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Original Article

A Retrospective Multicenter Real-World Study to Determine the Efficacy and Safety of PHESGO in HER2-Positive Breast Cancer from a Community Oncology Practice in Western India

Udip Maheshwari[1] Vashishth Maniar[1] Ashish Joshi[1] Pritam Kalaskar[1] Kshitij Joshi[1] Disha Morzaria[4] Pradip Kendre[1] Smit Sheth[1] Chandrashekhar Pethe[2] Sonal Dhande[2] Seema Jagiasi[1] Taha Sethjiwala[3] Krushna Chaudhari[3]

[1] Department of Medical Oncology, MOC Cancer Care & Research Centre, Mumbai, Maharashtra, India
[2] Department of Medical Oncology, MOC Cancer Care & Research Centre, Nashik, Maharashtra, India
[3] Department of Medical Oncology, MOC Cancer Care & Research Centre, Indore, Madhya Pradesh, India
[4] Department of Clinical Research, MOC Cancer Care & Research Centre, Mumbai, Maharashtra, India

Address for correspondence Udip Maheshwari, MD, Department of Medical Oncology, MOC Cancer Care & Research Centre, Nehru Road, Navpada, Vile Parle East, Vile Parle, Mumbai 400057, Maharashtra, India (e-mail: drudipdm@mocindia.co.in).

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Abstract

Introduction The treatment landscape for HER2-positive breast cancer has evolved with the introduction of targeted therapy using trastuzumab and pertuzumab. Though effective, intravenous (IV) administration presents challenges like infusion-related reactions and logistical issues, affecting patient adherence and quality of life. The advent of the subcutaneous (SC) formulation of PHESGO has emerged as a promising alternative, which enhances patient experience and adherence in the treatment of HER2-positive breast cancer.

Objectives This study evaluates the efficacy, safety, and patient preference of PHESGO in a real-world setting.

Materials and Methods This retrospective analysis included 30 patients with HER2-positive breast cancer receiving PHESGO as monotherapy or in combination with chemotherapy. Inclusion criteria encompassed patients aged 18 to 80 with comprehensive medical records and documented survival status. Data were extracted from electronic medical records to evaluate treatment efficacy, adverse events, and patient satisfaction, using validated Patient Preference and Therapeutic Antibody Satisfaction Questionnaire - Subcutaneous Injection (TASQ-SC) questionnaires.

Results The median (interquartile range) age was 53.5 (18.0) years, with most patients at cancer stage IV (36.7%). PHESGO achieved an 86.7% objective response rate (ORR) and 76.7% [95% CI: 59.07–88.21] progression-free survival over a median survival duration of 496 days. Nearly 90% of the patients remained alive at the end of the observation period. Among neoadjuvant chemotherapy patients, a 75.0% pathological complete response rate was observed. All participants (100%) preferred SC

Keywords
- breast neoplasms
- trastuzumab
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- drug administration routes
- patient preference

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administration, citing greater comfort and reduced clinic time, with 89.5% reporting minimal pain.

Conclusion The findings indicate comparable efficacy and a favorable safety profile of PHESGO relative to traditional IV administration. The high levels of satisfaction and preference for SC administration suggest that PHESGO not only meets clinical efficacy standards but also meaningfully enhances the overall patient experience.

Introduction

The HER2-positive breast cancer subtype accounts for ~20 to 30% of all breast cancer cases and is known to have strong tumor invasiveness.[1–3] HER2 overexpression serves as a strong indicator of unfavorable prognosis, high mortality, and poor overall survival (OS) rates. Patients with the HER2-positive subtype face a high risk of secondary visceral metastases,[4] which are often correlated with a higher incidence of metastases to both the bone and central nervous system (CNS).[4,5]

Treatment approaches for HER2-positive breast cancer involve a combination of chemotherapy and HER2-targeted monoclonal antibodies such as trastuzumab and pertuzumab.[6] Trastuzumab and pertuzumab have substantially transformed the treatment landscape for HER2-positive breast cancer by introducing a synergistic approach to targeting the HER2 receptor.[7,8] The safety profile of these two antibodies in the treatment of HER2-positive breast cancer was well established in the Clinical Evaluation of Pertuzumab and Trastuzumab (CLEOPATRA) trial.[9] The combination has also been approved for neoadjuvant treatment (NACT) of the stage II–III HER2-positive subtype.[10] Dual anti-HER2 therapy has become a standard of care for patients with HER2-positive metastatic breast cancer, showing higher pathological complete response (pCR) rates, improved progression-free survival (PFS), and OS outcomes.[11,12]

Intravenous (IV) administration of trastuzumab poses challenges, such as infusion-related reactions (IRRs), impacting treatment adherence.[13,14] Additionally, the route of venous access for IV systemic therapy remains a topic of interest, with uncertainties persisting despite advancements in chemotherapy regimens, particularly given the frequency of symptomatic peripherally inserted central catheter–related deep vein thrombosis (DVT) in cancer patients receiving chemotherapy.[15] These challenges can lead to patient discomfort, poor quality of life (QoL), and potentially result in patient dropouts due to safety concerns, as patient preferences play a crucial role in treatment adherence and satisfaction.[16] Studies have explored patient experiences with both IV and subcutaneous (SC) administration of trastuzumab to tailor treatment plans to improve patient compliance and overall QoL.[17,18]

Transitioning to SC administration of trastuzumab may offer a viable solution to patient convenience–related challenges associated with IV administration.[19] The preference for SC or IV administration of trastuzumab (PrefHer) study demonstrated the efficacy and safety of SC trastuzumab in comparison with the IV route for HER2-positive early breast cancer.[20] PHESGO, a novel fixed-dose combination of pertuzumab and trastuzumab for SC injections, maintains the same level of efficacy as IV treatment.[21] It offers several advantages over IV administration, with established improvements in patient satisfaction and potential time-saving benefits for both patients and healthcare providers.[22,23] It allows for a more convenient administration as approximately 5- to 8-minute injection, which is 71% shorter compared with the 60- to 150-minute IV infusion typically performed in a medical facility.[24,25] Patient preference studies have demonstrated high patient satisfaction with SC injection of PHESGO compared with IV infusion, with the majority of patients choosing to continue SC administration.[23]

Though multiple clinical trials have demonstrated the efficacy of PHESGO, there remains a need for more extensive real-world population studies to further validate these findings across diverse patient populations.

Materials and Methods

Study Design

Using real-world data (RWD) systematically extracted from electronic medical records (EMR) between June 2 and June 30, 2024, this retrospective observational study analyzed patient data from September 2022 to February 2024 across multiple centers. Diagnostic criteria were based on histopathology, radiologic tests, and clinical judgment. Treatment decisions, including PHESGO administration, were made by treating physicians based on disease stage and established treatment guidelines.

Study Participants and Sample Size

Thirty patients with HER2-positive breast cancer who received PHESGO treatment were enrolled in the study. Inclusion criteria require patients to be between 18 and 80 years of age, of any gender, and diagnosed with primary HER2-positive breast cancer. Participants must have received PHESGO either as monotherapy or in combination with chemotherapy, with their medical records available. Additionally, the survival status of the patients needed to be known and documented. Patients were excluded from the study if they were younger than 18 or older than 80 years, if their medical records were unavailable, or if their survival status was unknown.

No formal sample size calculation was performed, as the study was exploratory in nature, aimed at understanding the

outcomes of PHESGO treatment in routine clinical practice. Though limited in size, this cohort represents the first RWE for PHESGO in Western India. This limitation stems from the naturally low incidence of HER2-positive breast cancer in Western India.[26] Second, the study emphasized descriptive endpoints (e.g., pathologic complete response rates and safety), and a smaller sample size may suffice to identify clinically meaningful trends or safety signals, even in the absence of formal hypothesis testing.

Study Objectives

The primary objective of this study was to evaluate the effect of PHESGO in patients with HER2-positive breast cancer. Secondary objectives included assessing the treatment-emergent adverse events (TEAEs). Additionally, the study aimed to assess the comparative satisfaction levels of patients undergoing SC versus IV treatment.

Data Collection

The date of diagnosis, family history of breast cancer, and comorbidities that could potentially influence treatment outcomes were documented. The Eastern Cooperative Oncology Group (ECOG) Performance Status, the breast cancer stage at diagnosis, and the metastatic status at baseline were also assessed before the initiation of the treatment. Treatment-related details include the clinical setting in which PHESGO was administered, the line of treatments (first, second, third, fourth), and whether PHESGO was administered as a monotherapy or in combination with other chemotherapeutic agents (CTs). Information on the maintenance cycle of the patient and their treatment status was also collected.

Patient-reported outcomes were included only if they were already available in the EMRs. In routine practice, some patients were administered the Therapeutic Antibody Satisfaction Questionnaire - Subcutaneous Injection (TASQ-SC) and the Patient Preference Questionnaire during treatment visits, and their responses were documented by the treating clinicians. These preexisting records were retrospectively extracted and analyzed, and the analysis was restricted to this subset only.

Study Outcomes

The primary outcomes were pCR, objective response rate (ORR), and PFS, while the secondary outcomes were safety endpoints assessed through TEAEs, including adverse events (AEs) related to PHESGO alone or in combination with chemotherapy. The response to PHESGO was evaluated after six cycles to collect data on effectiveness and safety outcomes.

Efficacy of PHESGO

The efficacy of PHESGO was determined by evaluating key clinical endpoints, including pCR, ORR, and PFS. ORR was defined as the proportion of patients achieving complete or partial response (PR) based on the judgment of the clinician and radiologic assessment per routine practice; RECIST criteria were not uniformly applied. pCR was confirmed by histopathological examination of resected tumor specimens following NACT.

Safety Outcomes

The safety outcomes of PHESGO were analyzed through the monitoring of TEAEs, which include AEs related to PHESGO alone or in combination with other CT agents.

Patient Acceptance and Experience Assessment

Satisfaction levels of patients receiving PHESGO were evaluated using two distinct questionnaires. The Patient Preference Questionnaire explored the reasons behind patients' choices for SC administration, while the TASQ-SC[27] specifically assessed patient acceptance of PHESGO, focusing on factors such as ease of use, comfort, and overall experience compared with the IV route.

Statistical Analysis

Descriptive statistics were employed to summarize patient demographics and treatment outcomes. Categorical variables were summarized using frequencies and percentages to illustrate the distribution of different characteristics within the study population. Data for age were presented using medians and interquartile ranges (IQRs). Data accuracy was verified by cross-examination conducted by a secondary author before transferring the data to Excel for further analysis. Patients were censored at the last follow-up date if no progression or death occurred by study end. Given the modest cohort size ($n = 30$), formal subgroup analyses by treatment intent were not performed. Sample limitations preclude statistically stable comparisons due to underpowered subgroups and unacceptably wide confidence intervals. Thus, efficacy/safety outcomes are reported for the overall cohort, with subgroup trends presented descriptively only. The study relied on real-world evidence (RWE) drawn from available EMR data, ruling out the investigator and selection bias. While use of EMRs minimizes recall bias, selection bias remains possible, as treatment assignment to PHESGO was based on clinician discretion. Patient heterogeneity, including treatment settings (NACT, adjuvant, metastatic), may affect generalizability and confound interpretation.

Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) before initiation. The study was initiated following ethical review and approval from the IEC on June 1, 2024, with the approval number PHESGO/MOC/2K24RS12.

Study Reporting

The data were reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist.[28]

Results

Baseline Characteristics

The median (IQR) age of the patients was 53.5 years (18.0). The majority of the patients (i.e., 19 [63.3%]), had no comorbidities. A greater number of patients (i.e., 11 [36.7%]) had stage IV cancer at baseline. The ECOG status was 0 for 17 (56.7%) patients. PHESGO was used as an NACT in 12 (40.0%), as an adjuvant in 11 (36.7%), and as metastatic treatment in 7 (23.3%) patients. Most patients received PHESGO as the first-line treatment (22 [73.3%]). The maximum number of patients (28 [93.3%]) received PHESGO in combination with other CT agents. Trastuzumab was used as maintenance therapy in 10 (33.34%) patients who used maintenance therapy, followed by PHESGO alone (8 [26.67%]). Baseline characteristics are summarized in ►**Table 1**.

Table 1 Baseline characteristics of all 30 participants

Characteristics	*N* = 30
Age (in years) (median, IQR)	53.5 (18.0)
Comorbidities, *n* (%)	
IHD	1(3.3%)
HTN	7 (23.3%)
Others	5 (16.7%)
No comorbidity	19 (63.3%)
Family history, *n* (%)	
Yes	11 (36.7%)
No	19 (63.3%)
Breast cancer stage, *n* (%)	
I	3 (10.0%)
II	10 (33.3%)
III	6 (20.0%)
IV	11 (36.7%)
Metastatic at baseline, *n* (%)	
Yes	9 (30.0%)
No	21 (70.0%)
ECOG PS, *n* (%)	
0	17 (56.7%)
1	12 (40.0%)
3	1 (3.3%)
Clinical setting of PHESGO administration, *n* (%)	
Neoadjuvant	12 (40.0%)
Adjuvant	11 (36.7%)
Metastatic	7 (23.3%)
PHESGO line of Rx, *n* (%)	
1	22 (73.3%)
2	7 (23.3%)
4	1 (3.3%)
PHESGO therapy, *n* (%)	
Monotherapy	2 (6.7%)
Combination with other CT agents	28 (93.3%)
Days of PHESGO treatment in median (IQR)	105 (22.5)
Maintenance cycle, *n* (%)	
PHESGO	8 (26.67%)
PHESGO + other CT agents	1 (3.3%)
Trastuzumab	10 (33.34%)
Other CT agents	2 (6.7%)
TDM1	2 (6.7%)
TDM1 followed by PHESGO	1 (3.3%)
PHESGO followed by TDM1	1 (3.3%)
Others	5 (16.67%)

Abbreviations: CT, chemotherapeutic; ECOG PS, Eastern Cooperative Oncology Group Performance Status; HTN, hypertension; IHD, ischemic heart disease; IQR, interquartile range; TDM1, ado-trastuzumab emtansine.

Efficacy Outcomes

Objective Response Rate

PHESGO demonstrated an ORR of 86.67%, and stable disease (SD) was observed in two (6.67%) patients. For more details, refer to ►**Table 2**.

Overall Survival

►**Fig. 1** illustrates the OS of all patients over the entire period. The median survival duration was observed to be 496 days, and three (10%) deaths were reported during this period.

Approximately 90% of patients were alive toward the end of the observation period. Kaplan–Meier curve for the OS status and the hazard function for the same are shown in ►**Fig. 2 (A and B)**. The hazard plot shows a low risk of death for most participants, except for a brief spike between 150 and 200 days. After this, the hazard rate returned to zero, indicating stable survival beyond 200 days.

Progression-Free Survival

An estimated 76.7% (95% CI: 59.07–88.21) of patients remained progression-free at the end of the observation period (►**Fig. 3**).

Safety Outcomes

No TEAEs were observed with PHESGO alone (►**Table 3**). TEAEs were observed when PHESGO was used with other CT agents, with the most common being Grade II fatigue and diarrhea (13.34% each). Other events occurred less frequently (3.34–10%). No serious TEAEs were reported. Three patients who died were receiving PHESGO as adjuvant therapy in second-line treatment.

Subgroup Analysis: PHESGO as Neoadjuvant Chemotherapy

Baseline Characteristics

The median (IQR) age of patients receiving PHESGO NACT was 44.5 years (20.5), with the majority (9 [75%]) having no comorbidities and predominant breast cancer stage II (8

Table 2 Efficacy outcomes of all the 30 participants

Characteristics	$n = 30$
ORR, *n* (%)	
CR	13 (43.33%)
PR	13 (43.33%)
SD	2 (6.67%)
PD	1 (3.33%)

Abbreviations: CR, complete response; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease.

[66.7%]). Most patients (11 [91.67%]) received PHESGO in combination with other chemotherapy agents, with 11 (91.67%) completing treatment. Out of 30 patients, 12 (40%) received NACT, of whom 7 (58.3%) underwent surgery in the NACT setting. For details, please see ►**Table 4**.

Primary Outcomes

The response outcomes for PHESGO therapy show a high pCR rate of 9 (75%). Additionally, PR was observed in 3 (25%) patients who underwent NACT with PHESGO (►**Table 5**). Among those operated, 6 (85.7%) achieved a pCR.

Survival Status

All patients were alive, with survival times ranging from 189 to 538 days. The majority of the patients have survival durations exceeding 300 days, indicating a relatively high survival rate over the observed period (►**Fig. 4**).

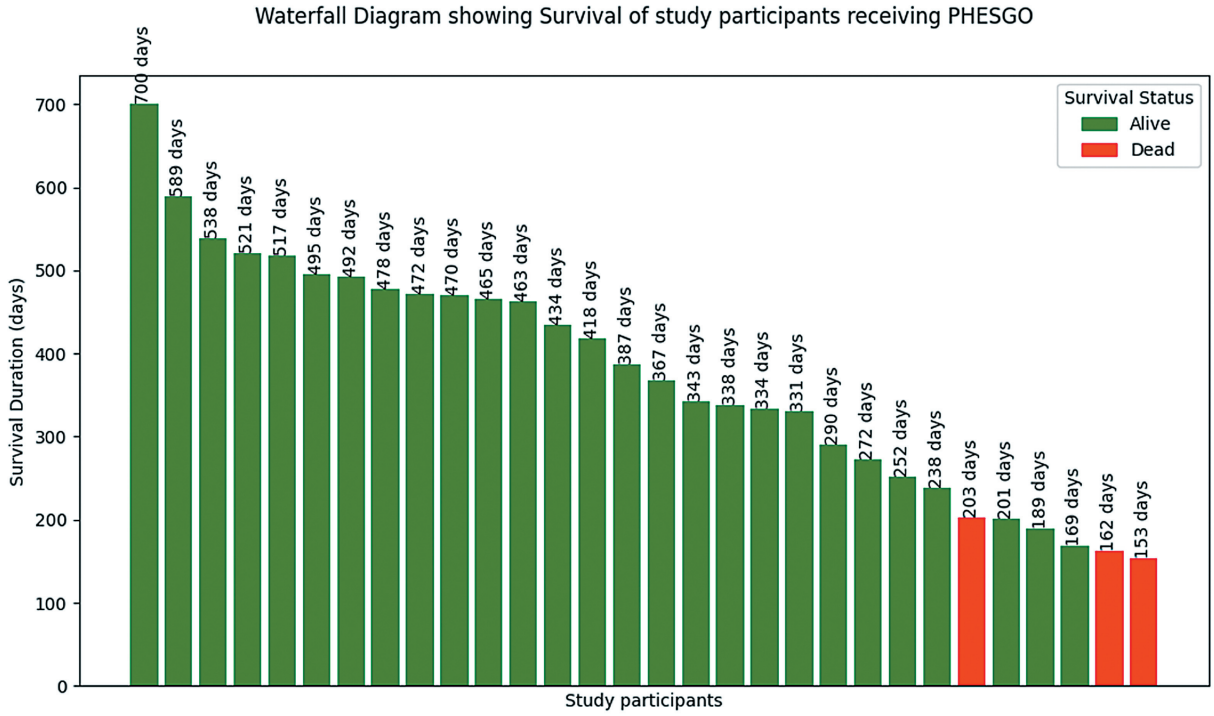

Fig. 1 Waterfall diagram representing the survival status of patients.

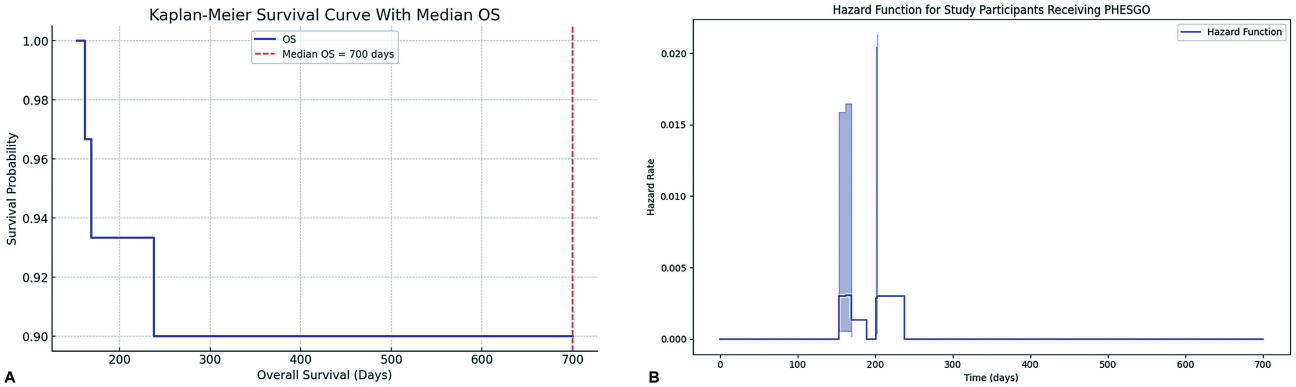

Fig. 2 (A) Kaplan–Meier survival curve for overall survival status ($n = 30$); (**B**) hazard function for the overall survival status ($n = 30$).

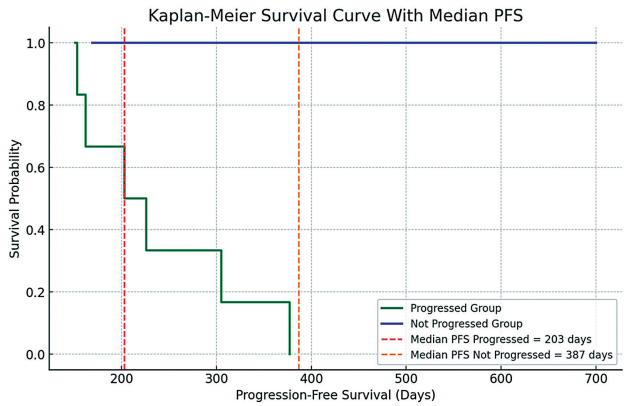

Fig. 3 Kaplan–Meier survival curve for progression-free survival (PFS).

Safety Outcomes

The most common TEAEs were Grade II fatigue and Grade II diarrhea, each affecting two patients (16.67%). Other AEs, including Grade III diarrhea, myalgia, thrombocytopenia, anemia, cramps, constipation, bleeding per vaginal (PV), and occasional palpitations, occurred less frequently, each affecting 1 patient (8.34%). For details, refer to ►**Supplementary Table S1** (available in the online version only).

Table 3 Treatment emergent adverse events (TEAEs)

TEAEs	*n* (%)
Grade II fatigue	4 (13.34%)
Grade III fatigue	1 (3.34%)
Grade II diarrhea	4 (13.34%)
Grade III diarrhea	2 (6.67%)
Grade II myalgia	3 (10%)
Grade II mucositis	1 (3.34%)
Grade II neuropathy	1 (3.34%)
Vomiting	2 (6.67%)
Nausea	1 (3.34%)
Constipation	1 (3.34%)
Skin rashes	1 (3.34%)
Steven-Johnson syndrome	1 (3.34%)
Grade IV PN	1 (3.34%)
Anemia	1 (3.34%)
Nose bleeding	1 (3.34%)
Occasional palpitation	1 (3.34%)
Onset breathlessness	1 (3.34%)
Cramps	1 (3.34%)
Thrombocytopenia	1 (3.34%)
Bleeding PV	1 (3.34%)
Choking sensation	1 (3.34%)

Abbreviations: IV, intravenous; PV, per vaginal; PN, peripheral neuropathy.

Table 4 Baseline characteristics of the sub-group

Characteristics	*n* = 12
Age (in years) (median, IQR)	44.5 (20.5)
Comorbidities, *n* (%)	
HTN	2 (16.7%)
Others	2 (16.7%)
No comorbidity	9 (75.0%)
Family history, *n* (%)	
Yes	4 (33.3%)
No	8 (66.7%)
Breast cancer stage, *n* (%)	
I	1 (8.3%)
II	8 (66.7%)
III	3 (25.0%)
ECOG PS, *n* (%)	
0	9 (75.0%)
1	2 (16.7%)
3	1 (8.3%)
PHESGO therapy, *n* (%)	
Monotherapy	1 (8.3%)
Combination with other CT agents	11 (91.67%)
Days of PHESGO treatment in median (IQR)	105 (42.75)
Maintenance cycle, *n* (%)	
PHESGO	3 (25.0%)
Trastuzumab	5 (41.67%)
Other CT agents	1 (8.3%)
TDM1	2 (16.7%)
Others	1 (8.33%)
Patient status, *n* (%)	
LTF	1 (8.33%)
Completed	11 (91.67%)

Abbreviations: CT, chemotherapeutic; ECOG PS, Eastern Cooperative Oncology Group Performance Status; HTN, hypertension; IHD, ischemic heart disease; IQR, interquartile range; LTF, lost to follow-up; TDM1, ado-trastuzumab emtansine.

Patient Satisfaction Assessment

Patient Preference Questionnaire Outcomes

Of the 19 patients who preferred the SC administration route for their treatment. Among them, 8 (42.1%) felt their

Table 5 Efficacy outcomes in the sub-group

Characteristics	*n* = 12
Pathological complete response, *n* (%)	
Yes	9 (75.0%)
No	3 (25.00%)

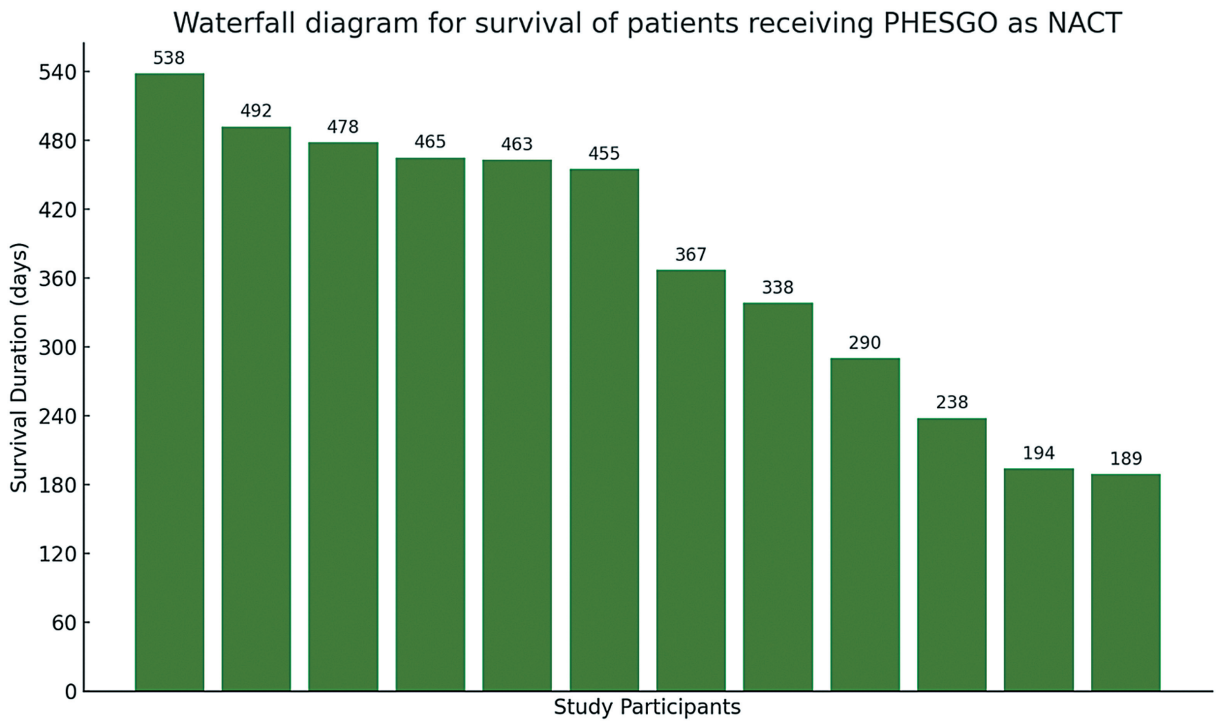

Fig. 4 Waterfall diagram representing the survival status of patients receiving PHESGO as NACT.

preference was very strong, 11 (57.9%) cited comfort during administration as a key reason, and 8 (42.1%) preferred it because it required less time in the clinic (►**Supplementary Table S2** [available in the online version only]).

TASQ-SC Questionnaire Outcomes

The majority of patients were satisfied with the SC injection —16 patients (84.2%) were satisfied, and 2 patients (10.5%) were very satisfied. Most reported minimal pain, swelling, or redness at the injection site, and 100% felt no restrictions during the procedure. SC injections were considered convenient by all patients, with 17 (89.5%) indicating they were not bothered by the time it took. A strong preference for SC injections over IV infusions was observed, with 16 (84.2%) preferring SC, and most (16 [84.2%]) would recommend this method to others (►**Supplementary Table S3** [available in the online version only]).

Discussion

The rationale for this study stems from the current lack of comprehensive RWE on the clinical efficacy and safety of PHESGO in HER2-positive breast cancer. While an existing RWE study on PHESGO has been published, it mainly emphasized patient convenience and comfort with SC administration, offering limited insights into broader clinical outcomes.[22] Our study provides a more robust analysis, thoroughly evaluating key efficacy endpoints such as ORR, PFS, and OS, along with a detailed assessment of the safety profile. This comprehensive analysis delivers valuable RWD to reinforce PHESGO's clinical role in managing HER2-positive breast cancer.

The pivotal fixed-dose combination of pertuzumab and trastuzumab for SC injection plus chemotherapy in the HER2-positive early breast cancer (FeDeriCa) trial demonstrated that PHESGO maintains equivalent therapeutic efficacy to the IV regimen, while also providing notable benefits in terms of reduced administration time and enhanced patient convenience.[28] The consistent pharmacokinetic profile of PHESGO ensures stable drug exposure comparable to that of the traditional IV regimen.[21,25] Furthermore, a previous study on the SC formulation of trastuzumab indicated that, unlike weight-adjusted IV dosing—which can lead to variability in drug levels—the fixed-dose SC formulation offers reliable therapeutic delivery.[29]

High pCR, ORR, and PFS rates observed with PHESGO are a result of the dual HER2 blockade mediated by trastuzumab and pertuzumab.[12,30] The results of this RWE study demonstrate that PHESGO exhibits strong therapeutic efficacy, achieving an ORR of 86.7%. Complete or PR was observed in 26 (86.7%) patients, emphasizing PHESGO's potent antitumor activity. Additionally, two patients (6.7%) experienced SD, indicating disease control, and only one patient (3.3%) progressed to progressive disease (PD), suggesting a low rate of treatment resistance. While our cohort ($n = 30$) reflects real-world feasibility in a specialized Indian community oncology setting, efficacy or safety outcomes align with pivotal trials (FeDeriCa,[21] $n = 500$; PHranceSCa,[23] $n = 160$). The 86.7% ORR and 75% pCR rates are clinically meaningful signals for HER2+ populations. The low hazard rate suggests PHESGO was largely effective in preventing failures/deaths, with only a short period of elevated risk. Furthermore, PFS was maintained in ~76.7% (95% CI: 59.07–88.21) of patients by the end of the observation period, indicating sustained disease control. OS analysis

showed a 10% mortality rate, with three deaths occurring during the study period. PFS can serve as a surrogate marker for OS,[31] and, to date, no studies have thoroughly investigated PFS as a clinical outcome for PHESGO, making this study unique in its detailed assessment of both efficacy and long-term disease control in HER2-positive breast cancer patients.[22] This investigation, therefore, fills a critical gap in RWD on PHESGO's clinical performance.

Achieving pCR in the NACT setting is also a key predictor of improved long-term survival outcomes.[32] The robust pCR rate observed in this retrospective study suggests that PHESGO, when used as NACT, may offer substantial therapeutic benefits. The reported pCR rate of 75.0% aligns closely with the 83.3% pCR observed in a previously published real-world study (RWS).[22]

The favorable tolerability profile of PHESGO, demonstrated by the absence of treatment discontinuations and the mild nature of reported TEAEs, aligns with safety data from multiple studies.[21,23,25] The ability of patients to complete their NACT treatment without severe AEs is essential, as it allows patients to receive the full therapeutic benefit of PHESGO without compromising their safety. The most reported TEAEs associated with PHESGO are typically mild to moderate in severity and are generally well tolerated, as observed in our study and supported by extensive research.[33,34] In comparison, IV trastuzumab administered with pertuzumab is associated with a range of side effects, including IRRs such as fever, myalgia, and hypotension. These reactions are particularly prevalent during initial infusions and can cause considerable discomfort for patients.[35,36] However, the SC formulation of PHESGO has been shown to markedly reduce the incidence of IRRs and systemic side effects, as evidenced in our analysis.[20,35,37]

Patient-reported outcomes from the Patient Preference Questionnaire and TASQ-SC show strong preference and high satisfaction with SC administration of PHESGO. SC therapy reduces treatment burden and clinic time, enhancing patient comfort during long-term cancer management. Notably, 84.2% of patients preferred SC over IV infusion and expressed willingness to recommend SC administration to others. These findings emphasize the value of SC therapy in delivering patient-centered care in oncology. These results are consistent with those of the preference for the fixed-dose combination of pertuzumab and trastuzumab for SC injection (PHranceSCa trial), where 85.3% of patients also favored SC administration.[23] In both studies, the primary reasons for this preference included shorter administration time and less pain, highlighting the patient-centered advantages of SC, PHESGO therapy.

The overall satisfaction rate of 94.7% among patients using PHESGO in our study aligns closely with the 92% satisfaction rate reported in a previous RWS.[22] Additionally, the positive experience with SC administration may contribute to better adherence to therapy, a critical factor in achieving optimal treatment outcomes.[17] The minimal pain associated with SC injections, as reported by 89.5% of patients, further supports the use of PHESGO as a patient-friendly alternative to traditional IV administration.

A key strength of this study is its use of RWD on PHESGO, with a design that mirrors routine clinical practice, thereby enhancing the applicability of the findings to everyday oncology care. This approach provides insights that are directly relevant to patient management.

However, while this study adds to the growing body of RWE supporting the use of SC, PHESGO, it has limitations, including a small sample size, a short follow-up period, and challenges in obtaining survey responses from all participants. Additionally, the study acknowledges the loss to follow-up rate, a common limitation in real-world research. The real-world nature of the study, although reflective of clinical practice, also introduces variability in treatment regimens and patient management.

Implications for Clinical Practice and Future Research

The findings have noteworthy clinical implications for the study. This study provides RWE supporting the efficacy, safety, and patient preference of PHESGO in HER2-positive breast cancer, with findings consistent with pivotal trials, thereby enhancing its generalizability to broader oncology practice, including community-based and resource-limited settings. Strong effect of PHESGO, favorable safety profile, and strong patient preference for SC administration suggest it could be a preferred treatment option for HER2-positive breast cancer. Future research should include long-term follow-up to assess response durability and explore its use in different HER2-positive cancer subtypes. Comparative studies evaluating PHESGO against other HER2-targeted therapies in real-world settings would also help refine treatment protocols and optimize patient outcomes. The biomarker-driven analyses may provide insights into patient subgroups who derive maximum benefit from PHESGO, optimizing individualized therapy. While patient-reported outcomes indicate strong satisfaction, in-depth qualitative studies are warranted to better understand patient experiences, adherence patterns, and the psychosocial impact of long-term SC therapy.

Conclusion

This study provides RWE on the comparable efficacy and safety of PHESGO to IV administration, with considerable benefits in patient satisfaction. The strong preference for SC administration, along with high pCR, ORR, and PFS, highlights its potential role in early breast cancer and advanced disease, respectively, shaping future HER2-positive breast cancer treatment. The growing acceptance of PHESGO, driven by shorter administration time and increased convenience, could further enhance the overall treatment experience.

Patients' Consent

Written informed consent was obtained from all participants before their inclusion in the study.

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None.

Conflict of Interest
None declared.

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