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RESEARCH ARTICLE

Prospective observational study to evaluate adverse drug reactions pattern in a tertiary level teaching hospital

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ABSTRACT

Background: Adverse drug reactions (ADRs) are a major cause of morbidity and hospitalizations have consistently increased, leading to economic burden to developing countries like India. Identification of ADRs and their reporting pattern can provide useful information for their management. **Aims and Objectives:** The objective of the study was to assess the pattern of ADRs in tertiary care teaching hospital with respective to various parameters. **Materials and Methods:** The present study was an observational, prospective study. ADR reports of 40 patients were collected from various clinical departments of Dr. D. Y. Patil School of Medicine, Navi Mumbai. The ADRs were collected during January 2018–July 2018, with ADR reporting form of Central Drugs Standard Control Organization, New Delhi. Data were analyzed using descriptive statistics. **Results:** A total of 40 ADRs were reported during this study; the mean age of the patients being 43.14 (±2.27) years. Gender distribution of the patients showed 26 (65%) female preponderance. The majority of ADRs were implicated to pulmonary department 13 (32.5%) and least in OBGY 2 (5%). Using Naranjo's causality assessment scale, there were 24 (60%) probable, 12 (30%) possible, and 4 (10%) doubtful/unlikely causality of the ADR with the suspected offending drug. **Conclusion:** We conclude that antitubercular, injectable iron, pentavalent vaccines, and psychotropic drugs are responsible for most of the ADRs and middle-aged population are most commonly affected with ADR. Completeness score was an average of 32.2 ± 2.6. The completeness score can be improved if the reporter spends sometime considering its their moral responsibility.

KEY WORDS: Pharmacovigilance; Causality; Adverse Drug Reaction; Evaluation of Adverse Drug Reaction Reporting Pattern

INTRODUCTION

Adverse drug reactions (ADRs) are a major cause of morbidity. ADRs related hospitalizations have consistently increased which has caused an economic burden to developing countries like India.[1,2] According to the World Health Organization (WHO), an ADR is defined 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 the modifications of physiological function. Although India accounts for around 10% of global intake of medicines, the reporting of ADRs of medicines is a meager 2% of the global occurrence. India is a part of the WHO program for the global monitoring of ADRs that depend on spontaneous reporting. This is largely due to the poor reporting of ADRs in India.[3] Despite this, India was the 7th in position among the top 10 countries contributing to global drug safety database. It is the most affordable system, which can identify serious reactions, rare ADRs as well as generate early safety signals for new drugs. The spontaneous reporting system has resulted in many marketed drugs being withdrawn for

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the safety concerns. To promote vigilance of adverse events (AEs) in India, Central Drugs Standard Control Organization initiated a nationwide pharmacovigilance programme in 2010. The process of pharmacovigilance is executed with the help of ADR monitoring centers (AMCs). At present, there are around 150 AMCs operational throughout India.[4] At present, the most common way through which various AMCs report the occurrence of ADRs or AEs is spontaneous reporting structure. However, spontaneous reporting structure suffers from the serious problem of underreporting which can be as high as 98%. It is very necessary to enhance the awareness regarding early detection, reporting, management, and further prevention of ADR and to ensure the drug safety and quality of life. The present study was conducted to evaluate the prevalence of ADRs in a tertiary care hospital in Navi Mumbai.

Objectives

The objective of the study was to assess the pattern of ADRs in tertiary care teaching hospital with respect to:

1. Completeness score.
2. Demography of ADR reporting.
   a. Age.
   b. Sex.
3. Department-wise reporting.
4. Group-wise ADR percentage.
5. Various ADRs reported to the department.

MATERIALS AND METHODS

Study Center

The study was conducted in the Pharmacology Department of Dr. D. Y. Patil Medical College, Nerul, Navi Mumbai. A total of 40 ADRs were reported from inpatient and outpatient department of various clinical departments of Dr. D. Y. Patil Hospital and Research Centre, Nerul, Navi Mumbai. The ADRs were collected from January 2018 to July 2018**.** The collected ADRs were analyzed for the following parameters: Completeness score, demography of ADR reporting - age and sex, department-wise reporting, various drug classes implicated in the ADRs, list of various ADRs reported to the pharmacology department, seriousness of the reaction, and causality assessment. The institutional ethics committee approval was taken before starting the study.

Inclusion Criteria

All the patients from Dr. D.Y. Patil Hospital and Research Centre, Nerul, Navi Mumbai, attending outpatient or inpatient department having any adverse reaction(s) after the commencement of treatment were included in the study.

Exclusion Criteria

Patients admitted for accidental or intentional poisoning due to drugs were excluded from the study. ADR forms with incomplete information were also excluded.

ADR Form Collection

The ADRs were collected and filled according to the "Suspected ADR Reporting Form (Indian Pharmacopoeia Commission)" version 1 and version 1.2. Causality assessment was done based on Naranjo's causality assessment score[5] as definite, probable, possible, and doubtful. Severity score of the various reactions was noted as per the modified Hartwig and Siegel scale[6] as mild, moderate, and severe. Completeness score of Individual case safety report (ICSR) was done by adopting the similar scale derived by Sachin Kumar Kuchya *et al*. (August 2017) as shown in **[**Figure 1**].**

RESULTS

In the present study, a total of 40 ADRs were reported during the study period of January 2018–July 2018, from the outpatient and inpatient department of various clinical departments of Dr. D. Y. Patil Hospital and Research Centre, Nerul, Navi Mumbai. The age of the patients ranged from 3 months to 70 years. Of 40 patients, five were from (birth - 20 years) 12.5%, while 27 patients belonged to 21–40 years age group (67.5%) and seven were from 41–60 years (17.5%) while 1 from 61 onward (2.5%). The mean age of the patients was 43.14 (±2.27) years [Figure 2].

Gender distribution of the patients showed that there were 26 female (65%) and 14 (35%) male patients indicating female preponderance [Figure 3]. Seasonal distribution was showing preponderance in rainy season 16 (40%) in July while no cases in May. Of 40 ADRs, the majority of ADRs were implicated to pulmonary department 13 (32.5%), closely followed by psychiatry 10 (25%), general medicine 6 (15%), pediatrics 4 (%), dermatology 3 (10%), OBGY 2 (5%), and surgery 2 (5%) [Table 1]. Of 40 patients who suffered ADRs, six recovered and 32 were recovering at the time of reporting, while two failed to recover from the adverse effects. There were two cases of fatality although the causality assessment indicated the relationship between the ADR and suspected drug to be possible. Using **N**aranjo**'s** causality assessment scale, there were 24 (60%) probable, 12 (30%) possible, and 4 (10%) doubtful/unlikely causality of the ADR with the suspected offending drug. Using Hartwig and Siegel scale of severity of ADR, it was found that there were mild 22 (58%), moderate 12 (13%), and severe 6 (30%) ADRs. In the present study, the 38 (95%) were valid containing the information in all four categories of the form, while only 2 (5%) were invalid and rejected. Completeness score was average of 32.2 ± 2.6.

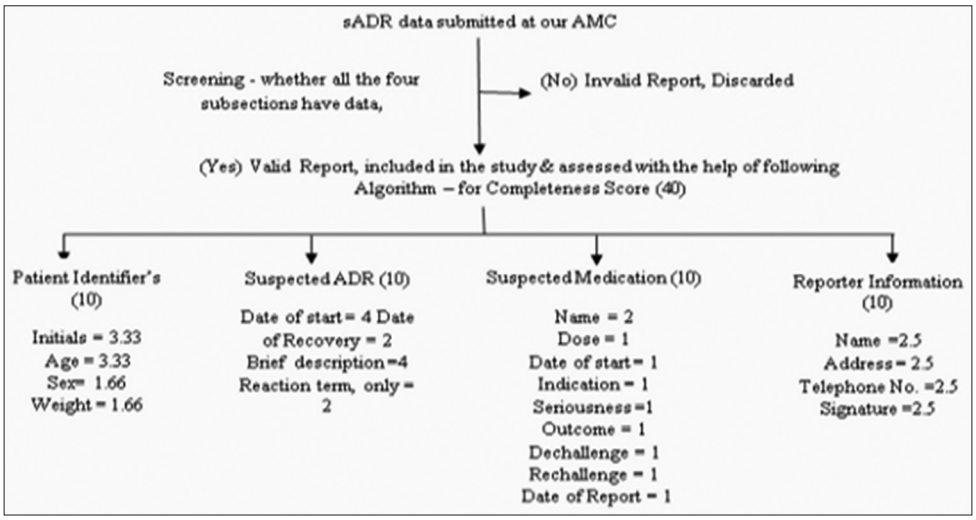

Figure 1: Completeness score

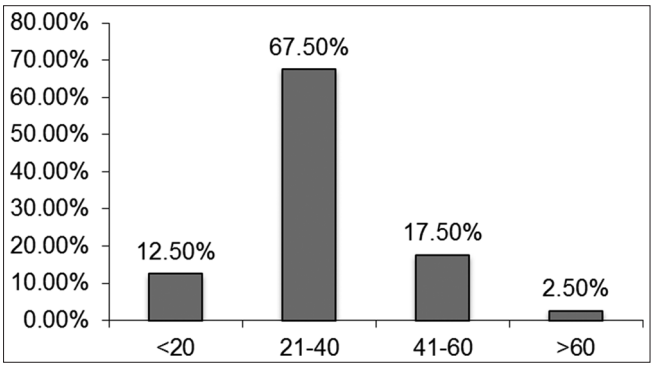

Figure 2: Age distribution in reported cases of adverse drug reaction

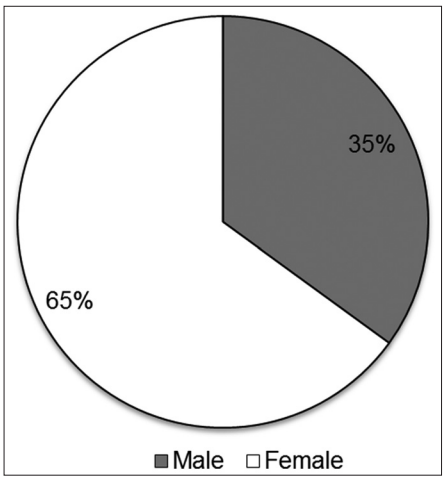

Figure 3: Gender distribution of adverse drug reaction reporting

Table 1: ADR reported from various departments

Name of ADR	Number of ADR
AKT-induced hepatitis	11
Lignocaine-altered behavior	1
Valproate-induced thrombocytopenia	1
Olanzapine weight gain	1
Sulfasalazine hypersensitivity	1
Iron hypersensitivity	3
Haloperidol EPS	3
Amitriptyline dry mouth	1
Stevens–Johnson syndrome allopurinol	1
Azathioprine bone marrow suppression	1
Oxcarbazepine vesicle	1
Anaphylaxis cefotaxime	1
Pentavalent skin plaque	1
Immunoglobulin-induced anaphylaxis – GB syndrome	1
AKT-induced hyperuricemia	5
Streptomycin-induced ototoxicity	1
Olanzapine dyslipidemia	1
Lithium toxicity	1
Pentavalent-induced convulsion	1
Perinorm-induced EPS	1
Blood in stool following typhoid vaccine	1
Oxcarbazepine thrombocytopenia	1

ADR: Adverse drug reaction, EPS: Extrapyramidal symptoms

DISCUSSION

In the pharmacotherapy of various diseases, most of the drugs are likely to have beneficial as well as adverse effect. Hence, the best way to control these adverse effects is to have a triple-pronged approach of prevention, treatment, and rehabilitation. In the present study, of total 40 study participants, the mean age of patients was 43.14 (±2.27) years. Majority of the patients (72%) were in the age group of 21–40 years which is similar to a study conducted by Daulat *et al.*[7] Gender distribution of the patients showed that there were 26 female (65%) and 14 (35%) male patients indicating female preponderance which is in contrast to most of the studies where there was male preponderance. The most common suspected ADR was AKT-induced hepatitis. In the present study, majority of the ADRs were from the

pulmonary medicine department 13 (32.5%) closely followed by psychiatry 10 (25%) and OBGY 2 (5%), surgery 2 (5%) is the least. This was in contrast with a study conducted by Gupta *et al*.[8] in which majority of the ADRs belonged to the dermatology department. In the present study, 58% of the patients had mild type of ADRs followed by severe (30%) and moderate (13%). In another study conducted by Ramakrishnaiah *et al*., in 2015, it was seen that majority of the cases had moderate (59%) ADRs followed by mild (37%) and severe (4%). In the present study, according to the probability scale, 22 cases were assessed to be probable and this result is in line with a study conducted by Ramakrishnaiah *et al*.[9] Hospital-based monitoring of suspected ADRs is convenient studies, but the main limitation of these studies is that they do not yield the exact incidence of suspected ADRs associated with a particular drug use. Other limitations were that the data were collected based on the spontaneous reporting. An active surveillance would be a better method of collecting data. The short duration of the study, less number of ADRs, and limited patient follow-up were other drawbacks of this study. Strength of our study is as follows: (1) The drug responsible for ADRs in our study is very commonly used, this proves that there is a need for continuous ADR monitoring system in hospitals and (2) this is the first data reported from our hospital about ADRs.

Careful planning and monitoring of drug therapy should be done to prevent majority of ADRs.

CONCLUSION

ADR is a significant limitation to the success of therapeutics. To deal with this problem, pharmacovigilance program was initiated. The Pharmacovigilance Programme of India suffers from the problem of gross underreporting. To curb this, spread awareness programs targeting health-care personnel at each and every level and implementation of viable pharmacovigilance programs in the hospitals are essential. It should be a continuous process to detect batch-specific ADRs. The limitations of our study were its short duration with less number of ADRs. We conclude that antitubercular, injectable iron, pentavalent vaccines, and psychotropic drugs are responsible for most of the ADRs and middle-aged population are most commonly affected with ADR. Completeness score was average of 32.2 ± 2.6 which is in line with similar study conducted by Sachin Kumar *et al.,* in 2017. The completeness score can be improved if the reporter spends sometime considering its their moral responsibility.

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