

TREATMENT OUTCOME OF NEOADJUVANT THERAPY WITH TCHP REGIMEN IN PATIENTS WITH HER2+ BREAST CANCER AT HANOI ONCOLOGY HOSPITAL

Le Thu Ha, Tran Thi Kim Anh*

ABSTRACT

Objective: To evaluate the efficacy of neoadjuvant treatment using the TCHP regimen in patients with HER2-positive breast cancer at Hanoi Oncology Hospital.

Materials and Methods: A combined retrospective and prospective cross-sectional descriptive study was conducted on patients with HER2-positive breast cancer treated with the TCHP regimen as neoadjuvant at Hanoi Oncology Hospital from January 2023 to September 2025.

Results: Among 36 enrolled patients, the average age was 48.6 years (range 30–70). There were 20 patients (55.6%) with stage II and 16 patients (44.4%) with stage III disease; 14 patients (38.9%) underwent clip placement before treatment. After 3 cycles, 7 patients (19.4%) achieved clinical complete response; after 6 cycles, this rate doubled to 14 patients (38.9%). The pathological complete response (pCR) rate was achieved in 24 patients (75%). Clinical complete response was a predictive factor for achieving pCR ($p < 0.05$), while no significant association was found between pCR and age, stage, histological grade, hormone receptor status, or Ki-67. No patients experienced disease progression during treatment. Most adverse events (AEs) were at grade 1–2. The most common grade 3–4 AE was neutropenia (3 patients, 8.3%). No grade 3–4 thrombocytopenia, hepatic, renal, or cardiac toxicities were observed. Two patients (5.6%) experienced grade 1 left ventricular ejection fraction reduction without requiring treatment delay.

Conclusion: The TCHP regimen demonstrates high efficacy with good tolerability and manageable, predictable AEs in patients with HER2+ breast cancer.

Keywords: HER2-positive breast cancer, neoadjuvant therapy, TCHP.

1. INTRODUCTION

Breast cancer is the most common cancer among women worldwide and the leading cause of cancer-

related mortality in females.[1]whereas around one in nine men and one in 12 women die from it. Lung cancer was the most frequently diagnosed cancer in 2022, responsible for almost 2.5 million new cases, or one in eight cancers worldwide (12.4% of all cancers globally According to GLOBOCAN 2022, there were 24,563 new cases of breast cancer, with an age-standardized incidence rate of 46.1 per 100,000 population in Vietnam. HER2-positive breast cancer is often associated with poor prognosis, rapid progression, and early recurrence.

Hanoi Oncology Hospital

*Corresponding author: Tran Thi Kim Anh

Email: lalapulaputa@gmail.com

Date received: 01/4/2026

Date reviewed: 10/4/2026

Date accepted for publication: 15/4/2026

Breast cancer treatment is a typical example of multimodal therapy combining local-regional approaches (surgery, radiotherapy) and systemic treatments (chemotherapy, endocrine therapy, targeted therapy, immunotherapy). Neoadjuvant chemotherapy is administered before surgery and has comparable survival outcomes to adjuvant chemotherapy. [2] Additionally, neoadjuvant therapy offers advantages such as downstaging inoperable tumors to operable status, increasing breast-conserving surgery rates, and enabling assessment of tumor response. In HER2-positive breast cancer, multiple studies have shown that achieving pathological complete response (pCR) is associated with improved disease-free survival (DFS) and overall survival (OS). [3] Therefore, pCR is an important prognostic factor and a key endpoint in evaluating treatment efficacy.

The TCHP regimen combines dual HER2-targeted therapy (trastuzumab and pertuzumab) with chemotherapy (docetaxel and carboplatin), administered every 3 weeks for 6 cycles before surgery. The TRYPHAENA trial demonstrated that TCHP achieved comparable efficacy to anthracycline-containing regimens, with a pCR rate of 66.2%. Patients achieving pCR had significantly improved DFS (HR = 0.27), while cardiac safety was favorable, with only 3.9% experiencing decreased left ventricular ejection fraction compared to 5.6% in anthracycline-containing regimens. [4] Despite its proven efficacy and widespread use, data on the TCHP regimen in Vietnam remain limited. Therefore, we conducted this study to evaluate the efficacy of this regimen in the neoadjuvant treatment of HER2-positive breast cancer.

2. MATERIALS AND METHODS

2.1. Study population

Patients with HER2-positive breast cancer treated with neoadjuvant TCHP at Hanoi Oncology

Hospital from January 2023 to September 2025 were included.

Inclusion criteria

Histologically confirmed invasive breast carcinoma with HER2 positivity on immunohistochemistry; cases with HER2 (++) required confirmation by dual-ISH or FISH amplification;

Stage II–III disease: tumor ≥ 2 cm or node-positive;

Received neoadjuvant TCHP regimen;

ECOG performance status ≤ 2 ;

No contraindications to anti-HER2 therapy: severe cardiovascular diseases, LVEF $< 50\%$;

Adequate hematologic and biochemical parameters;

Complete medical records available.

Exclusion criteria

Bilateral breast cancer;

Concurrent malignancies;

Severe comorbidities with high risk of mortality;

Non-compliance with treatment.

2.2. Methods

Study design: Retrospective–prospective descriptive study.

Study period: March 2024 to September 2025.

Sample size: Convenience sampling, all patients who satisfied the inclusion criteria and did not violate exclusion criteria were enrolled.

Data collection

Data collected from archived medical records (retrospective group) and inpatient records (prospective group).

Standardized medical report forms were used.

AEs were recorded and clinical response assessed after each cycle.

Response was evaluated after 3 and 6 cycles using clinical and imaging assessment, pCR was

evaluated following the pathology protocol.

Response rate and selected factors's association with pCR response were calculated.

Treatment regimen:

Table 1: TCHP regimen

Drug	Dose	Administration
Pertuzumab	840 mg Cycle 1	In 250 mL sodium chloride 0.9% over 60 minutes
	420 mg Cycle 2 - 6	In 250 mL sodium chloride 0.9% over 30-60 minutes
Trastuzumab	8 mg/kg Cycle 1	In 250 mL sodium chloride 0.9% over 90 minutes
	6 mg/kg Cycle 2 - 6	In 250 mL sodium chloride 0.9% over 30 minutes
Docetaxel	75 mg/m ²	In 250 mL to 500 mL sodium chloride 0.9% over 60 minutes
Carboplatin	AUC 6	In 500 mL glucose 5% over 30-60 minutes

Study variables

- Patient characteristics: age, PS, menopausal status, tumor characteristics (stage, immunohistochemistry, Dual-ISH, histological type, histological grade)

- Treatment outcomes: response rate and adverse events.

+ Clinical response was evaluated according to RECIST 1.1 criteria after every 3 cycles.

+ Pathological response was assessed according to the Chevallier classification. Based on this classification, responses were categorized into two groups: pathological complete response (pCR) yp T0/Tis ypN0. and non-pathological complete response (non-pCR).

+ Adverse events were graded according to CTCAE version 5.0

- Management of treatment-related adverse events:

+ Prophylaxis of neutropenia using pegfilgrastim administered on day 2, at least 24 hours after completion of chemotherapy infusion.

+ Patients experiencing AEs were managed according to severity.

+ Management of cardiotoxicity related to trastuzumab and pertuzumab: if LVEF < 50%, treatment was discontinued and the patient was referred for cardiology evaluation.

Statistical analysis

Data were analyzed using SPSS version 20.0.

2.3. Research ethics

The study regimen was approved and issued in the national guidelines for diagnosis and treatment by the Ministry of Health. The study was conducted with the approval of Hanoi Oncology Hospital Ethics Committee. This was a descriptive study and did not interfere with the patient's treatment process. All patient-related information and clinical data were kept confidential. The study results were intended solely to improve treatment quality and quality of life, and not for any other purposes.

4. RESULTS

4.1. Patient characteristics

Table 2. Patient characteristics

Patient characteristics	(n=36)	(%)
Age(mean: 48.6)		
Reason for hospital admission	5	13.5
Self-detected breast lump	24	66.7
Self-detected lymph node	5	13.9
Self-detected breast lump and node	7	19.4
Menstrual status		
Postmenopausal	15	41.7
Premenopausal	21	58.3
cT		
cT1	1	2.8
cT2	24	66.7
cT3	4	11.1
cT4	7	19.4
cN		
cN0	10	27.8
cN1	15	41.7
cN2	7	19.4
cN3	4	11.1
Stage		
IIA	10	27.8
IIB	10	27.8
IIA	7	19.4
IIB	5	13.9
IIC	4	11.1
Clip placement		
Yes	14	38.9
No	22	61.6
Pathology		

Patient characteristics	(n=36)	(%)
NST	34	94.4
Micropapillary carcinoma	1	2.8
Papillary carcinoma	1	2.8
Grade		
2	31	86.1
3	5	13.9
HR		
Positive	18	50
Negative	18	50
Ki-67		
< 15%	6	16.7
15-35%	9	25
> 35%	21	58.3

HR: Hormone receptor, NST: invasive carcinoma of no special type.

A total of 36 patients were enrolled, including 10 patients in the retrospective group and 26 patients in the prospective group. The characteristics of the study population are presented in the above Table 2.

4.2. Treatment efficacy

Table 3. Response rate

Response		N	%
Clinical response			
3 cycles	CR	7	19.4
	PR	25	69.4
	SD	4	11.1
	PD	0	0
6 cycles	CR	14	38.9
	PR	19	52.8
	SD	3	8.3
	PD	0	0

Response		N	%
Planned for surgery		36	100
Surgical methods	MRM	24	75
	SSM	7	21.9
	Conservation	1	3.1
	Total	32	100
Pathology response			
Chevallier classification	Grade 1	17	53.1
	Grade 2	7	21.9
	Grade 3	5	15.6
	Grade 4	3	9.4
	Total	32	100
pCR	pCR	24	75
	Non pCR	8	25
	Total	32	100

CR: complete response, PR: partial response, SD: stable disease, PD: progressive disease, MRM: modified radical mastectomy, SSM: skin-sparing mastectomy, pCR: pathology complete response (yp T0/Tis ypN0).

According to the above Table 3, clinical response was evaluated according to RECIST 1.1 criteria. The overall response rate was 88.9%. Four patients had stable disease, and no patients were reported to have disease progression during treatment. All 36 patients completed 6 cycles of neoadjuvant therapy and were planned for surgery. The majority underwent modified radical mastectomy (MRM), with only one patient undergoing breast-conserving surgery and seven patients undergoing skin-sparing mastectomy. Seventeen patients had no residual cancer in both the breast tumor and axillary lymph nodes (53.1%), while seven patients had residual carcinoma in situ (21.9%). The pCR rate (grade 1 and grade 2 according to Chevallier classification) was 75%.

Table 4. Response rate and correlated factors

Correlated factors	pCR	No pCR	p
Age(mean: 48.6)	50.5	42.6	0.109
cT			
cT1	0	1	
cT2	16	5	
			0.225
cT3	4	0	
cT4	4	2	
cN			
cN0	8	1	0.041
cN1	7	7	
cN2	6	0	
cN3	3	0	
Stage			
II	13	6	0.42
III	11	2	
<i>Clinical response</i>			
CR	14	0	0.001
PR	10	5	
SD	0	3	
Pathology			
NST	23	7	
			0.444
Other	1	1	
Grade			
2	19	8	
			0.296
3	5	0	
HR			
Positive	11	6	
			0.229
Negative	13	2	
Ki-67			

Correlated factors	pCR	No pCR	p
> 15%	3	3	0.346
15-35%	7	1	
> 35%	14	4	

CR: complete response, PR: partial response, SD: stable disease, PD: progressive disease, MRM: modified radical mastectomy, SSM: skin-sparing mastectomy, pCR: pathology complete response (yp T0/Tis ypN0), HR: hormone receptor, NST: invasive carcinoma of no special type.

Table 4 showed that the pCR rate was associated with nodal metastasis status ($p = 0.041$), and clinical response was a predictor of pCR ($p = 0.001$). Meanwhile, we did not observe any statistically significant differences in pCR rates when analyzing associations with age, tumor stage, overall stage, tumor histology, histological grade, hormone receptor status, and Ki-67 ($p > 0.05$).

Table 5. Treatment adverse events

Adverse Event (AE)	Grade 3, 4		Grade 1, 2	
	n = 36	%	n=36	%
Neutropenia	3	8.3	4	11.1
Febrile neutropenia	0	0		
Anemia	1	2.8	7	19.4
Thrombocytopenia	0	0	4	11.1
Nausea, vomiting	0	0	14	38.9
Increased serum creatinine	0	0	0	0
Increased AST	0	0	16	44.4
Increased ALT	0	0	17	47.2
Decreased LVEF	0	0	2	5.6

LVEF: left ventricular ejection fraction.

During treatment, most adverse events were at grade 1–2. The most common grade 3–4 AE was neutropenia. No grade 3–4 thrombocytopenia, hepatic, or renal toxicities were recorded. No patients developed heart failure or a decrease in left ventricular ejection fraction, leading to treatment delay or discontinuation. Two patients experienced grade 1 reduction in LVEF that did not require treatment delay.

5. DISCUSSION

Neoadjuvant chemotherapy was previously associated with concerns about delaying local treatment; if the disease progresses on neoadjuvant, patients could lose the chance of definitive treatment. However, breast cancer is considered a systemic disease, emphasizing the importance of systemic therapy. Numerous studies have demonstrated that neoadjuvant chemotherapy provides survival outcomes comparable to adjuvant therapy.[2] Recent evidences indicate that pCR is the most important endpoint, strongly associated with long-term outcomes such as OS and DFS.[3] It also allows treatment escalation or de-escalation strategies, particularly relevant in HER2-positive disease with the advancement of targeted therapies. The development of anti-HER2 therapies, starting with trastuzumab followed by pertuzumab, has demonstrated an improvement in pCR rates when dual HER2 blockade is combined. The NeoSphere study showed that the pCR rate increased from 29% to 46% with the combination of dual HER2 blockade and chemotherapy.[5] The combination of non-anthracycline chemotherapy with trastuzumab and pertuzumab helps reduce AEs without compromising pCR rates in the neoadjuvant setting.[6]

In our study, 24 patients achieved pCR (53.1% group 1 and 21.9% group 2 according to the Chevallier classification), accounting for 75%. This is a relatively high pCR rate compared with other studies such as the THP regimen in the NeoSphere study, where the pCR rate was 45.8%. [5] This difference may be explained by the fact that our regimen used a combination of two chemotherapeutic agents rather than docetaxel alone com-

bined with anti-HER2 therapy. When compared with the landmark studies using the same TCHP regimen, namely TRAIN-2 and TRYPHAENA, where the pCR rates were 68% and 66%, respectively, our response rate was also higher. Furthermore, when compared with anthracycline-based regimens, which have traditionally been considered the backbone of breast cancer treatment, the pCR rate of the TCHP regimen is not inferior, and may even be somewhat higher, as shown in the results of these two studies.[4], [6] When compared with real-world data from Kim et al. in South Korea (2022) using neoadjuvant TCHP, our pCR rate was also higher (75% vs. 64%).[7] Compared with a domestic study by Phung Thi Huyen (2021), which evaluated AC-THP and TCHP in 20 patients with neoadjuvant breast cancer and reported a pCR rate of 80%, our result was slightly lower.[8] This difference may be attributed to heterogeneity in study populations (high proportion of cT2, stage II, HR-negative status, treatment regimens, sample size, disease stage, and pathological and molecular characteristics). Therefore, further studies with larger sample sizes are needed.

Many studies have attempted to identify predictive factors for pCR. The TECHNO study showed no difference in pCR rates according to age (<40 vs. ≥40), histological type, histological grade, tumor stage, nodal stage, and hormone receptor status.[9] However, the GeparQuattro study demonstrated a significantly different pCR rate in the hormone receptor-negative group (43.5%) compared with the hormone receptor-positive group (23.4%), with $p < 0.001$. [10] In our analysis, while evaluating pCR according to age, tumor stage (T), nodal stage (N), overall stage, histological type, histological grade, hormone receptor status, and Ki-67, we did not observe any association between these factors and pCR, which is consistent with the TECHNO study. The pCR rate in our study was higher in patients who achieved clinical complete response (100% vs. 66.7%, $p < 0.05$). This finding is similar to that reported by

Hang D.N (2022), where a higher pCR rate was observed in patients achieving clinical complete response ($p < 0.001$). [11]

Our study also showed that the TCHP regimen was well tolerated. The most common grade 3–4 adverse events were neutropenia and anemia, with rates of 8.3% and 2.8%, respectively. These rates were significantly lower compared with the same regimen used in the TRYPHAENA study, where the rate of grade 3–4 neutropenia was 46%, and even higher in the TRAIN-2 study at 54%. [4], [5] This may be explained by the routine use of prophylactic G-CSF in all patients, as the TCHP regimen carries a high risk of neutropenia and is included in national guidelines. The higher rate of neutropenia in the TRAIN-2 study may also be due to the use of 9 cycles of TCHP instead of 6 cycles. This may be one of the reasons why 6 cycles of TCHP are recommended as the standard regimen, as 9 cycles do not improve efficacy but increase AEs. Cardiotoxicity is always a concern when using anti-HER2 therapies; however, in our study, no cases of severe cardiac events or treatment delay/discontinuation due to cardiac toxicity were observed. Overall, the TCHP regimen demonstrated good tolerability, both in terms of hematologic and non-hematologic AEs.

6. CONCLUSION

The TCHP regimen demonstrated high efficacy with a high pCR rate (75%) and good tolerability, with manageable AEs.

REFERENCES

- [1]. Bray F., Laversanne M., Sung H. et al. (2024). Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA: A Cancer Journal for Clinicians*, 74(3), 229–263.

- [2]. Mauri D., Pavlidis N., và Ioannidis J.P.A. (2005). Neoadjuvant versus adjuvant systemic treatment in breast cancer: a meta-analysis. *J Natl Cancer Inst*, 97(3), 188–194.
- [3]. Cortazar P., Zhang L., Untch M. et al. (2014). Pathological complete response and long-term clinical benefit in breast cancer: the CTNeoBC pooled analysis. *The Lancet*, 384(9938), 164–172.
- [4]. A. Schneeweiss, S. Chia, et al (2013). Pertuzumab plus trastuzumab in combination with standard neoadjuvant anthracycline-containing and anthracycline-free chemotherapy regimens in patients with HER2-positive early breast cancer: a randomized phase II cardiac safety study (TRYPHAENA), *Annals of Oncology*, Volume 24, Issue 9, 2013, Pages 2278-2284,
- [5]. Gianni L., Pienkowski T., Im Y.-H. et al. (2012). Efficacy and safety of neoadjuvant pertuzumab and trastuzumab in women with locally advanced, inflammatory, or early HER2-positive breast cancer (NeoSphere): a randomised multicentre, open-label, phase 2 trial. *The Lancet Oncology*, 13(1), 25–32.
- [6]. Ramshorst M.S. van, Voort A. van der, Werkhoven E.D. van. et al. (2018). Neoadjuvant chemotherapy with or without anthracyclines in the presence of dual HER2 blockade for HER2-positive breast cancer (TRAIN-2): a multicentre, open-label, randomised, phase 3 trial. *The Lancet Oncology*, 19(12), 1630–1640.
- [7]. Kim J.-Y., Nam S.J., Lee J.E. et al. (2022). Real World Evidence of Neoadjuvant Docetaxel/Carboplatin/Trastuzumab/Pertuzumab (TCHP) in Patients with HER2-Positive Early or Locally Advanced Breast Cancer: A Single-Institutional Clinical Experience. *Cancer Research and Treatment: Official Journal of Korean Cancer Association*, 54(4), 1091.
- [8]. Phung T.H. (2021). The outcome of neoadjuvant therapy with chemotherapy combined to trastuzumab and pertuzumab in early her2-neu positive breast cancer patients. *VMJ*, 509(1).
- [9]. Untch M., Fasching P.A., Konecny G.E. et al. (2011). Pathologic complete response after neoadjuvant chemotherapy plus trastuzumab predicts favorable survival in human epidermal growth factor receptor 2-overexpressing breast cancer: results from the TECHNO trial of the AGO and GBG study groups. *J Clin Oncol*, 29(25), 3351–3357.
- [10]. Untch M., Rezai M., Loibl S. et al. (2010). Neoadjuvant treatment with trastuzumab in HER2-positive breast cancer: results from the GeparQuattro study. *J Clin Oncol*, 28(12), 2024–2031.
- [11]. Đoan N.H., Trinh L.H. (2022). The outcome of neoadjuvant treatment with AC-T dose dense in patients with early breast cancer at Hanoi medical university hospital. *VMJ*, 519(1).