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Off-label use of rituximab in systemic autoimmune diseases

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Background and importance:

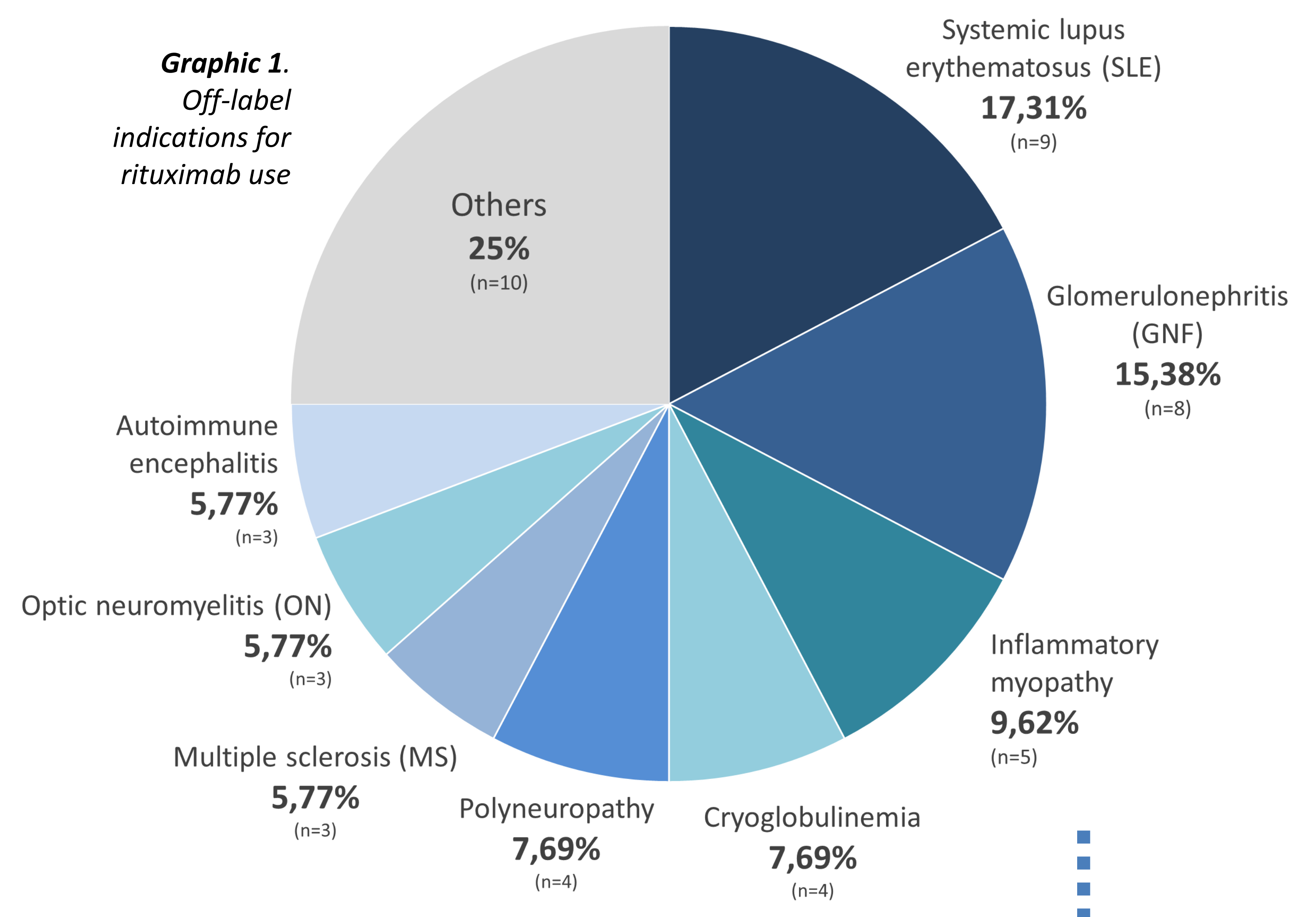
A large number of patients with systemic autoimmune diseases (SAD) do not respond or relapse to first-line therapies. Current guidelines recommend the off-label use of rituximab for many severe refractory SAD even though most of available data rely on observational studies and case reports.

Aim and objectives:

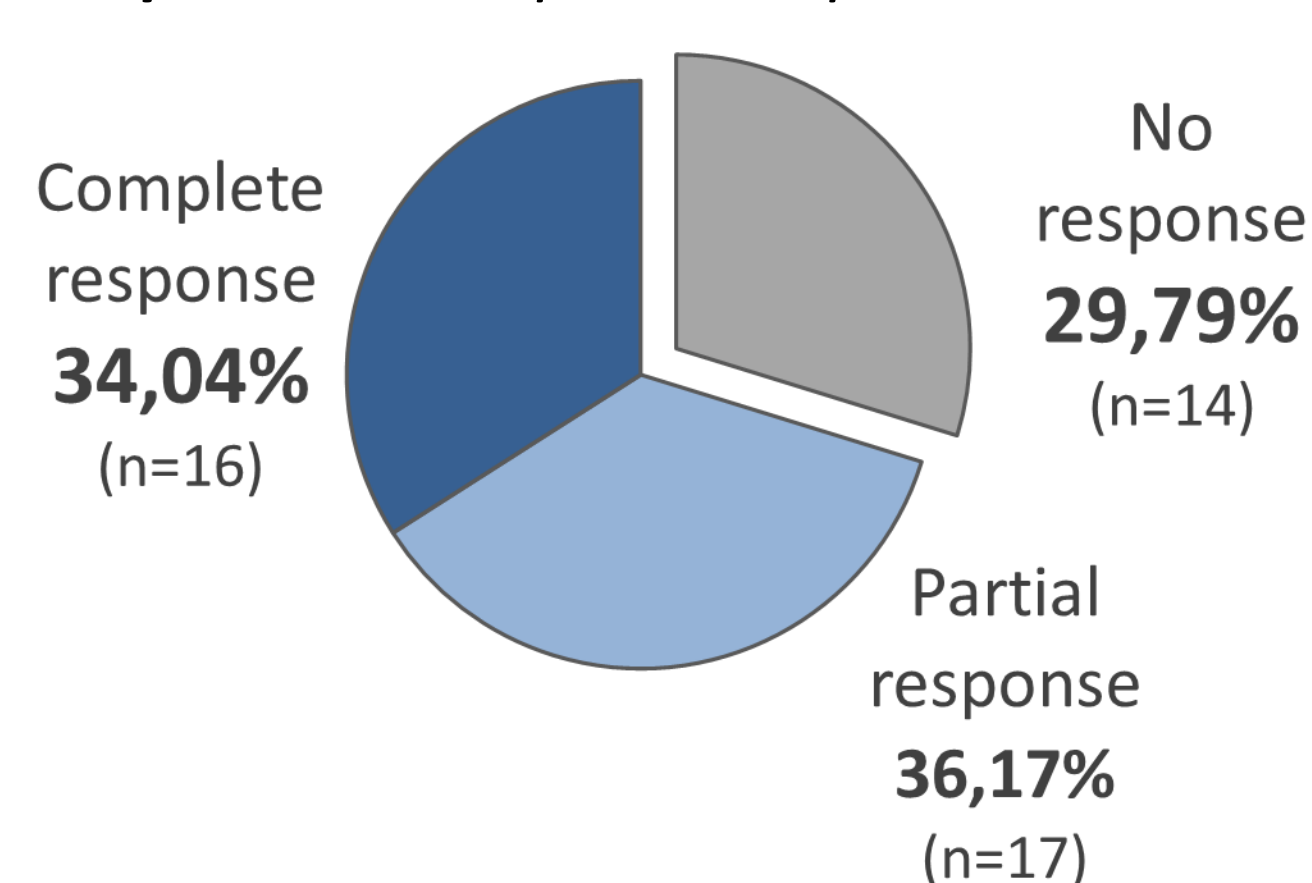
The aim of this study was to analyse the efficacy and safety of the off-label use of rituximab for patients with severe refractory SAD in a tertiary hospital.

Material and methods:

Off-label use of rituximab between January 2016 and December 2018 was reviewed. Clinical data was collected retrospectively. Therapeutic response was evaluated after 12 months of rituximab initiation based on clinical judgement: complete response was defined as no disease activity, partial response as a significant improvement (>50% of initial disease activity) and no response if there was no improvement or worsening of symptoms.



Graphic 2. Therapeutic response assesment



12 months
Therapeutic response
assessment

Baseline characteristics	
Age, mean	54,41 (SD 15,31)
Male/Female	54%/46%
Previous corticosteroids	82,4% (n=42)
Received ≥1 previous immunosuppressive drug	71,2% (n=37)

52 patients received
rituximab for
off-label use

Results:

A total of 52 applications were analyzed. There were 28 male (54%) and 24 female (46%), mean age was 54.41 years (SD 15.31). Indications for rituximab are shown at *Graphic 1*. As for previous therapies, 42 patients (82.4%) received corticosteroids and 37 (71.2%) received at least one immunosuppressive drugs. From all patients with an assessable treatment (N=47), 70.2% achieved an improvement of the disease after 12 months: 34% (N=16) a complete response and 36% (N=17) a partial response (*Graphic 2*). The most favorable results were found in the treatment of SLE, GNF, cryoglobulinemia, MS and ON in which more than 80% of patients obtained complete or partial response. Adverse events were reported in 22 patients (42.3%): the most frequent were infections (N=7) followed by infusion-related reactions (N=3). No serious or death-related adverse events were reported.

Conclusion and relevance:

Rituximab has acceptable tolerance and reduces disease activity in some severe refractory SAD. Future controlled trials are needed to confirm the potential use of rituximab in patients with SAD. In the meantime it is necessary to do a close follow-up of these patients.

References

M. Ramos-Casals et al. Off-label use of rituximab in 196 patients with severe, refractory systemic autoimmune diseases. *Clin Exp Rheumatol*. 2010; 28: 468-476., Spain.

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