Research article

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Evaluation of the efficacy of chemotherapy regimen with Taxane in combination with Trastuzumab biosimilars in preoperative treatment of HER2-positive breast cancer

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Abstract

Aims: To evaluate the overall response rate (ORR) and pathological complete response (pCR). Identify side effects of biosimilar trastuzumab in combination with taxane-based chemotherapy for patients with HER2-positive breast cancer.

Methods: Retrospective study of cases with HER2 (+) breast cancer, stage II-III-IV treated with biosimilar trastuzumab 8mg/kg at the first cycle, then following 6 mg/kg) in combination with taxane-based chemotherapy (TCH regimen including: Docetaxel 75mg/m^2 with or without Carboplatin AUC 6, or AC – TH (P) regimen including: Doxorubicin 60 mg/m^2, Cyclophosphamide 600 mg/m^2 – Docetaxel 100mg/m^2 with or without Pertuzumab 840 mg at the first cycle, then following 420 mg) at HCM city Oncology hospital from 01/01/2022-31/12/2022. Re-evalutaion for surgery is done after 6 cycles.

Results: The overall response rate was 95.7%, with a clinical partial response rate of 78.9% and a complete response rate of 16.8%. The pathological complete response rate was 49.5%. Side effects were controlled: no cases of congestive heart failure were reported, and 3.4% of cases developed grade 4 febrile neutropenia.

Conclusion: Biosimilar trastuzumab in combination with taxane-based chemotherapy for patients with HER2-positive breast cancer demonstrates a significant complete response rate with well-controlled toxicities.

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1. INTRODUCTION

Breast cancer is the most common type of cancer in women. According to GLOBOCAN 2020 [1], the incidence and mortality rate of breast cancer worldwide and in Vietnam are also the most common cancer in women, with annual incidence rates of 47.8/100,000 and 34.2/100,000, respectively, and mortality rates of 13.6/100,000 and 13.8/100,000.

Combination of targeting at HER2 with trastuzumab and chemotherapy in many studies has been noted to increase the rate of complete histopathological response, increase the operability in locally advanced and possibility of conservative surgery in early stage, reduce the rate of distant metastases and prolong survival compared to patients treated with chemotherapy alone.

The combination regimen with taxane and biosimilar trastuzumab has been approved by the FDA and has been included in international and Vietnamese

treatment guidelines for neoadjuvant therapy of HER2-positive breast cancer.

At Ho Chi Minh City Oncology Hospital, biosimilar drug trastuzumab for HER2-positive breast cancer patients has been implemented since 06/2018, then HER2-positive breast cancer patients have more opportunities to access HER2 inhibitor treatment. We conducted this study to evaluate the clinical and histopathological response to treatment with the biosimilar drug trastuzumab in patients with stage II, III, IV breast cancer who are HER2-positive.

Endpoints

1- Overall Clinical Response Rate (ORR) Assessment
2- Evaluation of histopathological complete response rate (tpCR)
3- Investigation of the toxicities of the combination regimen

2. MATERIALS-METHODS

2.1. Population and treatment

Female over 18 years of age, diagnosed with stage I, II, III, and IV HER2 (+) breast cancer, received preoperative chemotherapy with a chemotherapy regimen with taxane (TCH regimen including docetaxel 75 mg/m^2 in combination with or without carboplatin AUC 6, or AC – TH (P) including Doxorubicin 60 mg/m^2, Cyclophosphamide 600 mg/m^2 – Docetaxel 100mg/m^2 with or without Pertuzumab 840 mg in the first cycle, then 420 mg from the following cycle) in combination with trastuzumab (8mg/kg in the first cycle, 6 mg/kg from the next cycle) at Ho Chi Minh City Oncology Hospital. Ho Chi Minh City from 01/01/2022 to 31/12/2022. The patients were then assessed for the possibility of surgery after 6 cycles.

2.2 . Research method

Study design: A retrospective study, describing a series of cases.

Measurement of tumor and lymph node size on clinical mammography, ultrasound, mammography, and CT scan/MRI, assessed based on RECIST 1.1 criteria.

HER2 positive as determined by HER2 (3+) immunohistochemistry or a positive FISH test

Evaluation criteria for total clinical response (ORR) = complete response (CR) + partial response (PR) (WHO standard).

Histopathologically Complete Response (pCR): Defined as the absence of invasive tumor cells on the pathology upon postoperative specimen sample. Non-invasive residual tumors in the mammary gland are allowed. tpCR is a term defined as the absence of invasive cancer cells present upon microscopic examination of the residual primary tumor and axillary lymph nodes after surgery.

2.3 Toxicity

Toxicities are documented according to CTCAE standard version 4.03.

We recorded 119 medical records that met the inclusion criteria

The data is processed using SPSS v.23 software.

3. RESULTS

3.1 Clinical characteristics

Table 1. Clinical features

Character	**n=119**
Average age	47.8 (31-77 years old)
≤ 35 years old	9 (7.6%)
36 - 60 years old	103 (86.5%)
60 - 70 years old	5 (4.2%)
> 70 years old	2 (1.7%)
Tumor stage (T)	

T1	1 (0.8%)
T2	43 (36.1%)
T3	14 (11.8%)
T4	61 (51.3%)
Lymph node stage (N)	
N0	25 (21%)
N1, N2	61 (51.3%)
N3	33 (27.7%)
Stage	
IIA	16 (13.4%)
IIB	12 (10.1%)
IIIA	10 (8.4%)
IIIB	46 (38.7%)
IIIC	31 (26.1%)
IV	4 (3.4%)

Table 2. Pathological features

Character	**n=119**
Type of disease anatomy	
Duct of the mammary gland	119 (100%)
Histology	
1	1 (0.8%)
2	100 (84%)
3	18 (15.2%)
HER2 (immunohistochemistry)	
3+	119 (100%)
Hormonal receptor status (subgroup)	
ER(+)/ PR(+)	55 (46.3%)
ER(-) PR(-)	64 (53.7%)
Ki 67	
≤ 10%	7 (5.8%)
10-20%	22 (18.4%)
> 20%	90 (75.8%)

Table 3. Treatment

Character	**n=119**
Duration of preoperative chemotherapy treatment with taxane and biosimilar trastuzumab	
Full 6 months of neoadjuvant	118 (99.1%)
Regimen without combination of carboplatin, anthracycline*	4 (3.4%)
Regimen with carboplatin**	114 (95.8%)
Regimen with anthracyclin***	1 (0.8%)
Post-chemotherapy surgery	114 (95.7%)
Mastectomy – Axillary lymph node curettage	98 (82.3%)
Emulsion section - Save skin	16 (13.4%)
Irradiation	
Yes	114 (95.7%)

**Docetaxel - Cyclophosphamide - Trastuzumab (TCH), or Docetaxel-Trastuzumab regimen*
***Docetaxel - Carboplatin/Cyclophosphamide - Trastuzumab with or without Pertuzumab (TCH(P))*
****Doxorubicin - Cyclophosphamide - Docetaxel-Trastuzumab (AC-TH)*

One 77-year-old patient received only 4 cycles of preoperative treatment because of poor tolerance and achieved complete clinical tumor response

The patients who were assessed to be partially or completely responsive underwent axillary lymph node curettage surgery.

All patients receive adjuvant radiation therapy

In 4 stage IV patients: there was one patient with bone metastases, one patient with lung metastases, one patient with mediastinal lymph node metastases, one

patient with metastases from 2 or more organs

Three continues trastuzumab postoperative.

3.2 Treatment results

Table 4. Clinical response after neoadjuvant

Character	(n=119)
Partial Reponse (PR)	94 (78.9%)
Complete Response (CR)	20 (16.8%)
Progressiv Disease (PD)	5 (4.3%)
Clinical Overall Response Rate (cORR)	114 (95.7%)

Table 5. Histopathological response

Character	n=119 (%)	
Tumor		
T0	45 (37,8%)	71 (59,6%)
Carcinom insitu	26 (21,8%)	
Invasive carcinoma	43 (36,1%)	
Lymph nodes (pN)		
pN0	76 (63.8%)	
pN1	23 (29.3%)	
pN2	13 (10.9%)	
pN3	2 (1.6%)	
Tumor and lymph nodes		
Partial response (tpPR)	55 (46.2%)	
ypT0N0	38 (31.9%)	59 (49.5%)
ypTisN0	21 (17.6%)	

There were 33 cases reaching ypCR, T0 or Tis but not lymph node (tpPR).

Of the four stage IV patients: three patients achieved pCR, one patient progressed and did not receive further treatment.

There were five patients who did not receive surgery due to advanced disease or inoperationability: one patient with stage IV (ER(+)) and three patients with stage IIIB (two patients with negative endocrine receptors).

Table 6. Evaluation of histopathological response according to some pathological characteristics

Response rate	N=119 (%)	ypPR	ypCR	
By stage of the tumor (T)				
T1	1	0	1 (100%)	p = 0.04
T2	43	17 (41.9%)	25 (58.1%)	
T3	14	7 (50%)	7 (50%)	
T4	61	33 (52.4%)	24 (39.3%)	
By stage				
IIA	16	4 (25%)	12 (75%)	p = 0.001
IIB	12	6 (50%)	6 (50%)	
IIIA	10	4 (40%)	6 (60%)	
IIIB	46	27 (58.6%)	15 (32.6%)	
IIIC	31	16 (51.7%)	15 (48.3%)	
IV	4	0	3 (75)	
By histological				
Grade 1	1	1 (100%)		p = 0.147

Grade 2	100	50 (50%)	48 (48%)	
Grade 3	18	6 (33.3%)	9 (50%)	
By Ki67 status				
≤ 10%	7	2 (28.5%)	4 (57.1%)	p = 0.231
10-20%	22	12 (54.6%)	10 (45.4%)	
>20%	90	43 (47.7%)	43 (47.7%)	
By Hormonal receptor status				
ER(+)/ PR(+)	55	29 (52.7%)	23 (41.8%)	p = 0.182
ER(-) PR(-)	64	28 (43.7%)	34 (53.1%)	
By chemotherapy regimen				
Regimen without carboplatin, anthracycline-free*	4 (3.36%)	1 (25%)	1 (25%)	p = 0.211
Regimen with carboplatin**	114 (95.4%)	55 (48.2%)	56 (49.2%)	
Regimen with anthracyclin***	1 (0.8%)	*1 (100%)*	0	

Table 7. Correlation between clinical response and disease anatomy

Meet		**Pathology**		**Total**
		ypPR	**ypCR**	
Clinical	cPR	52	42	94
	cCR	3	17	20
Total		55	59	**Kappa=0.228**

3.3 Toxicity

The main adverse events of grade 1 and 2 include anemia, thrombopenia, diarrhea, skin rash and urticaria in 1-2 cycles. Four patients had grade 4 neutropenia fever in first cycle and were not treated prophylactical GCSF (3.4%).

There were five cases hospitalized for blood transfusions in cycles 3 and 4. (4.2%)

There are no cases of heart failure as well as a decrease in LVEF of more than 10% or less than 50%.

4. DISCUSSION

In neoadjuvant therapy, research data show that the combination of chemotherapy and trastuzumab has a combined effect: a 50% reduction in recurrent rates and 30% in mortality.

Especially when it comes to the choice of chemotherapy drugs in combination with trastuzumab, the taxane group (Paclitaxel and Docetaxel) is considered the most effective agent, although there are still questions about which type of taxane is more effective or which course is more effective: weekly or every 3 weeks.

HER2-targeted drugs are a guarantee for increased treatment efficacy in both advanced and early-stage breast cancer group. The introduction of the biosimilar drug trastuzumab has eased patients to

receive more effective treatments while saving medical and economic resources for many countries.

In a study of Tran Nguyen Ha [2] and Le T. T. My Hoa [3] at the Oncology Hospital in 2013 and 2016 and a study from Northern of Do T. T. Mai [4] about neoadjuvant treatment for breast cancer patients with HER2 receptor (+) receptors, the number of patient records treated with trastuzumab was 33, respectively, 22 and 39.

From 06/2018, the biosimilar drug trastuzumab was approved by the health insurance system, increasing the number of patients using HER2 receptor inhibitors to 124 records as reported by Dr. Tran T Vy [5] from 2019 to 2021.

In our study, the result was similar or no significant different rate than the previous authors.

The mean age of the patients in the study was 47.8. The minimum age is 31 years old.

Of the 119 cases, there were 2 patients over 70 years old, who were prophylaxis with GCSF and adjusted the dose by 75%. In which, the oldest patient was 77 years old and received only 4 preoperative chemotherapy prescriptions due to poor chemotherapy tolerance and reach complete response in clinical.

There were 4 patients at stage IV admitted to the study, including one patient with bone metastases, one patient with lung metastases, one patient with mediastinal lymph node metastases, and one patient with metastases from 2 or more organs. This is different from the neoadjuvant treatment studies that have been conducted before.

4.1 Operation phase

Of the 119 patients, 114 cases were operated on, accounting for 95.7%, 4 cases were over indicated for surgery or advanced disease (1 patient in stage IV, 3 patients in stage IIIB).

Of the 114 surgical cases 82.3% were axillary lymph node dissection, skin-sparing mastectomy accounted for 13.4% and there were no cases of conservative surgery. The proportion of patients in stage III before treatment accounts for 73%, which explains the high rate of axillary lymph node dissection.

Among the 3 stage IV patients who underwent surgery, patients with lone bone metastases were further evaluated by bone scan and recorded stable disease. Patients with mediastinal lymph node metastases and bone metastases and one patient with lung metastases were all re-examined by PET scan before deciding on surgical treatment.

The NeoALTTO study [6] showed that factors such as surgical planning at diagnosis, multicenter tumor, endocrine receptor status, tumor size, and tumor residual after chemotherapy are factors that determine the type of surgy. The decision is also influenced by the geography, attitude and psychology of the patient.

4.2 Adjuvant phase

There were 95.7% of patients received chest wall radiation therapy 42.56 Gy/16 times, and to the supraclavicular region in the case of cN3.

All patients have now completed or are continuing biologically similar trastuzumab according to the protocol.

Patients with positive endocrine receptors were treated with endocrine therapy.

Overall survival efficacy and time to disease recurrence or metastasis require more long – term follow-up.

4.3 Clinical Response Assessment

Of the 94 cases that achieved cPR, 42 cases achieved histopathological pCR, which correlation between clinical and histopathological was under the median with kappa ratio =0.228. Most of these patients have no breast lesion on ultrasound, mammography or CT scan. Therefore, the ratio of false positives to malignant lesions of CT scan and ultrasound is high.

This issue can be explained by the improvement of tissue sample analysis techniques at the GPB department, the results of slice analysis for accurate histopathological results. (attached procedure). According to a report at the Department of Anatomy at Oncology Hospital, there are 30-50% of patients who are fully clinically responsive but still have tumor tissue on the surgical sample, on the contrast, 20% of cases are recorded and the clinical tumor reaches pCR.

Comparison of clinical overall response rates with domestic authors:

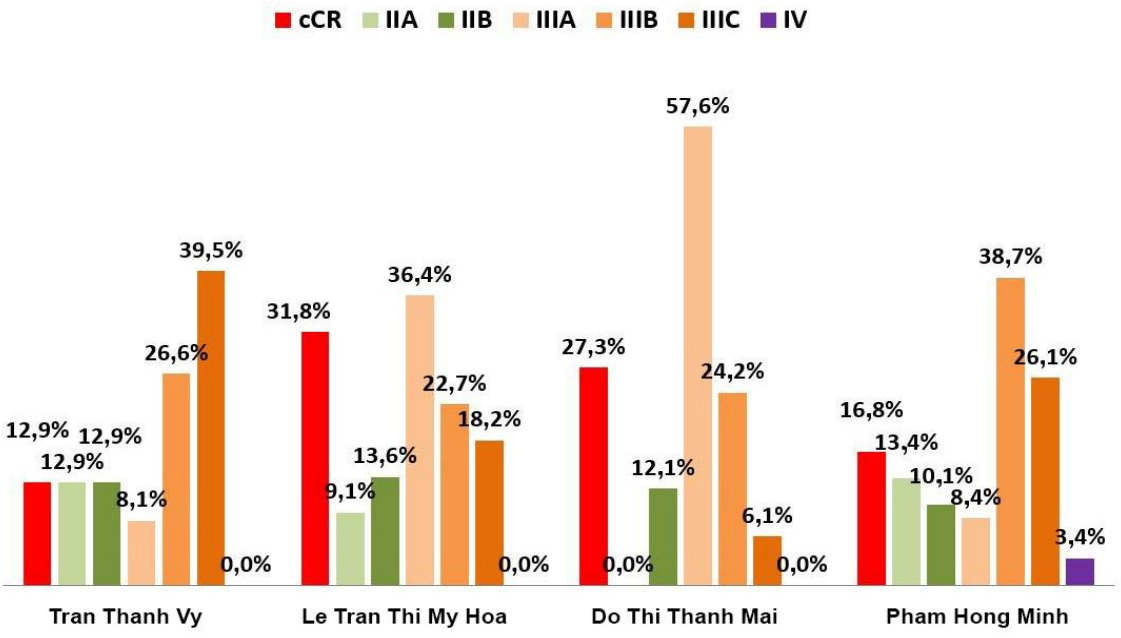


Fig 1. Comparison of clinical overall response rates with domestic authors

This difference may be due to the higher number of patients at stage III and the inclusion of stage IV patients.

4.4 Evaluation of histopathological response

In a 2012 meta-analysis [7], nearly 2000 patients with HER2-positive breast cancer treated with trastuzumab in combination with neoadjuvant chemotherapy increased the pCR rate from 23% to 40% and was associated with long-term outcomes in patients with HER2 positive, regardless of endocrine receptor status (HR EFS = 0.39, 95% KTC = 0.31 – 0.50; HR OS = 0.34, KTC 95% = 0.24 – 0.47).

In studies comparing chemotherapy combined with trastuzumab with neoadjuvant chemotherapy, the pCR rate in patients receiving trastuzumab was quite high from 43 to 65 percent, compared with 20 to 26.3 percent in the chemotherapy group (NeoCarth study, Buzdar AU and cs study [8]; NOAH study [9]).

Comparison with domestic authors using HER2 inhibitor therapy

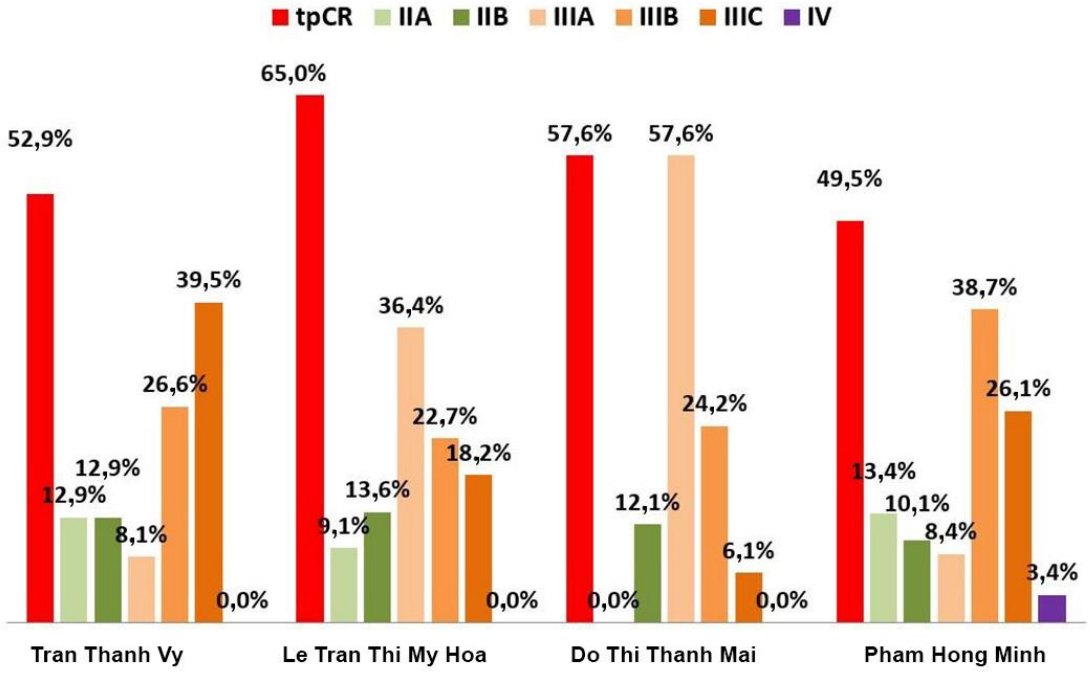


Fig 2. Comparison with domestic authors using HER2 inhibitor therapy

This difference can be explained by the fact that in our study the number of patients at stage III and IV patients is higher, and the patients at stage II patients is lower.

4.5 Evaluation of histopathological response according to pathological and treatment features

The TECHNO study [10] showed no difference in tpCR rates when considering age, histopathological type, histological degree, tumor stage, lymph node stage, and endocrine receptor status. In contrast, the GeparQuattro study showed that the pCR rate was higher in the negative endocrine receptor group of 43.5%, in the positive endocrine receptor group it was only 23.4% with a $p < 0.001$, and no pCR rate related to histology was recorded.

Our study noted a statistically significant association between the pCR rate with the tumor stage (T) and the ganglion stage (N) with a $p < 0.05$, similar to the results of author Tran T. Vy.

Considering endocrine receptors, pCR factor has not shown constance in overall survival prognosis for patients with HER2(+) and endocrine receptor (+).

Thus, histopathological status, Ki67, and endocrine receptors do not currently have consistent independent prognostic significance in neoadjuvant studies using Trastuzumab. This condition may be related to patient characteristics, staging, and specimen management.

Comparison with studies using biosimilar trastuzumab in other countries

Table 8. Comparison with studies using biosimilar trastuzumab in other countries [11]

	Main objectives	**Result**
Pivot X - Georgievich et al.	bpCR	51.70%
Von Minckwitz et al.	tpCR	48.00%

Stebbing, J et al.	tpCR	46.80%
Krivorotko, P et al.	tpCR	48.80%
Pivot, X - Bondarenko et al.	tpCR	49.80%
N Koudri et al (ESMO 2023)	pCR	41.50%
Our Research	**tpCR**	**0.495**

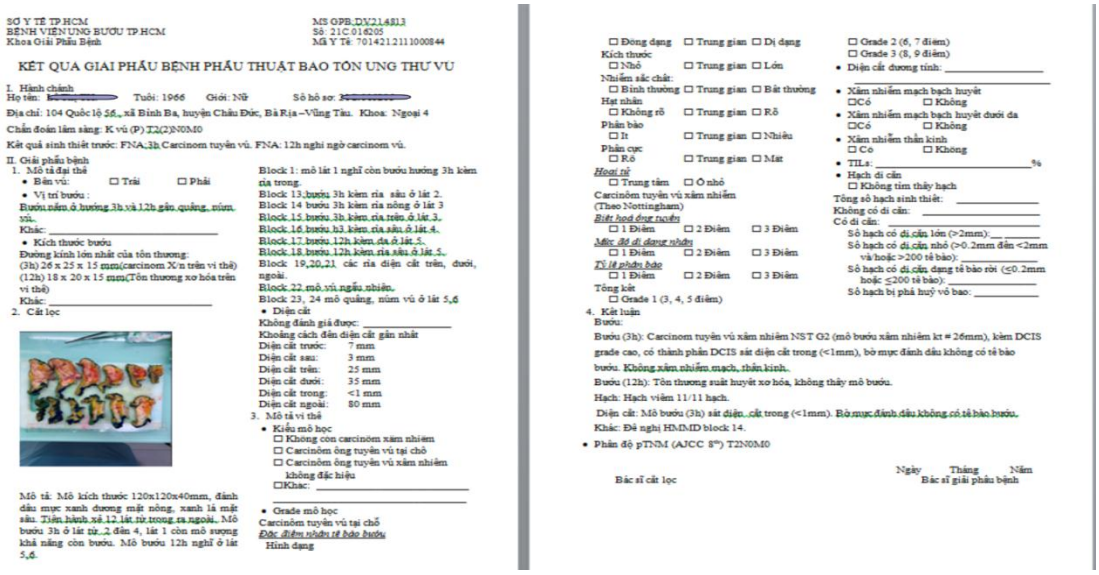
4.6 Adverse events:

The toxicities in this study is reported similarly to other studies' previously, mainly hematologic toxicities such as anemia, leukopenia, and granulocytopenia, however tolerable. There is no case of a decrease in LEVF of more than 10% points or a decrease of less than 50%.

5. CONCLUSION

Our study of 119 cases of breast cancer treated with chemotherapy using a taxane agent combined with trastuzumab biosimilars at the Oncology Hospital from January 1, 2022, to December 31, 2022, recorded the following results:

1. The overall response rate (ORR) was 95.7%, of which the cCR rate was 16.8%, the cPR was 78.9%, and the cPD was 4.2%.
2. The complete histopathological response rate in tumors and lymph nodes (tpCR) was 49.5%.
3. Toxicity was low, manageable, and could be monitored: 3.4% of patients developed grade 4 febrile neutropenia, 4.2% required hospitalization for blood transfusion, and no cases of increased heart rate, heart failure, or a left ventricular ejection fraction (LVEF) decrease of ≥10% were reported.


SỞ Y TẾ TP HCM
BỆNH VIỆN UNG BƯỚU TP HCM
Khoa Giải Phẫu Bệnh

MS GPB:DV21.4813
Số: 21C.014205
Mã Y Tế: 701421211000844

KẾT QUẢ GIẢI PHẪU BỆNH PHẪU THUẬT BẢO TỒN UNG THƯ VÚ

I. Hành chánh
Họ tên: [redacted] Tuổi: 1966 Giới: Nữ Số hồ sơ: [redacted]
Địa chỉ: 104 Quốc lộ 56, xã Bình Ba, huyện Châu Đức, Bà Rịa –Vũng Tàu. Khoa: Ngoại 4
Chẩn đoán lâm sàng: K vú (P) T2(2)N0M0
Kết quả sinh thiết trước: FNA:3h Carcinom tuyến vú. FNA: 12h nghĩ ngờ carcinom vú.

II. Giải phẫu bệnh
1. Mô tả đại thể
• Bên vú: ☐ Trái ☐ Phải
• Vị trí bướu :
Bướu nằm ở bướng 3h và 12h gần quầng, núm vú.
Khác: _____
• Kích thước bướu
Đường kính lớn nhất của tổn thương:
(3h) 26 x 25 x 15 mm(carcinom X/n trên vi thể)
(12h) 18 x 20 x 15 mm(Tổn thương xơ hóa trên vi thể)
Khác: _____
2. Cắt lọc

Mô tả: Mô kích thước 120x120x40mm, đánh dấu mực xanh dương mặt nông, xanh lá mặt sâu. Tiến hành xẻ 12 lát từ trong ra ngoài. Mô bướu 3h ở lát từ 2 đến 4, lát 1 còn mô sượng khả năng còn bướu. Mô bướu 12h nghĩ ở lát 5,6.

Block 1: mô lát 1 nghĩ còn bướu hướng 3h kèm rìa trong.
Block 13,bướu 3h kèm rìa sâu ở lát 2.
Block 14 bướu 3h kèm rìa nông ở lát 3
Block 15 bướu 3h kèm rìa trên ở lát 3.
Block 16 bướu h3 kèm rìa sâu ở lát 4.
Block 17 bướu 12h kèm da ở lát 5.
Block 18 bướu 12h kèm rìa sâu ở lát 5.
Block 19,20,21 các rìa diện cắt trên, dưới, ngoài.
Block 22 mô vú ngẫu nhiên.
Block 23, 24 mô quầng, núm vú ở lát 5,6
• Diện cắt
Không đánh giá được: _____
Khoảng cách đến diện cắt gần nhất
Diện cắt trước: 7 mm
Diện cắt sau: 3 mm
Diện cắt trên: 25 mm
Diện cắt dưới: 35 mm
Diện cắt trong: <1 mm
Diện cắt ngoài: 80 mm
3. Mô tả vi thể
• Kiểu mô học
☐ Không còn carcinôm xâm nhiễm
☐ Carcinôm ống tuyến vú tại chỗ
☐ Carcinôm ống tuyến vú xâm nhiễm không đặc hiệu
☐Khác: _____
• Grade mô học
Carcinôm tuyến vú tại chỗ
Đặc điểm nhân tế bào bướu
Hình dạng
☐ Đồng dạng ☐ Trung gian ☐ Dị dạng
Kích thước
☐ Nhỏ ☐ Trung gian ☐ Lớn
Nhiễm sắc chất:
☐ Bình thường ☐ Trung gian ☐ Bất thường
Hạt nhân
☐ Không rõ ☐ Trung gian ☐ Rõ
Phân bào
☐ Ít ☐ Trung gian ☐ Nhiều
Phân cực
☐ Rõ ☐ Trung gian ☐ Mất
Hoại tử
☐ Trung tâm ☐ Ô nhỏ
Carcinôm tuyến vú xâm nhiễm
(Theo Nottingham)
Bậc hoá học tuyến
☐ 1 Điểm ☐ 2 Điểm ☐ 3 Điểm
Mức độ dị dạng nhân
☐ 1 Điểm ☐ 2 Điểm ☐ 3 Điểm
Tỷ lệ phân bào
☐ 1 Điểm ☐ 2 Điểm ☐ 3 Điểm
Tổng kết
☐ Grade 1 (3, 4, 5 điểm)
☐ Grade 2 (6, 7 điểm)
☐ Grade 3 (8, 9 điểm)
• Diện cắt dương tính: _____
• Xâm nhiễm mạch bạch huyết
☐Có ☐ Không
• Xâm nhiễm mạch bạch huyết dưới da
☐Có ☐ Không
• Xâm nhiễm thần kinh
☐ Có ☐ Không
• TILs: _____%
• Hạch di căn
☐ Không tìm thấy hạch
Tổng số hạch sinh thiết: _____
Không có di căn: _____
Có di căn:
Số hạch có di căn lớn (>2mm): _____
Số hạch có di căn nhỏ (>0.2mm đến <2mm và/hoặc >200 tế bào): _____
Số hạch có di căn dạng tế bào rời (≤0.2mm hoặc ≤200 tế bào): _____
Số hạch bị phá huỷ vỏ bao: _____
4. Kết luận
Bướu:
Bướu (3h): Carcinom tuyến vú xâm nhiễm NST G2 (mô bướu xâm nhiễm kt = 26mm), kèm DCIS grade cao, có thành phần DCIS sát diện cắt trong (<1mm), bờ mực đánh dấu không có tế bào bướu. Không xâm nhiễm mạch, thần kinh.
Bướu (12h): Tổn thương suất huyết xơ hóa, không thấy mô bướu.
Hạch: Hạch viêm 11/11 hạch.
Diện cắt: Mô bướu (3h) sát diện cắt trong (<1mm). Bờ mực đánh dấu không có tế bào bướu.
Khác: Đề nghị HMMD block 14.
• Phân độ pTNM (AJCC 8th) T2N0M0

Ngày Tháng Năm
Bác sĩ cắt lọc
Bác sĩ giải phẫu bệnh

Fig 3. Detailed anatomical report at the Oncology Hospital

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