

Original article:

Drug Utilization Study of Pediatric Patients Admitted with Respiratory Illness in Tertiary Care Hospital

Sumit Patel¹, Akanksha Prajapati², Nikunj H. Patel^{3*}

¹Assistant Professor, Department of Pharmacology, GCS Medical College, Ahmedabad, Gujarat, India.

²Tutor, Department of Pharmacology, GCS Medical College, Ahmedabad, Gujarat, India.

³Assistant Professor, Department of Pharmacology, Index Medical College, Indore, Madhya Pradesh, India.

Corresponding Author: Dr. Nikunj H. Patel, Assistant Professor, Department of Pharmacology, Index Medical College, Indore, Madhya Pradesh, India.

Date of submission: 11 July 2016, Date of acceptance: 24 August 2016

Abstract

Background: In comparison to adults, drug used in pediatrics is not extensively researched and the range availability of licensed drugs in appropriate dosage form is also limited. Effective medical treatment of pediatric patient is based upon an accurate diagnosis and optimum course of therapy. The pharmacokinetic and pharmacodynamics of the administered drugs are greatly altered in the pediatric age group due to the changing physiology. In the realm of pediatric pharmacotherapy, the investigation of drug utilization is used to examine different outcomes, including the examination of prescribing trends in clinical settings, the extent to which best practices in children differ from drug monograms/labelling and adult dosing guidelines

Method: This was prospective, observational, longitudinal single centre study conducted in pediatric ward of tertiary care teaching hospital. A total of 300 patients who were admitted in pediatric ward with respiratory diseases during the study period were included in the study.

Results: It was observed that of the 300 patients, Average number of drugs prescribed were 4.88. The antimicrobial agents were prescribed in 82% patients. Total 91% of the patients were treated with parenteral preparations while the remaining drugs were administered orally. According to National immunization program, 63.00 % were completely immunized, 28 % were partially immunized and 10% patients were found to have not received any vaccination as per their age.

Conclusion: We have found the need for a standard treatment guideline for our own hospital for the management of pediatric respiratory diseases.

Key words: Drug Utilization, Immunization, Outcome, Respiratory Illness.

INTRODUCTION

Pediatric age group comprises a major part of whole of the Indian population, almost about 40%.¹ Infancy and childhood is a period of rapid growth and development. Infants and children suffer from frequent but usually non-serious illnesses and the problem affecting children are often multifactorial. However, 50% of all deaths occurring among children during the first five years of life in the

developing world are attributed to premature birth, malnutrition and poor socio-economic status.² Effective medical treatment of pediatric patient is based upon an accurate diagnosis and optimum course of therapy. The pharmacokinetic and pharmacodynamics of the administered drugs are greatly altered in the pediatric age group due to the changing physiology.³ In comparison to adults, drug used in pediatrics is not extensively researched and

the range of availability of licensed drugs in appropriate dosage form is also limited. Most diseases encountered in pediatric age group are self-limiting however, they are often treated not only inappropriately but, also over enthusiastically that resort to the practice of poly-pharmacy.⁴

Studies show that respiratory tract infections are the most common cause of morbidity in pediatric age group.⁵ Respiratory disease includes the diseases of upper and lower respiratory tracts for example tonsillitis, sinusitis, otitis media, asthma, tuberculosis and pneumonia etc. The survey study conducted in the urban and rural areas revealed that the overall incidence of respiratory diseases in pediatric age group to be 20 % and it was found to be more in the urban areas (23%) as compared to rural areas (17.65 %). In the same study it was suggested that the incidence of pneumonia was 16 per 1000 children in urban area, 5 per 1000 in rural area, with the incidence being highest in the infant group.⁵

Different drug groups are used for the treatment of respiratory illnesses that include antimicrobials, bronchodilators, antihistaminic drugs, expectorants, antipyretics and many more.⁶ The use of antimicrobial agents, especially antibiotics has become a routine practice for the treatment of pediatric respiratory illnesses which at times could be irrational which may be causing even more serious health problems to the patients than the originally diagnosed ones.⁷ Studies from the U.S.A. and Canada have shown that the rate of antibiotic use in children less than 15 years of age was three times higher than any other age group, which clearly demonstrated that antimicrobial drug use was highest among children.⁸ Many of the antibiotics are unnecessarily prescribed for viral infections such as common cold.⁹ The rising incidence of bacterial resistance to common antibiotic has prompted the need to use antibiotics judiciously in pediatrics

practice. The pediatricians and other health care providers for infants and children in developing countries confront a number of challenges during the day to day practice of medicine due to the shortage of appropriate drugs and other facilities.¹⁰ In the realm of pediatric pharmacotherapy, the investigation of drug utilization is used to examine different outcomes, including the examination of prescribing trends in clinical settings, the extent to which best practices in children differ from drug monograms/labelling and adult dosing guidelines, and the correlation between medication errors and utilization.^{11,12}

Considering all these factors related to pediatric pharmacotherapy, we planned to undertake this study with the aim of analysing drug utilization pattern and outcome of patients with respiratory illness in a tertiary care teaching hospital.

MATERIALS AND METHODS

This was prospective, observational, cross-sectional, single centre study conducted in pediatric ward of tertiary care teaching hospital. A total of 300 patients who were admitted in pediatric ward with respiratory diseases during the study period were included in the study. In Inclusion criteria, we have included patients aged one month to 18 years of age and suffering from respiratory illness of any kind. We have excluded patients who were less than one month of age and suffering from other than respiratory illness.

The patients and parents/guardians of patients who read the Participant Information Sheet and who were willing to participate in the study were explained about the purpose and method of the study in the language they understood and only those patients were enrolled, whose guardians were willing to give written consent in the Informed Consent Form. Permission from the Institutional Ethics Committee was obtained before conducting the study.

An appropriate Case record Form (CRF) to evaluate management of patients was prepared which includes: Demographic information of the patient, presenting complaints, past history, family history, general and systemic examination including developmental milestones, vaccination history, laboratory investigations and diagnosis and

management of disease. The follow up of the patients was done till he/she was discharged or transferred to another department.

All data were entered in Microsoft excel, expressed as percentage, mean and standard deviation. They were analyzed and Chi-square test was applied where applicable.

Table 1: Total percentage of respiratory illness in patients (including both gender) grouped according to their age:

Groups of patients according to age	Age range	Number of patients		Total No. of patients (%)
		Male	Female	
I	1 month to 1 year	29	18	47 (15.66)
II	1-2 year	39	19	58 (19.33)
III	3-5 year	51	33	84 (28)
IV	6-11 year	42	26	68 (22.66)
V	12-18 years	27	16	43 (14.33)

Table 2: The diagnosis of the respiratory illness in the enrolled patients (including both genders).

Respiratory diseases	No. of patients affected (n=300)		Total patients (n=300)	Percentage (%)	P value
	Male	Female			
A. Upper respiratory tract illness					
Rhinitis/Sinusitis	21*	17	38	12.67	0.001
Pharyngitis	12*	10	22	7.33	0.001
Tonsillitis	13	15*	28	9.33	0.001
Foreign body inhalation	2	4	6	2.00	>0.05
Otitis media	12*	7	19	6.33	0.001
B. Lower respiratory tract illness					
Acute bronchitis	21	31*	51	17.33	0.001
Acute bronchiolitis	11*	7	18	6.00	0.001
Bronchial Asthma	13	28*	41	13.67	0.001
Status asthmaticus	3	2	5	1.67	>0.05
Pneumonia	43*	24	67	22.33	0.001

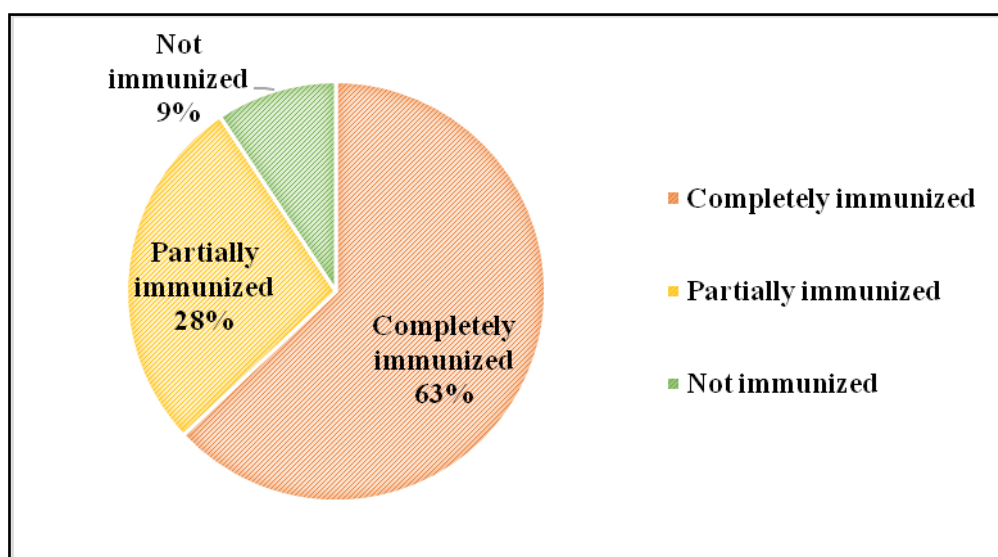
Table 3: The analysis of drugs prescribed in enrolled patients according to the WHO core indicators.

WHO core indicators	Participants (n=300)
Number of drugs prescribed per encounter (mean±SD)	4.88 ± 1.57
Number of drugs prescribed by generic name (%)	352 (52.87)
Number of encounters resulting in the prescription of an antimicrobials (%)	247 (82.00%)
Number of encounters resulting in the prescription of an injection (%)	273 (91%)
Number of drugs prescribed from National Essential Medicines List (EML) 2011 (%)	391 (60.37%)

Table 4: Percentage of antimicrobials prescribed for the enrolled patients (n=300).

Number of encounters with prescription of antimicrobial agent	Number of participants (n=300) (%)
0	23 (7.67)
1	187 (62.33)
2	59 (19.66)
≥3	21 (7.00)

Figure 1: Immunization status of Patients



RESULTS

Among the enrolled patients, 188 (62.67%) were male and 112 (37.33%) were female. The mean age of patients admitted with respiratory illness was 5.28 ±2.71 years. A total of 84 (28%) patients were from the age group comprising of 3 to 5 years. (Table 1) Out of the enrolled 300 patients, only 201 (67%) were given definitive diagnosis during the time of admission while we observed that in 99 (33%) patients, no definitive diagnosis was done. However, of all the 300 patients with respiratory illness, 117 (39%) patients were diagnosed with the upper respiratory tract illness and 183 (61%) patients with the lower respiratory tract illness. Of the upper respiratory tract illnesses with which the patients were admitted, we found that the male patients suffering with sinusitis/rhinitis, pharyngitis and otitis media were found to be highly significant on chi-square analysis (p value <0.001) as compared

to female patients, while the p value was highly significant (p value <0.001) for the female patients suffering with tonsillitis as compared to the male patients.

Similarly, when observed for lower respiratory tract illnesses, incidence of acute bronchitis and bronchial asthma were found to be highly significant (p value <0.001) in female patients as compared to male patients, whereas the suffering with acute bronchiolitis and pneumonia was found to be highly significant (p value <0.001) in male patients as compared to the female patients (Table-2).

The prescribed drugs were analyzed on the basis of WHO core indicators that include: number of drugs prescribed per encounter, number of drugs prescribed by generic name, number of encounters resulting in the prescription of an antimicrobial, number of encounters resulting in the prescription of an injection and number of drugs prescribed from

National Essential Medicines List (EML) 2011. We observed that poly-pharmacy was practiced in all the patients treated for the respiratory illness. The antimicrobial agents were prescribed in 247 (82%) patients, 273 (91%) of the patients were treated with parenteral preparations while the remaining drugs were administered orally. Whereas, of the total 932 drugs prescribed for the enrolled 300 patients, it was observed that only 352 (52.18%) drugs were prescribed by their generic names, while 391 (60.37%) drugs that were prescribed belonged to the National Essential Medicine List of 2011. (Table- 3) It was observed that a total of 247 (82.33%) patients received antimicrobial drugs among the enrolled participants. Of the 247 patients, 187 (62.33%) received single antimicrobial agent, 39 (19.66%) received two antimicrobial agents and 21 (7%) received three or more than three antimicrobial agents during their course of treatment while 23 patients were not treated with any antimicrobial agent. (Table-4) The commonly prescribed antimicrobials were amoxicillin with clavulanic acid, ceftriaxone, cefotaxime. Of all the patients enrolled in the study, a total of 163 (54.33%) were prescribed with cough and cold medicines including bronchodilators. The commonly used CCMs were Pheniramine maleate (7.98%), nasal saline drops (9.20%) and dextromethorphan 11 (6.75%), while the commonly used bronchodilators included; salbutamol (50.92%), ipratropium bromide (9.82%) and levosalbutamol (4.91%). It was also observed that of all CCMs and bronchodilators, 114 (63%) preparations were prescribed in the form of fixed dose combinations (FDCs).

It was observed that out of the 300 patients, 189 (63.00 %) were completely immunized (as per the Universal immunization programme), 83 (27.66 %) were partially immunized and 28 (9.33 %) patients were found to have not received any vaccination till the date of admission. (Figure 1).

DISCUSSION

Drug Utilization Studies (DUS) are done with the aim of understanding how drugs are used. It is an important component of many research initiatives that examine the clinical and economic effectiveness of pharmacotherapy for various health problems. Although several studies have been conducted in other parts of the world on the utilization pattern of drugs for the treatment of respiratory diseases in children, similar studies in India is less evident especially in indoor patients.^{13,14}

In India the pediatric age group forms a sizable population which is prone for respiratory illnesses. The increased incidence with the infections is even more common in children below 5 years of age among the pediatric patients.¹ A total of 84 (32%) patients were from the age group of 2 to 5 years in our study. It is observed that the worldwide population constitutes about 28 % of children and infants who are most susceptible to diseases due to under development of immune system.¹⁵ Children are often considered as little adults in terms of dosage while the drugs are prescribed. With more than three decades ago the term therapeutic orphans were created to highlight the fact that children were not included in clinical trials for a new drug development.¹⁶

The pediatric respiratory illness calls for emergency hospital visits in rural as well as urban setups as many of these conditions may lead to life threatening events. Such respiratory illness includes; foreign body aspiration, allergic reactions, neoplasms, trauma, congenital anomalies etc. In our study, 39 % of the patients were diagnosed with the upper respiratory tract diseases while 61% with the lower respiratory tract diseases and most frequent presenting complaint was cough (96.33%) followed by fever (89.33%). We found that occurrence of sinusitis/rhinitis, pharyngitis and otitis media were common in male while tonsillitis in female.

The average of 4.88 ± 1.57 drugs were prescribed per encounter and more the 50% of drugs were prescribed by brand name in this study. Prescription of the unlicensed preparations (11%) and off labelled drugs (30-50%) is found to be highly prevalent in hospitalized children as a routine practice which is evident in several studies.^{17,18} In our study, antimicrobial agents were found to be prescribed in 247 (82%) patients. Several other studies have reported that 50 % to 85 % of the children receive antibiotics in both developed and developing countries. Respiratory tract infections being the second most common condition indicating the use of antibiotics accounts for 10 % of all prescriptions annually. Although several studies indicate that use of antimicrobial agents are not indicated in all the cases of upper respiratory tract infections, since the etiological agents in most of the upper respiratory diseases are viruses, however, in our study we observed that the antimicrobial agents were made use of.¹⁹ Therefore, the observation in our study is disturbing as far as the appropriateness of the use of antimicrobials for the upper respiratory diseases is concerned. All efforts to promote rational drug use have been mainly targeted at the health care services of various setups could it be primary, secondary or tertiary, with the principle concept that,

a limited number of drugs would lead to a better supply of drugs, better prescribing, better patient compliance and low expenses towards the health care.

A total of 163 (54.33%) patients were prescribed with cough and cold medicines (CCMs) including bronchodilators which comprised the second common group of drugs prescribed for respiratory illness, as a symptomatic medication which is justified. Although with some studies it has been evident that the cough and cold medicines in children have not substantially benefited, in United States it is observed that almost 64 % of the CCMs are prescribed as FDCs in the management of respiratory illness.²⁰ Although we had not calculated economic impact in this study, several studies which has estimated the cost in management of respiratory diseases and it has shown to increase the economic burden.^{21,22}

The importance of this study cannot be undermined. We have found the need for a standard treatment guideline for our own hospital for the management of pediatric respiratory diseases. Such guidelines should be made taking into account of common disease pattern, severity, sensitivity pattern of organism, safety, suitability and cost of pharmacotherapy.

References

1. Park K. Park's Textbook of Preventive and Social Medicine. 20th ed. Jabalpur (India): Banarsidas Bhanot; 2009; Ch. 40:P. 159.
2. Jindal SK. Respiratory diseases epidemiology in India. *Lung*. 2006; 23:93-4.
3. Park K. Park's Textbook of Preventive and Social Medicine. 20th ed. Jabalpur (India): Banarsidas Bhanot; 2009;p-163-4.
4. Ghai OP, Paul VK. Rational drug therapy in pediatric practice. *Indian Pediatr* 2006;25:1095-1109.
5. Ramana kumar AV, Aparajita C. Respiratory Disease Burden In Rural India: A Review From Multiple Data Sources. *The Int J of Epidemiology* 2005;2:2.
6. Chakravathy S, Singh RB, Swaminathan S, Venkatesan P. Prevalence of Asthma in urban and rural children in Tamilnadu. *Natl Med J India* 2002 Sept;15(5):260-3.

7. McCaig LF, Hughes JM. Trends in Antimicrobial drug prescribing among office-based physician in the United States. *JAMA* 1995;273:214-9.
8. Strand J, Rokstad K, Heggedal U. Drug prescribing for children in general practice: A report from the More and Romsdal prescription study. *Acta Paediatrica* 1998;87:218-24.
9. Chatterjee S, Mandal A, Lyle N, Mukherjee S, Singh AK. Drug utilization study in a neonatology unit of a tertiary care hospital in eastern India. *Pharmacoepidemiology and Drug Safety* 2007;16:1141-5.
10. Davies A, Bateman M, Yates A, Bruno M. Pediatric regulations in Europe & the US. *Regulatory Affairs Focus* 2005;10:18-22.
11. Zuppa A, Vijayakumar S, Jayaraman B, Patel D, Narayan M, Vijayakumar K et al. An informatics approach to assess pediatric pharmacotherapy: Design and implementation of a hospital drug utilization system. *J Clin Pharmacol* 2007;47:1172-80.
12. Okasha D, Kassis I, Haddad S, Krivoy N. General medications utilization and cost patterns in hospitalized children. *Pharmacy Practice (Internet)* 2009 Jan-Mar;7(1):54-8.
13. Ashraf H, Handa S, Khan NA. Prescribing pattern of drugs in outpatient department of child care centre in Moradabad city. *Int J of Pharmaceutical Sciences Review and Research* 2010;3(2):1-5.
14. Shankar PR, Partha P, Shenoy N. Self-Medication and non-doctor prescription practices in Pokhara valley. *Westren Nepal: MC Family Practice* 2002;3:17.
15. Moorthi C, Paul PR, Srinivasan A, Senthil CK. Irrational use of antibiotics in paediatric prescriptions: A pilot study at community pharmacy in Erode City. *Der Pharmacia Letter* 2011;3(3):171-7.
16. Shirkey H. Therapeutic orphans. *Pediatrics* 1999;104:583-4.
17. Carvalho PA, Carvalho CG, Alievi PT, Martinbiancho JK, Trotta E. Prescription of Drugs not Appropriate for Children in a Pediatric Intensive Care Unit. *J Pediatr* 2003;79:397-402.
18. Hsien L, Breddemann A, Frobel AK, Heusch A, Schmidt KG, Laer S. Off-Label Drug Use Among Hospitalized Children: Identifying Areas with the Highest Need for Research. *Pharm World Sci.* 2008;30:497-502.
19. Wong DM, Blumberg DA, Lowe LG. Guidelines for the use of antibiotics in acute upper respiratory tract infections. *Am Fam Physician* 2006;74:956-66.
20. Schroeder K, Fahey T. Over-the-counter medications for acute cough in children and adults in ambulatory settings. *Cochrane Database of Systematic Reviews* 2004;4.
21. Ayieko P, Akumu AO, Griffiths UK, English M. The economic burden of inpatient pediatric care in Kenya: household and providers cost for treatment of pneumonia, malaria and meningitis. *Cost Effectiveness and Resource Allocation* 2009;7:3-15.
22. Chola L, Robberstad B. Estimating average inpatient and outpatient costs and childhood pneumonia and diarrhoea treatment costs in an urban health centre in Zambia. *Cost Effectiveness and Resource Allocation* 2009;7:16.