

# Assessment and Monitoring of Adverse Drug Reaction in Pediatric, Medicine, Psychiatric Department

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**Abstract:** *The adverse drug reactions (ADRs) detection is an important aspect in the concern of drug safety. The drugs very widely used in day to day life also have some serious ADRs. Objectives: To identify the adverse drug reaction in medicine, pediatric ,psychiatric and dermatology department of a tertiary care hospital and assessment of ADRs by using different standard scales. Materials and Methods: Aprospective observational study was carried among the patients in paediatric, medicine, psychiatric, and dermatology departments of Basaveshwara Medical College & Hospital, Chitradurga. Results: The causality assessment of ADRs was done by the Naranjo scale, possible category were 64.1% .The Hartwing scale reveals that the most of the ADRs were moderate 60.1%. The schumock scale reveals that the most of the ADRs were definitely preventable46.6%. Conclusion: The 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*

**Keywords:** Adverse Drug Reaction, Drug safety, Pharmavcovigilance, Risk factors

## 1. Introduction

Adverse drug reactions (ADRs) are one of the major challenges occurred during the hospital admission and treatment<sup>1</sup>. 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<sup>[2]</sup>

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).<sup>3</sup> Pharmacovigilance which deals with the detection, assessment, understanding, and prevention of ADRs can help in providing continuous information on safety of drugs used.<sup>[2]</sup>

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.<sup>[33]</sup>

On the other hand, an unwanted side effect occurs via some other mechanism and may be dose related or not. For example, the dose related anticholinergic effect of a tricyclic antidepressant is a side effect, since this action is not associated with the therapeutic effect; similarly, non dose related anaphylaxis with penicillin is a side effect. The term adverse effect encompasses all unwanted effects; it makes

no assumptions about mechanism, evokes no ambiguity, and avoids the risk of misclassification.<sup>[33]</sup>

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. 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.

As to achieve the quality outcome of treatment following factors are considered for the cause of ADR this study such as age, sex, education, predisposing factors, drug monitoring, drug re-challenge and de-challenging , dose , dosage form and assessment

## 2. Literature Survey

**Amrinde R et al.,(2016)** Conducted a study on Monitoring of Cutaneous Adverse Drug Reactions in a Tertiary Care Hospital. In the present study, the highest incidence of cutaneous ADRs was in the age group of 31-40 years (25.0%), and more frequently in female patients (54.2%). Causality assessment was certain, probable and possible for 1.6%, 93.3% and 41.5% of the reactions, respectively. 109 cases were of level 3 severities, 10 cases to level 4 severities and one case of level 7 where ADR was responsible for death in one patient. Most of the adverse drug reactions are preventable, provided the drugs are used rationally.<sup>32</sup>

**Lucca M J et al.,(2014)** Conducted a prospective Interventional study on Identification and management of

adverse effects of antipsychotics in a tertiary care teaching hospital. This study is carried out to identify the adverse drug reactions (ADRs) to antipsychotics and its management in psychiatric patients. This post marketing surveillance study provides a representative data of the ADR profile of the antipsychotics likely to be encountered in psychiatric patients in an Indian tertiary care hospital.<sup>31</sup>

**Davies E C et al.,(2014)** conducted a prospective study on “Adverse Drug Reactions in Hospital In-Patients: A Prospective Analysis of 3695 Patient-Episodes”. In their study they found to be, Out of the 3695 patient episodes assessed for ADRs, 545 (14.7%, 95% CI 13.6–15.9%) experienced one or more ADRs. Half of ADRs were definitely or possibly avoidable.

**Vijayakuma M.T. et al., (2013)** conducted a prospective study on Description of Adverse Drug Reactions in a Multi-specialty Teaching Hospital. During the study period, a total of 208 adverse drug events were reported, in which 183 reports from 172 patients were confirmed as ADRs. Out of 183 ADRs, 171 reactions were reported in in-patient departments and the remaining 12 from the outpatient department. Of all the ADRs, 132 (72.1%) reports during the hospital stay and 27.9% of ADR-related admissions were observed.

**Raut L A et al.,(2012)** Conducted a Prospective Observational study on “Preventability, Predictability and Seriousness of Adverse Drug Reactions amongst Medicine Inpatients in a Teaching Hospital: A Prospective Observational Study”. Primary objectives were to assess the preventability and seriousness of reported ADRs.

### 3. Methods

The study was an observational study conducted under the supervision of S J M College of pharmacy chitradurga, and ethical committee approved the protocol of the study. Informed consent was obtained from the patients and/or their parent or caretaker.

During 6 months from August 2016 to February 2017. The study carried in subjects treated in following paediatric, medicine, psychiatric, and dermatology wards for various diseases. Patients with less than 24h hospitalization and Pregnant and lactating women were excluded from the study. The study was approved by the Institutional Ethical Committee of Basaweshwara Medical College Hospital & Research Centre, Chitradurga. Vide number: SJMCP/IEC/16/2016-17

All patient’s 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  $\alpha$  level of 0.05.

### 4. Result

Out of 292 study population 158 (54.1%) were male and 134 (45.8%) were female. The result are shown in table 1 and graphically represented in figure.1

Gender	Number of Patients	%Of Patients
Male	158	54.1%
Female	134	45.8%
Total	292	100.0

#### 1. Incidence of ADRs

The incidence of ADRs was found in 103 (35.27%) patients of 292 study population as mentioned in the Table no.2 and Figure no.2.

ADR	Frequency	
	Number	Percentage
Yes	103	35.27
No	189	64.72
Total	292	100

#### 2. Based on Naranjo scale

The causality assessment of ADRs was done by the Naranjo scale, the Table no.7 and Figure no.8 shown that among the 103 ADRs possible category were 66 (64.1%) more than probable 22 (21.4%) and definite 15 (14.6%).

Probability scale	No of ADRs	Percentage
Definite	15	14.6%
Possible	66	64.1%
Probable	22	21.4%
Total	103	100%

#### 3. Based on Hartwing and Seigels Severity Scale

Among the 103 ADRs the severity of the ADRs which were categorized by the Hartwing scale reveals that the most of the ADRs were moderate 62 (60.1%), followed by mild ADRs 36 (34.9%) and only severe ADRs 5 (4.9%) was observed in the Table

Severity scale	No of ADRs	Percentage
Mild	36	34.9%
Moderate	62	60.1%
Severe	5	4.9%
Total	103	100%

#### 4. Schumock preventability scale

Among the 103 ADRs the preventability of the ADRs which were categorized by the schumock scale reveals that the most of the ADRs were definitely preventable 48 (46.6%), followed by not preventable ADRs 36 (35%), and probably preventable 19 (18.4%) was observed in Table

Preventability Scale	No of ADRs (n)	Percentage (%)
Definitely preventable	48	46.6%
Probably preventable	19	18.4%
Not preventable	36	35%
Total	103	100%

### 5. Pharmacological class of drug implicated to cause ADRs

From the 103 ADRs the suspected drugs caused them were classified according to the class in Table no.10 and Figure no.11 revealed that antimicrobials 29(28.1%) were the most frequent involved in causing ADRs, with the 15(14.8%) anti hypertensives drug caused more number of ADRs, followed by anti diabetic drugs 12(11.6%) NSAIDs and Blood product are the same number of ADRs 10(9.7%), were CNS drugs 7(6.7%), were anti coagulants drugs 4(3.9%) . And remaining 16(15.5%) caused by the other drugs.

Drug classes	No of ADRs	Percentage
Antimicrobials	29	28.1%
Antihypertensives	15	14.8%
Antidiabetic	12	11.6%
NSAIDs	10	9.7%
Blood product	10	9.7%
CNS drugs	7	6.7%
Anticoagulants	4	3.9%
Others	16	15.5%
Total	103	100%

### 5. 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 Basaveswara medical college hospital, Chitradurga.

A total of 292 patients were enrolled randomly in the study among which 103 patients experienced ADRs. The incidence of patients with ADRs was 35.27%.

In these 292 patients 158(54.1%) are males and 134(45.8%) are females among these 34(33%) females experienced ADRs where as 69(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.

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.<sup>64</sup> The study done by Martinez M I et al revealed that 4.3% of hospital admissions caused by drugs.<sup>65</sup> 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.

The Naranjo Algorithm 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.<sup>48</sup> The above studies were showing that more number of ADRs comes under the category of probable.

In our study Antibacterials were most ADRs implicating drugs with 28.1% following antihypertensive drugs (14.8%). The study of Jha N et al also revealed that antibiotics were leading cause with 14 ADRs.<sup>48</sup> 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%).<sup>39</sup>

### 6. Conclusion

According to the analyzed results and from view of literature, the conclusions made are; In the current scenario there are number of drug available in the market without sufficient safety data which are frequently implicating ADRs. And patient to patient response to drug varies. So that it become a challenging issue in predicting, preventing and managing the ADRs. Also the severe ADRs can be fatal too. In our study 29 ADRs were observed among more number of ADRs was due to the usage of Antimicrobials, which are very often prescribed. The high incidence of ADRs alerts the need of drug care. The serious ADRs observed were SJS, Seizure, Excessive erections of penis. These severe ADRs will cause patient hospitalization as well as more economic burden too.

Patient with poly pharmacy should be strictly monitored for the ADRs where it was most observed predisposing factor. The geriatric as well as paediatric patients more prone to get the ADRs so they should be exclusively monitored because of limited drug clinical trial and safety data. The preventable ADRs were more reported during the study , which indicating the significance of pharmacist in the prevention of ADRs.

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.

### 7. Future Scope

The study should be done with more number of sample size as well as for more time period to get results of with more statistical power. Conduction of Study for longer duration of time provides better results. outpatients can be involved for the betterment of the study. The study should also extend to community set up. The economic burden occurring to patient due to ADR also to be studied.

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