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ORIGINAL RESEARCH

Neoadjuvant Docetaxel-Carboplatin-Trastuzumab Therapy in HER2-Positive Breast Cancer: A Single-Center Experience from Vietnam

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Purpose: To evaluate the efficacy of neoadjuvant therapy and identify associated factors influencing treatment response in patients with HER2-positive breast cancer.

Subjects and Methods: A prospective, longitudinal study of 40 women with a mean age of 50.68 ± 10.53 years diagnosed with HER2-positive breast cancer. All patients received neoadjuvant treatment using Docetaxel-Carboplatin-Trastuzumab (TCH) regimens. These patients were evaluated for treatment response based on the Response Evaluation Criteria In Solid Tumors (RECIST) after six 21-day treatment cycles.

Results: The proportion of good responders was 45.0% (18/40 patients). Younger age, earlier clinical stage, and lower baseline serum CA15-3 levels were significantly associated with a better response ($p < 0.05$). The incidence of adverse events was also significantly lower in good responders ($p < 0.05$). Multivariate analysis identified younger age and lower CA15-3 concentration as independent predictors of favorable response, with area under the Receiver Operating Characteristic (ROC) curves (AUC) of 0.758 and 0.821, respectively ($p = 0.006$ and $p = 0.001$).

Conclusion: Neoadjuvant treatment using the Docetaxel-Carboplatin-Trastuzumab regimen provides favorable clinical outcomes in HER2-positive breast cancer patients. Baseline CA15-3 levels may serve as a useful predictor of treatment response.

Keywords: breast cancer, HER2-positive, neoadjuvant therapy, cancer antigen 15-3

Introduction

Breast cancer is a heterogeneous group of malignant tumors originating in the mammary gland and remains a significant global health burden, particularly among women.[1,2] According to a 2022 survey of 185 countries, there were 2.3 million new cases and 670,000 deaths due to breast cancer. Annual incidence rates increased by 1–5% in half of the surveyed countries, with projections indicating a 38% increase in new cases and a 68% increase in deaths by 2050.[3] Some Asian countries, including Vietnam, lack comprehensive national data on breast cancer incidence and mortality, primarily due to the absence of large-scale epidemiological surveys.[4,5]

Breast cancer development involves a complex interplay of genetic predisposition, environmental exposures, lifestyle factors, chronic inflammation, and oxidative stress, all of which contribute to hormonal imbalance and immunosuppression.[6,7] Early diagnosis and radical surgical resection remain the cornerstone of treatment. Multimodal approaches, including surgery, chemotherapy, radiation, and targeted therapies, are considered standard care based on disease subtype and stage.[8–10]

HER2-positive breast cancer, characterized by overexpression of the human epidermal growth factor receptor 2, accounts for approximately 15–20% of cases and is associated with aggressive behavior, increased cell proliferation, angiogenesis, and poor prognosis.[11,12] Neoadjuvant therapy combining chemotherapy and HER2-targeted agents has demonstrated efficacy in downstaging tumors, facilitating curative surgery.[13–15] However, implementation remains challenging in low-resource settings due to financial constraints. This study aimed to evaluate the clinical outcomes

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and predictive factors associated with the Docetaxel-Carboplatin-Trastuzumab (TCH) neoadjuvant regimen in Vietnamese patients with HER2-positive breast cancer.

Subjects and Methods

Study Design and Population

This was a prospective, longitudinal, non-interventional study involving female patients diagnosed with HER2-positive breast cancer who received neoadjuvant therapy with the TCH regimen at the Nuclear Medicine and Oncology Center, Bach Mai Hospital (Hanoi, Vietnam) from January 2023 to January 2024. Exclusion criteria included: age < 18 years; stage IV breast cancer; prior treatment for breast cancer; use of alternative neoadjuvant regimens; concurrent malignancies; acute infections; suspected surgical pathology; non-compliance with treatment protocol; pregnancy or lactation.

A total of 40 eligible patients provided informed consent and were enrolled in the study.

Neoadjuvant Treatment Protocol and Outcome Evaluation

Patients received the following regimen: Docetaxel 75 mg/m² and Carboplatin (AUC = 6 mg/mL/min) intravenously on day 1; Trastuzumab loading dose 8 mg/kg on day 1 of cycle 1, followed by 6 mg/kg in subsequent cycles. Treatment was administered every 21 days for a total of six cycles.

Baseline clinical and laboratory data were recorded prior to treatment initiation. Patients were re-evaluated every three cycles. Adverse events were monitored and recorded throughout the treatment period. Venous blood samples were collected at baseline and after completion of the sixth cycle to assess complete blood count, serum biochemistry, liver and renal function, and tumor markers. Additional assessments included liver ultrasound, ECG, echocardiography, and neuromuscular studies.

Treatment response was assessed according to RECIST criteria.[16] Patients were categorized into two groups:

- Good responders (n = 18): patients achieving clinical complete response (cCR) and eligible for curative surgery.
- Poor responders (n = 22): patients with partial response, stable disease, or progressive disease without indication for radical surgery.

Statistical Analysis

Continuous variables with a normal distribution were presented as mean ± standard deviation and compared using the Student's *t*-test or one-way ANOVA, as appropriate. Non-normally distributed variables were expressed as the median and interquartile range (IQR), with group comparisons conducted using the Mann–Whitney *U*-test or Kruskal–Wallis test. Categorical variables were summarized as frequencies and percentages and analyzed using the Chi-square test or Fisher's exact test, as appropriate.

Multivariate logistic regression was employed to identify independent predictors of treatment response. The predictive performance was assessed using receiver operating characteristic (ROC) curve analysis, and the area under the curve (AUC) was reported.

All statistical analyses were conducted using SPSS version 22.0 (Chicago, IL, USA), with a p-value of < 0.05 considered statistically significant.

Results

Table 1 shows that 45.0% of patients achieved a good response to treatment. Compared to the poor response group, patients with a good response had a lower mean age, a lower menopausal rate, a lower incidence of stage 2 and 3 disease, and lower serum CA15-3 levels. These differences were statistically significant ($p < 0.05$).

Table 2 presents a comparative analysis of adverse event incidence between patients with good and poor treatment responses. A wide range of side effects was observed, with 100% of patients experiencing anorexia and alopecia and 95% reporting nausea and vomiting. Regarding organ-specific toxicity, 100% of patients experienced at least one manifestation of hematologic toxicity, while neurotoxicity and hepatotoxicity were observed in 80% and 15% of patients,

Table 1 Clinical and Paraclinical Comparison Between Good and Poor Treatment Response Groups

Clinical Characteristics and Laboratory Parameters	Total (n=40)	Good Response (n=18)	Poor Response (n=22)	p
Age (years)	50.68 ± 10.53	45.61 ± 10.93	54.82 ± 8.33	**0.004**
Reason for hospital visit (n,%)				
- Palpable breast mass	36 (90)	17 (94.4)	19 (86.4)	0.613
- Breast pain	8 (20)	5 (27.8)	3 (13.6)	0.430
- Change in breast skin color or ulceration	3 (7.5)	0 (0)	3 (13.6)	0.238
Menopausal status (n,%)				
- Postmenopausal	21 (52.5)	6 (33.3)	15 (68.2)	**0.028**
- Premenopausal	19 (47.5)	12 (66.7)	7 (31.8)	
Breast lesion status (n,%)				
- Multifocal lesion	8 (20)	2 (11.1)	6 (27.3)	0.258
- Fixed mass	15 (37.5)	5 (27.8)	10 (45.5)	0.251
- Erythema	3 (7.5)	1 (5.6)	2 (9.1)	1.000
- Skin adhesions	1 (2.5)	1 (5.6)	0 (0)	0.450
- Skin retraction	2 (5)	1 (5.6)	1 (4.5)	1.000
- Ulceration	2 (5)	0 (0)	2 (9.1)	0.492
- Nipple retraction	1 (2.5)	0 (0)	1 (4.5)	1.000
Tumor location (n,%)				
- Right breast	19 (47.5)	10 (55.6)	9 (40.9)	0.356
- Left breast	21 (52.5)	8 (44.4)	13 (59.1)	
Lymph node involvement, n (%)				
- Axillary lymph nodes	31 (77.5)	12 (66.7)	19 (86.4)	0.253
- Supraclavicular lymph nodes	2 (5)	0 (0)	2 (9.1)	0.492
- Internal mammary lymph nodes	4 (10)	2 (11.1)	2 (9.1)	1.000
T Stage (n,%)				
- T1	3 (7.5)	2 (11.1)	1 (4.5)	0.812
- T2	29 (72.5)	13 (72.2)	16 (72.7)	
- T3	2 (5)	1 (5.6)	1 (4.5)	
- T4	6 (15)	2 (11.1)	4 (18.2)	
N Stage (n,%)				
- N0	4 (10)	3 (16.7)	1 (4.5)	**0.032**
- N1	24 (60)	13 (72.2)	11 (50)	
- N2	10 (25)	1 (5.6)	9 (40.9)	
- N3	2 (5)	1 (5.6)	1 (4.5)	
Disease stage (n,%)				
- IIA	7 (17.5)	5 (27.8)	2 (9.1)	0.221
- IIB	20 (50)	10 (55.6)	10 (45.5)	
- IIIA	4 (10)	0 (0)	4 (18.2)	
- IIIB	6 (15)	2 (11.1)	4 (18.2)	
- IIIC	3 (7.5)	1 (5.6)	2 (9.1)	
Pathological lesion type (n,%)				
- Tubular epithelial cancer	36 (90)	17 (94.4)	19 (86.4)	0.158
- Lobular epithelial cancer	3 (7.5)	0 (0)	3 (13.6)	
- Mucinous epithelial cancer	1 (2.5)	1 (5.6)	0 (0)	
CA15-3 (U/mL)	17.35 (8.65–38.85)	9.85 (5.85–17.3)	30.2 (16.66–49.8)	**0.001**
Good response (n,%)	18 (45.0)	-	-	-

Abbreviations: T, Tumor; N, Node; CA, Cancer Antigen. Bold values, significant differences.

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Table 2 Comparison of Patient Rates According to Adverse Events Between the Good and Poor Response Groups

Undesirable effects	Total (n=40)	Good Response (n=18)	Poor Response (n=22)	p
Side effect (n,%)				
- Anorexia	40 (100)	18 (100)	22 (100)	N/A
- Nausea and vomiting	38 (95)	17 (94.4)	21 (95.5)	1.000
- Oral mucositis	5 (12.5)	0 (0)	5 (22.7)	N/A
- Diarrhea	13 (32.5)	2 (11.1)	11 (50)	**0.009**
- Hair loss	40 (100)	18 (100)	22 (100)	N/A
- Hepatotoxicity	6 (15)	0 (0)	6 (27.3)	N/A
- Renal toxicity	0 (0)	0 (0)	0 (0)	N/A
- Cardiotoxicity	0 (0)	0 (0)	0 (0)	N/A
- Neurotoxicity	32 (80)	12 (66.7)	20 (90)	0.11
Hematologic toxicity (n,%)				
- Decreased WBC	25 (62.5)	8 (44.4)	17 (77.3)	**0.033**
- Decreased neutrophils	28 (70)	9 (50)	19 (86.4)	**0.013**
- Decreased platelets	2 (5)	0 (0)	2 (9.1)	N/A
- Decreased hemoglobin	12 (30)	2 (11.1)	10 (45.5)	**0.018**

Abbreviations: WBC, White blood cell. Bold values, significant differences.

respectively. No instances of renal or cardiac toxicity were reported. Notably, the frequency of both side effects and hematologic toxicity was significantly lower in the good response group compared to the poor response group ($p < 0.05$).

Among the variables analyzed, younger age (OR = 0.815; 95% CI: 0.701–0.949; $p = 0.008$) and lower CA15-3 levels (OR = 0.890; 95% CI: 0.798–0.992; $p = 0.036$) were found to be statistically significant independent predictors of good response to treatment ($p < 0.05$). Other variables, including Stage III disease and decreased neutrophil count, did not reach statistical significance.

Figure 1 illustrates that age and CA15-3 levels are potential predictors of favorable treatment response in patients with HER2-positive breast cancer. Notably, CA15-3 demonstrated high predictive value, with an area under the curve (AUC) of 0.821 and a statistically significant p-value < 0.001.

Discussion

Outcomes of Neoadjuvant Treatment with the Docetaxel-Carboplatin-Trastuzumab Regimen in Patients with HER2-Positive Breast Cancer

Radical surgery remains the cornerstone in the management of breast cancer. Depending on the stage of the disease, patients may undergo lumpectomy, lumpectomy combined with mastectomy, or lumpectomy/mastectomy with regional lymph node dissection.[17,18] In some instances, patients may present with locally advanced disease at the time of initial diagnosis, necessitating tumor downstaging prior to surgery. Neoadjuvant therapy has been widely adopted to achieve this goal and increase the rate of breast conservation. Adding trastuzumab to neoadjuvant therapy has demonstrated significant clinical benefits, including the pathological complete response (pCR) rate, promoting tumor shrinkage, and improving breast-conservation outcomes in HER2-positive breast cancer.[13,19,20] Targeting the HER2 pathway with trastuzumab has increased the pathological complete response rate. The Docetaxel-Carboplatin-Trastuzumab (TCH) regimen demonstrates high efficacy and safety, with favorable 5-year disease-free survival and overall survival outcomes in patients with HER2-positive breast cancer.[21] Trastuzumab is now established as a key therapeutic agent in both early-stage and metastatic HER2-positive breast cancer due to its capacity to disrupt HER2 signaling and modulate the tumor immune microenvironment.[22,23] Carboplatin, a platinum-based agent, enhances the immunogenic effects of chemotherapy and provides clinical benefit in early HER2-positive breast cancer.[24,25] Docetaxel is frequently employed as part of

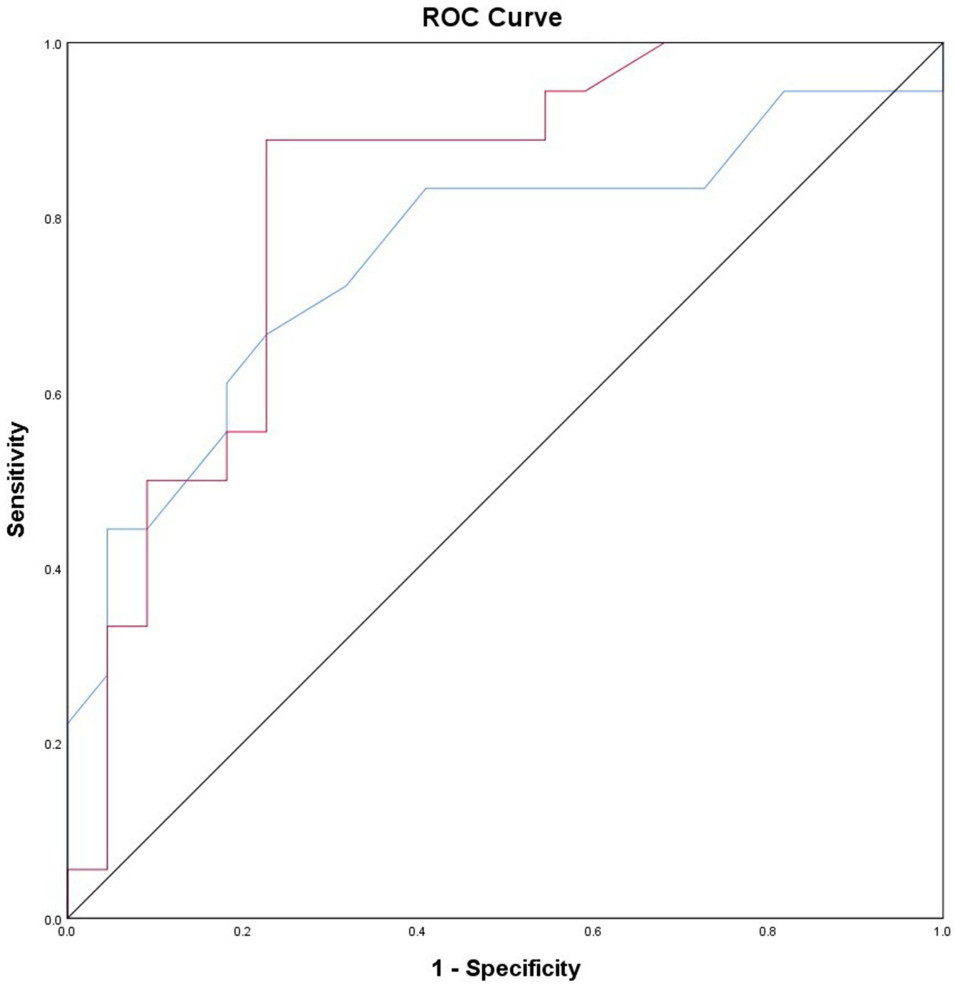

Figure 1 ROC curves of some tumor factors predict a good treatment response (Blue line: Age; Red line: CA15-3; Black line: Reference line).
Notes: Age: AUC = 0.758; p = 0.006; cut-off value = 48.5 years; sensitivity = 77.3%; specificity = 66.7%; CA15-3: AUC = 0.821; p = 0.001; cut-off value = 17.75 U/mL; sensitivity = 77.3%; specificity = 88.9%.

first-line combination therapy for patients with HER-2-positive metastatic breast cancer, attributed to its potent antitumor activity.[26]

Our study supports these findings, reporting a clinical complete response (cCR) rate of 45.0% (18 out of 40 patients; Table 1). Regarding toxicity, both systemic and organ-specific adverse events were observed, with a safety profile consistent with previously published studies.[21,27] Our results confirm that neoadjuvant therapy with the Docetaxel-Carboplatin-Trastuzumab regimen yields favorable efficacy and safety outcomes in HER2-positive breast cancer. We believe that this treatment approach demonstrates promising outcomes and may serve as a valuable reference for clinicians worldwide, particularly in Vietnam, in the management of patients with HER2-positive breast cancer.

Predictive Factors Associated with Good Treatment Response

Despite the clinical benefits of the Docetaxel-Carboplatin-Trastuzumab regimen, its use in Vietnam remains limited due to the high cost. In our study, 45.0% (18/40) of patients responded favorably (Table 1). Upon comparing clinical characteristics between responders and non-responders, we found that the good response group was characterized by younger age, earlier disease stage, fewer hematologic toxicities, and lower serum CA15-3 levels (Tables 1 and 2).

Table 3 Multivariate Analysis of Independent Tumor Factors Associated with Good Treatment Response

Variable	Odds Ratio	95% CI	p
Ages	0.815	0.701–0.949	**0.008**
Stage III	0.157	0.011–2.228	0.171
CA 15–3 level	0.890	0.798–0.992	**0.036**
Decreased neutrophils	0.130	0.004–4.819	0.269

Abbreviations: CA, Cancer Antigen. Bold values: significant differences.

Multivariate analysis identified younger age and reduced CA15-3 levels as independent predictors of favorable response (Table 3). Specifically, patients aged < 48 years (p = 0.006) or with CA15-3 levels < 17.75 U/mL (p = 0.001) were significantly more likely to benefit from neoadjuvant treatment with this regimen (Figure 1).

Various clinical and paraclinical markers have been explored as predictors of treatment response. For instance, Wang L. et al identified elevated IL-6, NK-T cells, the CD4+/CD8+ T-cell ratio, and tumor-infiltrating lymphocytes as predictive markers for response to six cycles of neoadjuvant docetaxel, carboplatin, and trastuzumab in 42 HER2-positive patients.[28] More recently, Bion M. et al suggested Trop-2 expression as a potential biomarker of resistance to neoadjuvant chemotherapy with dual HER2 blockers in a cohort of 41 HER2-positive breast cancer patients.[29] Our findings suggest that serum CA15-3 levels and patient age can serve as accessible, cost-effective indicators for predicting response to neoadjuvant therapy with Docetaxel-Carboplatin-Trastuzumab regimen in HER2-positive breast cancer patients.

Our study results have achieved the objectives, however, the study has some limitations as follows: The sample size was relatively small, comprising only 40 cases from a single center, which limits the generalizability of the findings. Furthermore, the follow-up duration was short, and pathological complete response (pCR) was not assessed, preventing an evaluation of disease recurrence.

Conclusion

Neoadjuvant therapy with the Docetaxel-Carboplatin-Trastuzumab regimen in 40 patients with HER2-positive breast cancer demonstrated favorable clinical outcomes. The overall good response rate was 45.0% (18/40 patients). A lower plasma CA15-3 level was significantly associated with treatment efficacy, with an AUC of 0.821 and a p-value of 0.001.

Data Sharing Statement

The data presented in this study are available on request from the corresponding author.

Ethics Approval

This study was approved by the Ethical Committee of Bach Mai Hospital (No: 4676/QĐ-BVBM).

Animals did not participate in this research. All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2008.

Consent for Publication

Informed consent was obtained from all the participants.

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The authors have no relevant financial or non-financial interests to disclose.

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