

REPORTS OF ADVERSE REACTIONS TO ANTIBIOTICS IN THE TUSCAN PHARMASEARCH DATABASE

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Introduction: Pharmasearch is a network for spontaneous reporting of adverse drug reactions (ADRs), activated in 2001 by the Italian Society of General Medicine. It is particularly devoted to continue education of general practitioners (GPs) in the field of post-marketing drug surveillance. Antibiotics are frequently prescribed in general practice and represent a major source of ADRs. This analysis describes the profile of ADRs to antibiotic medications as reported to the Tuscan section of Pharmasearch from 2001 to 2007. **Methods:** All reports of suspected ADR referring to at least one antibiotic medication were selected for this evaluation. Severity of ADRs was assessed in accordance with the World Health Organisation criteria. Drugs were classified on the basis of the Anatomical Therapeutic Chemical (ATC) classification system, and ADRs were coded using the WHOART dictionary. **Results:** Between December 2001 and January 2007, the Tuscan section of Pharmasearch received 660 reports describing a total of 121 ADRs. Sixty-nine reports indicated at least one antibiotic as a suspected drug. Twenty-seven of these reports (39,13%) were classified as “serious”. ADRs included mainly skin (n = 27), gastrointestinal (n = 26), psychiatric (n = 15) and neurological (n = 14) events. ADRs occurred most frequently with the following drug classes: fluoroquinolones (35 reports; serious events: 37%), macrolides and ketolides (14 reports; serious events: 35%), penicillins (6 reports; serious events: 33%) and cephalosporins (5 reports; serious events: 40%). Adverse events associated with fluoroquinolones consisted mainly of psychiatric (n = 14) or neurological (n = 7) disorders, while skin and gastrointestinal events were reported more frequently for other antibiotic classes. **Conclusions:** Antibiotics are associated with different ADR reporting profiles. In particular, fluoroquinolones appear to exert pharmacological effects directed mainly against the central nervous system, probably as a consequence of their blocking activity on GABA-receptor pathways (1). Physicians should be made aware of the different tolerability profiles of antibiotic medications and prescribe these drugs with caution in patients carrying particular risk factors.

References

1) Lode H. Potential interactions of the extended-spectrum fluoroquinolones with the CNS. Drug Saf. 1999;21:123-35.