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DRUG PRESCRIPTION PATTERN OBSERVATION AT A ENT OPD DEPARTMENT IN A TERTIARY CARE HOSPITAL AT MALAPPURAM DISTRICT OF KERALA

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ABSTRACT: Affordability to healthcare is one of the major factors that have impact on the health care access in the Indian subcontinent. It is the main responsibility of the pharmacist in ensuring that patients get the right drug in the right quantity at the right time. Thus, such prescription pattern monitoring studies can promote appropriate use and reduction of abuse or misuse of monitored drug. The aim of such studies is to facilitate the rational use of drugs in the population. Irrational use of medicines leads to increased incidence of treatment failure, antimicrobial resistance and economic burden on the patient and the community as a whole. This is a descriptive observational prospective study in monitoring the drug prescription pattern in an ENT outpatient department. The objective of this study is to evaluate the patterns of drug prescribing practised. The study conducted observed that the drug prescription pattern was not as per the WHO guidelines and its indicators. ENT disorders led to school absenteeism as most of them where school going children.

INTRODUCTION: Disease of the ear, nose and throat affects the functioning of adults as well as children, often with significant impairment of daily life activities, work loss and school absenteeism. It has envisaged that with increase in global population, infections remain the most important cause of disease. According to the world health report of 2010, it has been estimated that respiratory infections generated 94.6 disability adjusted life years lost worldwide and were the fourth major cause of mortality responsible for global number of deaths.[1]

The vast majority of acute upper respiratory tract infections are caused by viruses. For instance, common cold is caused by viruses and in most circumstance does not require an antimicrobial agent unless it is complicated by acute ottitis media, tonsillitis, and sinusitis and lower tract respiratory infections.[2]

The results of different surveys were in agreement showing that antibiotic preparations were given in approximately 40% of all consultations of rhino pharyngitis and in 80% of those with acute bronchitis, and antibiotics were prescribed in more than 90% of cases of pharyngitis, irrespective of the age of the patients. In a publication from Thailand, more than 80% of the prescriptions for upper respiratory tract infections contained antimicrobials. [3] The variability in antibiotic prescription is attributable to the infecting organism

and antimicrobial susceptibility that differ from country to country or even from region to region but other factors may also be involved including physician preference, patients, local policy, physical working environments, cost and lack of local guidelines.[4]

Disease of the Ear:

An ear infection is caused by a bacteria or virus in the middle ear. This infection often results from another illness like cold, flu, allergy that causes congestion and swelling of the nasal passage, throat and Eustachian tube. Other related ear diseases are otitis media with effusion and fluid build up in the middle ear and chronic suppurative otitis media, a persistent ear infection resulting in tearing or perforation of the eardrum.[5]

Symptoms:

Ear pain, fullness in ear, hearing loss, ringing in the ears, discharge, nausea, vomiting, vertigo.

Risk Factors:

The risk factors are – Children aged between 6 months and 2 years are more susceptible to ear infections because of size and shape of the Eustachian tube and poorly developed immune system. Babies who drink from a bottle especially while lying down have more ear infections than breast feeding babies. Ear infections are also seen more in winter seasons. Exposure to tobacco smoke or high levels of air pollution can also increase the risk of ear infection.

Complications:

Persistent infection or persistent fluid in the middle ear may result in significant hearing loss. And the spread of infection to the nearby tissue causes mastoiditis. If hearing is temporarily or permanently delayed in infants or toddlers, they may experience delays in speech, social and developmental skills.

Disease of the Nose:
Sinus Infection:

Teeny holes that connect nasal passage to sinuses get blocked and causing growth of microorganisms leads to sinus infection. Sinus infection may either be caused by virus, where antibiotics don't help as these drugs kills only bacteria's. Allergens and pollutants can also cause sinus infection. Growth that develops from nose called as nasal polyps prevent mucus from draining and thus leads to sinus infection.

A large community based survey observed a high prevalence of ENT symptoms and incidence of otitis media among residents of Scotland, often with considerable variation between age, gender, occupation and socio-economic groups.[6] Acute pharyngitis is the most common cause of a sore throat and is diagnosed in more than 1.9 million people a year in the united states.[7]

Asia is one of the regions where the problem of resistance is more prominent. In India, almost 100% of the healthy population carries bacteria that are resistant to Ampicillin, Trimethoprim, Nalidixic acid and Chloramphenicol. Poor patient compliance or noncompliance with medications is particularly important in clinical practise. It has been found to be associated with treatment failure and all its consequence namely, deterioration of patients health, need for additional consultations, use of extra drugs, additional hospital admissions and increase in direct and indirect cost of disease management.

Despite the lack of evidence of efficacy of antibiotic agent for treating upper respiratory tract infection (URTI) symptoms (i.e., acute cough, sore throat, purulent nasal discharge, bronchitis and common cold), primary care providers frequently prescribe antimicrobial agents for patients presenting with such symptoms. And without any benefit such therapies contribute to a number of adverse consequences, including development of bacterial resistance [8] and increased hospital cost for treating resistant microbes. A cross sectional study was conducted to compare antibiotic prescribing for inpatients, in two private sector tertiary care hospitals in Ujjain; which also showed an inappropriate use of antibiotics.[9] Irrational drug pattern has been widely reported from both developed as well as developing countries.[10]

The strategies to prevent irrational use of drug is by conducting field surveys and providing scientific evidences.[11] Despite several years of clinical use of antibiotics, little is known about how these drugs

should be used optimally in the clinic. Various indicators where developed by international network for the rational use of drugs (INRUD) in collaboration with WHO that provided objectives indices to allow for assessment of drug use practises. Still, there is a need for data on both antibiotic use and determinants of use from all the regions of the world.[12] Therefore it is 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 patients. In a study conducted in a tertiary care hospital 60% of antimicrobial prescription was irrational.[13]

To deal with the rising microbial resistance, physicians readily accept and arbitrarily use newly developed expensive and broad spectrum antibiotics which further contribute to increased rates of antimicrobial resistance. Studies reviewed the trends in the antimicrobial prescribing for Bronchitis and URTI from 1993-1999, among children and adults taking in account of awareness before and after National Paediatric Practise recommendations of over use of antimicrobial agents. It was observed that though there was a decrease in antimicrobial prescribing for these two conditions but there was enormous increase in prescribing of broad spectrum antimicrobials (i.e. from 10.6% to 40.5%) [14]. The emerging problem of antibiotic resistance has become a major threat to the medical field. Excessive and inappropriate use of antibiotics has been a major contributor to this ever-growing problem.[15] Various studies have been conducted to assess the prescribing practises of medical practitioner. A cross sectional prospective study was carried out in inpatient department (ENT, Surgery, Orthopaedics, Ophthalmology, Medicine and Paediatrics) at a tertiary care hospital in Trivandrum to evaluate the prescribing pattern of antibiotics.[16]

Prescription pattern monitoring studies is to facilitate rational use of drugs and reduction of abuse or misuse of monitored drugs and also guides and supports prescribers, dispensers and the general public in appropriate use of drugs. It is important that the prescription pattern monitoring studies should be consultative and transparent, selection

criteria be explicit, and selection of the medicines be linked to evidence-based standard clinical guidelines.

This prospective study was conducted with the aim of analyzing the prescribing practises of physicians and to assess the extent to which the goal of rational use of medicines has been achieved. The study also includes the prescribing trends of antimicrobials due to the growing concern of antimicrobial resistance in ENT outpatient department so that adequate measures can be taken to prevent problem of antimicrobial resistance in the region. The study also aimed to treat major ailments and to analyze the prescription using drug indicators used in ENT outpatient department.

MATERIALS AND METHODS:
This chapter comprises of study site, study design, data collection and data analysis.

Study Site:
Study was carried out in ENT outpatient department of Mission hospital located at Malappuram district, Kerala having 100 beds and specialized in general medicine, paediatrics, ophthalmology, gynaecology and a 24 hour working casualty.
Data were collected from ENT outpatient department by interviewing the patient and collecting data from the patient prescriptions.

Study Design:
A descriptive, observational prospective study with questionnaire to evaluate the drug prescription pattern in ENT outpatient department.

Study Period:
The study was carried out from November 2014 to August 2015 (10 months).

Study Population:
The study population consist of 595 patients who qualified the inclusion criteria.

Study Criteria:
Inclusion Criteria:

- Patients visiting ENT department

- Patients between age group 6 to 65 years.

- Patients of both sexes.

Exclusion Criteria:

- Inpatients were excluded.

- Surgery patients were excluded.

- Follow up visit patients were excluded.

Data Collection:
Permission was obtained from hospital administration and doctors to conduct the study in the hospital. The study was carried out in 595 patients who visited the ENT outpatient department and data was collected from patient prescription. Informed consent was obtained before collecting the data.

Study Procedures
The dissertation work was planned in four phases and was carried out for a period of 10 months study from November 2014 to August 2015. The proposal was designed as given below:

Phase -1:

- Initial study to identify the scope of work

- Literature survey

- Preparation of study protocol

Phase-2:

- Selection of hospital

- Designing of data collection formats with reference to patient data collection form.

Phase-3:

- Details about patient data present in the prescription.

- Data collection

Phase-4:

- Analysis of data

- Compilation

- Correlation

- Submission of report

RESULTS AND DISCUSSION: The study attended to observe the drug prescription pattern in patients suffering from ENT disease. In this study the highest numbers of patients were from the age group of 16-25 years amounting to 27.7%, followed by 26-35 years of about 24.4% and then followed by both the age group 6-15 years and 36-45 years respectively with 18.5% and 17.5% each. The least number of people were found in the age group 56-65 years with 3.5% as depicted in **Table-1**. And according to the sex wise distribution 67% of the study population were males and 33% were females.

TABLE 1: AGE AND SEX WISE DISTRIBUTION (N=595)

Age range in years	Male	Female	Total No. of patients	% Total
6-15	74	36	110	18.5
16-25	114	51	165	27.7
25-35	74	71	145	24.4
35-45	70	34	104	17.5
45-55	48	3	51	8.6
55-65	20	0	20	3.4

Body Mass Index:
BMI range was divided into four categories- underweight, normal, overweight and obesity class I and II. As **Fig.1** shows; the highest number of study population of about 48% belonged to the group of overweight followed by 27% of patients belonging to obese I & II category and 22% of patients belonged to the normal group and only 3% contributed to the underweight category.
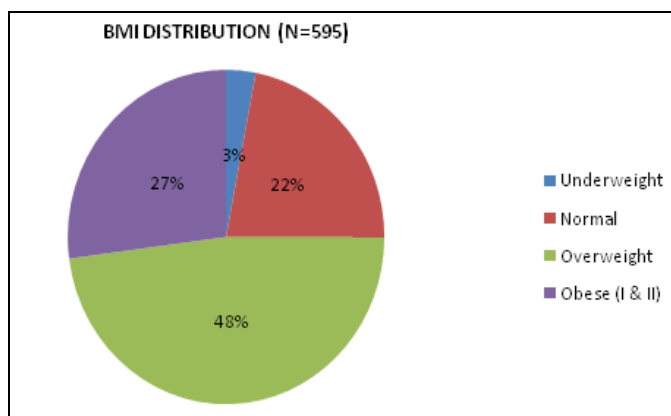
FIG.1: BMI DISTRIBUTION DATA

Education Data:
The study shows that highest number of people of 50.1% belonged to graduate/diploma group followed by post-graduate with 25.9% and 24% of patients were from below Hsc qualification.

Occupation Data:
The study shows that 35.5% of patients were employed followed by 31.6% of students and 25.7% patients were from other category and the least number of patients of about 7.2% were from self employed group.

Current Anti Infective Medication Classification:
In this survey the highest amount of prescription contained Penicillin class of drug of 67.5%, followed by 23% of patients received Quinolones for any kind of infection. Cephalosporins were prescribed in 21.9% of patients, Chloramphenicol in 14.9% and Macrolides in 12.4% of patients. Tetracyclines and aminoglycosides were prescribed for 5.9% and 2.4% of patients respectively, as shown in **Fig.2**.
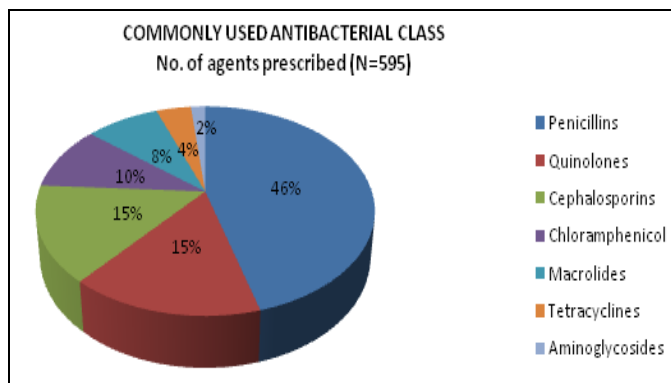

FIG.2: COMMONLY USED ANTIBACTERIAL CLASS

Prescribing Indicators:
The prescribing indicators for ENT disease included- number of drugs prescribed, number of drugs prescribed in generic name, number of injections prescribed, number of antibiotics prescribed.

Table 2 depicts the prescribing indicators. In total of 595 patients 1142 drugs were prescribed and the mean drug usage was 1.9 per patient. The WHO guidelines are a maximum of mean of 1. Only 91 drugs were prescribed in generic names of about 8.0% where the mean was 0.15 and 161 injections were prescribed in total amounting to 14.1% of the total drugs prescribed with a mean of 0.3. And 857 antibiotic prescriptions were catered amounting to as high as 75% with a mean of 1.4, whereas other studies has also documented that number of prescription of drugs was as high as three drugs.[17]

TABLE 2: PRESCRIBING INDICATORS

Indicators	No. of prescriptions (N=595)	% Total (N=1142)	Mean
No. of drugs prescribed	1142	100	1.9
No. of drugs prescribed in generic name	91	8.0	0.15
No, of injections prescribed	161	14.1	0.3
No. of antibiotics Prescribed	857	75.0	1.4

Therapy Choices:
Fig.3 depicts; In 47.1% of the cases single agent were used, followed by 22.5% of cases multiple agents were used, then followed by 20.3% of cases double agents were used. And triple and quadruple agents were used about 6.1% and 4% respectively.
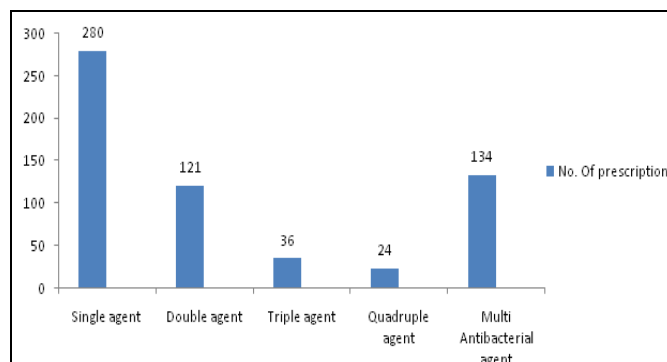

FIG.3: THERAPY CHOICES- SINGLE VS MULTIPLE AGENTS (N=595)

Under the class of Quinolones (Class wise agent -1) Ciprofloxacin was found to be used in 23% of patients, Ofloxacin in 51%, Levofloxacin in 24% and Norfloxacin in 2% of patients. In the class of Macrolides (Class wise agent - 2) Azithromycin contributed to about 72.2% and Clarithromycin to about 27.8% of patients.

The highly prescribed antibacterials were from Betalactams (Class wise agent -3) comprising of Penicillin's and Cephalosporins. The highest prescribed was Co-Amoxyclav in 35.5% of patients followed by Cefpodoxime in 18.9% and Amoxicillin, Cefaclor, Cefdinir and Cefixime contributed to some extent. This findings was in par with several other studies conducted by Khan et al. (2011)[18]

Tetracycline (Class wise agents 4) contributed to about 55.9% of the population and 44.1% population by Doxycycline.

In Aminoglycoside group (Class wise agent – 5) Neomycin combinations contributed to 78.6% and Tobramycin followed by 21.4%

Table 3 depicts data on the specific organ of treatment in the ENT group. 41.5% treatments were on Ear ailments, followed by 35.8% for throat and 15.3% for nose, finally 7.4% treatment were for combined diseases of the organs.

Ear Diseases:
In ear disorder a total of 247 patients suffered and out of the ear disease the combined disease like the middle and the inner ear infection were the largest with 60.7% of patients, followed by 21.9% with Otitis media, then wax was the major problem in 7.3% followed by Otitis externa in 7.3% and the least was Otomycosis in 2.8%.

TABLE 3: NUMBER OF PATIENTS WITH EAR DISEASE (N=247)

Infection	No. of patients	% to Total
Combined disorders	150	60.7
Otitis media	54	21.9
Otitis externa	18	7.3
Wax	18	7.3
Otomycosis	7	2.8

Nose Diseases:
Table 4 depicts data of nose disorders in which a total of 91 patients, maximum of them suffered by combined disorders with 26.4%, followed by Epistaxis in 22% of the population, Rhinitis in 19.8% and Vestibulitis in 12.1%

TABLE 4: NUMBER OF PATIENTS WITH NOSE DISEASE (N=91)

| Infection	No. of patients	% to Total
Combined disorders	24	26.4
Epistaxis	20	22.0
Sinusitis	18	19.8
Rhinitis	18	19.8
Vestibulitis	11	12.1

Throat Diseases:
Table 5 depicts the data on throat disorders of which a total of 213 patients, sore throat was seen highest of 34% of the population, followed by 24% of patients from combined throat disorders, 22% from Pharyngitis, 19% from Tonsillitis, and 1% of patients suffered from Adenoiditis.

TABLE 5: NUMBER OF PATIENTS WITH THROAT DISEASE (N=213)

Infection	No. of patients	% to Total
Sore throat	73	34.3
Combined disorders	50	23.5
Pharyngitis	46	21.6
Tonsillitis	41	19.2
adenoiditis	3	1.4

Combined diseases:
Fig.4 shows the data of combined disease. In this group a total of 44% of patients had disorders involving the nose, throat and ear. 52.3% suffered from URTI, followed by 22.7% of people with URTI and Common cold and 15.9% with Common cold and Sore throat, 4.5% of patients with URTI and Acute otitis media and 4.5% suffered from Sinusitis and Tonsillitis.
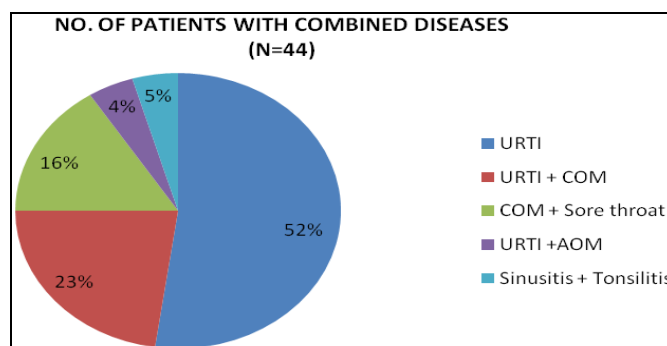
FIG.4: NUMBER OF PATIENTS WITH COMBINED DISEASES (N=44)

CONCLUSION: This study reveals the major ailments treated and the drug prescription pattern studied in ENT outpatient department, which was not in accordance with the WHO guidelines, with a maximum of mean of 1, while the study shows the mean of drug usage to be 1.9 per patient.

Ear disease was seen highest in the total study population. And Betalactams and cephalosporin were the most widely used antimicrobial agents. It was also found that single agents (47.1%) were used mostly in treating the major ailments of patients followed by multiple antibacterial agents (22.5%).

The prevalence of ENT disorders was seen highest in 16 to 35 age group and school going children where, ENT disorders has a major threat in school going children leading to school absenteeism.

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REFERENCES

1. Murray C.J.L, Barber R.M, Foreman K.J. Global, regional and national disability-adjusted life years for 306 disease injuries and healthy life expectancy (HALE) for 188 countries, 1990-2013: quantifying the epidemiological transition. Lancet. 2015
2. Kenealy T, Arroll B. Antibiotics for the common cold and acute purulent rhinitis; Cochrane database systematic review.2013
3. Issarachaikul R and Suankratay C. Antibiotic prescriptions for adults with upper respiratory tract infection and acute bronchitis at King Chulalongkorn Memorial hospital, Thailand. Asian Biomedicine 2013; 7(1): 15-20.
4. Ozgenc, Genc VE. Antibiotic resistance study group of Turkish association of clinical microbiology and infectious disease, Indian J Med.microbiol, 2011; 29,124-129.
5. Wiwanitkit S, Wiwanitkit V. Pyrogenic brain abscess in Thailand. N Am J Med Sci 2012; 4:245-8.
6. Kozyrskyj A, Klassen TP, Moffatt M, Harvey K. Short-course antibiotics for acute otitis media. Cochrane Database Syst Rev 2010; 9.
7. Marx John. Chapter 30. In: Rosen's emergency medicine: concepts and clinical practise. 7th edition, Philadelphia, Pennsylvania: Mosby/Elsevier 2010; 509.
8. Head M.G, Fitchett J.R, Cooke M.K, Wurie F.B, Hayward A.C, Atun R. UK investment in global infectious research 1997-2010: A case study Lancet Infect. Dis. 2013; 13:55-64.
9. Sharma M, Eriksson B. Antibiotic prescribing in two private sector hospitals; one teaching and one non-teaching: A cross sectional study in Ujjain, India. BMC Infect Dis 2012; 12:155.
10. Kumar J, Shaik MM, Kathi MC, Deka A Prescribing patterns of use of antibiotics among medical outpatients in a teaching hospital of central Nepal. Journal of college of Medical Sciences 2010; 6(2):7-13
11. Akdag, Republic of Turkey Ministry of health, Turkey health transformation program evaluation report (2003-2010) 2011; No: 839 ISBN: 978-975-590-377-4.
12. Anteneh Assefa Desalgegn, Assessment of drug use pattern using WHO prescribing indicators at Hawassa university teaching and referral hospital, South Ethiopia; A cross sectional study BMC Health Services Research,2013
13. Farhan Ahmad Khan, Vinod Kumar Singh. A prospective study on the antimicrobial usage in the medicine department of a tertiary care hospital. Journal of clinical and Diagnostic Research: JCDR.2013
14. Mojtaba Anvarinejad, Gholamreza Pouladfar, Aziz Japoni. Isolation and antibiotic Susceptibility of the microorganism isolated from diabetic foot infections in Nemazee hospital, Southern Iran. Journal of pathogens; 2015
15. Nandimath MK, Ahuja S. Drug prescribing pattern in upper respiratory tract infection in children aged 1-14 years. IJBS.2012; 3(1): 299-308.
16. Remesh A, Salim S, Gayathri AM, Nair U, Retnavally KG. Antibiotics prescribing pattern in the in-patient department of a tertiary care hospital. Arch Pharma Pract. 2013; 4:71-6.
17. Ain MR, Shahzad N, Aqil M, Alam MS and Khanam R. Drug utilization pattern of antibacterials used in ear, nose and throat outpatient and inpatient departments of a university hospital at New Delhi, India. J Pharm Bioall Sci 2010; 2: 8-12
18. Khan FA, Nizamuddin S and Salman MT. Drug utilization pattern of antimicrobial agents in the outpatient department of ENT in a tertiary care teaching hospital of North India. JAPHR 2011; 1 (2): 22-30.