

Causality, Severity and Preventability profiling of Adverse Drug Reactions among Medicine Inpatients in a Tertiary Care Public Teaching Hospital, India

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ABSTRACT

BACKGROUND:

Adverse drug reactions (ADRs) represent the risk associated with the anticipated benefits of drug therapy and are known to be leading cause of morbidity and mortality worldwide. ADRs constitute an enormous clinical and economic burden on health care system. Evidence also suggests that approximately half of the ADRs are preventable.

OBJECTIVES:

This study was aimed to characterize the ADRs and to assess their causality, severity and preventability.

METHODOLOGY:

This prospective observational study was conducted in the patients admitted to medicine wards of a public teaching hospital. Patients of all age groups and either sex admitted in medicine wards were included in this study. Those not willing or able to give informed consent were excluded. The causality of ADRs was assessed using Naranjo's scale and WHO-UMC criteria. Severity and preventability were assessed using modified Hartwig's severity scale and modified Schumock & Thornton criteria, respectively.

RESULTS:

Over the period of six months, data from 808 patients was collected. Of which 776 (486 male, 290 female) were analysed as they met the inclusion criteria. Out of 776 patients with complete documentation, 77 patients (45 male, 32 female) developed 82 ADRs during their stay in hospital with an incidence of 9.9%. 65.8% ADRs were observed in adults and 34.2% in geriatrics. Maximum number of ADRs were observed in age group of 40-49 years (25.6%). The highest number of ADRs were associated with antimicrobial drugs (24.4%) followed by diuretics (15.80%), opioid analgesics (14.6%), anticoagulants (14.6%) and antidiabetics (13.4%). Among the organs affected, approximately half of the ADRs were associated with GIT (46.3%) followed by metabolic (35.3%), haematological (14.6) and cutaneous (9.7%). Constipation (19.5%) followed by hypokalemia (19.5%), coagulopathy (14.6%), hypoglycaemia (13.4%) and hypersensitivity reactions (9.7%) were most commonly observed ADRs.

Causality assessment by Naranjo's scale revealed that 13.4% of ADRs were 'definite', 52.4% were 'probable' and 34.2% were 'possible' in nature. WHO-UMC criteria showed 15.8% of

ADRs were ‘certain’, 37.8% were ‘probable’ and 46.2% were ‘possible’. Of the 82 ADRs, 31.7% were ‘mild’ and 68.3% were ‘moderate’. Preventability assessment showed that 34.2% of ADRs were ‘definitely preventable’, 46.3% were ‘probably preventable’ and 19.5% were ‘not preventable’. Also 90% of the ADRs were Type A in nature.
Chi-squared test was used to observe the relationship of predisposing factors for ADRs and P-value less than 0.05 were considered as significant. Based on the results of chi-squared test, length of hospitalization, number of drugs prescribed and number of diagnosis were identified as significant predisposing factors for adverse drug reactions. In contrast, no significant difference was seen in the incidence of ADRs observed in male and female. Though statistically non-significant, incidence of ADRs in females was relatively higher as compared to males.

CONCLUSION:

ADRs encountered in this study were either ‘definitely preventable’ or ‘probably preventable’. A regular mechanism to monitor the patients may be an option to minimise the ADRs.

KEYWORDS: Adverse drug reactions, Causality, Preventability, Predisposing factors.

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