Study of Adverse Drug Reactions (ADRs) Occurring with the Drug Use in a Tertiary Hospital

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Abstract

Aim: To study the adverse drug reactions (ADRs) occurring with the drug use in a tertiary care hospital.

Materials and Method: This observational study conducted over a period of four months (01-Nov-2015 to 29—Feb-2016). The Central Drug Standard Control Organization (CDSCO) suspect ADR forms (15) were distributed to all clinical departments personally in Kerala medical college hospital and research center, Mangode, Cherpullaserry. Regular visits were carried out twice a week for collecting data reports. They were then analyzed, compared with state data, national data, and international data. **Results** A total of 25 suspected Adverse Drug Reactions forms were reported during the period of four months of the study of the out patients and in patients departments of the hospital. Among all drugs NSAIDS, followed by Antimicrobials, Antipsychotics, Bronchodilators, Antihypertensive and oral hypoglycemic agent etc.. were reported to have adverse drug reactions. Most common route of adverse drug reactions was oral, followed by IV, IM, S/C, Topical and Inhalational routes. Reactions mostly seen affecting Skin, Gastrointestinal systems, Central nervous system, and Hematological system Most patients recovered from adverse events taking suitable measures like complete stopping the offending agent, or were prescribed antihistamines, steroids in addition **Conclusion:** Awareness about ADR reporting is still poor amongst healthcare professionals in India. The incidence and severity of Adverse Drug Reactions documented in our study are lower than those reported in other studies. NSAIDS comprise the major drug family associated with adverse drug reactions so should be rationally prescribed. Improved communication between the physicians and nurses with the pharmacovigillance centre in the hospital is suggested.

Key words: *Adverse drug reactions, CDSCO, Pharmacovigillance*

Introduction

According to WHO definition an Adverse Drug Reaction (ADR) is a response to a drug that is noxious and unintended, and occurs at doses normally used in human for the prophylaxis, diagnosis, and treatment of disease or modification of physiological function.[1]

Ultimately pharmacovigilance is concerned with identifying the hazards associated with pharmaceutical products and with minimizing the risk of any harm that may come to the patient.

The safety of prescription drugs represents a major public health concern. Adverse drug reactions are considered to be one of the leading causes of death among hospitalized patients.[2] Previous studies suggest that approximately 0.5% of all emergency department visits and tertiary care visits result from adverse drug reactions.

However, low- to middle income countries, which represents more than two thirds of the world population account for a tiny fraction of all the adverse drug reaction data. Among the reasons for this under-reporting are the difficulty that the patients and the providers may have

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liking a particular symptom or condition to a specific drug particularly for individuals who have chronic illness and are taking several medications, a common clinical scenario in tertiary care. Thus, there is a need to capture safety data for drugs in a country like India.

Documentation of Adverse Drug Reactions:

The significant adverse reaction of any drug should be notified within seven days. The other facts related to adverse events should be informed within eight days. [3] The drug reaction form can be collected at pharmacovigillance center.

The filled adverse drug reaction form can be submitted to the peripheral pharmacovigilance center. After reviewing the form, the center forwards it to the regional center and after that it is propelled to zonal center.[5,6,7]

This program is overseen by the central drugs standard control organization. (CDSCO).[8,9]

Patient reporting has been incorporated into pharmacovigillance systems in several countries including U.S.A, Canada, Australia, Newzeland Denmark, Sweden, and the Netherlands. Until very recently, however, patients in the U.K. were not able to report directly suspected Adverse Drug Reactions to Medicine and Health Care Regulatory Agency (MHRA), although some organizations has been proposing this for several years. In 2001, the UK Consumer Association called for patient reporting to be introduced after highlighting the fact that doctors were often failing to pass on information about suspected adverse reactions to drugs to MHRA. [10]

Aim of the study

To study the Adverse Drug Reactions occurring with the drug use in tertiary care hospital

Objective of the study

1. Critically evaluate the Adverse Drug Reactions occurring with the use of drugs in a tertiary care hospital over a period of 4 months (2015-16)
2. To establish the causality of Adverse Drug Reactions occurring with the use of drugs in the tertiary care hospital using the WHO causality assessment scale and the Naranjo causality assessment scale.
3. To compare the incidences of Adverse Drug Reactions occurring in tertiary hospital, with state data, and international (global) data.

Methodology

This observational study is to be conducted over a period of 4 months (01-Nov-2015 to 29—Feb-2016). Permission obtained from the Review and approval by the Institutional Ethics Committee to conduct the study. An introductory lecture is organized in the academic society of the institute to orient the clinicians towards pharmacovigilance and spontaneous reporting system. The Central Drug Standard Control Organization (CDSCO) suspect Adverse Drug Reactions forms (downloaded from CDSCO website) was distributed to all the clinical departments personally in Kerala medical college hospital and research center, Mangode, Cherpullaserry. . The forms contains the patient details, The description of the reactions, concomitant medication, coexisting illness, any rechallenge, dechallange etc.

On receiving information from the clinical departments, visit to the hospital and interact with the doctors to gather complete information on the Adverse Drug Reactions. The suspected Adverse Drug Reactions will be carefully analyzed and documented. Apart from this, regular visits will be carried out in respective departments and forms were collected twice in a week for analyzing the data and comparing the incidences of Adverse Drug Reactions occurring in a tertiary care hospital, with State data, national data and international (global) data

Results

Out of 25 cases reported with Adverse Drug Reactions in 4 months period, NSAIDS was found to be the most common implicating agent followed by Antimicrobials, Antipsychotics, Antacids, Vitamins and Minerals, Bronchodilators, Antihypertensive and oral hypoglycemic agent etc.. were reported to have adverse drug reactions.

Most Affected organ system was Skin, followed by Gastrointestinal systems, Central nervous system, and Hematological system.

According to Naranjo's Causality assessment scale(16) , 18 (72%) cases were Definite, 4 (16%) Probable and Possibly (Unrelated) 2 (4%) cases were reported as causing Adverse Drug Reactions.

As per the Hartwigs level of severity scale(13) 15 (60%) cases were found to have mild reaction and 5 (20%) cases each with moderate and severe reactions

According to Rawlins and Thomson(12) the type of reaction was classified as Type A (Predictable) with 21 (84%) cases and 4 (16%) cases with type B (Bizarre) reactions.

Looking for the Outcome of the patients, 15 (60%) cases were treated on OPD basis, and 10 (40%) cases required Hospitalization. Among them, 14 (56%) cases were recovered completely, 8 (32%) cases were in a state of recovering and 3 (12%) cases were continuing the treatment.

Most common route of adverse drug reactions was oral, followed by IV, IM, S/C, Topical and Inhalational routes.

Most patients recovered from adverse events taking suitable measures like complete stopping the offending agent, or were prescribed antihistamines and steroids.

Discussion

This study tried to find out the pattern of adverse drug reactions of drugs used in tertiary care hospital. The number of reports we received were 25 out of 30747 cases treated, which amounted to an incidence of 0.081% in our set up. In comparison with the study for search of adverse drug reactions in hospital patients in Embase and Medline found the occurance of 2 – 27.7%, this can be considered as under reporting.[11] It is a universal problem and many reasons are identified such as busy schedule of clinicians, lack of knowledge about the exact authority to report adverse drug reactions to, lack of incentives, reporting process being tedious and inadequate expertise. Our verbal discussions with clinicians revealed similar reasons for underreporting in our institution.

The demographic details of our study showed female gender predominance over males, which was similar to that reported in other studies found in the literature. [12, 13] This might be due to higher emotion quotient in females which makes them more sensitive to the pharmacological actions of medicines.

The most common category associated with adverse drug reactions was dermatology (44%). This finding is concurrent with the study carried out by Coelho et al. (2002) and Rajesh et al. (2008), but it differs from reports of Suh et al. (2000), where gastrointestinal manifestations had the highest rate. Of the dermatological reactions observed in the hospital , itching were seen in 45.45 % and rashes in 36.36%

The incidence rate of NSAIDS adverse drug reactions in this study was found to be comparatively high when compared to other drugs.

Conclusion

The reporting rate appeared to be low so there is need for increasing knowledge and awareness. Educational interventions like conducting CME and training programmes can improve the knowledge towards pharmacovigilance. However monitoring adverse drug reactions is an ongoing and continuing process. Since newer and newer drugs hit the market the need for pharmacovigillance grows more than ever before. Imparting knowledge and awareness of adverse drug reactions reporting of health care professionals would introduce the reporting culture among medical practitioners and increase the reporting rates of adverse drug reactions. Careful considerations involved in planning and monitoring of drug therapy will lead to preventions of adverse drug reactions.

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