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To Evaluate Response Rate, Time To Disease Progression And the Toxicity Of Vinorelbine Monotherapy in Second Line Treatment Of Patients With Recurrent and Metastatic Breast Cancer at Viet Nam National Cancer Hospital

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Abstract

Objective: To evaluate response rate, time to disease progression and the toxicity of vinorelbine monotherapy in second line treatment of patients with recurrent and metastatic **breast cancer** at Viet Nam National Cancer hospital.

Patients and Methods: Prospective combined retrospective descriptive study. The study based on 71 patients with breast cancer recurrence and metastasis after radical treatment with Taxane/ Anthracycline frist lines at Viet Nam National Cancer Hospital from 4/2015 to 6/2018 were treated with weekly Vinorelbine 25 mg/m2 IV or Vinorelbine 60mg/m2 PO or combination on day 1 every week, at least 6 weeks.

Results: The presence of recurrent metastasis most common of this group in the second year, third year after radical treatment 57,8%. There was 15,5% of patients with metastatic recurrence after 5 years. Free – recurrence survival was 21 ± 10,44 months. There was 30,1% of the cases of recurrence metastasis without clinical symptoms. In all cases of bone pain symptoms, the most common, accounting of 40,3%. Most patients with recurrent metastatic had multiple locations at the time of diagnosis (70,4%). Metastase bone, lung, liver were most commonly as 61,9%; 46,5%; 40%, respectively. Complete response rate is 4,2%, partial response of 30,6%. In which 59,2% patients had no response, 38,1% stable disease and 21,1% progress disease. Time to disease progression is 7,2 months. There was no significant difference in RR and PFS was observed between the arms. Grade 3 and 4 hematologic and non-hematologic toxicity rate were low. The rate of hematologic toxicity were significantly higher in Vinorelbine IV with the rates of leukopenia and neutropenia were 43,2% and 41,5%, non-hematologic toxicity rate were significantly higher in Vinorelbine OP with the rates of nausea/ vomiting; diarrhoea; mucositis were 45,2%; 42,1% and 42,1%.

Conclusion: The regimen has good results and safe.

Keywords: Breast cancer, Winorelbine, Chemotherapy, Metastasis

Introduction

The results of treatment of advanced breast cancer have been slowly improving in recent years. The median overall survival in this group of patients ranges between 2 and 3 years. Palliative systemic treatment of patients with metastatic breast cancer is based on sequential use of successive lines of therapy (chemotherapy, hormonal therapy or targeted therapy) [1].

The first line of treatment consists of anthracyclines and taxanes. Capecitabine as the single agent or in combination with other drugs is the most commonly used regimen after anthracycline/taxane-based chemotherapy failure. The sequence and the efficacy of further lines of treatment are still being evaluated, and available data are based on single-center studies or retrospective analyses. Vinorelbine is a cytotoxic drug of proven efficacy in the first line treatment of metastatic breast cancer but now is most commonly used in further lines of therapy. Therefore it seems appropriate to assess the efficacy and tolerability of vinorelbine in the treatment failures in patients with advanced/metastatic breast cancer [2].

To evaluate the efficacy and safety of vinorelbine-based chemotherapy in patients with metastatic breast cancer previously treated with an anthracycline/taxane-based regimen.A total of 103 patients with metastatic breast cancer treated with vinorelbine-based regimens between January 2001 and October 2010 were enrolled in the study. Eligible patients were required to have received anthracycline/taxane-based chemotherapy for the treatment of metastatic disease. Patients were treated with one of the chemotherapy regimens summarized Cycles were repeated every 3–4 weeks. Patients treated with an oral form of vinorelbine were not enrolled in the study. The selection of a treatment regimen was based on the earlier use of fluoropyrimidine (fluorouracil or capecitabine). Patients with HER2 receptor. Over expression or HER2 gene amplification were previously treated with trastuzumab [3].

Granulocyte colony-stimulating factor (G-CSF) use was allowed in the case of neutropenic fever, infectious complications during neutropenia G3/G4 and as the secondary prophylaxis for patients who experienced febrile neutropenia during previous cycles. Ondansetron was administered as anti-emetic prophylaxis. Patients received 6 cycles of standard chemotherapy. Decisions to extend treatment beyond six cycles were made individually. The treatment was continued until progression of the disease or unacceptable toxicity [4].

The total number of cycles and doses of cytotoxics received by patients were summarized, and then the toxicity of therapy using the NCI CTC scale was evaluated (version 3). The efficacy was evaluated in patients who received at least two cycles of treatment, while those who received only 1 cycle were evaluated for toxicity only. The primary endpoint was progression-free survival (PFS). The evaluation of tumor response was performed according to WHO criteria [5].

MS Access 2007 was used to collect, store, and maintain the data regarding the treatment. To perform statistical analyses we used the statistical program Statistica.

Results

Among the group of 103 patients, 97 patients (94.5%) had tumor progression, and 6 patients (5.5%) are still receiving chemotherapy or are still alive without evidence of disease progression at the time of the most recent follow-up. A total of 417 cycles of chemotherapy were administered: 177 cycles of vinorelbine with 5-FU and 137 cycles of vinorelbine monotherapy. Patients were treated for a median of 4 cycles Thirty-one patients received at least 6 cycles of treatment. Ten patients were excluded from the evaluation of treatment efficacy due to receiving only one treatment cycle. The completion of treatment after one cycle was associated with a documented rapid progression of the disease in four cases, and six patients discontinued treatment due to adverse events. Therapeutic efficacy of vinorelbine-based chemotherapy was assessed in a group of 93 patients. Median progression-free survival (PFS) for the whole study group was 18 weeks (range: 6–253 weeks), 22 weeks for patients receiving vinorelbine and 5-FU (range: 6 to 253 weeks), and 16 weeks for a group treated with vinorelbine alone (range: 6–165 weeks). The progression-free survival curves for each of the treatment groups

A total of 39 patients (42%) achieved an objective response or stabilization of disease lasting for at least 6 months (clinical benefit), 24 (50%) patients treated with vinorelbine and 5-FU and 15 (33%) patients treated with vinorelbine alone. Overall survival was not assessed due to the different treatment regimens used after the vinorelbine-based chemotherapy failure.

The treatment-related toxicities were observed and reported during 198 cycles of the chemotherapy (47%), 123 cycles (54%) of vinorelbine/5-FU and 78 cycles (41%) of vinorelbine monotherapy.

The most common adverse events were hematologic toxicity (112 cycles), nausea and vomiting (54 cycles). Grade 3/4 adverse events were observed in 13% of cycles (53), with hematologic toxicity observed during 38 cycles. Injection site reaction and gastrointestinal disorders (mucositis, motility disorders) were frequent complications, leading to treatment discontinuation in four patients.

Granulocyte colony-stimulating factor was used during 29% of cycles of chemotherapy (121 cycles), as the secondary prophylaxis in 86 cycles and as a part of the therapy in 35 cycles. We performed a single chemotherapy dose reduction in 26 patients.

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