

STUDY ON THE USE OF OFF-LABEL DRUGS IN A GENERAL HOSPITAL

BACKGROUND

Off-label use of medication is common in hospital clinical practice and should be applied together with follow-up of a healthcare treatment protocol and in compliance with a procedure which ensures that the patient is informed and that he or she provides informed consent.

PURPOSE

The study aims to assess the clinical practice of off-label use of medicines in the hospital setting.

MATERIALS AND METHODS

Cross-sectional study with retrospective data collection, which analyzed prescriptions issued to 1890 patients from January 2007 to January 2017 in a 500-bed general hospital.

RESULTS

1890 patients were treated with off-label drugs, 22 (46,3 %) women and 8 (53,5 %) men, with an average age of 51,7 years (36-65 DS).

The off-label drugs were used in the following physician specialties: 5,2% neurology, 6,1% endocrinology, 6,3% nephrology, 5,8% rheumatology, 6,7% gastroenterology, 4,3% dermatology, 5% hematology, 10% gynaecology, 11% ophthalmology, 12% pain specialty, 18,4% oncology, 8,2% others.

In all these cases there is scientific and medical evidence justify off-label use. In 80% of cases its use was due to the absence of other therapeutic alternatives.

When the use of drug out of indications approved will be frequent, there must be clinical protocols to use these off-label drugs in the hospital. During the period of study, 58 protocols were approved for the following indications: autoimmune thrombocytopenia, hemolytic anemia, lichen planus, hidradenitis suppurativa, atopic dermatitis, myelodysplastic syndromes, chronic idiopathic urticaria, gastric carcinoma, colon carcinoma, head and neck carcinoma, ulcerative colitis, myofascial pain syndrome, antithrombotic, allergic asthma, lupus nephritis, arthroplasties, anal fissure, refractory alopecia, gastroparesis, uveitis, spastic paraparesis, Sjögren's syndrome, cluster headache, psoriasis, neuropathic pain, fibromyalgia, amyotrophic lateral sclerosis, urothelial tumors, etc...

100% patients (1890) signed consent form prior to initiating treatment.

CONCLUSIONS

In the hospital area the use of medicines is frequent out of the indications approved in the specification sheet, these situations should be gathered in therapeutic protocols welfare and

regulated by the Commission of Drugstore and Therapeutics. In all the cases it is necessary to inform the patient adequately and possess his assent.