.3%), (3.4%)and the Pseudomonas spp. (3.4%).¹¹ The choice of antimicrobial agent in present study, overall, was injection haltax (injection cefotaxime) which is a third-generation cephalosporin. In a study done by Joel et al, it was found that majority of the patients were prescribed with cephalosporin which includes ceftriaxone (52.2%) and cefixime (37.5%).¹⁰ In another study, done by Padda et al, it was found that cefotaxime is effective as an empirical treatment of suspected infection due to susceptible organisms.¹² In a study done by Sridevi et al, the antibacterial commonly used were β -lactams (56%), fluoroquinolones macrolides (14%), (12%).aminoglycosides (8%).¹³ While in IPD, out of total 581 drugs prescribed, 234 drugs (40 %) were prescribed by their generic names, while rest 347 drugs (60 %) were prescribed by their brand names. In a study done by Silfwerbrand et al, it was found that overall, the prescriptions made using generic names were significantly higher.14

Limitations

Since this was a quantitative type of drug utilization study with the WHO/INRUD core prescribing indicators,

determining the quality of diagnosis and the appropriateness of drug choices was beyond the scope of prescribing indicators.

ADR reporting i.e., pharmacovigilance could have been noticed if both IPD and OPD patients report their adverse reactions to the drugs, this would help in the improvement of the therapeutics of all the pharmaceutical agents.

CONCLUSION

DUS has become a vital part of pharmacoepidemiology. It provides the insights into various aspects of drug prescribing and drug use like pattern of use, quality of use, determinants of use and outcomes of use. Therefore, periodical auditing of drug utilization pattern is crucial for promotion of rational use of drugs, for increasing the therapeutic efficacy and the cost effectiveness, for decreasing the adverse effects and to provide feedback to the prescribers.

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