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EFFECTIVENESS AND SECURITY OF ALEMTUZUMAB IN RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background

Alemtuzumab is a humanized monoclonal antibody that selectively targets CD52, resulting in depletion and subsequent distinct repopulation of circulating T and B lymphocytes.

Purpose

To evaluate effectiveness and security of Alemtuzumab in patients diagnosed with RRMS.

Material and methods

Retrospective and observational study between 12/2014-11/2017 of patients diagnosed with RRMS after 1 year of treatment with alemtuzumab.
Variables collected: age, sex, years with RRMS diagnosis, EDSS, percentage of patients without outbreaks and outbreaks/patient-year, previous treatments and ADRs.
The effectiveness of treatment was assessed by calculating ARRs and change in disability status by EDSS. Change in disability was defined according to criteria of Fernández et al. that defined improvement as any decrease ≥1 point, stabilization as any change <1 point and aggravation as an increase ≥1 point in the EDSS scale.

Results

25 patients were included (72% female). Only 1 patient used alemtuzumab as first line.
One year follow-up showed EDSS improved by 0.08 ± 0.27 point. Improved disability status was observed in two patient (one point decrease in EDDS)(8%), stabilization in 23 patients (88%) and worsening in one patient (one point increase in EDSS) (4%).

VARIABLES	RESULTS
mean age	39.6 ± 9.7 years
mean disease duration	11 ± 5.7 years
mean baseline EDSS	4.5 ± 1.6
mean previous treatment	2.4 ± 1
percentage of patients without outbreaks	80%
AAR	0.24 outbreaks /patient-year

Registered ADRs:	% of patients
Skin reactions (exanthems/pruritus)	44
headache	12
digestive/urinary tract infections	8
fever/pseudopyroid Syndrome	12
tremor/tingling	4
dipoplia	4
respiratory distress	4
autoimmune hypothyroidism	4

One patient was diagnosed with Glioblastoma, so 2º cycle were discontinued.

Conclusion

Alemtuzumab is a moderately effective drug with acceptable toxicity in patients who have failed other treatments. In Phase III clinical trials, ADRs incidence was >90%, being mild to moderate in severity and generally included headache, rash, pyrexia, nausea, flushing, urticaria, insomnia and pruritus. Also, >10% of patients showed cardiac disorders, in particular tachycardia.