

BIOLOGICAL DRUGS IN THE TREATMENT OF IMMUNE MEDIATED INFLAMMATORY DISEASES: MONITORING OF PRESCRIPTION APPROPRIATENESS.

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BACKGROUND AND IMPORTANCE

The introduction of biological drugs in the clinical practice represented a new goal for the treatment of highly disabling inflammatory immune-mediated diseases. Our Region adopted the Guidelines for the use of biological drugs in the Rheumatology, Dermatology and Gastroenterology; the specialists must draw up the Therapeutic Plan to implement the prescriptive appropriateness. The Italian Drug Agency has issued a Position Paper recommending the prescription of biosimilars where possible.



AIM AND OBJECTIVES

To evaluate the prescriptive trend and appropriateness of the biological drugs for the inflammatory immune-mediated diseases in our Health District also in order to implement the use of biosimilars.

MATERIAL AND METHODS

We analyzed the Therapeutic Plan of biological drugs received by the Territorial Pharmacy of our Health District (about 164.000 inhabitants). We extracted from the company database the data relating to biological drugs dispensed in the period January 2018-August 2019 and subsequently processed using an electronic worksheet, paying attention to therapeutic shifts and biosimilar drugs.

RESULTS

The patients underwent therapy with biological drugs are 556, of which 61.15% suffering from rheumatologic diseases, 29.32% with dermatological diseases and 9.53% with gastrointestinal diseases (Fig.1). The number of patients increased by 6.64% in the January-August 2019 period compared to 2018; similarly, the use of these medicines in terms of units in the first eight months of 2019 increased by 22.72% compared to the same period in 2018. The 11.15% of patients had a shift to another biological drug; in 88.71% of cases the change is attributable to therapeutic ineffectiveness, while the remaining 11.29% is passed to the relative biosimilar (Fig.2) ($\Delta\%$ 2019-2018 = +33.33%).

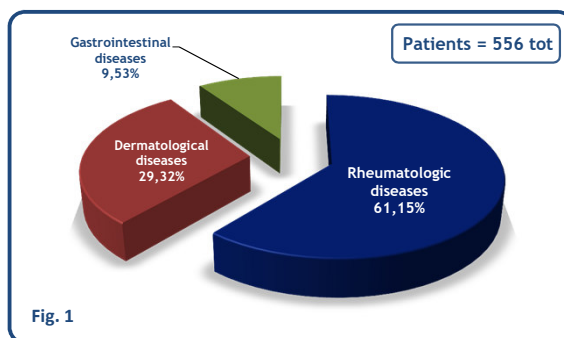


Fig. 1

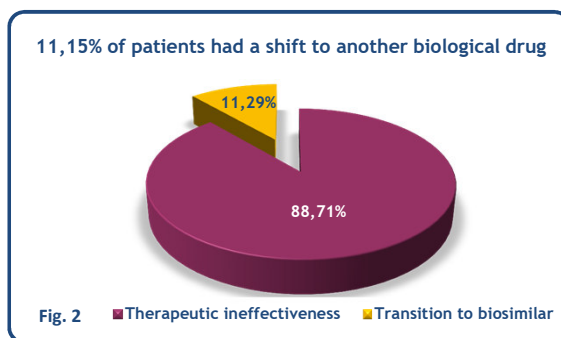


Fig. 2

CONCLUSIONS AND RELEVANCE

Access to biologics has led to a significant improvement in patients' quality of life. Given the complexity of immune-mediated inflammatory pathologies, the identification of the correct therapy represents the critical issue at the first diagnosis. The use of biosimilar drugs increased during the analysis period; we therefore propose to promote the prescriptive appropriateness and to start a biosimilar drug prescription awareness program, according to the regional and national legislation, with a view to the sustainability of the health system, guaranteeing effectiveness, safety and quality for the patients. At the same time, therapeutic efficacy will be evaluated in patients receiving biosimilars.