



# Real-world outcome and safety of pyrotinib in HER-2 positive metastatic breast cancer (MBC) patients: a prospective cohort study

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Abstract #2226

## Background

- Pyrotinib, a novel irreversible EGFR/HER2 dual tyrosine kinase inhibitor, shows promising antitumor activity and acceptable tolerability in phase II and phase III randomized clinical trials.
- However, the real-world data of pyrotinib have been rarely reported. Here, we assessed the treatment outcomes of pyrotinib in real-world practice in patients with HER2-positive MBC patients.

## Methods

- This was a Chinese population-based, prospective, real-world, observational cohort study.
- HER-2 positive MBC patients treated with pyrotinib were identified from the Breast Cancer Information Management System between 2017/06 and 2020/09.
- Treatment outcomes assessment included provider-reported objective response rate (ORR), progression-free survival (PFS) and overall survival (OS). The responses were determined by RECIST 1.1, and adverse events were assessed using patients and clinical records.

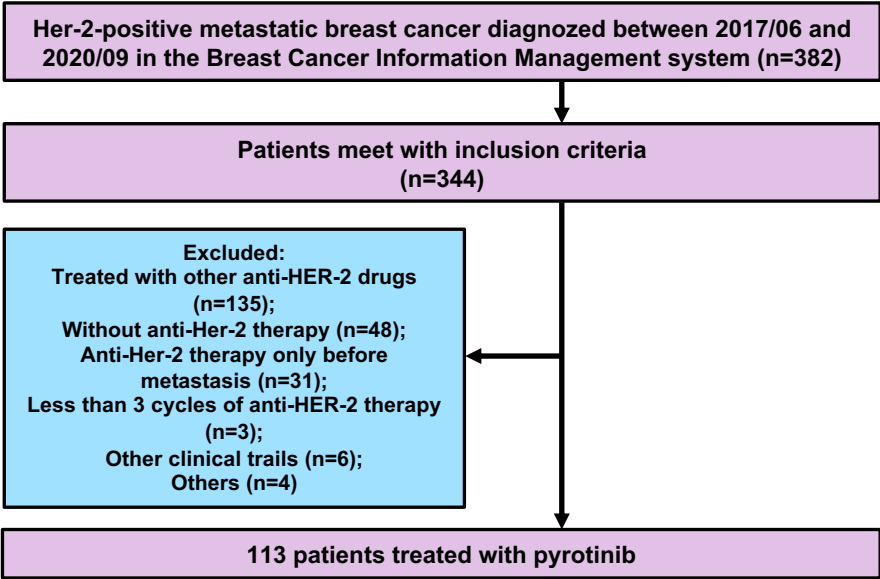


Figure 1. Flow diagram of 113 pyrotinib-treated patients included in the study

## Results

### Patients

Characteristic	Patients (N=113)
Median age (range), years	51 (24-76)
<50	42 (37.17%)
≥50	71 (62.83%)
HER2 Status <sup>a</sup> (%)	
3+	88 (77.88%)
2+ and FISH Amplification	25 (22.12%)
Surgery (%)	
No	25 (22.12%)
Yes	88 (77.88%)
Chemotherapy (%)	
No	6 (5.31%)
Yes	107 (94.69%)
Radiotherapy (%)	
No	61 (53.98%)
Yes	52 (46.02%)
Endocrinotherapy (%)	
No	69 (61.06%)
Yes	44 (38.94%)
Number of Metastases (%)	
1	49 (43.36%)
2	33 (29.20%)
≥3	31 (27.43%)
Metastasis site (%)	
Brain	30 (26.55%)
Lung	51 (45.13%)
Liver	44 (38.94%)
Bone only	9 (7.96%)
Other	15 (13.27%)
Anti-HER2 Therapy (%)	
No	11 (9.73%)
Only Early Stage	24 (21.24%)
Only Advanced Stage	64 (56.64%)
Early and Advanced Stage	14(12.39%)
Pyrotinib Advanced Anti-HER2 Therapy Lines (%)	
First Line	20 (17.70%)
Second Line	61 (53.98%)
Third Line and Beyond	32 (28.32%)

Table 1. Baseline characteristics of all included patients

<sup>a</sup> HER-2 positive was defined as IHC<sup>3+</sup> and/ or FISH+; IHC, immunohistochemistry; FISH, fluorescence in situ hybridization.

## Efficacy

- Complete response, partial response and stable disease were observed in 9 (7.96%), 66 (58.41%), and 17 (15.04%) patients, respectively; progressive disease was recorded in 20 (17.70%) patients. ORR reached 66.96% (75/113) by the clinical response assessment.
- The median PFS was 14.10 months (95% CI: 12.50-17.80). The median OS was 34.10 months after a median follow up of 17.17 months (95% CI: 14.33-19.63).
- Among the patients with brain metastases, the median PFS and OS was 15.2 and 19.8 months, respectively.

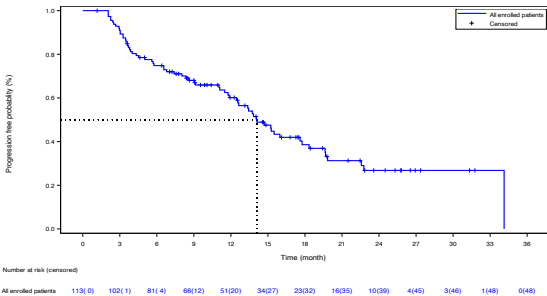


Figure 2. Kaplan-Meier curves of PFS for patients treated with pyrotinib

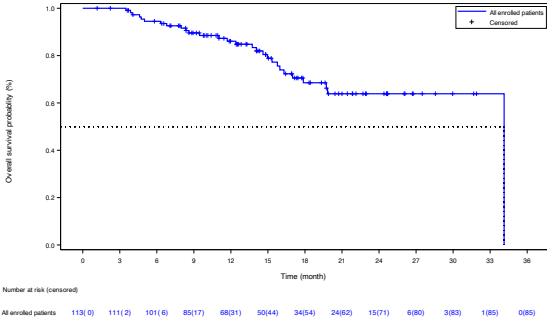


Figure 3. Kaplan-Meier curves of OS for patients treated with pyrotinib

## Safety

- The most common adverse events of any grade were diarrhea (87.6%), vomiting (31.9%), palmar-plantar erythrodysesthesia syndrome (26.6%), nausea (18.6%), and mucositis oral (17.7%).

Event	Patients (n=113)			
	Any Grade	Grade 1	Grade 2	Grade 3
Diarrhea (%)	99 (87.61%)	49 (43.36%)	37 (32.74%)	13 (11.5%)
Vomiting (%)	36 (31.86%)	21 (18.58%)	15 (13.27%)	0
Palmar-plantar Erythrodysesthesia Syndrome (%)	30 (26.55%)	14 (12.39%)	14 (12.39%)	2 (1.77%)
Nausea (%)	21 (18.58%)	17 (15.04%)	4 (3.54%)	0
Mucositis Oral (%)	20 (17.70%)	14 (12.39%)	5 (4.42%)	1 (0.88%)
Rash (%)	16 (14.16%)	9 (7.96%)	7 (6.19%)	0
Malaise (%)	14 (12.39%)	14 (12.39%)	0	0
Abdominal Distension/Abdominal Pain (%)	12 (10.62%)	10 (8.85%)	2 (1.77%)	0
White Blood Cell Decreased (%)	6 (5.31%)	5 (4.42%)	1 (0.88%)	0
Anorexia (%)	8 (7.08%)	8 (7.08%)	0	0
Headache/Dizziness (%)	5 (4.42%)	5 (4.42%)	0	0
Constipation (%)	3 (2.65%)	3 (2.65%)	0	0
Liver Impairment (%)	2 (1.77%)	2 (1.77%)	0	0
Numbness of Teh Extremities (%)	3 (2.65%)	3 (2.65%)	0	0
Dryness of The Nasal Cavity (%)	2 (1.77%)	2 (1.77%)	0	0

## Conclusions

- Compared with phase II and phase III clinical trails of pyrotinib, our real-world data showed similar clinical effectiveness in HER-2 positive MBC patients and, in particular, improved outcomes in patients with brain metastasis.

The first author and co-authors has no conflicts of interest to declare. This Study was sponsored by Heng Rui Medicine (Recipient: TL).

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