RESEARCH ARTICLE
An annual retrospective analysis of adverse drug reactions reported at adverse drug reaction monitoring center, Nalgonda

Shivaraj B Patil, Ramani Gade, Raghuveer B, Venkatarao Y, Yamini V

Department of Pharmacology, Kamineni Institute of Medical Sciences, Nalgonda, Telangana, India

Correspondence to: Shivaraj B Patil, E-mail: shivarajpatil85@gmail.com

Received: July 01, 2021; Accepted: July 24, 2021

ABSTRACT

Background: Adverse drug reaction (ADR) monitoring is important for risk benefit analysis and for patient’s safety. ADR monitoring helps in maintaining the database which is specific to Indian population. Aims and Objectives: This study aims to analyze the pattern of ADRs, drug implicated, organ system affected, severity of ADRs, and their causality assessment.

Materials and Methods: It was a retrospective analysis of all the ADRs reported to ADR monitoring center, Nalgonda, from January 2019 to December 2019. Prior ethics committee approval was obtained. ADRs were collected using suspected ADR forms provided by National Coordination Center-Pharmacovigilance Programme of India (NCC PVPI). All the ADRs were reported to NCC PVPI through VigiFlow software.

Results: A total of 273 ADRs were reported of which 59% were female and 41% were male. According to the age group, 30–39 years were the most common age group affected about 26%. The most common drug class implicated for ADRs was antimicrobials. Skin was the most common system affected. Most of the ADRs belonged to probable category according to the WHO causality assessment scale. Only 9 (3%) ADRs were of serious nature.

Conclusion: Pharmacovigilance is important for identification of ADRs due to drugs. Still, lot of awareness about pharmacovigilance needs to be created among health-care professionals to improve the reporting of ADRs. This, in turn, will improve the drug safety among patients.

KEY WORDS: Adverse Drug Reactions; Pharmacovigilance; Adverse Drug Reaction Monitoring Center

INTRODUCTION

All drugs are like double-edged sword, they can have therapeutic effects but can also cause adverse drug reactions (ADRs).[1] ADRs as defined by the World Health Organization (WHO) are “Anoxious, unintended and undesirable effect that occurs as a result of dose normally used in man for diagnosis, prophylaxis, and treatment of disease or modification of physiological function.”[2] ADRs increase the duration of stay in hospital, which in turn will increase the economic burden and will also decrease the patient compliance.[3]

ADRs show negative impact on the patient’s quality of life and also on health-care system. ADRs are the one of the leading causes of morbidity and death rate.[4] ADR monitoring becomes even more important in today’s world as every week a new drug is approved for use, whose ADRs database is required for risk–benefit analysis in the patients. ADR monitoring will generate signals which help the regulatory authorities in communicating the risks associated with drugs to health-care professionals, revision of drug label, and banning the drugs if risk–benefit ratio of a particular drug is disproportionate.[5] Worldwide various ADR reporting...
systems are functioning but in India, voluntary reporting system is adopted. ADR reporting helps in maintaining the database which is specific to Indian population and we need not have to depend on other country database.[6,7] This study aims to analyze the pattern of ADRs, drug implicated, organ system affected, severity of ADRs, and their causality assessment.

MATERIALS AND METHODS

Study Procedure

It was a retrospective analysis of all the ADRs reported from January 2019 to December 2019 to ADR monitoring center (AMC) – Nalgonda working under National Coordination Center-Pharmacovigilance Programme of India (NCC-PVPI). ADRs were collected using Version 1.3 Suspected ADR form for health-care professionals and consumer forms as provided by PVPI. ADRs were also collected from antiretroviral therapy center, primary health centers, and district tuberculosis center, Nalgonda. ADRs collected were checked for completeness and any missing information was collected by going through the case sheet or contacting the treating physician. All the ADRs were reported to NCC PVPI through VigiFlow software. The collected ADRs were analyzed to review the impact of varied aspects such as age group, gender, drug class implicated, organ system affected, and seriousness of ADR. The causality assessment was done by causality assessment committee using the WHO causality assessment scale.[8]

Ethical Approval

Approval from the Institutional Ethics Committee was obtained (ref no. ETHICS COMMITTEE/KIMS/NKP/2021).

Statistical Analysis

The data were analyzed and presented as counts and percentages.

RESULTS

The total number of ADRs reported to AMC for the year 2019 was 273. The average number of ADRs reported per month in AMC was 22. The percentage of female population affected by ADRs was 59% and the contribution was higher when compared to male population (41%). Most common age group affected by ADRs was 30–39 years about 26% [Table 1]. Regarding the causality assessment, 59% of ADRs were assessed as probable and remaining 41% as possible. Antimicrobials were the most common drug class implicated in causing ADRs [Table 2]. Most common system affected by ADRs was skin (26.7%) followed by gastrointestinal tract (20.9%) and central nervous system (CNS) (20.9%), as depicted in Table 3. Figure 1 shows the severity of ADRs. Number of serious ADRs reported was 9 (3.3%) as compared to non-serious ADRs which were 264 (96.7%).

DISCUSSION

ADRs are a public health problem. Extremes of age, female gender, disease conditions, polypharmacy, history of ADR, and genetic factors are some of the risk factors which increase the incidence of ADRs.[9] ADR monitoring is a ongoing proces which helps in developing the database of ADRs which, in turn, helps the treating physician to take an informed decision while prescribing.
A total of 273 ADRs were reported to our ADR monitoring center during the study period. Maximum number of ADRs were reported in the female population (59%) as compared to males. Antimicrobials were the most common drug class causing ADRs. Skin was the most common system affected by ADRs. Most of the ADRs were non-serious except nine ADRs which were serious. All the serious ADRs were managed appropriately by our health-care professionals and no deaths were reported due to adverse reactions.

With continuous awareness campaigns run by pharmacology department in our hospital and also extending the coverage to peripheral centers including ART center, district tuberculosis center, Nalgonda, the ADR reporting is slowly increasing year after year. Singh et al.[10] and Swamy et al.[11] reported higher incidence of ADRs in females. Similar observation was made in our study also. It is well established that female patients have 1.5–1.7 times increased risk of developing ADRs which is evident in this study also.[12]

Most common drug class implicated in ADRs were antimicrobials, which was in line with other studies.[11,13] Among antimicrobials, antiretroviral drugs contributed the most followed by antitubercular drugs. Both antiretroviral drugs and antitubercular drugs are given for long duration and multiple drugs are used in combination which could be the reason for high incidence of ADRs in these patients. Most of the studies reported skin being frequently affected by ADRs.[14,15] This finding was observed in our study also. People recognize ADRs affecting the skin most frequently may be because of cosmetic concern.

This study highlights the importance of continuous monitoring of ADRs. There were few limitations in our study. ADR analysis was done in one particular region of India so cannot be generalized to large population. There could be underreporting of ADRs since spontaneous voluntary reporting of ADRs is followed as recommended by PVPI.

CONCLUSION

ADR monitoring is a continuous process which helps in developing the country wise ADR database which, in turn, will help the regulatory authorities to take necessary action on the drugs for the safety of the population.

ACKNOWLEDGMENT

We would like to acknowledge NCC-PVPI for providing the technical support and technical associate. We would also thank our management Kamineni Institute of Medical Sciences – Nalgonda for their constant support. Last but not the least, we also thank ART center, DTCO – District Hospital, Nalgonda, for reporting the ADRs to our center.

REFERENCES


How to cite this article: Patil SB, Gade R, Raghuveer B, Venkatarao Y, Yamini V. An annual retrospective analysis of adverse drug reactions reported at adverse drug reaction monitoring center, Nalgonda. Natl J Physiol Pharm Pharmacol 2021;12 (Online First). DOI: 10.5455/njppp.2022.11.07256202124072021

Source of Support: Nil, Conflicts of Interest: None declared.