

2nd International Conference and Exhibition on Pharmacovigilance & Clinical Trials

November 18-19, 2013 Hilton San Antonio Airport, TX, USA

A prospective study on adverse drug reactions and signal detection

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Background: ADRs have a major impact on public health, reducing patients' quality of life and imposing a considerable financial burden on the health care systems.

Objectives: The main objectives were to analyze the pattern and extent of occurrence of ADRs in the hospital, identify comorbidities, past and present illness, assess causality and identify the offending drugs, assess the severity and preventability of adverse drug reactions.

Method: A prospective observational spontaneous reporting study was carried out with both active and passive methods from January 2009 to August 2012.

Results: A total of 950 ADRs were accepted from the reported total of 1227 ADRs. Female patients experienced more number of ADRs when compared to male patients. Fever was the most commonly observed reason for admission. Maculopapular skin rashes were the commonly observed ADR in the study population. Amoxicillin and clavulenic acid combination implicated more number of ADRs in the antibiotic category than others. Sixty one percent of the ADRs were moderate in severity followed by minor and severe ADRs. Most of reactions in the study population were managed by withdrawing the offending drug and rechallenge was performed in few subjects. Most of ADRs in the study were definitely preventable (40%) and were predictable in nature. Eighty percent of the reactions were probably related to the offending drugs, 758 reactions in the likely to cause ADRs. Twenty five percent of the ADRs were treated symptomatically in the study population.

Conclusion: The reporting of ADRs needs continuous stimulation. It is important to achieve the development of a positive attitude towards pharmacovigilance among health care professionals, including pharmacist, so that ADRs reporting becomes an accepted and understood routine.

Biography

Sivanandy Palanisamy has completed his Ph.D. from Tamilnadu Dr. MGR. Medical University, Chennai. He has published more than 30 research papers in reputed international and national journals and serving as an editorial board member of many reputed journals.. He has presented many papers in national and international conferences and bagged many grants.

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