

Changes in depression severity and functionality after 5-month treatment with esketamine nasal spray in a Spanish real-world population

Interim analysis of the HIPOCRAT-ESK study

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BACKGROUND

Treatment-resistant depression (TRD) is defined as inadequate response to ≥ 2 adequate antidepressant trials and affects roughly one third of patients with major depressive disorder.^{1,2}

Compared to non-resistant depression, it carries greater severity, chronicity, functional impairment and burden. It also drives higher healthcare use and adverse outcomes, including excess mortality.²

HIPOCRAT-ESK is an observational, prospective cohort conducted at 43 sites in Spain. Its primary objective is to evaluate functional remission after 6-month-treatment with intranasal esketamine in patients with TRD.

The study aims to compare differences in 3 cohorts depending on the moment of the introduction of esketamine: 4th line, 5th line or 6th or more lines.



OBJECTIVES

This interim analysis (5 months) reports preliminary outcomes on:

- Depression severity — clinician-rated (MADRS) and self-reported (PHQ-9).
- Suicidal ideation (MADRS item 10) over follow-up.
- Functionality, productivity and evolution of medical leaves.
- Hospitalizations / emergency room visits
- Adverse events and discontinuations.



Population (n=122)

Baseline characteristics

49.6
mean age (yrs)

65.6%
women

18.3 months
current episode

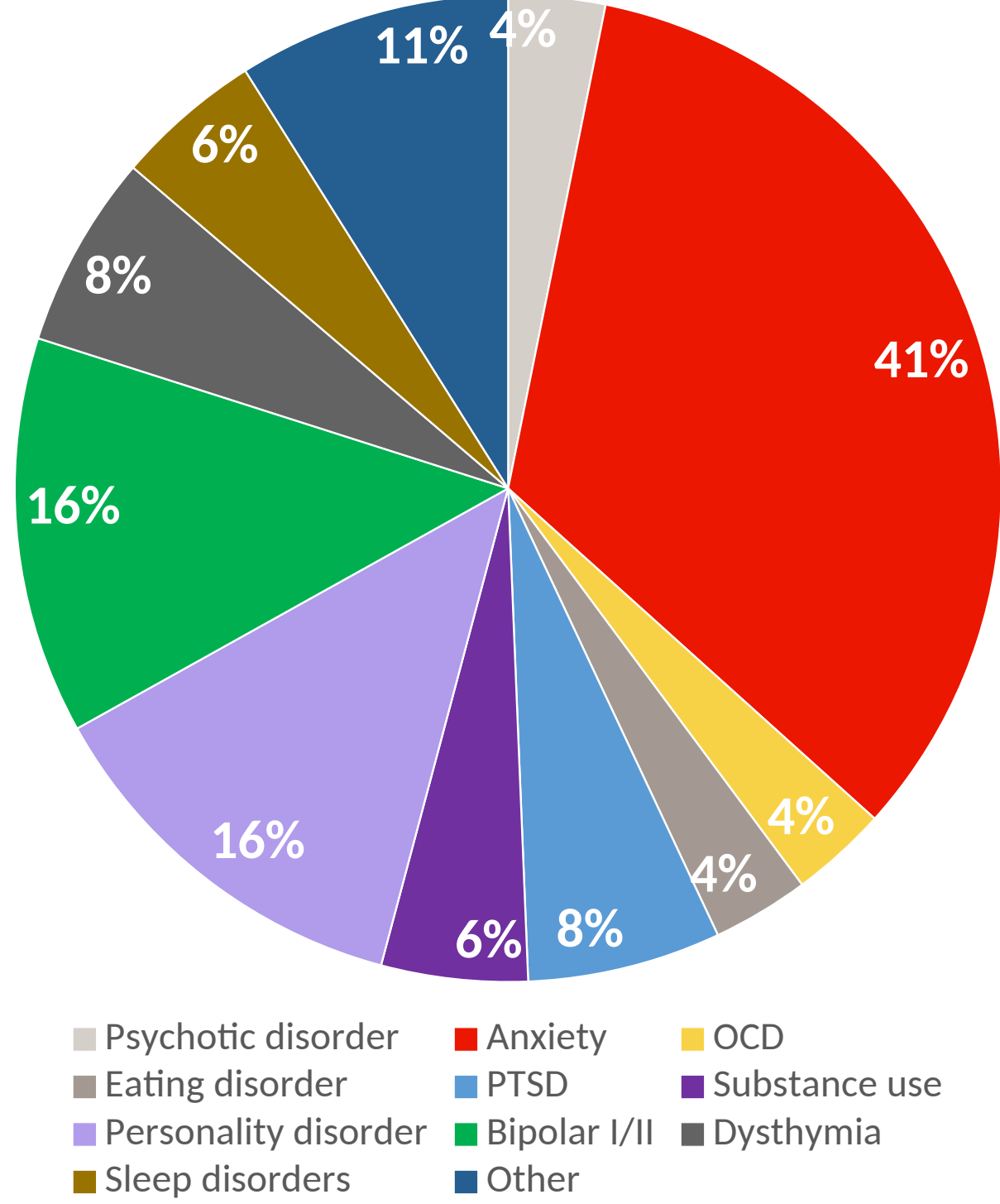
3.9
prior episodes

37.2
baseline MADRS

20.8
baseline PHQ-9

37.7%
with suicidal ideation at baseline

Psychiatric comorbidities (%)



51 of 122 patients reported 62 psychiatric comorbidities.

RESULTS

Depression severity, suicidality & functionality over 5 months (Day 155) · n = 122

Fig 1. Remission & response (MADRS), by line

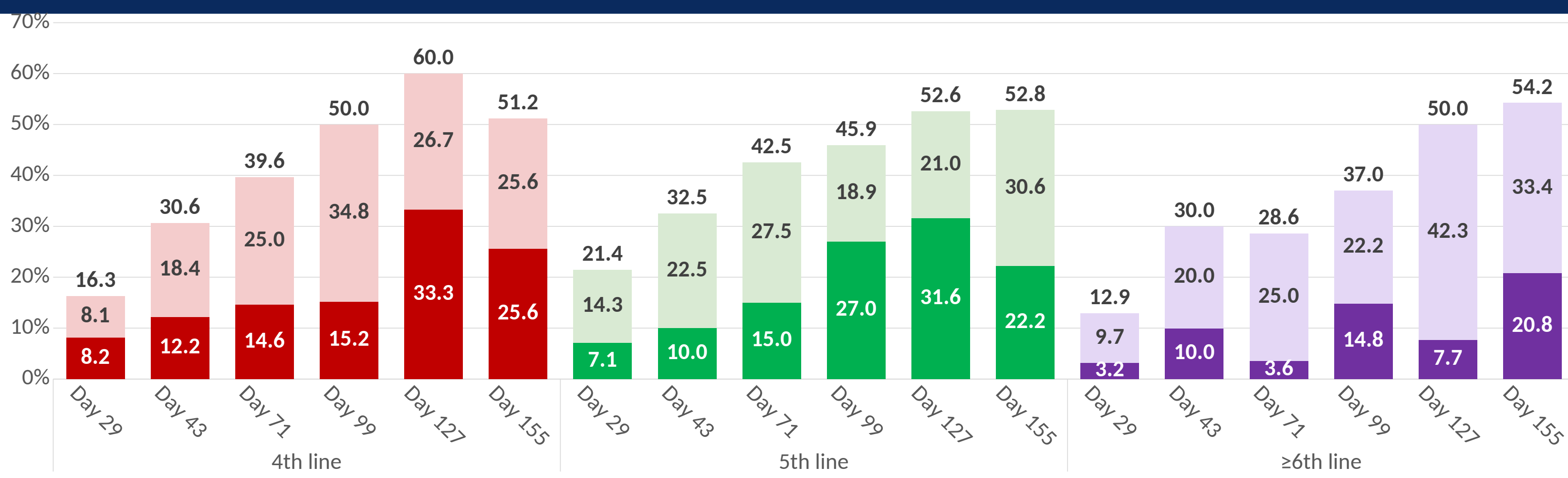


Fig 2. PHQ-9 severity categories over time (%)

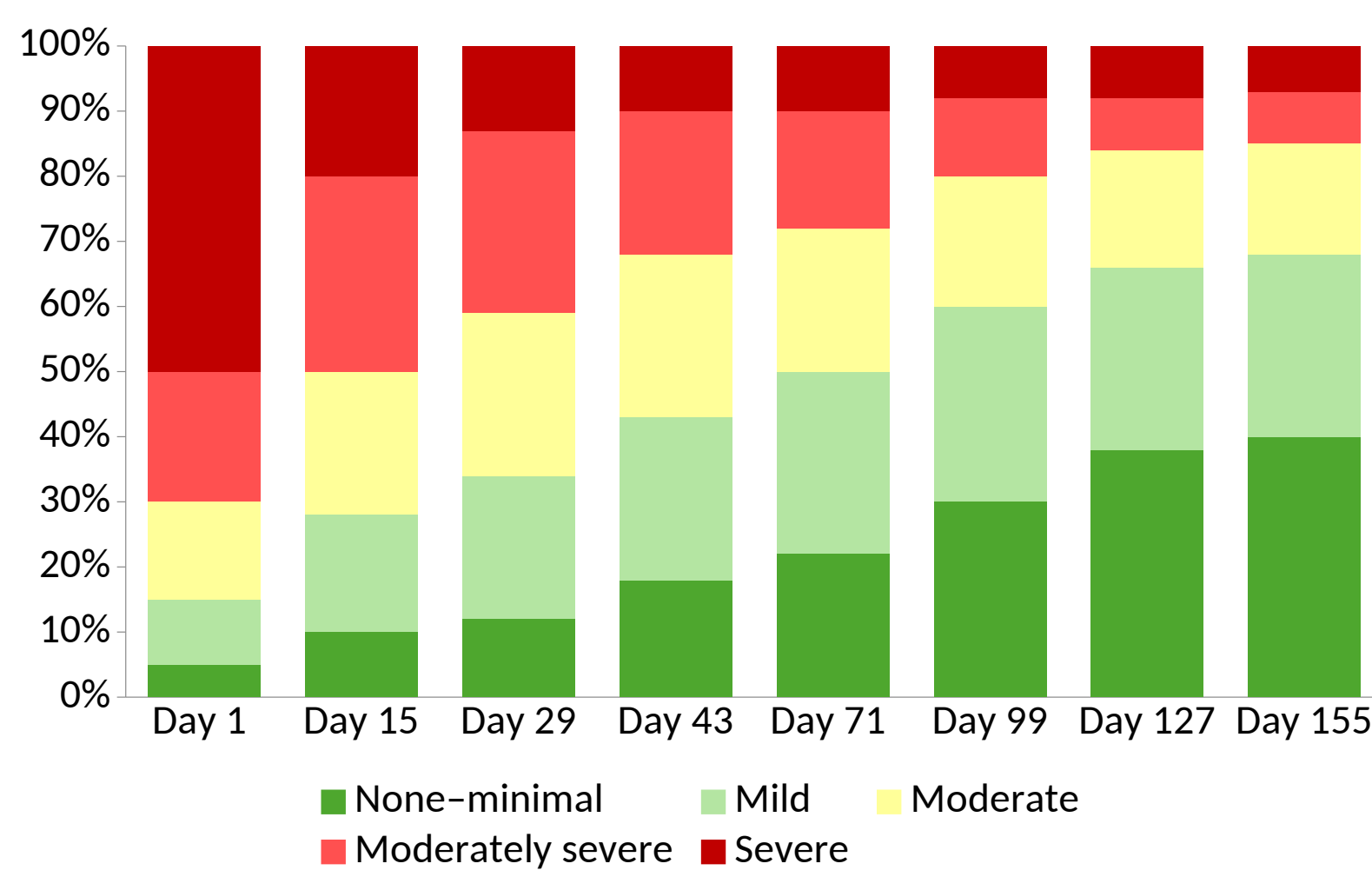


Fig 3. Emergency Department visits and hospitalizations, 6M pre-inclusion and during treatment

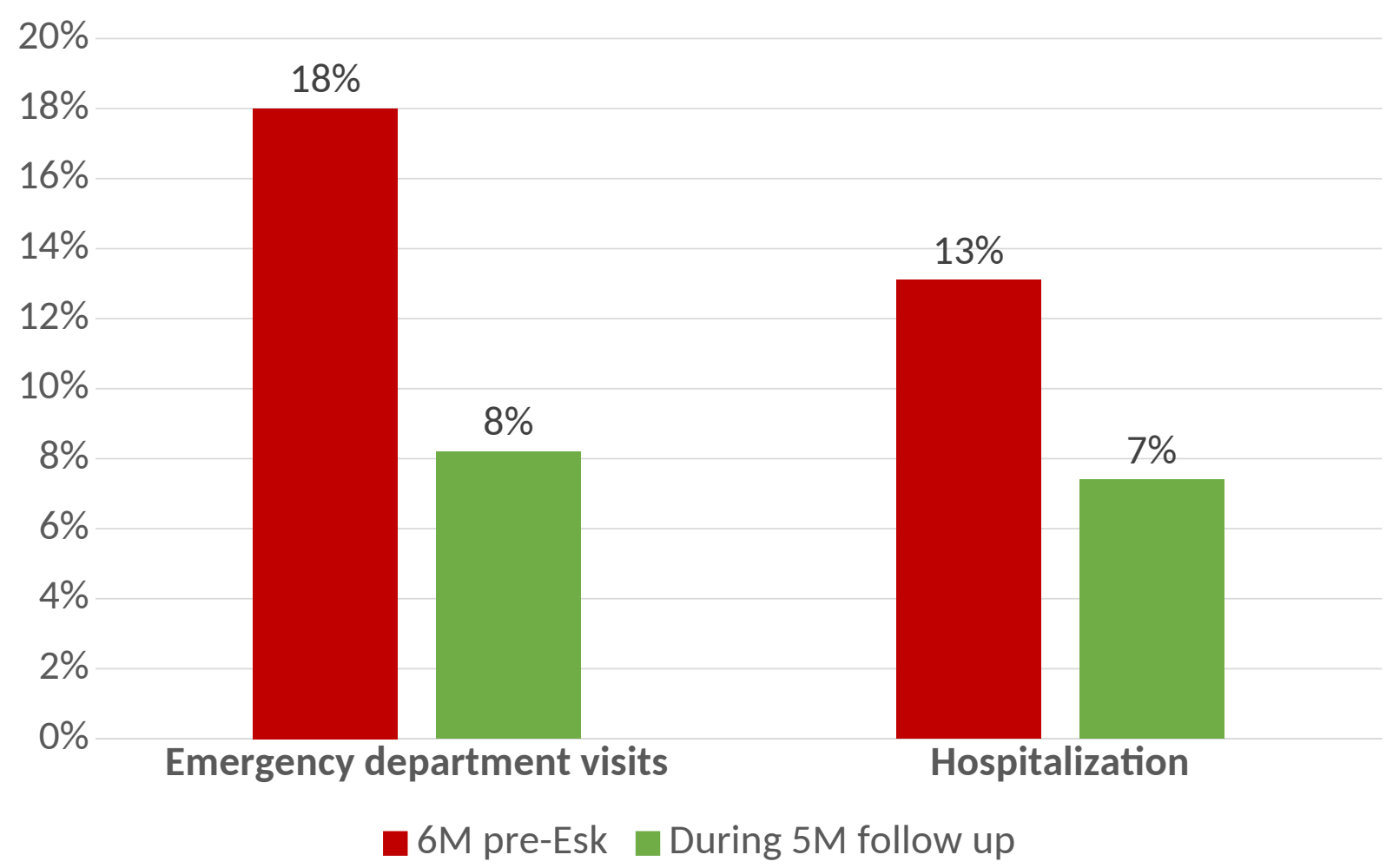


Fig 4. Suicidal ideation over time (MADRS item 10, %)

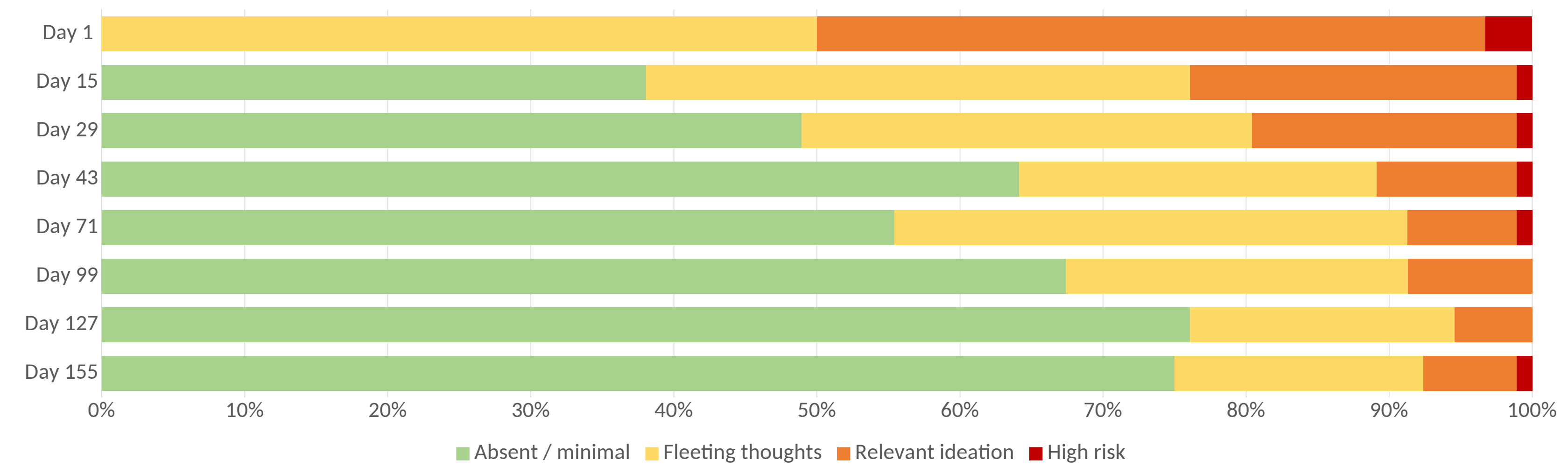


Fig 5. SDS functionality score evolution over time, by line (0-30)

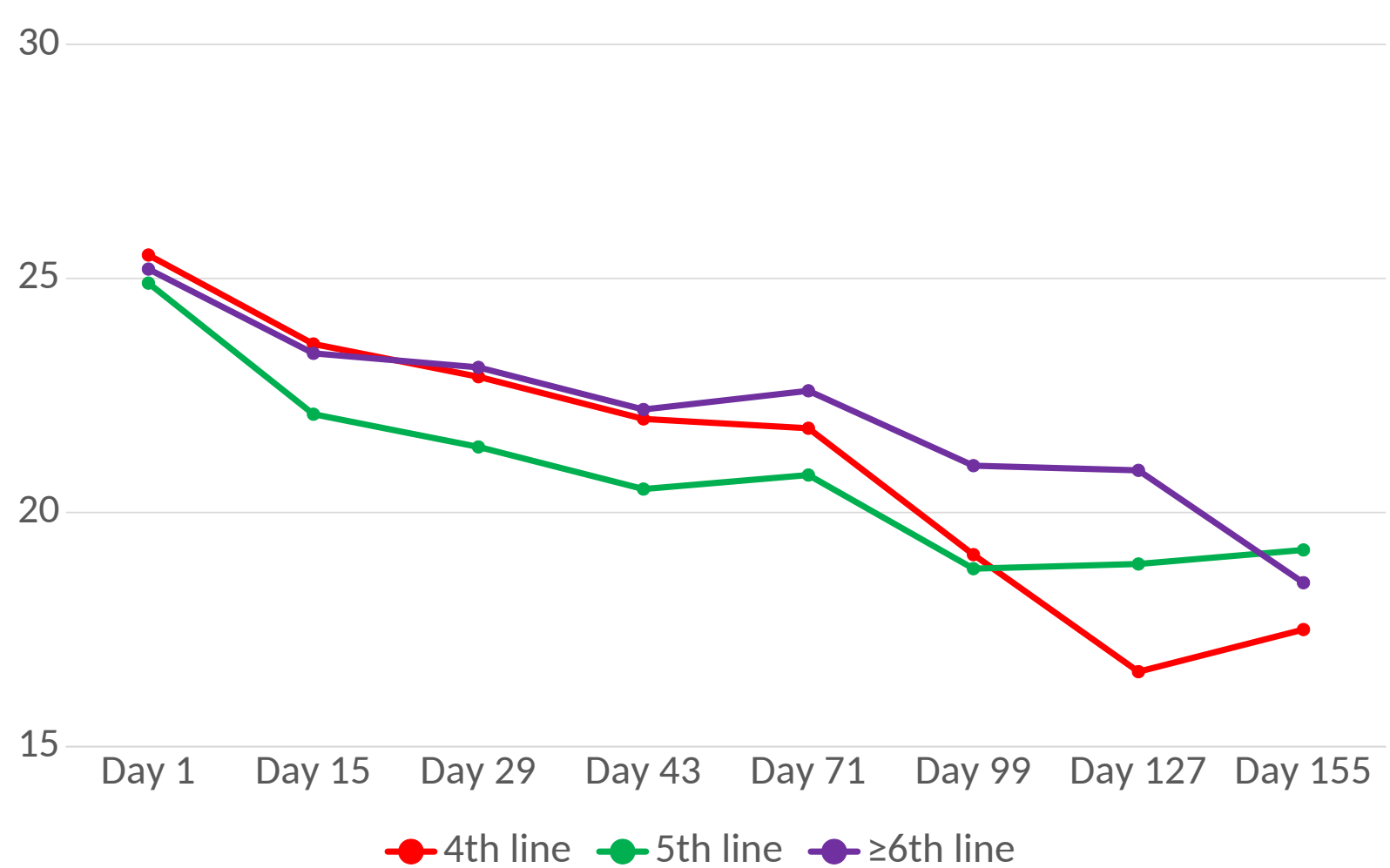


Fig 6. Reduction in lost days per week, by line

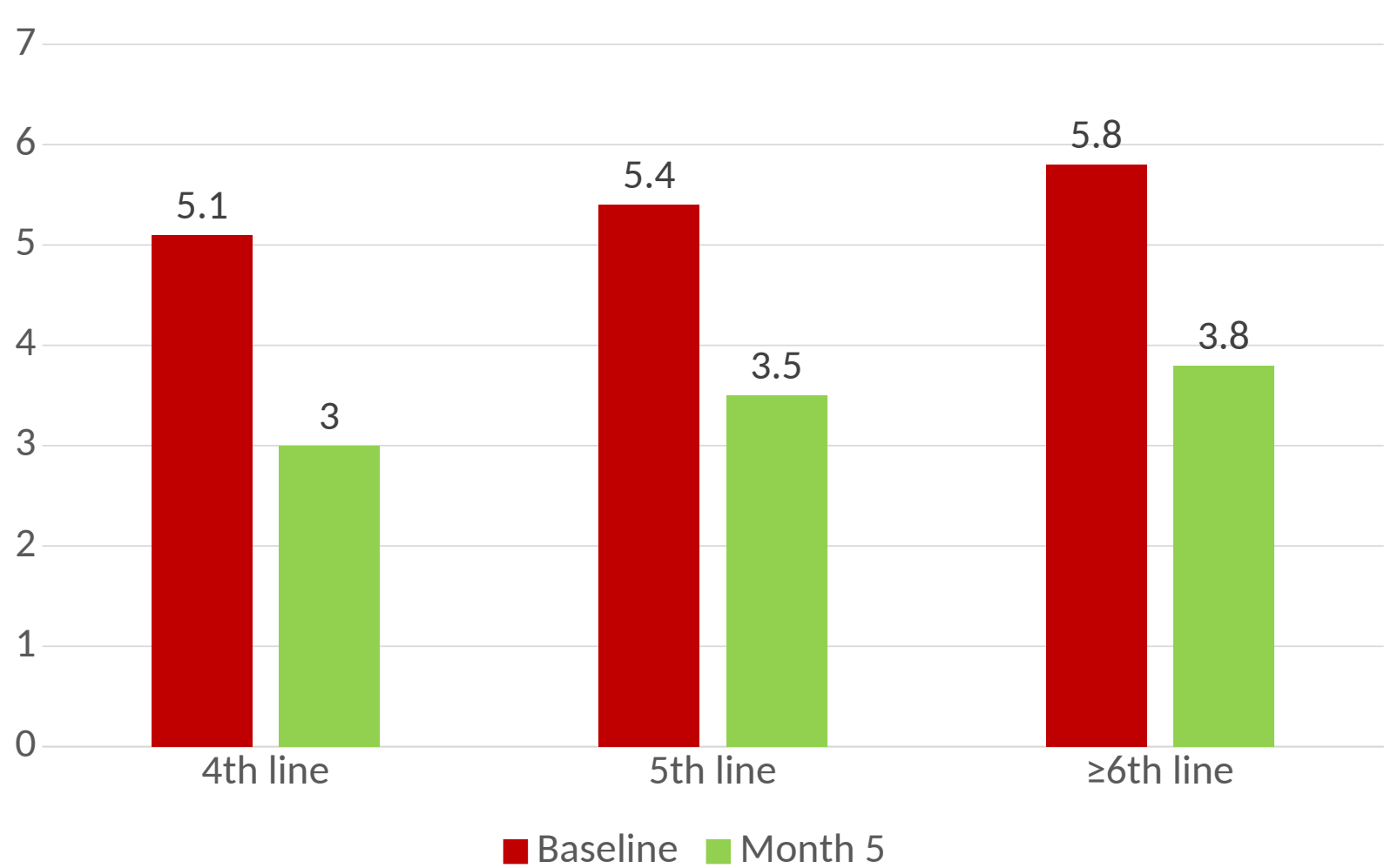
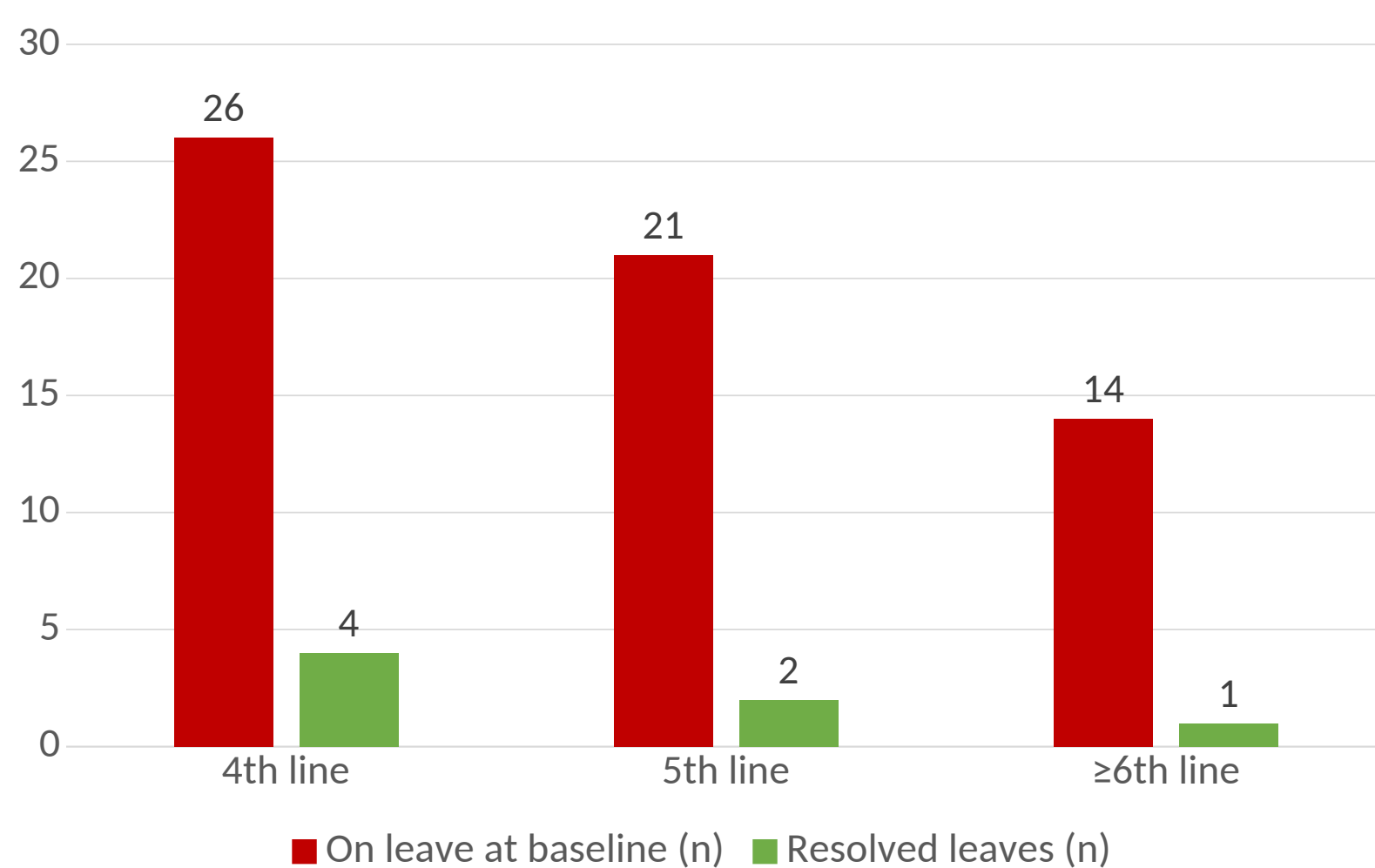


Fig 7. Medical leave — on leave vs resolved, by line



DISCONTINUATIONS DURING FOLLOW UP (5M)

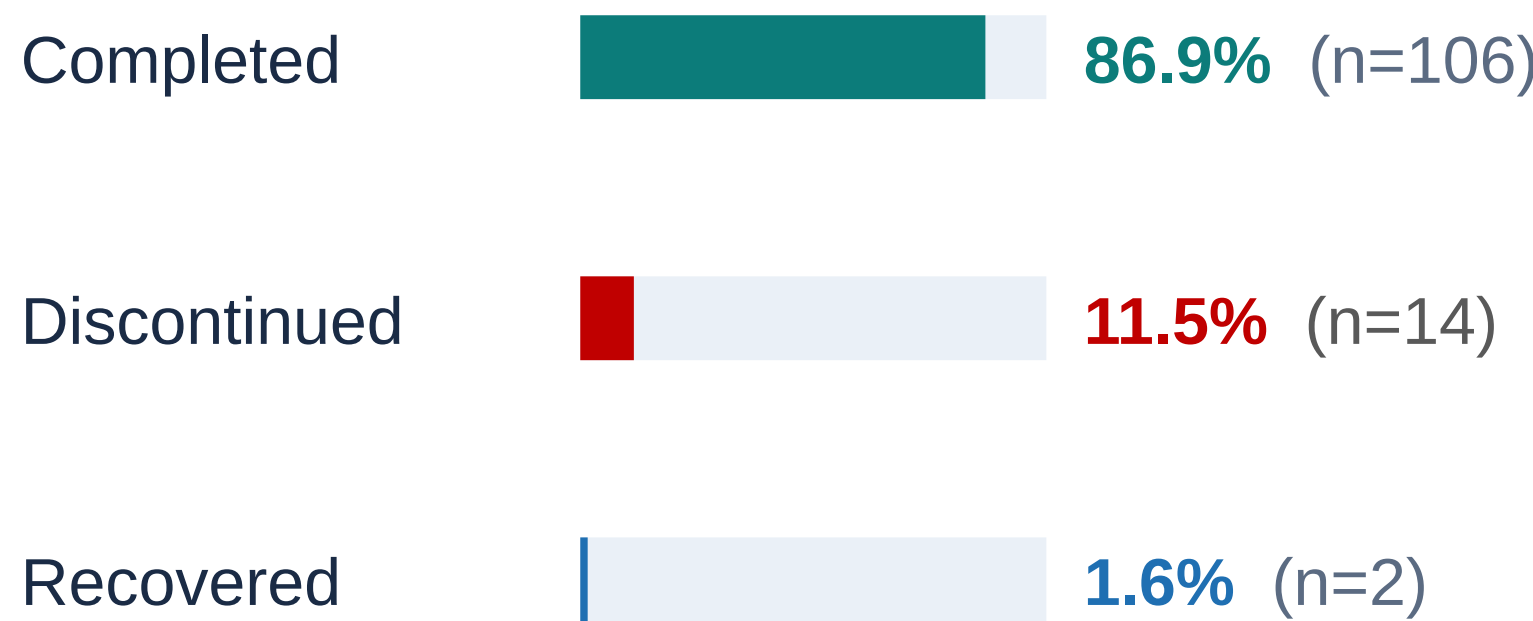
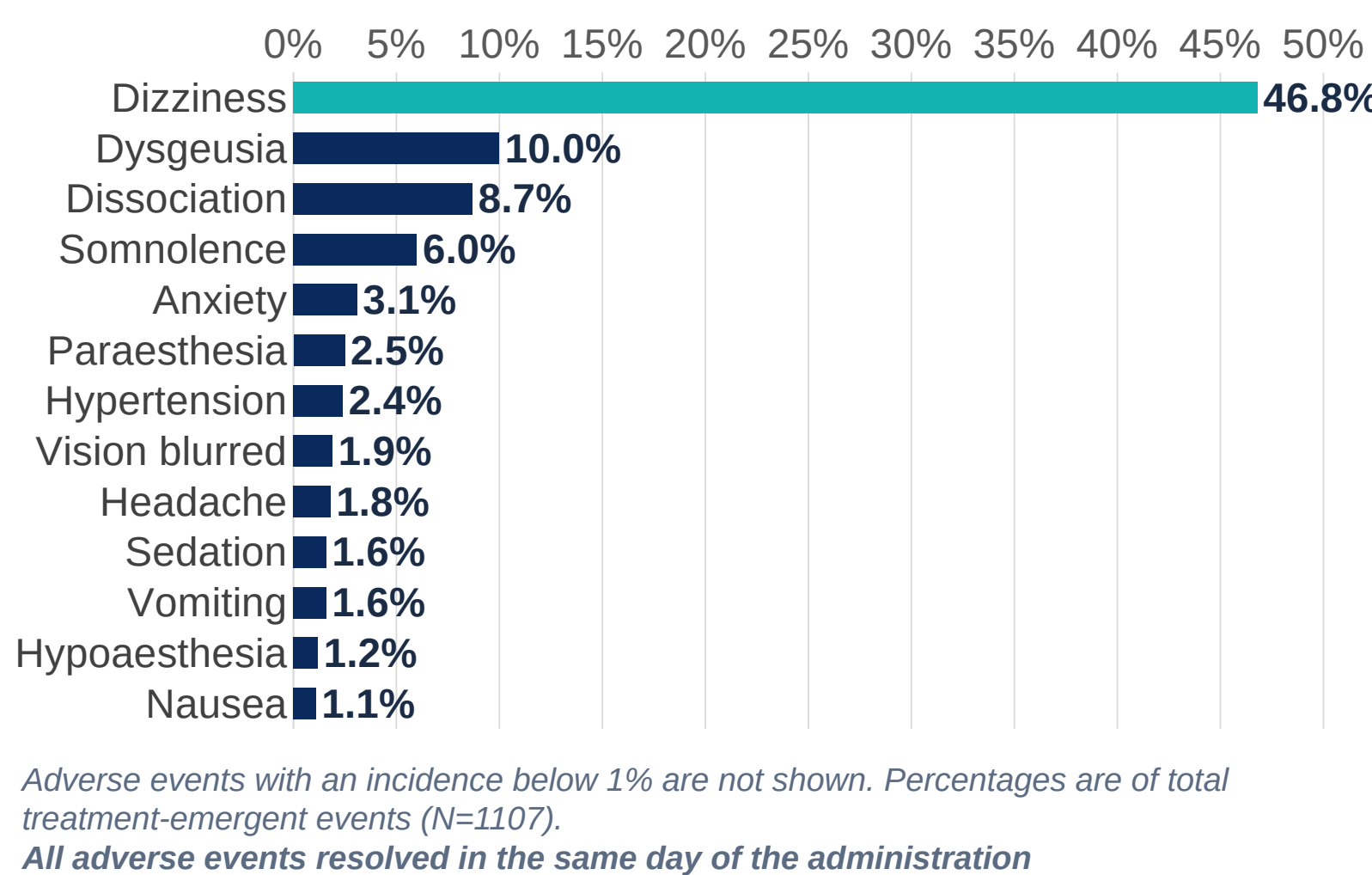


Fig 8. Most frequent adverse events by preferred term (incidence $\geq 1\%$)



CONCLUSIONS

Depression severity fell progressively, baseline suicidal ideation resolved in 75% of patients, hospitalizations and emergency room visits were reduced compared to 6M before receiving esketamine, and functionality and medical leave rates were improved.

Overall, treatment with Esketamine was associated with clinically meaningful improvements across all lines, with a trend toward greater benefit in patients with shorter disease evolution.

These results highlight the importance of detecting and treating TRD patients in order to improve treatment outcomes

DISCLOSURES This study is funded by Johnson & Johnson.

REFERENCES 1. Oliveira-Maia AJ, et al. Adv Ther. 2024. 2. Baig-Ward KM, Jha MK, Trivedi MH. Psychiatr Clin North Am. 2023;46(2):211-226.

MADRS, Montgomery-Åsberg Depression Rating Scale · PHQ-9, Patient Health Questionnaire-9 · TRD, treatment-resistant depression.