A PROSPECTIVE STUDY ON ADR MONITORING IN GENERAL MEDICINE DEPARTMENT

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BACKGROUND: Adverse Drug Reactions (ADRs) are recognised hazards caused by any class of drugs. ADRs impose major effects on public health by reducing patient’s quality of life and increasing financial burden.

AIM: The objectives of the study were to analyse the pattern and extent of occurrence of ADR, to assess the causality and severity of ADR, to evaluate the management of ADR and to document and report the detected ADR.

METHOD: It is a hospital based prospective observational study which was carried out in inpatients of general medicine department over a 6 months period. The data obtained includes demographic details, past history, findings on general and systemic examination, laboratory investigation reports, diagnosis, treatment, description of reaction, date and time of onset of reaction, suspected drugs and management of ADR. ADRs obtained were categorized based on causality and severity. They were also be categorized based on consequence of ADR, the organ system affected, group of drugs involved, length of stay.

RESULTS: A total number of 16 ADRs were found during the study period. Out of 16 ADRs, 3 (18.7%) ADR as a cause of admission and 13 (81.2%) ADRs occurring during the hospital stay.

Assessment of ADRs by Naranjo’s showed that out of 16 ADRs 5(31.25%) were probable and 11 (68.75%) were possible and that of WHO showed 3 (18.75%) probable and 13 (81.25%) possible. Severity assessment showed that 62.5% were moderate and 37.5% were mild reactions. In our study, the ADRs were marginally more documented in females than in males. Systems most commonly affected were skin (56.25%), CNS (25.0%), GI (12.5%) and haemopoetic system (6.25%). Drug classes that are mostly associated with ADRs were antibiotics (37.5%).

CONCLUSION: In our study 16 ADRs were confirmed. Of which 3 (18.7%) ADR as cause of admission and 13 (81.2%) ADRs occurred during the hospital stay. Females are slightly more susceptible to ADR than males.

The age group highly affected was found to be in range of 25-40 years. The highly implicated class of drugs were antibiotics accounting for 37.5%. The highly affected organ system was skin (56.25%). Among the ADRs 62.5% were moderate and 37.5% were mild reactions.

Keywords: Adverse Drug Reaction, Causality, Severity