PATTERN OF ADVERSE DRUG REACTIONS AMONG PATIENTS ADMITTED IN A TERTIARY CARE TEACHING HOSPITAL: A PROSPECTIVE OBSERVATIONAL STUDY

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Introduction

- A response to a drug which is noxious and unintended, and which occurs at doses normally used in man, for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.

- 2.9-5.6% of all hospital admissions are caused by ADRs.

- 35% of hospitalized patients experience an ADR during their hospital stay.

- An incidence of fatal ADRs is 0.23 - 0.41%.
Contd...

• Essential to have **constant surveillance**, collection & analysis of data regarding adverse drug reaction in a systematic manner.

• For assessing the safety of drugs in a hospital setting.

• **Prolongs Hospital stay & financial burden** on the patient.
Objectives

• To monitor and study the pattern & frequency of Adverse drug reactions.
• Assess the causality.
• Assess the severity.
Materials and Methods

• Study conducted based on ADRs reported between November 2013 and April 2014 (6 months) to the ADR reporting unit of S.S.Institute Of Medical Sciences & Research Centre, Davangere.

• Suspected Adverse Drug Reaction Reporting Form.
Contd...

• **Details collected in the ADR reporting form:**

  • Patient profile - Age, sex and weight.
  • Patient medication details (generic name of the medicine, dose frequency, strength, date of start & stop).
  • Description of the adverse event.
  • Onset and ablation of adverse event.
  • Other relevant history including pre-existing medical conditions.
Analysis

• Total of 71 ADRs were reported during study period.

• Descriptive analysis of the ADR data collected was done by Microsoft Excel software and expressed as percentage comparison.

• Causality assessment done using Naranjo Probability Scale.

• Severity assessment done using Modified Hartwig and Siegel scale.
RESULTS

Genderwise ADR distribution

Typewise ADR distribution
Contd...

Age-wise ADR Distribution

<table>
<thead>
<tr>
<th>AGE- GROUP</th>
<th>PERCENTAGE OF ADRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-18 Years</td>
<td>16%</td>
</tr>
<tr>
<td>19-59 Years</td>
<td>70%</td>
</tr>
<tr>
<td>&gt; 60 years</td>
<td>14%</td>
</tr>
</tbody>
</table>

Causality assessment based on Naranjo Scale

<table>
<thead>
<tr>
<th>CAUSALITY</th>
<th>PERCENTAGE OF ADRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible</td>
<td>67%</td>
</tr>
<tr>
<td>Probable</td>
<td>33%</td>
</tr>
</tbody>
</table>
Severity assessment based on Modified Hartwig and Siegel scale

<table>
<thead>
<tr>
<th>SEVERITY</th>
<th>PERCENTAGE OF ADRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>19%</td>
</tr>
<tr>
<td>Moderate</td>
<td>76%</td>
</tr>
<tr>
<td>Severe</td>
<td>5%</td>
</tr>
</tbody>
</table>
Systemwise ADR involvement

- Skin: 88%
- CNS: 1%
- Fever & chills: 4%
- GIT: 7%
Contd...

- Antibiotics: 44%
- NSAIDs: 35%
- CNS drugs: 11%
- Iron preparations: 6.00%
- Laxatives: 2%
- Opioids: 2%
Contd...
DISCUSSION

• Demographic details of the present study showed female gender predominance over males for ADRs, this finding is similar to that of Singh et al.

• In the present study, a higher percentage of ADRs occurred in adult population (19-59 years)- similar to that reported by other studies.
Contd...

• Causality assessment revealed that most of the ADRs belonged to “possible” followed by “probable” category, this is consistent with that reported by Rao et al.

• The most common system associated with ADRs in our study were skin. Finding consistent with many studies which have reported a higher percentage of dermatological manifestations than others.
Contd...

• In our study, **antibiotics** were the most commonly involved drug classes in ADRs. This finding is consistent with previous study by Deepalatha et al.

• Amongst antimicrobial agents **Cephalosporins** accounted for the highest number of the ADR reports **followed by fluoroquinolones**. Other studies have also suggested similar findings.
CONCLUSION

• ADRs have proved a significant problem in healthcare.

• A wide clinical spectrum of ADRs was observed in our study and the majority of the causative drugs are antibiotics.

• Greater need for streamlining of hospital based ADR reporting and monitoring system to create awareness; and to promote the reporting of ADR among healthcare professionals of the country.
CONCLUSION

- Awareness programmes about the importance of ADR reporting for health care providers are essential to minimize drug related morbidity.

- The active initiation of Pharmacovigilance programme in all possible health care sectors will add further value in the protection of patient safety.
References


References

• 4) Murphy BM, Frigo LC. Development, implementation and results of a successful multidisciplinary adverse drug reactions reporting program in a University teaching hospital. *Hosp Pharm* 1993, 28: 1199–204

• 5) Deepalatha C, Raja Vikram Prasad, Satish Chandra, Murali Mohan P, Diclofenac-Induced Urticaria In Paediatric Patient *Asian journal of pharmaceutical and clinical research* 2013, 6(3) : 1-2