

Quality of Life in Patients with Generalized Myasthenia Gravis Achieving Sustained vs Transient Minimal Symptom Expression in the Phase 3 Vivacity-MG3 Trial

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Background

- Generalized myasthenia gravis (gMG) is a chronic, immunoglobulin G autoantibody-mediated autoimmune neuromuscular disease associated with unpredictable, fluctuating muscle weakness^{1,2}
- In the phase 3 Vivacity-MG3 study (NCT04951622), participants with gMG who received nipocalimab demonstrated improved and sustained efficacy versus those receiving placebo^{3,4}
- Minimal symptom expression (MSE), defined as a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of ≤1, is a treatment goal in gMG;⁵ however, functional outcomes associated with achieving sustained MSE have not been fully explored

Objective

The purpose of this post-hoc analysis was to evaluate MSE treatment response and quality of life (QoL) in participants achieving sustained versus transient MSE in Vivacity-MG3

Methods

Participants

- This Vivacity-MG3 post-hoc analysis included participants in the prespecified efficacy analysis population
 - Randomized participants who received ≥1 dose of study drug (nipocalimab or placebo) in the double-blind phase and were antibody positive for a gMG-related pathogenic antibody (anti-acetylcholine receptor, anti-muscle-specific tyrosine kinase, or anti-lipoprotein-receptor-related protein 4)
- Participants were stratified into groups based on MSE status over 24 weeks in the double-blind phase:
 - Never achieved MSE (no MSE)
 - Achieved MSE at least once but was not sustained for ≥8 weeks (transient MSE)
 - Achieved MSE and was sustained for ≥8 weeks (sustained MSE)

Assessments

- The proportion of participants achieving and sustaining MSE was evaluated for nipocalimab versus placebo
- Logistic regression models compared likelihood (odds ratio) of achieving transient or sustained MSE (reference=no MSE) for nipocalimab versus placebo
- Treatment groups were combined, stratified by MSE status, and then the impact of MSE status on quality of life was evaluated
 - Least squares mean change from baseline in Myasthenia Gravis Quality of Life-15 revised (MG-QoL-15r) total score was compared across MSE groups using analysis of covariance (ANCOVA) models at Week 24 with fixed effects for group, autoantibody status, and region, and baseline score as covariates

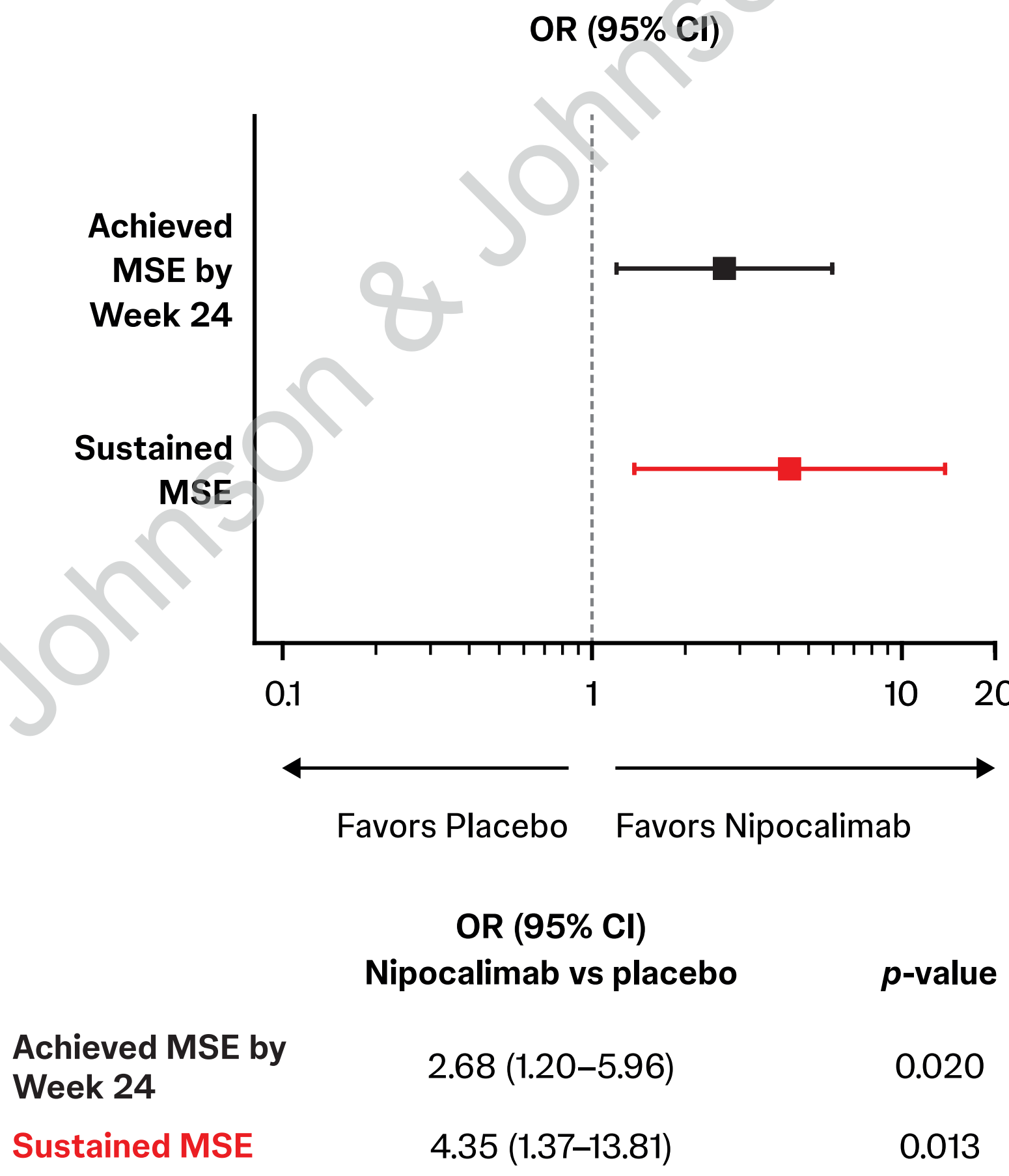
Results

Baseline participant characteristics			
	Nipocalimab + SOC (n=77)	Placebo + SOC (n=76)	Total (n=153)
Age, years, mean (SD)	52.5 (15.66)	52.3 (16.37)	52.4 (15.97)
Sex, female, n (%)	50 (64.9)	42 (55.3)	92 (60.1)
Baseline MG-ADL total score, mean (SD)	9.4 (2.73)	9.0 (1.97)	9.2 (2.38)
Baseline MG-QoL-15r total score, mean (range)	15.5 (5.0–28.0)	16.9 (0.0–28.0)	16.2 (0.0–28.0)
Baseline QMG total score, mean (SD)	15.1 (4.78)	15.7 (4.92)	15.4 (4.85)
Antibody positive at screening, n (%)			
AChR	63 (81.8)	71 (93.4)	134 (87.6)
MuSK	12 (15.6)	4 (5.3)	16 (10.5)
LRP4	2 (2.6)	1 (1.3)	3 (2.0)

AChR=acetylcholine receptor, LRP4=lipoprotein-receptor-related protein 4, MG-ADL=Myasthenia Gravis Activities of Daily Living, MG-QoL-15r=Myasthenia Gravis Quality of Life-15 revised, MuSK=muscle-specific tyrosine kinase, QMG=Quantitative Myasthenia Gravis, SD=standard deviation, SOC=standard of care.

Treatment effect for achieving MSE by Week 24 and ≥8-week sustained MSE

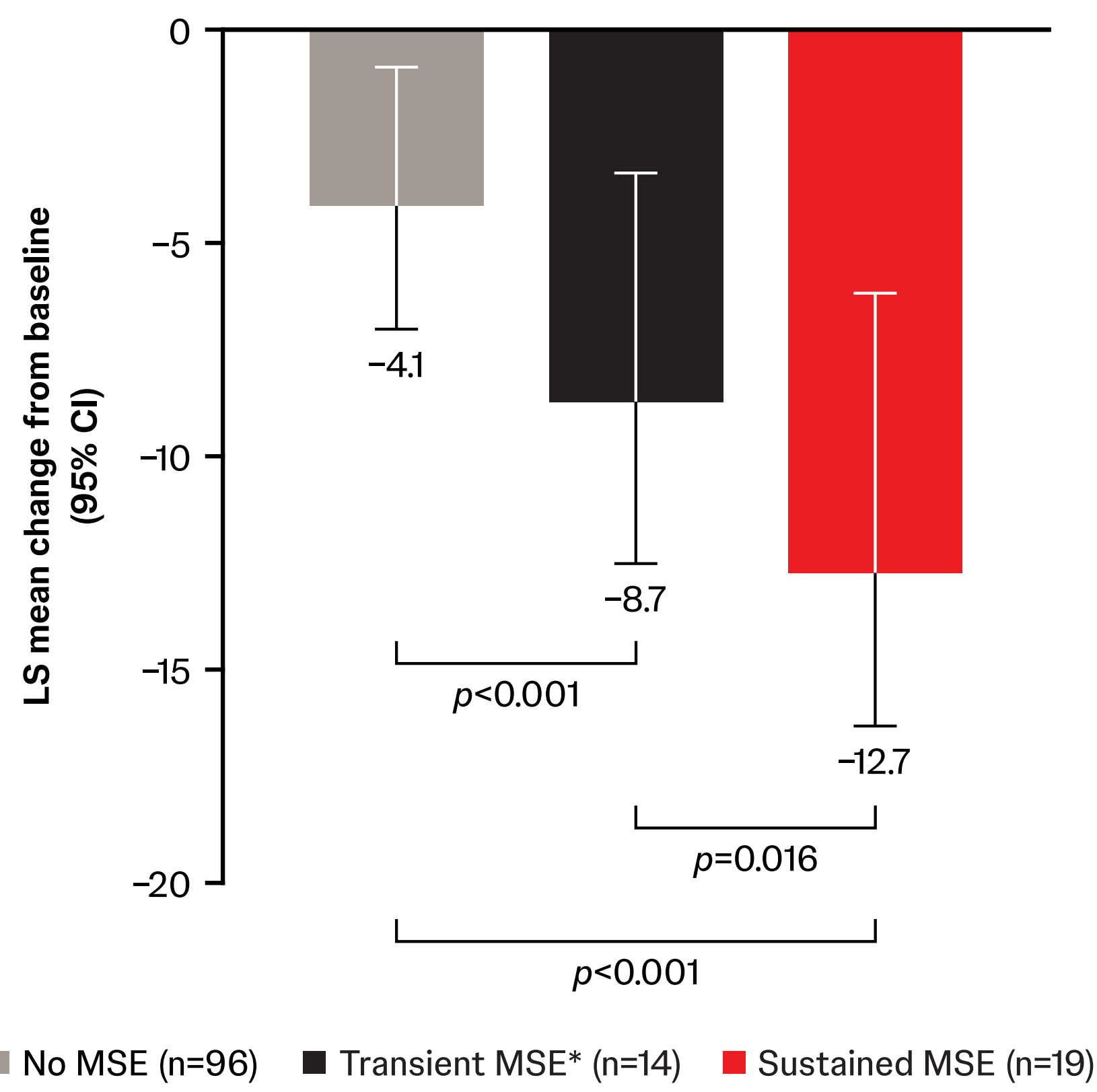
- Nipocalimab-treated participants were significantly more likely to achieve and sustain MSE versus placebo-treated participants



p-values are from Fisher's exact test. CI=confidence interval, MSE=minimal symptom expression, OR=odds ratio.

MG-QoL-15r improvement at Week 24

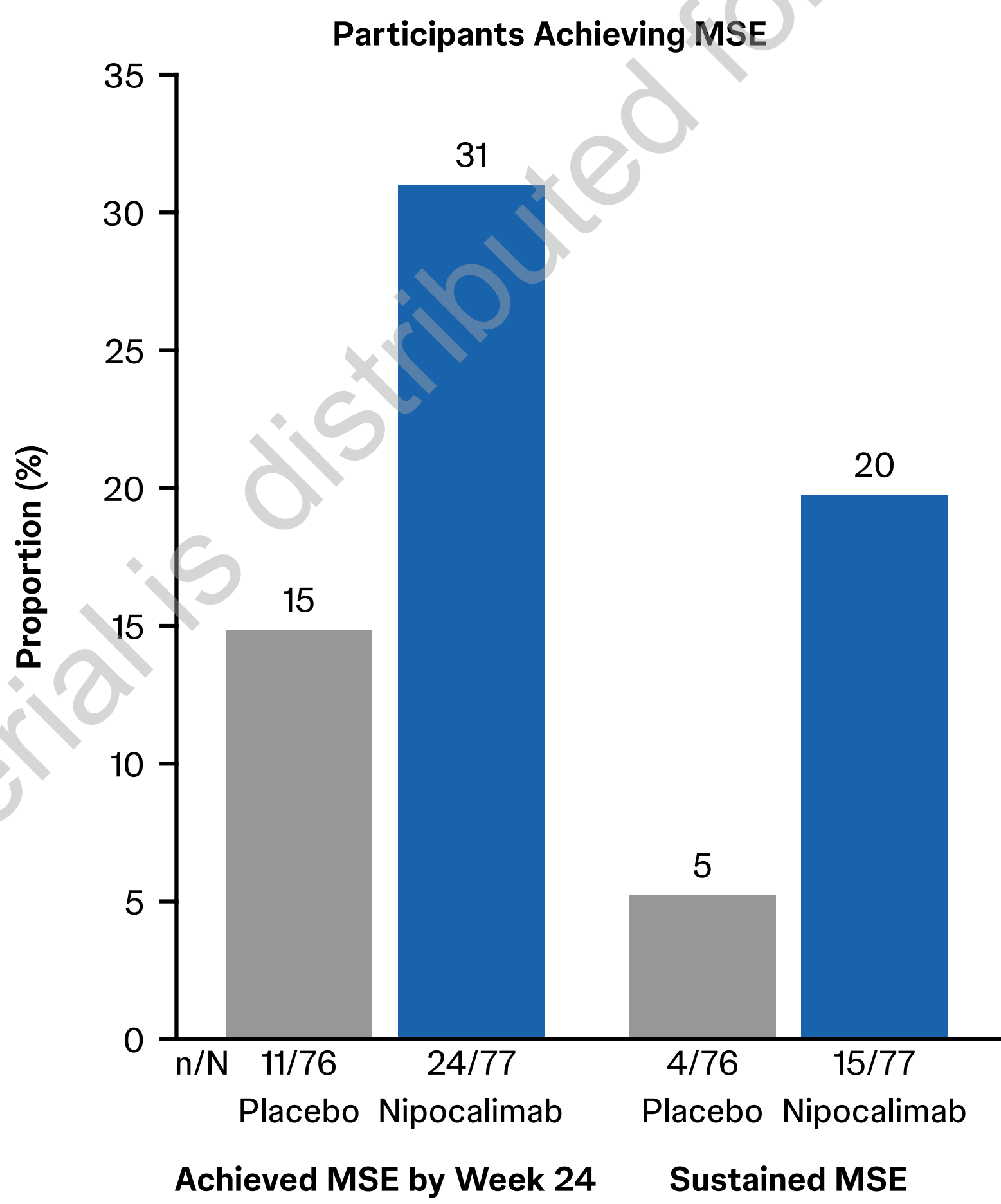
- Participants who achieved sustained MSE demonstrated significantly greater improvements in MG-QoL-15r scores versus those with transient MSE and versus those with no MSE



p-values are for change from baseline between group comparisons from an ANCOVA model with fixed effects for group, autoantibody status, and region, and baseline score as covariates. *The transient MSE cohort only includes patients who did not meet the sustained MSE condition during the 24-week follow-up period. ANCOVA=analysis of covariance, CI=confidence interval, LS=least squares, MG-QoL-15r=Myasthenia Gravis Quality of Life-15 revised; MSE=minimal symptom expression.

Proportion of participants in each treatment group who achieved MSE by Week 24 and ≥8-week sustained MSE

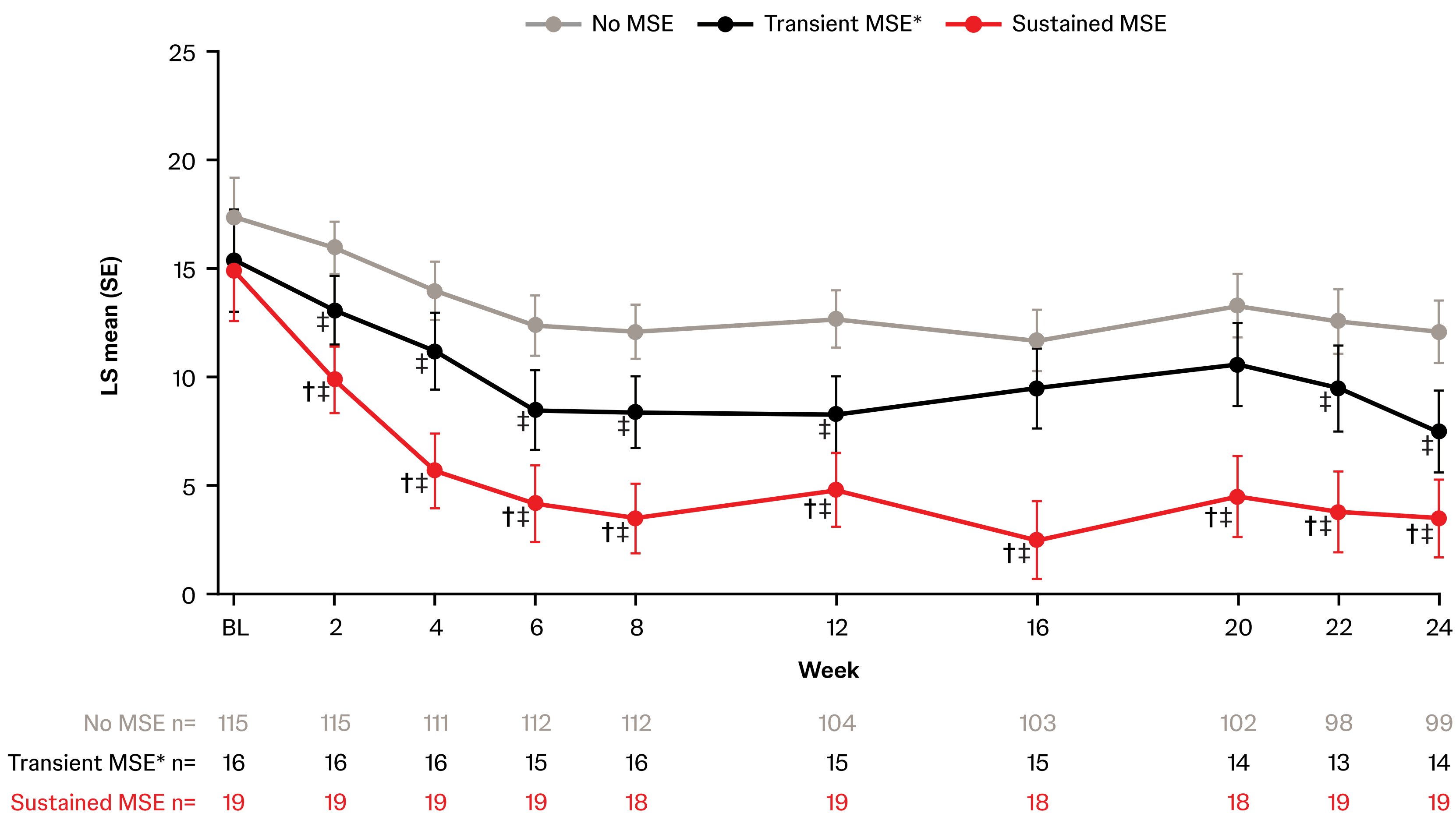
- Of 153 participants included in this analysis, 35 (23%) achieved MSE by Week 24 and 19 (12%) had sustained MSE



MSE=minimal symptom expression.

MG-QoL-15r improvement over time

- Significantly greater improvements in MG-QoL-15r scores were demonstrated in participants achieving sustained MSE at Week 2 and maintained through Week 24 compared with those achieving transient MSE and those not achieving MSE



p-values are for change from baseline between group comparisons from an ANCOVA model with fixed effects for group, autoantibody status, and region, and baseline score as covariates. *The transient MSE cohort only includes patients who did not meet the sustained MSE condition during the 24-week follow-up period. *p<0.05 vs transient MSE. *p<0.05 vs no MSE. ANCOVA=analysis of covariance, BL=baseline, LS=least squares, MG-QoL-15r=Myasthenia Gravis Quality of Life-15 revised; MSE=minimal symptom expression, SE=standard error.