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Health related quality of life in women with HR+/HER2- advanced or metastatic breast cancer treated in real world settings in Italy and Germany

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Background: Real-world data on health-related quality of life (HRQoL) in women with HR+/HER2- advanced/metastatic breast cancer (ABC/mBC) are limited. This study aims to address this gap.

Methods: MARIA is a non-interventional, prospective, multi-center study that includes women in Italy and Germany initiating their first or second therapy in the HR+/ HER2- ABC/mBC setting. Breast cancer specific HRQoL was assessed using the Functional Assessment of Cancer Therapy-Breast (FACT-B). We report baseline clinical characteristics and HRQoL assessments at enrollment (baseline) and at 3 and 6 months for the first 262 patients enrolled. Change from baseline was calculated for patients with both baseline and follow-up measurement and tested for statistical significance using t-tests for the overall cohort and within subgroups stratified by visceral and bone metastases status.

Results: Median age was 61 years and 46% had visceral disease. At enrollment, 32% were receiving endocrine monotherapy, 34% chemotherapy alone, 28% endocrine/ targeted therapy combinations, and 7% other regimens. A statistically significant (p < 0.05) deterioration was observed in the overall cohort at Month 3 for both FACT-B (-4.9 [14.9]) and FACT-G (-4.1 [13.2]) and at Month 6 for the total FACT-G score (-2.1 [12.7]). In the subgroup with visceral and bone metastases, a statistically significant (p < 0.05) deterioration was observed in FACT-G scores at 3 months: (-6.6 [16.1]) and at 6 months (-3.6 [12.3]) while no significant change was observed in FACT-B scores. A statistically significant (p < 0.05) deterioration from baseline was observed in the subgroup with visceral disease and without bone metastases in FACT-B score at 3 months (mean [SD]: -6.7 [13.9] and at 6 months (-3.9 [16.6]), respectively while no significant change was observed in FACT-G scores.

Conclusions: A statistically significant deterioration was observed in HRQOL scores at some time points after initiating a new line of therapy in the overall cohort and some subgroups of HR+ HER2- MBC patients in a prospective study In Italy and Germany. Further follow-up is ongoing to examine the longer-term impact of therapy on HROoI.

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