

Causality assessment and the severity of the adverse drug reactions (ADR) actively detected in in-ward patients in a tertiary care hospital in Sri Lanka

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Adverse drug reactions (ADR) are leading cause of hospitalization in many Sri Lankan hospitals. We conducted a survey on ADR in all patients admitted to a tertiary care hospital in Galle, Sri Lanka. A prospective observational study was conducted by actively screening for ADR for causation, causality and severity using validated scales. ADR reporting cards were used from the national pharmacovigilance centre in Sri Lanka. 149 patients were analyzed for severity of ADR referring the modified Karch and Lasagna Severity Assessment Scale. Casualty assessment was done using a WHO scale. The mean age of patients was 42 years. We found that 81.8% of patients had moderate ADR, severe, 16.1%, and 2.01% in fatal. Single most common cause of ADR was antibiotics (35.57%) and 64.42% were due to other drugs. Penicillin had the highest incidence of ADR among antibiotic subgroup. Anticonvulsants had caused most of the fatal and severe ADR. WHO causality assessment shows 60% of ADRs were probably drug-related and 18.46% of them were possibly drug related. Skin, nervous and gastrointestinal systems were commonly affected (41%, 18.53% and 14.6% respectively). 16% of patients had previous allergy. We found that females (56%) had higher number of ADR than males (43%). Challenge test had been done only in 3% of the patients and only 40% patients became positive for the test. Our study shows that most ADR detected were probably drug related and hence they are preventable. Prevention of ADR can reduce a big financial burden from the health budget. We suggest seeking contribution from clinical pharmacists and other stakeholders for active pharmacovigilance.

Key words: Adverse drug reactions, hartwigs scale, hospital pharmacovigilance

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