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A PROSPECTIVE OBSERVATIONAL STUDY OF MONITORING OF ADVERSE DRUG REACTIONS IN PEDIATRIC PATIENTS OF A TERTIARY CARE HOSPITAL

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Abstract

Introduction: Adverse drug reactions (ADRs) are one of the major challenges occurred during the hospital admission and treatment. The safety of drug in a patient cannot be extrapolated to all the population due to interpersonal variations. Pediatric, patients are more prone to develop ADRs and can have a relatively more severe effect when compared to adults. The Pharmacokinetics and Pharmacodynamics of commonly used drugs vary significantly between different age groups.

Materials and Methods: This prospective, observational intensive monitoring of ADR was conducted in pediatric hospitalized patients of Fathima Institute of Medical Sciences, Kadapa. The study was carried out over a period of 12 months in which all patients of either gender, up to 12 years and willing to participate in the study were enrolled after taking written informed consent from legally accepted representative (LAR) and informed assent if more than 7 years. Patients not willing to participate and those transferred to other departments after admission were excluded, except if they were transferred for management of an ADR. Investigator visited the selected units daily and monitored each patient enrolled as per inclusion and exclusion criteria till discharge or for the occurrence of ADR.

Results: Out of 146 study population 79 (54.1%) were male and 67 (45.8%) were female. The incidence of ADRs was found in 51(35.27%) patients of 146 study population. The causality assessment of ADRs was done by the Naranjo scale. Among the 51 ADRs possible category were 33(64.1%) more than probable 11(21.4%) and definite 7(14.6%). Among the 51 ADRs the severity of the ADRs which were categoried by the Hartwing scale reveals that the most of the ADRs were moderate 31(60.1%), followed by mild ADRs 18(34.9%) and only severe ADRs 3(4.9%) was observed.

Conclusion: Our study concludes that ADR monitoring is the prime and remarkable step in the maintaining the drug safety, to reduce drug ADR related morbidity and mortality. The effective method like Prescription Events Monitoring (PEM) for ADR detection could be adopted in Indian hospital settings to improve the health care service to the community.

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Key Words: Adverse drug reactions, Prescription Events Monitoring, Hartwing scale, Toxic effect.

INTRODUCTION

Adverse drug reactions (ADRs) are one of the major challenges occurred during the hospital admission and treatment. The safety of drug in a patient cannot be extrapolated to all the population due to interpersonal variations. Pediatric, patients are more prone to develop ADRs and can have a relatively more severe effect when compared to adults. The Pharmacokinetics and Pharmacodynamics of commonly used drugs vary significantly between different age groups.[1]

An ADR is defined as a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function. (WHO, 1972). Pharmacovigilance which deals with the detection, assessment, understanding, and prevention of ADRs can help in providing continuous information on safety of drugs used.[2]

The term adverse effect is preferable to other terms such as toxic effect or side effect. A toxic effect is one that occurs as an exaggeration of the desired therapeutic effect and which is not common at normal doses. For example, a headache due to a calcium antagonist is a toxic effect it occurs by the same mechanism as the therapeutic effect (vasodilatation). A toxic effect is always dose related.[3]

In order to improve the accuracy of our assessments, individual causality assessments were undertaken using the Naranjo's causality assessment scale which classifies drug reactions into definite, probable, possible and doubtful ADR.[4] Severity of the reaction was assessed using ADR Severity Assessment Scale (Modified Hartwig and Siegel) which classifies ADR into mild, moderate and severe. Preventability assessment was done by using Schumock and Thornton scale which classifies the ADRs into definitely preventable, probably preventable and not preventable.[5]

MATERIALS AND METHODS

Study design: A prospective, observational study.

Study location: Department of Pharmacology, Fathima Institute of Medical Sciences, Kadapa.

Sample Size: 116 patients.

This prospective, observational intensive monitoring of ADR was conducted in pediatric hospitalized patients of Fathima Institute of Medical Sciences, Kadapa. The study was carried out over a period of 12 months in which all patients of either gender, up to 12 years and willing

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to participate in the study were enrolled after taking written informed consent from legally accepted representative (LAR) and informed assent if more than 7 years. Patients not willing to participate and those transferred to other departments after admission were excluded, except if they were transferred for management of an ADR. Investigator visited the selected units daily and monitored each patient enrolled as per inclusion and exclusion criteria till discharge or for the occurrence of ADR. Details were collected from case records and recorded in a pretested case record form (CRF). Attending doctors and nurses were also informed about the study and were requested to inform any ADR, if any. The patients who developed the ADRs were monitored daily for the progression of ADRs. The patient who developed ADRs were analyzed for demographic characteristics, cost of drug treatment used for treatment of ADRs and appropriateness of therapy for the prescribed drug by Phadke's criteria.

All patients' demographic details, medication history, therapeutic category, their social activities collected and documented in a suitably designed data collection form. All the enrolled patients was monitored from the date of admission until discharge for any change in the drug therapy. Enquire and obtained data regarding adverse drug reaction from the patient or representatives and assessed by using Naranjo's causality assessment scale, Modified Schumock and Thornton Scale for preventability, Hartwig and Siegel Scale for severity. Statistical analysis of the results was performed by using the SPSS software version 19. Categorical data were analyzed by frequency & Percentage method. Quantitative data was analyzed by central tendency distribution. Significance of difference was calculated using 95% confidence interval, with α level of 0.05.

Data analysis: Data were represented as frequency, percentages or mean ± SEM wherever applicable. Statistical significance was analyzed using student's t test, ANOVA and Chi square test.

RESULTS

Out of 146 study population 79 (54.1%) were male and 67 (45.8%) were female. The incidence of ADRs was found in 51(35.27%) patients of 146 study population.

Table 1: Gender Distribution

Gender	Number of patients	Percentage
Male	79	54.1%
Female	67	45.8%
Total	146	100

Table 2: Incidence of ADRs

ADR	Frequency	
	Number of patients	Percentage
Yes	51	35.27%
No	95	64.27%
Total	146	100

Table 3: Based on Naranjo Scale

Probability Scale	No of ADRs	Percentage
Definite	7	14.6%
Possible	33	64.1%
Probable	11	21.4%
Total	51	100%

The causality assessment of ADRs was done by the Naranjo scale. Among the 51 ADRs possible category were 33(64.1%) more than probable 11(21.4%) and definite 7(14.6%).

Table 4: Hartwing and Seigels Severity Scale

Severity Scale	No of ADRs (N)	Percentage (%)
Mild	18	34.9%
Moderate	31	60.1%
Severe	2	4.9%
Total	51	100%

Among the 51 ADRs the severity of the ADRs which were categoried by the Hartwing scale reveals that the most of the ADRs were moderate 31(60.1%), followed by mild ADRs 18(34.9%) and only severe ADRs 3(4.9%) was observed.

Table 5: Preventability scale

Preventability Scale	No of ADRs (N)	Percentage (%)
Definitely preventable	24	46.6%
Probably preventable	9	18.4%
Not preventable	18	35%
Total	51	100%

Among the 51 ADRs the preventability of the ADRs which were categorized by the schumock scale reveals that the most of the ADRs were definitely preventable 24(46.6%), followed by not preventable ADRs 18(35%), and probably preventable 9(18.4%) was observed.

Table 6: Drug class

Drug classes	No of ADRs (N)	Percentage (%)
Antimicrobials	**15**	28.1%
Antihypertensives	**13**	14.8%

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Antidiabetic	**6**	11.6%
NSAIDs	**5**	9.7%
Blood product	**5**	9.7%
CNS drugs	**3**	6.7%
Anticoagulants	**2**	3.9%
Others	**8**	15.5%
Total	**51**	100%

DISCUSSION

The present prospective observational study was conducted to identify the prevalence and associated risk factors in developing the ADRs in the hospitalized patients of Fathima Institute of Medical Sciences, Kadapa.

A total of 146 patients were enrolled randomly in the study among which 51 patients experienced ADRs. The incidence of patients with ADRs was 35.27%.

In these 146 patients 79 (54.1%) are males and 67(45.8%) are females among these 17(33%) females experienced ADRs where as 34 (67%) male experienced ADRs. The total number of ADRs observed were 103. The study done by Shivastava M et al shown that men suffered more number of ADRs 59% compared to females 41% which were in contrast to our study result.[6]

During the study period we have observed 16(20.5%) ADR related hospital admissions. The study conducted by Conforti A et al founded in their results that 11.1% of hospital admissions caused by ADRs. The study done by Martinez M et al revealed that 4.3% of hospital admissions caused by drugs. The variation in the result was due to the sample included in the study where above mentioned studies have larger the sample data. It shows that much number of populations of community who suffered with ADRs won't come to hospital unless they are severe.[7]

The Naranjo Algorhythm of causality assessment of ADRs showed that 64.1% were possible, 21.4% were probable and 14.6% definite. The study of Jha N et al mentioned in their study that 35% were probable, 32% were definite and 19% were possible. The above studies were showing that more number of ADRs comes under the category of probable.[8]

In our study Antibacterials were most ADRs implicating drugs with 28.1% following antihypertensive drugs (14.8%).[9] The study of Jha N et al also revealed that antibiotics were leading cause with 14 ADRs. This shows that still care should be increased in the antibacterial usage. The Hartwig scale of severity of ADRs observed more were moderate in nature(67%), the results were consistent with the study of Signe Thiesen et al which also shown more number of moderate ADRs (73.1%).[10]

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CONCLUSION

Our study concludes that ADR monitoring is the prime and remarkable step in the maintaining the drug safety, to reduce drug ADR related morbidity and mortality. The effective method like Prescription Events Monitoring (PEM) for ADR detection could be adopted in Indian hospital settings to improve the health care service to the community.

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