

Psychometric Properties of the Multiple Myeloma Symptom and Impact Questionnaire (MySIm-Q) in Patients With Relapsed/Refractory Multiple Myeloma (RRMM): Analysis of the MajesTEC-3 Study

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Key Takeaway

Aligning with previous analyses of MySIm-Q measurement properties,^{2,3} our analysis provides additional evidence that MySIm-Q is a reliable, valid, fit-for-purpose instrument that can detect changes in MM symptoms with RRMM therapies, including bispecific antibodies

Conclusions

The MySIm-Q total symptom score showed evidence of reproducibility (Cronbach's α coefficient, 0.77) and demonstrated good convergent validity and known-groups validity

A high correlation was observed between MySIm-Q total symptom score and the estimated total symptom score from a second-order model, as determined through confirmatory factor analysis

Anchor- and distribution-based analyses demonstrated that the MySIm-Q total symptom score is responsive to change and capable of differentiating patients with improvement or worsening of their condition or health state

For the MySIm-Q total symptom score, the data suggested thresholds of -0.3 for minimum improvement and $+0.3$ for minimum worsening

Introduction

- With an expanding treatment landscape in multiple myeloma (MM), validated disease-specific measures are needed to assess the symptoms and impacts of treatment as experienced by patients with MM
- The MySIm-Q is a patient-reported outcome (PRO) instrument that was designed to evaluate the efficacy of novel treatments on disease-related symptoms and impacts that are the most relevant to patients with active MM¹
 - MySIm-Q was developed following guidance from the US Food and Drug Administration and European Medicines Agency
- Psychometric analyses of MySIm-Q in RRMM populations using data from previous MM clinical studies support MySIm-Q as a fit-for-purpose PRO instrument in MM studies^{2,3}
- The assessment of psychometric properties of the MySIm-Q total symptom score and validation of this score as an endpoint are confirmed using a sample of patients with RRMM from the MajesTEC-3 clinical study⁴

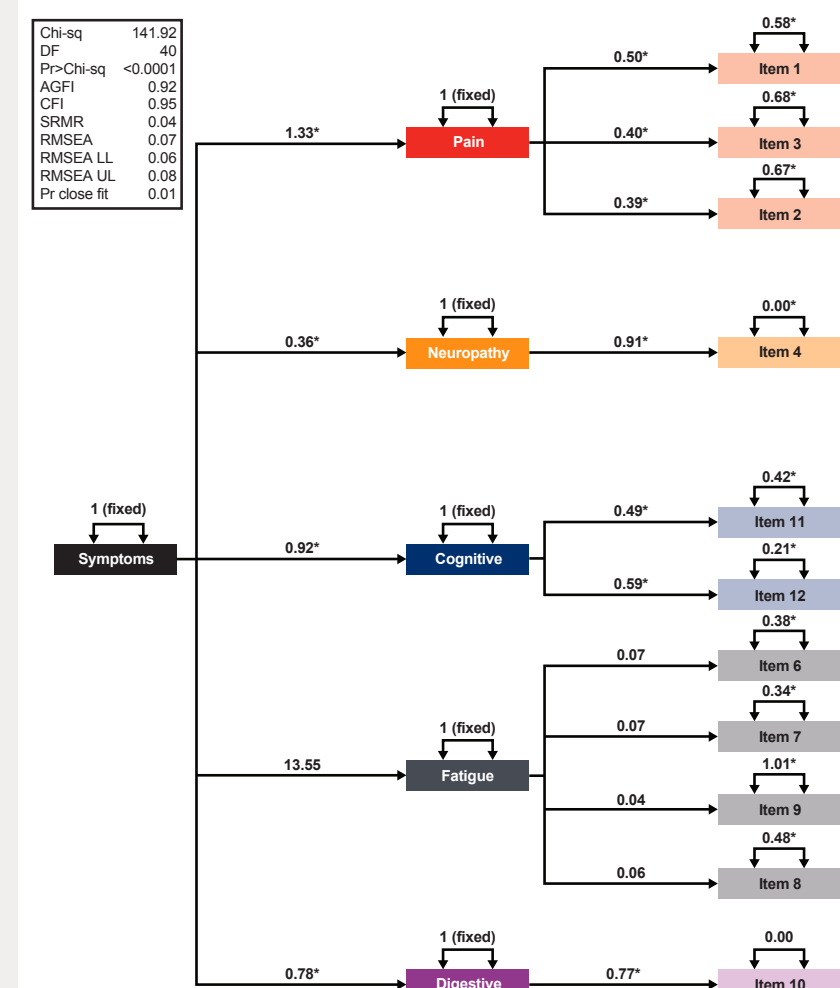
Methods

- MySIm-Q includes 17 items that address 5 symptom domains (pain, neuropathy, cognitive, fatigue, digestive) and 3 impact domains (activity, social, emotional) using symptom and impact subscales.¹ Total symptom score domains and items are shown in **Figure 1**
 - Recall period is "the past 7 days," with responses reported on a 5-point verbal rating scale (range, 0-4)
 - Total symptom and impact scores are calculated as the mean of scores from their respective domains
- Following an evaluation framework for PRO measurement properties, the MySIm-Q total symptom score was assessed through internal consistency, test-retest reliability, convergent validity, and known-groups validity
- Meaningful within-patient change in MySIm-Q symptom score was assessed through anchor-based and distribution-based methods using change in the Patient's Global Impression of Severity (PGIS) of Multiple Myeloma
- The analysis used data from MajesTEC-3, a randomized, phase 3 study⁴ that is investigating teclistamab + daratumumab versus investigator's choice of standard-of-care therapy (daratumumab + dexamethasone + pomalidomide or bortezomib [D-Pd or D-Vd] regimens) in patients with RRMM who had received 1 to 3 prior lines of therapy⁴
 - The presented data are based on an interim analysis of MajesTEC-3 (data cutoff of August 1, 2025), with data pooled without regard to treatment assignment
 - PRO data included in this analysis were collected on Day 1 of Cycle 1 (baseline) and Day 1 of Cycle 7

Results

- In total, 541 patients completed MySIm-Q assessments and were included in this analysis
- The internal consistency estimate for the MySIm-Q total symptom score (Cronbach's α coefficient, 0.77) exceeded the predefined threshold (≥ 0.70)
 - All evaluable symptom domains also met the predefined threshold, with a Cronbach's α coefficient of 0.70, 0.77, and 0.82 for the pain, cognitive, and fatigue domains, respectively
- The correlation between each item and its hypothesized scale exceeded 0.4 for all items, which met the criteria for item-level convergent validity
- Confirmatory factor model fitting found the best fit to be a second-order model with the 5 symptom scales as first-order factors loading onto a second-order factor of symptoms (**Figure 2**), with a root mean square error of approximation < 0.08 and comparative fit index of 0.95
 - The Pearson correlation coefficient between observed scores and estimated scores from the model was 0.92

Figure 2: Symptoms confirmatory factor model: second-order free weights

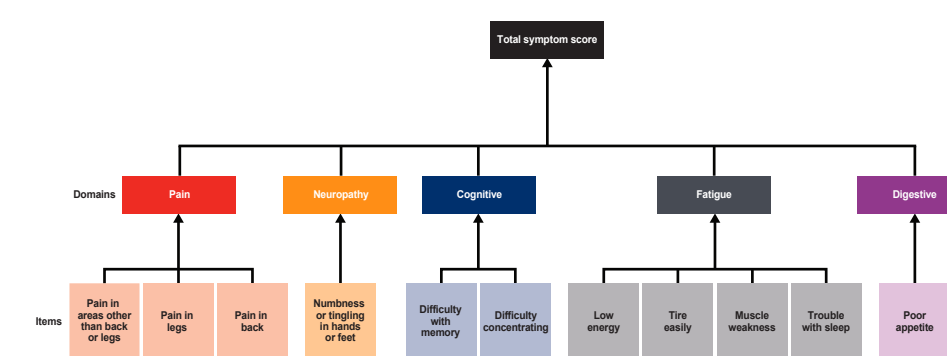


*P<0.05.
AGFI, adjusted goodness of fit index; CFI, comparative fit index; Chi-sq, chi-square; DF, degree of freedom; LL, lower limit; Pr, probability; RMSEA, root mean square error of approximation; SRMR, standardized root mean squared residual; UL, upper limit.

References

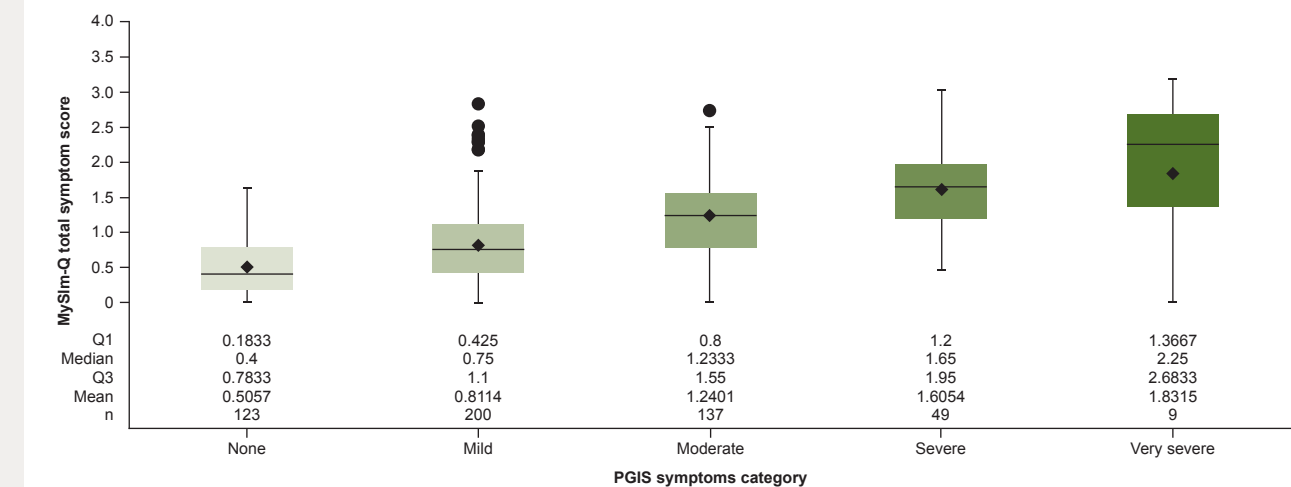
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Figure 1: Total symptom score domains and items¹



- Known-groups validity by PGIS symptom category at baseline is depicted in **Figure 3**; MySIm-Q total symptom scores increased with worsening PGIS severity, demonstrating clear discrimination across clinically meaningful severity groups and supporting interpretability of score differences

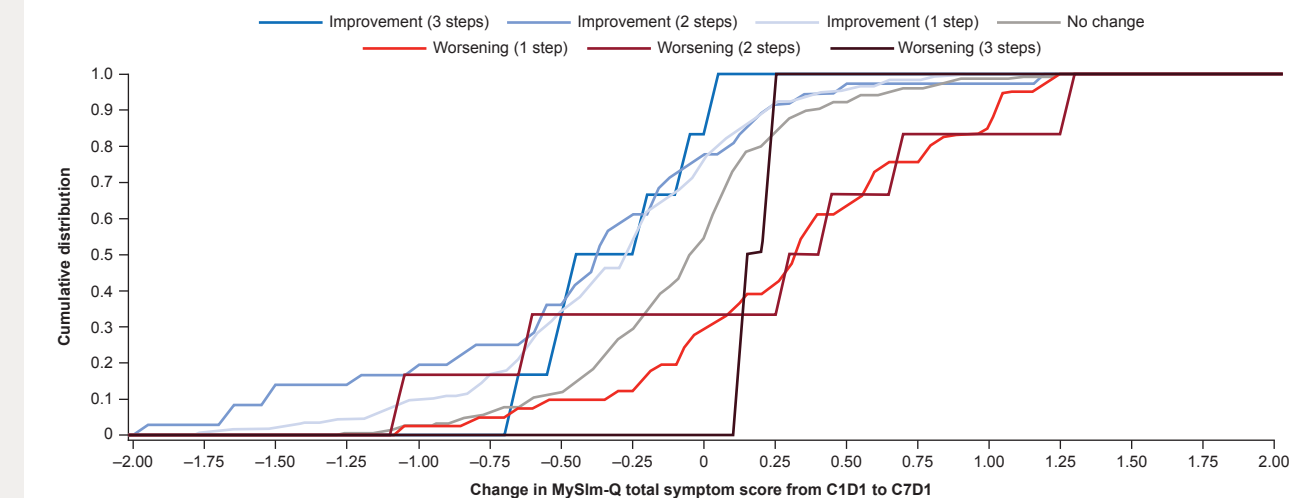
Figure 3: Box plots of MySIm-Q total symptom score by PGIS symptom category at C1D1



C, Cycle; D, Day; MySIm-Q, Multiple Myeloma Symptom and Impact Questionnaire; PGIS, Patient's Global Impression of Severity; Q1, quartile 1; Q3, quartile 3.

- The MySIm-Q total symptom score was able to detect changes in patient-reported symptoms from baseline to Day 1 of Cycle 7 based on PGIS symptoms criteria, with an effect size of 0.77 for improvement and 0.57 for worsening
- The MySIm-Q total symptom score also detected improvement and worsening in conditions based on multiple definitions; the cumulative distribution function for change in total symptom score by change in PGIS symptom category is shown in **Figure 4**; changes in MySIm-Q total symptom score were directionally and quantitatively aligned with changes in PGIS severity, demonstrating responsiveness and interpretability of symptom change
 - The threshold for minimum improvement (≤ -0.3 points) was met by 43/154 (27.9%) patients with no PGIS symptom change and by 60/119 (50.4%) patients with a 1-category PGIS symptom improvement
 - The threshold for worsening ($\geq +0.3$ points) was met by 19/154 (12.3%) patients with no PGIS symptom change and by 22/41 (53.7%) patients with a 1-category PGIS symptom worsening

Figure 4: Cumulative distribution function of change in MySIm-Q total symptom score by change in PGIS symptoms category at C7D1



C, Cycle; D, Day; MySIm-Q, Multiple Myeloma Symptom and Impact Questionnaire; PGIS, Patient's Global Impression of Severity.

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Disclosure

EGK is an employee of and may own stock or stock options in Johnson & Johnson.

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