

Off-label prescription of antineoplastic drugs: an Italian prospective, observational, multicenter survey

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ABSTRACT

Aims and background. An appropriate use of drugs should follow the registered indications. Different reasons can induce oncologists to prescribe drugs off-label. The aim of this study was to describe incidence and characteristics of these prescriptions in Italy.

Methods. Patients submitted to chemotherapy in 15 Italian oncology centers were evaluated for two randomized non-consecutive days of two weeks in May 2006.

Results. The study enrolled 644 patients receiving 1,053 drugs. Overall, 199 of 1053 (18.9%) prescriptions were off-label. In 92 of 199 cases (46.2%), the drugs were used for a neoplasm for which they were not approved, but there was scientific evidence (one or more randomized clinical trials or more phase II studies published in a major oncology journal) justifying the prescription. In 27 cases (13.6%), the drugs were prescribed for a rare neoplasm (cisplatin and gemcitabine in mesothelioma). In 20/21 cases (10.1%/10.5%), drugs were used in association/alone in contrast with the approved use (capecitabine in association in colorectal cancer). In 28/11 cases (14.0%/5.6%), the drugs were used in lines of chemotherapy subsequent/previous to that approved.

Conclusions. Off-label use of antineoplastic drugs, in this observational survey, represents less than 20% of the prescriptions, and most of them are based on scientific evidence of efficacy.

Key words: antineoplastic agents, chemotherapy, off-label.

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