

THE FREQUENCY OF OFF-LABEL DRUGS USE IN MEDICINE

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Introduction. Today we know about the off-label use of drugs is widespread in worldwide clinical practice because there are no drugs that are perfectly effective and safe for the most patients. According to medical practice off-label drugs used when the basic therapy does not help. But off-label drugs use can lead to adverse effects and the risk may outweigh the potential benefits. In Ukraine, as well as the worldwide, statistics of off-label drugs assignments frequency is poorly studied. So the study of the frequency of the off-label drugs use in the world and Ukrainian medical practice is relevant and appropriate.

Aim. The aim of this work is to study the frequency of the drugs use in medicine outside the instruction (off-label) for diseases treatment.

Materials and methods. Literature and electronic information sources on the frequency of drugs use in medicine according to indications which are not specified in the instructions (off-label) were chosen as the study subjects. Methods of logistics, statistics and generalization were used to evaluate the results

Results and discussion. The results of the Ukrainian scientist T.B.Rivak show that in 88% of irrational pharmacotherapy of traumatology department patients the treatment was not in compliance with instructions for the medical use of drugs. In Spain a metacentric prospective cohort study of 226 patients treated with off-label medicines was carried out in five hospitals from May 2011 to May 2012. It was established the frequency of off-label drugs use for 226 patients in such clinical services as gastroenterology – 33 (14,6%), internal medicine – 30 (13,3%), neurology – 28 (12,4%), pediatrics – 24 (10,6%), oncology – 14 (6,2%), allergology – 14 (6,2%), nephrology – 13 (5,8%), hematology – 13 (5,8%), dermatology – 12 (5,3%) and others – 45 (19,9%). The most frequent drugs were rituximab (21,1 %), botulinum toxin (10,7 %), omalizumab (in 6,0 %) and in 51,8 % of cases the level of clinical evidence for their use was low. The reasons for off-label drug use in patients were showed: in 72,1% of patients – lack of clinical response (or suboptimal) to the previous treatments; in 12,4% – no other drugs which are approved for that indication/condition; in 11,5% – intolerance to the previous treatments.

Conclusions. So the high frequency of the off-label drug use in patients of Ukraine (88%) and Spain (72%) was shown. Although clinical data on off-label drugs were often low, a clinical response was noted in many patients with previous multiple failure of treatment, which were due to some adverse effects and high costs. Therefore, the problem of frequent off-label drug use is relevant and requires further study.