Assessment of Prescribing Practices in Paediatric Patients in A Tertiary Level Referral Hospital

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ABSTRACT
Paediatrics differs from adult in many aspects of which body size and maturational changes plays an important role. Effective medical treatment of paediatric patient is based upon an accurate diagnosis and optimum course of therapy. Irrational drug prescription leads to ineffective treatment, occurrence of adverse effects, prolonged duration of illness and suffering to patient, and an increased economic burden to society. Therefore the aim of our study is to analyse prescribing practices in paediatric department of KIMS Al Shifa Hospital to identify the prevailing disease traits, ADRs, dosage form, route of administration and potential drug interactions among children over 6 months study period. The aim of the study is to assess the prescribing patterns of paediatric patients in a tertiary level referral hospital. A Prospective observational study was conducted for a period of 6 months that focus on Assessment of prescribing practices in paediatric patients. The study was carried out in Paediatric department of KIMS AL SHIFA SUPER SPECIALITY HOSPITAL, Perinthalmanna, Malappuram. The patients were selected based on Inclusion and Exclusion criteria. Out of 87 prescriptions analysed, we found a predominance of male patients as compared to female paediatric patients. The analysed prescriptions were contributed mainly by paediatric age group of 1-3 years (34.5%). LRTI (24.1%) was identified as the most prevailing disease. A total of 466 drugs were retrieved from the study, contributed mainly by antibiotics (24.2%) and antipyretics (11.2%). Among antibiotics cephalosporins (38.1%) were the most common ones. Bronchodilators (45.8%) were the most often used respiratory system drug and proton pump inhibitors (44.9%) were most repeatedly used GI drug. Branded drugs were most commonly prescribed as compared to generic drugs. Among dosage forms, injectable (36.1%) were most frequently prescribed over syrups (32.6%) and tablets (10.1%). Oral route was the most commonly used route of administration of drugs contributing (51.1%) followed by parenteral route (36.1%) and nasal route (10.3%) respectively. In our study of assessment of prescribing practices in paediatric patients in a tertiary level referral hospital in south Malabar region of Kerala, we analysed over 87 prescriptions. According to the results procured from the study, a total of 466 drugs were identified. LRTI was the most prevalent disease and was found to be the primary cause for hospitalisation in paediatric patients. Antibiotics were the most commonly prescribed class, contributed mainly by Cephalosporins. Most enrolled patients stayed in hospital for 3-5 days and majority of the prescriptions had 4 drugs. Among all available routes for administration, oral route was preferred over others, because it is not invasive and carries a low risk of pain. By using NFI, rationality and safety of prescribing pattern were analysed and using Medscape potential drug interactions were identified.

Keywords: Prescribing practices, Paediatric patients, Drug interaction.

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INTRODUCTION
Paediatrics is the branch of medicine dealing with the development, diseases and disorders in children. Effective medical treatment of a paediatric affected person is based upon an accurate analysis and superior route of therapy, which normally involves a medication regimen. Age group identified by ICH on pharmacokinetic and physiological difference is as follows:

- Pre term new-born (Infants)
- Term new-born infants (0-27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2-11 years)
- Adolescents (12years – 16-18 years [dependent on region]).

Prescribing practices are an indication of health professional’s skill to determine among the various choices of drugs and decide the ones that will most advantage to the patients. The study of prescribing pattern is a issue of the medical audit and seeks to reveal, examine and if necessary, recommend amendment in prescribing practices to make medical care rational and cost effective. Prescribing pattern studies are powerful exploratory equipment to verify the role of drugs in society. In a tertiary care centre, prescribing is anticipated to be judicious, secure, safe, effective and economical. The ultimate goal is to achieve rational and effective medical care, particularly in the economically developing countries. Considering these facts, this study is planned to analyse the prescribing pattern in paediatric patients at a tertiary care hospital. Medicines used in paediatric patients are complex compared to adults. Rational prescribing has been defined by the World Health Organisation as the judicious, secure, safe, effective and economical use of medicines.
Organisation as “when patients receive the appropriate medicines, in doses that meet their own individual requirements, for an adequate period of time, and at lowest cost both to them and the community”. 4

When designing and developing paediatric medicines, the route of administration, dosage form, and dose of the active ingredient (API) are decided on the basis of the expected duration of the therapy, the disease affecting a patient and his/her age, size, physio-pathological condition, API organoleptic and physicochemical properties (taste, aqueous solubility), its pharmacokinetic and pharmacodynamics properties, and stability during manufacture, storage, and use of the chosen formulation.5

Irrational utilization of medicines in paediatrics become very common in clinical practice due to many factors. It explores various factors like paediatric ethics, unlicensed or off-label use of medicines, unavailability of suitable formulations, administration difficulties, etc that influence in the rational prescribing in the paediatric population.6

METHODOLOGY

A Prospective observational study was conducted for a period of six months with an aim to assess the prescribing practices of paediatric patients in paediatric departments of KIMS Al-Shifa Super Speciality Hospital, Perinthalmanna, Malappuram. The patients were selected from the departments by checking inclusion and exclusion criteria. Inclusion criteria includes Patients of 0-12 years of age in Paediatric department and In-patients and Exclusion criteria includes Patients above 12 years of age in paediatric department ,Patients admitted in ICU and Outpatients The study was carried out for a period of six months, commencing from January 2021 to July 2021 in the Paediatric department of tertiary care hospital.All the patients from the selected departments were monitored during the study period and an inclusion and exclusion criteria was made. The inclusion and exclusion criteria as specified in the protocol submitted to IEC and approved by IEC of KIMS Al-Shifa Super Speciality Hospital. Literatures supporting the study were collected from authorized international and national journals. Information from the review of these literatures and the scenario in the study site were put together in developing a data collection form and a protocol. A suitably designed data collection form was used to collect and record patient data, which describes the patient’s demographics, patient’s medication and brand name, generic name, indication, dose, route, frequency, ADRs, drug interactions, medication error, etc. All relevant data for the study were collected from the various sources such as patient case file, case reports, treatment chart, diagnosis are recorded in the data collection form. The demographic data includes age, gender, MRD number, department, date of admission, date of discharge, etc. All the patient data were reviewed prospectively and monitored extensively. The sample size (n) is calculated according to the formula:

\[ n = \frac{Z^2 \cdot p(1-p)}{e^2} \]

where;

\[ Z = 1.96 \] for a confidence level (α) of 95% and got sample size equal to 87.

Data was analysed using the SPSS statistical software version 21 and MS Excel for analysing the descriptive statistics. Chi square test with 95% confidence interval is used to present the results and a P value < 0.05 is considered as statistically significant.

RESULTS

To assess the prescribing practices among paediatric in-patients, data has been collected from 87 patients admitted to Al Shifa hospital and observations are as follows: Among 87 prescriptions analysed, male patients (n=51) were more in number as compared to female patients (n=36). Paediatric age group 9of 1-3-years contribute 34.5% (n=30) of all prescriptions analysed, followed by infants (<1 years) of age 11.5% (n=10) and children (>11years) of age 3.4% (n=3).Out of all the prescriptions analysed, LRTI (24.1%, n=21) was the most frequently identified disease, followed by pneumonia (13.8% n=12), viral fever (9.2%, n=8), and acute viral hepatitis (5.7%, n=5).

| S.No | Diagnosis | No. of Prescription (n=87) |
|------|-----------|----------------------------|
| 1    | Pneumonia | 12                         |
| 2    | Acute lower respiratory infection | 21                      |
| 3    | Acute upper respiratory infection | 1                       |
| 4    | UTI       | 4                          |
| 5    | Diarrhea  | 4                          |
| 6    | Acute bronchiolitis | 2                      |
| 7    | Acute tonsilitis | 2                      |
| 8    | Wali      | 3                          |
| 9    | Acute gastritis | 4                      |
| 10   | Simple Febrile Seizure | 2                      |
| 11   | Dehydration | 1                       |
| 12   | Scarlet Fever | 4                       |
| 13   | Acute Kidney Injury | 1                       |
| 14   | Mesentric Adenitis | 2                      |
| 15   | Vir Fever  | 8                          |
| 16   | Seborrhoic Dermatitis | 1                      |
| 17   | Paracetamol Poisoning | 1                      |
| 18   | Acute Cervical Lymphadenitis | 1                      |
| 19   | Seizure   | 4                          |
| 20   | Iron deficiency anemia | 1                      |
| 21   | Anaphylactic Shock | 1                       |
| 22   | Bacterial Parotitis | 1                       |
| 23   | Acute Viral Hepatitis | 5                       |
| 24   | Meningitis | 1                       |

Table 1: Distribution of disease
Among all hospitalized paediatric patients, 41.4% (n=36) of patients stayed in hospital for 3-5 days, 32.2% (n=28) of patients stayed in hospital for 1-3 days. Among all 87 enrolled patients, a total of 466 drugs were identified. Distribution shows, 24.1% (n=21) patients were prescribed with 4 drugs and 21.8% (n=19) patients were prescribed with 5 drugs.

Table 2: Category of drugs

| S.No | Category of Drugs         | No.of Drugs (n=466) |
|------|---------------------------|---------------------|
| 1    | Antibiotic                | 113                 |
| 2    | Antiemetic                | 15                  |
| 3    | Anti histamine            | 34                  |
| 4    | Anti pyretic              | 52                  |
| 5    | Anti convulsant           | 10                  |
| 6    | Anti cholinergics         | 4                   |
| 7    | Analgesics                | 5                   |
| 8    | Bronchodilators           | 40                  |
| 9    | Calcium Supplements       | 3                   |
| 10   | Corticosteroids           | 15                  |
| 11   | Vitamin Supplements       | 33                  |
| 12   | ORS                        | 49                  |
| 13   | Leukotriene Receptor Antagonist | 1             |
| 14   | H2 Blockers               | 4                   |
| 15   | Expectorant               | 16                  |
| 16   | Pre-Probiotics            | 5                   |
| 17   | Benzodiazepines           | 8                   |
| 18   | Proton Pump Inhibitors    | 21                  |
| 19   | Decongestants             | 10                  |
| 20   | Mucolytics                | 2                   |
| 21   | Zinc Supplements          | 3                   |
| 22   | NSAID                      | 12                  |
| 23   | Antifungals               | 1                   |
| 24   | Antispasmodic             | 1                   |
| 25   | Hepatoprotectant          | 2                   |
| 26   | Laxative                  | 1                   |
| 27   | Skin Protectant           | 2                   |
| 28   | Anti diarrheal            | 1                   |
| 29   | Anti Viral                | 3                   |

A total of 466 drugs were analysed among 87 paediatric patients. Among all categories of drugs commonly used class was antibiotics (24.2%, n=113), followed by antipyretics (11.2%, n=52) and ORS (10.5%, n=49) respectively.

7 different classes of antibiotics were prescribed among paediatric patients, out of which cephalosporin (38.1%, n=43) and penicillin (34.5%, n=39) were prescribed most frequently followed by aminoglycoside, macrolide, carbapenams, fluoroquinolones, nitroimidazoles.

Figure 1: Number of drugs

Figure 2: Classes of Antibiotics

Among all the respiratory system drugs administered to paediatric patients, bronchodilators 48.1% (n=40) were the most common ones, followed by expectorants 19.2% (n=16), corticosteroids 18% (n=15), nasal decongestants 12% (n=10) and mucolytics 2.4% (n=2). Out of all the prescriptions analysed in paediatric department, the most commonly prescribed GI Drug was proton pump inhibitors 42.8% (n=21), followed by antiemetic 30.6% (n=15), 10.2% (n=5) pre-probiotics and 8.1% (n=4) H2 blocker. Oral was most commonly used route of administration of drugs contributing 51.1% (n=238), followed by parenteral 36.1% (n=168), nasal 10.3% (n=48) and topical 1.3% (n=6) respectively. Analysis of prescriptions showed that injectable (36.1%, n=168) was the most commonly used dosage form in paediatric patients, followed by syrups (32.6%, n=152) and tablets (10.1%, n=47). Brand drugs (89.5%, n=417) were commonly prescribed as compared to generic drugs (10.3%, n=49) in paediatric patients. Analysis of 87 prescriptions revealed presence of irrationality among them. Wrong dose contributed to 6.9% (n=6). Improper indication was identified in 1.2% (n=1) of prescription and improper route of administration was indicated by 1.2% (n=1) of prescriptions.
A total of 25 pDDIs were identified. Among these, most interactions were of mild severity (1.6%, n=15), followed by major (0.3%, n=3) and moderate (0.7% n=7).

Table 3: Drug interactions

| S.No | Severity | Frequency (n=466) |
|------|----------|------------------|
| 1    | Major    | 3                |
| 2    | Moderate | 7                |
| 3    | Mild     | 15               |
| 4    | Not Reported | 441          |

Analysis of association between disease distribution and age of 87 prescription revealed that the most frequently identified disease was LRTI among the children between 3 to 5 years of age (42.9%) and followed by pneumonia among the children between 1 to 3 years of age (41.1%). The obtained P value is 0.001, therefore the result is statistically significant. Analysis of association between disease distribution and category of drugs of 87 prescription revealed that antibiotics are the most commonly prescribed drug for children with LRTI (76.2%) and followed by Antiemetic in children with acute gastritis (37.5%). The P value obtained is 0.026, therefore the result is statistically significant.

DISCUSSIONS

This study mainly aims to analyse the current drug prescribing pattern in paediatric patients, in order to ensure the rational and safe use of medication. Study conducted by the Neelkanth Reddy Patil et al. and study by Venkateshwaramurthy N et al. had similar results. The age distribution of the patients showed that 10 patients were less than 1 year old, 30 patients were between 1-3 years old, 20 patients were between 3-5 years old, 15 patients were between 5-7 years old, 5 patients were between 7-9 years old, 4 patients were between 9-11 years old, 3 patients were greater than 11 years old. Prescription analysis identified that enrolled patients mostly belong to the age group of 1-3 (34.5%), followed by the age group of 3-5 (23%). Length of stay in hospital depends on cause and severity of disease. Most patients participating in the study stayed in hospital for duration of 3-5 days contributing to 41.4% of the population. Paediatric prescription analysis identified Acute Lower Respiratory Tract Infection (24.1%) and pneumonia (13.8%) as the most prevalent disease among them, which coincides with results obtained from Neelkanth Reddy Patil et al., where respiratory tract infections was identified as the most common disease contributing to 34.2% of all the prescriptions. About 21 patients were diagnosed with Acute Lower Respiratory Tract Infection (24.1%). 12 patients were found to be diagnosed with Pneumonia (13.8%). 24.1% were prescribed up to 4 drugs and 21.8% were prescribed up to 5 drugs which contradict with the study conducted by Ajapuje et al., where 40% of patients were prescribed up to 3 drugs and 60% were prescribed with 4-7 drugs. 15 At least 2 drugs were prescribed in every prescription. A total of 466 drugs were prescribed within the study period. Where antibiotics (24.2%) were the most commonly prescribed ones, followed by anti-pyretic (11.2%) and ORS (10.5%). This coincides with the study conducted by Ajapuje et al., where they obtained a total of 814 drugs and identified that antibiotics (24.9%) were most commonly prescribed followed by antipyretic drugs. 15 The most frequently prescribed drug class was antibiotics (n=113) 24.2%. In our study, we found that Cephalosporin (38.1%) as the most frequently prescribed antibiotic, followed by Penicillin (34.5%), Aminoglycoside (13.3%), Macrolides (10.6%), Nitroimidazoles (1.8%), Carbapenems and fluoroquinolones (0.9%) which was similar with the findings of Choudhary DK et al., where cephalosporin (41.5%) group of antibiotics were the most commonly prescribed antibiotics, followed by penicillin (38.5%), aminoglycoside (20%), macrolides (9%) and fluoroquinolones (1%). Among respiratory system drugs prescribed, Bronchodilators (48.1%) was the common ones followed by Expectorant (19.2%) and Corticosteroids (18.0%), this contradicts with the result of Venkateshwaramurthy N et al., where Nasal decongestants (45%) were mostly prescribed ones followed by bronchodilators (40%).3 Gastrointestinal drugs were prescribed in the pattern of Proton pump inhibitors (42.8%), Antiemetic (30.6%) in this study. This result is incompatible to the study done by Venkateshwaramurthy N et al., where antiemetics are most commonly prescribed4. In the study oral route (51.1%) were the most common route of administration followed by parenteral route (36.1%) and nasal route (10.3%) which was quite opposite to the study done by Tadele Antinafu et al., parenteral (48.4%) was identified as the most commonly
used route, followed by oral route (40.1%) and rectal route (9.6%). Injectable (36.1%) were the most commonly used dosage form in paediatrics followed by syrups (32.6%), tablets (10.1%), neboulisations (9.2%) and drops (5.6%). Younger children find tablet & capsule difficult to swallow & taste is also an issue for compliance. The study also evaluated Rationality within the study period where 1.2% prescriptions showed wrong indications and 6.9% prescriptions showed dosing errors. This contradicts to the study conducted by Rainu kaushal et al., showed 34% of dosing errors followed by route of administration. We found out 3 incomplete prescriptions which include prescription without weight, frequency and route of administration. Medscape was used to identify drug interactions throughout the study. The interactions are more in patients who receive a greater number of medications. Majority of the drug interaction found in the study population was mild (n=15 1.6%), which is followed by moderate (n=7 0.7%) and major (n=3 0.3%). Contrary to our study, Henok Getachew et al., observed that moderate interactions (50%) contributed the most, followed by major (42.7%) and minor (7.2%) interaction respectively. When we compared distribution of diseases with age, the highest incidence is found between the ages 3-5 years. LRTI is one of the most common illnesses followed by pneumonia. By comparing disease v/s category of drugs, 87 prescriptions revealed that antibiotics are the most commonly prescribed drug for children with LRTI (76.2%) and followed by Antiemetic in children with acute gastritis (37.5%). And the result obtained is statistically significant.

CONCLUSION

In our study of assessment of prescribing practices in paediatric patients in a tertiary level referral hospital in south Malabar region of Kerala, we analysed over 87 prescriptions. According to the results procured from the study, a total of 466 drugs were identified. There are many potential difficulties involved with prescribing to children. There is a paucity of randomized clinical studies designed to test medication use in children. LRTI was the most prevalent disease and was found to be the primary cause for hospitalisation in paediatric patients. Antibiotics were the most commonly prescribed class, contributed mainly by Cephalosporins. Most enrolled patients stayed in hospital for 3-5 days and majority of the prescriptions had 4 drugs. Among all available routes for administration, oral route was preferred over others, because it is not invasive and carries a low risk of pain. Parents will generally feel comfortable with this delivery method, leading to improved compliance for drugs via this route. By using NFI, rationality and safety of prescribing pattern were analysed and using Medscape potential drug interactions were identified.

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