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Quality assessment of Patient reported ADRS in an out-patient department of a tertiary care hospital in south India - A Pilot study

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Introduction: Adverse Drug Reactions (ADR) is among the leading causes of morbidity and mortality. Many developed countries consider patients as active members in the disease management, including ADR reporting. Patient reporting of suspected ADRs has the potential to increase the knowledge about the possible harm of drugs.

Objective: To initiate, evaluate and assess the quality of patient reporting of suspected ADRs in an ambulatory care setting.

Methodology: A Prospective observational study was conducted in the out-patient department of Internal Medicine in a South Indian tertiary-care teaching hospital over 6 months. On receiving a call the investigators obtained all necessary information by interviewing the patient and were recommended by a physician for further action. The collected data were then analysed using parametric and non-parametric statistics.

Results: A total of 1125 patients were enrolled of which 128 patients called back reporting 95 ADRs [Incidence (8.44%)]. The number of females [54 (57%)] reporting ADRs was found to be higher than males [41 (43%)] [P =0.001 Sig.]. Maximum number of reports were obtained from patients in the age group of 40-60 [38 (40%)]. It was also observed that the number of reports were more as the education was higher [UG 38.8%]. GI Disorders [34 (35.78%)] and Skin & Appendages [22 (23.10%)] comprised the majority of experienced ADRs. The patient reports were found to provide necessary data [Drug history, time-temporal relationship, Description of reaction, Fate of suspected drugs, Outcome of reaction] [89(93.64%)] and very few patients were unable to provide the entire information [6(6.31%)].

Conclusion: Patient reporting ADRs are a valuable tool which can strengthen the Pharmacovigilance of a country working synergistically in identifying and reporting ADRs thereby resulting in a safer medication use experience. Further awareness campaigns and computerization of patient case records can help in establishing an efficient method of detecting and reporting ADRs.

Biography

Pullagura Gokul Raj is currently pursuing his Internship, Doctor of Pharmacy at JSS College of Pharmacy, Mysore. He is interested in research areas like Pharmacoepidemiology, he wishes to pursue doctoral studies. He has currently completed his dissertation on the title 'Initiation and Evaluation of Patients reporting ADRs at the out-patient department of a tertiary care hospital in South India'. He is also an avid book reader and public speaker.

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