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Pharmacovigilance: Characterization and Methods of Causality Assessment

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Abstract

Pharmacovigilance (PV) is the science dealing with detecting, reporting and preventing the adverse drug effects. Adverse drug reactions (ADRs) classified to two types. Type A that dealing with unexpected effects of the drug and type B that is related to expected and known effects of the drug. Many researches developed different methods of causality assessment of adverse drug reactions but non of them is considered the gold standard. The current article will discuss the classifications of adverse drug reactions and the different methods of causality assessment of adverse drug reactions.

Key words: Pharmacovigilance (PV), Spontaneous Reporting System, (SRS), Adverse Drug Reactions (ADR) and Causality Assessment.

Introduction

Pharmacovigilance (PV) is the science dealing with the detection, reporting and prevention of long and short term adverse effects of drugs. A vast amount of adverse drug reactions can reduce the quality of life, increase hospitalization stays and increase the risk of death rates. Adverse drug reactions are projected to be 3-7% of hospital admissions in the US. The main universal obstacle is the under-reporting of adverse drugs reactions that can be due to the lack of time and report forms [1-4]. WHO has defined adverse drug reactions by «harmful or unintended reaction to a medication happens at a standard measurement». ADRs are mainly classified to Type A and Type B. Type A response is connected with the pharmacological activities of the medication and unlisted/unexpected adverse drug reaction. While Type B response is listed/expected adverse drug reaction. Type A response is 80% more major and common than Type B reaction. ADRs relate to mortality. Recent estimations show ADRs are the 6th real reason for death in the United States of America (USA). For every medication, one must measure benefits against risks. It is important to continuously monitor the advantages and dangers of medications [5-7].

The WHO characterizes pharmacovigilance as «the science and exercises identifying with the identification, appraisal, comprehension and counteractive action of unfavorable impacts or whatever other conceivable medication related problems». The pharmacovigilance aims to early detection of beforehand obscure ADRs, acknowledgment of recurrence of identified ADRs, differentiating proof of hazard elements and component of ADRs, quantitative examination of advantage/hazard proportion and dispersal of wellbeing information for objective medication recommending and direction [6,8]. The aim of pharmacovigilance is to improve patient care and safety in relation to the use of medicines with medical and paramedical interventions remains to be an important parameter. It includes showing the drugs' efficacy by monitoring their adverse effect for many years in relation to the use of medicines; encouraging the safe, rational and cost-effective use of drugs [8,9].

Many researchers developed different methods of causality assessment of ADRs but right now, there isn't a specific method for measuring ADRs. Although, there are some algorithmic methods that are used such as where no single one can be considered as a gold standard [10,11] :

a) Dangaumou's French method: used to distinguish intrinsic abused substances from bibliographical data by a criterion that is divided into seven segments [12].

b) Kramer et al. method: when the problematic drug is given and one adverse effect happened [13].

c) Naranjo et al. method (Naranjo Score): used to confirm causality using the categories and definitions of definite, probable, possible, and doubtful [14].

d) Balanced assessment method: evaluates a case report on various visual analog scale (VAS) models that each criterion is fulfilled individually [15].

e) Loupi et al. method: measures the teratogenic potential of drug [16].

f) Probabilistic or Bayesian: uses concrete findings in a case to transform a prior into a posterior probability of drug action [17].

Spontaneous reporting systems (SRS) are the primary method of collecting post-marketing information on the safety of drugs. The main function of SRS is the early detection of signals of new, rare and serious ADRs. A spontaneous reporting system enables physicians and, increasingly more often, pharmacists and patients to report suspected ADRs to a pharmacovigilance canter. The task of the pharmacovigilance Centre is to collect and analyze the reports and to inform stakeholders of the potential risk when signals of new ADRs arise. Spontaneous reporting is also used by the pharmaceutical industry to collect information about their drugs [18,19].

The definition of ADR has been adjusted to ensure that it embrace noxious and unintended effects resulting also from medication errors and uses outside the terms of the marketing authorization, including the misuse and abuse of the medicinal product. A rational possibility of causal association between a medicinal product and an adverse event is adequate reason for reporting. A new tool, called the Pharmacovigilance System Master File‖, is aimed to contribute to the appropriate planning and conduct of audits and the supervision of pharmacovigilance activities by the qualified person responsible for pharmacovigilance [20-23].

Conclusion

Pharmacovigilance remains a lively part between the clinicians and the patients. After the appearance of these adverse drugs effects, it is very important that these adverse reactions are timely reported and carefully analyzed. Not only the physicians should be aware of the presence of a pharmacovigilance program but also the patients themselves should be made aware of the methods of self-reporting any adverse drug reactions. While developed country have a great success in this field, developing countries are still in the growing phase and more reporting is necessary to reach the world's standard of reporting adverse events. Accurate and timely reporting of adverse drug reactions will lead to provide effective drug use in children, elderly and pregnant women, which are the most vulnerable populations of all.

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