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Original Research Article

Prescribing pattern of antimicrobials and adverse drug reactions in children suffering from lower respiratory tract infection in tertiary care hospital

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ABSTRACT

Background: Acute respiratory tract infections are leading cause of mortality in children in India. Further, indiscriminate use of antimicrobials has led to increased drug resistance and large number of adverse drug reactions (ADR). Therefore, aim of study was to study antimicrobial prescribing pattern and record incidence and causality assessment of ADRs in pediatric in-patients having lower respiratory tract infection (LRTI).
Methods: In this prospective and observational study total of 300 children aged 2 months to 12 years suffering from LRTI and hospitalized for minimum 48 hrs duration were included. A descriptive analysis was carried out to determine frequency and combinations of antibiotics prescribed and causality and number of ADRs.
Results: Out of 300 subjects, 70.3% of patients were males and 54.6% of cases with LRTI belonged to 2-6 months age group. The most frequently prescribed antibiotic was ceftriaxone alone in 67 (22.3%) patients while ceftriaxone and amikacin was the most common 2 drug combination in 60 (20%) patients. Ceftriaxone, ampicillin and gentamicin was most common 3 drug combination in 7 (2.3%) patients. There were 49 cases (16.3%) of ADRs and maximum were in 2-6 months age group and ceftriaxone with amikacin was associated with maximum number 10 (20.4%) of cases. Diarrhoea was most frequent adverse effect associated with antibiotics in 36 (76.6%) cases.
Conclusions: The use of cephalosporins (single or combination) are most commonly used drug and associated with maximum number of ADRs in 2-6 months male children with LRTI so clinicians should use them judiciously and rationally.

Keywords: Antimicrobials, Adverse drug reactions, Lower respiratory tract infection

INTRODUCTION

Acute respiratory tract infections (ARI) contribute to more than 75% of health care seeking in primary health care facilities.[1] About 90% of ARI deaths are due to pneumonia, which is usually bacterial, pneumococcus being the commonest pathogen.[2,3] Undernourished children, particularly the ones not exclusively breastfed or with inadequate zinc intake, are at a higher risk of developing pneumonia.[4] Similarly, children and infants suffering from other illnesses, such as AIDS or measles, are more likely to develop pneumonia. Environmental factors, such as living in crowded homes and exposure to parental smoking or indoor air pollution also play a role in increasing child susceptibility to pneumonia and its severe consequences.[5]

The most common LRTI are pneumonia, bronchitis and bronchiolitis.[6] In India, recent epidemiological assessments in under-fives suggest that 13% of deaths and 24% of national burden of disease is due to pneumonia while hospital-based studies have reported 20%-30% of admissions in under-fives attributable to same cause. Case fatality rates of 8.7%-47% have been reported in hospitalized children.[7,8] To help reduce mortality from these diseases, World Health Organization introduced case management guidelines based on simple clinical signs (fast breathing) for diagnosing pneumonia followed by empirical treatment with antibiotics.[9]

Chest X-rays and laboratory tests are used to confirm presence of LRTI, including extent and location of the infection and its cause. But in resource-poor settings without access to these technologies, suspected cases of LRTI are diagnosed by their clinical symptoms. Children and infants are presumed to have LRTI if they exhibit cough and fast or difficult breathing.[10] Caregivers, therefore, have an important role to play in recognizing the symptoms of LRTI in children and seeking appropriate medical care as necessary. Antimicrobial agents are the commonly prescribed drugs for children.[11] Because most cases of community acquired pneumonia are due to Haemophilus influenzae and Streptococcus pneumoniae, co-trimoxazole, penicillin, ampicillin, and amoxicillin have been recommended for control programmes.[12]

Most often, antibiotics are prescribed for diseases without laboratory confirmation of microbial etiology and in conditions where potential benefit of antibiotic therapy is uncertain (e.g. otitis media).[13] Inappropriate antibiotic prescription in acute respiratory infections (ARI) is a major problem in developed countries. Evidence on the extent of problem in developing countries is still limited.[14] Earlier studies have shown that use of broad-spectrum antibiotics increased from 10.6% to 40.6% for bronchitis in a span of 6 years from 1993 to 1999.[15] and 85% of antibiotics prescribed for respiratory tract infection in children less than 5 years of age were inappropriate.[1] In addition, indiscriminate use of antibiotics drives up the cost of health care, leads to plethora of side effects and drug interactions and fosters the emergence of bacterial resistance.[16]

Adverse drug reactions (ADRs) are an important public health problem. A meta-analysis of 17 prospective studies performed in United States and Europe in 1973-2000 period estimated that the incidence of ADRs in hospitalized children is 9.53% and in pediatric outpatients 1.46%.[17] However data supporting prescribing pattern of antimicrobials and ADRs in pediatric population is limited in Indian set-up and based on outdated research, therefore this study was done to provide current evidence which may be helpful in introducing and implementing possible policies and interventions on improving antibiotics usage and decreasing /avoiding incidence of ADRs in developing countries like India.

METHODS

The study was conducted in Department of Pediatrics and Pharmacology, UCMS and GTB Hospital; Delhi. The study design was prospective and observational with a sample size of 300 children. All consecutive patients suffering from lower respiratory tract infection and admitted in pediatric ward, GTB Hospital were included. Clearance from institutional human ethics committee, written informed consent (from parent or caretaker of each subject before participation in study) and care of each subject was done as per declaration of Helsinki and guidelines on good clinical practice.

Inclusion criteria

- Age 2 months to 12 years, both sexes
- Hospitalized children in pediatric ward, who were prescribed antimicrobials for lower respiratory tract infection (diagnosed on clinical grounds and routine investigations, with or without radiological changes).

Exclusion criteria

- Patients with less than 48 hours hospitalization
- Reactions as a result of drug administration error, drug overdose or abuse and therapeutic failure, any guardian or caretaker unwilling to participate in the study.

The following assessments were done during course of study

- Patient characteristics such as age, sex, body weight, cases with previous drug history, duration of hospitalization were noted in an appropriately designed 'case record form' (CRF).
- Admission and discharge diagnosis, and condition of patient on admission and discharge were recorded in appropriately designed 'proforma for prescribing pattern'.
- Drug data, including name of drug, dosage regimen (form, route, frequency and duration), and the date on which pharmacotherapy was instituted was recorded in 'Proforma for prescribing pattern'.
- All patients were visited daily for ADRs in ward during hospitalization and followed up on day 7th and day 14th after discharge in OPD or at home.
- When a suspected ADR was encountered, data of the drug and reaction were documented in a suitably designed ADR documentation form that included the drug name, dosage, route and frequency of consumption along with details of the ADR.
- ADRs were recorded and causality assessment was carried out as per WHO and Naranjo probability scale.[18,19]
- Subjects were divided into 3 age groups for comparative analysis i.e. 2 months- 6 months, >6 months to 2 years and >2 years-12 years. A p value of less than 0.05 was taken for significance.

RESULTS

In this study, number of male patients (211) was higher than female patients (89) (Table 1). Out of 300 patients, 164 patients belonged to 2 months-6 months age group whereas 92 and 44 patients belonged to age groups >6 months-2 years and >2 years-12 years respectively (Table 1). From 300 patients of LRTI, 186 patients were diagnosed with pneumonia, 86 were diagnosed with wheeze associated lower respiratory tract infection (WALRTI), 15 had pleural effusion with consolidation, 7 were empyema and6 patients were post measles broncho-pneumonia (Table 1, Table 2).

During hospitalization, 71 patients were prescribed 1 antibiotic, 212 patients were prescribed 2 antibiotics and 17 patients received prescription of 3 antibiotics (Table 3). In patients of 2 months-6 months of age group, combination of ceftriaxone with amikacin was given to 54 patients which was highest in this age group.

Ceftriaxone alone was prescribed to 42 patients (Table 4) whereas in children of >6 months- 2 years of age group, 23 patients were prescribed a single antimicrobial agent which included ceftriaxone in 19 subjects and ampicillin in 4 subjects.

Table 1: Pediatric in-patient characteristics.

Parameter	No. of patients	Percentage
Age		
2 months-6 months	164	54.6%
>6 months-2 years	92	30.6%
>2years-12 years	44	14.8%
Sex		
Male	211	70.3%
Female	89	29.7%
Diagnosis		
Pneumonia	186	62%
WALRTI[a]	86	28.6%
Pleural effusion with consolidation	15	5%
Post-measles BPN[b]	06	2%
Empyema	07	2.4%

[a]-Wheeze associated lower respiratory tract infection; [b]-Bronchopneumonia

Table 2: Diagnostic pattern of LRTI in different age groups.

Diagnosis	2 months - 6 months		>6 months - 2 years		>2 years- 12 years		Total no. of patients	% of total patients
	No. of patients	%	No. of patients	%	No. of patients	%		
Pneumonia	114	38	51	17	21	7	186	62
WALRTI[a]	48	16	32	10.6	06	2	86	28.6
Pleural effusion with consolidation	-	-	05	1.6	10	3.3	15	5
Post-measles BPN[b]	-	-	04	1.3	02	0.6	06	2
Empyema	02	0.6			05	1.6	07	2.3

[a]-Wheeze associated lower respiratory tract infection; [b]-Bronchopneumonia

Table 3: Pediatric in-patient exposure to antibiotic(s).

Antibiotic(s)/patient	No. of patient	Percentage
1	71	23.7%
2	212	70.7%
3	17	5.6%

Most frequently prescribed combination of 2 antimicrobials was ampicillin with chloramphenicol (Table 5). In patients of >2 years-12 years of age group, 6 patients were prescribed single antibiotic drug. Most frequently prescribed combination of 2 antimicrobial agents was ceftriaxone with cloxacillin (Table 6). Maximum average length of stay per underlying infection in hospital was 14.6 days seen in patients diagnosed with empyema while minimum average duration of stay per underlying infection was 5.2 days observed in patients with WALRTI. The overall average duration of hospital stay was 8.34 days (Table 7).

Table 4: Frequency of antibiotic /combination of antibiotics prescribed for LRTI in 2-6 months of age.

Anti-microbial/combination of anti-microbials	No. of patients	%
Ceftriaxone	42	25.6%
Ceftriaxone and amikacin	54	32.9%
Ampicillin and gentamicin	24	14.6%
Ceftriaxone and cloxacillin	13	7.9%
Ampicillin and chloramphenicol	09	5.4%
Ampicillin and chloromycetin	06	3.6%
Ceftriaxone and vancomycin	04	2.4%
Amikacin and cloxacillin	04	2.4%
Ceftriaxone and gentamicin	02	1.2%
Meropenem and vancomycin	01	0.6%
Ceftriaxone, ampicillin and gentamicin	03	1.8%
Ceftiaxone, amikacin and cloxacillin	01	0.6%

Table 5: Frequency of antibiotic/combination of antibiotics prescribed for LRTI in >6 months-2 years of age.

Antimicrobial / combination of antimicrobials	No. of patients	%
Ceftriaxone	19	20.6%
Ampicillin	04	4.3%
Ampicillin and chloramphenicol	20	21.7%
Ceftriaxone and cloxacillin	11	11.9%
Ampicillin and gentamicin	10	10.8%
Ceftriaxone and amikacin	06	6.5%
Ampicillin and chloromycetin	05	5.4%
Ceftriaxone and ampicillin	04	4.3%
Ceftriaxone and chloramphenicol	04	4.3%
Ceftriaxone and vancomycin	02	2.1%
Crystalline penicillin and chloramphenicol	02	2.1%
Meropenem and amikacin	01	1.08%
Ceftriaxone, ampicillin and gentamicin	04	4.3%

Table 6: Frequency of antibiotic /combination of antibiotics prescribed for LRTI in >2-12 years of age.

Antimicrobial/combination of antimicrobials	No. of patients	%
Ceftriaxone	06	13.6%
Ceftriaxone and cloxacillin	11	25%
Ampicillin and chloramphenicol	07	15.9%
Crystalline penicillin and chloramphenicol	06	13.6%
Ceftriaxone and vancomycin	04	9.09%
Ampicillin and gentamicin	04	9.09%
Meropenem and vancomycin	02	4.5%
Meropenem and clindamycin	01	2.2%
Ceftriaxone, cloxacillin and amikacin	03	6.8%

Table 7: Duration of stay per underlying infection in hospital.

Diagnosis	Duration of stay (days)
Pneumonia	6.6
WALRTI	5.2
Pleural effusion with consolidation	9.3
Post-measles pneumonia	6
Empyema	14.6
Average duration	8.34

In a total of 300 patients, 49 (16.33%) patients developed adverse drug reactions while 251 subjects showed no adverse reaction to any drug.

In a total of 211 males, 32 male patients showed adverse drug reactions while out of 89 female patients, 17 showed ADRs (Table 8).

Table 8: Distribution of ADRs according to gender.

Gender	No. of patients studied	ADRs present	ADRs absent	%
Male	211	32	179	15.2%
Female	89	17	72	19.1%
Total	300	49	251	16.3%

It was also observed that patients in age group 2 months-6 months had maximum ADRs (17.68%) while patients in age group >2 years-12 years had minimum ADRs (13.64%) (Table 9).

Table 9: Distribution of ADRs in different age groups.

Age group	No. of patients	ADRs present	ADRs absent	%
2-6 months	164	29	135	17.6%
>6 months-2 years	92	14	78	15.2%
>2 years-2 years	44	6	38	13.6%
Total	300	49	251	15.5%

In present study, out of 49 cases of ADRs, 10 cases (8 cases of diarrhoea and 1 case each of vomiting and constipation) were due to ceftriaxone alone, remaining 39 cases were due to combination of antibiotics. Besides ADRs of gastrointestinal system, skin rashes were observed in 4 cases due to combination of ceftriaxone with cloxacillin and ampicillin with gentamicin (Table 10).

Table 10: Number and percentage of subjects with different ADRs.

Adverse drug reaction	No. of patients with ADRs	%
Diarrhoea	36	73.4%
Constipation	04	8.2%
Vomiting	03	6.1%
Diarrhoea with vomiting	02	4.1%
Skin rashes	04	8.2%
Total	49	100%

Most common combination of antibiotics associated with maximum ADRs were ceftriaxone with amikacin, ampicillin with gentamicin and ampicillin with chloramphenicol (Table 11).

DISCUSSION

The prescription of antimicrobials in children is done by clinicians who might not be familiar with the rationality of

drug choices and this may result in significant implications for the patient, legal and economic implications for the hospital, and medico-legal implications for the physician.

Table 11: Type and number of ADRs associated with different antibiotics.

Anti-microbial	ADRs	No. of patients
Ceftriaxone (i.v.)	Diarrhoea	08
	Vomiting	01
	Constipation	01
Ceftriaxone (i.v.) with cloxacillin (i.v.)	Diarrhoea	02
	Vomiting	01
	Diarrhoea with Vomiting	02
	Skin rashes	02
Ceftriaxone (i.v.) with amikacin (i.v.)	Diarrhoea	10
	Constipation	02
Ceftriaxone (i.v.) with gentamicin (i.v.)	Diarrhoea	02
Ampicillin (i.v.) with gentamicin (i.v.)	Diarrhoea	07
	Skin rashes	02
Ampicillin (i.v.) with chloramphenicol (i.v.)	Diarrhoea	07
	Constipation	01
Meropenem (i.v.) with clindamycin (oral)	Vomiting	01

Previous surveys have demonstrated that in approximately half of hospitalized patients given antimicrobials there is no clear indication for its use or that the choice and duration of therapy is not the most appropriate for the patient's clinical condition.[20] A study by WHO program for appropriate health care technology has shown a correlation between the occurrence of multi-resistant bacteria and antibiotic consumption pattern.[21] Throughout the 1990s, public health and professional organizations, including the Centre for Disease Control and Prevention (CDC), American Academy of Pediatrics, American Academy of Family Practice, American Society for Microbiology, and Alliance for the Prudent Use of Antibiotics undertook campaigns and interventions to promote appropriate antimicrobial use which is defined as use that maximizes therapeutic impact while minimizing toxicity and development of resistance.[22]

Detailed knowledge of antibiotic prescription pattern is important before policies and measures can be implemented. The present study was therefore undertaken in order to determine the prescribing pattern of antimicrobials in children and determine incidence and nature of adverse drug reactions so that clinicians can be familiar with the most common side effects of most frequently used antimicrobials. This will provide help to clinicians, pharmacologists, pharmaco-epidemiologists and pharmaco-economists in devising a comprehensive plan for better child care, resource management and adoption of safe and rational drug policies.

In present study, a total of 300 patients suffering from LRTI and hospitalized in pediatric ward were included. The results showed that 70.6% of cases were males and 54.6% of cases belonged to 2 months- 6 months age group. This provides the evidence that young male infants in developing countries are at significant health risk and hence clinicians, caretakers and health planners should adopt better strategies for these children. In present study the most frequent diagnosis of LRTI for which antibiotic drugs were prescribed, was pneumonia (62%) followed by WALRTI (28.67%), pleural effusion with consolidation (5%), empyema (2.33%) and post-measles broncho-pneumonia (2%). This study result was supported by an earlier study done by Bosu et al, which found that maximum number of children who received antimicrobial drugs were hospitalized for acute pneumonia.[23] In present study, out of 300 patients, blood culture and sensitivity tests were done on 270 (90%) patients out of which 28 (10.37%) were culture positive and 242 (89.63%) were culture negative. Out of 28 culture positive results, in 21 cultures, etiologic agent was streptococcus pneumoniae and in 7 cultures, etiological agent was staphylococcus aureus. In literature it is mentioned that blood cultures are positive in only 10%-20% of children with pneumococcal pneumonia.[24] In this study, mostly empirical antibiotics were prescribed for clinical conditions before laboratory confirmation of microbial etiology. This has been documented as the leading cause of drug resistance.

The excessive use of injectables is common in many developing countries. In present study except for clindamycin, other antimicrobials were administered by injectable route in all patients included in the study. This provides evidence that clinicians might be overprescribing the injectable antibiotics, however individual case to case variations (severity of LRTI) should be taken into account.

In present study, 70.7% of hospitalized patients were prescribed at least two antibiotics which was different from the study conducted by Palikhe N, which showed use of single antibiotic more as compared to drug combination.[25] This might be due to variation in selection of antimicrobials by physician or variable severity of underlying infection. Out of 300 hospitalized patients, it was observed that 71 children were given a single antibiotic, while 2 and 3 antimicrobials were prescribed to 212 and 17 patients respectively. A similar study done by Bosu et al, showed variation in the percentage of patients who were prescribed at least one antibiotic in different health centers.[23] These results provide the evidence that use of antibiotic drug combinations far exceeds the single administration and this might be helpful for resource managers and health planners to ensure adequate drug supplies in tertiary care setup.

ADRs account for 2.9%-15.4% of all hospital admissions in US. According to Lazarou et al, 1998, more than 100,000 hospitalized patients in USA die each year due to ADRs.[26] Prospective pediatric drug surveillance studies performed in six different countries, with two each in Germany and France have shown ADR incidence 1.5%-

19.9% in hospitalized children.[20] There are only a few such studies in India, so present study was undertaken in order to determine the incidence of ADRs in children. Out of 300 patients in present study, ADRs occurred in 49 (16.3%) patients. In present study, it was observed that age group 2 months-6 months had highest percentage cases of ADRs i.e. 29 (17.68%) while age group 2 years-12 years had minimum number of ADR patients which was 6 (13.64%). This provides evidence that young infants are the most vulnerable group and extra efforts (clinical, social and economic) should be undertaken for care of these children. In the present study highest percentage of adverse reactions were related to gastrointestinal system and diarrhoea was most common ADR in 82.2% of 91.8% gastrointestinal-related ADRs followed by constipation 8.9%, vomiting 6.7%, and diarrhoea with vomiting 4.4%. Present study also revealed that largest percentage cases of diarrhoea were associated with combination of ceftriaxone and amikacin (27.7%). These findings were similar to an earlier study conducted by Hoffman T et al, according to which non-clostridium difficile diarrhoea was commonly associated with ampicillin, amoxicillin-clavulanic acid, ceftriaxone, macrolides or trovafloxacin.[27] Present study also showed that 8.2% of patients with ADR had skin rashes. In another study conducted by Clavenna A et al, skin and gastrointestinal tract were the organ systems most commonly involved, and antibiotics were the drugs most frequently associated with ADRs in children.[17] These results provide evidence that clinicians should be aware of the most common ADRs caused by antibiotics and efforts should be made to use these drugs as rationally as possible. As per Naranjo ADR Probability Scale or WHO-UMC causality categories, 49 adverse drug reactions in this study were all 'possible' reactions because in 39 patients, ADRs were attributed to concurrent antimicrobials (combination of antimicrobials) and in all patients withdrawal (dechallenge) of drug was not done. All adverse events were of 'mild' severity since none resulted in any significant disability or required any additional management or prolongation of hospitalization.

The results of present study provided the evidence that age group 2-6 months male children are particularly susceptible to LRTI and develop maximum number of ADRs with combination of ceftriaxone and amikacin or ceftriaxone alone and hence, physicians should possess a clear understanding of the need of microbiological diagnosis(be judicious in use of empirical therapy), use of correct antibiotics (prescribing drug combinations rationally) and making good judgment in clinical situations which will result in decrease in incidence and severity of ADRs (knowledge of common ADRs) following the use of anti-microbial therapy.

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