

Frequency of Sustained Response to Nipocalimab Versus Placebo Based on Myasthenia Gravis Activities of Daily Living and Quantitative Myasthenia Gravis Scales in the Phase 3 Vivacity-MG3 Study

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Introduction

- Generalized myasthenia gravis (gMG) is a chronic, autoimmune disorder characterized by fluctuating muscle weakness and fatigability, which may worsen over time without effective treatment¹
- Sustained disease control is a treatment goal in patients with gMG, as long-term maintenance of low disease activity can reduce exacerbations and improve functional outcomes²
- Nipocalimab is the first neonatal Fc receptor (FcRn) blocker approved for the treatment of gMG in both adult and adolescent (≥12 years of age) patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific kinase (MuSK) antibody-positive^{3,4}
- Nipocalimab added to standard-of-care (SOC) demonstrated sustained disease control versus placebo plus SOC during the 24-week phase 3, double-blind Vivacity-MG3 study in patients with seropositive gMG, as indicated by improvements in Myasthenia Gravis-Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG)⁵
- A significantly greater proportion of nipocalimab-treated patients achieved a clinically meaningful response sustained for ≥ 8, 12, 16, and 20 consecutive weeks versus placebo⁶

Objective

- A post hoc analysis of the Vivacity-MG3 study to evaluate frequency of sustained clinical response with nipocalimab+SOC using MG-ADL and QMG score in seropositive patients with gMG

Methods

Analysis Population

- All patients with gMG who were anti-AChR, anti-MuSK or anti-LRP4 (low-density lipoprotein receptor-related protein 4) antibody-positive and received ≥1 dose of nipocalimab+SOC or placebo+SOC during the double-blind phase of Vivacity-MG3 were included in this post hoc analysis

Assessments

- Meaningful clinical improvement (MCI) was defined as ≥2-point improvement in MG-ADL total score or ≥3-point improvement in QMG total score
 - The MG-ADL questionnaire was assessed at 12 visits over 24 weeks, and the QMG at 8 visits over 24 weeks
- Sustained clinical response was defined as achievement of MCI response for MG-ADL, ≥2-point improvement through ≥10 visits out of 12 visits; for QMG, ≥3-point improvement in ≥7 visits out of 8 visits
- Sustained substantial clinical response was defined as ≥3-point improvement in MG-ADL through ≥10 visits or ≥4-point improvement in QMG in ≥7 visits
- Sustained composite clinical response required MCI criteria to be met for both MG-ADL and QMG. Sustained composite clinical response was defined as achievement of MCI response for MG-ADL, ≥2-point improvement through ≥10 visits out of 12 visits and ≥3-point improvement in QMG in ≥7 visits out of 8 visits

Statistical Analysis

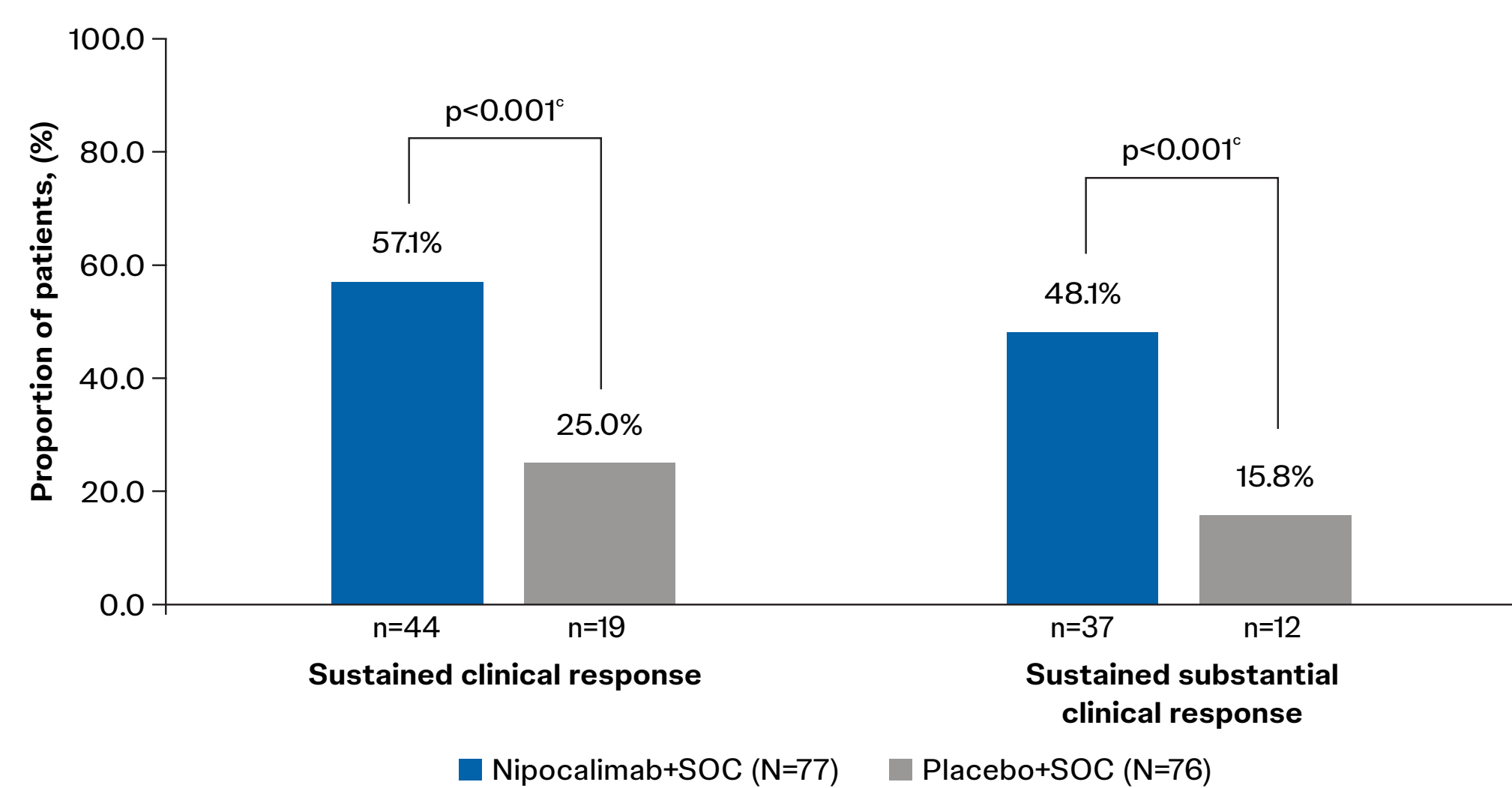
- Differences between treatment groups for proportions of sustained clinical response, sustained substantial clinical response, and composite MCI response were examined using odds ratios (ORs) and 95% confidence intervals (CIs). Unadjusted ORs are reported. p-values were calculated using Chi-square test

Results

MG-ADL: Sustained clinical response and sustained substantial clinical response

- Significantly greater proportion of patients treated with nipocalimab+SOC (vs placebo+SOC) achieved sustained clinical response and sustained substantial clinical response criteria for MG-ADL total score (Figure 1)

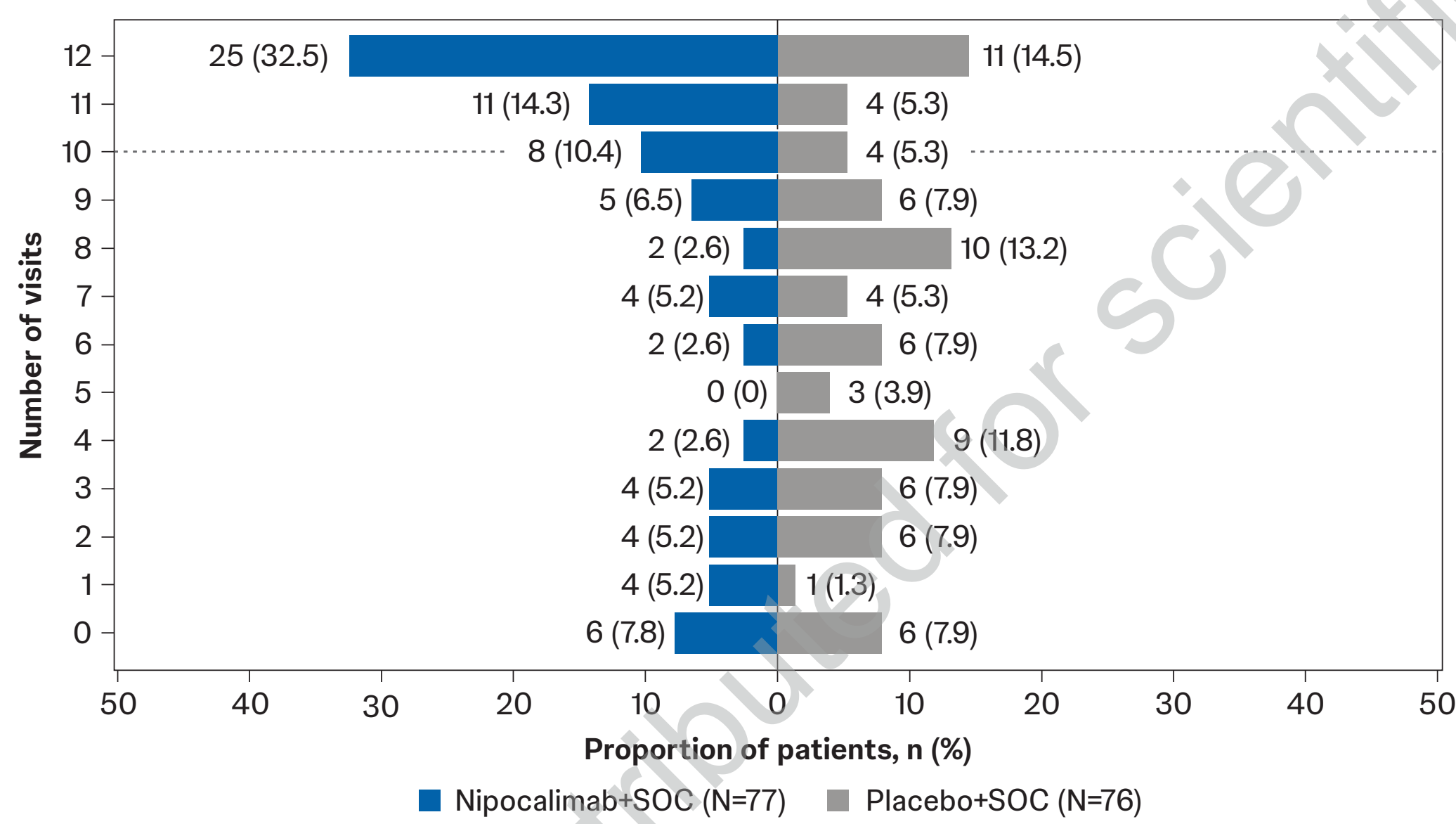
Figure 1. Proportion of patients achieving sustained clinical response^a and sustained substantial clinical response^b for MG-ADL over week 24



^aDefined as achievement of MCI response for MG-ADL, ≥2-point improvement through ≥10 visits out of 12 visits. ^bDefined as ≥3-point improvement in MG-ADL through ≥10 visits. *Calculated using Chi-square test. **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **SOC**=standard-of-care.

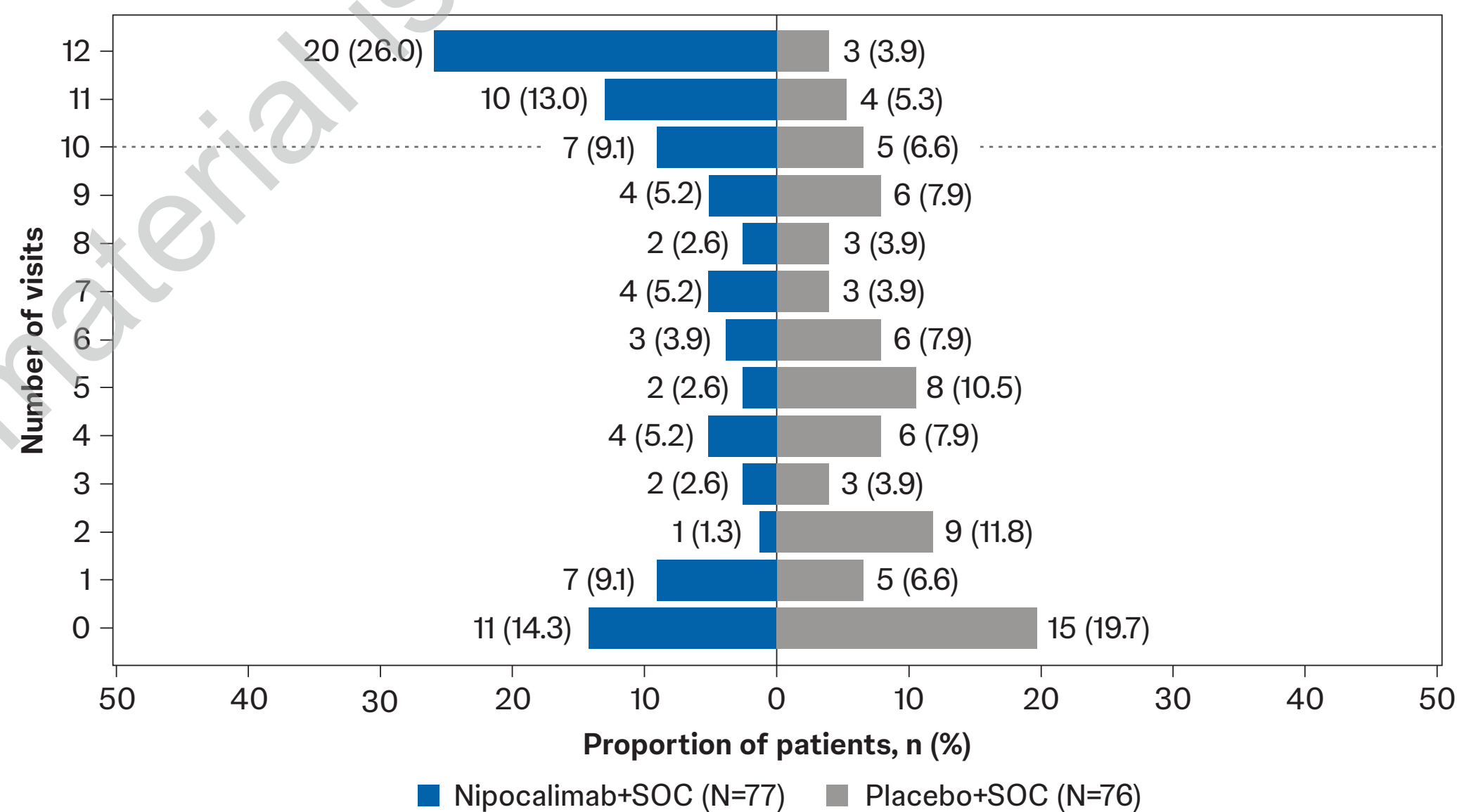
- Proportion of patients achieving both sustained clinical response and sustained substantial clinical response on the MG-ADL scale was higher with nipocalimab+SOC (vs placebo+SOC) for 10, 11, and 12 visits (Figure 2 & 3)
 - Among patients treated with nipocalimab+SOC, 57.1% achieved sustained clinical response and 48.1% achieved sustained substantial clinical response for ≥10 visits
- Among patients treated with placebo+SOC, the proportion of patients achieving and sustaining clinical response was greater at lower visit thresholds (Figure 2 & 3)

Figure 2. Proportion of patients with sustained clinical response^a for MG-ADL by number of visits



Note: Data are shown as n (%). ^aDefined as achievement of MCI response for MG-ADL, ≥2-point improvement through ≥10 visits out of 12 visits. **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **SOC**=standard-of-care.

Figure 3. Proportion of patients with sustained substantial clinical response^a for MG-ADL by number of visits

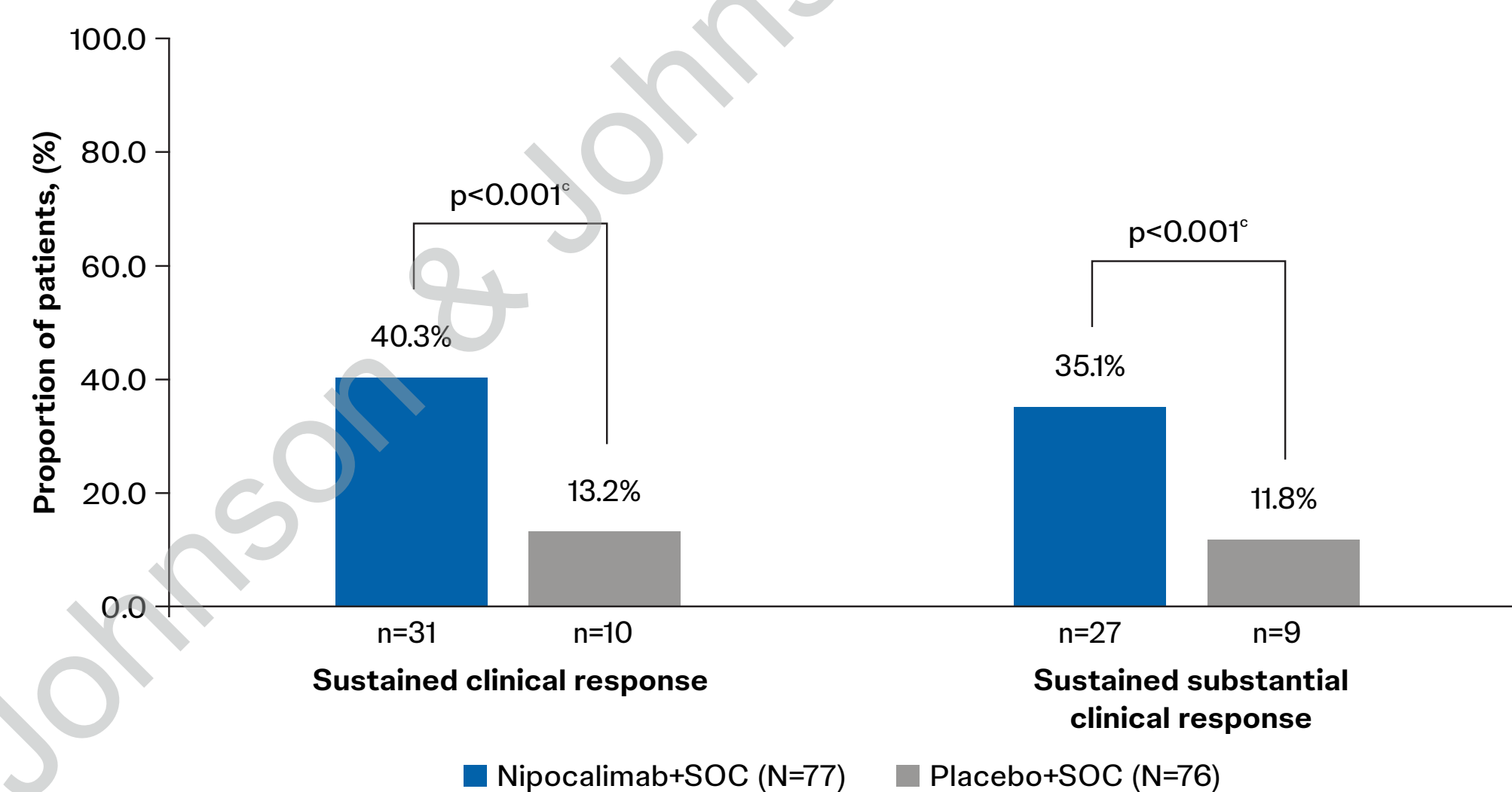


Note: Data are shown as n (%). ^aDefined as ≥3-point improvement in MG-ADL through ≥10 visits. **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **SOC**=standard-of-care.

QMG: Sustained clinical response and sustained substantial clinical response

- Significantly greater proportion of patients treated with nipocalimab+SOC (vs placebo+SOC) achieved sustained clinical response and sustained substantial clinical response criteria for QMG total score (Figure 4)

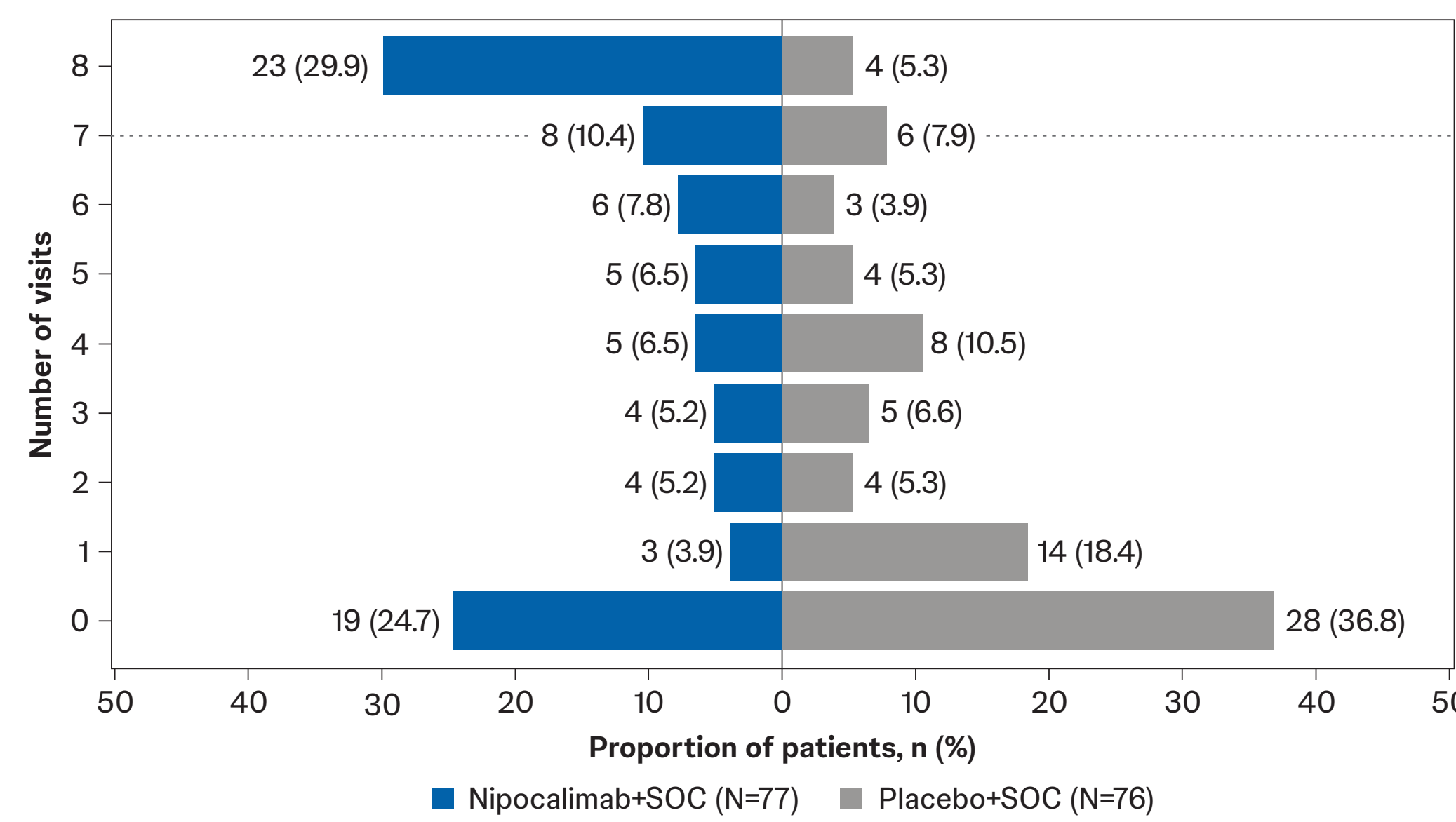
Figure 4. Proportion of patients achieving sustained clinical response^a and sustained substantial clinical response^b for QMG over week 24



^aDefined as achievement of MCI response for QMG, ≥3-point improvement in ≥7 visits out of 8 visits. ^bDefined as ≥4-point improvement in QMG in ≥7 visits. *Calculated using Chi-square test. **QMG**=Quantitative Myasthenia Gravis, **SOC**=standard-of-care.

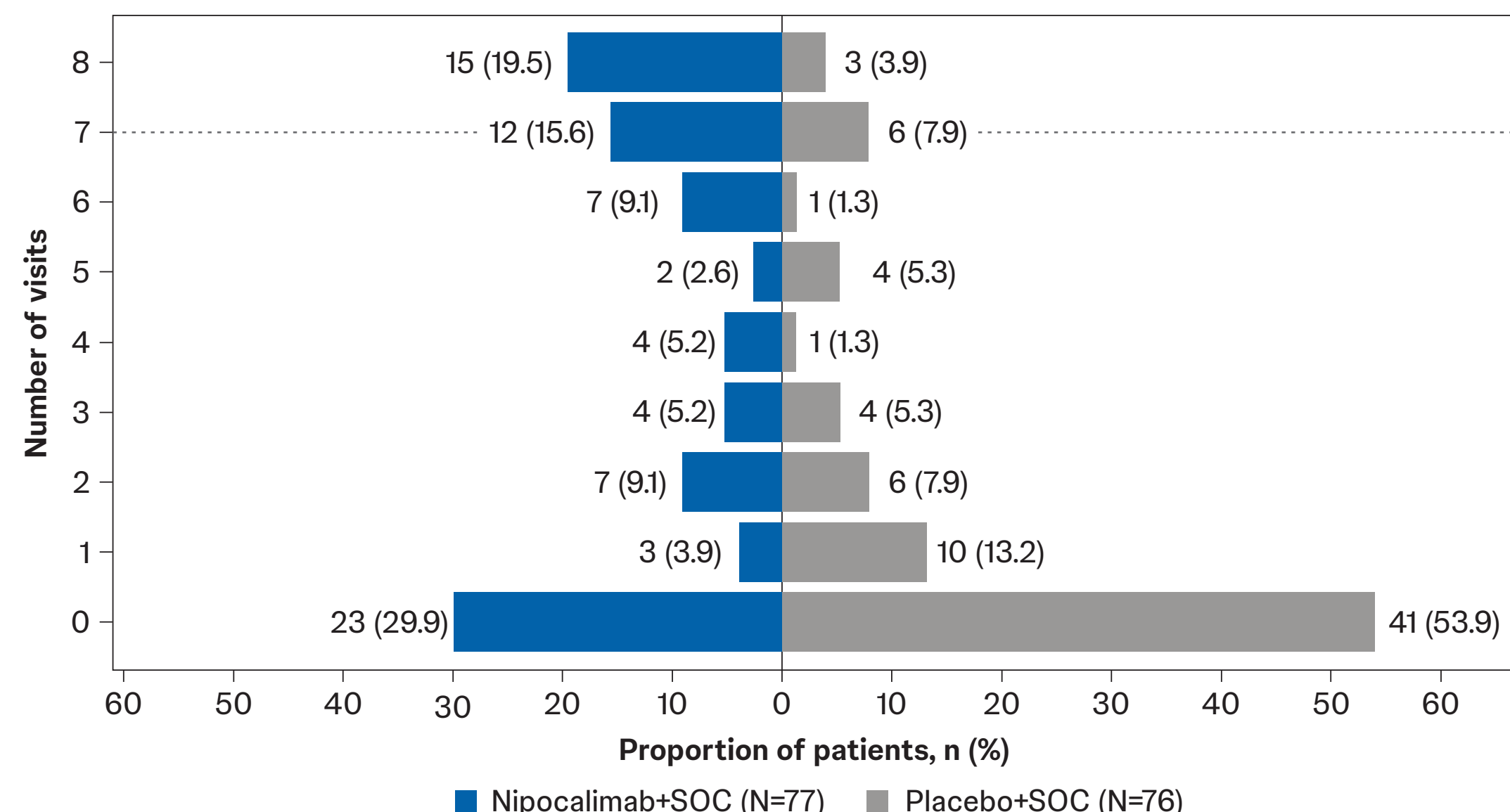
- Proportion of patients achieving both sustained clinical response and sustained substantial clinical response on the QMG scale was higher with nipocalimab+SOC (vs placebo+SOC) for 7 and 8 visits (Figure 5 & 6)
 - Among patients treated with nipocalimab+SOC, 40.3% achieved sustained clinical response and 35.1% achieved sustained substantial clinical response for ≥7 visits
- Among patients treated with placebo+SOC, the proportion of patients achieving and sustaining clinical response was greater at lower visit thresholds (Figure 5 & 6)

Figure 5. Proportion of patients with sustained clinical response^a for QMG by number of visits



Note: Data are shown as n (%). ^aDefined as achievement of MCI response for QMG, ≥3-point improvement in ≥7 visits out of 8 visits. **QMG**=Quantitative Myasthenia Gravis, **SOC**=standard-of-care.

Figure 6. Proportion of patients with sustained substantial clinical response^a for QMG by number of visits



Note: Data are shown as n (%). ^aDefined as ≥4-point improvement in QMG in ≥7 visits. **QMG**=Quantitative Myasthenia Gravis, **SOC**=standard-of-care.

Key Takeaways

- A significantly greater proportion of patients treated with nipocalimab+SOC achieved sustained and substantial MCI response in both MG-ADL and QMG total scores compared to those treated with placebo+SOC

- Patients treated with nipocalimab+SOC achieved sustained and sustained substantial clinical response on both MG-ADL and QMG at most visits compared with placebo

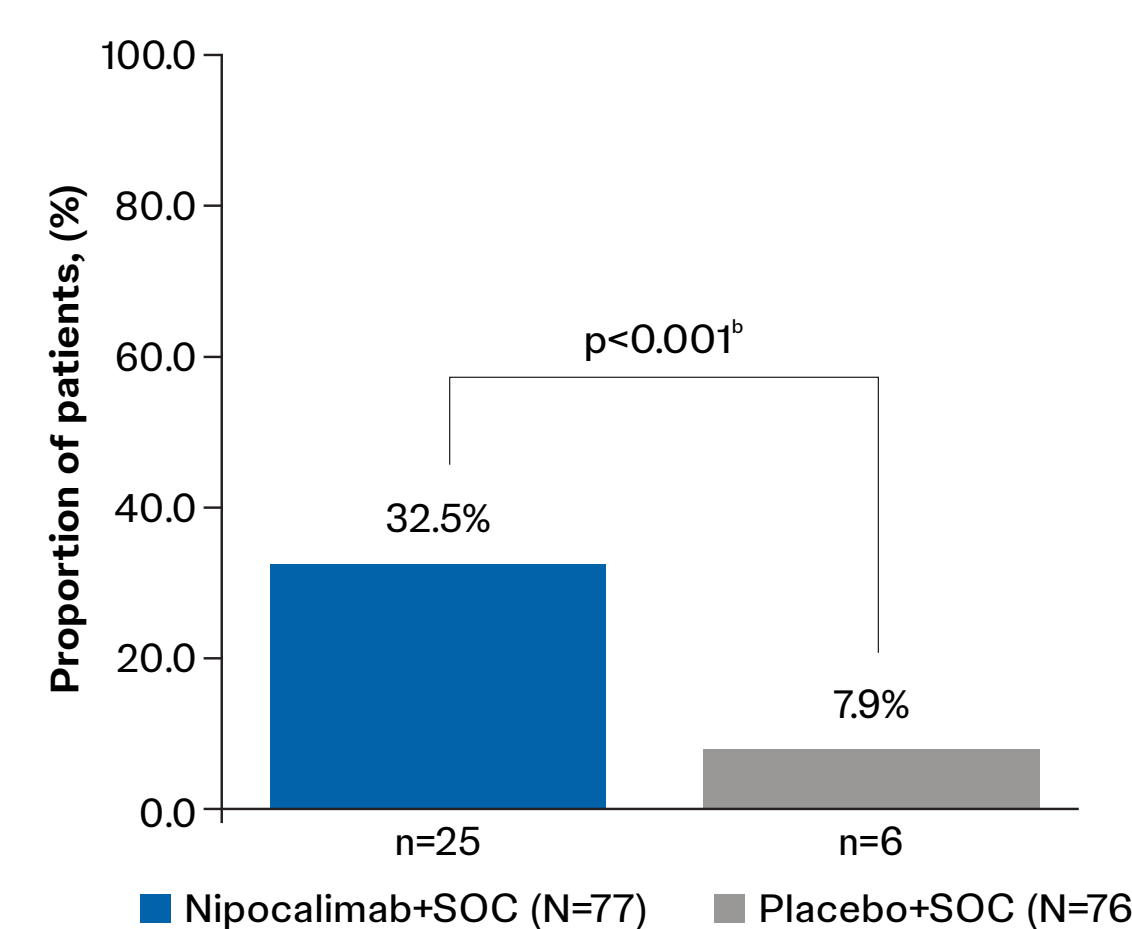
- A significantly greater proportion of patients treated with nipocalimab+SOC achieved sustained composite clinical response compared with patients treated with placebo+SOC

- In this post hoc analysis, treatment with nipocalimab was associated with greater frequency of sustained clinical responses, demonstrating sustained disease control over 24-weeks in seropositive patients with gMG

Sustained composite clinical response

- Significantly greater proportion of patients treated with nipocalimab+SOC (vs placebo+SOC) achieved sustained composite clinical response (Figure 7)

Figure 7. Proportion of patients achieving sustained composite clinical response^a over week 24

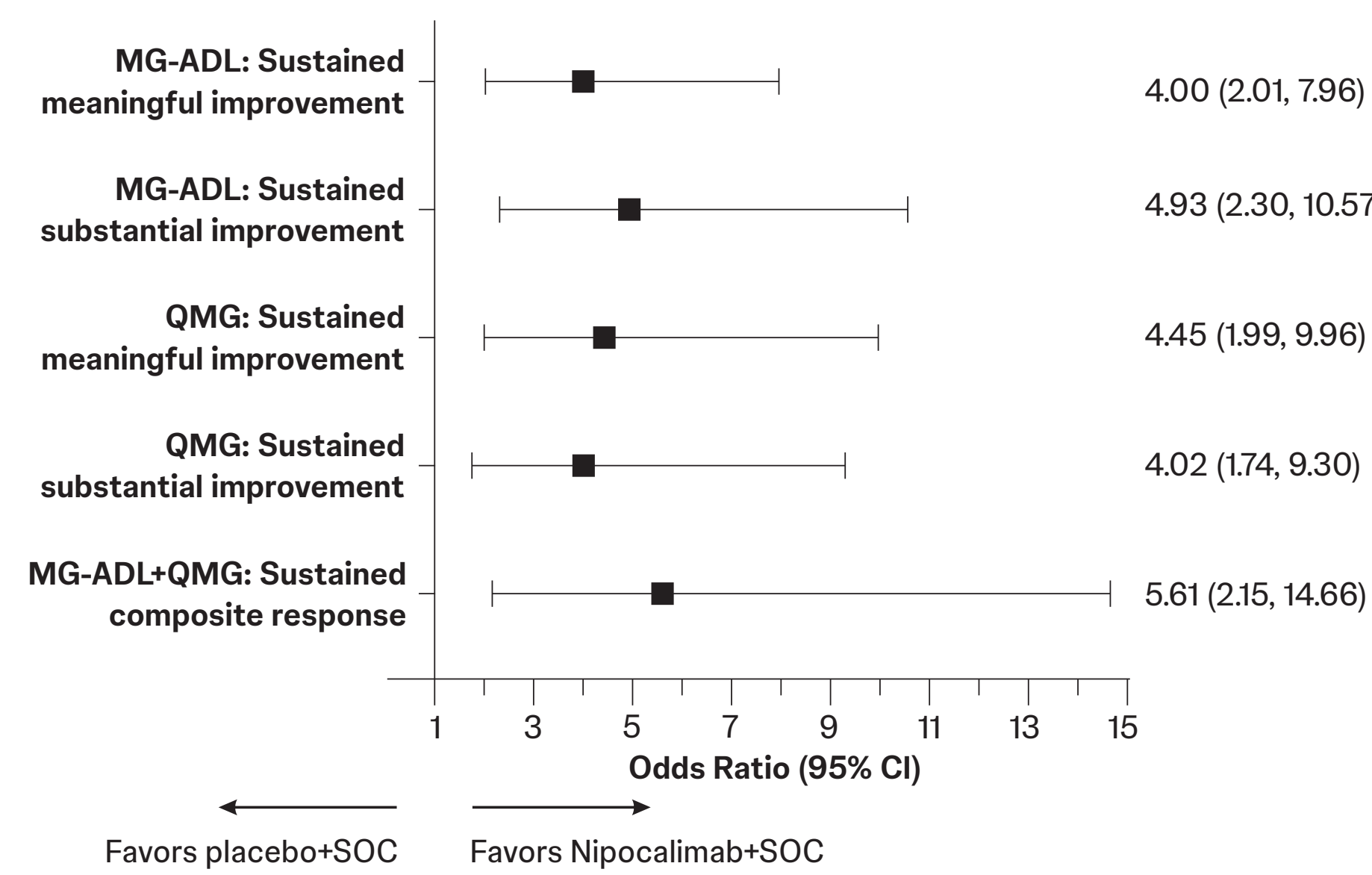


^aDefined as achievement of MCI response for MG-ADL, ≥2-point improvement through ≥10 visits out of 12 visits and ≥3-point improvement in QMG in ≥7 visits out of 8 visits. *Calculated using Chi-square test. **SOC**=standard-of-care.

Overall sustained disease control

- Patients treated with nipocalimab+SOC consistently showed higher rates of sustained clinical response across all endpoints compared with patients treated with placebo+SOC (Figure 8)
- Patients treated with nipocalimab+SOC had 4 times greater odds of achieving sustained clinical response and 4.9 times greater odds of achieving sustained substantial clinical response for MG-ADL compared with patients treated with placebo+SOC over 24 weeks
 - Sustained clinical response:** OR (95% CI): 4.00 (2.01, 7.96); p<0.001
 - Sustained substantial clinical response:** OR (95% CI): 4.93 (2.30, 10.57); p<0.001
- Patients treated with nipocalimab+SOC had 4.5 times greater odds of achieving sustained clinical response and 4 times greater odds of achieving sustained substantial clinical response for QMG compared with patients treated with placebo+SOC over 24 weeks
 - Sustained clinical response:** OR (95% CI): 4.45 (1.99, 9.96); p<0.001
 - Sustained substantial clinical response:** OR (95% CI): 4.02 (1.74, 9.30); p<0.001
- Patients treated with nipocalimab+SOC had 5.6 times greater odds of achieving sustained composite clinical response compared with patients treated with placebo+SOC over 24 weeks
 - Sustained composite clinical response:** OR (95% CI): 5.61 (2.15, 14.66); p<0.001

Figure 8. Sustained clinical improvements across endpoints



CI=confidence interval, **MG-ADL**=Myasthenia Gravis-Activities of Daily Living, **QMG**=Quantitative Myasthenia Gravis, **SOC**=standard-of-care.