ANALYSIS OF RITUXIMAB OFF-LABEL USE IN A TERTIARY HOSPITAL

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Background

The implementing Law 1015/2009 normalizes the compassionate use of investigational drugs, access to off-label and unauthorized drugs in our country. Rituximab is an anti-CD20 monoclonal antibody widely used in off-label conditions to treat autoimmune diseases.

Purpose

The creation of an Autoimmune Diseases Unit (ADU) in our hospital caused an increase in the use of rituximab in off-label conditions. This study aims to identify rituximab off-label uses and to describe the dosage prescribed in each indication.

Material and methods

Observational retrospective study (Jun-2009 to Mar-2017)

- Patients who received off-label rituximab (at least one dose) prescribed by ADU were included.
- Collected data: sex, age, rituximab off-label indication, dosage, number of cycles received.

Results

44 patients received off-label rituximab → age 55 ± 15 years old → 70.5% women, 29.5% men

Rituximab regimen → 4 doses of 375 mg/m² administered weekly

Rituximab off-label indications

- Systemic lupus erythematosus
- Vasculitis
- Inflammatory myopathy
- Scleroderma
- Mixed cryoglobulinemia
- Others

Number of rituximab cycles received

- 0 cycles
- 1 cycle
- 2 cycles
- 3 cycles
- ≥ 4 cycles

Conclusion

✔ Systemic lupus erythematosus and vasculitis were the most frequently rituximab off-label prescribed indications and 375 mg/m² weekly for 4 weeks was the prescribed dosage. These results agree with the data published in the literature.

✔ Considering the variety of off-label indications for which rituximab is prescribed in ADU, it would be useful developing protocols for the use of rituximab in these situations.