Associations between ECOG performance status (PS) and patient-reported outcomes (PROs) in patients with gastric or gastroesophageal junction (G/CEJC) adenocarcinoma: results from the RATIONALE-305 trial

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ABSTRACT

Background: PROs provide critical insight into how patients experience disease and treatment, capturing aspects not reflected in clinician-reported assessments. In clinical practice, ECOG-PS guides functional assessment and trial eligibility decisions, yet associations with patient-reported global health status (GHS) quality-of-life (QoL])/functioning and gastric cancer (GC)–specific symptoms in patients with G/GEJC remain underexplored. This study evaluates whether baseline ECOG-PS is associated with PROs.

Methods: Baseline (pre-treatment) PRO data from the RATIONALE-305 trial were pooled across treatment arms (tislelizumab + chemotherapy vs placebo + chemotherapy). Seven domains from the EORTC QLQ-C30 (GHS/QoL, physical and role functioning, fatigue, pain, constipation, diarrhea) and four QLQ-STO22 GC–specific domains (dietary restrictions, dysphagia, pain, upper gastrointestinal symptoms), plus the EQ-5D-5L visual analog scale were analyzed. Profile analysis using one-way multivariate analysis of variance (MANOVA) with Wilks' lambda was used to compare the pattern and magnitude of PRO scores between ECOG-PS groups (0 vs 1). Post-hoc *t*-tests compared ECOG-PS 0 vs 1 for each domain.

Results: Data from 932 patients were analyzed by baseline ECOG-PS (0 vs. 1). For the QLQ-C30, statistically significant differences in PRO domain means were observed across ECOG-PS groups

(MANOVA; $p = 0.021$). Profile analysis showed that while the overall pattern of symptom and function scores were similar between groups ($p = 0.056$), patients with ECOG 1 reported worse outcomes ($p = 0.040$). Post hoc *t*-tests demonstrated significantly lower GHS/QoL ($p < 0.001$) and physical functioning ($p = 0.023$), and higher pain ($p = 0.034$) for ECOG-PS 1 compared with ECOG-PS 0. No associations were observed for QLQ-STO22 GC–specific symptom domains.

Conclusion: Higher baseline ECOG-PS scores were significantly associated with lower patient-reported GHS/QoL, reduced physical functioning, and increased pain, but not with GC–specific domains, suggesting that ECOG may not fully capture GC–specific symptom burden at baseline. Taken with ECOG-PS's established role, these findings support using PROs as a complement to ECOG-PS at treatment initiation to inform clinical decision-making in patients with G/GEJC. Ongoing longitudinal analyses will clarify prognostic and tislelizumab-related associations.