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Original Research Article

An Evaluation of Antimicrobials Prescribing Pattern in Hospitalized Pediatric Patients at a Tertiary Care Centre: A Prospective Study

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Abstract:

Background: Antimicrobials are widely prescribed for the treatment of infectious disease in pediatric populations. This study was aimed to evaluate prescribing pattern of antimicrobial agents in hospitalized pediatric patients.

Material and Methods: The observational, prospective study was conducted at hospitalized pediatric patients, who were prescribed antimicrobials. Data were recorded at baseline and patients were followed up till discharge. Prescriptions were analyzed by using WHO (World Health Organization) core indicators, Phadke's criteria and Modified Kunin's criteria respectively. Data was analyzed by using Microsoft Excel version 2007.

Results: Total 600 patients were studied. Common infection observed was respiratory tract infection (40.66%). Most common prescribed antimicrobials were Beta-lactam antimicrobials. Rational, semi rational and irrational prescriptions were 69.66%, 27.34% and 3% respectively according to Phadke's criteria. According to Modified Kunin's criteria prescriptions were appropriate (69%) and inappropriate (31%). Majority (99.40%) of the Adverse drug reactions (ADRs) were non-serious, possible causal association with suspect drug and non-preventable in nature.

Conclusion: Majority antimicrobials prescribed were appropriate and rational.

Keywords: Antimicrobials Prescribing Pattern, Pediatric Patients, WHO, Core Indicators.

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Introduction

Pediatric population is about 40% of total population in India (Census, 2011). Risk of infectious disease in pediatric population is higher in developing countries like India because of low socioeconomic class, poverty, overcrowding, poor sanitization, poor housing conditions, lack of availability of safe drinking water, incomplete vaccination, protein energy malnutrition, low immunity, illiteracy and unawareness regarding infections (Park K, 2019). [1,2]

Common infectious diseases reported in India among pediatric populations are respiratory tract infections (i.e. upper respiratory tract infections (URTIs), whooping cough, ear infections, sinusitis etc.) central nervous system infections (i.e. meningitis, brain abcess etc.), gastrointestinal tract infections, urinary tract infections and other infectious diseases such as enteric fever, tuberculosis and malaria (Akash Gupta et al., 2017).Antimicrobial agents (AMAs) are used for the prophylaxis and treatment of the infection/disease AMAs are reported as the most commonly prescribed drugs among all the drugs prescribed in pediatric patients (PV kaur at al., 2016). [3,4] It has been observed that sometimes AMAs are overused and/or misused. Study reported that 30 to 40% of the antimicrobial prescribed irrationally and inappropriately. (Sondrva DB et al., 2016). Inappropriate and irrational use of antimicrobial agents leads to drug-drug interactions, adverse drug reactions and antimicrobial resistance etc. These may increase hospitalization, morbidity and mortality in pediatric patients. [5,6]

Thus, to avoid the complications of inappropriate or irrational use of AMAs, it is important to prescribe AMAs for prophylaxis and treatment of infectious disease appropriately and rationally as per indication and available local guideline. There are many tools for evaluation of an antimicrobial prescribing pattern, rationality and appropriateness of an AMA prescribing in outdoor, indoor, infants, pediatric and geriatric populations. World health organization (WHO) core prescribing indicators are used for evaluation of prescribing pattern, Phadke's

criteria is for rationality of an antimicrobial agents, Modified kunin's criteria for appropriateness of an AMA and Beer's criteria for evaluation of AMAs in geriatric populations were used. Standard treatment guidelines and antimicrobial policy for pediatric patients are useful for evaluation of AMA prescribing according to Phadke's criteria and Modified kunin's criteria. [7,8]

Our hospital is the largest tertiary care teaching hospital in Asia and majority of the pediatric patients are from lower and middle socioeconomic class and coming from rural area. In these populations, there is a higher risk of infectious disease. Hence, we carried out a study to evaluate of antimicrobial prescribing pattern in hospitalized pediatric patients.

Materials & Methods

An observational, prospective single center study conducted in Department of Pharmacology and Department of Pediatrics at B. J. Medical College and Civil Hospital, Ahmedabad over a period of 24 months duration.

Approval from Institutional Ethics Committee (IEC) of civil hospital, Ahmedabad (EC/Approval/40/15) and Head of Department of Pharmacology and Pediatrics was obtained. Patients were enrolled in the study after obtaining written informed consent and/or assent (if patients were above 7 years of age) taken from patients and/or patients' guardians. All patients from 0 to 12 years of age and of either gender, admitted at pediatrics inpatient ward for any condition and who were prescribed antimicrobials were included in the study. The patients transferred to another ward/centre, admitted to NICU or PICU, pre-term babies, diagnosed with human immunodeficiency virus (HIV) and tuberculosis (TB), discharged against medical advice and patients/patients' parents who were not willing to participate in the study were excluded.

The baseline demographic details, clinical history, past, personal and family history, breastfeeding history, immunization, details of laboratory investigations, diagnosis of the patients and details of drug treatment given were recorded in prevalidated case record form (CRF).

Recorded information of patients was entered in Microsoft Excel worksheet. All prescriptions were analyzed by using World health organization (WHO) core indicators for prescribing pattern. Rationality and appropriateness of AMA prescribed were analyzed by using Phadke's criteria and Modified Kunin's criteria.

WHO core indicators, WHO Essential Medicine List for children (WHO, 2013), Phadke's criteria (Phadke A., 1998), Modified kunin's criteria (Vlahovic-palcevski et al., 2007), Standard textbook of pediatrics (Ghai, 2019), Standard textbook of pharmacology (Satoskar RS et al., 2018) were used as a tool for analysis of prescriptions

Detail of adverse drug reaction (ADRs), if any was recorded and analyzed for Causality assessment WHO-UMC (1992) and Naranjo's algorithm (Naranjo CA, Busto U, et al., 1981). Severity of ADRs was assessed by a scale described by Hartwig and Siegel (1992). Preventability of ADRs was assessed by Modified Schumock and Thornton criteria.

Results

A total of 600 hospitalized pediatric patients were studied during 24 months of study periods.

Mean age of the patients was 36.99 + 1.21 months. [79.34% (0-5 years) and 20.66% (6 to 12 years)]. Male to female ratio was 1.5: 1 and mean weight was10.48 + 0.242 Kg. Data showed that 46 % from slum, 39% from rural and 15% patients were from urban area.

Immunization Status: As per National Immunization schedule according to age group, out of 600 patients, 60 patients (10%) were unimmunized, 332 patients (55.33%) were partially immunized and 208 patients (34.66%) were fully immunized at the time of admission as per the national immunization schedule.

Clinical Diagnosis of the Patients: Most common diagnosis was respiratory tract infection (40.66%) followed by central nervous system disorders (23.16%), infectious disease (13.5%), gastrointestinal and hepato-billiary disorder (11.66%), hematological disorder (5.5%), cardiovascular disease (2.6%), genitourinary tract disorder (2.0%), trauma (0.6%) and poisoning (0.16%).

Antimicrobial Prescription Pattern Evaluation: Total 1000 AMAs were given in 600 prescriptions. Mean number of AMAs were 1.6 per prescription with AMAs ranged from 1 to 4 AMAs per prescription. [2 antimicrobials (47.5%), 1 AMAs (42.5%), 3 AMAs (8.33%) and 4 AMAs (1.66%)]. Average duration of antimicrobial prescribing in hospitalized pediatric patients was 6.2 + 2.02 days. Table 1 showed commonly prescribed group of an antimicrobial agent.

Table 1: Most commonly prescribed group of AMAs

Sr. no	Class of AMAs	Percentage of drug prescription
1	β lactam group	54.7%
2	aminoglycosides	4.7%
3	Oxazolidinones	1.3%
4	Carbapenem	1.3%
5	Glycopeptide	1.2%
6	Macrolides	1.1%
7	Fluroquinolones	0.9%

Most commonly prescribed AMAs: Ceftriaxone (320; 32%) and amoxicillin plus clavulanic acid (295; 29.5%) were the most commonly prescribed followed by cefotaxime 119(11.9%), crystalline penicillin 76(7.6%), piperacillin plus tazobactam 49(4.9%), amikacin 42(4.2%), ampicillin 23(2.3%), linezolid 13(1.3%), meropenam 13(1.3%), vancomycin 12(1.2%), azithromycin 10(1.0%), cefixime 8(0.8%), gentamycin 5(0.5%), levofloxacin 4(0.4%), cefosulbactam 4(0.4%), ofloxacin 4(0.4%), ciprofloxacin 1(0.01%), ceftazidime 1(0.01%) and erythromycin 1 (0.01).

Drugs other than AMAs used for treatment of different conditions in indoor pediatric patients were vitamin (17.6%) followed by fluid and electrolyte 17.33%, nonsteroidal anti-inflammatory (15.13%), drugs for acid peptic disease (14.27%), antiemetic (14.9%), anticonvulsant (9.71%), antiepileptic (7.06%), steroids (2.04%), packed cell volume (0.39%), antihistamine (0.37%) and diuretics (0.19%). In our study, total 348 FDCs were prescribed out of which commonly used FDCs were amoxicillin + clavulanic acid (84.77%) followed by piperacillin + tazobactam (14.08%) and cefoperazone+ sulbactum in (1.14%).

Most commonly used dosage form of AMAs was injection 96.2 % followed by tablet (2.9) and syrup (0.9). Intravenous is the most commonly used route of administrations (96.2%) followed by oral route of administration (3.8%) in hospitalized pediatric patients. Out of total AMAs prescribed, 63.3% of the AMAs were given twice a day followed by three times a day (22.7%), four times a day (7.1%), once in a day (6.1%) and at a bed times (0.8%).

Change of antimicrobial treatment was done in 0.5% cases of meningitis. Evaluation of an antimicrobial prescribing pattern according to WHO core indicators is shown in table 2.

Table 2: WHO core indicators for evaluation of an antimicrobial prescribing pattern

WHO core prescribing indicators	Prescription analysis (n=600)
Average number of AMAs prescribed per encounter	1.6
Percentage encounter with antibiotics	100%
Average number of AMAs prescribed with injections	96.2%
Average number of AMAs prescribed by generic name	60.7%
Average number of AMAs prescribed from essential medicine list (EML) list	95.3%

Rationality of prescriptions according to Phadke's criteria: Rationality of prescriptions were analyzed by using Phadke's criteria of rationality out of total 600 prescriptions, 418 (69.66%) prescriptions were rational, 164 (27.34%) were semi-rational and 18 (3%) prescriptions were irrational.

Analysis of results for semi-rational and irrational prescriptions were use of second and third choice of main drugs in 12.66% (73 prescriptions) and inadequate or excess dose of main drugs was given in 20.16% (121) prescriptions. For complementary drugs, reasons observed for semi-rational and irrational prescriptions were use of second and third choice of drugs in 10.99% (66 prescriptions), inadequate or excess dose was given in 15.16% (91prescriptions).

Appropriateness of AMAs according to Modified Kunin's criteria: Analysis of appropriateness of AMAs was categorized according to modified Kunin's criteria. Results showed that prescriptions in category I (53%) and category II (16%) which were appropriate according to dose, duration, frequency and route of antimicrobial administration while category III (18%) and category IV (13%) which were inappropriate in their dose, duration, frequency and route of administrations according to modified Kunin's criteria. We did not observe any inappropriate therapy given as per category V in our study.

Adverse drug reactions: A total of 168 ADRs were observed during study in 600 pediatric patients. (Table 3)

Table 3: Analysis of an adverse drug reaction (n=168)

Sr.no.	Adverse drug reaction (n)	Suspected drug	Causality assessment	Severity score	Seriousness	Drug withdrawn Yes/No
1	Diarrhoea (66)	Amoxicillin+ clavulanic acid	Possible (+5)	Mild (level 1)	No	No
		Cefosulbactum	Possible (+5)	Mild (level 1)	No	No
2	Nausea (33)	Piperacillin+ tazo-bactam	Possible (+5)	Mild (level 1)	No	No
		Paracetamol	Possible (+5)	Mild (level 1)	No	No
3	Vomiting (39)	Piperacillin +Tazobactam	Possible (+5)	Mild (level 1)	No	No
4	Itching (18)	Ceftriaxone	Possible (+5)	Mild (level 1)	No	No
		Cefotaxime	Possible (+5)	Mild (level 1)	No	No
5	Tremor (11)	Sodium valproate	Possible (+5)	Mild (level 1)	No	No
6	Rash (1)	Paracetamol	Probable (+6)	Mild (level 2)	Yes	Yes

Discussion

The results of our study showed that the mean age of the 600 patients was 36.99 + 1.21 months. Which is also shown in studies done by M. Bala Gopal et al. (2017) and G. Sireesha et al. (2016). Results of our study showed that male: female ratio was 1.5:1. Out of these 61.33% patients were male and 38.66% female. Studies conducted in India (Sondarva Divyesh B. et al.,2015 & Teferra Abula et al. 2012) showed that majority of patients were male as compare to female which might be due to different sex ratio in Indian population. [9,10]

In our study, large numbers of patients are from rural & urban slum area where infectious diseases is reported as higher prevalence which can be due to low immunity, under nutrition, unawareness regarding immunizations. Mean weight of the patients in our study was 10.48 + 0.242 Kg which was similar in study by Sonderva DB et al., 2016 in Gujarat which might be due to similar food habit and body mass index in Gujarat population. [11,12,13]

There is a less immunization coverage in our study as compare to other study. (Chaudhri DK et al., 2013) There is a less immunization coverage in developing countries like, India as compared to developed countries. (Epidemiology of the unimmunized child, 2009). Most common infection in hospitalized pediatric patients was respiratory tract infections and penicillin and cephalosporin groups were the most commonly used antimicrobials in our study. This was also seen in studies done by Hafte Kahsay Kebede et al., 2017, Vishwanath M. et al., 2017 and Chaudhry DK et al, 2013. β- lactum group was the most commonly prescribed AMAs in our study. It might be due to pediatric populations are more vulnerable for respiratory tract disorders and disease prevalence was also different in different countries like India. (Nelson, 2019) Which was indicated in hospitalized pediatric populations according to diagnosis, guidelines for symptomatic relief and disease treatment based on patient's condition. (Satoskar et al., 2017) All drugs are prescribed according to standard treatment guidelines, by using generic name and as per the essential medicine list of children. [14,15,16]

According to WHO core indicators, Average number of antimicrobials prescribed was 1.6 per prescription and majority of the AMAs prescribed via injections and via generic name and from essential medicine list. This is similar to study by reported by Patel Neha et al. (2016) of evaluation of prescribing pattern of AMAs in indoor pediatric patients.

Comparison of our results with other studies showed that in our hospital average AMAs per prescription was less it might be due to AMAs are prescribed based on severity of infections or condition number of prescriptions with antimicrobials was 100% as my case included the patients who were prescribed antimicrobials were included so percentage of prescriptions with antimicrobials was 100%. [17,18,19] AMAs prescribed by injections were higher as compare to other study. (Patel Neha et al., 2016) In hospitalized patients parental AMAs are given in majority of the patients. (Paul & Bagga, 2019) AMAs prescribed by generic name were similar in our study and other studies. It is due to availability of AMAs as a generic and branded generic in of our hospital which is a tertiary care teaching hospital and AMAs were prescribed as per essential medicine list (WHO, 2013).

Results of analysis of rationality of prescriptions in our study showed that 69.66% prescriptions were rational, 27.34% semi-rational and 3% irrational according to Phadke's criteria. Study by Ambrish Gupta et al. (2017) showed 75% rational, 20% semi-rational and 5% irrational prescriptions. Another study (Shah AM et al., 2010) showed 53%, 30% and 28.3% rational, semi-rational and irrational prescriptions. Semi-rational and irrational prescription in our study might be due to patient's factors such as age, weight, body surface area, disease factors such liver and kidney diseases. Antimicrobial resistance in particular region, prescriber's knowledge and experience for the treatment of infections in particularly in pediatric age groups are also important factors for selection of AMAs for particular infection. [20]

Analysis of appropriateness was categorized according to modified Kunin's criteria (Vlahovic-palcevski V et al., 2007). Results of our study showed that majority (53%) of prescriptions were appropriate according to dose, duration, frequency and route of antimicrobial administration while 18% prescriptions were inappropriate in dose, duration, frequency and route of administrations. Which was similar to study conducted in Gujarat (Prajapati V et al., 2014) and other study done by Deshmukh VS et al., 2013. Reason for inappropriate choice of AMAs were might be due to antimicrobials were prescribed empirically particularly in URTI where majority of cases are due to viral origin and not require antimicrobials. In addition, inappropriate dose, duration and frequency might be due to hospitalized patient require emergency treatment so drugs may not prescribe drug according to pediatric age and weight and availability of trained nursing staff, standard treatment guidelines, essential medicine list, hospital antimicrobial policy are required. Most common observed ADRs were diarrhea followed by vomiting. Most common system organ class affected by ADRs was gastrointestinal. [21]

Similar results also found in M. Shamma et al. (2013). In study done by Sandip Baidya et al. (2017) in pediatric patients observed that half of the patients have diarrhea as a common adverse drug effects. At our institute, although antimicrobial policy is not available & AMAs are given based on clinical judgment and available of guidelines. Majority of AMAs prescribed were rational, semirational and appropriate.

There are a few limitations of our study. We have included only indoor pediatric patients who were prescribed antimicrobials. Pediatric patients admitted to neonatal intensive care unit (NICU), pediatric intensive care unit patients (PICU), patients diagnosed with tuberculosis or HIV and preterm birth baby were not included. As our study was observational, we have not carried out resistance to AMAs. [22,23] Hospital antimicrobial policy for pediatric population is not available at our institution; thus, analysis of prescribed AMAs was done on the basis of guidelines and clinical judgments. Availability of national and state treatment guidelines, availability of essential medicine list and hospital antimicrobial policy are useful for rational use of antimicrobials, particularly at Tertiary care teaching hospital where prescribers are having higher patient load and junior doctors are under training. Periodic prescription analysis and effective feedback to prescribers based on results, training for prescribing of antimicrobials to junior doctors by organizing scientific academic sessions will further helpful to improve rational use of AMAs in pediatric age group and to reduce resistance to AMAs. In addition, analysis of bacterial resistance pattern will also useful for better treatment outcome. [24]

Conclusion

Antimicrobial prescribing among hospitalized pediatric patients was largely rational and appropriate according to WHO, Phadke's, and Modified Kunin's criteria. Respiratory tract infections accounted for the largest proportion of antimicrobial use, with β-lactam antibiotics being the most frequently prescribed agents.

Periodic prescription audits, antimicrobial stewardship programs, and institution-specific treatment guidelines are essential to further optimize antimicrobial use and reduce antimicrobial resistance.

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