

The Quality of Clinical Information in Adverse Drug Reaction Reports by Patients and Healthcare Professionals: A Retrospective Comparative Analysis

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Abstract

Introduction Clinical information is needed to assess the causal relationship between a drug and an adverse drug reaction (ADR) in a reliable way. Little is known about the level of relevant clinical information about the ADRs reported by patients.

Objective The aim was to determine to what extent patients report relevant clinical information about an ADR compared with their healthcare professional.

Methods A retrospective analysis of all ADR reports on the same case, i.e., cases with a report from both the patient and the patient's healthcare professional, selected from the database of the Dutch Pharmacovigilance Center Lareb, was conducted. The extent to which relevant clinical information was reported was assessed by trained pharmacovigilance assessors, using a structured tool. The following four domains were assessed: ADR, chronology, suspected drug, and patient characteristics. For each domain, the proportion of reported information in relation to information deemed relevant was calculated. An average score of all relevant domains was determined and categorized as poorly (B45%), moderately (from 46 to 74%) or well (C75%) reported. Data were analyzed using a paired sample t test and Wilcoxon signed rank test.

Results A total of 197 cases were included. In 107 cases (54.3%), patients and healthcare professionals reported a similar level of clinical information. Statistical analysis demonstrated no overall differences between the groups ($p = 0.126$).

Conclusions In a unique study of cases of ADRs reported by patients and healthcare professionals, we found that patients report clinical information at a similar level as their healthcare professional. For an optimal pharmacovigilance, both healthcare professionals and patient should be encouraged to report.