SAFETY EVALUATION OF RITUXIMAB OFF-LABEL USE FOR SYSTEMIC AUTOIMMUNE RHEUMATIC 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 on the surface of B-Lymphocytes and thus potentially active against SARDs refractory to conventional treatment: steroids and immunosuppressants.

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 electronical 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).

A. Clinical parameters: infection was detected on 5 patients (23%), severe cytopenia in 1 patient (4,7%) and peripheral neurological symptomatology in another one. Nor cardiovascular disease or neoplasia were detected.
B. Complementary tests: patient presented severe thrombocytopenia (platelets < 2,000/mCL).
C. 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.

SAFETY OF SUNITINIB VERSUS PAZOPANIB IN METASTATIC RENAL CANCER IN A TERTIARY HOSPITAL

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Background Sunitinib and pazopanib are tyrosine kinase inhibitors used in the treatment of metastatic renal cancer. Pazopanib has been approved more recently, so the user experience is not as extensive as with sunitinib.

Purpose To evaluate the safety profile of pazopanib and sunitinib in patients with metastatic renal cancer.

To compare the incidence of adverse reactions between the two drugs.

Materials and Methods We identified patients treated with sunitinib and pazopanib at the hospital in the past two years, using the pharmacy database.

We looked at the medical records of patients through digital medical records, collecting dose patterns, line of therapy, adverse reactions detected, their severity and if dose reductions were necessary, using Excel.

Results A total of 26 patients with metastatic renal cancer were identified: 16 treated with sunitinib and 10 with pazopanib.

Asthenia was the most frequent drug-related toxic effect in both treatment groups, with an incidence of 93.75% for sunitinib and 60% for pazopanib.

Nausea/vomiting and diarrhoea were detected in 50% of patients treated with pazopanib. In sunitinib patients nausea/vomiting were detected in 6.25% of patients and diarrhoea was detected in 68.75% of patients.

For patients who received pazopanib, the rate of mucositis was 20%, whereas for those treated with sunitinib it was 75%. Palmar-plantar erythrodysesthesia syndrome occurred in 43.75% of those on sunitinib treatment, while none was detected for pazopanib, and the frequency of other skin pigmentation disorders for the two drugs was 62.5% and 30% respectively.

Blood pressure was decompensated in 37.5% of patients treated with sunitinib and 10% of those taking pazopanib, although most patients required antihypertensive drugs to get better control.

Dose adjustment was required of sunitinib in 43.75% of cases and in 25% pazopanib.
Conclusions Pazopanib may be better tolerated than sunitinib, with an acceptable adverse event profile and fewer dose adjustments. Also, the severity of adverse events looks lower with pazopanib. However, the number of patients was too small to arrive at definitive conclusions, so it is necessary to enlarge this study. No conflict of interest.

**Purpose** To assess the incidence of positive allergic reactions in tested patients and to define the culprit drugs and their potential allergic role in these reactions.

**Materials and Methods** The study was conducted between 2007 and 2010 on patients from our hospital. We collected information on the characteristics of the adverse drug reaction on skin, the drugs tested, the tests performed and their results.

**Results** In the period studied, 220 patients referred by other practitioners (from the hospital or from ambulatory practitioners) for serious cutaneous reactions were tested and 3225 preparations were performed by the pharmacy. 92 patients had an immediate reaction to the drug and 128 had a non-immediate reaction. 64 (29%) patients developed a positive response: 48 (75%) through skin tests (patch, prick and IDR) and 16 (25%) through a Drug Challenge Test (DCT). The drugs most often involved in the positive tests were anti-infectious drugs (46%), paracetamol (16%) and iodinated contrast media (10%).

**Conclusions** The percentage of positive tests in this cohort agrees with the data found in the literature (5–76%). The large difference is due to the variability in patient recruitment.

However, it is difficult to compare these data because the preparation and interpretation of the tests are not standardised.

Allergology tests still improve the care of patients as with negative skin tests and DFTs many patients were able to continue with their treatment.

Manufacturing tests by the pharmacy standardise preparation conditions within the hospital and reduce cross contamination and microbial contamination. No conflict of interest.