Original Research Article

A study on drug induced cutaneous adverse drug reactions at a tertiary care hospital, Mysore, India

Kishore M. S.*, Shashikala S. Konnur

ABSTRACT

Background: Drugs, however safe and efficacious, are associated with risk of adverse reactions. Adverse Drug Reactions (ADRs) are one of the leading causes of morbidity and mortality. ADRs was rated as the fifth leading cause of death among all diseases. Consequences of ADRs range from diminished quality of life, increased physician visits, hospitalizations, and even death. The objectives of the study were to obtain information about drug induced cutaneous adverse reactions and to establish the causal relationship.

Methods: Observational cross sectional study, a total of 76 patients were recruited for the study, conducted in dermatology outpatient department of K R Hospital Mysore Medical College And Research Institute Mysore for 3 months. The drug reactions were recorded in ADR form of Central Drugs Standard Control Organisation (CDSCO). Causality was assessed using Naranjo algorithm and World Health Organization- Uppsala monitoring centre (WHO-UMC) criteria.

Results: 76 patients with CADRs were included in the study during the 3 months study period. Most common age group with CADRs was 20-30 years; with 55.73% of females 20.26% male and the most common suspected drug group causing CADRs was antimicrobial 35.46%. And most common lesion is maculopapular rashles. According to Naranjos scale 67.30% of CADRs were probably caused by drugs.

Conclusions: variety of drugs causes CADRs. Awareness among clinicians is required for active reporting of CADRs. Patients need to be educated for the cautious use of drugs causing ADRs to prevent the same.

Keywords: Cutaneous adverse drug reactions, Naranjos probability scale, Pharmacovigilance, Post-marketing surveillance

INTRODUCTION

Drugs, no matter how safe and efficacious, are coupled with an escapeable risk of adverse reactions. Adverse Drug Reactions (ADRs) are considered as one among the leading causes of morbidity and mortality.1 An ‘adverse drug reaction’, as defined by the World Health Organization, is a noxious, unintended effect of a drug, which occurs at normal doses in humans for the prophylaxis, diagnosis, or the therapy of the disease or for the modification of its physiological function.2 Dermatological conditions are common in clinical practice accounting for up to 2% of consultations in general practice worldwide. Cutaneous ADRs are the commonest ADRs (30-45%) and are responsible for about 2% of hospital admissions. Approximately 2.7% of these may be severe. The incidence of dermatological ADRs among in-patients in developed countries ranges from 1-3% whereas in developing countries such as India it is 2-5% Approximately 5-8% of all hospitalization worldwide is due to adverse drug reactions.3
The pattern of skin disease varies from one country to another and across different parts within the same country.4 In India the most prevalent dermatological condition include scabies, pyoderma, dermatitis, urticaria, fungal skin infection, acne, alopecia and less common are eczematous disorder like psoriasis, skin cancer and cutaneous adverse drug reaction.5 The pattern of cutaneous reactions differs among various drugs. Hence, understanding the precise nature of CADR may help narrow down the search for the offending agent. Knowledge of drugs that can cause CADR can help physicians in choosing safer drugs and therefore can be helpful to society at-large, early detection, evaluation and monitoring of ADR are essential to reduce harm to patients and thus improve public health.6 7

Thus, this present study is designed to obtain information about drug induced cutaneous adverse reactions and assessing the causality of the drug and adverse reactions by using various scales.

METHODS

The study was approved by the Institutional Ethics Committee. Patients with drug induced adverse reactions attending dermatology Out Patient Department, K R Hospital, Mysore Medical College and Research Institute Mysore, from June to August 2017.

It was an observational cross sectional study of drug induced cutaneous adverse drug reactions which were reported at Dermatology Department K R Hospital Mysore Medical College Research Institute Mysore during 3 months period was evaluated. The details of CADRS were recorded in ADR form of Central Drugs Standard Control Organization (CDSCO). Causality was assessed using Naranjo algorithm and also with causality assessment of scale as per World Health Organization- Uppsala monitoring centre (WHO-UMC) criteria.

Inclusion criteria

Patients following criteria were included in the study:

- Those in which the diagnosis of the cutaneous adverse reaction was in accordance with the definition of ADRs which was provided by the WHO
- Those in which there was no alternate explanation for the reaction.
- Those in which there was a plausible time relationship between the introduction of the drug and the onset of a reaction.
- Those in which there was improvement in the condition of the patient after dechallenge/withdrawal of the suspected drug.

Exclusion criteria

- Subjects who complained of only symptoms (e.g., itching) without visible skin lesions
- Those who could not recall the name of the suspect medicines consumed, and those whose lesions turned out to be disease related (e.g., viral exanthems, rash of rickettsia infections, and collagen vascular disease) on closer examination.
- Subjects who reported to have consumed indigenous (ayurvedic and homeopathic) medicines were also excluded as the herbal ingredients could not be identified in their case.

Statistical analysis

The ADR’S were assessed using Naranjo algorithm and also with causality assessment of scale as per World Health Organization- Uppsala monitoring centre (WHO-UMC) criteria.

The descriptive statistical analysis has been carried out to find the sex, age, pharmacological, class wise distribution of the adverse drug reactions. The total number of particular reactions was also calculated. All the data have been expressed in terms of percentage and analysis was done using R - software 20TH version.

RESULTS

In the current study 76 patients were assessed for CADRS for 3 months of period.

Demographics

Majority of patients were in the age group of 20-30 years (44.73%), with a mean age of 24.99 years (Table 1).

Table 1: Age distribution of CADR.

<table>
<thead>
<tr>
<th>Age</th>
<th>Total no. of CADR</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20 yrs</td>
<td>15</td>
<td>19.73%</td>
</tr>
<tr>
<td>20-30 yrs</td>
<td>34</td>
<td>44.73%</td>
</tr>
<tr>
<td>30-40 yrs</td>
<td>15</td>
<td>19.73%</td>
</tr>
<tr>
<td>&gt;40</td>
<td>12</td>
<td>15.78%</td>
</tr>
</tbody>
</table>

Out of 76 patients studied,55 (73.32%) were female and 21 (26.88%) were male patients (Table 2). In present study there was a female preponderance over the male patients.

Table 2: Sex distribution of CADR.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Total no ADR</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>21</td>
<td>26.68%</td>
</tr>
<tr>
<td>Female</td>
<td>55</td>
<td>73.32%</td>
</tr>
</tbody>
</table>

Most frequently encountered drugs causing CADRS Antibiotics 36 (47.36%), Steroids 18 (23.88%), NSAIDS16 (21.05) and in others 6 (7.80) it includes Anticonvulsants, contracts dyes, antihypertensives (Table 3). The current study showed that, according clinical observations. Distribution of types of CADRS caused by drugs maculopapular lesions (39.47%) and followed by
with visible rash (27.63%), photosensitivity (23.68%) and angioedema (9.21%) showed in the Figure 1.

Table 3: Drugs causing CADRs.

<table>
<thead>
<tr>
<th>Pharmacological class</th>
<th>NR of ADR</th>
<th>Percentage of ADR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steroids</td>
<td>18</td>
<td>23.88%</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>36</td>
<td>47.36%</td>
</tr>
<tr>
<td>NSAIDS</td>
<td>16</td>
<td>21.05%</td>
</tr>
<tr>
<td>Others</td>
<td>6</td>
<td>7.80%</td>
</tr>
</tbody>
</table>

Figure 1: Distribution of types of CADRs caused by drugs.

In this present study it showed frequency of distribution of drugs causing reactions, most commonly it was seen with antibiotics (47.36%), steroids (23.68%), NSAIDS (21.05%) and others (contrast dye, antihypertensive, anticonvulsants) (7.8%) (Figure 2).

Figure 2: Distribution of drugs causing CADRs.

Current study assessed the CADRs by using WHO-UMC scale according to that scale 67% of reactions were probable, 29% possible, and 4% definite (Figure 3).

Figure 3: Assessment of percentage drugs causing CADRs by WHO-UMC scale.

In this study it showed 67.4% probable, 28.6% possible, 4% definite reactions occurred by Naranjo scale of causality preventability assessment scale (Figure 4).

DISCUSSION

Cutaneous reactions are most common type reactions to occurs with drugs. Which ranging from maculopapular rashes to toxic epidermal necrolysis can be produced by various drugs which is commonly prescribed by treating patients from treating physicians and also by availability of over the counter medicine. Some severe CADRs may results in serious morbidity causing increased length of stay at hospital and causing economic burden for patient as well as family and even death due to serious life treating reactions.

In the present study, a total of 76 CADRs were reported. This number may not represent the true prevalence of occurrence of CADRs. During study period as patients with incomplete history and doubtful diagnosis were excluded from the study. Moreover, the exclusion of many minor cutaneous reactions which do not require hospitalisation and underreporting by patients might have contributed to the decreased prevalence in this study.

In this study we found that major age group who presented with CADR in between the age groups 20-30 years (44.73%), 30-40 years (19.73%) and younger age group below 20 years of age (19.73%) affected with drug reactions and least onset of adverse reaction occurred...
CONCLUSION

CADRS are reactions which are potentially preventable reactions by consulting right doctor at right time and for right durations of treatment. Doctors can also prevent this reactions occurrence by prescribing right drug to right patient by knowing proper drug interactions and selecting it based on need of the patients.

In this study we focused on the pattern of dermatological cutaneous adverse reactions of a drug class in post marketing surveillance studies to find out variety of adverse reactions occurred due to drugs. ADRS may vary from rash to angioneurotic edema where it requires immediate treatment and withdrawal of offending drug with hospitalization of the patient.

This difference in distribution of various drugs causing reaction was due to patients needs more symptomatic treatment than cure because of that prescribers use “pill for every illa” policy and uses antibiotics for almost all the illness, and availability of steroids, because of steroid property of all inflammatory conditions and presence of tropical forms of steroids which makes skin whitening girls are more attracted for this and develops ADR’s with this.

And if patient failed follow up specially having seizures and starts taking drugs with same prescriptions for long periods may end up with ADR’S.

ADR’s are assessed by using various scale so that, easy identify and prevention of these types of reactions further occurring in future and helpful for reducing its occurrence causing severe burden to the society and family causality assessment that means most of reactions were preventable if we take proper measures to reduce the incidence of reactions by making restrict rule of not using over the counter drug and avoiding pill for every ill policy.

Thus by preventing unnecessary occurrence of reactions causing socio economic burden to patients and society and increasing morbidity and mortality of the person.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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3. Sajith M, Lokhande KD, Padma S, Pawar AP. Prevalence of various skin disorders and prescribing


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