Poster# **438eP**

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Real-world characteristics, treatment patterns, and outcomes in patients with HR+/HER2− early breast cancer from China and the US

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KEY FINDINGS & CONCLUSIONS

- This harmonized analysis of 2 large, real-world databases highlights the differences in clinical characteristics and treatment patterns between patients with HR+/HER2− EBC treated in routine clinical practice in China and the US
- Patients with HR+/HER2- EBC in China were diagnosed at a younger age, were more likely to be premenopausal, and had higher rates of axillary node involvement, consequently they were more likely to undergo total mastectomy and be treated with adjuvant chemotherapy than patients in the US
- The risk of overall and distant recurrence was considerable in these 2 diverse populations, despite receiving available standard-of-care therapies
  - 3- and 5-year RFS and DRFS rates were similar both in China and the US in the overall population, across nodal status, and in the overall NATALEE-eligible population
- Despite differences in patient characteristics in China and the US, outcomes were comparable across these populations, and highlights a significant unmet need for patients with HR+/HER2− EBC

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INTRODUCTION

- Previous studies have suggested that there are major differences between the US and China in the characteristics (eg, age, stage at diagnosis) and treatment patterns (eg, rates of [neo]adjuvant therapy, breast-conserving surgery) in patients with all subtypes of breast cancer (BC)[1,2]
  - In the setting of hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) early BC (EBC), the treatment landscape in China and the US is similar, with standard-of-care therapies including surgery, chemotherapy, and/or radiation therapy followed by adjuvant endocrine therapy[3,4]
  - Further studies are needed to better understand the characteristics, treatment patterns, and outcomes in patients with HR+/HER2- EBC
- In the phase 3 NATALEE and monarchE trials, ribociclib and abemaciclib, respectively, demonstrated a reduction in the risk of recurrence in patients with HR+/HER2− EBC, which led to their approval in the adjuvant setting in both the US and China[5-7]
  - With the introduction of these treatments, assessment of treatment patterns and outcomes in Chinese and US patient populations can help in understanding unmet needs and aid in clinical decision-making in patients with high risk of recurrence
- In this analysis, we assess patient characteristics, eligibility for adjuvant CDK4/6 inhibitor, treatment patterns, and outcomes from Chinese and US electronic health record (EHR) databases of patients diagnosed with HR+/HER2− EBC between 2013 and 2022

METHODS

- This retrospective study used deidentified secondary data from the National Cancer Information Database (NCID) of China and the Flatiron Health US EHR database[8]
- Patients in this analysis were aged ≥18 and ≤80 years, were initially diagnosed with stage I to III HR+/HER2− EBC (in accordance with the American Joint Committee on Cancer's *Cancer Staging Manual*, 8th Edition) between 1 January 2013 and 31 December 2022, had undergone BC resection, and received ≥1 adjuvant therapy of any type (**Figure 1**)
  - Patients were identified as NATALEE or monarchE eligible based on criteria from each study (NATALEE: patients with N0 with high-risk features or node-positive [N1-3]; monarchE: patients N1 with high-risk features or N2-3)[5-7]
- Demographics and clinical characteristics were analyzed using descriptive statistics
- Recurrence-free survival (RFS) and distant recurrence-free survival (DRFS) analyses, defined based on STEEP version 2.0 criteria, were conducted using the Kaplan-Meier method
  - RFS and DRFS analysis were assessed in the overall population and subgroups of patients defined by nodal status (N0 with high-risk features [N0-NATALEE-eligible], N0 without high-risk features [N0-NATALEE-ineligible], N1, and N2-3)

RESULTS

- In the China and US populations, 28,623 and 5930 patients met the selection criteria and were included in this analysis (**Figure 1**)
- The median duration of follow-up from initial diagnosis was 33.6 months (IQR, 19.2-56.4 months) in China and 52.3 months (IQR, 27.7-77.8 months) in the US

Figure 1. Flowchart of Patient Selection

Criteria	NCID China	Flatiron Health US
Initial EBC diagnosis from 1 Jan 2013 to 31 Dec 2022	N = 442,257[a]	N = 12,138
Patients without other cancers at initial diagnosis	n = 401,871	n = 11,742[b]
Patients diagnosed with HR+/HER2– EBC	n = 130,205	n = 6953
Patients aged ≥18 and ≤80 years at initial diagnosis	n = 129,222	n = 6451
Patients diagnosed with stage I-III disease	n = 104,394	n = 6197
Received primary tumor BC surgical resection at any time	n = 45,858	n = 6148
Received adjuvant therapy and had ≥2 visits after surgery	n = 28,623	n = 5930

[a]Includes patients diagnosed with EBC and metastatic BC. [b]Includes patients without another malignancy any time prior to the EBC diagnosis.

Baseline Characteristics and Treatment Patterns

- Characteristics and treatment patterns in in patients in China and the US are included in **Table 1**
  - In the China and US populations, 16,743 (58.5%) and 2058 (34.7%) patients were NATALEE-eligible and 11,088 (38.7%) and 954 (16.1%) were monarchE-eligible, respectively
  - Patients in China vs the US were younger (median age 49 vs 63 years), were more likely to be premenopausal (44.6% vs 20.9%), and had higher rates of axillary node involvement (N0, 52.0% vs 71.5%; N1, 30.4% vs 22.1%; N2-3, 17.6% vs 6.4%), respectively
  - Patients in China vs the US were more likely to undergo total mastectomy (79.4% vs 37.1%) and receive adjuvant chemotherapy (79.0% vs 23.0%), respectively

Outcomes in China and US Populations: RFS and DRFS

- 3- and 5-year RFS and DRFS rates were similar in the overall and overall NATALEE-eligible population in China and the US (**Table 2)**
- Similar patterns were observed for RFS and DRFS by nodal status in China and US populations (**Figures 2** and **3)**

Table 1. Demographics and Characteristics of Patients with HR+/HER2− EBC

Characteristic	NCID China (n = 28,623)	Flatiron Health US (n = 5930)
Median age (IQR), years	49 (43-58)	63 (54-70)
Sex, n (%)		
Female	28,467 (99.5)	5894 (99.4)
Male	156 (0.5)	36 (0.6)
Menopausal status, n (%)		
Pre-menopausal	12,761 (44.6)	1242 (20.9)
Postmenopausal	9621 (33.6)	4374 (73.8)
Other (male patient)/unknown	6241 (21.8)	314 (5.3)
Trial eligibility criteria, n (%)		
NATALEE-eligible	16,743 (58.5)	2058 (34.7)
MonarchE-eligible	11,088 (38.7)	954 (16.1)
Nodal status, n (%)		
N0	14,886 (52.0)	4241 (71.5)
N0 NATALEE-ineligible	9474 (33.1)	3742 (63.1)
N0 NATALEE-eligible	3010 (10.5)	499 (8.4)
N0 risk unknown[a]	2402 (8.4)	0
N1	8694 (30.4)	1311 (22.1)
N2-3	5043 (17.6)	378 (6.4)
Anatomic stage, n (%)		
I	8666 (30.3)	3374 (56.9)
II	14,149 (49.4)	2002 (33.8)
III	5808 (20.3)	554 (9.3)
Type of surgery, n (%)[b]		
Mastectomy	22,725 (79.4)	2200 (37.1)
Breast conservation	2916 (10.2)	3961 (66.8)
Unknown	2982 (10.4)	–
Type of adjuvant therapy, n (%)[b]		
Radiotherapy	18,337 (64.1)	3576 (60.3)
Chemotherapy	22,623 (79.0)	1365 (23.0)
Endocrine therapy	25,071 (87.6)	5765 (97.2)
CDK4/6 inhibitor	611 (2.1)	74 (1.2)
Other targeted therapy	–	3 (0.1)[c]
PARP inhibitor	–	4 (0.1)

[a]These patients had incomplete information to assess risk. [b]Patients may have received multiple treatment options; column percentages may add up to >100%. [c]For the US cohort, other targeted therapy included alpelisib, everolimus, and idelalisib.

Table 2. Outcomes in China and US: RFS and DRFS

	NCID China (n = 28,623)		Flatiron Health US (n = 5930)	
RFS (95% CI), %	3-year	5-year	3-year	5-year
Overall population	92.1 (91.7-92.5)	85.8 (85.2-86.4)	94.4 (93.7-95.0)	89.7 (88.7-90.6)
Overall NATALEE-eligible	89.1 (88.6-89.7)	81.2 (80.3-82.0)	89.2 (87.6-90.5)	81.8 (79.7-83.7)
DRFS (95% CI), %	3-year	5-year	3-year	5-year
Overall population	94.3 (94.0-94.7)	89.1 (88.5-89.6)	95.3 (94.6-95.8)	91.2 (90.3-92.0)
Overall NATALEE-eligible	91.7 (91.2-92.2)	84.5 (83.7-85.3)	90.4 (88.9-91.7)	83.6 (81.6-85.4)

Figure 2. RFS by Nodal Status

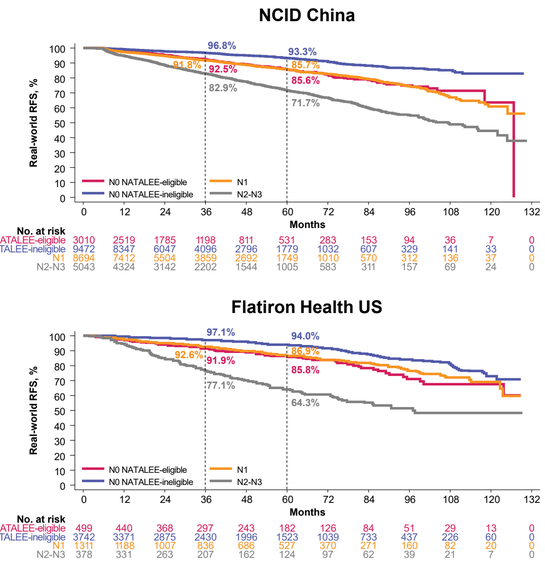
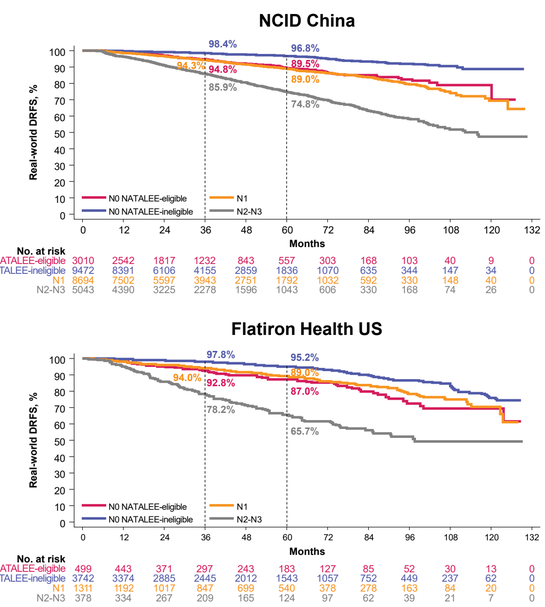


Figure 3. DRFS by Nodal Status



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