GRP-166 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 refractories 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.

GRP-167 SAFETY OF ADJUVANT CHEMOTHERAPY IN ELDERLY COLON CANCER PATIENTS

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Background Adjuvant chemotherapy trials provide little information on safety in elderly patients because they exclude them or pool their results with those of younger patients.

Purpose To describe the safety of the different adjuvant chemotherapy treatments used in elderly patients with colon cancer.

Materials and Methods Retrospective observational study of colon cancer patients (age >65) diagnosed in 2010 and treated with adjuvant chemotherapy. Each patient was followed from the beginning of the treatment until the end of it. Demographic data, disease stage, antineoplastic agents and treatment-related toxicities were collected from patients' clinical histories.

Results 16 patients (5 women, 11 men) were included in the study with a mean age of 75.1 years. 87.5% and 12.5% of patients had stage III and stage II disease, respectively. 6 patients (37.5%) were treated with a combination of 5-fluorouracil and oxaliplatin regimen (FOLFOX), 4 patients (25%) with capecitabine in monotherapy and the remaining 6 patients (37.5%) with a combination of capecitabine and oxaliplatin regimen (XELOX). Adverse events were documented in 100% of patients. 57 adverse reactions were detected, the most frequent toxicities being: neurotoxicity (75% of patients), fatigue and anorexia (68.8%), diarrhoea (37.5%) and thrombocytopenia (37.5%). 54.5% of the undesirable effects were grade 1, 30.9% grade 2 and 14.6% grade 3 toxicities. There were no grade 4 adverse reactions. XELOX was associated with high rates of hand-foot-syndrome (75% of patients) and XELOX and FOLFOX with a high incidence of neurotoxicity (100% and 83.3% respectively). Oncologists had to delay the cycle or reduce the treatment doses in 11 patients (68.8%) and 5 patients (31.3%) had to discontinue the treatment due to the toxicity.

Conclusions A high number of adverse reactions were detected, but majority were grade 1–2. The safety profile of drugs studied in our population is in line with that described in the literature in younger patients.

No conflict of interest.

GRP-168 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 erythrodysaesthesia 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.