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Original Research Article

Drug utilization pattern in patients of upper respiratory tract infections in pediatrics outpatient department at a tertiary care hospital

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ABSTRACT

Background: Upper respiratory tract infections are the most common and frequently occurring infections in the pediatric population. These infections include conditions like common cold, laryngitis, pharyngitis, tonsillitis, acute rhinitis, acute rhinosinusitis and acute otitis media. Young children have an average of 6-8 colds per year, however 10-15% of children have at least 12 infections per year. This study concentrates on prescription pattern of Upper Respiratory Tract Infections in children. primary objective was to study the prescription pattern of drugs used in URTI in pediatric outpatient department and the secondary objective was to determine whether the drugs being prescribed comply with those listed in the National list of essential medicines.

Methods: This study was a Cross-sectional, observational study conducted at the Pediatric Outpatient Department in a tertiary care hospital, India. The data was collected from patients visiting Pediatrics OPD from June 2021 to December 2021 after taking written informed consent. Sample size was calculated to be 303.

Results: Total 943 drugs were prescribed for 303 patients with an average of 3.11 ± 1.15 drugs per prescription. Most common class of drugs prescribed was Antipyretics of which Paracetamol was the most common drug. Antibiotics were prescribed for 19.80% patients & combination of Amoxicillin and Clavulanic acid was the most common antibiotic prescribed. 68.29% drugs were prescribed by generic name. 43.16% drugs were prescribed from National List of Essential Medicines 2015.

Conclusions: The study revealed that the majority of children suffering from URTI were below 5 years of age. Our study highlighted the prescribing trends of drugs used in treatment of URTI in children and provided insights for better patient management decisions.

Keywords: Drug utilization study, Pediatric population, Essential medicines, Prescription pattern

INTRODUCTION

Upper Respiratory Tract Infections (URTI) are the most common and frequently occurring infections in the pediatric population.¹ It is described as an acute, self-limiting inflammation of the upper respiratory tract mucosa that may involve any or all of the nose, throat, sinuses and larynx.² The infections of this tract include conditions like common cold, laryngitis, pharyngitis,

tonsillitis, acute rhinitis, acute rhinosinusitis and acute otitis media.³ These infections have a high cost to society, being responsible for absenteeism of children from school and parents from work.⁴ Young children have an average of 6-8 colds per year, however 10 to 15% of children have at least 12 infections per year.⁵ Upper Respiratory Tract Infections account for the most frequent visits to pediatricians than any other infectious diseases among children.⁴ It accounts for 20-65% of outpatient and 12-35% of inpatient attendance in General Hospitals.⁶ Most of the

time URTIs have a viral origin; Only 10% of URTI has been attributable to bacterial etiology.⁷ Viruses that usually cause these infections include rhinoviruses, parainfluenza viruses, respiratory syncytial virus and coronaviruses. Other agents that occasionally cause upper respiratory tract infections include adenoviruses, enteroviruses, influenza viruses, reoviruses and *Mycoplasma pneumoniae*.⁸ URTIs are characterised by nasal congestion, rhinorrhoea, sneezing, runny nose, cough, sore throat, fever, myalgia and anorexia with a median duration of symptoms of 7-15 days.^{3,9} The management of URTI of viral origin involves symptomatic treatment like antihistamines, antipyretics or anti-inflammatory agents, antitussives, mucolytics and decongestants.¹ Therefore, antimicrobial agents are not required unless the infection is complicated by tonsillitis, sinusitis, acute otitis media as well as infection of lower respiratory tract.⁴

Drug utilization study is defined by the World Health Organization (WHO) as “the marketing, distribution, prescription and use of drugs in society, with special emphasis on the resulting medical, social and economic consequences.”¹⁰ Prescription pattern covers the extent of profiles of drug use, trends in drug use and cost over time.¹⁰ Prescription monitoring may help in identifying the problems that are involved in therapeutic decision and promote the rational drug prescribing.¹¹ The primary objective of this study is to understand the prescription pattern of drugs used in upper respiratory tract infection in pediatric outpatient department at a tertiary care hospital in India and the secondary objective is to determine whether the drugs being prescribed comply with those listed in the National list of essential medicines 2015.

METHODS

This study was a cross-sectional, observational study conducted at the pediatric outpatient department of Topiwala National Medical College and B. Y. L. Nair Charitable Hospital, a tertiary care teaching hospital in Mumbai city of Maharashtra state of India. The data was collected from the case paper sheets of patients visiting Pediatrics OPD from June 2021 to December 2021. Sample size was calculated based on the patient load of URTI cases in pediatric outpatient department which was approximately 60 per week which came to around 240 in a month. To represent 6 months patient population of 1440, sample size was calculated using 95% confidence level and 5% confidence interval as per sample size calculator¹² which came to be 303. Convenient sampling technique was used.

Study was conducted after taking written informed consent from the patient's parent/guardian if child was less than 7 years of age and child assent statement verbally if age of the child was more than 7 years. Inclusion criteria were pediatric patients up to 12 years, Patients with URTI of either gender, who were prescribed with at least one drug.

Exclusion criteria were patients/Guardians not willing to participate, mentally retarded patients, patients suspected with lower respiratory tract infections. Data was collected on case record form (CRF) by personal interview with patients, patient's parents/guardian and case paper sheets. Demographic details (age, gender), necessary clinical data (presenting complaints, diagnosis) was noted. Medication details included total number of drugs prescribed per prescription, antimicrobials per prescription, name, frequency, dose, duration and route of administration of drug, prescribed by generic or brand name, fixed dose combinations used, number of drugs prescribed from National List of Essential Medicines (NLEM). Data was analysed using descriptive statistics on Microsoft excel 365.

RESULTS

Total 303 prescriptions of URTI were analyzed.

Table 1: Various classes of total number of drugs prescribed (n=943).

| Class of drugs | N | Percentage | |
|--------------------------------------|-----------------------|------------|-------|
| Antipyretics | 154 | 16.33 | |
| Nasal preparations | 144 | 15.27 | |
| Antihistamines | 111 | 11.77 | |
| Mucolytics | 87 | 9.23 | |
| Antibiotics | 65 | 6.89 | |
| Cough and cold preparations | 58 | 6.15 | |
| Bronchodilators | 17 | 1.80 | |
| Antitussives | 6 | 0.64 | |
| Otic agents | 2 | 0.21 | |
| Concomitant drugs | Vitamins and Minerals | 246 | 26.09 |
| | Others | 53 | 5.62 |
| | | | |
| Total no. of drugs prescribed | 943 | 100 | |

Table 2: Number and percentage of various groups of drugs prescribed (n=303).

| Group of drugs prescribed | N | Percentage | |
|-----------------------------|-----------------------|------------|-------|
| Antipyretics | 154 | 50.82 | |
| Nasal preparations | 144 | 47.52 | |
| Antihistaminic | 111 | 36.63 | |
| Mucolytics | 87 | 28.71 | |
| Antibiotics | 60 | 19.80 | |
| Cough and cold preparations | 58 | 19.14 | |
| Bronchodilators | 17 | 5.61 | |
| Antitussives | 6 | 1.98 | |
| Otic agents | 2 | 0.66 | |
| Concomitant drugs | Vitamins and minerals | 151 | 49.83 |
| | Others | 35 | 11.55 |
| | | | |

Table 3: Total number and Percentage of prescriptions with antibiotics.

| Class | Total no. of antibiotics | % of total no. of antibiotics prescribed (N=65) | Percentage of prescriptions with antibiotics (N=303) |
|---------------------------------------|--------------------------|---|--|
| Penicillin + Beta lactamase inhibitor | 53 | 81.54 | 17.49 |
| Fluoroquinolones | 4 | 6.15 | 1.32 |
| Cephalosporins | 3 | 4.62 | 0.99 |
| Macrolides | 3 | 4.62 | 0.99 |
| Aminoglycosides | 2 | 3.07 | 0.66 |
| Total antibiotics | 65 | 100 | 19.80 |

Table 4: Total number and percentage of prescriptions with antipyretics prescribed.

| Name of antipyretic drug | Total no. of antipyretics | % of total no. of antipyretics prescribed (N=154) | Percentage of prescriptions with antipyretics (N=303) |
|--------------------------|---------------------------|---|---|
| Paracetamol | 147 | 95.45 | 48.51 |
| Ibuprofen+Paracetamol | 7 | 4.55 | 2.31 |
| Total | 154 | 100 | 50.82 |

Table 5: Total number and percentage of prescriptions with antihistamines prescribed.

| Name of Antihistaminic drug | Total no. of antihistamines | % of total no. of antihistamines prescribed (N=111) | Percentage of prescriptions with antihistamines (N=303) |
|--------------------------------|-----------------------------|---|---|
| Chlorpheniramine Maleate (CPM) | 76 | 68.47 | 25.08 |
| Levocetirizine | 15 | 13.51 | 4.95 |
| Cetirizine | 12 | 10.81 | 3.96 |
| Fexofenadine | 8 | 7.21 | 2.64 |
| Total | 111 | 100 | 36.63 |

Table 6: Total number and percentage of prescriptions with cough and cold preparations prescribed.

| Name of cough and cold preparation | Total no. of cough and cold prep. prescribed | % of total no. of cough and cold preparation prescribed (N=58) | Percentage of prescriptions with cough and cold preparation (N=303) |
|---|--|--|---|
| Chlorpheniramine Maleate (CPM)+Dextromethorphan | 39 | 67.24 | 12.87 |
| CPM+Phenylephrine+PCM +Sodium Citrate | 9 | 15.52 | 2.97 |
| Phenylephrine+Chlorpheniramine Maleate+Dextromethorphan | 3 | 5.17 | 0.99 |
| Montelukast+Levocetirizine | 3 | 5.17 | 0.99 |
| CPM+Phenylephrine | 2 | 3.45 | 0.66 |
| Ambroxol+levosalbutam+ Guaifenesin | 2 | 3.45 | 0.66 |
| Total | 58 | 100 | 19.14 |

Total 57.10% of the total study population was males and 42.90% were females (Figure 1). Male to female ratio is 1.33:1. Age distribution is depicted in (Figure 2) which shows that Majority of patients i.e., 105 (34.65%) were of age group 1 month to 1 year. Out of 303 patients, 218

patients (71.95%) were diagnosed as Non- Specific URTI (Figure 3). The average number of total drugs per prescription were 3.11 ± 1.15 (Mean \pm SD). Most common route of administration was oral (82.71%) followed by topical (16.55%) and inhalational (0.74%).

Table 7: Total number and Percentage of prescriptions with Nasal preparations prescribed.

| Name of Nasal preparation | Total no. of Nasal preparation prescribed | % of total no. of Nasal preparation prescribed (n=144) | Percentage of Prescriptions with Nasal preparation (n=303) |
|---------------------------------------|---|--|--|
| Normal Saline (Sodium Chloride) | 80 | 55.56 | 26.40 |
| Benzalkonium Chloride+Sodium Chloride | 64 | 44.44 | 21.12 |
| Total | 144 | 100 | 47.52 |

Table 8: Fixed dose combinations prescribed for management of URTI.

| Name of drugs | N | % |
|---|------------|------------|
| Benzalkonium chloride+sodium chloride | 64 | 34.04 |
| Amoxicillin+Clavulanic Acid | 53 | 28.19 |
| Dextromethorphan+Chlorpheniramine Maleate | 39 | 20.74 |
| Chlorpheniramine Maleate+Phenylephrine+Paracetamol+Sodium Citrate | 9 | 4.79 |
| Ibuprofen+Paracetamol | 7 | 3.72 |
| Montelukast+Levocetirizine | 3 | 1.60 |
| Phenylephrine+Chlorpheniramine Maleate +Dextromethorphan Hydrobromide | 3 | 1.60 |
| Benzocaine+Chlorbutol+Paradichlorobenzene +Turpentine oil | 2 | 1.06 |
| Chlorpheniramine Maleate+Phenylephrine | 2 | 1.06 |
| Ambroxol+Levosaltbutamol+Guaifenesin | 2 | 1.06 |
| Neomycin+Polymyxin B | 2 | 1.06 |
| Asthalin+Budesonide | 2 | 1.06 |
| Total | 188 | 100 |

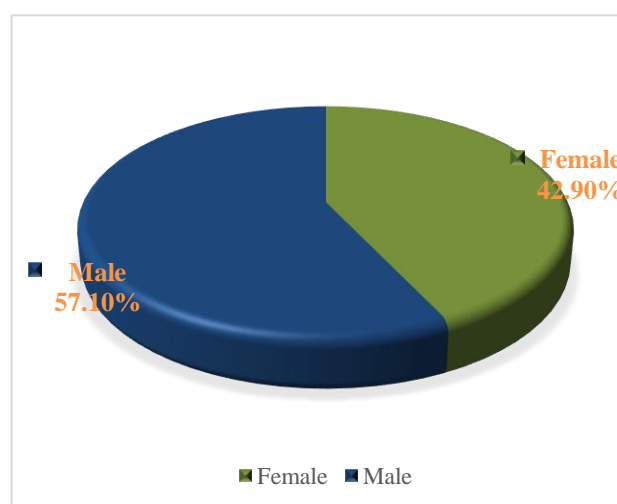
Total 943 drugs were prescribed in 303 prescriptions. Out of these, 644 (68.29%) drugs were prescribed for the management of URTI and 299 (31.71%) drugs were concomitant drugs. The drugs were divided into 10 classes (Table 1-2).

Table 9: Number and percentage of drugs for management of URTI prescribed.

| Name of drug | N | % |
|-------------------------------|------------|------------|
| Paracetamol | 147 | 48.84 |
| Chlorpheniramine Maleate | 76 | 25.25 |
| Amoxicillin + Clavulanic acid | 53 | 17.61 |
| Cetirizine | 12 | 3.99 |
| Salbutamol | 5 | 1.66 |
| Azithromycin | 3 | 1.00 |
| Cefixime | 3 | 1.00 |
| Ciprofloxacin | 2 | 0.66 |
| Total | 301 | 100 |

The most common class of drug prescribed for the management of URTI was antipyretics i.e., 154 (16.33%) (Table 2) depicts the number and percentage of various groups of drugs in total prescriptions. In 303 prescriptions, a total of 65 (21.45%) antibiotics were prescribed. Penicillin+Beta lactamase inhibitor (Amoxicillin+Clavulanic Acid) was the most commonly prescribed antibiotic (81.54%) (Table 3). As depicted in (Table 4),

total number of antipyretics prescribed were 154 (50.82%) in total prescriptions. Paracetamol was the most common antipyretic prescribed (95.45%).

**Figure 1: Gender distribution.**

In this study, 4 different antihistaminic drugs were prescribed in 111 (36.63%) prescriptions and it constituted 11.77% of total drugs (Table 5). Chlorpheniramine Maleate (CPM) was the most commonly prescribed antihistaminic drug (68.47%).

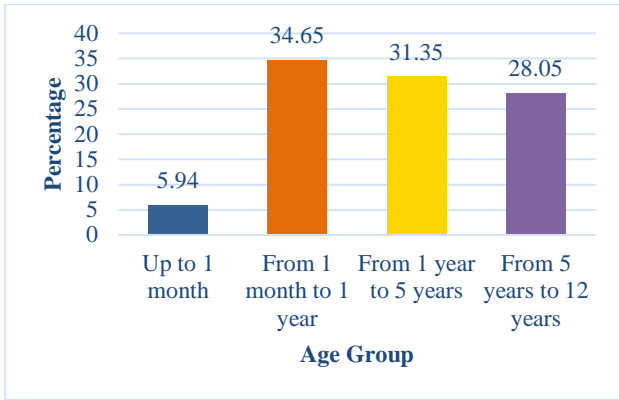


Figure 2: Age distribution.

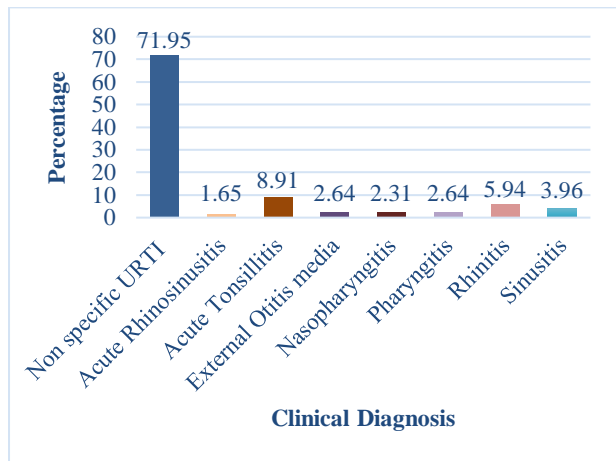


Figure 3: Clinical diagnosis.

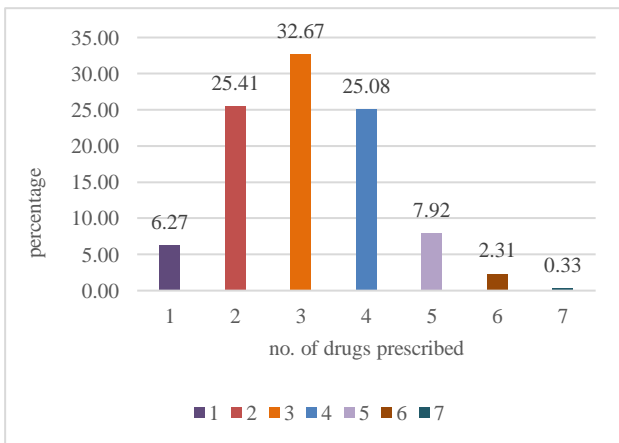


Figure 4: Number and percentage of drugs prescribed per prescription.

Among the 303 prescriptions, total number of cough and cold preparations prescribed was 58 (19.14%). Chlorpheniramine Maleate (CPM) + dextromethorphan was the most commonly prescribed cough and cold preparation. (67.24%) as depicted in (Table 6). As shown in (Table 7), Total number of nasal preparations prescribed was 144 (47.52%). and constituted 15.27% of total drugs. Normal Saline nasal drops was most commonly prescribed

nasal preparation. (55.56%). Out of the total 943 drugs, 299 (31.71%) were prescribed by brand name and 644 drugs (68.29%) were prescribed by generic name. As shown in (Table 8), 341 (36.16%) drugs were prescribed as fixed dose combinations. Among these 341 fixed dose combinations, 188 (55.13%) FDCs were prescribed specifically for Upper Respiratory Tract Infections and 153 (44.87%) FDCs were concomitant drugs like vitamins, minerals and other drugs. As shown in (Figure 4), out of the total 303 prescriptions, 19 (6.27%) prescriptions had only one drug (monotherapy) and the remaining 284 (93.73%) prescriptions had 2 or more than 2 drugs. Average number of drugs prescribed per prescription was 3.11 ± 1.15 . Out of the total 943 drugs prescribed, 407 (43.16%) drugs were prescribed from National List of Essential Medicines 2015. Out of the total 644 drugs prescribed for management of URTI, 301 (46.74%) drugs were prescribed from NLEM 2015 as shown in (Table 9).

DISCUSSION

The primary aim of our study was to monitor drug utilization pattern in pediatric patients of URTI attending the Pediatrics OPD in our hospital. Total 303 prescriptions were analyzed. 57.10% of the patients were males whereas 42.90% were females similar to study done by Joshi et al (58.33% males) and Tiwari et al (55.47% males).^{1,3} 71.94% of URTI in children were seen in up to 5 years of age. This was in accordance with study conducted by Das et al (75.6% patients in the age group 0 to 5 years).¹³ This may be due to less immunity at younger age, more susceptibility for infections or due to a relatively greater concern for child's health. Non-specific URTI was most common diagnosis in 71.95% patients which was higher as compared to studies by Mungrue et al (54.5%) and Bharathi et al (49.1%).^{14,15} This may be because defining most of respiratory diseases is difficult as the presentations are partly overlapping. Most common route of administration was oral (82.71%) followed by topical route (16.55%) similar to studies by Tiwari et al (86%) and Alkahtani et al (95.6%).^{3,16} Oral route is the most preferred route as it is safe and convenient to administer in children in outpatient setting. Most commonly prescribed class of drugs was Antipyretics (50.83%). In study done by Alkahtani et al it was 30.27%.¹⁶ This result is expected as most of the children with URTIs may need an anti-pyretic agent because they are likely to present with fever. Antibiotics were prescribed to 19.80% patients and the most commonly prescribed antibiotic was Amoxicillin+Clavulanic Acid similar to study conducted by Das et al.¹³ The use of antibiotics in our study was lower than Alkahtani et al (72.70%) and Mohsin et al (93%).^{16,17} Most of the time URTIs have a viral origin; Only 10% of URTI has been attributable to bacterial etiology.⁷ Thus, use of antibiotic in children for the treatment of URTI is evidently inappropriate unless the infection was proven to be bacterial. The misuse of antibiotic, especially in children can lead to bacterial resistance and various undesirable side effects associated with the antibiotic use. In present study, a large number of patients were treated without the

use of antibiotic, which is a good sign of rational prescribing. Chlorpheniramine was most commonly prescribed antihistaminic drug (68.47%) in our study. In study done by Bharathi et al it was 40.4%.¹⁵ Chlorpheniramine is preferred as it is part of NLEM, economical and can aid patient to sleep better because of its sedative action. Antipyretic drugs constituted 16.33% of total drugs and Paracetamol was most commonly prescribed drug (95.45%) similar to study done by Das et al (18.8%) in which Paracetamol (81.3%) was most commonly prescribed drug.¹³ Most of the children with URTIs may need an antipyretic agent because they are likely to present with fever. Paracetamol is commonly used because it is one of the best drugs to be used as antipyretic for fever due to any cause, especially in children.¹⁸ Cough and cold preparations were prescribed in 19.14% prescriptions similar to study done by Alkahtani et al (19.18%).¹⁶ Nasal preparations constituted 15.27% of total drugs similar to study done by Tiwari et al (15%).³ Nasal drops help relieve congestion and makes breathing easier for children hence commonly used. Average number of drugs prescribed per prescription is an important indicator for assessing rationality of prescription. In our study, it was 3.11 which was higher than the study conducted by Ghosh et al (1.98) Alkahtani et al (2.24) and Das et al (2.37) and lower than Mohsin et al (3.75), Bharathi et al (3.38).^{13,15-19} It is preferable to keep the mean number of drugs per prescription as low as possible to prevent the unfavourable outcomes of polypharmacy. In our study, 68.84% drugs were prescribed by generic name which is higher than study done by Ghosh et al (60%).¹⁹ In contrast, Study conducted by Sankhla et al reported 86.61%, prescribed by brand names.²⁰ Prescribing by generic name should be promoted as it helps the hospital pharmacy to have a better inventory control, limits commercial influence and are often more economical than the branded ones. In our study, 36.16% drugs were prescribed as FDCs which is lower than Tiwari et al (56%), Das et al (59.2%).^{3,13} In our study, 43.16% drugs were prescribed from National List of Essential Medicine 2015 which was higher than Tiwari P. et al (38%) whereas Ghosh et al reported 56.5% of drugs prescribed from NLEM.^{3,19} The prescribing from the NLEM should be promoted for optimal use of financial resources and to satisfy the health care needs of the majority of the population safely.

CONCLUSION

Our study highlighted the prescribing trends of drugs used in treatment of URTI in children and provided insights for better patient management decisions. To the best of our knowledge, our study was the first of its kind to be done in our institute in recent years. Limitations of our study were that it was a cross-sectional observational study with limited sample size. The study duration was short and hence seasonal variations could not be assessed. Our study was carried out at a single centre; Hence the results of this study cannot be generalized.

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