

# Psychometric Validation of the EORTC QLQ-HCC18 in Patients with Previously Treated Unresectable Hepatocellular Carcinoma

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**OBJECTIVES :** To evaluate the measurement properties of the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Hepatocellular Carcinoma 18-question module (EORTC QLQ-HCC18) within a previously treated, unresectable HCC clinical trial population that was distinct from the published QLQ-HCC18 validation populations.

**METHODS :** Analyses were conducted using data from BGB-A317-208, an open label, international, clinical trial assessing efficacy and safety of the monoclonal antibody tislelizumab in adult HCC patients. The EORTC Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) and QLQ-HCC18 instruments were assessed at baseline, week 3 and week 9 follow-up visits. Per US Food and Drug Administration guidance, psychometric validation of the QLQ-HCC18 included reliability (internal consistency and test-retest), construct validity (convergent validity and known-groups validity), ability to detect change, and meaningful within-patient change (MWPC).

**RESULTS :** A total of 248 patients were included. Only the QLQ-HCC18 fatigue, nutrition, and index domains demonstrated acceptable internal consistency; acceptable test-retest reliability was found for domains of fatigue, body image, nutrition, pain, index, and the sexual interest item. The QLQ-HCC18 fatigue domain achieved the pre-specified criterion defining acceptable concurrent validity for 13 of 16 correlations, whereas the index domain achieved the pre-specified criterion for 15 of 16 correlations. In the assessment of ability to detect change, clear differentiation of the QLQ-HCC18 change scores between improvement and maintenance anchor groups were observed for body image, fatigue, pain, and index domains, whereas differentiation between deterioration and maintenance anchor groups were observed for fever and fatigue domains. MWPC estimates defining improvement for the QLQ-HCC18 fatigue and index domains were -7.18 and -4.07, respectively; MWPC estimates defining deterioration were 5.34 and 3.16, respectively.

**CONCLUSIONS :** The EORTC QLQ-HCC18 fatigue and index domains consistently demonstrated robust psychometric properties, supporting the use of these domains as suitable patient-reported endpoints within a previously treated, unresectable HCC patient population.

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