Quality of life analysis from the phase II RIGHT Choice study of first-line ribociclib + endocrine therapy vs combination chemotherapy in aggressive HR+/HER2– advanced breast cancer

INTRODUCTION
Combination chemotherapy (combo CT), which is associated with symptomatic adverse events such as nausea, vomiting, fatigue, and diarrhea, is the recommended first-line treatment for women with advanced breast cancer (ABC) who have hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative disease. In advanced ABC, disease has a substantial impact on quality of life (QOL), and the goal of treatment is to improve QOL of patients receiving RIB + ET than those receiving combo CT.

The QOL in HR+/HER2– patients receiving RIB + ET was numerically higher than in those receiving combo CT (Figure 4). Lower rates of discontinuation due to disease progression with respect to all deterioration events in the RIB + ET arm (HR 0.54; 95% CI, 0.36-0.85) contributed to the longer QOL compared with the QOL in the combo CT arm (HR 0.65; 95% CI, 0.37-1.13).

The QOL analysis of the RIGHT Choice trial showed that patients receiving RIB + ET gained statistically and clinically meaningful improvement in QOL compared with patients receiving combo CT.

METHODS
Premenopausal women with HR+ HER2– ABC were randomized 1:1 to receive RIB + ET or combo CT (Figure 1). The Functional Assessment of Cancer Therapy Breast (FACT-B) scores were determined at baseline and on completion of treatment. The authors also calculated the analysis of the composite end point of QOL and the trial outcome index (TOI) scores was determined by Kaplan-Meier methods.

RESULTS
TTD in Overall Health Status With RIB + ET vs Combo CT
The mTTD based on the composite end point for overall health status was longer by 8.0 months in the RIB + ET arm than in the combo CT arm (Figure 2A).

The mTTD based on a ≥ 10% decrease in FACT-B scores was 35.2 months in the RIB + ET arm and not reached in the combo CT arm (Figure 2B).

The cumulative incidence of a ≥ 10% decrease in FACT-B overall health status score was lower in the RIB + ET arm (49.2%) than in the combo CT arm (61.5%) (HR, 0.79; 95% CI, 0.66-0.95; P = 0.0076).

The mTTD based on a ≥ 10% decrease in FACT-B B overall health status score was longer by 3.5 months in the RIB + ET arm (39.3 months) than in the combo CT arm (35.8 months; HR, 0.69; 95% CI, 0.55-0.88; P = 0.0036).

TITD in Pain With RIB + ET vs Combo CT
The mTTD based on a ≥ 10% decrease in FACT-B pain score was 35.2 months in the RIB + ET arm and not reached in the combo CT arm (Figure 3).

The mTTD based on a ≥ 10% decrease in FACT-B pain score was 2.6 months longer in patients receiving RIB + ET than in those receiving combo CT (Figure 4).

The mTTD based on a ≥ 10% decrease in FACT-B pain score in the RIB + ET arm (34.7 months) was longer by 9.2 months compared with the mTTD in the combo CT arm (25.5 months; HR, 0.42; 95% CI, 0.26-0.69; P < 0.0001).

TND in Naused With RIB + ET vs Combo CT
The mTTD based on a ≥ 10% decrease in FACT-B nausea score was 27.3 months in the RIB + ET arm and not reached in the combo CT arm (Figure 5).

The mTTD based on a ≥ 10% decrease in FACT-B nausea score was 3.9 months longer in patients receiving RIB + ET than in those receiving combo CT (Figure 6).

The mTTD based on a ≥ 10% decrease in FACT-B nausea score in the RIB + ET arm (31.2 months) was longer by 10.3 months compared with the mTTD in the combo CT arm (20.9 months; HR, 0.50; 95% CI, 0.34-0.74; P = 0.0009).

KEY FINDINGS & CONCLUSIONS
This prospective QOL analysis of the RIGHT Choice trial showed that patients receiving RIB + ET, in general, experienced a statistically and clinically meaningful delay in deterioration of QOL compared with those receiving combo CT.

The TTD outcomes based on a ≥ 10% increase in FACT-B scores for overall health status, TOI, or nausea scores were favorable in patients receiving RIB + ET vs combo CT.

The TTD outcomes based on a ≥ 10% increase in FACT-B scores for pain was similar in patients receiving RIB + ET vs combo CT.

The TTD outcomes based on composite end points for overall health status, TITD, pain, or nausea scores were favorable in patients receiving RIB + ET vs those receiving combo CT.

A numerical trend favoring RIB + ET over combo CT in change in FACT-B overall health status was observed in patients receiving RIB + ET, those receiving combo CT, and those receiving both.

This analysis shows that treatment with first-line RIB + ET is associated with better QOL than with combo CT in patients with clinically aggressive HR+/HER2– ABC, providing additional supportive evidence for RIB + ET use in this patient population.

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