ADVERSE DRUG REACTION REPORTING- A RETROSPECTIVE ANALYSIS

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CASE STUDY

Steven Johnson Syndrome (SJS/TEN)

A seven year boy admitted to hospital with skin blisters and eruptions followed by necrosis of the epidermal tissue.

History:
- k/c/o Trabeculoma in brain with c/o seizures and prescribed with carbamazepine.
- Started on ATT 9 days back, skin reactions observed on the 9th day.
Various reactions

Fixed drug eruptions

Urticaria
examples

• **Urticaria**
NSAIDs, antimicrobials, anticancer drugs, ACE inhibitors, corticosteroids

• **Fixed-drug eruptions**
Tetracyclines, barbiturates, sulfonamides, codeine, carbamazepine, acetaminophen, NSAIDs

• **SJS and TEN**
Antibacterial sulfonamides, anticonvulsants, oxicam NSAIDs, allopurinol, nevirapine
Introduction

The World Health Organisation (WHO) defines an ADR as “a response to a drug that is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for modification of physiological function”
WHY ? monitoring ADRs

• Worldwide incidence of ADRs is steadily increasing

  ➢ Up to **35% of hospitalized patients** experience ADRs

  ➢ Approximately **5% to 10%** of all hospital admissions are due to ADRs

  ➢ The incidence of **fatal ADRs** is estimated to be **0.23% to 0.41%**
• Adversely affect patients’ quality of life
• ADRs are one of the leading causes of morbidity and mortality
• Cause patients to lose confidence in their doctors
• Increase costs of patient care
Objective of study

• Assess the incidence and pattern of reported ADRs

• Assess causality and offending drugs that caused ADRs

• Assess the severity and preventability of reported ADRs
Methodology

• **Study Site:** A Tertiary Care Hospital, Bangalore

• **Study Design:** Retrospective observational study

• **Source of Data:** Documented ADRs 2009-2015

• **Data Analysis:** Microsoft Excel
Documented ADRS from 2009-2015 were collected. Causality, Severity, preventability were assessed using different scales. Results were analyzed using MS Excel.
Results and Discussion
Gender distribution

<table>
<thead>
<tr>
<th>Gender</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEMALE</td>
<td>58</td>
</tr>
<tr>
<td>MALE</td>
<td>69</td>
</tr>
</tbody>
</table>
**Age Group affected by ADRs**

- **71-80**: 3
- **61-70**: 14
- **51-60**: 22
- **41-50**: 34
- **31-40**: 20
- **21-30**: 23
- **11-20**: 8
- **1-10**: 3
Rawling’s and Thompson Classification

<table>
<thead>
<tr>
<th>R &amp; T Class</th>
<th>52%</th>
<th>48%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type B</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Type A | 61 |
| Type B | 66 |
Severity Assessment

HARTWIGS SEVERITY ASSESSMENT SCALE

<table>
<thead>
<tr>
<th>Level</th>
<th>No of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>26</td>
</tr>
<tr>
<td>Moderate</td>
<td>95</td>
</tr>
<tr>
<td>Severe</td>
<td>6</td>
</tr>
</tbody>
</table>
Preventability assessment

- Definitely: 8
- Probably: 29
- Not preventable: 90
### Systems Affected by ADRs

<table>
<thead>
<tr>
<th>System</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin</td>
<td>43</td>
</tr>
<tr>
<td>Respiratory</td>
<td>3</td>
</tr>
<tr>
<td>Renal</td>
<td>1</td>
</tr>
<tr>
<td>Neurological</td>
<td>9</td>
</tr>
<tr>
<td>Metabolic</td>
<td>3</td>
</tr>
<tr>
<td>GI</td>
<td>33</td>
</tr>
<tr>
<td>Electrolyte imbalance</td>
<td>6</td>
</tr>
<tr>
<td>Chills &amp; fever</td>
<td>4</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>10</td>
</tr>
<tr>
<td>Body as whole</td>
<td>3</td>
</tr>
<tr>
<td>Hematological</td>
<td>3</td>
</tr>
<tr>
<td>Allergy</td>
<td>9</td>
</tr>
</tbody>
</table>
### Class of Drugs associated with ADRs

<table>
<thead>
<tr>
<th>Class of Drugs</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sympatholytic</td>
<td>2</td>
</tr>
<tr>
<td>Immunosuppressive</td>
<td>2</td>
</tr>
<tr>
<td>Supplement</td>
<td>5</td>
</tr>
<tr>
<td>Quinolone</td>
<td>11</td>
</tr>
<tr>
<td>Penicillin</td>
<td>7</td>
</tr>
<tr>
<td>Nitroimidazole</td>
<td>5</td>
</tr>
<tr>
<td>Macrolide</td>
<td>4</td>
</tr>
<tr>
<td>Glycopeptide</td>
<td>3</td>
</tr>
<tr>
<td>Diuretics</td>
<td>3</td>
</tr>
<tr>
<td>Contrast dye</td>
<td>7</td>
</tr>
<tr>
<td>Cephalosporins</td>
<td>25</td>
</tr>
<tr>
<td>Carbapenem</td>
<td>4</td>
</tr>
<tr>
<td>Beta-blocker</td>
<td>3</td>
</tr>
<tr>
<td>Antimycobacterial</td>
<td>6</td>
</tr>
<tr>
<td>Anticonvulsant</td>
<td>5</td>
</tr>
<tr>
<td>Analgesic</td>
<td>26</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>9</td>
</tr>
</tbody>
</table>
Frequency of ADRs from 2009-2015

Number of ADRs reported

Six month intervals
Conclusion

- Need for streamlining hospital based ADR reporting and monitoring
- Need for HCPs involvement.
- Conducting educational classes for HCPs
- Electronic documentation of medication history
- Encouraging ADR based studies
- Computerized reporting system
LIMITATIONS

– Under reporting by health care professionals.
– Lack of awareness of where and how to report.
– Study was not conducted on neonates and pregnant women.
– Inadequate knowledge about importance of reporting ADRs.
– Inconclusive submission of ADR forms.
FUTURE DIRECTIVES

– Provide patient counselling with emphasis on drug utilization.
– ADR assessing studies along with feedback.
– Provision of CMEs for HCPs on ADRs.
– To implement computerized reporting system in hospital setup to hasten reporting of ADRs in more efficient manner.
Future directives

– Computerized identification system

NAME:                                                AGE:                                                SEX:

DIAGNOSIS:

RX
1.                                                   2.                                                   3.                                                   4.                                                   

MINOR INTERACTION 1&4                                MODERATE INTERACTION 3 & 4                           MAJOR INTERACTION 1 & 2
Dr. NAME, CODE                                       Dr. NAME, CODE                                       Dr. NAME, CODE

OK  CHANGE                                          OK  CHANGE                                          OK  CHANGE

Dr. XYZ
CODE
Take home message

“ADR VIGILANCE SAVES”
References


Thank you