# Study of rituximab in off-label situations

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## OBJECTIVES

The use of rituximab, a chimeric human/mouse monoclonal anti CD20 antibody, in unlabeled uses is common in the daily clinical practice. The depletion caused in pre-mature and mature B lymphocytes leads to a wide range of possibilities to treat inflammatory and autoimmune disorders. We evaluate the effectivity and safety of rituximab in off-label situations.

## METHODS

Observational, descriptive and retrospective study. Data was collected from medical records and pharmacy database from patients who received rituximab as off-label therapy between January 2011 and December 2012. The primary endpoint was the effectivity of the immunosuppressive therapy measured from analytical value of B lymphocyte count. It was also described the number of cycles and doses administered in each pacient. Safety was measured in second place, describing the adverse reactions appeared during the treatment.

## RESULTS

In 2011, a total of 71 patients were treated with rituximab in a university hospital. Six of them (8 %) were treated with rituximab in unlabeled uses. In 2012, from 28 patients using rituximab, seven were off-label uses. We collected data from 13 total patients treated with rituximab. The indications for its use are showed in figure 1.
At the time of first course rituximab, all patients had active disease. Some patients showed a partial clinical outcome after the therapy. B cell deplection before and after rituximab first administration of four patients appears in figure 2.

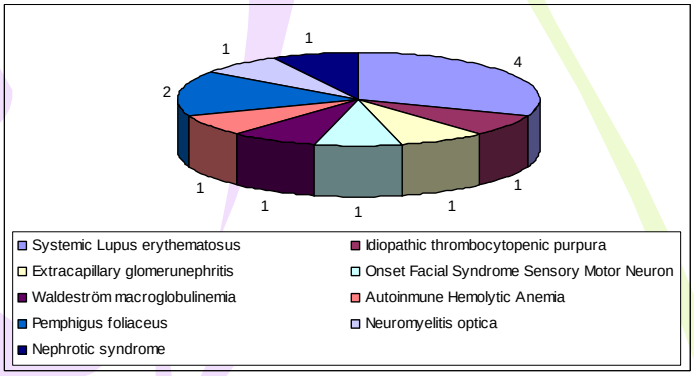


**Figure 1: Unlabel use of Rituximab**

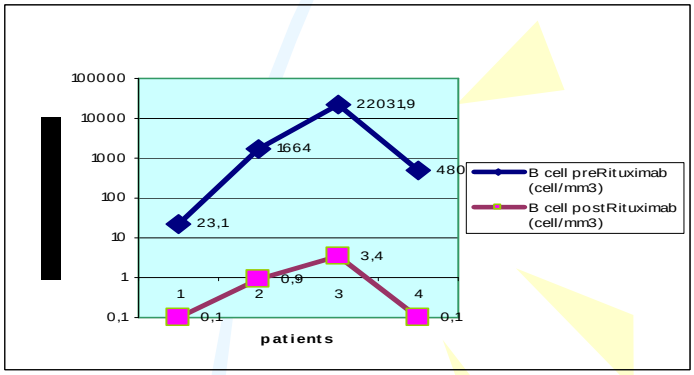


**Figure 2: B cell level before and after rituximab infusion of four patients**

In most cases rituximab was administered as 4 doses of 375 mg/m2 each given 1 week apart. The mean number of cycles was 4 per patient.
Regarding safety, rituximab showed two anaphylaxis infusion-related reactions. Both resolved and not ocurred on further administrations.

## DISCUSSION AND CONCLUSIONS

Thought effectivity was not very high, rituximab as a therapy for inflammatory and autoimmune diseases has been used in the last two years in a university hospital. Strategies to help define the optimal therapeutic usage of rituximab in this off-label situations need to be evaluated.
In most cases rituximab was well tolerated with no severe adverse reactions observed.