



Pharmacovigilance of self-medication: a review of Adverse Drug Reactions (ADRs) registered in a pharmacovigilance database



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Introduction

Self-medication accounted for 7-8% of drug sales in France. There are few data about its Adverse Drug Reactions (ADRs).

The present study investigated the main characteristics of self-medication ADRs reported to a regional French pharmacovigilance center.

Methods

All notifications defined as related to self-medication drug(s) and recorded in the Midi-Pyrénées Pharmacovigilance Database (MP-PVDB) between 2008 and 2014 were included. The main characteristics of the patients (age, gender), drugs (suspect, associated, Anatomical Therapeutic Chemical (ATC) classification) and ADRs (seriousness, evolution) were registered.

Results

- **Percentages:** Among the twelve thousand three hundred and sixty-five (12,365) notifications recorded, 160 (1.3%) were related to self-medication drugs with 186 different drugs (brand names) and 275 ADRs (216 serious, 78.5%). Mean age was 48.8 years [1-91] with 56.3% females.
- **Reporters:** the 160 cases were more frequently reported by *physicians* (107 cases, 66.9%) followed by pharmacists (36 cases, 22.5%). Patients reported these ADRs in only 3.1% of cases.
- **Evolution:** mainly *favorable* with recovery in 239 (86.9%) of cases (1 death).
- **The most frequent ADRs** were *gastrointestinal* (21.1%), nervous (13.3%), general (11.2%), cutaneous (10.9%) and psychiatric (7.4%).
- **Origin of self-medication:** Among the 186 drugs, 92 (49.5%) were drugs previously prescribed for the patient, the 94 others being true self-medication (i.e. without medical advice).
- **Main drug classes** were *musculo-skeletal* (55 cases, 29.6%), nervous (29.6%) and respiratory (12.4%) drugs. Phytotherapy-homeopathy accounted for 9.1% of drugs involved in reports. Associated drugs were involved in 33 cases.
- **The most frequent associations drug-ADR** were gastrointestinal pain (6 cases), bleedings (5), renal insufficiency (4) or pancreatitis (3) with non steroidal anti-Inflammatory drugs (ketoprofen, ibuprofen...), nausea-vomiting (7), bleedings (5), confusional states (4) or pancreatitis (2) with analgesics (tramadol, paracetamol...) and asthenia (4), confusional states (3) or loss of memory (3) with psycholeptics (oxazepam, zolpidem...). With phytotherapy-homeopathy, cholestasis (3 cases), arrhythmias (3) and pancreatitis (2) were registered. Misuse was found for 67 (36%) drugs.

Conclusion

- **ADRs of self-medication are frequently reported to pharmacovigilance centers: they represent around 1 out of 100 of registered ADRs in MP-PVDB.**
- **They are "serious" in around ¾ of cases and occurred most frequently in women, mainly with NSAIDs, analgesics and benzodiazepines.**
- **Pharmacovigilance of self-medication must be developed in order to better define the benefit-risk ratio of these drugs.**



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