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Correlation from work productivity loss (WPL) and European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ-C30) domains from the MONALEESA-7 (ML-7) trial of premenopausal women with HR+/HER2− advanced breast cancer (ABC)

Background: The international, randomized, double-blind, placebo-controlled, Phase III ML-7 trial (NCT02278120) assessed ribociclib + endocrine therapy (ET) vs ET alone in premenopausal women with HR+/HER2− ABC. To our knowledge, the relationship between WPL and domains of the EORTC QLQ-C30 and the tumor-specific module for breast cancer (QLQ-BR23) has not been explored in ABC. In this post hoc analysis (data cutoff, November 30, 2018) of all patients (pts) enrolled in ML-7, we assessed the correlation between the WPL component of the Work Productivity and Activity Impairment: General Health (WPAI:GH) questionnaire and domains of the EORTC QLQ-C30/BR23.

Methods: We analyzed EORTC and WPAI:GH data from all pts enrolled in ML-7 who were employed at any point during the trial (N = 329 of 672 total pts). Domains of the EORTC QLQ-C30 and QLQ-BR23 that had the greatest correlation (pairwise Pearson correlation) with WPL were prioritized for analysis. Separate univariable mixed-model repeated-measures regression models were fitted for each domain, with WPL as the dependent variable and each EORTC domain as a single fixed-effect covariate. Linear and quadratic relationships were considered. Model selection was based on the Akaike information criterion (AIC).

Results: Linear models were favored over quadratic models. WPL was negatively correlated with global health status (GHS) and the physical, role, social, and emotional functioning domains and was positively correlated with the fatigue and pain domains of the QLQ-C30 ($P < .001$; Table). The coefficients indicated the estimated mean change in WPL was associated with a 1-unit increase in each QLQ-C30 domain. For example, a 10-point increase in GHS was associated with an estimated mean decrease of 7.8% (95% CI, 7.1%-8.5%) in WPL.

Conclusions: Greater WPL was associated with higher levels of fatigue and pain and with lower levels of overall quality of life and physical, role, social, and emotional functioning among pts with HR+/HER2− ABC in ML-7. Further investigation of the correlation with QLQ-BR23 and multivariable analysis could determine which EORTC domains and items independently drive these findings.

Domain	AIC (Linear)	AIC (Quadratic)	Regression Coefficient (Linear Model) (95% CI)	*P* Value
Fatigue	19,475.96	19,486.02	0.61 (0.54 to 0.67)	< .001
Pain	19,469.70	19,470.45	0.53 (0.47 to 0.59)	< .001
Physical functioning	19,383.55	19,389.79	−0.98 (−1.07 to −0.88)	< .001
Global health status	19,291.10	19,303.40	−0.78 (−0.85 to −0.71)	< .001
Role functioning	19,359.71	19,373.50	−0.65 (−0.71 to −0.60)	< .001
Social functioning	19,443.55	19,457.02	−0.59 (−0.65 to −0.53)	< .001
Emotional functioning	19,557.42	19,570.86	−0.49 (−0.56 to −0.42)	< .001