ISSN 2515-8260 Volume 09, Issue 01, 2022

ORIGINAL RESEARCH

Assessment of adverse drug reactions in known population

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ABSTRACT

Background: Pharmacovigilance relates to the activities concerning the detection, assessment, understanding and prevention of these adverse drug reactions. The present study was conducted to asses adverse drug reactions in known population.

Materials & Methods: 250 adverse drug reactions reported in 1 year were recorded. The data were obtained from the ADR monitoring centre. Each ADR was assessed for demographic data, relationship to drugs as per causality assessment, and frequency of ADRs.

Results: Age group 20-40 years had 35 male and 30 female, 40-60 years had 40 male and 55 females and >60 years had 45 male and 45 females. ADRs were reported in oncology in 12, dermatology in 45, ENT in 30, orthopaedics in 20, general surgery in 50, general medicine in 43, gynaecology in 35 and psychiatry in 15 cases. Type of reaction was nausea/ vomiting in 45%, rash in 30%, headache in 12%, abdominal pain in 4%, diarrhoea in 5% and constipation in 4%. Common drugs leading to ADRs were NSAIDs in 35%, antibiotics in 20%, anti- hypertensive in 8%, anti- diabetics in 12%, anti- tubercular in 15% and CNS drugs in 10%. The difference was significant (P< 0.05).

Conclusion: Common drugs leading to ADRs were NSAIDs, antibiotics, anti-hypertensive, anti- diabetics, anti- tubercular and CNS drugs.

Key words: antibiotics, anti- hypertensive, CNS drugs

INTRODUCTION

World Health Organization (WHO) defined adverse drug reaction as a noxious and unintended response of a drug, which occurs at a dose normally used in humans for prophylaxis, diagnosis, or therapy.[1]Previous reports have suggested that 2% of ADRs result in hospitalization and that the mean cost of ADRs leading to admission was 2721 Euros per patient. Previous studies on ADRs have focused on inpatient care settings. While hospitalized patients are under close medical monitoring, outpatients are not.[2]Because the contact is intermittent and consultation hours are constrained, it is difficult for physicians to secure sufficient communication time to ascertain the presence of ADRs in ambulatory care settings.

Thus, the risk and expense of treatment of ADRs in outpatients may increase because remedial action is often delayed.[3]

Pharmacovigilance relates to the activities concerning the detection, assessment, understanding and prevention of these adverse drug reactions. Although the field of science is developing by leaps and bounds, there is a lot of underreporting of the ADRs that takes place, thus giving a wrong picture.[4]It is important for the clinicians to be aware of the toxicity of the prescribing drugs and be vigilant of the reactions that can occur. Proper information is useful to identify and minimize, if possible, the preventable ADRs, thus ensuring a safe and effective use of the drug.[4]

It is easy for patients to visit community pharmacies because of their wide geographical distribution and accessibility without the need for an appointment. As CPs serve patients with and without prescriptions, their active involvement in ADR monitoring and reporting is likely to improve the scope and quality of spontaneous ADR reporting.[5]The present study was conducted to asses adverse drug reactions in known population.

MATERIALS & METHODS

The present study comprised of 250 adverse drug reactions reported in 1 year. Ethical clearance was obtained before starting the study.

The data were obtained from the ADR monitoring centre. Each ADR was assessed for demographic data, relationship to drugs as per causality assessment, and frequency of ADRs. Results of the study was assessed statistically. P value less than 0.05 was considered significant.

RESULTS

Table I Age and gender wise distribution of ADRs

Age group (years)	Male	Female	P value
20-40	35	30	0.91
40-60	40	55	
>60	45	45	
Total	120	130	

Table I shows that age group 20-40 years had 35 male and 30 female, 40-60 years had 40 male and 55 females and >60 years had 45 male and 45 females. The difference was non-significant (P< 0.05).

Table II ADRs as per various departments

ADR	Number	P value
Oncology	12	0.07
Dermatology	45	
ENT	30	
Orthopaedics	20	
General surgery	50	
General medicine	43	
Gynaecology	35	
Psychiatry	15	

Table II, graph I shows that ADRs were reported in oncology in 12, dermatology in 45, ENT in 30, orthopaedics in 20, general surgery in 50, general medicine in 43, gynaecology in 35 and psychiatry in 15 cases. The difference was significant (P< 0.05).

Graph IADRs as per various departments

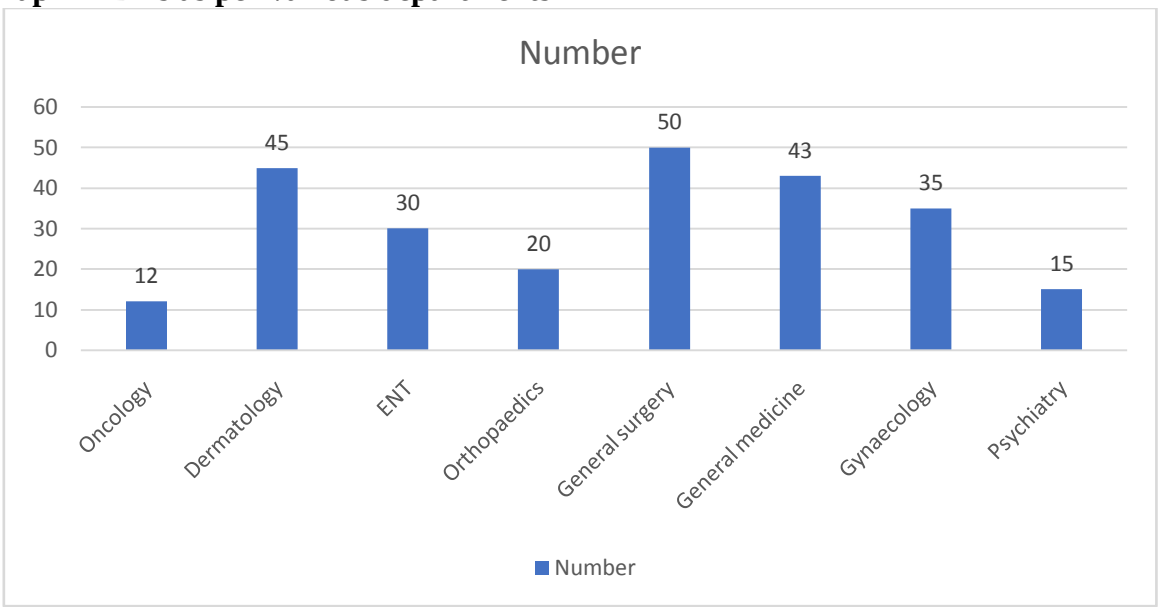


Table III Type of reactions due to ADR

Type	Percentage	P value
Nausea/ vomiting	45%	0.01
Rash	30%	
Headache	12%	
Abdominal pain	4%	
Diarrhoea	5%	
Constipation	4%	

Table III, graph II shows that type of reaction was nausea/ vomiting in 45%, rash in 30%, headache in 12%, abdominal pain in 4%, diarrhoea in 5% and constipation in 4%. The difference was significant (P< 0.05).

Graph II Type of reactions due to ADR

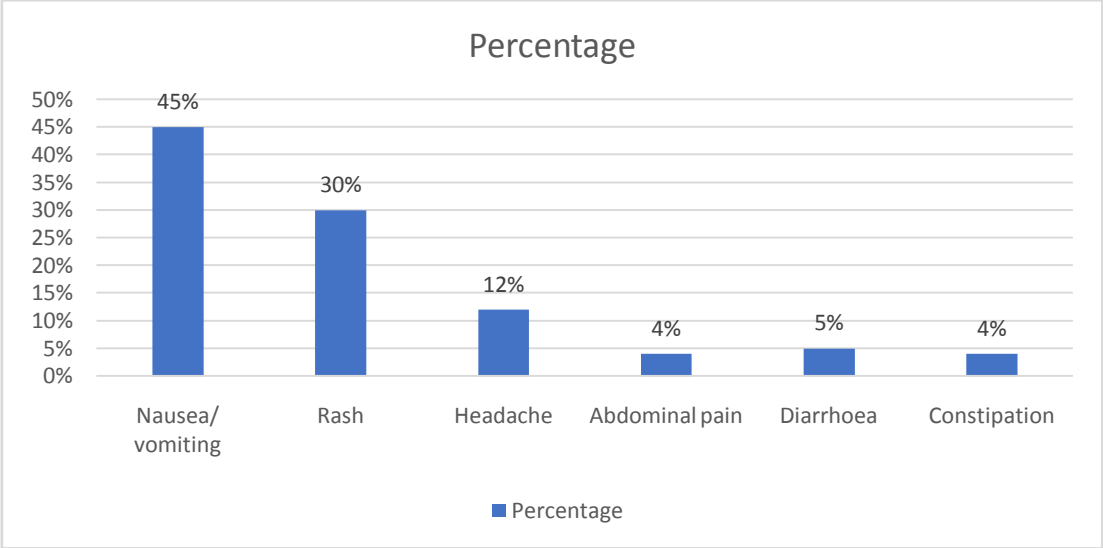
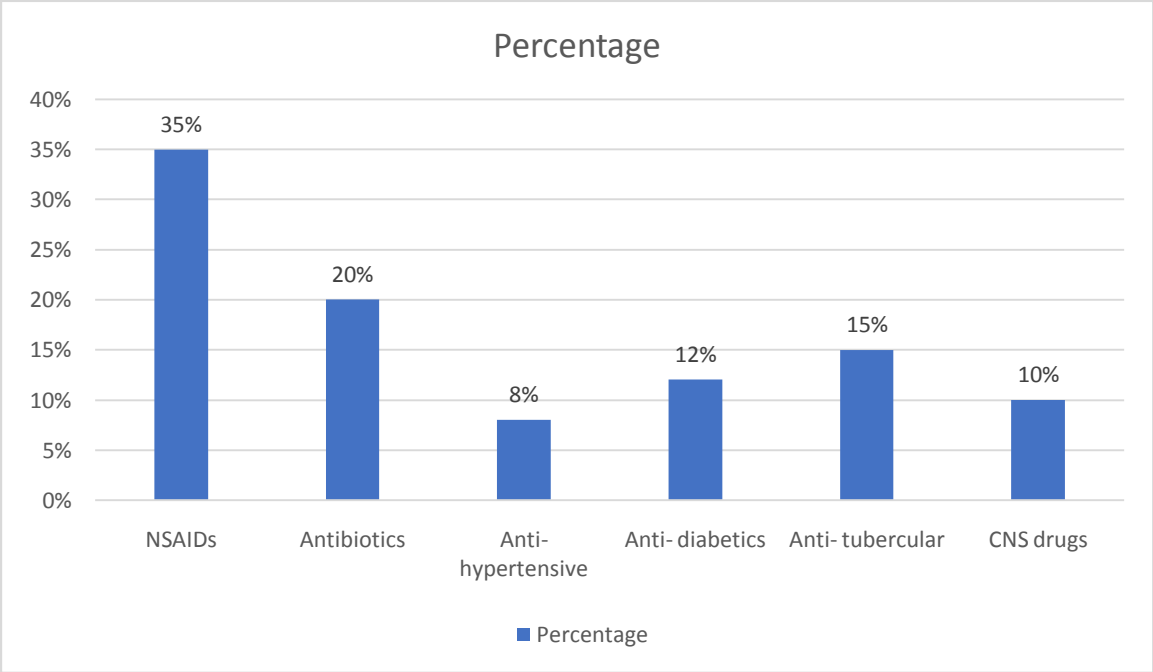


Table IV ADRs as per pharmacological class

Class	Percentage	P value
NSAIDs	35%	0.42
Antibiotics	20%	
Anti- hypertensive	8%	
Anti- diabetics	12%	
Anti- tubercular	15%	
CNS drugs	10%	

Table IV, graph III shows that common drugs leading to ADRs were NSAIDs in 35%, antibiotics in 20%, anti- hypertensive in 8%, anti- diabetics in 12%, anti- tubercular in 15% and CNS drugs in 10%. The difference was significant (P< 0.05).

Graph III ADRs as per pharmacological class



DISCUSSION

Adverse drug reactions (ADRs) are considered as one among the leading causes of morbidity and mortality.[6]Around 6% of hospital admissions are estimated to be due to ADRs and about 6–15% of hospitalised patients experience a serious ADR. Reporting of ADRs has become an important component of monitoring and evaluation activities performed in hospitals.[7]Such ADR reporting programs encourage surveillance for ADRs, promote the reporting of ADRs and stimulate the education of health professionals regarding potential ADRs.[8] A productive hospital-based reporting program can be instrumental in providing valuable information regarding potential problems of drug usage in an institution. Through these efforts, problems are identified and resolved, which results in continuous improvement in patient care.[9]The present study was conducted to asses adverse drug reactions in known population.

In present study, age group 20-40 years had 35 male and 30 female, 40-60 years had 40 male and 55 females and >60 years had 45 male and 45 females. Jose et al[10] found that the overall incidence of ADR calculated from the patient population was 0.15%. At least one ADR was reported in 1.14% of the hospitalised patients and in 0.012% of the outpatients. No significant difference was seen in the overall incidence of ADRs observed in males and females. Incidence of ADRs among elderly adults and older adults (0.23%) were significantly higher

than other age groups. Type A reactions (72.5%) accounted for majority of the reports and a greater share of the ADRs were described to be very common (43.4%) in the literature. Dermatological system (23.5%) was the most commonly affected organ system with skin rash (10.5%) as the most frequently reported reaction. Antineoplastic agents (21.8%) was the drug class most commonly involved, while phenytoin (7.8%) was the individual drug most frequently reported. The suspected drug was withdrawn for the management of the ADR in majority (56.6%) of the reports. In 74.8% of the reports the patient recovered from the reaction at the time of evaluation. Upon causality assessment, majority of the reports were rated as probable (53.7%). Mild and moderate reactions accounted for 50.5 and 43.9%, respectively. In 28.7% of the reports, the reaction was considered to be preventable. At least one predisposing factor was present in 79.9% of the reports and the most common predisposing factors associated were polypharmacy and multiple disease state. Evaluating the relationship between patient characteristics and reaction characteristics, type A reactions were more common among elderly adults (85.92%) and type B reactions more common in adults (35.01%) compared to other age groups.

We found that ADRs were reported in oncology in 12, dermatology in 45, ENT in 30, orthopaedics in 20, general surgery in 50, general medicine in 43, gynaecology in 35 and psychiatry in 15 cases. Sulabhet al[11] reported a total of 200 ADRs were reported from both outpatients and inpatients of various departments. Most of the ADRs were found in females (55%) and patients of the age group 20 to 50 years (85%). Most of the ADRs were reported from the ART center (39%), dermatology (20%), oncology (11%), pediatrics (9%), and medicine (8%). The number of ADRs was distributed according to the department where they were reported. Overall, 40% of the ADRs are due to the anti-retroviral therapy, 29% due to the antibiotics, and 14% due to the nonsteroidal anti-inflammatory drugs (NSAIDs). Causality assessment was done by using the WHO-UMC scale, in which most of the ADRs were reported as probable (50%) followed by possible (48%). Severity assessment was done by a modified Hartwig and Siegel scale, in which most of them are mild (74%). The most commonly occurred ADRs were rash (40%), followed by nausea and vomiting (25%).

We observed that type of reaction was nausea/ vomiting in 45%, rash in 30%, headache in 12%, abdominal pain in 4%, diarrhoea in 5% and constipation in 4%. Yousef et al[12] in their study a total of 17,730 ADR cases were reported during study period. An annual increase in ADRs was clearly evident. Approximately 54% of the total ADRs reported were serious. Most commonly reported ATC drug classes were anti-infective agents for systemic use (22.27%), antineoplastic and immunomodulating agents (21.49%), alimentary tract and metabolism (15.48 %), cardiovascular system (11.11%) and nervous system (10.23%). Vancomycin (2.7%), ceftiraxone (1.8%), fingolimod (1.4%) and paracetamol (1.4%) were the most common drugs associated with serious ADRs.

We found that common drugs leading to ADRs were NSAIDs in 35%, antibiotics in 20%, anti- hypertensive in 8%, anti- diabetics in 12%, anti- tubercular in 15% and CNS drugs in 10%. Yu et al[13] evaluated causality using the WHO-Uppsala Monitoring centre system. The patient population was classified into three age groups. They assessed 31,398 (74.9%) ADRs from 9,705 patients, identified as having a causal relationship, from a total pool of 41,930 ADRs from 9,873 patients. Median patient age was 58.0 years; 66.9% were female. Gastrointestinal system (34.4%), nervous system (14.4%), and psychiatric (12.1%) disorders were the most frequent symptoms. Prevalent causative drugs were those for acid related disorders (11.4%), anti-inflammatory products (10.5%), analgesics (7.2%), and anti-bacterials (7.1%). Comparisons by age revealed diarrhea and anti-bacterials to be most commonly associated with ADRs in children ($p < 0.001$), whereas dizziness was prevalent in the elderly ($p < 0.001$). Anaphylactic reaction was the most frequent serious event (19.7%), mainly

associated with cephalosporins and non-steroidal anti-inflammatory drugs. Among 612 ADRs caused by non-prescription drugs, the leading symptoms and causative drugs were skin disorders (29.6%) and non-steroidal anti-inflammatory drugs (16.2%), respectively.

CONCLUSION

Authors found thatcommon drugs leading to ADRs were NSAIDs, antibiotics, anti-hypertensive, anti- diabetics, anti- tubercular and CNS drugs.

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