

Quality of life in patients with generalised myasthenia gravis receiving rozanolixizumab: *Post hoc* analysis of MycarinG

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Introduction

- MG is a chronic autoimmune disease characterised by fluctuating muscle weakness/fatigability that can significantly impact many aspects of patients' HRQoL^{1,2}
- The MG-QoL15r is a PRO instrument designed to investigate the physiological, social and emotional impact of MG-specific impairment, comprising 15 items (total score: 0–30), where higher scores reflect worse HRQoL³
- In the MycarinG study (NCT03971422), rozanolixizumab significantly improved MG-specific outcomes versus placebo in patients with gMG⁴
- Here, we evaluate the impact of rozanolixizumab on different facets of HRQoL in patients with gMG, using three themes of the MG-QoL15r in a *post hoc* analysis of MycarinG data

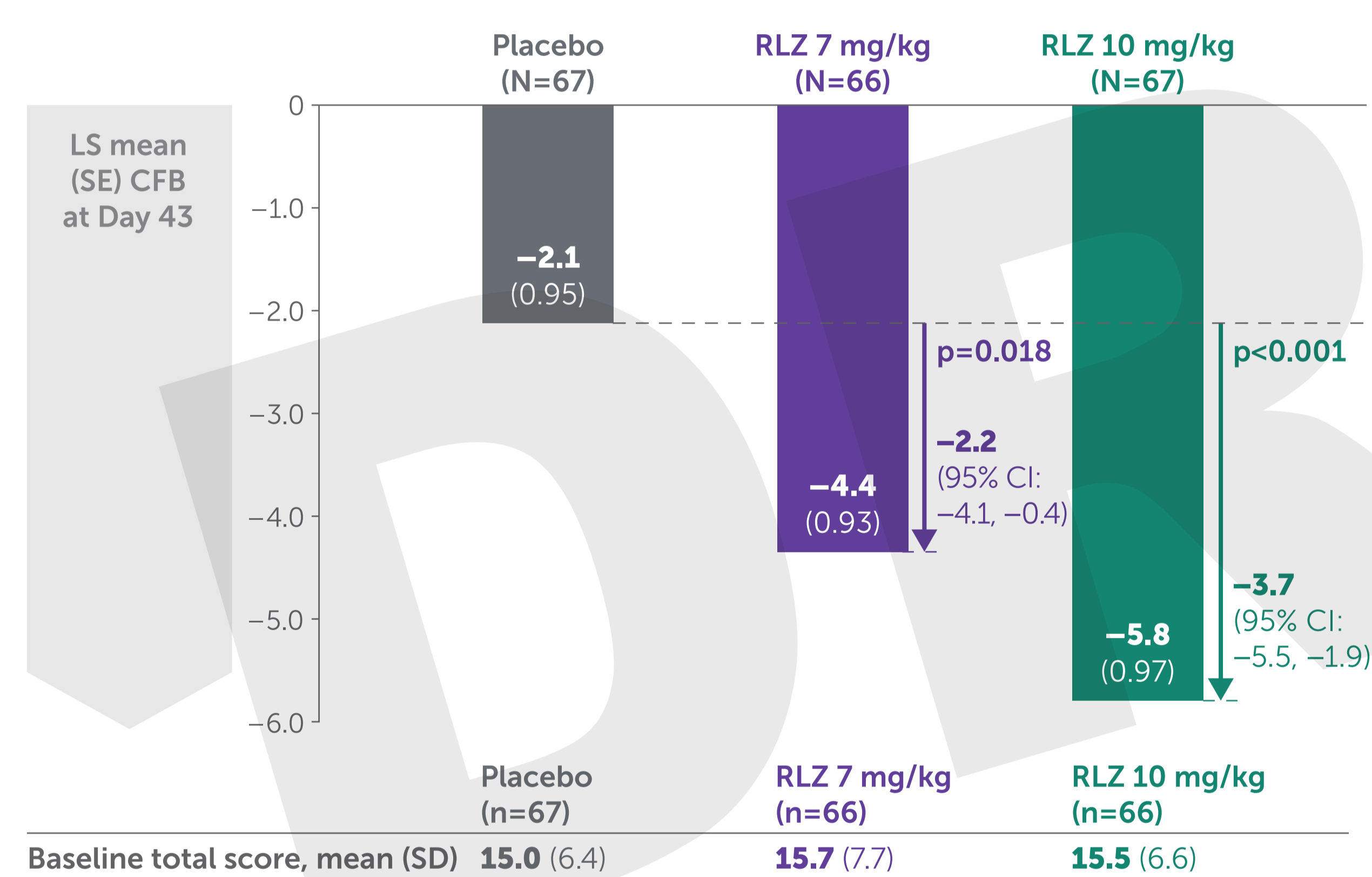
Methods

- Patients were randomised 1:1:1 to receive once-weekly SC rozanolixizumab 7 mg/kg, rozanolixizumab 10 mg/kg or placebo for 6 weeks (to Day 43), followed by an 8-week observation period
- LS mean (95% CI) CFB in MG-QoL15r at Day 43 was determined *post hoc* for the three treatment groups using an MMRM ANCOVA model
- The 15 items of the MG-QoL15r were grouped into three themes: physical (score range: 0–14), social (score range: 0–8) and emotional (score range: 0–8; **Table 1**)
 - Descriptive analyses of the CFB in MG-QoL15r scores at Day 43 for each theme were conducted

Results

- Overall, 200 patients received rozanolixizumab 7 mg/kg (n=66), rozanolixizumab 10 mg/kg (n=67) or placebo (n=67)

Figure 1 LS mean CFB in MG-QoL15r total score at Day 43 was greater with both rozanolixizumab doses than with placebo



Baseline MG-QoL15r data were missing for one patient in the RLZ 10 mg/kg dose group.

Table 1 MG-QoL15r items were assigned to three themes

Please indicate how true each statement has been (over the past few weeks)	Physical	Social	Emotional
1. I am frustrated by my MG			X
2. I have trouble using my eyes because of my MG (e.g. double vision)	X		
3. I have trouble eating because of my MG	X		
4. I have limited my social activity because of my MG		X	
5. My MG limits my ability to enjoy hobbies and fun activities		X	
6. I have trouble meeting the needs of my family because of my MG		X	
7. I have to make plans around my MG		X	
8. I am bothered by limitations in my performing at work (include work at home) because of my MG			X
9. I have difficulty speaking due to MG	X		
10. I have lost some personal independence because of my MG (e.g. driving, shopping, running errands)	X		
11. I am depressed about my MG			X
12. I have trouble walking due to MG	X		
13. I have trouble getting around in public places because of my MG	X		
14. I feel overwhelmed by my MG			X
15. I have trouble performing my personal grooming needs due to MG	X		

Abbreviations: ANCOVA, analysis of covariance; CFB, change from baseline; CI, confidence interval; gMG, generalised myasthenia gravis; HRQoL, health-related quality of life; LS, least squares; MG, myasthenia gravis; MG-QoL15r, Myasthenia Gravis Quality of Life 15-item Scale - Revised; MMRM, mixed model for repeated measures; PRO, patient-reported outcome; SC, subcutaneous; SD, standard deviation; SE, standard error.
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the USF Site Principal Investigator for MG clinical trials sponsored by Alexion/AstraZeneca Rare Disease, Amgen, argenx, Cartesian Therapeutics, COUR Pharmaceuticals, Dianthus Therapeutics, Immunovant, Johnson & Johnson, NMD Pharma, Regeneron Pharmaceuticals and UCB, and has served as a speaker for Alexion/AstraZeneca Rare Disease, argenx and CSL Behring. He has performed consulting work for Alexion/AstraZeneca Rare Disease, argenx, Dianthus Therapeutics and Immunovant. Jos Bloemers, Fiona Grimson and Thais Tarancón are employees and shareholders of UCB. Vera Brill is a Consultant for Alexion Pharmaceuticals, Alnylam, argenx, CSL, Grifols, Immunovant, Ionis, Janssen Pharmaceuticals (now Johnson & Johnson Innovative Medicine), Momenta (now Johnson & Johnson), Novo Nordisk, Octapharma, Pfizer, Powell Mansfield, Roche, Sanofi, Takeda Pharmaceuticals and UCB. She has received research support from Alexion Pharmaceuticals, argenx, CSL, Grifols, Immunovant, Ionis, Momenta (now Johnson & Johnson), Octapharma, Takeda Pharmaceuticals, UCB and Vela Bio (now Amgen).
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Summary and conclusions



Improvements in MG-QoL15r total score were greater and nominally statistically significant in the rozanolixizumab treatment groups compared with the placebo group



Mean CFB at Day 43 was greater in physical, social and emotional themes of the MG-QoL15r for both rozanolixizumab groups compared with placebo



Across the three themes, greater proportions of patients in the rozanolixizumab groups achieved an absence of impact of symptoms on HRQoL as measured by the MG-QoL15r



These data demonstrate that patients benefit from rozanolixizumab treatment across the breadth of impacts that MG symptoms have on patients' HRQoL

Figure 2 Across the three themes of the MG-QoL15r, mean CFB at Day 43 was greater with both rozanolixizumab doses than with placebo

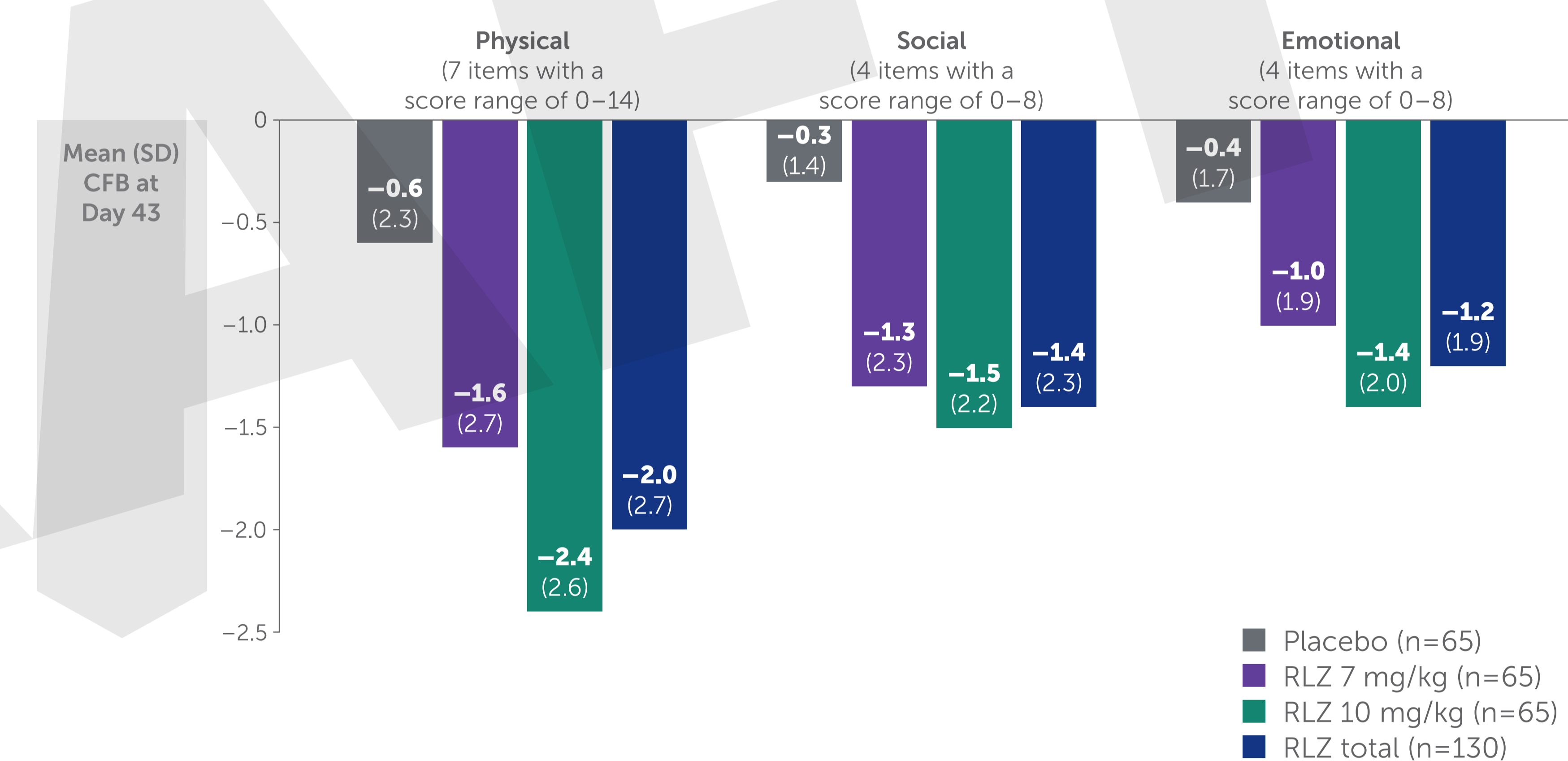


Table 2 Across the three themes, there was a greater increase in the proportion of patients with no impact of symptoms on QoL (score of 0) at Day 43 in both rozanolixizumab dose groups than with placebo

Theme	Patients with score of 0 at baseline, n (%)			Patients with score of 0 at Day 43, n (%)		
	Placebo	RLZ 7 mg/kg	RLZ 10 mg/kg	Placebo	RLZ 7 mg/kg	RLZ 10 mg/kg
Physical	0 (0)	4 (6.1)	2 (3.0)	2 (3.1)	11 (16.9)	12 (18.2)
Social	3 (4.5)	3 (4.5)	3 (4.5)	3 (4.6)	11 (16.9)	14 (21.2)
Emotional	1 (1.5)	2 (3.0)	4 (6.1)	2 (3.1)	12 (18.5)	15 (22.7)
Physical and social	0 (0)	2 (3.0)	1 (1.5)	0 (0)	8 (12.1)	9 (13.4)
Physical and emotional	0 (0)	1 (1.5)	0 (0)	0 (0)	6 (9.1)	9 (13.4)
Social and emotional	0 (0)	1 (1.5)	2 (3.0)	0 (0)	7 (10.6)	10 (14.9)
Physical, social and emotional	0 (0)	1 (1.5)	0 (0)	0 (0)	5 (7.7)	7 (10.6)

