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Original Research Article

An Evaluation of Adverse Drug Reactions Profile at a Tertiary Care Teaching Hospital

Akanksha Mathur, Nimit Goswami, Prashant Shah, Niyati Trivedi

Department Of Pharmacology, Medical College Baroda, Vadodara (Gujarat)-390001.

Corresponding Author: Akanksha Mathur

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ABSTRACT

Objective: Adverse drug reactions (ADRs) are inevitable consequences of drug therapy as no pharmacotherapeutic agent is completely free from noxious and unintended effects. However, ADR reporting in India is inadequate. Developing awareness in patients and healthcare professionals (HCPs) will help in reducing the ADRs, its suffering and socioeconomic impact. Hence, the present study was carried out in various clinical departments of a tertiary care teaching hospital with the main objective to assess the ADR patterns in outpatient and inpatient of the hospital and also to assess the causality, severity, and preventability of these ADRs.

Materials and Methods: A prospective study was conducted over 2 years. Spontaneous type of reporting method was used. The WHO definition of ADR was adopted. All the patients reported to have ADR were included in the study. The study plan included analysis and assessment of spectrum of ADRs reported based on causality, severity and preventability factors.

Results: A total of 225 ADRs were reported and evaluated. 55.11% were males and 44.88% females. The most common drug group causing ADRs was antitubercular (26.66%) followed by antibacterial (23.11%) and antiepileptic agents (17.33%). Skin (45.77%) was the most common organ system involved followed by central nervous system (19.11%) and gastrointestinal system (10.22%).As per WHO causality assessment, 50.66% of ADRs were possible and 48.88% were probable.

Conclusion: The clinical spectrum of ADRs ranged from the more common mild reactions to life threatening reactions and disability. The predominant causative drug was antitubercular agents. The majority of ADRs were possible in causality assessment, mild in severity and not preventable.

Keywords: Adverse drug reactions, Pharmacovigilance, Causality.

INTRODUCTION

The aim of pharmacotherapy is to provide maximum benefits with minimal risk due to adverse effects. The WHO defines Adverse Drug Reactions as a response to a drug 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 modifications of physiological function. [1] ADR is a major limitation in providing health care to patients at a global level. It affects patient's recovery as well as the economy of health care. In various studies adverse drug reactions have been implicated as a leading cause of considerable morbidity and mortality. The incidence of ADRs globally varies with studies which show incidences ranging from as low as 0.15% to as high as 30%. [2]

Indian reports on ADR monitoring have been very few. This may be because ADR monitoring is still developing here. [2]

Hospital based ADR monitoring and reporting programmes aim to identify and quantify the risks associated with use of

drugs. This information may be useful in identifying and minimizing preventable ADRs while generally enhancing the knowledge of prescribers to deal with ADRs more efficiently.

There is a tremendous need of ADR database especially in developing countries like ours. It leads to the earliest possible detection of various unknown ADRs and drug interactions. It also helps in estimation and analysis of the risk: benefit ratio and dissemination of the information for improving drug prescribing and drug regulation. Therefore, Pharmacovigilance Programme of India was initiated for protecting the health of the patients by assuring drug safety. The present study was conducted at a tertiary care teaching hospital which is also designated as ADR monitoring centre. Of all the sources of data for drug safety monitoring, the spontaneous reporting systems provide the highest volume of information at the lowest maintenance cost, [3] and have proven their value in the early detection of patient safety issues. [4] The most important function of spontaneous reporting systems is the early identification of signals [5] and formulation of hypotheses, leading to further confirmatory investigations or sometimes regulatory warnings and changes of product information leaflets. In some instances, withdrawals of marketing authorizations are also based on Individual case safety reports.

The objective of this study was to assess the inpatient and outpatient ADR patterns in various clinical departments at a tertiary care teaching hospital using spontaneous reporting method. Evaluation of the causality, severity, and preventability of reported ADRs was also carried out.

MATERIALS AND METHODS

A prospective study was conducted at Sir Sayajirao Gaekwad Hospital, Vadodara in various clinical departments from February 2014 to January 2016. ADRs reported spontaneously by the treating physicians of all indoor and outdoor patients receiving treatment at a tertiary care teaching hospital in Gujarat during the mentioned time period were included in the study. Confidentiality of the information obtained was assured throughout the study.

Data of spontaneously reported ADRs for each patient by Health Care Professional was collected. A detailed history including drug details, patients' demographics, family, past medical history, and history of previous drug allergy was documented from the case record files and after discussion with the treating physician. ADR pattern, extent, severity, duration of the reactions were clinically scrutinized, interpreted and analyzed for the causative drugs. Causality of the reactions was assessed by WHO-UMC causality assessment scale. [6] Severity of ADR was evaluated using Hartwig and Seigel criteria, [7] while Modified Schumock and Thornton scale [8] was adopted to assess preventability of reported ADRS.

The recorded data was analyzed by using descriptive statistics. Information was entered in the MS Excel data sheet 2007 and data was analysed.

RESULTS

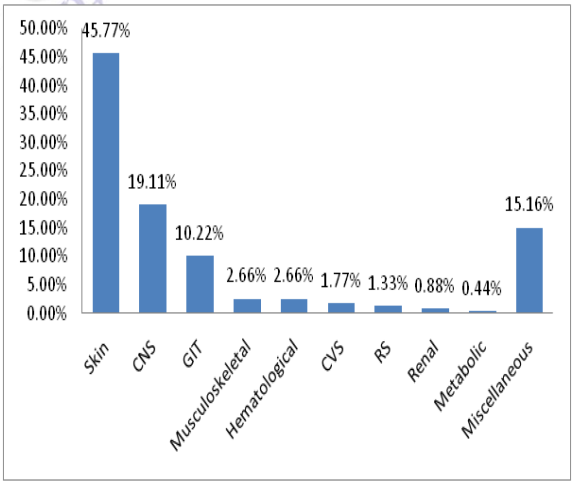

Fig. I: Organ System Involved

A total of 225 adverse drug reactions were reported during the study period, out of which male patients (55.11%) predominated the females (44.88%) in ADR occurrence. Adults (age group 19-59yrs) (68.88%) were the most affected population as compared to children (age group 0-18

years) (16.88%) and elderly (>60 years) (14.22%). Results have also shown that the skin (45.77%) was the most common organ system involved in the development of ADR followed by central nervous system (19.11%) and gastrointestinal system (10.22%) as depicted in Fig I.

The drugs causing ADRs are shown in Fig II which revealed that antitubercular agents (26.66%) was the most accounted drug class followed by antibacterial therapy (23.11%) and antiepileptics (17.33%).

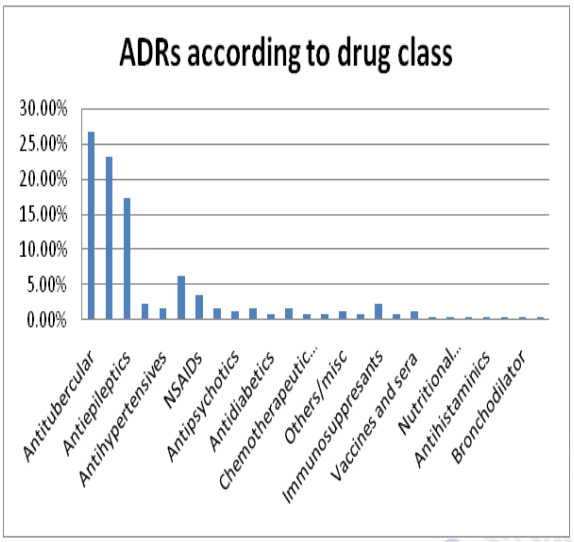

Fig. II: Drugs Causing ADRs

Among antitubercular agents, cycloserine (16) caused maximum reactions followed by isoniazid (11) and kanamycin (10). Maximum ADRs in antibacterials was caused by fluoroquinolones (15) followed by beta lactams (12) and cephalosporins (7). In antiepileptics, carbamazepine (18) was associated with maximum ADRs followed by sodium valproate (5).

According to ADR classification by Rawlin and Thomson, [9] type B reactions (51.11%) predominated over type A reactions (48.88%). WHO causality assessment [6] showed that 50.66% of reactions were of 'possible' type, 48.88% were of 'probable' type and 0.40% had 'certain' causality.

Severity assessment according to Modified Hartwig and Seigel Criteria [7] showed that the majority of reactions reported were mild (48%) as depicted in Fig.III.

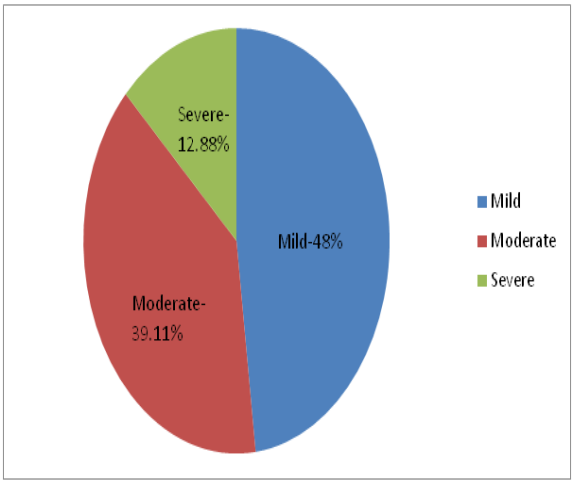

Fig.III: Severity Assessment

Preventability assessment was done according to Schumock and Thornton Criteria [8] and it revealed that majority of reactions were not preventable (75.11%) as shown in Fig. IV.

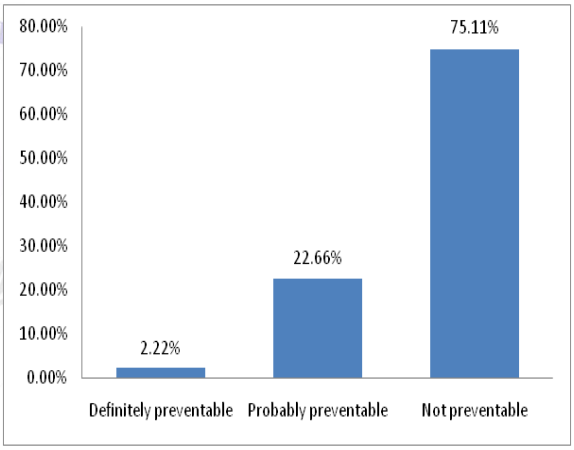

Fig. IV: Preventability Assessment

Out of 225 ADRs, 29 required admission, 17 needed prolonged hospitalization, 9 were life threatening and 10 resulted into disability. Rests were treated on OPD basis.

DISCUSSION

In the present study, male patients (55.11%) were more predisposed to ADRs compared to females and similar pattern of gender distribution was evident in past few studies. [10-12] Out of 225 patients included in the study, 68.88% were adults (age group 19-59 years). Similar results were recorded in other studies. [12,13]

Skin (45.77%) was the chief organ system affected with the most common

ADR reported as skin rash. This finding is in accordance with various other studies. [10,14] The majority of ADRs in the present study were caused by antitubercular agents (26.66%) followed by antibacterial agents (23.11%). This finding is discordant with other studies in which most ADRs were due to antimicrobials. [2,15,16] This may be because of the spontaneous method of reporting which is solely dependent on awareness and willingness of treating physician regarding pharmacovigilance system.

In our study majority of ADRs were of type B (51.11%). This finding is also discordant with other studies in which most ADRs were type A. [11,12,16] A possible explanation for this discrepancy could be that as type B reactions are acute in onset, this may influence the patients to go to the health care professionals and also make the treating physicians to report it as it is a spontaneous type of reporting method. Type a reactions which are predictable and well known usually go unreported by the clinicians as well as patients until or unless they are severe in nature or the physician is very much aware with the pharmacovigilance system.

In the present study, the causality assessment performed according to WHO criteria [6] showed that the majority of reactions were of 'possible' type (50.66%). Other studies noted 'probable' as the most common type of causality. [10,13,16] It may be because most of the ADRs reported in our study were from outpatient basis and the information about drug withdrawal was usually lacking.

The present study showed that majority of ADRs were mild (48%). Similar results were obtained by other studies. [12,13]

Preventability assessment done by Modified Schumock and Thornton scale [7] showed that majority of reactions were not preventable (75.11%). A possible reason could be that as the majority of reactions were of type B, they are usually not preventable.

A clear limitation of our study is that as the spontaneous method of reporting was used the data obtained was completely dependent upon the awareness of the treating physician towards pharmacovigilance. Moreover, it was conducted in one hospital and there is likely to be variation between different hospitals because of difference in local population characteristics and specialities within the hospital. So, the results cannot be generalised.

The study also revealed that there is under reporting of ADRs by most of the departments in the hospital. In spite of the limitations, our study provided baseline data for further larger studies and has ascertained the importance of ADR monitoring in the pharmacovigilance studies.

CONCLUSION

The studies concluded that majority of adverse drug reactions involved skin and are mild, not preventable and have a possible causality relationship with the offending drug. The number of ADRs reported in the given time period were very less. So, continued education regarding Pharmacovigilance Programme of India is required to increase the awareness and knowledge of the health care professionals regarding the same, hence improving patient care and outcome by optimizing drug use.

The study also reveals the opportunities for intervention and policy initiatives to ensure safer use of drugs in future.

Ethical issues: *Less than minimal risk*

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