

STUDY TITLE: Intensive Pharmacovigilance in Pediatric In-Patients In A Tertiary Care Hospital: A Step Towards Safe Prescribing of Drugs.

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Abstract

Introduction: Adverse Drug Reaction is a response to the drug that is unintended which occurs at doses normally used in humans for prophylaxis, diagnosis and treatment of disease. ADRs in children can result in prolonged hospital stay or permanent deformities or even death. ADRs in paediatric population can be estimated by Paediatric Trigger tools. Hence, this study was conducted to estimate performance of a Paediatric Adverse Drug Trigger Tools and in detecting ADR leading to development of time saving strategy

Method: There was conduction of a cross-sectional study consisting of comparison of 2 methods which involves implication of a multifaceted method to identify ADRs to obtain a reference comparison and use of paediatric medication-focused trigger tool in a new cohort of patients. The primary outcome was evaluation of ADRs. The secondary outcome was be the difference in time investment between the 2 methods.

Results: Out of total 50 patients, 20 had documented ADRs with trigger tools and 30 patients had trigger tools but not ADRs. These patients were considered as controls. Mean number of drugs prescribed in patients who experienced ADR were 4.21 ± 1.437 . Mean number of drugs prescribed in controls were 4 ± 1.067 . There was no significant difference in number of drugs prescribed in both groups. The most common drug group causing ADR was Antimicrobial. Most common ADR observed was diarrhoea (25%) and vomiting (20%) patients respectively.

According to WHO UMC causality scale, all were probable (related to drug). Naranjo algorithm ADRs were labelled as possible. According to Modified Hartwig and Siegel severity scale, number of mild, moderate and severe ADRs were 11, 8 and 1 respectively. According to Schumock and Thorton Preventability scale, most of ADRs were not preventable. 109 triggers were positive in total 50 patients. Most common trigger seen was due to use of Antiemetic drugs which was seen in 36% of patients followed alteration in sodium, potassium and creatinine level.

Conclusion: In our study, 20 patients had ADRs out of which most were related to GI tract. On causality assessment they were found related to drug. ADRs were of moderate severity. 109 triggers were positive in 50 patients. Most common triggers were Antiemetics drugs followed by alteration in sodium and potassium levels.

Keywords: ADRs, paediatric trigger tool kit, multifaceted method.

Biography:

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