

ADVERSE DRUG REACTIONS BY BIOLOGICAL DRUGS IN GASTROENTEROLOGY UNITS

1)Palleria C. 2)De sarro G. 3)Bennardo L. 4)Luzza F. 5)Larusso T. 6)Doldo P. 7)Spagnuolo R. 8)Rodinò S. 9)Russo E.

University of Catanzaro

Therapy for inflammatory bowel disease (IBD) has changed with the introduction of biologics agents. The era of biologic therapy saw remarkable progresses in IBD therapy [1,2]. It has led surely to the resolution of difficult clinical conditions, inducing remission and maintaining steroid-free remission but it has created new problems related to the safety of these drugs [3]. In fact, biological drugs have been associated with significantly higher rates of overall adverse events, discontinuation of treatment due to occurrence of adverse drug reactions (ADRs). Aim of this study was to evaluate the incidence of ADRs in patients with gastroenterological diseases treated with biologics.

The study enrolled patients treated with biologics afferent to the gastroenterology units of the "Mater Domini" University and "Pugliese-Ciaccio" Hospital of Catanzaro, "San Giovanni di Dio" Hospital of Crotona and Annunziata Hospital of Cosenza.

Prior informed consent, patients were interviewed every three months to know if the administration of biologic drugs had caused ADRs. If there had been, it has been asked a detailed description. Patients were monitored for a period of 3 to 24 months.

We have enrolled 115 patients with the following characteristics: 41% female, median age 41 years, 41% affected by Crohn's disease and 59% by ulcerative colitis. The average age at disease onset was 32 years and a median of 8 years of illness. Our analysis showed that were made 138 therapeutic cycle for 115 patients (61% infliximab, 21% adalimumab, 10% golimumab, 8% vedolizumab) and 23 therapeutic switches due to therapeutic failure (75%) or to the occurrence of an ADR (25%).

Data analysis showed the detection of 51 ADRs. The higher frequency of ADRs occurred with the administration of infliximab (44%), followed by adalimumab (27.6%), golimumab (28.6%), vedolizumab (18%). 12% of ADRs was considered severe, 20% moderate, 68% not serious. More severe ADRs occurred during adalimumab treatment (36%).

ADRs observed during the period in order of incidence were: asthenia (6 cases), hematochemical parameter alterations (2 cases), immune-allergic reactions (4 cases), musculoskeletal reactions (12 cases), gastrointestinal reactions (3 cases), infections (5 cases) other reactions are manifested with a lower incidence and therefore are not reported. Overall these drugs appear relatively safe, although are reported some serious ADRs such as increased risk of infections probably related to their immune-modulator effects that need to be assessed for and addressed promptly [4]. Therefore, further pharmacovigilance studies are necessary to better describe the safety profile in the long term of these new agents.

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