PS3-11-26:A real-world study of pyrotinib as neoadjuvant therapy for HER2-positive breast cancer

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Background

- A double-blind, randomized Phase 3 clinical study, PHEDRA, met its primary endpoint with a significantly higher tpCR rate than placebo in patients treated with pyrotinib, trastuzumab, and docetaxel in HER2-positive early or locally advanced breast cancer[1] (41.0% vs. 22.0%, unilateral P< 0.0001).
- At present, trastuzumab combined with pyrotinib and docetaxel has become the standard neoadjuvant treatment strategy for HER2-positive early or locally breast cancer[2] .
- We aim to evaluate the efficacy and safety of pyrotinib-containing regimen as neoadjuvant therapy for HER2-positive early or locally advanced breast cancer in a real-world setting.

Methods

- This is a prospective, real-world, one-arm study.
- Patients with untreated HER2-positive operable early or locally advanced breast cancer were enrolled. Eligible patients received pyrotinib-containing regimen. Surgery was performed after the completion of the last cycle of study treatment.
- The primary endpoint was tpCR (ypT0/Tis ypN0) and secondary endpoints included objective response rate (ORR), bpCR and safety.

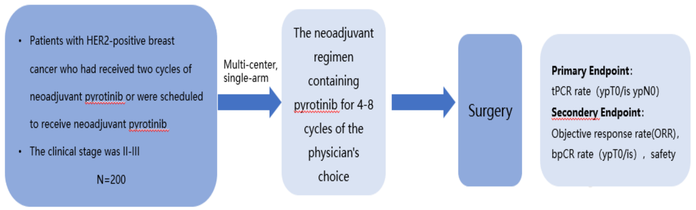


Figure 1. The design of the Study

Results

- Between Feb 13, 2022, and May 29, 2025, a total of 104 patients with a median age of 51 years (range:26-66) were enrolled.
- As of the data cutoff on Jun12, 2025, 66 patients underwent surgery, tpCR rate was 58%. The tpCR rates of HR- and HR+ patients were 68% and 42% respectively .
- 47(45%) patients received AC/EC-THPy,39(38%) patients received TCbHPy, and 16(15%) patients received THPy regimens.The pCR rates were 51.7%、57.1% and 75% respectively.

Table 1. The Characteristics of enrolled patients

Characteristics	Patients (n=104)
Median Age (Range)	51 (26-66)
≤51 years	55 (53%)
> 51 years	49 (47%)
Menopausal Status n,(%)	
Premenopausal or perimenopausal	42 (40%)
Postmenopausal	62 (60%)
Node Status n,(%)	
negetive	28 (27%)
positive	76 (73%)
Tumor Size n,(%)	
T1-2	79(76%)
T3-4	25(24%)
TNM Stage n,(%)	
II	75 (72%)
III	29 (28%)
HR Status n,(%)	
negetive	56(54%)
positive	48(46%)

- Out of the 84 patients with evaluable response, 2 achieved complete and 66 achieved partial response, resulting in an ORR of 81%.
- The grade 3 or 4 adverse events were 24.03%. The most common treatment-related adverse events (AEs) were diarrhea (50%), Vomiting (26.9%), and decreased appetite (11.5%). Most AEs were tolerable.

Table 2. The Treatment Response

Response	Per-protocol population [n, (%)]
Total pathological complete response	**38/66(58.0%)**
Miller-Payne system granding	
MP-5	38
MP-4	15
MP-3	11
MP-2	1
MP-1	1
Objective response rate	**68/84(81%)**
CR	2
PR	66
SD	15
PD	1

Figure 2 . pCR rate in subgroups

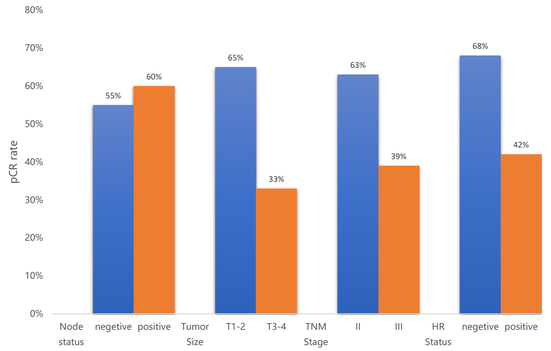


Table 3. The Overall Safety

Overall Safety	N(%)
TRAEs(Treatment-Related Adverse Events)	
Grade 3	25 (24.03%)
Grade 4	1 (1%)
Grade 5	0
Dose Reduction of Pyrotinib Due to Adverse Events	17 (16.3%)
Dose Interruption of Pyrotinib Due to Adverse Events	24 (23.1%)
Death Due to Adverse Events	0

Table 4. The Adverse Events

Adverse Event	All grade (n=104)	≥3 grade(n=104)
All AE	66.30%	24.03%
diarrhea	50.0%	15.4%
Vomiting	26.9%	6.7%
Decreased appetite	11.5%	1%
Rash	8.6%	
Constipation	5.8%	
Nausea	2.9%	
fatigue	4.8%	
Oral ulcer	2.9%	
Headache	2.10%	
Gastrointestinal AE (bloating, gastroesophageal reflux, stomachache)	5.8%	
Bronchopneumonia	1%	
Decreased white-cell count	4.8%	2.90%
Febrile neutropenia		1.9%
Hypokalemia	2.8%	
Pulmonary infection		1%
Abnormal liver function	4.8%	1%

Conclusions

In this real-world study, neoadjuvant pyrotinib- containing regimens showed promising efficacy and safety in patients with HER2-positive breast cancer, further verify its effectiveness and safety in the real world.

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References:
1. Wu J, Jiang Z, Liu Z, et al. Neoadjuvant pyrotinib, trastuzumab, and docetaxel for HER2-positive breast cancer (PHEDRA): a double-blind, randomized phase 3 trial. *BMC Med.* 2022;20(1):498. doi:10.1186/s12916-022-02708-3
2. 2025 Guidelines of Chinese Society of Clinical Oncology of Breast Cancer

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