

Development And Psychometric Validation of a Patient-Reported Core Symptom Set for Lung Cancer Patients on Chemotherapy

Ye Yang1,a, Juan Li1,a, Cheng Lei2, Xiangyu Tan3, Min Zheng1, Xiaoling Liu1, Zixin Wei1, Sudan Zheng1, Qiuling Shi4*, Xi Luo1*

1 Department of Medical Oncology, Sichuan Clinical Research Center for Cancer, Sichuan Cancer Hospital & Institute, Sichuan Cancer Center, Affiliated Cancer Hospital of the University of Electronic Science and Technology of China,Chengdu, China.

2 Department of Thoracic Surgery, Sichuan Clinical Research Center for Cancer, Sichuan Cancer Hospital & Institute, Sichuan Cancer Center, Affiliated Cancer Hospital of University of Electronic Science and Technology of China.Chengdu, China.

3 School of Public Health, Chongqing Medical University, Chongqing, China.

4 State Key Laboratory of Ultrasound in Medicine and Engineering,School of Public Health, Chongqing Medical University, Chongqing, China.

a Ye Yang and Juan Li contributed equally to this work and should be considered co-first authors.

Correspondence: Xi Luo, Email: luoxi@uestc.edu.cn; Qiuling Shi, Email: qshi@cqmu.edu.cn.

INTRODUCTION

Lung cancer patients often suffer multiple overlapping symptoms during chemotherapy. Existing patient-reported outcome (PRO) tools are frequently too long or poorly tailored for routine monitoring of chemotherapy-associated symptoms. This study aimed to develop a concise, clinically meaningful core-symptom scale and validate its psychometric properties for clinical use.

METHODS

This single-center prospective observational study developed a symptom-monitoring instrument. Twenty-four patients completed daily MDASI-LC (0-10 symptom scoring) throughout one chemotherapy cycle (Days 1-21). High-burden symptoms were screened by descriptive statistics and cluster analysis, and finalized by a 12-member expert panel (anonymous voting, consensus $\geq 75\%$). Psychometric properties were validated in 150 independent patients. Using two symptom-score windows and Day-7 EQ-5D-5L VAS as external reference, CTT and graded-response IRT were applied to evaluate reliability, validity and precision. Analyses were performed in R 4.5.2 (two-sided $p < 0.05$). Ethics approval was obtained (SCCHEC-02-2024-242).

DISCUSSION AND CONCLUSION

This study developed and validated a concise 6-item core symptom set (insomnia, fatigue, cough, nausea, constipation, shortness of breath) for high-frequency symptom monitoring in patients with lung cancer receiving chemotherapy. Multidimensional psychometric analyses confirmed acceptable measurement properties. As a brief tool lowering patient response burden, it meets clinical needs for routine symptom surveillance.

Several limitations should be acknowledged. The single-center design and validation limited to reliability and construct validity may restrict generalizability. Larger multicenter cohorts are required to evaluate scale transportability and longitudinal responsiveness. Further implementation studies within ePRO systems are needed to assess clinical feasibility, patient adherence and clinician workload, supporting external validation and real-world adoption.

ACKNOWLEDGEMENTS

- We thank all study participants for their support. We acknowledge Xu Wang, Qing Guo and Daofeng Shen from ePRO Vision (Beijing) Health Technology Co., Ltd. for technical support of the electronic symptom-management system.
- Doubao AI was used solely for language polishing. All scientific content, data interpretation and clinical assessments reflect the authors' independent work; no AI tool affected the scientific integrity of this poster

RESULTS

Six symptoms were retained: insomnia, fatigue, cough, nausea, constipation, and shortness of breath (Table 1). The core symptom set showed good internal consistency (Cronbach's $\alpha = 0.842$); item-deletion analysis indicated dropping any item would lower this coefficient. Acceptable agreement was observed across adjacent time windows (all ICCs ≥ 0.542 , $p < 0.001$). Exploratory factor analysis supported unidimensionality, with one factor accounting for 56.5% of variance. Moderate correlation between higher core-symptom scores and poorer EQ-5D-5L VAS scores confirmed convergent validity. Scores declined from Week 1 to Week 2 with small-to-moderate effect sizes (Cohen's $d = 0.217$ - 0.628), demonstrating responsiveness. IRT analyses revealed favorable item discrimination, ordered thresholds, and optimal measurement precision for mild-to-moderate symptom burden.

Table 1. Descriptive Statistics, Internal Consistency, and Factor Loadings for the Six-Item Core Symptom Set (n = 150).

Item	M	SD	Cronbach's α		retest reliability		Structural validity		
			Total	if item deleted	ICC	p	Factor loading	Communality (h^2)	Item-total correlation ($r_{i\cdot}$)
Total	2.88	1.72	0.842	-	-	-	-	-	-
Insomnia	3.53	2.60	-	0.824	0.578	<0.001	0.719	0.517	0.587**
Fatigue	3.61	2.40	-	0.783	0.563	<0.001	0.867	0.752	0.776**
Nausea	2.22	2.29	-	0.823	0.545	<0.001	0.715	0.511	0.582**
Constipation	3.13	2.42	-	0.822	0.542	<0.001	0.722	0.522	0.591**
Cough	2.27	1.95	-	0.834	0.743	<0.001	0.662	0.438	0.519**
Shortness of breath	2.52	2.06	-	0.805	0.556	<0.001	0.806	0.649	0.687**

Note. ** $p < 0.01$. One-factor solution extracted. Overall KMO = 0.857; Bartlett's test of sphericity $X^2 = 1064.2$, $p < 0.001$. The first factor had an eigenvalue of 3.389 and explained 56.5% of the total variance. Retest reliability was assessed between window 1 and window 2. Abbreviations: M, Mean; SD, Standard Deviation; ICC, Intraclass Correlation Coefficient; KMO, Kaiser-Meyer-Olkin.