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Original Research Article

A cross-sectional study on prescription pattern, essential medicines adherence and drug-drug interactions in patients attending ENT outpatient department of a tertiary care hospital

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ABSTRACT

Background: Ear, nose, and throat (ENT) disorders are common across all age groups and pose a significant socioeconomic burden. Effective management depends on rational drug prescribing. This study aimed to evaluate prescribing patterns in the ENT outpatient department of a tertiary care hospital, assess adherence to the National List of Essential Medicines (NLEM) 2022, and identify potential drug-drug interactions.

Methods: A cross-sectional observational study was conducted in the ENT outpatient department, involving 326 patients who received at least one drug. Data on demographics, diagnoses, comorbidities, and prescriptions were collected. Drug interactions were assessed using the Medscape drug interaction checker. Descriptive statistics were applied.

Results: Chronic suppurative otitis media (26.1%) was the most common diagnosis, followed by pharyngitis (11%). A total of 1204 drugs were prescribed, with an average of 3.7 ± 1.3 drugs per prescription. Antimicrobials were the most frequently prescribed class, with Amoxicillin + Clavulanic acid being the most common oral agent (52.5%). Oral administration (74.4%), mainly in tablet form, was predominant, along with topical formulations like ear and nasal drops. Generic prescribing was observed in 66.4% of cases. Of the 56 drugs prescribed, 34% were from the hospital formulary and 41% from NLEM 2022. Potential minor drug-drug interactions were identified in only 2.1% of prescriptions.

Conclusions: The study reflects common ENT prescribing practices, with a focus on antimicrobials and oral formulations. While generic prescribing is fairly common, adherence to the NLEM and hospital formulary can be improved. Drug interaction incidence was low, indicating responsible prescribing practices.

Keywords: Drug utilization, Otorhinolaryngology, Essential medicines, Drug-drug interactions, Medscape drug interaction checker

INTRODUCTION

Diseases affecting the ear, nose, and throat (ENT) significantly impact essential human functions such as hearing, breathing, speech, and olfaction, consequently influencing daily activities and overall quality of life. These disorders, prevalent across all age groups, range from minor infections like the common cold to chronic

conditions such as chronic suppurative otitis media (CSOM) and tonsillitis.¹ They can be congenital, infectious, inflammatory, neurological, or trauma induced.

Common ENT conditions include otitis media, otitis externa, vertigo, rhinitis, sinusitis, tonsillitis, pharyngitis, laryngitis, epistaxis, and nasal polyps.²

Globally, about 1.5 billion people suffer from hearing impairment, with 6.3% of Indians affected.³ CSOM, which impacts 5.2% of India's population, is a major, yet preventable cause, often linked to poor nutrition, socioeconomic factors, and recurrent respiratory infections.⁴ Rhinitis, primarily caused by rhinoviruses, along with adenovirus and respiratory syncytial virus, is widespread.⁵ Allergic rhinitis affects up to 40% of adults and 25% of children, with peak incidence between ages 20-40.⁶ Sinusitis remains a frequent reason for medical consultations, with a global prevalence of 146 per 1,000 individuals. These conditions contribute to absenteeism from school and work, further emphasizing their socioeconomic burden.⁷

The primary treatment goals for ENT disorders include symptom alleviation, infection eradication, and morbidity reduction. Commonly prescribed drug categories include antimicrobials, antihistamines, antacids, analgesics, antipyretics, nasal decongestants, local anaesthetics, corticosteroids, and nutritional supplements, administered either orally or topically.¹

Prescription pattern monitoring studies (PPMS), a subset of drug utilization research, evaluate prescribing, dispensing, and drug administration trends. These studies aim to improve prescribing practices, identify drug overuse, underuse, or misuse, and compare observed prescribing patterns with standard guidelines. They also assess the utilization of essential and generic medicines in clinical settings.⁸

The ENT outpatient department (OPD) serves as an ideal setting for evaluating prescribing trends due to the broad spectrum of conditions encountered and the frequent use of multiple medications. Polypharmacy, which is often intended to achieve synergistic therapeutic effects or manage comorbidities, is common especially among the elderly and patients with chronic illnesses, increasing the risk of drug-drug interactions.⁹ These interactions can alter drug efficacy, leading to either diminished therapeutic outcomes or heightened toxicity, underscoring the necessity of comprehensive medication review and monitoring.

This study aimed to evaluate prescription patterns in patients attending ENT OPD of a tertiary care hospital, assess adherence to the National List of Essential Medicines (NLEM) 2022, and analyse potential drug-drug interactions. Identifying inappropriate prescribing trends and implementing corrective measures can enhance patient safety and treatment efficacy, thereby promoting rational pharmacotherapy.

METHODS

Study design and approval

A single-centre, cross-sectional, observational study was conducted over 18 months in a tertiary care teaching

hospital after taking approval from the Ethics Committee for Academic Research Projects (ECARP/2022/131) and permission from the concerned department heads.

Inclusion criteria

Inclusion criteria included patients aged over 18 years of either gender visiting the ENT OPD and prescribed at least one medication were included.

Exclusion criteria

Exclusion criteria included patients unwilling to provide consent.

Sample size calculation

The study included 326 patients, representing a six-month patient population of 2160. The sample size was determined using a 95% confidence level and a 5% confidence interval.

Methodology

Written informed consent was obtained from all the patients. Data were collected from patients' medical records and through personal interviews, then documented in the case record form (CRF). The recorded information included demographic details, clinical parameters such as diagnosis and comorbidities, and medication details. Drug – drug interactions were assessed by using Medscape drug interaction checker, a widely used online tool that provides comprehensive information on potential interactions between medications.

Statistical analysis

Data were entered and analysed in Microsoft Excel 365. Continuous variables were represented as the mean±standard deviation (SD), while categorical variables were presented as frequencies and percentages.

RESULTS

Demographic details

Of the 326 patients included in this study, 166 (50.9%) were male, and 160 (49.1%) were female, resulting in a male-to-female ratio of 1.03:1. The age of the patients ranged from 18 to 80 years, with a mean age of 38.2±13.9 years. The majority of the patients (n=207, 63.5%) were within the 18–40 years age group.

Data on disease distribution and comorbidities

Among the 326 patients studied, ear disorders were the most common reason for ENT consultation (164, 50.3%), followed by throat (70, 21.5%), nasal (65, 19.9%), and other head and neck conditions (27, 8.3%). CSOM was the most common diagnosis, observed in 85 (26.1%) patients.

Pharyngitis was the second most frequent diagnosis overall and the leading throat disorder (36, 11.0%). Among nasal conditions, non-allergic rhinitis was most prevalent (19, 5.8%), followed by deviated nasal septum (DNS) in 16 (4.9%). Conditions not classified under ear, nose, or throat – such as gastro-oesophageal reflux disease (GERD) (4%), cervical lymphadenopathy (2.1%), submandibular and infra-auricular swellings (0.9% each) and vestibular migraine (0.3%) – were categorized as 'others'. The distribution of diagnoses is illustrated in Figure 1. Comorbidities were present in 42 patients (12.9%), with hypertension being most common (15, 35.7%), followed by hypothyroidism (13, 31%). Other comorbidities included diabetes with hypertension (4, 9.5%), diabetes alone (3, 7.1%), rheumatoid arthritis and depression (2, 4.8% each), and single cases of bronchial asthma, cerebrovascular accident, and ulcerative colitis (2.4% each).

Analysis of the prescription pattern of drugs

A total of 326 prescriptions, comprising 1204 drugs, were analysed, with an average of 3.7±1.3 drugs per

prescription. Monotherapy was observed in 14 (4.3%) prescriptions, while the majority (312, 95.7%) included two or more drugs as depicted in Figure 2.

The prescribed drugs were categorized into 15 classes (Figure 3). Antimicrobials were most frequently prescribed, appearing in 236 (72.4%) prescriptions, with 19 different agents used. The most common oral antimicrobial was Amoxicillin + Clavulanic acid (171, 52.5%), while Clotrimazole was the most used topical agent (75, 23%). Antihistamines followed, prescribed in 221 (67.8%) prescriptions, predominantly Levocetirizine (202, 62%).

Other commonly prescribed drug classes included nonsteroidal anti-inflammatory drugs (NSAIDs), proton pump inhibitors (PPIs), corticosteroids, and local anaesthetics, with paracetamol, pantoprazole, beclomethasone and lignocaine among the most frequently used medications. Supportive medications such as nasal decongestants, antacids, nutritional supplements, and antiseptics were also frequently included. A detailed breakdown of drug categories and their distribution is provided in Table 1.

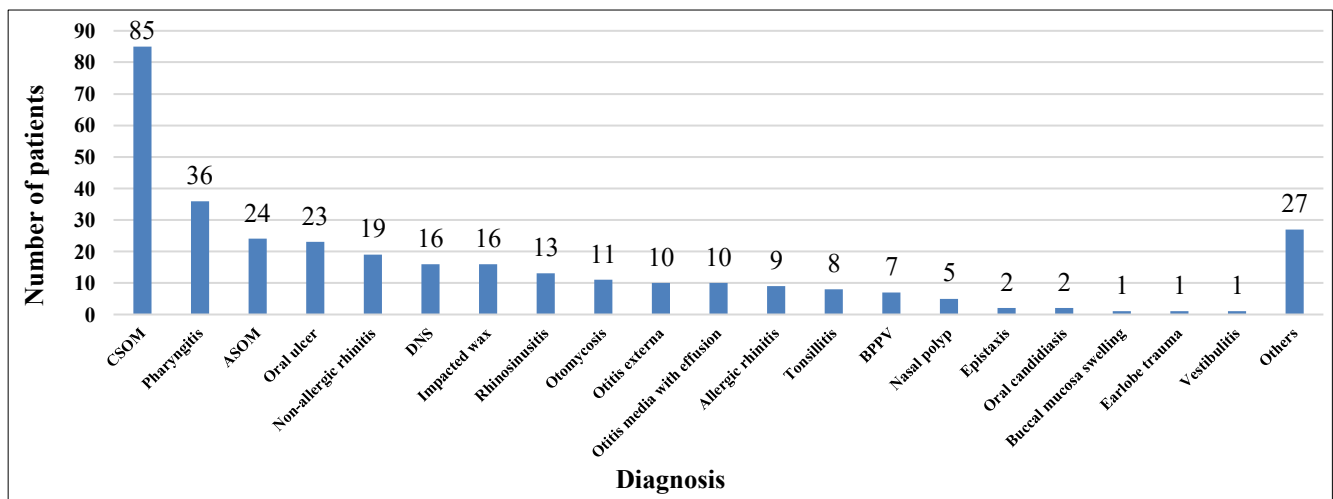


Figure 1: Disease distribution of the study population.

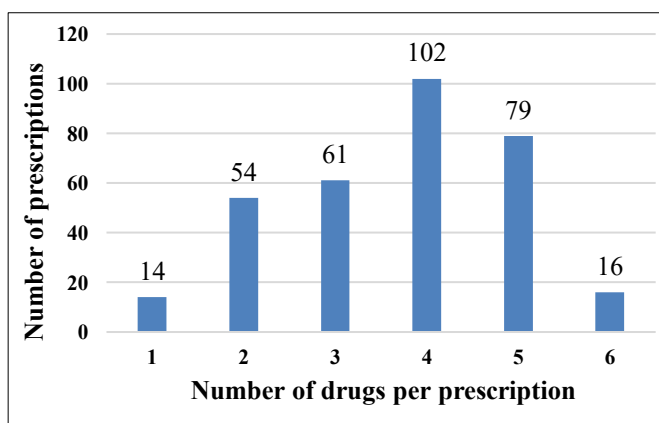


Figure 2: Distribution of total number of drugs prescribed per prescription.

Dosage forms

The oral route accounted for 896 drugs (74.4%), with tablets being the most common form (824, 68.4%). Topical medications accounted for 308 drugs (25.6%), primarily in the form of ear and nasal drops (211, 17.5%). No injectables were prescribed (Figure 4). Of the 1204 drugs, 799 (66.4%) were prescribed by generic name and 405 (33.6%) by brand name.

Fixed-dose combinations (FDCs)

They accounted for 473 drugs (39.3%), with 26 different combinations. The most frequently used FDCs were Amoxicillin + Clavulanic acid (171, 52.5%), Neomycin + Beclomethasone + Clotrimazole + Lidocaine (56, 17.2%), and Oxethazaine + Aluminium hydroxide + Magnesium

hydroxide (44, 13.5%). Other commonly used FDCs included Levocetirizine + Montelukast (40, 12.3%) and multivitamin B-complex (MVBC) (39, 12.0%). Remaining combinations, each contributing less than 5%, included various antimicrobials, anti-inflammatory agents, antiallergics, gastrointestinal drugs, and cough preparations.

Hospital formulary and NLEM 2022

A total of 56 different drugs were prescribed, with 19 (34%) listed in the hospital formulary and 23 (41%) in the NLEM 2022. Fourteen drugs were common to both, including pantoprazole, amoxicillin + clavulanic acid, paracetamol, xylometazoline, povidone iodine, ciprofloxacin (oral and topical), montelukast, vitamin c,

cefixime, cetirizine, azithromycin, fluconazole, doxycycline, and folic acid.

Drugs present in the formulary but absent from NLEM included levocetirizine, trypsin chymotrypsin, MVBC, and a topical combination of benzocaine, chlorbutol, paradichlorobenzene, and turpentine oil. Conversely, chlorhexidine gluconate, clotrimazole, tranexamic acid, cefuroxime, clindamycin, mupirocin, flunarizine, and prednisolone were part of NLEM but not in the formulary.

Drug–drug interactions

Out of 326 prescriptions, 7 (2.1%) exhibited minor interactions, while no major drug interactions were observed (Table 2).

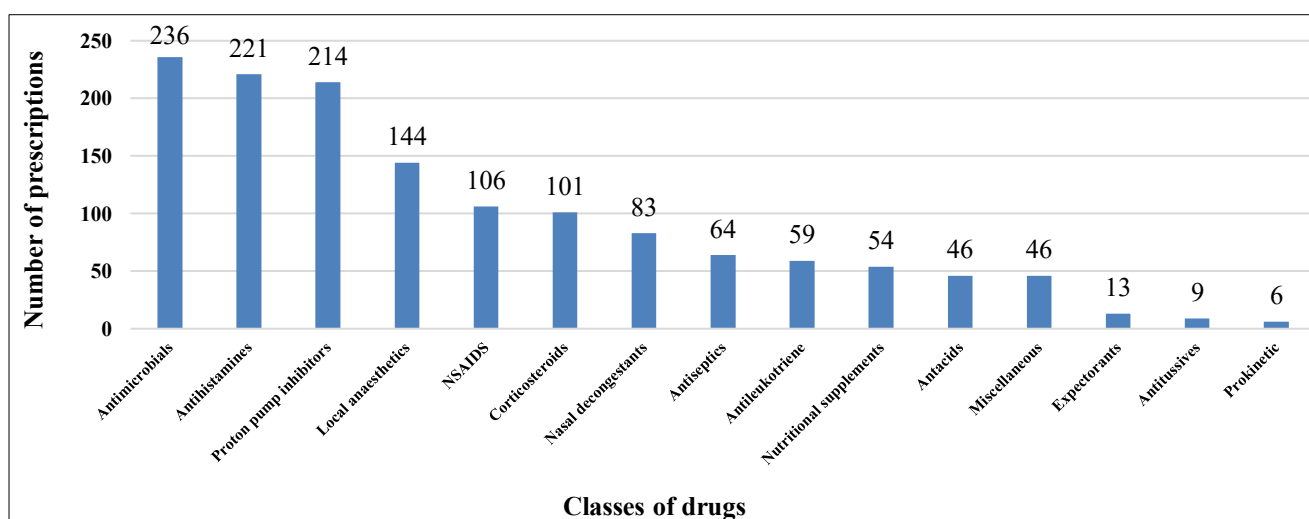


Figure 3: Various classes of drugs prescribed.

Table 1: Distribution of various drugs prescribed (n=326).

| Drug class | Drug name | Route | Number of prescriptions, N (%) |
|-----------------------|--|---------|--------------------------------|
| Antimicrobials | Amoxicillin + clavulanic acid | Oral | 171 (52.5) |
| | Clotrimazole | Topical | 75 (23.0) |
| | Neomycin sulphate | Topical | 62 (19.0) |
| | Ciprofloxacin | Topical | 39 (12.0) |
| | Metronidazole | Topical | 20 (6.1) |
| | Ciprofloxacin | Oral | 10 (3.1) |
| | Cefixime | Oral | 8 (2.5) |
| | Cefixime + clavulanic acid | Oral | 8 (2.5) |
| | Chloramphenicol | Topical | 8 (2.5) |
| | Gentamicin | Topical | 6 (1.8) |
| | Azithromycin | Oral | 3 (0.9) |
| | Cefpodoxime proxetil + clavulanic acid | Oral | 2 (0.6) |
| | Fluconazole | Oral | 2 (0.6) |
| | Fluconazole | Oral | 2 (0.6) |
| | Polymyxin B | Topical | 2 (0.6) |
| | Cefuroxime | Oral | 1 (0.3) |
| | Doxycycline | Oral | 1 (0.3) |
| | Clindamycin | Oral | 1 (0.3) |
| Ofloxacin | Topical | 1 (0.3) | |

Continued.

| Drug class | Drug name | Route | Number of prescriptions, N (%) |
|--------------------------------|---|--------------|--------------------------------|
| | Mupirocin | Topical | 1 (0.3) |
| Antihistaminics | Levocetirizine | Oral | 202 (62.0) |
| | Cetirizine | Oral | 12 (3.7) |
| | Chlorpheniramine | Oral | 9 (2.8) |
| | Azelastine | Topical | 5 (1.5) |
| | Fexofenadine | Oral | 4 (1.2) |
| Local anaesthetics | Lignocaine | Topical | 93 (28.5) |
| | Oxethazaine | Oral | 44 (13.5) |
| | Benzocaine | Topical | 16 (4.9) |
| Corticosteroids | Beclomethasone | Topical | 70 (21.5) |
| | Fluticasone | Topical | 18 (5.5) |
| | Dexamethasone | Topical | 6 (1.8) |
| | Betamethasone | Topical | 4 (1.2) |
| | Prednisolone | Topical | 1 (0.3) |
| | Prednisolone | Oral | 1 (0.3) |
| | Triamcinolone acetonide | Topical | 1 (0.3) |
| Nasal decongestants | Xylometazoline | Topical | 76 (23.3) |
| | Phenylephrine | Oral | 10 (3.1) |
| Expectorants | Ambroxol hydrochloride | Oral | 10 (3.1) |
| | Ammonium chloride | Oral | 3 (0.9) |
| | Guaiphenesin | Oral | 3 (0.9) |
| Antitussives | Dextromethorphan | Oral | 5 (1.5) |
| | Levodropropizine | Oral | 4 (1.2) |
| Proton pump inhibitors | Pantoprazole | Oral | 208 (63.8) |
| | Rabeprazole | Oral | 6 (1.8) |
| NSAIDS | Paracetamol | Oral | 106 (32.5) |
| Antiseptics | Povidone iodine | Topical | 42 (12.9) |
| | Chlorhexidine gluconate | Topical | 25 (7.7) |
| Antileukotriene | Montelukast | Oral | 59 (18.1) |
| Nutritional supplements | MVBC, vitamin C, folic acid | Oral | 54 (16.6) |
| Antacids | Aluminium hydroxide, magnesium hydroxide, sodium bicarbonate, calcium carbonate | Oral | 46 (14.1) |
| Prokinetic | Domperidone | Oral | 6 (1.8) |
| Miscellaneous | Wax softeners, Hemocoagulase, Serratiopeptidase, Trypsin chymotrypsin, Tranexamic acid, Flunarizine, Sodium alginate, Prochlorperazine, Betahistine | Oral/topical | 46 (14.1) |

Table 2: List of the minor potential drug interactions found in the analysed prescriptions.

| Drug prescribed to patients in ENT OPD | Drug prescribed for comorbidity | No. of prescriptions with drug-drug interactions (n=326) | Percentage of prescriptions |
|--|---------------------------------|--|-----------------------------|
| Amoxicillin | Methotrexate | 2 | 0.6 |
| Pantoprazole | | | |
| Amoxicillin | Aspirin | 1 | 0.3 |
| Amoxicillin | Sulfasalazine | 1 | 0.3 |
| Diclofenac | Escitalopram | 1 | 0.3 |
| Aluminium hydroxide | Rosuvastatin | 1 | 0.3 |
| Prochlorperazine | Metformin | 1 | 0.3 |

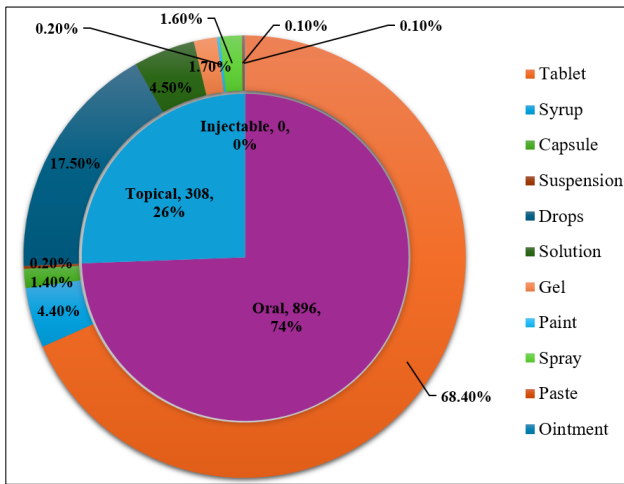


Figure 4: Routes of administration with various dosage forms prescribed.

DISCUSSION

The gender distribution in our study showed minimal difference, with 50.9% male and 49.1% female patients (male-to-female ratio: 1.03:1), aligning with findings by Vijay et al.¹⁰ The urban setting of our tertiary care hospital may account for this distribution, as greater awareness of self-care in cities contrasts with studies from rural areas. Most patients (63.5%) were aged 18–40 years, similar to findings by Kumari et al (53.3%) and Aalasyam et al (44.8%), likely due to higher environmental exposure among the working population.^{11,12}

CSOM was the most common ear disorder, affecting 85 (26.1%) patients, consistent with studies by Aalasyam et al, and Sah et al.^{12,13} The higher incidence of CSOM in developing countries is likely due to socioeconomic constraints, malnutrition, and limited healthcare access. Inadequate management of eustachian tube dysfunction at peripheral healthcare centres may contribute to chronic infections requiring tertiary care intervention.¹⁴ Pharyngitis was the most frequent throat disorder, diagnosed in 36 (11%) patients, similar to findings by Sah et al.¹³ Delayed hospital visits for sore throat, often perceived as a minor issue, may contribute to its prevalence. Non-infectious factors such as smoking, pollution, acid reflux, and postnasal drip could also play a role.¹⁵

A total of 1204 drugs were prescribed to 326 patients, averaging 3.7 ± 1.3 drugs per prescription, with most prescriptions containing 4 (31.3%) or 5 (24.2%) drugs, consistent with findings by Kumari et al (average 3.3).¹¹ Polypharmacy, defined as the concurrent use of five or more medications, was observed due to the empirical treatment of multiple ENT symptoms such as otorrhea, ear pain, and sore throat.¹⁶ Various drug classes, including antimicrobials, antihistamines, analgesics, antacids, and nasal decongestants, contributed to this trend.

Antimicrobials were the most frequently prescribed drugs (72.4%), followed by antihistamines (67.8%), similar to study by Kumari et al.¹¹ While many ENT infections are viral and self-limiting, differentiating bacterial from viral causes based on symptoms alone is challenging, often leading to empirical antibiotic use to prevent complications. Amoxicillin with clavulanic acid was the most prescribed oral antimicrobial and FDC (52.5%), aligning with findings by Aalasyam et al.¹² This combination is preferred for its effectiveness against β -lactamase-producing bacteria, commonly implicated in ENT infections such as otitis media, sinusitis, and tonsillitis.¹⁷ Clotrimazole (23%) was the most commonly used topical antimicrobial, often combined with corticosteroids and anaesthetics for effectively treating fungal infections secondary to antibacterial use.

Levocetirizine was the most prescribed antihistamine (62%), preferred over cetirizine (3.7%) due to its reduced sedative effects and higher efficacy at lower doses.¹⁸ These findings are consistent with Sah et al, whereas Sonawane et al reported cetirizine as the preferred choice.^{13,19} Antihistamines play a crucial role in alleviating rhinitis symptoms such as itching, sneezing, and rhinorrhoea, further justifying levocetirizine's widespread use.¹⁸

In our study, PPIs were primarily prescribed for GERD, oral ulcers, and to prevent gastrointestinal side effects of antimicrobials, analgesics, and antipyretics. Pantoprazole was the preferred choice, likely due to its lower risk of drug interactions compared to omeprazole.²⁰ Paracetamol was the most common NSAID due to its safety and efficacy as an antipyretic and analgesic, consistent with the symptomatic nature of ENT conditions. Xylometazoline nasal drops were commonly used for conditions such as rhinitis, deviated nasal septum, and rhinosinusitis, owing to their efficacy in reducing nasal congestion.²¹

In our study, tablets were the most commonly prescribed dosage form, aligning with findings from Vijay et al.¹⁰ This preference is attributed to the frequent use of antimicrobials and antihistamines, which are primarily available in tablet form, offering convenience and patient compliance. Syrups were preferred for expectorants and antitussives to manage cough and throat irritation, while topical formulations like ear and nasal drops were widely used for conditions such as otitis media and rhinitis. Dosage forms were chosen to ensure patient compliance and targeted treatment.

Generic prescribing accounted for 66.4% of drugs, aligning with studies by Aalasyam et al, Sonawane et al, promoting cost-effective, rational therapy.^{12,19} The most common topical FDC was Neomycin Sulphate + Beclomethasone + Clotrimazole + Lidocaine ear drops, offering comprehensive management of infections, inflammation, and pain relief. Only 34% of prescribed drugs were from the hospital formulary, significantly lower than findings of Aalasyam et al (96%), highlighting the need for better formulary alignment with prescribing trends.¹²

In our study, 41% of drugs were prescribed from NLEM 2022, lower than the rates reported by Sonawane et al (81.48%).¹⁹ NLEM promotes rational drug use by ensuring safety, efficacy, and cost-effectiveness while encouraging generic prescribing.²² Pantoprazole and amoxicillin + clavulanic acid were the most commonly used NLEM-listed drugs, whereas levocetirizine, though not in NLEM, was frequently prescribed as part of the hospital formulary. The variation between NLEM and hospital formulary reflects differing national and local healthcare priorities.

Drug-drug interactions (DDIs) occur when one drug alters the effects of another when taken concurrently. Major interactions pose serious risks, while minor interactions, though less severe, should still be avoided.²³ In our study, no major DDIs were identified, but 2.1% of prescriptions had potential minor interactions. Below, we have discussed a few interactions as examples rather than an exhaustive list of all observed cases.

Two prescriptions showed a potential interaction between methotrexate and either amoxicillin or pantoprazole, both of which can decrease methotrexate clearance, leading to toxicity. Patients receiving these combinations should be closely monitored for adverse effects such as myelosuppression and gastrointestinal toxicity.²⁴ A minor interaction was noted in one prescription between amoxicillin and sulfasalazine, where amoxicillin may reduce sulfasalazine's conversion into its active components, 5-aminosalicylic acid and sulfapyridine, potentially lowering its efficacy in conditions like ulcerative colitis and rheumatoid arthritis.²⁵ Monitoring and dosage adjustments may be necessary.

These findings underscore the importance of monitoring potential interactions to improve patient safety.

Limitations

Being a cross-sectional observational study with a limited sample size, it does not capture long-term prescription trends or seasonal variations in disease patterns. Additionally, since it was conducted in a single tertiary care hospital within one ENT OPD unit, the findings may not be generalizable to broader populations.

CONCLUSION

This study provides valuable insights into the prescribing patterns in the ENT outpatient department, highlighting key trends in drug selection, dosage forms, and prescribing practices. The findings emphasize the predominance of oral and topical medications, with antimicrobials being the most frequently prescribed class of drugs. While a significant proportion of prescriptions adhered to generic prescribing and rational drug use principles, the lower inclusion of hospital formulary and NLEM-listed drugs suggests opportunities for optimizing prescribing practices. The minimal occurrence of potential drug-drug interactions reflects careful prescription monitoring; however,

continued vigilance is essential to enhance patient safety. These observations underscore the importance of periodic prescription audits to ensure adherence to evidence-based guidelines, promote rational drug use, and improve overall prescribing trends in clinical practice.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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