5PSQ-130. ANALYSIS OF RITUXIMAB OFF-LABEL USE

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Background

Rituximab is a monoclonal antibody indicated in Spain in adults with non-Hodgkin's lymphoma, chronic lymphatic leukaemia, rheumatoid arthritis and granulomatosis with polyangiitis and microscopic polyangiitis.

Purpose

To evaluate the use of rituximab in a district hospital in off-label conditions which did not respond to corticosteroids or immunosuppressants treatment.

Material and methods

We carried out a retrospective observational study of the use of rituximab off-label from its inclusion in the pharmacotherapeutic guide of the hospital in 2009 until July 2018. Data collected: number of patients, sex, age, diagnosis, previous treatment with rituximab, concomitant treatment with rituximab, treatment schemes and adverse effects 6 months after the start of treatment. Digital clinical history and external consultations application were used. Statistical analysis was performed with SPSS version 24.

Results

Number of patients	21
Sex	11 (52.4%) males
Age	53.3

TREATMENT SCHEMES	
15 day cycles with a fixed dose of 1000mg on days 1 and 15.	8 (38.1%) patients
500 mg weekly for 4 weeks	10 (47.6%) patients
875 mg/m^2 weekly fo 4 weeks	3 (14.3%) patients

DIAGNOSTIC GROUPS	
Glomerulonephritis	6 (28.6%) patients
Lupus	5 (23.8%) patients
Vasculitis for cryoglobulins and ANCA positive	5 (23.8%) patients
Myositis	3 (14.3%) patients
Pemphigus	2 (9,5%) patients

CONCONMITANT TREATMENT WITH RITUXIMAB	
Prednisone	21 (100%) patients
Hydroxychloroquine	5 (23.8%) patients
Azathioprine	5 (23.8%) patients
Mycophenolate mofetil	4 (19%) patients
Tacrolimus	2 (9.5%) patients

TREATMENT PRIOR TO RITUXIMAB	
Prednisona	21 (100%) patients
Mycophenolate mofetiil	11(52.4%) patients
Azathioprine	10 (47.6%) patients
Ciclosporine	10 (47.6%) patients
Hydroxychloroquine	6 (28.6%) patients
Methotrexate	3 (14.3%) patients
Tacrolimus	2 (9.5%) patients
Inmunoglobulins	1 (4.6%) patients
Monoclonal antibodies	1 (4.6%) patients

ADVERSE REACTIONS	
Cytopaenia Anaemia (the most frequent cytopenia)	11 (52.4%) patients 5 (45.4%) patients
Pneumonia or sepsis that required hospital admission	7 (33.3%) patients
Atrial fibrillation	1 (4,8%) patients
Reactions related to the perfusion of rituximab	0 patients

Conclusion

The use of rituximab off-label has increased in recent years. It is therefore necessary to develop protocols to unify the criteria for use, evaluating its effectiveness and safety profile to increase the quality of care