Real-world outcomes associated with pyrotinib-based therapy for HER2-positive metastatic breast cancer

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Background

- Pyrotinib has been shown to have significant anti-tumor activity and tolerable toxicity in patients with HER2-positive advanced breast cancer in existing clinical trials. However, there are few real-world data.
- This multicenter restrospective study was conducted to evaluate the effectiveness and safety of pyrotinib in the treatment of HER2-positive metastatic breast cancer in the real world setting.

Methods

- A total of 305 patients who received pyrotinib for the treatment of HER2-positive metastatic breast cancer from 12 medical institutions in China between March 2019 and April 2021 were included in this study, and 279 patients with available objective response rate (ORR) and progression-free survival (PFS) data were analyzed in this report.

Results

- Among the 279 patients, 56.6% had received at least 2-line systemic therapy before pyrotinib treatment, and 78.1% had been exposed to at least one anti-HER2 agent (Table 1).
- The ORR in the total study population was 34.1%, and the median PFS (mPFS) was 8.8 months. The ORR and mPFS in subgroups are shown in Table 2 and Figure 1, respectively.
- Cox multivariate analysis showed that frontline use of pyrotinib-based systemic therapy, no brain metastases, and no change in HER2 status were independent prognostic factors of PFS.
- The most common grade 3-4 adverse events were diarrhea (21.6%) and hand-foot syndrome (8.2%).

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Table 1. Patient characteristics at baseline

Characteristic	Patients (N=279)
Age, years, median (range)	52 (27-81)
Eastern Cooperative Oncology Group performance status	
0-1	248 (88.9)
≥2	31 (11.1)
Hormone receptor status	
Hormone receptor positive	182 (65.2)
Hormone receptor negative	97 (34.8)
Surgery for primary breast cancer	245 (87.8)
Adjuvant therapy with trastuzumab	64 (22.9)
Disease-free interval, years	
≤1	59 (21.1)
>1	186 (66.7)
Metastatic disease at diagnosis	34 (12.2)
Metastatic sites	
Lymph nodes	155 (55.6)
Lung	149 (53.4)
Bone	117 (41.9)
Liver	116 (41.6)
Brain	94 (33.7)
Chest wall	53 (19.0)
Pleura	26 (9.3)
Contralateral breast	17 (6.1)
Skin	5 (1.8)
Number of metastatic sites	
1	59 (21.1)
2	76 (27.3)
≥3	144 (51.6)
Visceral metastases	233 (83.5)
Lines of systemic therapy with pyrotinib	
1	45 (16.1)
2	76 (27.3)
≥3	158 (56.6)
Lines of anti-HER2 therapy with pyrotinib	
1	61 (21.9)
2	165 (59.1)
≥3	53 (19.0)
Prior HER2-targeted therapy	
Trastuzumab	250 (89.6)
Lapatinib	58 (20.8)
Antibody-drug conjugate	10 (3.6)
Pertuzumab	5 (1.8)
Neratinib	1 (0.4)
First-line anti-HER2 therapy	
Trastuzumab	201 (72.0)
Lapatinib	13 (4.7)
Pyrotinib	61 (21.9)
Others	4 (1.4)
Trastuzumab resistance status	
Resistant	50 (17.9)
Refractory	192 (68.8)
Unknown	37 (13.3)
Ki-67 level	
≤30%	127 (45.5)
>30%	131 (47.0)
Unknown	21 (7.5)
Change in HER2 status	
Positive to negative	4 (1.4)
Negative to positive	18 (6.5)
No change	77 (27.6)
No second biopsy	180 (64.5)

Data are shown as n (%), unless otherwise indicated.

Table 2. ORR in subgroups

Subgroups	ORR	P
Lines of systemic therapy with pyrotinib		
1 (n=45)	53%	
2 (n=76)	41%	0.001
≥3 (n=158)	25%	
Lines of anti-HER2 therapy with pyrotinib		
1 (n=61)	46%	
2 (n=165)	35%	0.010
≥3 (n=53)	19%	
Pyrotinib-based therapy		
Combination therapy (n=251)	36%	0.020
Monotherapy (n=28)	14%	
Pyrotinib-based combination		
Pyrotinib plus capecitabine (n=159)	41%	0.045
Pyrotinib plus other chemotherapy drugs (n=92)	28%	
Prior exposure to lapatinib		
Yes (n=58)	21%	0.016
No (n=221)	38%	
Liver metastases		
Yes (n=116)	27%	0.029
No (n=163)	39%	
Brain metastases		
Yes (n=94)	31%	0.422
No (n=185)	36%	
Change in HER2 status		
Yes (n=22)	14%	0.016
No (n=77)	42%	

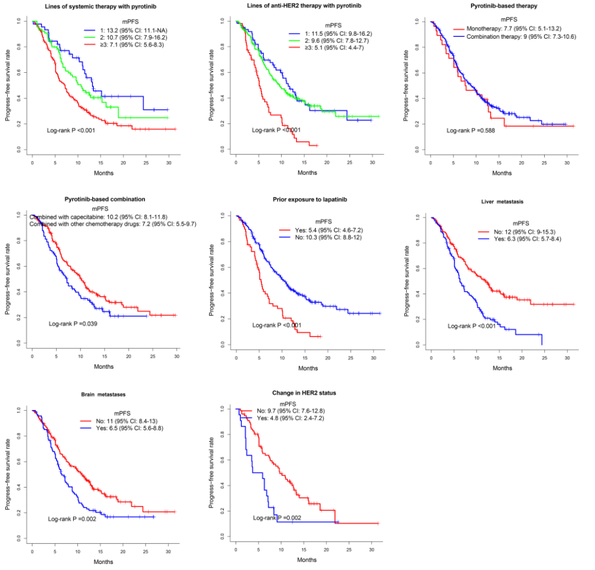

Figure 1. Kaplan–Meier curves of PFS and log-rank analysis for patients with HER2-positive metastatic breast cancer.

Conclusion

- This study is currently the largest real-world study of pyrotinib in the treatment of HER2-positive metastatic breast cancer with a relatively long follow-up period. It demonstrates that pyrotinib has an encouraging efficacy and good tolerability in actual clinical practice. It is also effective for patients who have previously used lapatinib or who present with brain metastases, and it is suggested that frontline use of pyrotinib-based therapy may result in higher effective rate and better prognosis. Patients with liver metastases or HER2 status transition have a poor prognosis and require more attention in clinical work.