A cross-sectional study of patterns of adverse drug reactions reported in the department of pharmacology of a tertiary care teaching hospital in North East India

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Abstract

Introduction: Adverse Drug Reactions (ADRs) are a great cause of concern to the general public, medical profession, the patients and the pharmaceutical industry. For this reason Pharmacovigilance, which is an evolving science dedicated for reducing medicine related harm to patients, is a good tool for ensuring safe and effective use of medicine. The information may be useful in identifying and minimizing preventable ADRs, while generally enhancing the knowledge of the prescribers to deal with them more efficiently. There are hardly any studies regarding ADR patterns in North East India. Hence a study was undertaken to record and analyze the pattern of adverse drug reaction in a Tertiary Care Hospital of North East India.

Materials and Methods: All the ADRs that were collected in ADR monitoring centre of Department of Pharmacology of our Institute during the period of January 2015 to July 2016 were analysed according to demographic distribution, organ system wise distribution, most commonly involved drugs associated with ADRs and causality analysis was done by using WHO causality analysis scale.

Results: Only 272 ADRs were reported during the 18 months study period. Females were affected more than males. Skin and subcutaneous tissue was the most commonly affected system followed by GIT and CNS. Among drug classes anticancer agents were responsible for highest number of ADRs followed by 3rd generation Cephalosporin and NSAID Aceclofenac.

Conclusion: The ADR reporting rate is very less in our study. So there is an urgent need streamlining of hospital based ADR reporting and monitoring system to create awareness and to promote the reporting of ADR among Healthcare Professionals.

Keywords: Adverse drug reactions, Pharmacovigilance, ADR monitoring centre, Causality analysis, North East India.

Introduction

Adverse Drug Reactions (ADRs) are a great cause of concern to the general public, medical profession, the patients and the pharmaceutical industry.(1) They are common and can be life threatening and unnecessarily expensive. For this reason it is important for prescribing clinicians to be aware of the toxic profile of drugs they prescribe for these diseases and to be ever vigilant for the occurrence of unexpected adverse reactions.(2) Pharmacovigilance, which is an evolving science dedicated for reducing medicine related harm to patients, is a good tool for ensuring safe and effective use of medicine. The information may be useful in identifying and minimizing preventable ADRs, while generally enhancing the knowledge of the prescribers to deal with them more efficiently.(3) To transform the concept of Pharmacovigilance into practice for enhancing the safety of patients, ADR monitoring centres (AMCs) are being set up across the country under Pharmacovigilance Programme of India (PvPI). Spontaneous reporting of ADRs has played a major role in the detection of unsuspected, serious, and unusual ADRs previously undetected during the clinical trial phases. This has led to the withdrawal of many drugs in the recent past, i.e., rofecoxib, cisapride, terfenadine.(4)

Though ADRs are of great concern to the general public, the medical profession, the pharmaceutical industry and the regulatory authorities, the concept of ADR reporting is still new in North East India. There are very few centres in North East India to monitor ADRs and hardly any detailed ADR surveys done in this part of India. Hence a study was undertaken to record and analyze the pattern of adverse drug reaction in a Tertiary Care Hospital of North East India.

Objective

To analyze the pattern of Adverse Drug Reactions (ADRs) reported In the Department of Pharmacology of a Tertiary care Teaching Hospital in North East India during the period of January 2015 to July 2016.

Materials and Methods

All of the spontaneous and solicited reports that reach ADR Monitoring Centre (AMC) of our teaching Hospital during the period of January 2015 to July 2016 and satisfy the minimum criteria of reporting were included and analysed.

All the spontaneous reports were collected by the Health Care Professionals of different Departments of our Institute. Solicited reports were collected by the Pharmacovigilance Associate of our AMC who regularly visited different Departments of our Institute.

Minimum criteria of reporting were as: (a) an identifiable reporter, (b) an identifiable patient, (c) at least one suspected drug, and (d) at least one ADR.

The results were analyzed under the following headings:

1. Causality analysis by using UMC– WHO scale.
2. Types of reactions based on the system involved.
3. Groups of drugs commonly associated with ADR

All the reports were sent to National Coordinating Centre (NCC) by uploading in Vigiflow Software which ultimately was reported to WHO Uppsala Monitoring Centre (UMC), Sweden.

UMC– WHO scale: Certain, probable, possible, unassessable/unclassifiable, unlikely, and conditional/unclassified.

Statistical Analysis: The observations pertaining to baseline demographics and the pattern of ADRs were expressed as frequency percentages.

Results

Pattern of ADRs: The study was conducted in the Department of Pharmacology of a Tertiary Care Teaching Hospital in North East India to analyze the pattern of ADRs reported in AMC during the study period of January 2015 to July 2016.

Fig 1: Shows that total numbers of ADR collected during the 18 months study period was 272. Out of these 272 ADRs, 45.22% were males and 54.78% were Females

Table 1: Shows that highest number of ADRs was seen in the age group of 41-60 years (37.50%) followed by the group of 21-40 years (29.41%),>60 years (17.27%) and 1-20 years (15.80%)

Table 2: Shows that skin & subcutaneous tissue (37.5 % of all ADRS) were mostly affected followed by GIT (36.39%), CNS (16.17%), Circulatory (5.89%) and Respiratory systems (1.8%)

Fig. 2: Shows anticancer agents were the drugs which caused maximum number of adverse effects followed by Antimicrobials (3rd Generation) and NSAIDS (Aceclofenac)

Table 3: Shows according to WHO causality analysis of ADRs most of the ADRs were Probable (70.22%) followed by Possible (29.40%)

Discussion

Adverse drug reactions are a common occurrence, but are often not recognized. Even if they are recognized they are under-reported as many physicians are unaware that clinically important ADRs should be reported to ADRs monitoring centres.

Total number of ADRs collected in our Hospital is only 272.

The yearly OPD attendance in our Hospital is around 4.5 lakhs and yearly approx 50000 patients admit in the Hospital. So in 18 months period the total patient attendance is approx 7.5 lakhs. So the number of ADRs reported is very less in our Hospital.

In our study females were found to suffer more from ADRs than males. Similar findings were observed by **Gulnihal Ozcan et al** in which 56.5 % females suffered from ADRs.[5] There may be various factors contributing to the higher rate of reporting in females: the incidence of ADRs may be higher in females, female patients visit hospitals more frequently than males or female patients may more frequently consult a healthcare professional concerning an ADR.

Highest rate of ADRs was seen in the age group of 41-60 years. Similarly, In the study conducted by Kumar A et al, this age group of 41-60 years showed high incidence of ADRs (38.4%).[3] Similar findings were shown by Palanisamy et al who observed the same age group (41-60 years) with 42.71% of ADRs.[6] At this age people usually suffer from several systemic diseases like diabetes, hypertension and other comorbid conditions. So they consume lots of medication which may be the cause of more number of ADRs in this age group.

In our study Skin and subcutaneous tissue was highest involved followed by GIT and CNS. In study conducted by **Gulnihal Ozcan et al**, skin & subcutaneous tissue related adverse effect was most frequently reported.[5] Dermatological ADRs are very easy to identify and detect for the patients which may be the cause of high incidence of dermatological ADRs.

Among the different classes of drugs anticancer agents showed the highest rate of ADRs (36 cases) followed by 3rd Gen Cephalosporin (24 cases) and NSAIDS.

Anticancer drug therapies are more prone to cause ADRs as these agents are cytotoxic and can damage the normally dividing cells along with the cancerous cells. Another reason of more ADRs in patient receiving anticancer drugs is that such patients remain on multi drug treatments making them more vulnerable to ADRs.[7]

Similarly Antineoplastic agents (21.8%) were the drug class most commonly involved in a study conducted by **Jimmy Jose, Padma G.M Rao**.[8]

In our study most of the ADRs were probable (70.22%). **Palanisamy S et al** also found highest rate of ADRs which were probable (90.62%) followed by 4.17% Possible ADRs.[6]

Conclusion

Adverse drug reactions are an inevitable risk factors associated with the use of drugs. However, careful attention to dosage, age, and renal function can minimize the risk of developing ADRs in many patients. The ADR reporting rate is very less in our Hospital than that of found in other studies. This strongly suggests that there is an urgent need for streamlining of hospital based ADR reporting and

monitoring system to create awareness and to promote the reporting of ADR among healthcare.

Professionals. Measures to improve detection and reporting of ADR by all health care professionals should be undertaken, to ensure patient's safety. An early detection of these ADRs may help in minimizing the damage by either modifying the dose or changing the offending agent. This knowledge can also prevent the occurrence of similar such reactions in the future.

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