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RESEARCH ARTICLE

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ADR Monitoring in a tertiary care center in Jorhat

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ARTICLE INFO ABSTRACT

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Introduction: Adverse Drug Reactions (ADR) are encountered daily in a hospital setting. They have a significant impact on patients' quality of life. Knowledge of the common ADRs and severity preventability could go a long way in improving the prevailing health scenario. The aim of our study was first, to review types of ADRs related to drugs used in a tertiary care hospital in Jorhat, Assam, India. Second, to analyze the ADRs for causality, severity, and preventability.
Methods: The study was carried out in a tertiary care hospital in Jorhat for six months from 1-June-2016 to 30-Nov-2016. The study population included patients reporting the adverse drug event during the study period in hospital OPD or IPD. Suspected ADRs were reviewed for casualty, severity, and preventability.
Results: Forty-two patients were detected with 9 types of ADRs; with incidence higher in males (61.9 %) than females (38.1 %). The most frequently reported ADRs were tremors (33.3 %), followed by a rash, dizziness, facial and pedal edema. Most of the ADRs were assessed as possible (85.7 %), severity was moderate (61.9 %), and non-preventable (80.9 %) in the majority of the cases.
Conclusions: Significant ($p < 0.05$) difference was present between the use of multiple drugs and history of previous allergies in between the severity categories of ADRs. The result of our study indicates that the patient taking such drugs should be closely monitored. A database built upon the basis of such studies conducted across multiple centers can go a long way in avoiding clinically significant harmful consequences where the benefits will outweigh the harm.

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Introduction

The World Health Organization (WHO) defines an adverse drug reaction (ADR) as "a response to a medicine which is noxious and unintended, and which occurs at doses normally used in man". The adverse effect is “any undesirable or unintended consequence of drug administration”; and “ADR requires treatment or decrease in dose or indicates caution in the future use of the same drug” (Tripathi et al, 2013). ADRs are encountered daily in an outpatient and in-patient hospital setting. Hospital admissions of 3 to 6 % of all admissions are due to ADR; and ADRs can occur in 10 to 15 % of hospitalized patients, which can result in morbidity, prolonged hospitalization, and risk of mortality (Thong B et al., 2011). The prevalence of ADR is on the rise due to the increasing number of drugs being marketed on a large scale, increasing population, and the trend of polypharmacy being practiced in most health care institutions. Barr mentioned that "One of the great hazards in the use of potent drugs is their inherent toxicity

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and the dangers of the drug appear to be greater now than ever before" (Wiffen P et al., 2002). With the rapid availability and use of medications in the last few decades, the number of adverse events associated with drugs is on the rise.

ADR can significantly increase mortality and morbidity, affecting the quality of life and prolonging the hospital stay. ADRs are also the reason for 3-6 % of all hospital admission worldwide. The United Kingdom (UK) and Europe see an annual hospital admission of 14,60,000 due to ADRs and the United States of America has about half of those in Europe and the UK (Wiffen P et al., 2002). The necessity of reporting ADR is important for the benefit of the patient and the health care delivery system. The actual incidence of ADRs can be even more as the reported cases are just the tip of the iceberg. It is thus imperative to give attention to quickly identifying the ADRs, the population at risk, and the drugs commonly involved.

The aim of our study is first, to review types of ADRs related to drugs used in a tertiary care hospital in Jorhat, Assam, India, and second, to analyze the ADRs for causality, severity, and preventability.

Methods

The study was carried out in a tertiary care hospital in Jorhat after getting approval from Institutional Ethical Committee, for six months from 1-June-2015 to 30-Nov-2015.

The study population included patients reporting the adverse drug event during the study period in the hospital outpatient department (OPD) or Indoor patient department (IPD). Information on accidental intake, self-harm with drugs, and other medication errors were excluded from the study.

Study wards and OPDs were visited daily and the ADR details were collected from the reporting physician, patient, or the attendant in an ADR reporting form available at Central Drugs Standard Control Organization (CDSCO), Government of India website (CDSCO, 2019). In addition, health staff was informed to inform directly, either in person or through ADR forms that were made available in the OPDs and wards. The ADR reporting form could be filled in by a designated reporter with the required information (suspected drug, suspected reactions, identifiable patient, and reporter) to make it a valid report.

Suspected ADRs were reviewed for casualty according to the Naranjo probability scale wherever applicable where-Definite= Score equal to or more than 9, Probable = 5-8, Possible = 1-4, and Doubtful= 0 (Naranjo et al, 1981). The severity of the adverse reactions was assessed using Modified Hartwig and Siegel ADR Severity Assessment Scale - which classifies ADR into mild, moderate, and severe (Srinivasan et al., 2011). And lastly, the preventability assessment was done by using Schumock and Thornton scale. It classifies ADRs into definitely preventable, probably preventable, and not preventable (Schumock et al., 1992). According to this scale, the ADRs were "definitely preventable" if the answer was "yes" to one or more questions in section A. If answers were all negative then we proceeded to section B. ADRs were "probably preventable" if the answer was "yes" to one or more questions in section B. If answers were all negative then we proceeded to section C. In Section C the ADRs was non-preventable.

Statistical analysis was done using Microsoft excel. We calculated the mean, median, and frequencies of multiple risk factors like age group, gender, drug group, causative drugs. Comparison between groups was done using the Chi-square statistical test for assessing significance. The p-value < 0.05 was taken as significant.

Results

Forty-two cases of ADRs were detected, with 9 different types of ADRs; with incidence higher in males (61.9 %) than females (38.1 %). Outpatients subjects were 37 (88.1 %), and 5 (11.9 %) were inpatients. The proportion of patients aged < 18, 18-65 and > 65 years were 11.9 %, 85.7 %, and 2.4 %, respectively.

Commonly reported ADRs were tremors with an incidence of (33.3 %), followed by a rash, dizziness, facial and pedal edema (**Figure 1**). In our study, the drug with maximum ADRs was haloperidol followed by amoxicillin and diclofenac. No history of previous drug history and systemic illness was present.

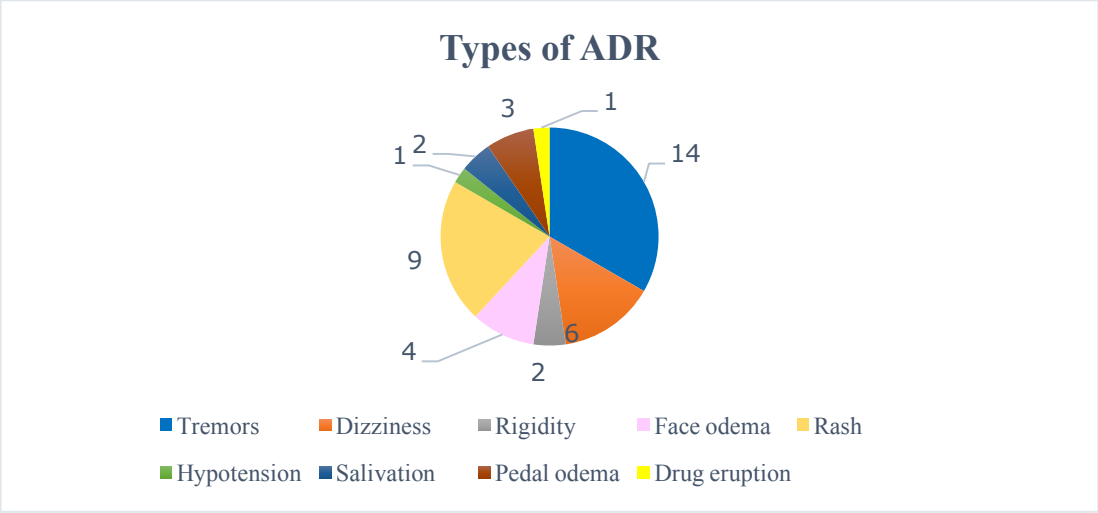


Figure 1: Pie representation of ADRs types

The casualty, severity, and preventability are mentioned below:

Table 1: Casualty of ADRs

Types	Number of ADRs	Percentage (%)
Possible	36	85.7
Probable	4	9.5
Definite	2	4.8
Total	42	100

Table 2: Severity assessment of ADRs

Category	Number of ADRs	Percentage (%)
Mild	16	38.1
Moderate	26	61.9
Severe	0	0
Total	42	100

Table 3: Preventability assessment of ADRs

Types	Number of ADRs	Percentage (%)
Definitely preventable	2	4.8
Probably preventable	6	14.3
Not preventable	34	80.9
Total	42	100

To find out the significant risk factors Chi-square test was applied. Multiple drug therapy and history of allergies had a significant *p*-value when compared with the severity of the reaction. The study- groups were divided into 2 as shown below:

Table 4: Comparison between mild & moderate groups

Category	Mild	Moderate	p-value
Age	29.5	29.9	0.80
History of previous allergies	9	33	<0.05
Multiple drugs	17	25	<0.05

Most of the ADRs were assessed as possible (85.7 %), severity was moderate (61.9 %) in the majority of the cases, and non-preventable (80.9 %) in most of the cases.

The age group of the patients with ADR did not show any significant difference. However, a significant ($p < 0.05$) difference was present between the use of multiple drugs and history of previous allergies in between the severity categories of ADRs.

Discussion

The Lazarou review has been criticized recently on several points, including heterogeneity of studies and the value of extrapolating small numbers of fatal ADRs to a whole population (Lazarou et al, 1998). Nonetheless, there are consistent patterns of ADRs that are significant to individuals and institutions.

ADRs were highly distributed in males (Male: Female ratio is 13:8). It contrasts a few pieces of literature which mention that ADR is more common in females. There was no significant difference between the age groups of the patients having ADRs. This is in contrast to studies that suggest the very young and very old populations are more susceptible to having more ADRs, reflecting the age-related difference in body composition and activity of metabolic pathways. If the suspected drugs are analyzed as per the ATC (Anatomical Therapeutic Chemical) classification, the drugs for nervous system disorders are the most common causative drugs (psycholeptics, anti-depressants) of ADRs. Our study is in accordance with the study of Pourpak et. al., where the risk factors, including multiple concomitant drug intake, history of allergies, are associated with the severity level of the ADRs (Pourpak et al., 2008).

Most of the ADRs were considered possible where the event could be attributed to the offending drugs with a plausible onset latency and other factors like the absence of a confounding factor or a positive dechallenge. The majority of the ADRs were moderately severe as accessed by the Modified Hartwig's Severity Assessment Scale. In subjects with a history of allergy and multiple concomitant drugs, developed a greater number of moderate level severity reactions which was statistically significant. There were ~ 5-15 % preventable ADRs which have a previous history of similar reactions and a lack of awareness had led to its recurrence. Prevention of these reactions could have been made possible by educating the patient regarding the drug and the symptoms of associated ADRs.

Our study has its limitations considering small sample size and a shorter timeline. Hence these results cannot be extrapolated to the rest of the population. A re-challenge test was not conducted due to patient concerns and ethical issues. Allergic patch test was not done and missing information in ADR reporting forms were other constraints faced during the study. There are variations when compared with other study populations.

Conclusions

The result of our study indicates that the patient taking such drugs should be closely monitored. The present study will give an opportunity to achieve the aim using preparing and collecting useful information on ADRs. A database built upon the basis of such studies conducted across multiple centers can go a long way in avoiding clinically significant harmful consequences.

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Conflict of interest

The authors declare no conflict of interest.

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