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Original Research Article

Drug utilization pattern in sick paediatric patients: analysis for rationality and other aspects

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ABSTRACT

Background: The aim of this research work was to study the drug utilization pattern in the indoor paediatric patients with specific objective to analyse the rationality status of prescriptions and other aspects.
Methods: A retrospective observational study was conducted for a period of 6 months. We analysed 120 prescriptions for the rationality status and different other parameters using Phadke's criteria and W.H.O. prescribing indicators.
Results: In our study out of total 120 prescriptions; 90 were rational followed by semi-rational and irrational. Average number of drugs prescribed was 5.39 drugs per prescription. Out of total FDCs prescribed 30% were irrational. Most commonly prescribed drug was anti-bacterial. Among anti-bacterial, most commonly prescribed anti-bacterial was from the cephalosporin group; which is categorized as "WATCH" category in W.H.O.-EML for children, March 2017.
Conclusions: Though the results in present study reflect rational prescribing in pediatric patients in our hospital set up, there is still scope of improvement in prescription habits like avoid prescribing unnecessary drugs and irrational FDCs. There is also need of prescribing by generic names.

Keywords: Drug utilization paediatrics, Prescription auditing, Rational prescribing

INTRODUCTION

Doctors regularly prescribe drugs. They are expected to apply their knowledge of therapeutics to select appropriate drugs for their patients' condition and then prescribe these in correct doses and for the right duration so as to optimize the benefit to the patient. This is how it is supposed to happen in an ideal world, with ideal doctors who are ideally trained. The opening remarks by the WHO on its 'Rational Medicine Use' webpage underscore the existing situation: "The irrational use of medicines is a major problem worldwide. WHO estimate that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take

them in right manner. The overuse, underuse or misuse of medicines results in wastage of scarce resources and widespread health hazard.[1]

Infants and children constitute a large proportion of the population in developing countries. They are especially vulnerable to contract illnesses and to the harmful effect of drugs. They suffer from frequent but usually non-serious illnesses. Most of these are self-limiting and often treated not only inappropriately but also resorting to polypharmacy. Promotion of appropriate and safe drugs in children is the need of the hour globally. Pediatric population by itself is a spectrum of different physiologies with significant variation in pharmacodynamics and pharmacokinetics. Unfortunately, 50-90% of drugs used in children today have never been actually studied in this population, and the results of drug studies done in adults are often extrapolated for use in children. Many medicines in pediatrics are off label or unlicensed. There is a spurt in drug resistance due to the overzealous prescription of antimicrobials not indicated, such as, using inadequate dosage or duration of drug regime leading to partially treated infections, using the wrong antimicrobial due to ignorance of causative organism, and finally using indigenous, irrational combinations.

Prescription auditing is a type of vigilance activity, which is beneficial in clinical practice in terms of reducing the burden of disease because of medication errors, i.e. because of irrational prescribing.[2]

Drug utilization research is defined by WHO as "the marketing, distribution, prescription, and use of drug in a society, with special emphasis on the resulting medical, social and economic consequences".[3] Considering all these facts, the present study was designed to check the rationality status and drug utilization pattern in indoor patients of paediatrics department.

The aim of this research work was to study the drug utilization pattern in the indoor paediatric patients with specific objectives as follows:

- To analyse the rationality status of prescriptions.
- To analyse the prescriptions in the light of W.H.O.-prescribing indicators.

METHODS

This retrospective observational study was conducted in pediatric in-patient high dependency unit (HDU) of Shyam Children and Maternity Centre, Kalyanpur, Kanpur (A sub-urban based economy hospital affordable to rural population within 100 k.m.) jointly with Rainbow Medical Centre, Kanpur and department of pharmacology, G.S.V.M. Medical College, Kanpur; U.P., India for 6 months duration.

All patients in pediatric age group of either sex, admitted at pediatrics inpatient ward and intensive care unit for any condition were included in the study. The patients referred to or from other specialties with conditions which can influence physician's prescription were excluded. Data of total 120 pediatrics in-patients were collected from hospital records while they were admitted in the hospital. An attempt was made to include patients of different conditions or diseases admitted in pediatrics inpatient ward as far as possible.

After collecting data of all prescriptions, data were analyzed for rationality and drug utilization pattern by following criteria.

Prescription analysis

All prescriptions were analyzed by using Phadke's criteria.[4,5] While analyzing the prescriptions, to decide for the correctness of the drug, standard textbook of pediatrics (Essential Pediatrics; OP Ghai; 8th Edition) and pharmacology (Essentials of medical Pharmacology; K.D. Tripathi; 8th Edition) were referred. Prescriptions were discussed with consultants for more clarification in case of some query regarding prescription.

Prescription were analyzed for:

- Rationality score
- Rationality status of prescriptions
- Number of prescriptions showing use of unnecessary drugs, unnecessary injections, irrational drugs or combinations.

For study of rationality status of prescriptions, a maximum of 30 points score system was assigned as follows:

- Main drug - 20 points
- Complementary drug - 10 points

Out of these total points, half of the points of each category of drugs were to be allotted for the correctness of the choice of drug according to condition and half for the correctness of the dose, route, frequency of drug administration and the duration of the treatment. If more than two drugs were needed to be given in a condition; the points allocated were subdivided accordingly. From total score obtained, points were deducted if prescription include Unnecessary drug (-5 points), Unnecessary injection (-5 points), Irrational drug / combination (-5 points) or Hazardous drug (-10 points). Based on the mentioned criteria for analysis, net score was calculated, and prescription were categorized as:

- 0 to 14 points - Irrational
- 15 to 24 points - Semi-rational
- 25 to 30 points - Rational

Drug utilization pattern

By using the prescribing indicators according to the standard WHO guidelines, the data were analyzed to study

- Diagnosis mentioned or not
- Number of drugs prescribed per prescription
- Number of drugs prescribed by brand name or generic name
- Percentage of prescription with an antibiotic prescribed
- Most commonly prescribed drug
- Most commonly prescribed anti-bacterial
- Number of fixed drug combinations used.[6]

RESULTS

We analyzed total 120 prescriptions in our study. Out Of total 120 prescriptions, 90, 24 and 6 prescriptions were rational, semi-rational and irrational respectively (Figure 1). When rationality score was calculated; 75 prescriptions had score value 25, 15 prescriptions had score value 26 followed by 24 and 6 prescriptions in range of 15-21 score and 8-13 score respectively. Minimum score of 8 was observed in two prescriptions. Mean rationality score was 22.99. For total 120 prescriptions with rationality score less than 30, different reasons for less score were-unnecessary drug/injection 64 (53.3%) prescriptions, second or wrong choice of drugs in 11 (9.1%) prescriptions and both of these 26 (21.6%) prescriptions (Table 1).

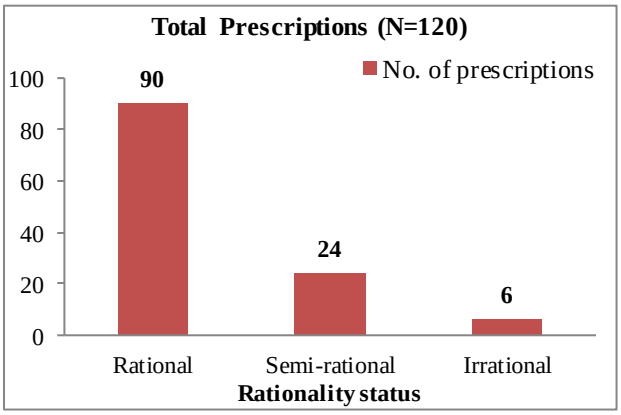

Figure 1: Rationality status of prescriptions.

Table 1: Myriad reasons for rationality score <30.

Reasons	% of prescriptions (Number)
Unnecessary drug/injection (A)	53.3% (64)
2nd choice or wrong choice of drug (B)	9.1% (11)
Both (A+B)	21.6% (26)
Improper dose (C)	8.3% (10)
A+C	5% (6)
Irrational drug (D)	2.5% (3)

In all the prescriptions drugs were prescribed by brand names. No drug was prescribed by generic name.

In 104 prescriptions, only final diagnosis was mentioned; while in 12 prescriptions only provisional diagnosis and in 4 prescriptions both provisional plus final diagnosis were mentioned (Figure 2).

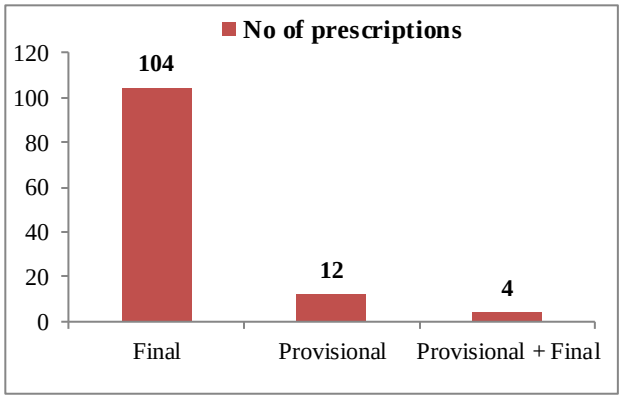

Figure 2: Diagnosis status of prescriptions.

In present study, number of drugs prescribed in any given patient ranged from 4 to 7 (Figure-3). Average number of drugs per encounter was 5.39. We also analyzed all prescriptions on the line of WHO- prescribing indicators (Table 2).

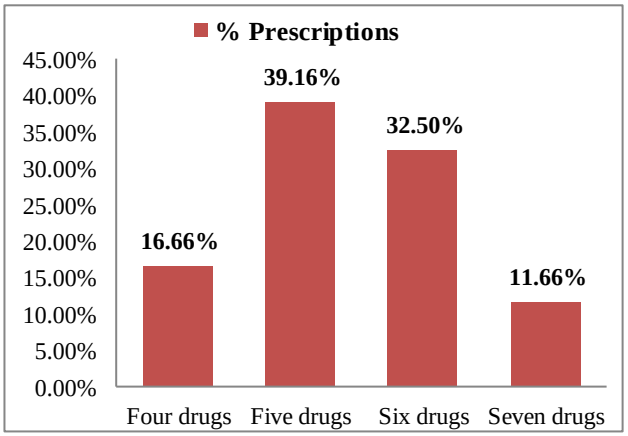

Figure 3: Number of drugs prescribed per prescription.

Drugs used for treatment of different conditions in pediatric cases were anti-bacterial (97.50%) oral and i.v. fluids (90.80%), H_2 blockers (89.10%), NSAIDs (58.30%) and others (Figure 4).

Table 2: Analysis of prescriptions in the light of W.H.O. prescribing indicators.

Parameters	Observed value
Total no. of prescriptions analyzed	120
Total no. of drugs prescribed	647
Average no. of drugs per encounter	5.39
% of encounter with an anti-bacterial	97.50%
Total no. of anti-bacterials prescribed	179
Anti- bacterials per prescription	1.49
% of prescriptions with an FDCs	54.16%

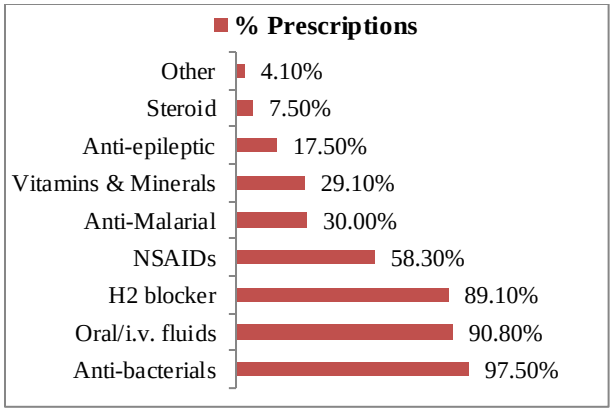

Figure 4: Different drug group prescribed.

Out of 117 prescriptions having antibacterial agent; in 59 prescriptions one and 58 prescriptions two anti-bacterial were prescribed respectively. Maximum number of anti-bacterial per prescription was 3 in present study. The most frequently prescribed group of anti-bacterial was cephalosporin (62%) followed by penicillin (Figure 5). Among cephalosporin most commonly prescribed was ceftriaxone (78.30%) followed by FDC of ceftriaxone + sulbactam (9.90%). Among penicillin most commonly prescribed was FDC of ampicillin + sulbactam (41.10%) followed by FDC of ampicillin + dicloxacillin (Figure 6 and Figure 7).

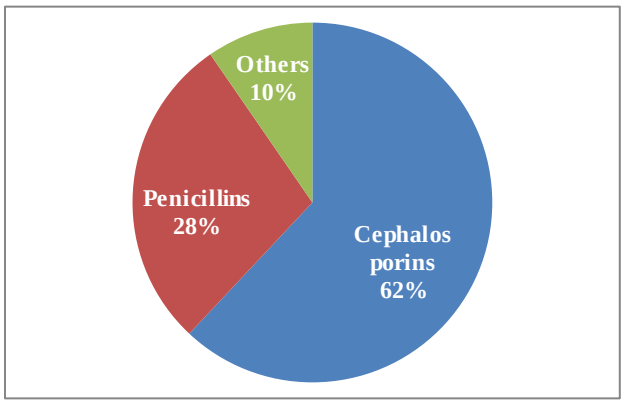

Figure 5: Anti-bacterial prescribing pattern.

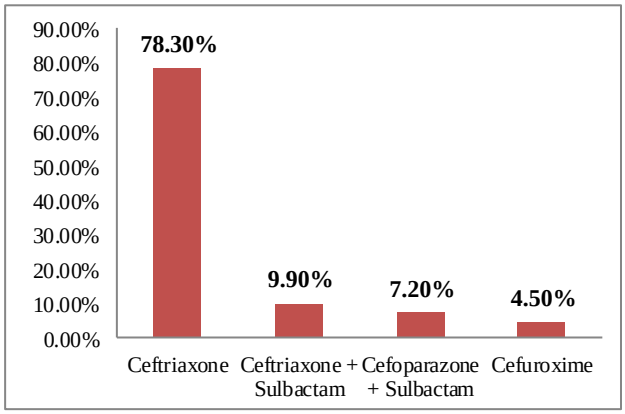

Figure 6: Prescription pattern of cephalosporin.

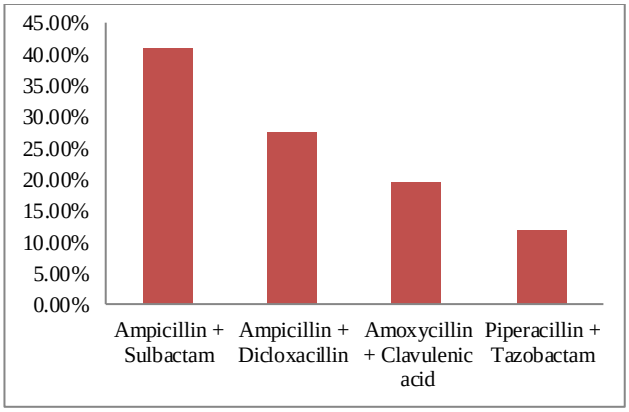

Figure 7: Prescription pattern of penicillin.

In present study, total 10 FDCs were prescribed out of which 7 FDCs were rational and 3 were irrational (Figure 8). Of 7 rational FDCs, 3 were present in WHO-EML for children- March-2017. Out of those 3 one FDC was categorized as "watch category" in W.H.O.-EML for children (Piperacillin+Tazobactam). Three irrational FDCs included Ampicillin + dicloxacillin, ibuprofen + paracetamol and mefenamic acid + paracetamol.

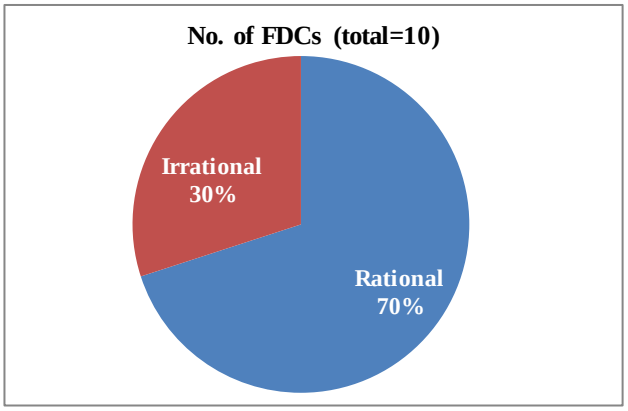

Figure 8: Status of fixed dose combinations.

DISCUSSION

India is the country with significant drug use problems. There is concern regarding the irrational production, prescription and use of FDCs. Rational prescribing is an essential part of patient care. WHO has developed Essential Medicine List to promote rational prescribing. Irrational prescribing is common worldwide with different prevalence rate at different set up.

The rationality of fixed dose combination is the most controversial and debated issue in today's clinical practice. The Indian laws have not been properly defined to grant marketing approvals for the FDCs by state or central drug controlling authorities. Therefore the state drug controlling authorities have continuously been approving various FDCs, lacking any pharmacokinetic or pharmacodynamic advantage and acceptable rationale. This type of

prescription audit study helps in evaluating the extent to which rational prescribing is practiced by clinician in government as well as private set up. Pharmacological treatment is the most common and important form of treatment in the care of paediatric patients and irrational prescribing may lead to drug-drug interactions, development of resistance, adverse effects of drugs and all these ultimately leads to increased cost of health care management to the society.

When we analysed all prescriptions for the rationality, we found 75% prescriptions as rational, 20% semi-rational and 5% prescriptions as irrational. In a study authors found, 39.5%, 32.3%, and 28.3% rational, semi-rational and irrational prescriptions respectively while in another study found, 53%, 30% and 17% prescriptions to be rational, semi-rational and irrational respectively.[5,7] When rationality score was calculated, 75 prescriptions had 25 score, 15 prescriptions had 26 score followed by 24 and 6 prescriptions in range of 15-21 score and 8-13 score respectively. Minimum score of 8 was observed in two prescriptions. Mean rationality score was 22.99. In another study, in which prescriptions of 100 OPD patients of tertiary care teaching hospital were analyzed, the mean rationality score found was 20.56.[7] In a similar study for geriatric patients (age ≥65 years) carried out by Geriatric patients at tertiary care teaching hospital, the mean rationality score was 18.47.[5] In prescription audit study done by In another studies; collecting prescriptions from general practitioners from public and private sectors, using same Phadke's criteria; the mean rationality score was 25.83 for public sector and 20.45 for private sector.[8] In another work reported average rationality score of 19.23 and 20.83 for prescription obtained from physician of teaching institute and private sector respectively.[4]

Differences found in rationality score and rationality status of prescriptions in different studies could be because of following reasons, operating one or more at a time.

- Difference in the hospital setup where studies were done viz. public/private, primary/secondary/tertiary.
- Difference in patients included viz. outpatients/inpatients/both.
- Different Prescribing doctors either MBBS or MD/MS in different studies.
- For some conditions, standard treatment guidelines are available making prescription analysis easy. For majority of conditions, standard treatment guidelines are not available, and researchers have to refer some standard reference for deciding rationality of treatment. Referring different sources may lead to variations in rationality score.

For all 120 prescriptions with rationality score less than 30; different reasons for less score were:

- Unnecessary drug/injection prescription 64 (53.3%)
- Second or wrong choice of drugs in 11 (9.1%) prescriptions
- Both of these 26 (21.6%) prescriptions

In a study there were 47.4%, 23.8%, 10.5% and 19% prescriptions containing unnecessary drugs, unnecessary injections, hazardous drugs and irrational drug respectively.[8]

In 104 prescriptions, only final diagnosis was mentioned; while in 12 prescriptions only provisional diagnosis and in 4 prescriptions both provisional and final diagnosis were mentioned. In another studies, found 81% (public sector) and 84% (private sector) prescriptions in which diagnosis was mentioned while another study found 60% (teaching institute) and 89% (private sector) prescriptions with diagnosis mentioned.[4,8]

Prescribing minimum required number of drugs per patient carries less chances of drug - drug interactions and adverse effects of drugs, decreased cost of therapy and increased patient's compliance. In present study, number of drugs prescribed in any patient ranged from 4 to 7 with an average of 5.39 drugs per patient. In other studies, average number of drugs per encounter were 5.69 (inpatients), 5.61 (outpatients + inpatients) 2.7 (outpatients + inpatients) 2.35 (outpatients).[9-12] In another studies, authors found in their study found that average number of drugs prescribed was 2.79 for government doctors and 3.12 for private practitioners.[13] In the similar study, done by, average number of drugs per prescription was 2.11 and 2.22 for tertiary care teaching hospital and private hospitals respectively.[14]

Improper use of antibacterial - overuse or not using when required - is one of the important reasons of irrational prescribing and development of antimicrobial resistance. Out of 120 prescriptions, antibacterial agent was prescribed in 97.50% prescriptions, among which in 59 prescriptions one and in 58 prescriptions two antibacterial were prescribed. Maximum number of antibacterial prescribed was 3 in this study. In a study, found use of anti-infective in 81.12% patients while In another study, found use of antibiotics in 32% patients.[10,11] It was found that antibiotics were prescribed in 218 out of 286 prescriptions. Of this, 124 (43.4%) had a single antibiotic, while 70 (24.5%), 21 (7.3%) and 3 (1%) had 2, 3 and 4 antibiotics per prescription respectively.[15]

In present study, total 179 antibacterial agents were prescribed. The most frequently prescribed group of antibacterial were cephalosporin (62%) followed by penicillin (Figure 4). Among cephalosporin most commonly prescribed was ceftriaxone (78.30%) followed by FDC of ceftriaxone + sulbactam (9.90%). Among penicillin most commonly prescribed was FDC of ampicillin + sulbactam (41.10%) followed by FDC of ampicillin + dicloxacillin. In the study by In a study among antimicrobials, among antimicrobials, penicillins (28.75%) were most commonly prescribed, followed by aminoglycosides (23.33%) and cephalosporins (17.5%).[9] In a study it was found that among antimicrobials, most commonly prescribed were beta-lactams followed by quinolones and

aminoglycosides, while author found that cefixime was most commonly prescribed antibiotic followed by ceftriaxone and amoxicillin.[11,15]

Drugs used for treatment of different conditions in pediatric cases were antibacterials (97.50%) oral and i.v. fluids (90.80%), H2 blockers (89.10%), NSAIDs (58.30%) and others. Akhtar et al. (2011) in their study found that most commonly prescribed pharmacological group was antipyretics (100%) followed by cold and cough preparations (88.81%) and anti-infectives (81.12%).[10] In the study, it was found that most commonly prescribed pharmacological group was antimicrobial (28.10%) followed by drugs acting on respiratory system (12.18%) and NSAIDs (7.50%).[9] In the study was found that most commonly prescribed drug groups were antimicrobials (37.81% and 37.99%) followed by vitamins/ minerals (22.74% and 18.47%) and analgesics (13.46% and 11.87%) in tertiary care teaching hospital and private hospitals respectively, while in similar study, most commonly prescribed, pharmacological groups were antimicrobials (25.44% and 25.96%) followed by NSAIDs (19.80% and 21.66%) in prescriptions of government doctors and private practitioners respectively.[13,14] In a study author found, found that most commonly prescribed group was anti-infective (24.8%) followed by anti inflammatory (20.6%) and drugs of gastro intestinal system (14.7%).[15]

In present study, total 10 FDCs were prescribed out of which 7 FDCs were rational and 3 were irrational. Of 7 rational FDCs, 3 were present in WHO-EML for children, March-2017. Out of those 3 only one FDC was in "watch category" (Piperacillin+Tazobactam). Three irrational FDCs included Ampicillin + dicloxacillin, ibuprofen + paracetamol and mefenamic acid + paracetamol. In the study by, 43 (39.81%) FDCs were prescribed in which 12 (27.91%) were rational and 9 (20.93%) were from WHO-EML for children.[12] In the study total 139 and 97 FDCs were prescribed in public and private sector respectively, out of which 55 and 35 were rational and 45 and 23 were present in WHO-EML for children for public and private sector respectively.[14]

CONCLUSION

To conclude these types of prescription audit studies, help to evaluate, monitor and if necessary, suggest changes or modifications in prescribing practices of clinicians which will ultimately make patient care more rational and cost-effective.

Though the results in present study reflect rational prescribing in pediatric patients in our hospital set up, there is still scope of improvement in prescription habits like avoid prescribing unnecessary drugs and irrational FDCs. There is also need of prescribing by generic names.

Developing and implementing Standard Treatment Guidelines in the light of WHO-ELM for children will promote more and more rational prescribing. Periodic prescriptions auditing and effective feedback to clinician should be done based on results to ensure rational prescribing and cost effective treatment of pediatric patients.

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