AN EVALUATION OF ADVERSE DRUG REACTIONS AT ADR MONITORING CENTER IN TERTIARY CARE HOSPITAL

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ABSTRACT

Background : Medicines are the most common medical interventions to relieve sufferings but as said rightly "drugs are double edged weapons'' with a potential to cause benefit, as well as harm.

Methods : A prospective hospital-based study over a period of six months (January 2015-june 2015) was carried out by the Department of Pharmacology under PvPIinKamineni Institute Of Medical Sciences. The ADRs of in-patient and outpatient were recorded. The data were subjected to descriptive analysis. The study plan included analysis and assessment of the clinical pattern, spectrum of ADRs reported based on causality, severity, preventability factors.

Results : A total of 100 patients were included in study. Out of which 58%(34.81±6.43) were females and 42% (35.47± 7.23)males. The most common drug group causing ADRs was antimicrobials (51%), followed by NSAID's(20%) and anti-epileptics (10%). The dermatological reactions (43%) were more, followed by gastrointestinal system (31%) and CNS (18%). Majority of ADR's were reported from OBG department (27%) followed by orthopaedics (24%).95% of ADRs were non-serious, 5% were serious but recovered. As per WHO assessment method 77% ADRs were probable and 23% possible.

Conclusion : The clinical spectrum of ADRs ranged from the more common mild reactions such as skin rashes, itching, nausea, and vomiting to moderately severe reactions prolonging the hospital stay. The predominant causative drugs were antimicrobials, non-steroidal anti-inflammatory drugs. The majority of ADRs were probable/likely in causality assessment, mild in severity and probably preventable. ADRs contribute to increased morbidity and mortality in patients; thereby pose a huge burden on the society.

Keywords: Adverse drug reaction, Causality assessment, Pharmacovigilance, adverse drug reaction centre.

INTRODUCTION

Medicines are the most common medical interventions to relieve sufferings but as said rightly "drugs are double edged weapons'' with a potential to cause benefit, as well as harm.[1] The most crucial step toward making drugs safer for human use is to prevent the occurrence of an adverse drug reaction (ADR). ADR is defined 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."[2] The incidence of ADRs varies from as low as 0.15% to as high as 30%.[3] They are a major clinical problem, accounting for 2-6% of all the hospital admissions.[4]

It is an inevitable consequence of drug therapy, as no pharmacotherapeutic agent is completely safe and more than 50% of approved drugs are associated with some type of adverse effects that are not detected prior to their approval for clinical use.[5,6] ADR reporting and monitoring activities are of vital importance for patient safety, which can generate valid data regarding causality association, preventability and severity of ADRs in the human population. This study was therefore designed to evaluate incidence and the patterns of ADRs from the reports collected from various clinical departments of this hospital and to establish the causal link between the suspected drug and the reaction by using the WHO causality definitions.[7]

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MATERIAL AND METHODS

This prospective study, was done over a period of six months (January 1, 2015 to June 30, 2015) in the clinical departments of Kamineni Institute Of Medical Sciences,(KIMS) Telangana. Institutional Ethical Review Board approval was obtained before starting the study. The Department of Pharmacology,KIMS is regional ADR monitoring center under PvPI. The reports are collected from both inpatient and outpatient departments of hospital for suspected ADRs. Data is collected using structured format as per CDSCO ADR reporting form.[8] Causality assessment is performed using WHO Uppsala Monitoring Centre (UMC) Global introspection method. The reports are then

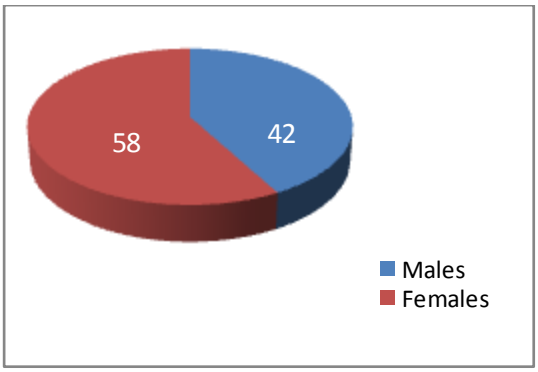

Figure 1: Gender distribution of adverse drug reactions.

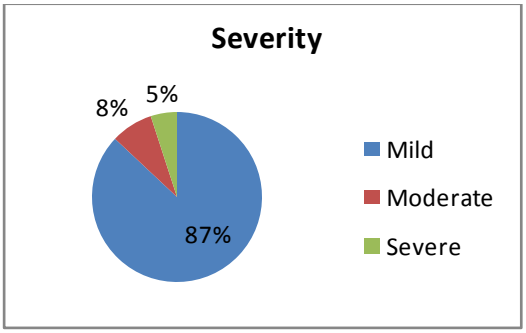

Figure 2: Severity of reaction

uploaded in Vigiflow software and sent to National Coordinating Centre, Indian Pharmacopoeia Commission, Ghaziabad, which then transmits the reports to the Uppsala Monitoring Center's ADR database where signal processing is carried out.

The 100 suspected ADR reports received by Pharmacovigilance unit at the Department of Pharmacology between January 2015 and june 2015 were evaluated and analyzed for the incidence and the patterns of ADRs on each ADR proforma. Data on demographic details for patient profile (age and sex), prescribed medications (generic name of the medicine, dose frequency, strength, date of start and stop) were evaluated. ADRs were evaluated with respect to description of the adverse event, onset and end of the adverse event, seriousness, information on de-challenge, rechallenge. Causality assessment was carried out using WHO-UMC global introspection method [9] and "Naranjo algorithm or ADR Probability Scale"respectively.[10] Seriousness of reaction was categorized as "serious" and "non-serious" according to WHO criteria.[9]

Data analysis

Data were entered in Microsoft Excel 2010. Descriptive analysis was done to assess mean ± SD and the percentages as applicable for age, gender, causa/tive drug, seriousness, severity, and causality.

RESULTS

A total of 100 ADR reports were reported. There was a predominance of females (58%) as compared to males (42%). Mean age of the patients was 40.3 years ± 16.4 years (standard deviation) with maximum number of patients in the age group of 30-60 years (35.33%).

The leading therapeutic class of medicines implicated were antimicrobials, including ß-lactam antibiotics (Ex: Penicillins), fluoroquinolones, macrolides, aminoglycosides, antifungals, antitubercular, antiprotozoals (51%), followed by NSAID's (20%).

Table 1: Therapeutic class of drugs causing ADR's in study patients. N=100

Drugs	Percentage (%)
Anti-microbials	51%
NSAID's	20%
Anti-epileptics	10%
Proton pump inhibitors	9%
Others	10%

The most commonly affected organ system was Skin (43%) followed by gastrointestinal (GIT) system (31%) .

Table 2: various organ systems involved in reported adverse drug reactions.

Organ systems involved	Percentage (%)
Skin	43%
Gastrointestinal	31%
Central nervous system	18%
Cardiovascular system	5%
Others (genitourinary, ENT etc)	3%

The majority of reactions were non-serious (95%) and 5% serious. The causality was almost consistent with both Narinjo's and WHO probability scale. On causality assessment using WHO Probability Scale 77% ADRs were categorized as probable and 23% were categorized as possible. Naranjo's Probability Scale showed, 74% ADRs were categorized as probable (score ranging from 5 to 8) and 26% were categorized as possible (scores ranging from 1 to 4).

DISCUSSION

Since adverse drug reactions are one of the common causes for poor adherence to treatment, evaluation of ADRs may help clinicians to optimize

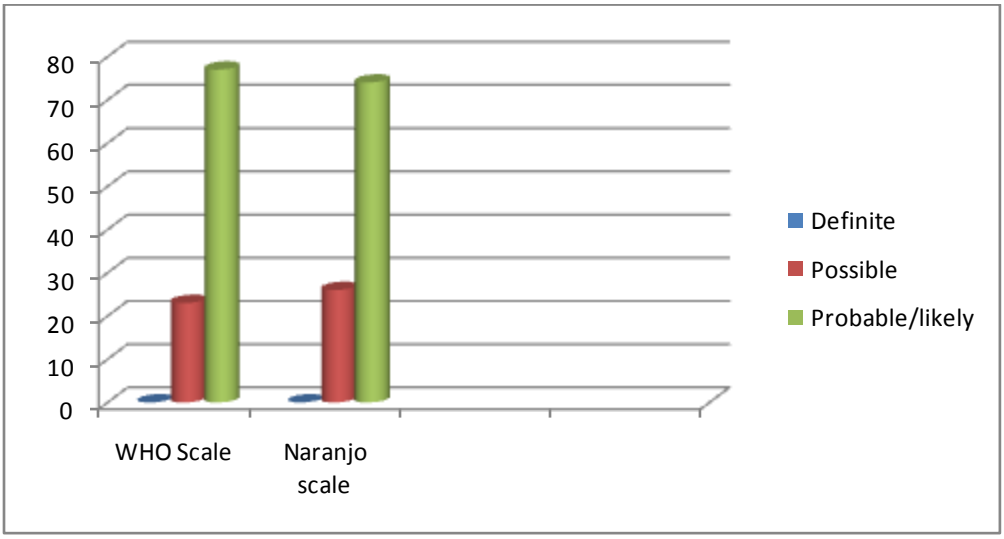

Figure 3: Causality Assessment

the drug regimens. In recent times, spontaneous reporting of ADRs has become the most favored method for practicing pharmacovigilance by the healthcare professionals. ADR reporting adds to increased vigilance and influence recommendations of drug use, which has now become a National Programme in the Indian context. The present study is an attempt to carry out an appraisal of spontaneous reported suspected ADRs in a tertiary care center and included 100 reports in 6 months period. The demographic details of the present analysis showed female gender predominance over males with respect to ADRs, which was similar to the findings of some other studies.[11,12]Several other studies have found that ADRs are more common in males than in females.[13,14]However, another study showed no difference in the occurrence of ADRs in male and female patients[15]showing thereby that the influence of gender may be incidental only and have no influence on the number of ADRs reported. The most frequently implicated group of medicines in the ADRs was antimicrobial agents, this finding is consistent with other studies.[16,17] The organ system most often affected by ADRs in this evaluation was dermatological manifestations(43%).[18-20]The majority of reactions 95% were non-serious and 5% were serious. The causality was almost consistent with both Naranjo's probability scale and WHO global introspection method. Early identification and management of ADRs are essential to imply the safe and rational use of drugs as the impact on patient's quality of life is major. The current Indian scenario of Pharmacovigilance programme of India (PvPI) is upholding well and the combined effort of regulatory authorities and healthcare professionals is raising the data contribution but still there are many healthcare professionals totally unaware of the Pharmacovigilance programme and the need of reporting and monitoring of ADRs.

CONCLUSION

The monitoring and reporting of suspected ADRs by healthcare professionals aids in improved patient welfare. This also acts as an alerting mechanism for physicians. ADRs to drugs happen commonly, and their reporting is important for the early recognition and prevention of ADRs. It not only help in generating signals but also helps the regulatory authorities in making the policy decision. Furthermore, the awareness about risk factors and in-depth knowledge of the literature of ADRs can help physicians to identify patients with greater risk of ADRs.

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