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Patient-reported outcomes of adjuvant therapy with CDK4/6 inhibitors for HR+/HER2- early breast cancer: a retrospective cohort study

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Introduction

- Breast cancer (BC) has consistently ranked as the most frequently diagnosed cancer and one of the leading causes of cancer-related mortality among women worldwide, HR+/HER2- is accounting for approximately 70% of all BC cases[1-2].
- The NATALEE[3] and MonarchE[4] studies consistently confirmed that the addition of CDK4/6 inhibitors (Ribociclib (RIB) and Abemaciclib (ABE)) to standard adjuvant endocrine therapy significantly improved survival prognosis.
- Patient-reported outcomes (PROs) play a critical role in evaluating drug efficacy, adverse events, and QoL in cancer patients, and have emerged as one of the key indicators for measuring treatment effects[5].

Objective

- To compare the patient-reported outcomes (PROs) and quality of life in patients with HR+/HER2- early breast cancer (EBC) treated with ribociclib (RIB) and abemciclib (ABE) as adjuvant therapy.

Methods and Materials

- A multicenter, retrospective cohort study was conducted in Chinese patients receiving ribociclib or abemciclib as adjuvant therapy for HR+/HER2- EBC.
- PRO data were collected via an electronic questionnaire. The questionnaire was based on the PRO scale for breast cancer patients in China (NCC-BC-A scale), EQ-5D-5L and safety information of CDK4/6 inhibitors, including six dimensions of physiological function, psychological status, social support, treatment related symptoms, economic dimension and overall self-evaluation.
- The higher score of the questionnaire, the better quality of life.

Results

- Between Mar 15, and May 12, 2025, 197 patients completed the survey, including 94 patients who received ribociclib and 103 patients who received abemciclib.
- Overall, 195 patients (99%) were female and two (1%) were male. No difference was observed in baseline characteristics such as age, employment status, medical insurance, and concomitant treatment.
- The total score of the PRO in ribociclib group was higher than that in abemciclib group (187.14±17.57 vs 180.66±22.26, p=0.024). In therapeutic domain, the score was significantly higher in ribociclib group (34.81±5.29 vs 32.77±5.51, p=0.009) (**Table 1**).
- Patients in ribociclib group were less affected by the treatment-related symptoms of diarrhea (3.88±0.53 vs 2.31±1.33, p<0.001), fatigue (2.29±0.91 vs 2.00±1.02, p=0.038) and hair loss (2.94±1.39 vs 2.49±1.24, p=0.018).
- The proportion of patients receiving ribociclib who discontinued due to the adverse events of long-term treatment (28.6% vs 50%) or reduced the dose due to adverse events (22.2% vs 70%) was lower (**Figure 1**).
- The overall health status score of ribociclib group was higher (6.67±1.27 vs 5.83±1.45, p<0.001).

Table 1. PRO total score and each dimension score

Category	Number of items	Total score	RIB (n=94)	ABE (n=103)	t-value	p-value
Physiological functional domain	8	32	25.34 ± 2.47	24.76 ± 3.23	1.432	0.154
Psychological domain	4	16	12.85 ± 2.11	12.27 ± 2.42	1.793	0.075
Social support domain	7	28	21.54 ± 2.79	21.95 ± 2.76	-1.034	0.302
Therapeutic domain	11	44	34.81 ± 5.29	32.77 ± 5.51	2.653	0.009
Economic dimension	1	4	2.13 ± 1.19	2.01 ± 1.25	0.678	0.499
Self-evaluation domain	4	112	90.47 ± 11.92	86.90 ± 14.69	1.878	0.062
Total	35	236	187.14 ± 17.57	180.66 ± 22.26	2.276	0.024

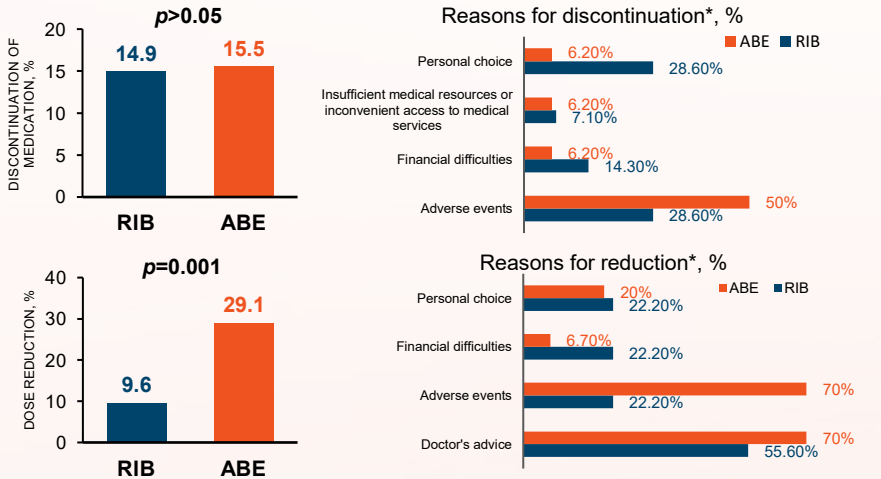


Figure 1. Summary of treatment

Results: Discontinuation of medication was reported for 14 patients (14.9%) in the RIB group and 16 patients (15.5%) in the ABE group. Dose reduction was experienced by 9 patients (9.6%) in the RIB group and 30 patients (29.1%) in the ABE group. The dose reduction rate was significantly lower in the RIB group.

Conclusion

- HR+HER2- EBC patients who received ribociclib had a better PRO score than those who received abemciclib. Patients in ribociclib group experienced less treatment-related adverse reactions, especially diarrhea, fatigue, and hair loss, and had a lower rate of discontinuation/reduction due to adverse events, a better self-evaluation of their overall health status.

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Ethics approval and consent to participate

This study was approved by the Medical Ethics Committee of Shandong First Medical University Affiliated Cancer Hospital (Ethics No. SDC202503003), and written informed consent was obtained from all participants prior to enrollment.

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