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50P Efficacy and safety analysis of pyrotinib in lapatinib resistant HER2-positive metastatic breast cancer: A retrospective study

Y. Hua, F. Yang, Y. Yang, S. Bao, C. Sun, X. Yan, T. Zeng, M. Jiang, X. Huang, H. Wu, J. Li, W. Li, Y. Yin

Oncology, Jiangsu Province Hospital - The First Affiliated Hospital with Nanjing Medical University, Nanjing, China

Background: Lapatinib has shown effectiveness in treating HER2-positive metastatic breast cancer, but therapies after lapatinib resistance are still controversial. In this retrospective study, we assessed the efficacy and safety of pyrotinib in lapatinib resistant HER2-positive metastatic breast cancer.

Methods: From August 2018 to March 2020, 76 HER2-positive metastatic breast cancer patients who previously failed by lapatinib received pyrotinib in four hospitals. The primary endpoint was investigator-assessed progression-free survival (PFS) per Respond Evaluation Criteria in Solid Tumors (RECIST) version 1.1. The secondary endpoint was the overall survival (OS) and safety of pyrotinib.

Results: 66 (86.8%) patients received pyrotinib immediately after lapatinib and 10 (13.2%) received pyrotinib following one or more other therapies. The median PFS of pyrotinib was 8.0 months (95%CI 5.1-10.9) and OS has not reached. Objective response rate (ORR) was 17.1%, and clinical benefit rate (CBR) was 60.5%. Patients who benefited from lapatinib $\geq$6.0 months were found to have a longer PFS (P=0.034; stratified hazard ratio [HR] 0.534, 95%CI 0.293-0.975). In patients who had received lapatinib in 3 or later line therapy (35, 46.1%), the median PFS of pyrotinib was 9.9 months (95%CI 6.97-12.83) and was relevant to whether lapatinib PFS had reached 6.0 months (P=0.044; HR 0.412, 95%CI 0.167-1.013). No relations were detected between pyrotinib PFS and estrogen receptor (ER) status, trastuzumab resistance, brain metastasis or the sequential use of pyrotinib. In patients who had received lapatinib earlier (41,53.9%), the median PFS of pyrotinib was 6.4 months (95%CI 3.57-9.23). No relevant factors were observed. There was no difference in PFS between these two groups with different lapatinib lines. Toxicity profiles were similar in both groups. The most common adverse effects were diarrhea (34, 44.7%) and hand-foot syndrome (10, 13.2%).

Conclusions: Pyrotinib could improve the survival of HER2-positive metastatic breast cancer patients after the failure of lapatinib. For patients who benefited from lapatinib $\geq$ 6.0 months in 3 or later line therapy, pyrotinib could provide a clinically meaningful longer PFS.

Legal entity responsible for the study: The authors.

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51P Real world outcomes in elderly women with HER2-positive advanced breast cancer

N. Evans[1], A. Anton[1], R. Wong[1], S.W. Lok[2], R. De Boer[3], L. Malik[4], S. Greenberg[5], B. Yeo[6], L. Nott[7], G. Richardson[8], I.M. Collins[9], J. Torres[10], F. Barnett[11], P. Gibbs[2], B. Devitt[1]

[1]Oncology, Eastern Health, Melbourne, Australia; [2]Oncology, Walter and Eliza Hall, Melbourne, Australia; [3]Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia; [4]Oncology, Canberra Hospital, Garran, Australia; [5]Oncology, Western Health, Melbourne, Australia; [6]Olivia Newton John Centre, Austin Health, Melbourne, Australia; [7]Oncology, Royal Hobart Hospital, Hobart, Australia; [8]Oncology, Cabrini Health, Melbourne, Australia; [9]Oncology, South West Healthcare, Warnambool, Australia; [10]Oncology, Goulburn Valley Health, Shepparton, Australia; [11]Oncology, Northern Hospital, Melbourne, Australia

Background: The development of anti-human epidermal growth factor receptor 2 (HER2) therapies has significantly improved disease outcomes in patients with HER2-positive advanced breast cancer (ABC). However, elderly patients are largely underrepresented in clinical trials. We examined treatment patterns and outcomes in an elderly (defined as $\geq$70) 'real world' Australian population.

Methods: Data was extracted from the Treatment of Advanced Breast Cancer in the HER2-positive Australian Patient (TABITHA) multi-site clinical registry, and patients stratified according to age ($<$70 and $\geq$70 years). Descriptive statistics were used to report baseline characteristics and compared using T-tests and Chi square analyses. Treatment duration and overall survival were calculated via the Kaplan-Meier method.

Results: We identified 319 patients, including 67 patients (21%) aged $\geq$70 years. Older patients were more likely to have an Eastern Cooperative Oncology Group performance status of $\geq$2 (16% vs 3%; p$<$0.001) and a Charlson Comorbidity Index of $\geq$2 (13% vs 7%; p$<$0.001). There were no significant differences in hormone receptor status, de novo metastatic presentation, or presence of visceral disease. A similar proportion of patients in each group received first line HER2-directed therapy, and the duration of therapy was not significantly different. Despite no difference in the proportion of patients who received first-line chemotherapy, older patients demonstrated shorter chemotherapy durations (2.7 months vs 3.5 months; p$<$0.02). Median overall survival was significantly longer in younger patients (82.4 months vs 42.3 months; hazard ratio, 0.50; 95%CI, 0.29-0.87; p$<$0.001). In the first-line setting, adverse events rates were higher in the older group (34% vs 20%; p=0.04), including cardiotoxicity (7% vs 0.9%; p=0.02), and on-treatment deaths (5% vs 0%; p=0.01).

Conclusions: Elderly patients with HER2-positive ABC demonstrated shorter chemotherapy durations, poorer overall survival, and increased rates of adverse events despite having similar disease characteristics and treatment patterns. Prospective studies are required to improve outcomes in the elderly population.

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52P Chemotherapy selection in routine clinical practice in Japan for HER2-negative advanced or metastatic breast cancer (KBCRN A001: E-SPEC Study)

Y. Kang[1], Y. Kikawa[2], T. Kotake[3], S. Tsuyuki[1], S. Takahara[4], H. Yamashiro[5], H. Yoshibayashi[6], M. Takada[7], R. Yasuoka[8], K. Yamagami[9], H. Suwa[10], T. Okuno[11], I. Nakayama[12], T. Kato[13], Y. Moriguchi[14], H. Ishiguro[15], T. Kagimura[16], T. Taguchi[8], T. Sugie[2], M. Toi[7]

[1]Department of Breast Surgery, Osaka Red Cross Hospital, Osaka, Japan; [2]Department of Breast Surgery, Kansai Medical University, Hirakata, Japan; [3]Medical Oncology, Kansai Electric Power Hospital, Osaka, Japan; [4]Department of Breast Surgery, Tazuke Kofukai Medical Research Institute, Kitano Hospital, Osaka, Japan; [5]Department of Breast Surgery, Tenri Hospital, Nara, Japan; [6]Department of Breast Surgery, Japanese Red CrossWakayama Medical Center, Wakayama, Japan; [7]Breast Surgery Department, Kyoto University Hospital, Kyoto, Japan; [8]Department of Endocrine and Breast Surgery, Kyoto Prefectural University of Medicine, Kyoto, Japan; [9]Department of Breast Surgery, Shinko Hospital, Hyogo, Japan; [10]Department of Breast Surgery, Hyogo Prefectural Amagasaki General Medical Center, Hyogo, Japan; [11]Department of Breast Surgery, Kobe City Nishi-Kobe Medical Center, Hyogo, Japan; [12]Department of Breast Surgery, Kyoto Min-iren Chuo Hospital, Kyoto, Japan; [13]Department of Breast Surgery, Yamato Takada Municipal Hospital, Nara, Japan; [14]Department of Breast Surgery, Kyoto City Hospital, Kyoto, Japan; [15]Medical Oncology, International University of Health and Welfare Hospital, Chiba, Japan; [16]Translational Research Center for Medical Innovation, Foundation for Biomedical Research and Innovation at Kobe, Hyogo, Japan

Background: Anthracycline-based (A) and taxane-based (T) chemotherapy (ChT) are standards of care for triple-negative (TN) or hormone-resistant advanced/metastatic breast cancer (AMBC) in 1st- or 2nd-line ChT. However, the choice of regimen for oncologists and patients is diverse, requiring consideration of not only survival benefit but also quality of life issues. We reported that most patients received eribulin (E) in 1st- or 2nd- line therapy in the Japanese real-world setting at the ESMO 2018