(RESEARCH ARTICLE)

Assessment of drug therapy problems in pediatric patients using Cipolle/Morley/strand classification: A hospital based study

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Abstract

Drug plays an important role in treating diseases and improving health. However, inappropriate drug use can lead to the occurrence of drug-Therapy problems (DTPs). According to Cipolle/Morley/Strand classification DTPs are any undesirable event experienced by the patient that involves or is suspected to involve drug therapy and that actually or potentially interferes with a desired patient outcome. The purpose of this study was to assess the drug therapy problems in a pediatric ward of Srinivas institute of medical science and research centre and to identify associated factors for drug therapy problems.

A retrospective observational study was carried out to assess drug therapy problems (DTPs) in paediatric patients using Cipolle/Morley/Strand classification from January to June 2024. Ethical approval was obtained, and informed consent was signed by each study participant's parent before the commencement of the study. All paediatric out patients and patients admitted to the paediatric ward during the study period were included in the study. Data were collected through medical record reviews of patients and using semi structured questionnaire. Data was analysed using Microsoft Excel.

The participants mean age was 2.32 years. Among 150 patients, 116 (77.33%) of them had at least one drug therapy problem per patient which indicates that the prevalence of the drug therapy problem was substantially high. On the other hand, Adverse drug reaction was the least 4 (3.38%) drug therapy problem. Hence to ensure optimum care in paediatric patients, a targeted approach is essential. Thus, the present study concluded that pharmacists can be helpful in the identification of the drug therapy problems, their causes and the risk factors involved and thus lead to a better health care outcome.

Keywords: Drug Therapy Problems; Paediatric Population; Cipolle/ Morley/Strand Classification

1. Introduction

Drugs plays an important role in treating diseases and improving health. However, inappropriate drug use can lead to the occurrence of Drug therapy problems (DTPs). According to Cipolle/Morley/Strand classification DTPs are any undesirable event experienced by the patient that involves or is suspected to involve drug therapy and that actually or potentially interferes with a desired patient outcome [1]. DTPs could be identified by comparing the appropriateness of indications, dose, drug administration time, and drug Adverse reactions with commonly used recommendations (Table 1). Paediatric patients represent a population at high risk for drug-related problems.[2] DTPs can occur in various patient populations and ages. In particular, the appearance of DTPs in paediatric patients has become a major concern, with about 30 to 40% of paediatric patients experiencing at least one DTP. [2,3] Most DTPs are related to prescribing: drug

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selection, dosage, and usage, DTP occurrence may result in treatment failure, and increase the rate of follow-up visits and rehospitalization, as well as significantly increase the need to prescribe additional drugs and the treatment costs. [4,5,7] To provide appropriate solutions to minimize DTPs and achieve desired outcomes at optimal costs, it is vital to identify and classify DTPs

Table 1 Drug Therapy Problems

Drug-Therapy Problem	Definition
Indication	
Need for additional therapy	The patient has a medical indication that callsfor additional drug therapy but is not receiving a drug for the same.
Unnecessary therapy	The patient is taking a drug for no medically valid indication.
Drug dose too high	The drug is prescribed with high single dose and/or excessive number of times taking medicine daily, resulting in a 24-h dose that is higher than the maximum recommended dose.
Drug dose too low	The drug is prescribed with low single dose and/or excessive number of times taking medicine daily, resulting in a 24-h dose that is lower than the minimum recommended dose.
Adverse drug reactions	The patient has a medical problem due to an Adverse Drug Reaction or adverse effect.
Wrong drug	The prescribed drug is invalid for the indication.
Adherence problem	The patient fails to adhere to his medications.

Children always need special health care due to their vulnerable features, thus gaining more medical attention than adults. However, because of the complexity of paediatric cases treatment, the DTPs rate in some developing countries was surprisingly high, reported from 31.57% to 80.1%.[7] Even though DTPs in outpatients are very common and contribute to iatrogenic morbidity, studies have accessed DTPs in the inpatient paediatric setting,[8] and little is known about this outpatient rate.[9] Additionally, the impacts of DRPs occurring in outpatients and inpatients are the same in terms of treatment efficacy, safety, and cost. However, since the medications are mostly administered to a child and tracked by parents and caregivers at home or school, it is difficult to determine and subsequently monitor the harmful consequences of DTPs in paediatric outpatient treatment.[10] Therefore, taking the initiative to detect and prevent these DTPs is basically needed. For this reason, this study has been conducted in which the aim is to evaluate the types and impact of DTPs on treatment effectiveness, safety, cost, and factors related to DTP occurrence when prescribing for paediatric outpatient and inpatient.

OBJECTIVES

- To identify and assess the various types of drug therapy problems in paediatric patients using Cipolle/Morley/Strand classification

2. Materials and Methods

- **Study Site:** A hospital based observational study was carried out in Srinivas institute of medical science and research centre.
- **Study Design:** A hospital based observational study.
- **Study Period:** The study was conducted for a duration of 6 months.
- **Study Sample Size:** 150 patients
- **Ethical Clearance:** The ethical clearance was obtained from the Institutional Ethics Committee (IEC) of Srinivas Institute of Medical Science and Research Centre (SIMS & RC), Mukka, Mangaluru.
- **Subjects:** The study was conducted among pediatric population between the age group of 1 month – 17 years.

2.1. Study Criteria

2.1.1. Inclusion Criteria

- Patients of both sexes between age group of 1 month-17 years

- Patients with any illness (1 month-17 years)

2.1.2. Exclusion Criteria

- Patient care taker who are not willing to participate in the study
- **Source of Data:** The data for the study were collected using data collection forms. The data collected included patient's demographic details, personal history, medical and medication history, current diagnosis and drug therapy details, and any problems that were observed by the patient during the course of the treatment.
- **Materials Used:** Data were collected using a structured patient caretaker interview form.
- **Study Method:** Ethical committee approval was obtained before starting of this study. Patient interview form was designed as per need of the study. Hospital visits were done and data were collected via patient interview and patient interview forms. The data included patient demographic data, personal history, medical and medication history, current diagnosis and drug therapy details and any problems that were observed by the patient during the course of the treatment. The collected data were analysed by the investigators and the type of DTPs were identified. All the data were kept confidential.
- **Data Analysis:** Data collected were analysed using Microsoft Excel

3. Results

3.1. Demographic details

A total of 150 Paediatric patients (aged between 1 month-17 years old) were enrolled in the study. Patient details along with their medical history was collected from each of them with the help of patient interview form. Out of 150 patients, 88 were male and 62 were female. Among the 150 patients who participated in the study, 142 patients had just one ailment and 16 patients were prescribed with more than 5 drugs. The detailed demographic features of patients participated in this study is given in Table 1.

Table 2 Demographic features and clinical characterization of the patient

Variable	Category	Frequency n=150	Percentage (%)
AGE	0-1month	1	0.67
	1month-1 year	14	9.33
	2years-12 years	111	74
	13years-17years	24	16
GENDER	Male	88	58.67
	Female	62	41.33
NUMBER OF DRUGS PRESCRIBED	1-4	134	89.33
	≥ 5	16	10.67
NUMBER OF AILMENTS	Single ailment	142	94.67
	Multiple ailment	8	5.33
	Number(n=118)	Percentage (%)	
COMPLICATIONS			
YES	4	3.39	
NO	114	96.61	

3.2. Level of significance of DTPs

In this study, the severity of identified DTPs was classified as major, moderate, and minor.[27]

- **Major:** Major DTPs are those which require intervention to prevent serious or irreversible detrimental effects on the patient.
- **Moderate:** These DTPs require moderate adjustments in the therapy and hence reduce the patient morbidity and treatment costs.
- **Minor:** Minor DTPs are those which require only minor adjustments and alterations in the therapy.

Out of 116 patients who had DTPs, 82 (70.69%) were classified as 'minor', 33 (28.45%) as 'moderate' and 3 (2.59%) as 'major'.
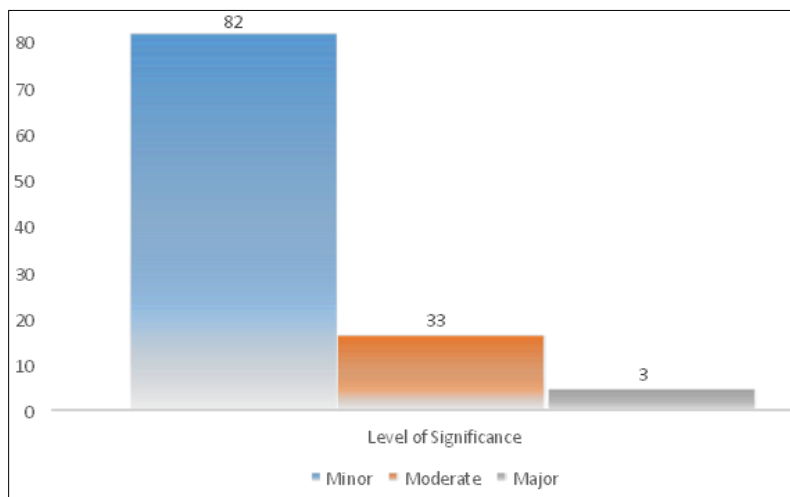
Figure 1 Level of Significance of DTPs

3.3. Distribution of dtps among study subjects

Out of 150 patients, 116 patients were found to have DTPs. Among them, a total of 118 DTPs were identified. The identified DTPs were classified based on the Cipolle/Morley/Strand classification as shown in Table 3.

Table 3 Distribution of DTPs among study population using the Cipolle/Morley/Strand classification

Types of DTPs	Description	Frequency N= 150	Percentage (%)
Need for additional therapy	The patient has a medical indication that calls for additional drug therapy but is not receiving a drug for the same.	9	7.63
Unnecessary therapy	The patient is taking a drug for no medically valid indication.	8	6.78
Dose is too high	The drug is prescribed with high single dose and/or excessive number of times taking medicine daily, resulting in a 24-h dose that is higher than the maximum recommended dose.	21	17.8
Dose too low	The drug is prescribed with low single dose and/or excessive number of times taking medicine daily, resulting in a 24-h dose that is lower than the minimum recommended dose.	11	9.32
Wrong drug	The prescribed drug is invalid for the indication.	0	0
Adverse Drug Reactions	The patient has a medical problem due to an Adverse Drug Reaction or adverse effect.	4	3.39
Adherence problem	The patient fails to adhere to his medications.	65	55.08

In the present study, Adherence problem (55.08%) were most identified DTPs followed by dose too high (17.8%), Dose too low (9.32%), Need for additional therapy (7.63%) and Unnecessary therapy (6.78%).

4. Discussion

Drug therapy problems are becoming a major public health concern. Paediatric patients are particularly highly vulnerable to DTP's caused by multiple factors such as poly-pharmacy, and inappropriate prescribing. Many of these pharmaceutical groups contain active ingredients that are potentially associated with a higher incidence, or more serious, adverse reactions in Paediatric patients, and for this reason they have been included in various lists of drugs that have to be avoided.[11] Hence, identification and prevention of DTP's in this population is very crucial. So, an observational study was conducted to identify and assess various Drug Therapy problems by using Cipolle/ Morley/ Strand classification.

Several reasons exist for the relative lack of information about the drug therapy problems in the paediatric. In contrast to in-patients, out-patients are responsible for both procuring and administering their own medications. Also, physicians do not have regular contact with outpatients and are hence less likely to be aware of their problems. According to Cipolle/Morley/Strand classification DTPs are any undesirable event experienced by the patient that involves or is suspected to involve drug therapy and that actually or potentially interferes with a desired patient outcome.[1] The finding that Adherence problem is the most common DTP was also noted by in the study conducted in Ethiopia(28.65%) and Côte d'Ivoire (24.1%).[8] The expense and numerous drugs that the patient was prescribed were the most frequent reasons for noncompliance with patient care taker reports. Dosage forms have occasionally been mentioned by the patient caretaker as a reason for non-compliance. 150 paediatric patients of either sex, diagnosed with one or more disorders, ranging in age from one month to seventeen years, took part in the current study. 116 of the 150 patients who took part in the trial had DTPs, it was discovered. 118 DTPs in all were found among the 116 patients. The finding was greater than the 74.3% of the Ethiopian study. The fact that the hospital environments differ and that clinical chemists are more readily available in paediatric ward.[2]

Of the 116 individuals diagnosed with DTPs, 67 (68.29%) were male and 51 (75%) were female. This suggests that male patients are more likely than female patients to have DTPs. Approximately 70% of participants were younger than 6 years old. These age groups' physiological traits and physical development closely matched those of male and female patients, indicating that sex had no bearing on the likelihood of developing DTP.[7]

The severity of identified DTPs was classified as minor, moderate and major. Out of 118 DTPs in 116 patients, 82 (70.69%) were classified as 'minor', 33 (28.45%) as 'moderate' and 3 (2.59%) as 'major'. Thus, minor drug therapy problems were found to be more in number followed by moderate and major. Major DTPs were defined as DTPs that require intervention to prevent major or irreversible detrimental effects or due to lack of appropriate therapy in circumstances where evidence-based options were available. While moderate DTPs included DTPs in which interventions would result in moderate benefit for the patient. The DTPs that require only small adjustments, such as modifications to dosage timings were considered as Minor DTPs.[12]

Unnecessary drug selection involved the patient's medical condition being treated with a drug that is not necessary for the patient's needs. 8 out of the 118 DTPs identified belong to this category (6.78 %). For example, in the present study, it was identified that a patient was given with Syp. tonoferon which is usually given for the treatment of folate deficiency but the patients folate levels were normal and no medications were given which would affect patients folate levels hence making syp. tonoferon an unnecessary medication, this medication along being unnecessary caused bloating in the patients leading to withdrawal of the medication. Taking medications without any valid medical indication can lead to unnecessary exposure of the paediatric patients to the drugs increasing the risk of DTP's.

The category Dose too high involves the patient being prescribed with high single dose and/or excessive number of times taking medicine daily, resulting in a 24-h dose that is higher than the maximum recommended dose. 21 of the total 118 DTP's accounting to 17.8% in the study belonged to this category. As per the guidelines for the dosage selection for paediatric patients, appropriate dose of acetaminophen to be given for the treatment of fever is 160mg every 6 hours for a 4-year-old patient where as in this study it was found that the patient was given 250mg every 6 hours which far exceeds the recommended dose, such high does when given can result in gastric disturbance, rashes etc.

Dose too low refers to the drug being prescribed with low single dose and/or excessive number of times taking medicine daily, resulting in a 24-h dose that is lower than the minimum recommended dose. 11 patients (9.32%) in this study receiving lower dose than required were identified. An example for this was a patient of 15-year-old diagnosed with chicken pox was prescribed with Paracetamol 250mg every 6hours, when the maximum dose per day for a 15 year old is 650 mg every 6 hours as a result of which the patients fever was not resolved despite adhering to the regimen. Similar results were seen in the study by Yadeta Babu Beyene et al., where the incidence of underdosage was low (26%) as compared to other DTP's.[13]

The category Need for additional therapy refers to a patient having medical indication that calls for additional drug therapy but is not receiving a drug for the same. 9 of the total 118 DTP's accounting to 7.63% in the study belonged to this category. For example, a patient who was diagnosed with bronchopneumonia experienced nasal congestion for which no medication was given leading to a lot of inconvenience.

Therefore, the present study provides an extensive data on the DTP's encountered by the paediatric population in the hospital settings of Srinivas institute of medical sciences and research centre. An important task for clinical pharmacists is therefore to identify, resolve and prevent the occurrence of DTP in this group of patients for a better health outcome.

4.1. Future prospectives

This study can be more effectively carried out in a larger population for better outcomes and more statistically significant data generation. Our findings set the stage for future studies to address the causal relation between paediatric patients and the potential DTP's encountered where the primary goal is to identify, resolve and prevent the occurrence of DTP's for a better health outcome in these group of people.

5. Conclusion

The results of this study demonstrate the contribution that pharmacists can make in promoting better medication use and ensuring that the paediatric patients receive appropriate medications for their conditions considering the physiologic factors, polypharmacy etc. and thereby minimizing the risk of potential drug therapy problems. Current prescribing practices of paediatrics showed inappropriate medications, making these population more vulnerable to ADR's. Hence, judicious prescription of drugs and careful and frequent monitoring of drug therapy are necessary to reduce the risk of drug therapy problems. Thus, the present study concluded that pharmacists can be helpful in the identification of the drug therapy problems, and thus lead to a better health care outcome.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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