Anti-FcRn treatment for generalized Myasthenia Gravis: a real word experience with Rozanolixizumab in AChR-Ab and MuSK-Ab positive patients.

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Introduction and Objectives

Inhibition of the neonatal Fc receptor (FcRn), represents a novel therapeutic approach for antibody-mediated disorders. **Rozanolixizumab, a neonatal Fc receptor blocker, has recently been approved for the treatment of myasthenia gravis (MG)**. The phase 3 clinical trial MycarinG demonstrated the safety and efficacy of Rozanolixizumab in patients with generalized myasthenia gravis (gMG) who are positive for AChR or MuSK autoantibodies.

We report our **real-world experience with Rozanolixizumab in 13 patients** with generalized myasthenia gravis (gMG), with a mean clinical **follow-up of 12.4 ± 4.9 months**

Methods

13 patients were treated with Rozanolixizumab s.c. according to MG0024 protocol (Protocol version 11 mar 2024), from May2024 and September 2025 (follow-up 12,4 ± 4,9 months).

9 patients 69,2%, were positive for MuSK-Ab, 4 patients 30,8% for AChR-Ab. 5 patients 38,5% were considered treatment-refractory (Sanders et.al.2016).

Clinical outcomes were evaluated by means of MG-ADL, QMG, and MG-QOL-15-r scales. Inclusion criteria were: Age ≥ 18 years, History of gMG, MGFA classification II, III, IV, autoantibodies to AchR or MuSK.

Treatment schedule Rozanolixizumab was administered s.c.7mg/Kg according to the patient body weight in cycles of 6 weekly infusions. Patients were assessed at each s.c. infusion and 7 days after the last s.c. infusion.

Body weight	≥35 to <50 kg	≥50 to <70 kg	≥70 to <100 kg	≥100 kg
Weekly dose (mg)	280 mg	420 mg	560 mg	840 mg
Weekly dose volume (ml)	2 ml	3 ml	4 ml	6 ml
Number of 2 ml vials to be used*	1	2**	2	3

Table 1

Baseline demographich and clinical characteristics	Patients N.:13
Age	**51,3 (SD 15,9)**
Sex Male Female	 **3 (23,1%)** **10 (76,9%)**
MG duration(years)	**9,7 (SD 7,2)**
Age at diagnosis	**42,8 (SD 14,8)**
Follow-up (months) **Range follow-up (max-min)**	**12,4 (SD 4,9)** **17-3**
MGFA at Baseline IIA IIB IIIA IIIB IVA IVB	 **1 (7,7%)** **4 (30,8%)** **2 (15,4%)** **4 (30,8%)** **1 (7,7%)** **1 (7,7%)**
Baseline Scores QMG MG-ADL MgQoL-15r	 **11,5 (SD 5,2)** **6,3 (SD 3,2)** **12,8 (SD 6,6)**
Ongoing therapies Only Procholinergics (P) Only Corticosteroids (C) Only Immunosuppressants (I) C+I P+C P+I P+C+I	**13 (100%)** **2 (15,4%)** **4 (30,8%)** **2 (15,4%)** **1 (7,7%)** **2 (15,4%)** **0 (0%)** **2 (15,4%)**
Previous thymectomy	**2 (15,4%)**
Time since thymectomy (years)	**10,5 (9,5)**
Thymoma	**0 (0%)**

Table 2

Table 1: Doses according patient body weight
Table 2: Baseline demographic and clinical characteristics

Results

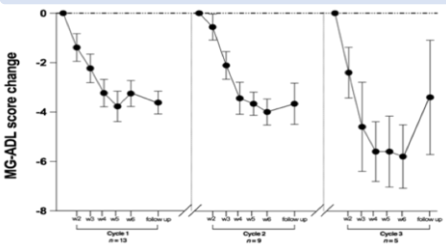

Figure 1: MG-ADL changes during follow-up

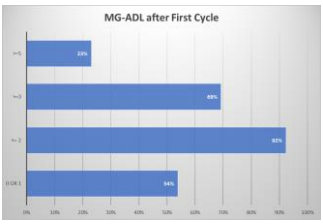

Figure 2: %responders after first cycle of treatment

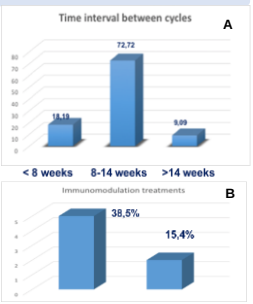

Figure 3:
A Time interval between cycles
B Immunomodulation before ad after Rozanolixizumab

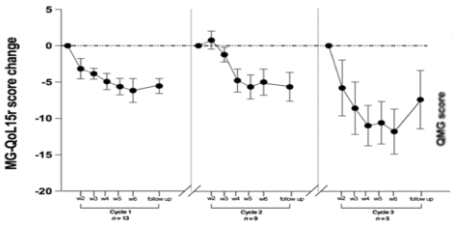

Figure 4: MG-QoL-15r changes during follow-up

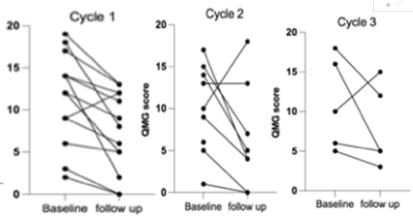

Figure 5: QMG changes during follow-up for each patient

Conclusions

Rozanolixizumab, a neonatal Fc Receptor inhibitor led to rapid and clinically meaningful improvement in our gMG patients, with a positive impact on the disease course. Rozanolixizumab prevented the most severe forms of the disease and reduced the need for immunomodulation (when compared to the two years before Rozanolixizumab). Rozanolixizumab enhanced the patients 'quality of life. No major adverse events occurred. Two patients lost response and discontinued the treatment. Further studies in a real world setting on large series of patients are needed to confirm these findings.

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