

Psychometric validation of QLQ-OES18 in 2L esophageal squamous cell cancer (ESCC) patients treated with tislelizumab versus chemotherapy

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OBJECTIVES

The purpose of this analysis was to evaluate the measurement properties of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Oesophageal Cancer 18 question module (EORTC QLQ-OES18) in patients with advanced or metastatic ESCC.

METHODS

Analyses were conducted using data from RATIONALE 302 (NCT03430843), a global, open-label, randomized, phase 3 study, that investigated tislelizumab versus investigator-chosen chemotherapy as second-line treatment for patients with advanced or metastatic ESCC whose disease progressed after first-line systemic therapy. The EORTC Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) and QLQ-OES18 instruments at baseline and week 3 were used in the analysis. Psychometric validation of the QLQ-OES18 included tests of reliability (internal consistency and test-retest reliability) and construct validity (convergent and known-groups validity).

RESULTS

A total of 512 patients were included. Three of the four QLQ-OES18 domain scores (dysphagia, eating, and pain) and index score demonstrated acceptable internal consistency ($\alpha \geq 0.70$). The intraclass correlation coefficient (ICC) estimates ranged between 0.41 to 0.78; three domain scores (dysphagia, eating, and pain) and the index score met the pre-specified criterion of $ICC \geq 0.70$, demonstrating acceptable test-retest reliability. Associations between QLQ-OES18 scores and the convergent/discriminant validators were as expected. The QLQ-OES18 pain score had a positive and strong correlation with the QLQ-C30 pain score. The QLQ-OES18 scores did not correlate with the QLQ-C30 constipation, diarrhea, and financial difficulties scores. For known-groups analyses, 88.64% of analyses demonstrated the hypothesized direction of effect, suggesting that the expected differences in QLQ-OES18 scores between pre-specified groups (i.e., region) were observed.

CONCLUSIONS

Within the RATIONALE 302 population, specific domains within the EORTC QLQ-OES18 demonstrated consistent quality in psychometric properties. Specifically, the dysphagia

domain consistently demonstrated robust psychometric properties, supporting its use as a suitable patient-reported endpoint within this ESCC population.