INTRODUCTION

Increasing morbidity and mortality owing to infectious diseases, in spite of the availability of lifesaving antibiotics, is an alarming global situation. Infectious diseases are common among pediatric patients in India and contribute to the total mortality rate, which is the highest in the world.

Antibiotic resistance, which is a threat to public health, is rapidly increasing globally. In order to avoid unnecessary antibiotic prescribing and development of antibiotic resistance, pediatric healthcare facilities in India are advised to follow the Indian Academy of Pediatrics list of essential medicines (IAP-LEM). The present study was conducted to evaluate the prescription patterns of antibacterial drugs used in upper respiratory tract infection in pediatric age group admitted to a tertiary care hospital and to study whether there is any deviation from standard protocol in the usage of antibacterial drugs among them.

AIM

To evaluate the prescription patterns of antibacterial drugs used in upper respiratory tract infection in pediatric age group admitted to a tertiary care hospital.

ABSTRACT

Introduction: Infectious diseases like diarrhea, URTI are common among pediatric patients in India. Appropriate use of antibiotics is vital in reducing the mortality caused by bacterial infections. However, antibiotics are often prescribed incorrectly and improperly for un-indicated conditions. Thus the present study was conducted to evaluate the prescription patterns of antibacterial drugs used in URTI in pediatric age group admitted to a tertiary care hospital and whether there is any deviation from standard protocol in the usage of the drugs. Method: A cross-sectional study conducted at Dr.D.Y.Patil Medical College, Hospital and Research Center, Pune from January 2016 to December 2016 with sample size of 150 which included the diagnosed cases of URTI of either gender who are on none other than antibacterial drugs upto age of 14 years whose parents’ consent is obtained. For evaluation of the antibacterial prescription patterns, Modified Kunin’s criteria and Case Record Forms were used. The study was approved by Institutional Ethics Committee. Appropriate statistical calculations were done on Excel sheet. Results and Discussion: Among 150 cases, highest cases of URTI were males of less than 5 years old with male to female ratio of 1.2:1. The most common symptom was cough, present in 105 cases and throat congestion being the sign in 82 cases. 64 cases were diagnosed with common cold. Multiple antibiotics were given in 79 cases, most preferred was Cefpodoxime. Majority of the children were given oral antibiotics for 3-7 days. According to Kunin’s criteria, 55 cases fell under Category II. Conclusion: This study has found the need for a standard treatment guideline, taking into account the local sensitivity pattern of the organisms. The present study serves to highlight the current treatment practice of these infections in our hospital and pave the way for further interventions that can help implement the rational use of medicines.

KEY-WORDS: URTI, Antibiotic, Kunin’s Criteria, Paediatric.
OBJECTIVES
1. To study the prescription patterns of antibacterial drugs used in upper respiratory tract infection in pediatric age group admitted to a tertiary care hospital.

2. To study whether there is any deviation from standard protocol in the usage of antibacterial drugs in the pediatric age group.

The present study was conducted among 150 children (≤14 years) to evaluate the prescription patterns of antibacterial drugs used in upper respiratory tract infection admitted to a tertiary care hospital.

MATERIAL AND METHODS
The study approved by Institutional Ethics Committee was explained and written informed consent was obtained.

An observational cross sectional study was conducted in Dr. D. Y. Patil Medical College, Hospital and Research Center, Pune from January 2016 to December 2016.

The sample size was 140 at 99% confidence interval calculated by using OperEPi software.4 Additional 10 samples were taken considering loss of sample after data collection. Final sample size was kept 150.

The study involved diagnosed cases of URTI in children upto 14 years age whose parents’ consent is obtained and children of either gender who are prescribed antibacterial drugs. Children of parents with negative consent and those prescribed other drugs than antibacterials were excluded.

For evaluation following methods were used
- Modified Kunin’s criteria,3
- Case record form.

Modified Kunin’s criteria: Appropriateness of the antibacterial drug used on the basis of this criteria which considers choice, dose, route, frequency and duration for the drug. The treatment was scored from 1 to 5 with 5 being most appropriate and 1 being least.

The cases are categorized as follows
1. Indication and protocol of the antibacterial therapy are appropriate
2. Agree with the use of antibacterial therapy, the protocol is probably appropriate. Microbiological evidence is lacking to confirm the diagnosis
3. Agree with the use of antibacterial therapy, but a different drug (less expensive, less toxic, narrower spectrum, other combination) will be appropriate.
4. Agree with the use of antibacterial therapy but a modified dose, interval, duration or route of administration will be appropriate
5. Disagree with the use of antibacterial therapy, administration is unjustified.

Categories I and II indicated ‘appropriate therapy’, Categories III and IV indicated ‘major deficiency’ in the choice or use of antibacterials, and Category V indicated ‘unnecessary’ antibacterial use.

Following data were included in the case record form
1. Patient details
2. Chief complaints
3. Personal history
4. Past history
5. Family history
6. General examination
7. Systemic examination
8. Lab investigations
9. Diagnosis
10. Drug therapy – brand and generic name, dosage form, schedule, route, date of administration, date of stopping and cost.

Statistical Analysis
Appropriate statistical calculations are done for analysis. Graphs were prepared using microsoft excel sheet.

OBSERVATIONS AND RESULTS
Following tables and graph shows observations of the study.

Age wise distribution of study cases.
Table 1: Age wise distribution of study cases.

<table>
<thead>
<tr>
<th>Age</th>
<th>Number of Patients (%)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;5 yr</td>
<td>63</td>
<td>42.0</td>
</tr>
<tr>
<td>5-10 yr</td>
<td>54</td>
<td>36.0</td>
</tr>
<tr>
<td>10-14 yr</td>
<td>33</td>
<td>22.0</td>
</tr>
<tr>
<td>Total</td>
<td>150</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 1 shows distribution of the cases according to their age. Among the 150 cases, highest cases [63 (42%)] of URTI were less than 5 year old followed by 54 (36%) cases aged between 5 and 10 years. Remaining 33 (22%) cases from age group 10-14 years. Mean age of cases was 6.69 years with Standard deviation of 3.1 yr.

Gender wise distribution of study cases.
Table 2: Gender wise distribution of study cases.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number of Patients (%)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>82</td>
<td>54.7</td>
</tr>
<tr>
<td>Female</td>
<td>68</td>
<td>45.3</td>
</tr>
<tr>
<td>Total</td>
<td>150</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Table 2 shows distribution of the cases according to their gender. Among the 150 cases of URTI males were 82 (54.7%) and females were 68 (45.3%). Male to female ratio was 1.2:1.
Distribution of study cases according to presenting symptoms

Figure 1 shows distribution of the cases according to their presenting symptoms. Among the 150 cases, cough was the most common symptom present in 105 (70%) cases followed by running nose (57.3%) and sore throat (43.3%). Other presenting symptoms were fever, stridor, wheezing, ear pain and ear discharge.

Distribution of cases according to clinical signs

Figure 2 shows distribution of the cases according to clinical signs. Among the 150 cases, throat congestion was the most common sign present in 82 (54.6%) cases. Second most common sign was fever above 38°C (25.3%) followed by exudate (10.6%) and tender cervical lymphnodes (9.3%).

Distribution of cases according to clinical diagnosis

Figure 3 shows distribution of the cases according to clinical diagnosis. Among the 150 cases, common cold was most commonly diagnosed in 64 (42.7%) cases. Second most common diagnosis was pharyngitis (25.3%) followed by tonsillitis (18%) and bronchitis (6.7%). Other less frequency diagnosis includes otitis media, bronchiolitis and pneumonia. 5 cases (3.3%) were having multiple conditions.

Distribution of cases according to antimicrobial agent prescription

Figure 4 shows distribution of the cases of URTI according to antibiotics prescribed for the treatment. As shown in the table, the most common drug was CEFPODOXIME which was prescribed in 76 (30%) cases followed by AZITHROMYCIN which was prescribed in 63 (24.9%) cases. Combination formula of AMOXICILLIN + CLAVULANATE was prescribed in 48 (19.0%) cases and AMOXICILLIN alone prescribed in 35 (13.8%) cases. Amoxicillin alone and in combination together made the count of 83 (32.8%). CO-TRIMOXAZOLE was prescribed in 18 (7.1%), CEFIXIME in 7 (2.8%), ERYTHROMYCIN in 4 (1.6%) and DOXYCYCLINE in 2 (0.8%) cases. OFLOXACIN, CEFUROXIME and CIPROFLOXACIN were not prescribed in any cases.

Distribution of cases according to number of antibiotic prescription

Figure 5 shows distribution of the cases according to number of Antibiotic prescription.
Figure 5 shows distribution of the cases according to number of antibiotic prescription for treatment. Among the 150 cases, single antibiotic was prescribed in 24 (16%) cases. Multiple antibiotics were prescribed in 79 (52.7%) children and fixed dose combinations in 47 (31.3%) cases.

Distribution of cases according to duration of antimicrobial therapy

![Bar chart showing distribution of cases according to duration of therapy](image)

Figure 6: Distribution of cases according to duration of Antimicrobial therapy.

Figure 6 shows distribution of the cases according to duration of antibiotic therapy. Among the 150 cases, less than 3 days therapy was prescribed in 24 (16%) cases. 3 to 7 days therapy was prescribed in 79 (52.7%) cases and more than 7 days therapy in 47 (31.3%) cases. Mean duration of prescribed therapy was 4.9 days with standard deviation of 1.8 days.

Distribution of cases according to route of administration of antibiotic.

![Pie chart showing distribution of cases according to route of administration](image)

Figure 7: Distribution of cases according to route of administration of Antibiotic.

Figure 7 shows distribution of the cases according to route of administration of antibiotics. Among the 150 cases, most common route of antibiotic administration was oral ingestion in 110 (73.3%) cases. Intramuscular antibiotic was given in 7 (4.7%) cases and Intravenous antibiotic was given in 33 (22%) cases.
Distribution of cases according to Kunin’s criteria

Table 3: Distribution of cases according to Kunin’s criteria.

<table>
<thead>
<tr>
<th>Kunin’s criteria</th>
<th>Cases</th>
<th>Percentage</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria I</td>
<td>42</td>
<td>28.0</td>
<td>Evidence of Laboratory reports concluding the etiology of infection and treating accordingly</td>
</tr>
<tr>
<td>Criteria II</td>
<td>55</td>
<td>36.7</td>
<td>Microbiology testing was not performed to confirm diagnoses. Clinical improvement speaks in favor of correct empiric treatment</td>
</tr>
<tr>
<td>Criteria III</td>
<td>26</td>
<td>17.3</td>
<td>Too many antibacterials were given concomitantly, the combination of antibacterials was not synergistic or antibiotic cover was inadequate in some cases</td>
</tr>
<tr>
<td>Criteria IV</td>
<td>11</td>
<td>7.3</td>
<td>The patients were given intravenous antibacterial when patient was able to take orally</td>
</tr>
<tr>
<td>Criteria V</td>
<td>16</td>
<td>10.7</td>
<td>Infections were viral in origin, antibacterials not required</td>
</tr>
</tbody>
</table>

| Total            | 150   | 100.0      | |

**DISCUSSION**

**Age profile of URTI cases:** Among the 150 cases, highest cases [63 (42%)] of URTI were less than 5 year old followed by 54 (36%) cases aged between 5 and 10 years. Remaining 33 (22%) cases from age group 10-14 years. Mean age of cases was 6.69 years with Standard deviation of 3.1 yr.

Similar age distribution was also observed in a study by Al-khalidi YM et al where about 50% of children were under the age of 5 years. In a study by Iyer GS et al the mean age of the study subjects was 2.26 ± 2.42 years (range 1.5 months to 11 years) and about half the patients (45.8%) were less than one-year-old.

**Gender distribution of URTI cases:** Among the 150 cases of URTI, male were 82 (54.7%) and female were 68 (45.3%). Male to female ratio was 1.2:1.

In a study by Iyer GS et al the number of boys (69.6%) was almost twice the number of girls. Higher proportion of male child was also observed in a study by Al-khalidi YM et al, where male were 55% and female 45%.

**Symptomatology of URTI cases:** Among the 150 cases, cough was the most common symptom present in 105 (70%) cases followed by running nose (57.3%) and sore throat (43.3%). Other presenting symptoms were fever, stridor, wheezing, ear pain and ear discharge.

In a study by Iyer GS et al the most common presenting complaints were cough (97%), fever (92%), and breathlessness (50%). Al-khalidi YM et al, in their study observed that the main complaints were cough (70%), runny nose (57%), and sore throat (43%).

**Antibiotic prescribed among URTI cases:** Among 150 cases, the most common drug was CEFPODOXIME which was prescribed in 76 (30%) cases followed by AZITHROMYCIN which was prescribed in 63 (24.9%) cases. Combination formula of AMOXICILLIN + CLAVULANATE was prescribed in 48 (19.0%) cases and AMOXICILLIN alone prescribed in 35 (13.8%) cases. Amoxicillin alone and in combination together made the count of 83 (32.8%). CO-TRIMOXAZOLE was prescribed in 18 (7.1%), CEFIXIME in 7 (2.8%), ERYTHROMYCIN in 4 (1.6%) and DOXYCYCLINE in 2 (0.8%) cases. OFLOXACIN, CEFUROXIME and CIPROFLOXACIN were not prescribed in any cases.

In a study by Iyer GS et al amoxicillin/clavulanate (47%) and cefotaxime (22%) were the most common antibiotics prescribed for URTI. This finding is
comparable to other studies reported from Kathmandu\textsuperscript{[8]} and Palestine.\textsuperscript{[9]}

**Combination of antibiotic therapy:** Among the 150 cases, single antibiotic was prescribed in 24 (16%) cases. Multiple antibiotics prescribed in 79 (52.7%) and fixed dose combinations were prescribed in 47 (31.3%) cases.

In a study by Iyer GS et al\textsuperscript{7} majority (125/201) cases received two or more antibiotics.

In Japan, the resistance of group-A streptococcal isolates to erythromycin, which was 62% in 1974, fell to less than 2% in 1988 when macrolides use was reduced from 22% to 8%.\textsuperscript{[10]}

**Duration of antibiotic therapy:** Among the 150 cases, less than 3 days therapy was prescribed in 24 (16%) cases. 3 to 7 days therapy in 79 (52.7%) cases and more than 7 days therapy in 47 (31.3%) cases. Mean duration of prescribed therapy was 4.9 days with standard deviation of 1.8 days.

In a study by Iyer GS et al\textsuperscript{7} the average number of antibacterials prescribed per patient was 1.85 ± 0.86 (range 1-5).

**Appropriateness of antibacterial use by the modified Kunin’s criteria:** Based on Kunin’s criteria, 42 (28%) prescription fall under Category I. In 55 (36.7%) prescriptions the criteria was according to Category II. 26 (17.3%) prescriptions were in accordance with Category III. 11 (7.3%) prescriptions were classified in Category IV and 16 (10.7%) cases, according to the Category V. It was observed that antibacterials were prescribed in bronchiolitis where they have a limited value.\textsuperscript{[11]} Similar observations have been made before.\textsuperscript{[9]}

In a study by Iyer GS et al\textsuperscript{7} no case could be classified under category I and cases falling under category II were 42%, almost half were in category III and 9% cases were in category V.

Studies conducted world-wide\textsuperscript{[5,11,12]} reported ADRs due to irrational use of antibacterials, which were preventable.

Drug Utilization Studies can help us facilitate the rational use of medicines and ensure the prudent use of the available resources.\textsuperscript{[13]} Education of the prescribers and the caregivers is imperative.

As observed in the present and the other studies, over-prescribing of antibiotics for ARIs is widespread globally, across medical specialties and payment sources.\textsuperscript{[14]} The majority of antibiotics prescribed in ambulatory practice in the USA are for acute sinusitis, acute pharyngitis, and nonspecific URTI.\textsuperscript{[15]}

There have been many forms of interventions aimed at changing physicians’ prescribing behaviour, like audit studies, group discussion and feedback, introduction of general practice drug formulary or hospital formulary\textsuperscript{[16]}, guidelines for antibiotics\textsuperscript{[17]} use.

Khoja et al\textsuperscript{[18]} have pointed out that the implementation of ARTI protocol resulted in the reduction of prescribing different medications including antibiotics.

**CONCLUSION**

In conclusion, this study has found the need for a standard treatment guideline for our own hospital, taking into account the local sensitivity pattern of the organisms. Although culture and antibiotic susceptibility were not performed to confirm the rationality of the antibacterial used, the present study serves to highlight the current treatment practice of these infections in our hospital and pave the way for further interventions that can help implement the rational use of medicines.

**REFERENCES**


