ANALYSIS OF OFF-LABEL USE IN BIOLOGICAL THERAPIES

M. Gutiérrez Lorenzo1, D. Furones Araujo1, A. Linares Alarcón1, I. Muñoz Castillo1.
1Hospital Regional de Málaga, Pharmacy, Málaga, Spain.

DI-011
L-04

Background

Biologics are usually prescribed off-label in severe immune-mediated inflammatory diseases. Unfortunately, off-label prescription is sometimes hampered in these diseases due to a lack of evidence for effectiveness.

Purpose

Assess the risk and outcome of biological therapies on off-label practices in the pharmacy department of a tertiary hospital.

Material and methods

This study included all patients treated between January 2014 and June 2016 with an off-label biological prescription. The data were collected from the clinical history of the patients and from the pharmacy programs: athos prisma® and cafydim®. We analyzed these variables: treatment time, doses, adverse drug reactions (ADRs), previous/subsequent treatments. The treatment repercussion has been evaluated. The data were analyzed through an statistical descriptive study.

Results

A total of 5 types off-label biologics were requested and administered to 30 patients for 9 different diseases.
In 80%(24) of cases, the patient was treated previously with corticosteroids and/or methotrexate. In the 20%(6) the previous treatment was a biologic (not off label prescription).

Most of the prescriptions were adalimumab: 20(67%) of which 8(40%) were treatment for Behcet's syndrome, 5(25%) for uveitis in children, 5(25%) for sarcoidosis (one of whom was a child of 11 years old), 1(5%) for mesenteric panniculitis and 1(5%) for systemic lupus erythematosus (SLE). All other prescriptions were: 2 golimumab for synovitis and sarcoidosis, 2 tocilizumab for SLE, 1 anakinra for familial Mediterranean fever, 3 ustekinumab for enteritis, Crohn's disease and Wegener's granulomatosis and 2 certolizumab for uveitis and enteritis.

Only for 1 patient (3,3%), treatment was not effective: adalimumab for sarcoidosis, more over it produced him ADRs (increased morning stiffness and pain in joints) after 30 months so he returned to methotrexate monotherapy.

A total of 9(30%) patients developed ADRs: were by 6 adalimumab (of which 3 were in children), the remaining 3 ADRs were by golimumab, tocilizumab and anakinra, all were mild/moderate and were not grounds for cease treatment.

Conclusion

In our assessment, off-label biological therapies have been effective in most of patients (96,6%) and safe (70%). Evaluation of the cost of off-label biological therapies, in terms of medication risk and effects on the cost of healthcare, will be essential to its widespread clinical utility.