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Rituximab for autoimmune retinopathy: Results of a Phase I/II clinical trial.

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PURPOSE: This prospective study evaluates whether rituximab is a safe and potentially effective treatment for nonparaneoplastic autoimmune retinopathy (npAIR). MATERIALS AND METHODS: Five npAIR patients were enrolled in a Phase I/II, prospective, nonrandomized, open-label, single-center study. All patients received a cycle of 1000 mg intravenous rituximab at weeks 0 and 2, with a second cycle of rituximab 6 to 9 months later. Clinical evaluation was performed at baseline, 6 and 12 weeks after each rituximab cycle, and then every 3 months for a total duration of 18 months. The primary outcome for this study was treatment success based on visual field and full-field electroretinography at 6 months. The secondary outcomes included treatment success at months 12 and 18, drug-related adverse events, changes in visual symptoms, and changes in quality of life. RESULTS: Two patients met criteria for treatment success: one based solely on electroretinography and the other based solely on visual field area, but treatment success was not sustained. Clinical response over the course of the 18-month study showed disease stabilization in three patients and treatment failure in two patients. There were no severe drug-related adverse events. CONCLUSION: This is the first clinical trial prospectively evaluating the effect of rituximab in npAIR and, although rituximab was well tolerated, there was no clear-cut clinical improvement conferred by B cell depletion with rituximab.

DOI: 10.4103/tjo.tjo_32_20 PMCID: PMC7971443 PMID: 33767957

Conflict of interest statement: The authors declare that there are no conflicts of interests of this paper.