SAFETY EVALUATION OF RITUXIMAB OFF-LABEL USE FOR SYSTEMIC AUTOIMMUNE RHEMATIC DISEASES

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Background Systemic Autoimmune Rheumatic Diseases (SARDs) are a group of syndromes caused by antibodies inflammation related. Rituximab is a biological drug that targets antigen CD-20 present in the surface of B-Lymphocytes and thus potentially active against SARDs refractory to conventional treatment: steroids and immunosuppressors.

Purpose To describe and evaluate safety parameters of the risk management protocol for adults SARDs patients treated with off-label Rituximab.

Materials and Methods Descriptive-observational study from January 2011 to July 2012 realised by the Pharmacy and Rheumatology Service. Data were obtained from electronic medical records. Three types of risk management protocol data were evaluated. A) Clinical parameters: infection (including Tuberculosis), cardiovascular disease, severe cytopenia, neoplasia or new neurologic symptoms. B) Complementary tests: hemogram and general biochemistry while on Rituximab. C) Others: adverse events related with Rituximab infusion.

Results 21 patients were included (mean age 52.71 ± 16.11 years). Diagnoses were Sjögren’s Syndrome (10), Systemic Lupus Erythematosus (4), Mixed Connective Tissue Disease (3), inflammatory myopathy (2), Systemic Sclerosis (1) and Wegener’s Granulomatosis (1).

- Clinical parameters: infection was detected on 5 patients (23%), severe cytopenia in 1 patient (4.7%) and peripheral neurological symptomatology in another one. No cardiovascular disease or neoplasia were detected.
- Complementary tests: patient presented severe thrombocytopenia (platelets < 2.000/mCL).
- Adverse events infusion related: detected on 19% of patients.

Conclusions Rituximab off-label use for SARDs has increased over the last years and pharmacovigilance strategies as well as risk management protocols have proved useful identifying risks, controlling adverse events, improving quality of care and integrating Pharmacist into direct patient care.

No conflict of interest.