To study the pattern of suspected adverse drug reactions in patients coming to the department of dermatology in Gauhati Medical College and Hospital, Guwahati, Assam, India

Ajoy Borah¹*, Mangala Lahkar¹, Binita Singha¹, Ratan J. Lihite², Debeeka Hazarika³

ABSTRACT

Background: Cutaneous adverse drug reactions (ADRs) are the commonest ADRs (30-45%) and are responsible for about 2% of hospital admissions. This study was conducted to study the pattern of ADRs coming to the department of dermatology in a Tertiary Health Care Hospital. The objectives of the study were to assess the causality, severity, preventability, age distribution, sex distribution and the reactions occurring.

Methods: Cross-sectional study. The suspected adverse drug reactions (ADRs) reported from the department of dermatology in the Spontaneous ADR reporting form was analysed in this study over a period of one year.

Results: A total of 513 cases of reported ADRs were analysed. The highest number of ADRs was reported in the Age group 21-40 years with female preponderance. Erythematous maculopapular lesions were the most common ADR and maximum cases of ADRs were observed with steroids. Most cases were found to be probable (causality assessment), of mild severity and were probably preventable.

Conclusions: The study showed that a number of drugs cause dermatological ADRs. These ADRs vary in their appearance, duration, causality, severity, and preventability.

Keywords: Cutaneous, Dermatology, Skin, Drug reactions, Pharmacovigilance

INTRODUCTION

Drugs, however safe and efficacious, are associated with inescapable risk of adverse reactions. Adverse Drug Reactions (ADRs) are one of the leading causes of morbidity and mortality.¹ According to WHO, an adverse drug reaction is defined as “a response to a drug that is noxious and unintended and occurs at doses, used in man for prophylaxis, diagnosis, or therapy of a disease or for modification of physiological function.”² Consequences of ADRs range from diminished quality of life, increased physician visits, hospitalizations, and even death. In a study, ADRs was rated as the fifth leading cause of death among all diseases. Approximately 5-8% of all hospitalization worldwide is due to adverse drug reactions.³ Cutaneous ADRs are the commonest ADRs (30-45%) and are responsible for about 2% of hospital admissions.⁴,⁵ Approximately 2-7% of these may be severe.⁵ 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%. The incidence of drug-induced adverse skin reactions is found to be 2-15% at a dermatology outpatient setting.⁶ Many ADRs are commonly known and are present in literature but some are rare and may present without warning. Cutaneous drug eruptions are one of the most
common types of adverse reaction to drug therapy, with an overall incidence rate of 2-3% in hospitalized patients.\textsuperscript{7, 8} This study was therefore conducted to study the pattern of ADRs coming to the department of dermatology in a tertiary health care hospital. The objectives of the study were to assess the causality, severity, preventability, age distribution, sex distribution and the reactions occurring.

**METHODS**

The study was carried out in the adverse drug reaction monitoring centre in the department of pharmacology, Guwahati medical college.

The protocol was approved by the Institutional Ethics Committee of Gauhati Medical College and Hospital, Guwahati bearing approval no. MC/233/2013/106.

It was an observational study of cross sectional design. The Suspected adverse drug reactions reported from the department of dermatology in the spontaneous ADR reporting forms were analysed in this study.

The duration of this study was one year (March 2014 - February 2015).

**Data analysis**

The suspected adverse drug reactions were assessed for causality, severity and preventability. Naranjo’s scale was used for causality assessment, hart wig and Siegel’s scale was used for assessment of severity and Schumock and Thornton’s criteria was used to assess the preventability of the ADRs.\textsuperscript{9-11} The reactions were also assessed to find the sex distribution, age group distribution and pharmacological class wise distribution of the suspected adverse drug reactions. The total number of particular reactions was also calculated. All the data have been expressed in terms of percentage.

**RESULTS**

**Table 1: Age distribution of adverse drug reactions coming to dermatology OPD.**

<table>
<thead>
<tr>
<th>Age group</th>
<th>Males</th>
<th>Females</th>
<th>Total no. of ADRs</th>
<th>Percentage of total ADRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10 years</td>
<td>12</td>
<td>15</td>
<td>27</td>
<td>5.26%</td>
</tr>
<tr>
<td>11-20 years</td>
<td>30</td>
<td>68</td>
<td>98</td>
<td>19.10%</td>
</tr>
<tr>
<td>21-40 years</td>
<td>94</td>
<td>201</td>
<td>295</td>
<td>57.50%</td>
</tr>
<tr>
<td>41-60 years</td>
<td>32</td>
<td>46</td>
<td>78</td>
<td>15.20%</td>
</tr>
<tr>
<td>&gt;60 years</td>
<td>6</td>
<td>11</td>
<td>15</td>
<td>2.92%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>174</strong></td>
<td><strong>339</strong></td>
<td><strong>513</strong></td>
<td></td>
</tr>
</tbody>
</table>

The results of the study have been expressed in Tables 1, 2, 3, 4 and Figures 1, 2, 3, 4. A total of 513 cases of ADRs were reported during the period of the study. The highest number of ADRs was reported in the age group 21-40 years (295 cases, 57.50% of the total number of cases. Refer Table 1).

**Table 2: Sex distribution of adverse drug reactions coming to dermatology OPD.**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Total no. of ADRs</th>
<th>Percentage of total ADRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>174</td>
<td>33.91%</td>
</tr>
<tr>
<td>Female</td>
<td>339</td>
<td>66.08%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>513</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Figure 1: Causality assessment of the dermatological ADRs using Naranjo’s scale (n = total number of cases).**

**Figure 2: Severity assessment of the dermatological ADRs using Hart wig scale (n = total number of cases).**

Female to male ratio of ADRs was found to be 2:1 (Table 1, 2).

Erythematous maculopapular lesions were the most commonly reported ADR (165 cases, 27.48%). 9 cases of SJS (Stevens Johnsons syndrome) and 3 cases of TEN (toxic epidermal necrolysis) were also reported (Refer Table 4 and Figure 4).
Figure 3: Assessment of the preventability of the dermatological ADRs using Schumock Thronton scale (n = total number of cases).

Maximum incidence of dermatological ADRs were observed with Steroids (73.68%, 378 cases) followed by Anti-Microbial agents (11.1%, 57 cases), Non-steroidal Anti-inflammatory drugs (5.26%, 27 cases), Antiepileptic agents (2.92%, 15 cases), Oral contraceptive pills (5.26%, 9 cases). 27 cases (5.26%) of ADRs were also reported due to intake of herbal medicines (Refer Table 3).

DISCUSSION

513 cases of Cutaneous ADRs were analysed in the study over duration of one year. Female predominance (66.08%) was seen in this study. This is seen in
CONCLUSIONS

The study showed that a number of drugs cause dermatological ADRs. These ADRs vary in their appearance, duration, causality, severity, and preventability.

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