Giovannoni: *Intrinsic Activity*, 2017; **5**(Suppl.1):A5.2
doi:10.25006/IA.5.S1-A5.2
published online: 25 September 2017

INTRINSIC ACTIVITY

23rd Scientific Symposium of the Austrian Pharmacological Society

Innsbruck, 28–29 September 2017

MEETING ABSTRACT

A5.2

Adverse drug reactions reported to the regional pharmacovigilance center Zurich in 2014–2016: a retrospective, monocentre cohort study

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doi:10.25006/IA.5.S1-A5.2

Background: Serious adverse drug reactions (ADRs) resulting in death, hospitalization, disability or life-threatening effects must be reported to regional pharmacovigilance centers (RPVC) in Switzerland. All ADRs reported to the RPVC Zurich, as the biggest RPVZ in Switzerland, over the last 3 years were analyzed. The aim of the retrospective study was to identify reporting trends within and between the respective years, with a focus on drug classes, severity of the ADRs as well as causality assessment between drug exposure and ADRs.

Methods: All ADR reports from the RPVC Zurich collected between January 2014 and December 2016 were included. Relevant data on the ADRs were extracted from the official reports, Swissmedic forms and internal documents. Information included labelledness of the reaction, its severity, outcome and causality of the ADRs besides other reporting factors. Further aspects such source of the reports and reporting methods of the notifications were also integrated. Statistical analyses were performed with SPSS Statistics (v. 23; 2015).

Results: Over 3 years, 2,060 ADRs were collected at the RPVC Zurich, with a mean of 687 annual reports, and with a slight increment over the 3 years. A dominant trend within the severity of the ADRs was observed with 684 (33.2%) hospitalizations overall. Other severe outcomes were decisively less frequent, displaying 64 (3.1%) cases of death, 76 (3.7%) permanent disabilities, and 330 (16.0%) reactions leading to outpatient treatment categorized as medically important. The remaining outcomes were either “medically non-important” or “not reported”. Causality assessment between the suspected drug and the respective ADR was categorized as “possible” in 1,323 (64.2%) cases, in 564 (26.5%) as “likely”, and in 95 (4.6%) as “certain”. In most of the cases, patients “completely recovered” at the time of the report (48.5%), whereas only 18.9% were still affected. In 1,531 (74.3%) notifications, the ADR was specified in the professional Swiss product information of the suspected drug (“ADR labelled”), while in 419 reports the information on the ADR was not mentioned in the product information. The most common drugs implicated in death cases were antineoplastic agents (25.0%), antithrombotic agents (18.8%), immunosuppressants (9.4%) and analgesics (7.8%). The prevailing conditions leading to death were hemorrhage (18.8%)—mostly affecting the central nervous system (58.3%) and the gastrointestinal tract (33.3%)—, sepsis (9.4%), anaphylaxis (9.4%) and sudden cardiac death (7.8%).

Discussion: In 2014–2016, ADRs leading to hospitalizations were reported in approximately one-third of the reported patients, while 3% reported that ADRs caused death. The prevailing drug classes implicated in death were antineoplastics, immunosuppressants and anticoagulants. The majority of the patients completely recovered of the respective ADR at the time of the notification.

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