ADVERSE DRUG REACTIONS WITH BIOLOGICAL DRUGS IN RHEUMATOLOGY AND DERMATOLOGY UNITS

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The introduction of biological drugs resulted in a significant advance in the treatment of many immune-mediated inflammatory diseases, representing the new therapeutic frontier for the treatment of these pathologies. Recently, an increase in the use of biological drugs and their use in combination with traditional drugs has been made more frequent considering the primary therapeutic goal to obtain the remission of the disease [1-2].

Surely, this led to the resolution of difficult clinical conditions, but at the same time created problems regarding the safety and tolerability [3]. Biological drugs have been associated with significantly higher rates of overall adverse drug reactions (ADRs) and discontinuation of treatment due to occurrence of adverse events [4].

Aim of this study was to evaluate the incidence of ADRs in patients with rheumatological or dermatological diseases treated with biologics.

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. The study enrolled patients treated with biologics afferent to rheumatology unit of the “Mater Domini” University Hospital of Catanzaro and to dermatologic unit of the “San Giovanni di Dio” Hospital of Crotone.

We have enrolled 128 patients with the following characteristics: 44% females, 49% are included in the age group 41-60 year (39% >61 vs 12% <40), 19% affected by rheumatoid arthritis, 47% by psoriatic arthritis, 27% by vulgaris psoriasis, 4% by ankylosing spondylitis, 1.6% by spondyloarthritis, less 1.4% by idiopathic arthritis and psoriasis guttata.

Our analysis showed that were made 142 therapeutic cycle for 128 patients (32% etanercept, 24% adalimumab, 14% infliximab, 12% ustekinumab,9% abatacept, 5% golimumab) and 14 therapeutic switch due to the occurrence of an adverse drug reaction. Data analysis showed the detection of 57 ADRs. The higher frequency of ADRs occurred with the administration of golimumab (86%), following by adalimumab (61%), etanercept (43%), ustekinumab (41%), infliximab (21%), tocilizumab (20%), abatacept (<1%). 28% of ADR was considered severe, 21% moderate, 51% not serious. The majority of ADRs occurred in patients older than 60 years (46%). More severe ADRs occurred during adalimumab treatment (30%). ADRs observed during the period in order of incidence were: asthenia (22 cases), hematochemical parameter alterations (8 cases), increase in serum tumor markers (6 cases), immune-allergic reactions (10 cases), musculoskeletal reactions (8 cases), gastrointestinal reactions (5 cases), infections (4 cases), mood disorders (4 cases), neurological reactions (4 cases), cancer (4 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 cancer and infections probably related to their immune-modulator effects [5-6]. Further pharmacovigilance studies are needed to define the tolerability profile of these molecules and monitor whether in the long term they may be administered without risks in patients. Health care providers should be involved in the evaluation and monitoring of ADRs from biological drugs in order to better define the safety profile of these treatments.

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