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## Prospective Study On Adverse Drug Reactions: A Step Towards Patient Safety

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### ABSTRACT

To identify the adverse drug reactions in the patients. To increase the reporting and awareness among the staffs. To evaluate the causality assessment and severity of ADRs. A prospective study was conducted for a period of one year from February 2019 to January 2020 in the Inpatients of AJ Hospital and Research Centre. Identified and reported ADRs were analyzed. ADR reporting questionnaire was provided to healthcare professionals to assess the knowledge about ADR. ADR causality assessment was carried out using WHO probability scale. Severity assessment of ADRs was done using modified Hartwig and Siegel severity scale. Paired t-test was applied to find the association between the two phases. A total of 100 ADRs were identified from 1120 patients. Causality assessment indicated that most of the ADRs were probably (85%) drug related. Severity of 79% reactions were reported as moderate. Study was categorized into two phases; Phase I and Phase II. Knowledge rate among respondents was found to be 67% in phase-I which had a remarkable increase in phase-II (92%). Common barrier for underreporting of ADR was lack of knowledge regarding ADR. The study concluded that interventions such as implementation of well-established reporting process and continuous training will help to reduce the current underreporting crisis.

**Keywords:** Adverse drug reactions, Causality assessment and severity, underreporting, interventions

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## INTRODUCTION

Adverse drug reactions (ADRs) are considered to be one of the leading causes for morbidity and mortality. Hospitalization and complications during hospitalization, such as prolonged hospital stay and increased healthcare costs, are the burdens mainly associated with ADRs <sup>1</sup>. The WHO defines an ADR as “any response to a drug which is noxious and unintended, and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function”<sup>2</sup>. According to the WHO “Pharmacovigilance is the sciences and activity relating to detection, assessment, understanding and prevention of ADR or any other medicine related risks, particularly long term and short term adverse effect of medicine”<sup>3</sup>. Using causality assessment the relationship between drugs exposure and occurrence of ADR can be identified. It is important to distinguish whether the reaction will be definite, probable or possible. The assessment of can be ADR done by using WHO causality scale <sup>4</sup>. The WHO causality scale classifies the ADR as certain, probable, possible, unclassifiable, unlikely, conditional/unclassified <sup>4</sup>.

ADRs rank among the top 10 leading causes of mortality. It is really important to study ADRs to create awareness among patients and to motivate health care professionals in the hospital to report ADRs in order to minimize the risk of occurrence of ADRs. Early detection, evaluation and monitoring of ADR are necessary to reduce patient harm and to improve patient safety.

Adverse Drug Reactions underreporting is a great challenge to pharmacovigilance. It is important to identify the barriers involved in underreporting of suspected ADRs <sup>5</sup>. ADR could be monitored through active monitoring or through voluntary reporting system in a hospital but well established reporting system for ADR reporting in the hospital can help underreporting to greater extent. Identification, reporting and assessment of ADRs can impart useful information regarding the ADR and for its management.

This study aims to analyse the pattern of ADRs, causality assessment and severity of ADRs occurring in the hospital. Study also analyse the knowledge about ADR among healthcare professionals. Few strategies were implemented through this study in the view of patient safety related to ADR.

## MATERIALS AND METHOD

### **Study design:**

A prospective observational study was for the In-patients of a tertiary care hospital. Routine case sheet review were done for identifying ADR and also the reported ADRs were analyzed. WHO probability scale was used for the ADR causality assessment. Severity assessment of ADRs was

carried out using modified Hartwig and Siegel severity scale. Study was classified into two phases to assess the knowledge about ADR among health care professionals prior to interventions and after interventions.

1. Phase I: pre- intervention
2. Phase II: Post- intervention

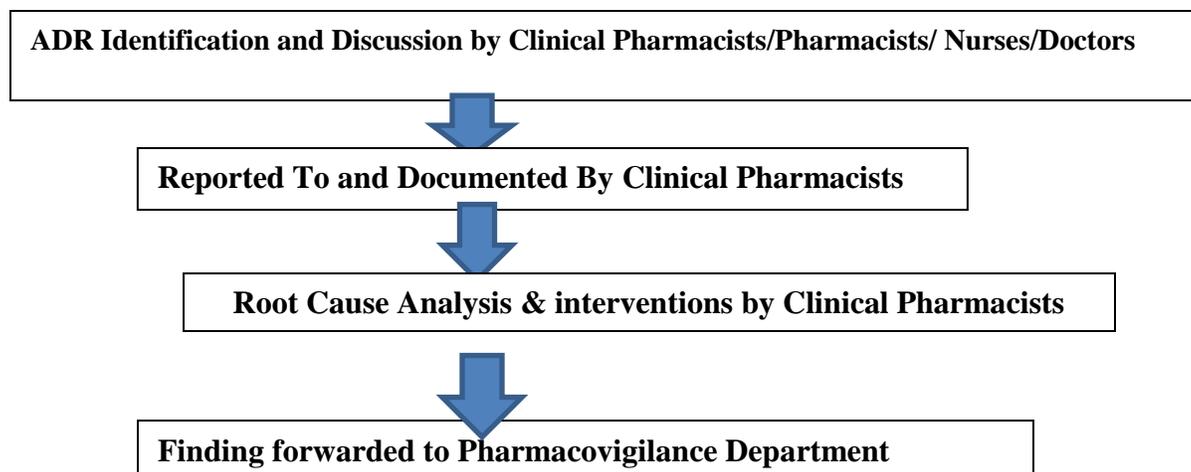
A pre-determined questionnaire was prepared which comprised of 10 questions were distributed among health care professionals to assess the knowledge about ADR and also to identify the barriers related to underreporting of ADR.

#### **Study duration:**

The study was conducted for a period of one year from August 2018 to September 2019.

#### **ADR reporting process:**

Awareness regarding ADR monitoring and reporting was given to all health care professionals in the hospital. The below shown process was introduced and followed for improved ADR reporting. ADR reporting form also was implemented for better documentation of ADR.



#### **Exclusion criteria:**

Following patients were excluded from the study: out- patients and In-patients who did not receive any drugs.

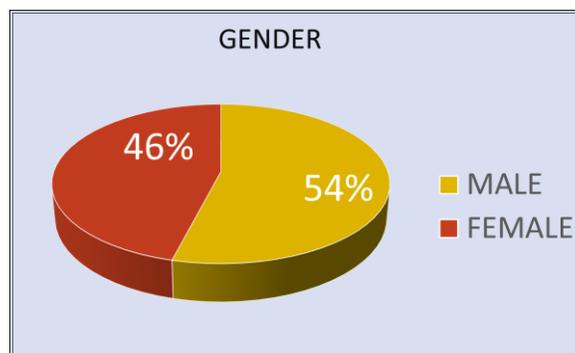
#### **Statistical Methods:**

Paired t-test was applied to find the association between the two phases and p-value less than 0.05 were considered as significant.

## **RESULTS AND DISCUSSION**

Out of 1120 patients studied, a total of 100 ADRs were identified (8.9%) in 97 patients. Based on the total population, occurrence of ADRs was slightly higher in males (54%) than females (46%) [Figure: 1]. Higher incidence of adverse events occurred in patients who were prescribed with 6-

10 (42%) number of drugs followed by those prescribed with 3-5 number of drugs (35%) [Table: 1].

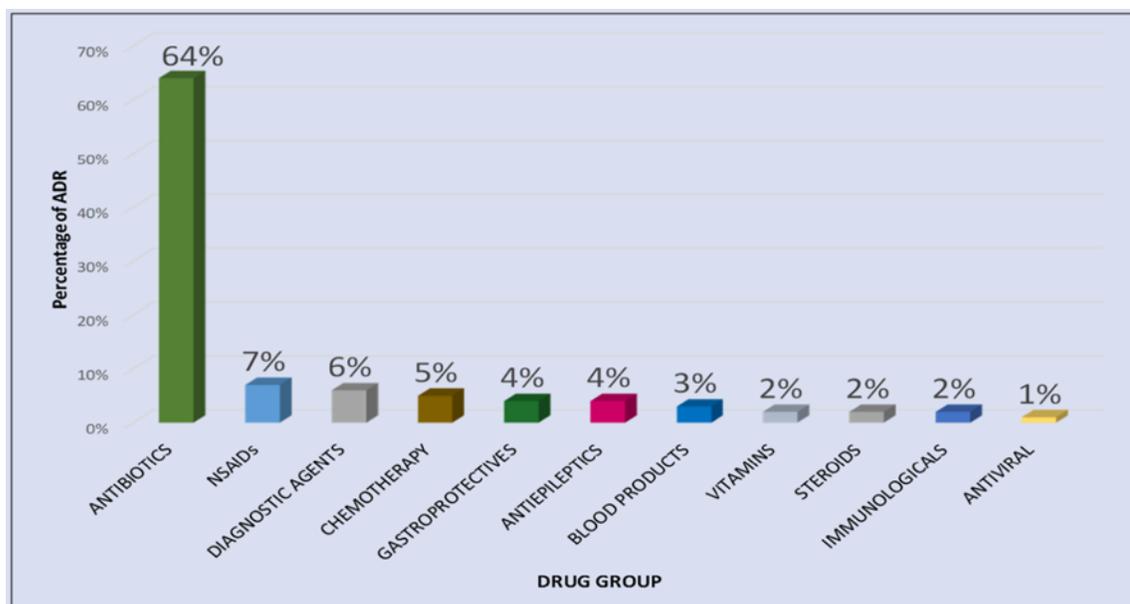


**Figure 1: ADRs based on gender of the patient**

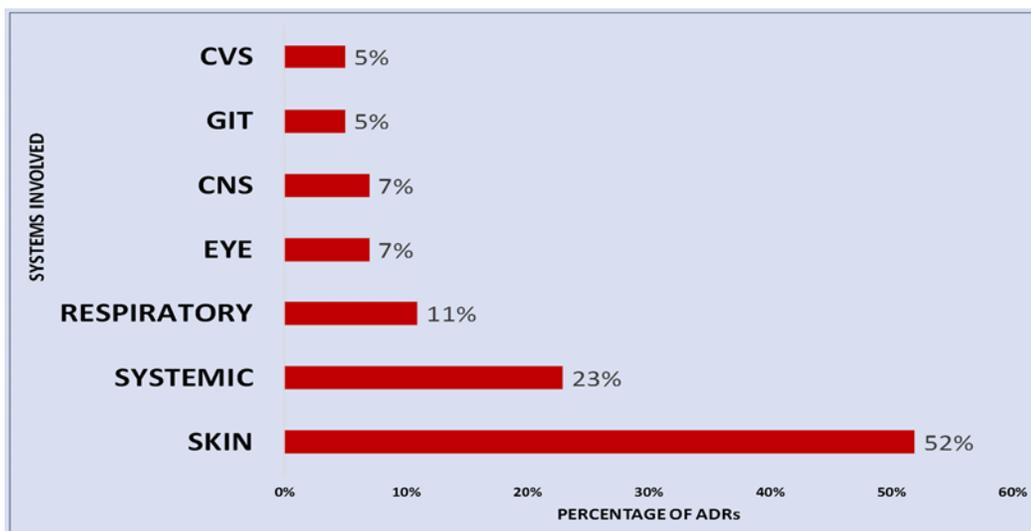
**Table 1: Number of drugs prescribed v/s Number of patient developed ADR**

Number of medications prescribed	Number of ADRs (N=87)	Without ADRs(N=1023)
Up to 2	6 (6.1%)	126(12.31%)
3-5	34 (35%)	423(41.3%)
6-10	41 (42%)	358(34.9%)
>10	16 (16.4%)	110(11.82%)

Drug class mostly associated with ADRs were Antimicrobials (64%) followed by NSAIDs (7%) and diagnostic agents (6%) [Figure: 2]. Out of 64 antimicrobials detected, maximum ADRs were reported with Inj piperacillin+Tazobactam (17.1%) followed by Ceftriaxone (21.8%), Ciprofloxacin (10.9%), Cefotaxim (6.25%). Out of 100 ADRs, Skin (52%) was the most frequently affected organ system with ADRs followed by systemic reactions involving the entire body (23%) and respiratory system (11%) [Figure: 3].

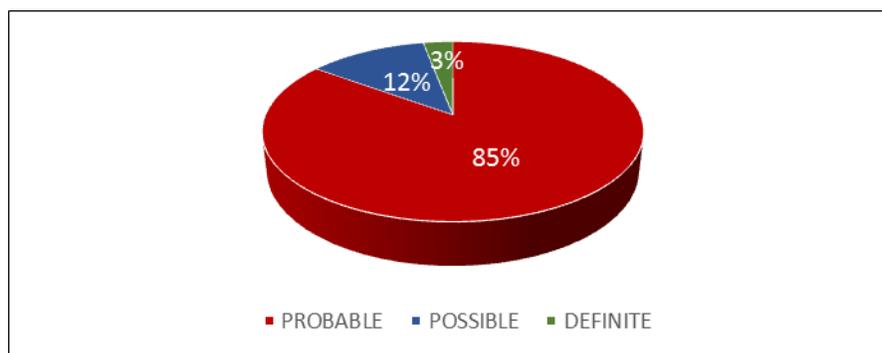


**Figure 2: Therapeutic classes of drugs implicated to cause ADRs**



**Figure 3: Organ systems involved in ADR**

Causality assessment through WHO scale indicated that most of the ADRs were probably (85%) drug related, whereas 12% were possibly drug related [Figure: 4]. 95% of the suspected drugs were withdrawn while 5% drugs were continued in the patient. Severity assessment of ADRs was performed using Modified Hartwig and Siegel scale and it was identified that severity of 79% reactions were reported as moderate, whereas 13% were considered as severe [Table: 2].



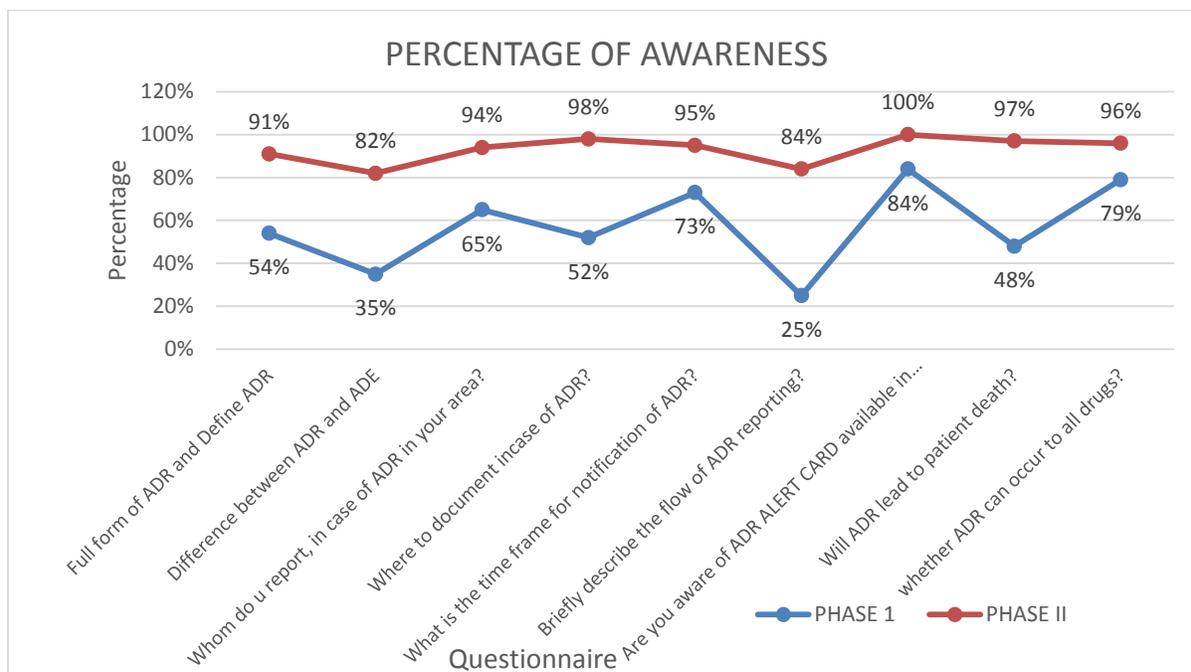
**Figure 4: Causality assessment of ADRs (using the WHO probability scale)**

**Table 2: Severity of ADRs using Modified Hartwig and Siegel Scale**

Severity	Percentage of Severity
Mild	8%
Moderate	79%
Severe	13%

Knowledge rate among 150 respondents was 57% in phase-I which had a remarkable increase in phase-II (93%). Interventions taken during phase-I were implementation of ADR reporting process and continuous training [Table: 3]. Awareness program on ADR among the health care professionals was conducted and questionnaire study revealed a significant improvement in ADR awareness ( $p < 0.001$ ) post training [Figure: 5]. Common barrier for the underreporting of ADR

was lack of knowledge regarding ADR (34%) followed by lack of knowledge about the reporting process of ADR (28%) [Table: 3].

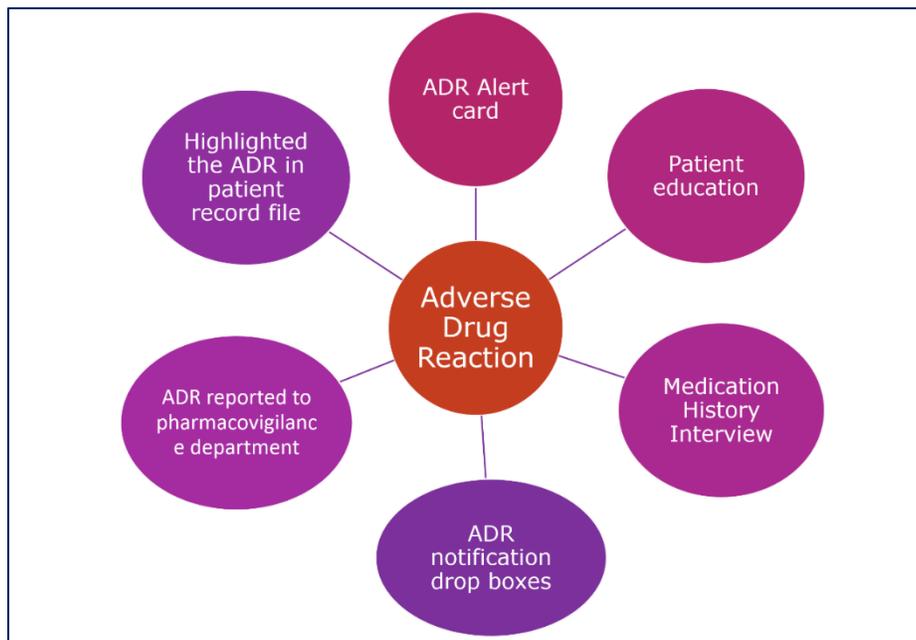


**Figure 5: Knowledge of health-care professional regarding ADR (n=150)**

**Table 3: Interventions taken for the required improvements**

Improvements required	Interventions taken
Implementation of proper reporting process	Well- established reporting process were made
Awareness regarding the ADR and ADR reporting	Continuous training to all staffs done for improved awareness.
Patient education after the occurrence of ADR	The provision of “alert card” was implemented and provided to the patients for better awareness regarding the ADR.
Proper documentation of suspected ADR	ADR is being highlighted in patient’s clinical record. The ADR forms are filled and documented and the same are forwarded to pharmacovigilance department

Few steps were put forwarded to prevent further adverse drug reactions related event. Medication history interview was carried out for the patients who came to the hospital. The provision of “alert card” along with patient education was aimed at preventing the occurrence of the similar ADR to the same drug in the same patient. ADR was highlighted in patient’s clinical record. ADR notification drop boxes made available in the hospital for improved ADR reporting. All ADRs were forwarded to the pharmacovigilance department [Figure: 6].



**Figure 6: Interventions made in the view of patient safety to reduce ADR**

In this study, the incidence rate of ADR was 8.92%. Most of the studies have reported the incidence of adverse drug reactions ranging from 2% to 20%. In the study conducted by AP Gor et.al reported the incidence of ADR as 3%<sup>6</sup>. Incidence of ADR was high in males than females as this was due to the highest number patient who got admitted in the hospital were males than females. The study results was resembling with the reports of M.Shamna et.al<sup>7</sup> which showed male predominance whereas other study conducted by Prasad RV et.al<sup>8</sup> showed higher incidence of ADR in females. The present study reveals that majority of the ADRs occurred for patient who were prescribed with 6 to 10- number of drugs (41%) In contradiction with the study conducted by NM Rayees et al.<sup>9</sup> which exhibited that, incidence of ADRs were high in patients prescribed with more than 10 number of drugs.

This study revealed that the therapeutic class of drugs which mostly accounted for ADR was Antimicrobials (64%). The result was in correspondence with study done by Shiram S et.al<sup>1</sup> which showed that mostly associated drug class with ADRs were antibiotics. Therefore the study indicates that close monitoring should be done for the patients who receive antibiotics.

Present study reveals that the most common organ system affected with ADR was skin (52%) and this results were comparable with a study done by Suh et al, which exhibited that the systems that were badly affected with ADR was the dermatological and gastrointestinal system. The study conducted by Arulmani R et al<sup>10</sup> exhibited that higher percentage ADRs affected the dermal system (56%). Causality assessment of ADRs was done using WHO probability scale which indicated that most of the reactions were found to be probable with less number of possible and

definite reactions and no reactions were unlikely in nature. This findings correlates with the study conducted by Starveva et al <sup>11</sup> and contradict with the results given in the study by Oshikoya et al <sup>12</sup>. Severity assessment of ADRs was performed using Modified Hartwig and Siegel scale which revealed that the severity of 79% reactions were moderate which were consistent with other studies done by Jimmy Jose et al and Priyadharsini et al.<sup>13</sup>

In this study, the improvements required were identified in phase-I such as the poor awareness regarding the ADR, proper documentation of ADR, patient education about the suspected ADR and a systematic reporting process. When compared with the study done by shiram S et.al <sup>1</sup>, explains the importance of ADR reporting and the ADR monitoring systems to promote better awareness among the health care workers. After identifying all these limitations interventions were put forward such as provision of 'alert card' was implemented to educate the patients about the suspected ADR so as to prevent reoccurrence of the ADR, documentation of ADR induced drug were entered in patients' medical record also documented electronically in "Medblaze software", implemented a proper reporting system of ADR and ADR notification boxes were placed in specific areas of the hospital.

The next challenge was to educate the health care professionals about the ADR and ADR reporting process. During phase-I, knowledge assessment regarding the ADR and reporting process was made using a pre-determined questionnaire. Since the awareness was less continuous training classes were provided to all health care professionals along with display of ADR reporting process in patient care areas. Hence in phase-II once more the questionnaire was provided and the awareness was increased by 93% from 57%. Present study reveals that adequate training and education can improve the ADR reporting and monitoring which is in correspondence with the study done by Priyadharsini R et al<sup>5</sup>.

The barriers for underreporting was also analysed using the questionnaire which showed that lack of knowledge about ADR and reporting process was the major limitation for reporting the ADR. This result is consistent with the study conducted by Priyadharsini R et al<sup>5</sup>.

## CONCLUSION

This study helped to find the incidence, pattern of ADR and also assess the severity and causality of suspected ADRs. Thus it enabled healthcare professionals to identify and provide better attention regarding the ADR which is an important aspect in patient safety. Through this study, it is observed that interventions such as implementation of well-established reporting process and continuous training for the thorough knowledge about ADRs helped to reduce the existing underreporting crisis and occurrence of ADR. This can result in a positive impact on patient's

health and economic outcomes, improved quality of life, and reduced morbidity and mortality related to ADR.

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