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CASE REPORT

A study on adverse drug reactions in a tertiary care hospital of Northeast India

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KEYWORDS

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Northeast;
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Abstract *Objective:* Purpose of this study was to monitor adverse drug reactions reported from various departments of a tertiary care hospital in Northeast India. Reported adverse drug reactions were analysed for causality and severity assessment.

Methods: This cross sectional study was conducted in a tertiary care hospital at Guwahati, Northeast India, for 7 months. Patients of all age and either sex were included. Adverse drug reactions were reported by the physicians of this hospital and their causality and severity assessments were performed as per Naranjo's and Hartwig's assessment criteria respectively. Descriptive statistics were used for data analysis.

Results: Total 255 adverse drug reactions were reported from various departments of this tertiary care hospital. Most of the adverse drug reactions were observed in the age group of 21–30 year. Acne (46) was commonly reported reaction. Topical steroids, betamethasone sodium phosphate and clobetasol were reported to induce maximum number of reactions (59). Skin (227, 66.9%) was commonly affected organ system. Most of the adverse drug reactions were possible (240, 94.1%) and mild (222, 87%) in nature.

Conclusions: The topical steroid (betamethasone sodium phosphate) was reported to induce adverse drug reactions in majority of the patients. The commonly reported reaction was acne.

1. Introduction

Drugs prescribed for disease are often themselves the cause of serious amount of adverse reactions ranging from mere inconvenience to permanent disability and death. According to DJP Barker, "There are three actions of a drug: The one you want,

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the one you don't want, and the one you don't know about".[1] Since drugs are intended to relieve suffering, patients find it particularly offensive that they can also cause disease. It has been reported that ADRs account for 5% of all hospital admissions and occur in 10–20% of hospitalized patients.[2] An overall incidence of serious and fatal ADR among hospitalized patients is 6.7% and 0.32%, respectively.[3] Sometimes, ADR-related costs, such as hospitalization, surgery and lost productivity, exceed the cost of the medications.[4] The recent epidemiological studies have estimated that adverse drug reactions are the fourth to sixth leading causes of death.[5] Moreover, detection of ADRs has become increasingly significant because of introduction of a large number of potent toxic chemicals as drug in last two or three decades. Thus, it became very crucial to monitor both known and unknown adverse effects of medicines.

As per WHO, pharmacovigilance is an activity concerned with the detection, assessment, understanding, management and prevention of adverse reactions to medicines, contributes to their safe and rational use.[6] ADR can also be defined as "an appreciably harmful or unpleasant reaction, resulting from intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product." Though ADRs are of great concern to the general public, medical profession, pharmaceutical industry and regulatory authorities, the concept of ADR reporting is still new in India and reporting of ADRs is scarce. Govt. of India under the aegis of Ministry of Health & Family Welfare has also initiated Pharmacovigilance Programme of India and established adverse drug reaction monitoring centres in various tertiary care hospitals across the country to monitor ADRs.[7] Northeast region comprised of 8 Indian states with varied tribal community and ethnicity. However, from this region still there is underreporting of ADRs. Hence, this study was undertaken to record and analyse adverse drug reactions reported from various departments of a tertiary care hospital situated at Guwahati, known as gateway to Northeast India. We have also analysed ADRs for causality and severity.

2. Methods

An observational, cross-sectional study was carried out for 7 months from January 2015 to July 2015 at outpatient and inpatient setting of a tertiary care hospital in Guwahati, Northeast India. Permission from Institutional Ethical Committee of the hospital was obtained prior to the initiation of this study. ADRs were reported from outpatient departments as well as from wards of cardiology, dermatology, gynaecology, haematology, medicine, ophthalmology, paediatric, psychiatry, TB and chest, and neurology department of the hospital. The contact number and email id of study authors were circulated among the physicians of respective departments to facilitate reporting of ADR. Those cases which were identified and reported by physicians of this hospital were considered as an ADR and recorded. The collected information included patient's initial, age, gender, reporting department of the hospital, description of the reaction, duration of reaction, name of the suspected drug causing reaction, and outcomes. Drugs causality assessment was performed by Naranjo's probability assessment scale[8] and Hartwig's criterion[9] was used for severity assessment. Rechallenge was not attempted in any patient. Outcome of the patients with ADR were recorded as fatal, fully recovered (patient fully recovered during study period), recovering (patient recovering, but not fully recovered during study period) and unknown (insufficient information and not documented).

2.1. Inclusion criteria

All the suspected ADRs that may be due to the medications, both prescribed and over the counter, taken by patients either as inpatients or outpatients, that were ultimately noted.

2.2. Exclusion criteria

The use of alternative system of medicines such as Ayurveda, Homeopathy, Unani, etc. as well as over prescribing, over dosage, excess consumption and patients taking more than ten prescription drugs were excluded. All mentally retarded, drug addicted, and unconscious patients were also excluded from the study. Patients admitted due to alcohol or drug abuse, a suicide attempt or admissions planned more than 24 h in advance were not recorded.

Naranjo ADR probability scale for causality assessment.[8]

		Yes	No	Do not know
1	Are there previous conclusive reports on this reaction?	+1	0	0
2	Did adverse event appear after the suspected drug was administered?	+2	−1	0
3	Did the adverse reaction improve when the drug was discontinued or a specific antagonist was administered?	+1	0	0
4	Did the adverse reaction appear when the drug was readministered?	+2	−1	0
5	Are there any alternative causes (other than the drug) that could on their own have caused the reaction?	−1	+2	0
6	Did the reaction reappear when placebo was given?	−1	+1	0
7	Was the drug detected in the blood (or other fluids) in concentration known to be toxic?	+1	0	0
8	Was the reaction more severe when the dose was increased or less severe when the dose is decreased?	+1	0	0
9	Did the patient have a similar reaction to the same drug or similar drugs in any previous exposure?	+1	0	0
10	Was the adverse event confirmed by any objective evidence?	+1	0	0

ADR probability classification	Score
Causality assessment score	
Definite	9
Probable	5–8
Possible	1–4
Doubtful	0

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