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# ADVERSE DRUG REACTION ANALYSIS IN A TERTIARY CARE HOSPITAL: PHARMACOVIGILANCE PERSPECTIVE

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## ABSTRACT

**Introduction**: Pharmacovigilance (PV) is defined as the detection, assessment, understanding and prevention of Adverse Drug Reactions (ADRs) when a drug is used. In many countries, ADRs ranks among the top ten leading cause of morbidity and mortality. There is a lack of proper protocol for monitoring and reporting of ADRs in India in most of places with rate of ADR reporting rate is as less as 1% as compared to 5% in other part of world. **Aim**: To undertake ADR monitoring in various departments of a tertiary care government hospital and to cultivate the culture of ADR reporting among fellow physicians and interns. **Materials and Methods:** This is an observational, retrospective study conducted by analysing the spontaneous ADR forms, collected over a period of 6 months (March 2017 to August 2017) at Government Dharmapuri Medical College by Department of Pharmacology. **Results:** During the period of one year, around 200 ADR forms were collected from inpatients of the hospital. Male: Female ratio was 1.44:1.Geriatric age group was most commonly affected and most of the cases were from general medicine department. Antibiotics were the most common drug which caused reactions followed by analgesics. Gastritis was most common adverse effect.Most of the patients recovered from adverse effect in course of treatment. **Conclusion:** ADR reporting is an ongoing and continuous process. Studies from the institute helps to identify and rectify the problems related to ADR reporting. The lacunae in reporting can be cleared by creating awareness among physicians and interns there by improving the ADR reporting among them.

**KEYWORDS:** ADR reporting, Drugs, Pharmacovigilance, Pharmacovigilance program of India.

## INTRODUCTION

India is basically a country with wide diversity in ethnicity, hence they are accustomed to variable modalities of medicine like ancient, traditional to the modern and alternative medicine. But there is lack of a proper structure for monitoring and reporting of adverse drug reactions (ADRs) in India, with ADR reporting rate being only 1% as compare to 5% in world[1]. Hence Pharmacovigilance (PV) is required for drug all through the time of its action. Pharmacovigilance is defined as detection, assessment, understanding and prevention of ADRs[2]. It is related to monitoring of ADRs which happens during intake of a drug.

Reporting of ADR in India has a long history since 1986 in some academic institutions.[3] In India first ADR monitoring programme was started with 12 regional centres, but this programme had a rise only after joining with WHO ADR Monitoring Program Uppsala, Sweden in 1997. It was only in 2005 National PV Program (NPVP) for India was made operational and India became member of WHO Programme for International Drug Monitoring managed by the Uppsala Monitoring Centre (UMC), Sweden and in July 2010 revised ADR monitoring programme was launched and named as Pharmacovigilance Programme of India (PvPI) under the aegis of Health Ministry, Government of India. So far 150 AMCs (ADR Monitoring Centres) are formed in Indian medical colleges overall in India. Each AMCs is responsible for collecting ADR reporting forms filled by the clinician in their college and nearby hospitals.

ADRs is generally defined as per textbook as "Any harmful or unpleasant response to a medicinal products which is unintended and which results at doses normally used for diagnosis or treatment of disease and its future administration to the patient warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product".[4] It accounts for increased patient suffering, hospitalization and economic burden to the patient and has considerable negative impact on quality of life for patient and one of the reasons for poor drug compliance. Due to this reason it has become the integral part of drug therapy and voluntary reporting of ADR is being promoted aggressively. Therefore the aim of this study was to undertake ADR monitoring in various departments of a tertiary care government

hospital and to cultivate the culture of ADR reporting among fellow physicians and interns.

## MATERIALS AND METHODS

This is an observational, retrospective study conducted by analysing the spontaneous ADR forms, collected over a period of 6 months (March 2017 to August 2017) at Government Dharmapuri Medical College, which is a tertiary care reference centre and a teaching hospital located in Dharmapuri and Department of Pharmacology. The study was commenced after obtaining approval from the Institutional Human Ethics Committee. All spontaneously reported ADR forms collected were evaluated. The causality assessment done and categorised as "certain," "probable," and/or "possible" based on Naranjo's algorithm.[5] Cases of medication errors, doubtful causality, and ADR forms with insufficient information were excluded from the analysis.

The data we received were analysed and evaluated based on Patient characteristics like age, sex type of reaction. Organ or system affected, drug causing the reaction, route, Outcome of the reaction and management were all analysed. Severity assessment: was classified into mild, moderate and severe depending on their severity with the help of severity assessment criteria developed by Hartwig et al.[6]

## RESULTS

### Characteristics of the patients

During the period of six months from March to August 2017 a total of 200 ADR were reported. Males experienced more ADRs (118, 59%) than females (82, 41%). Male: Female ratio was 1.44:1. The maximum number of reported ADRs were found in the geriatric age group (64, 32%), while next were adults above age of 30 years (50, 25%) followed by patients between 18-30 years (32,16%), while paediatric and rest had minimal reactions. The age ranges from 2 year to 85 year.

The department of general medicine reported the maximum number of ADRs (67, 33.5%), followed by the Departments of dermatology (35, 17.5%), Department of general surgery followed with 26 (13%) reports. A minimal number of ADR around 6 in total were reported voluntarily by patients". This small number was also very encouraging for us as these it was generated passively so it would help to broaden the coverage of data collection.

The intravenous route is the most common route in causing ADR with 108 (54%) patients followed by oral route related in 70 (35%) ADR's. Other routes like Topical, intramuscular, subcutaneous, intradermal, and nasal routes together constituted only 11% of ADR cases.

Gastritis in 49(24.5%) patients is the most common ADR followed by vomiting 19(9.5%) while rashes and itching were seen in 9(4.5%) patients, drowsiness was seen in few cases on OHA's, electrolyte abnormalities like potassium level disturbances were seen in few cases.

Coming to the drugs causing such reactions antibiotics were involved in the most cases (95, 47.5%), followed by analgesics (28, 14%), blood and other products (18, 9%) and oral hypoglycaemics (15, 7.5%). Among the ADR we analysed possible ADR 128 (64%), were more than probable which was around 68 (34%) and very minimal ADRs were found to be definite (4,2%). Among our study group 184 (92%) patients were completely recovered and 16 (8%) were in the process of recovery. No cases had fatal outcome. The drug which caused the reaction was stopped in 164 (82%) cases, changed in 24 (12%) cases dose was decreased in 7(3.5%) and no change was made in rest of cases.

## DISCUSSION

Adverse drug reactions are very common in daily management of patients but these are often missed by the clinician and even if they are found and reported by patients or clinician they are less-reported as many are unaware that clinically important ADRs should be reported to ADRs monitoring centres. In our study we found 200 ADR. Demographic data showed increased incidence of ADR in males in our study which was similar to study of Sharma H et al.[7] Elderly showed higher frequency of reaction which is similar to previous studies done.[3]

Majority of ADR in our study was related to intravenous route which was not similar to previous studies done like one by Shamna et al., where oral route was the major contributor to ADR, this may be justified that majority of patients in our study were inpatients for some conditions.[8] However, intravenous and oral routes together constituted over 89% of ADR. Our study reported more cases from general medicine which was different from previous studies where more cases were from dermatology.[9]

Every alternate ADR were related to either antimicrobials or analgesics in our study. Such high incidences of ADR with these drugs were also seen in some previous studies.[10] Most of the cases in our study the causality assessment was "possible" which was similar to one previous study done by Khobragade A et al. Most of the cases in our study group recovered completely. This results was similar to a study done by Arulmani et al.[10] Drug causing the reaction was discontinued in maximum cases which was also similar to previous studies.[7]

### Limitation

There are routine issues like polypharmacy, difficulties in causality assessment as re-challenge test was not done due to ethical reasons and recovery was unknown in some cases due to difficulty in follow-up after discharge. Also as most of case were inpatients there may be bias in results pertaining to the commonest route.

## CONCLUSION

ADR reporting has utmost importance as it is very much needed for drug safety evaluation in the post marketing phase. It is an ongoing and continuous process. Such studies will help us to identify and reduce the lacunae in ADR reporting. Definitely there are some hindrance in ADR reporting due to polypharmacy, diagnosis of ADR, problems with lack of time and high workload on physicians etc. Hence is very much important to create awareness and to promote the reporting of ADR amongst doctors and interns so that there will be improvement in ADR reporting in large scale.

By this study we could identify the commonest ADR in our hospital and further intensive monitoring can reduce such reactions and also this knowledge will help physicians in management of patients while using such drugs.

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