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Real-World Evaluation of Trastuzumab Emtansine Biosimilar in Early-Stage HER2-Positive Breast Cancer: Results from a Single-Center Retrospective Study in India

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ABSTRACT

Background: Trastuzumab emtansine (T-DM1), an antibody-drug conjugate targeting HER2, is an established adjuvant therapy for residual invasive HER2-positive breast cancer after neoadjuvant treatment. Real-world evidence on trastuzumab emtansine biosimilars in early-stage disease is limited. This study evaluated invasive disease-free survival (iDFS) and safety outcomes with a trastuzumab emtansine biosimilar in routine practice.

Methods: This retrospective, single-center observational study include 24 women with stage II and III HER2-positive breast cancer who received adjuvant trastuzumab emtansine biosimilar (3.6 mg/kg every 21 days) after neoadjuvant chemotherapy and surgery. The primary endpoint was iDFS; secondary endpoints were relapse patterns and treatment-emergent adverse events.

Results: Median age was 60.3 years; 83.3% were postmenopausal. At diagnosis, 20.8% had stage II and 79.2% had stage III disease. With a median follow-up of 14 months, 5 iDFS events occurred and no deaths were reported. The 12-month iDFS rate was 79.2%. Relapse occurred in 20.8% (5/24 patients); sites of recurrence included bone (n=2, 40%), liver (n=2, 40%), and brain (n=1, 20%), reflecting a predominantly skeletal and visceral, distant metastatic pattern. Common adverse events were thrombocytopenia (95.8%), neutropenia (79.2%), and anemia (41.7%), predominantly grade 1–2. Left ventricular ejection fraction declined to <50% in 20.8%.

Conclusion: Adjuvant trastuzumab emtansine biosimilar use was feasible with a manageable safety profile in this single-center real-world cohort. Efficacy findings are exploratory and require confirmation in larger prospective studies.

INTRODUCTION

HER2-positive breast cancer is a biologically distinct subtype characterized by amplification of the *ERBB2* gene and overexpression of the HER2 protein, leading to activation of oncogenic signaling pathways and aggressive tumor behavior.[1–3] This phenotype accounts for approximately 19% of invasive breast cancers globally. Historically, before HER2-targeted therapy became standard, patients experienced 10-year recurrence rates of 30% to 50% and lower 5-year survival rates (85.7% for hormone receptor [HR]–negative/HER2-positive and 91.5% for HR-positive/HER2-positive) compared with the higher survival rates seen in HER2-negative disease.[4] Survival outcomes in both early and advanced HER2-positive disease have improved following the introduction of targeted therapies, beginning with trastuzumab (FDA approved in September 1998) and

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later including pertuzumab and antibody-drug conjugates.[5,6] Trastuzumab emtansine (T-DM1) is an antibody-drug conjugate that links trastuzumab to the cytotoxic agent DM1 via a stable linker, enabling targeted delivery of chemotherapy to HER2-expressing tumor cells while retaining trastuzumab's anti-HER2 effects.[7]

Breast cancer is a major global health concern, with more than 2.3 million new cases and 685 000 deaths reported in 2020, accounting for nearly 1 in 4 cancer diagnoses among women.[8] In India, breast cancer has surpassed cervical cancer as the leading malignancy among women, with an estimated age-standardized incidence rate of 25.8 per 100 000 and a significant proportion of cases presenting at locally advanced stages. The prevalence of HER2 positivity in Indian breast cancer cohorts is comparable to global rates, typically ranging between 18% and 25%.[9,10] However, the burden of late-stage presentation, limited screening, variability in access to HER2 testing, and high treatment costs pose unique challenges in delivering guideline-based care in low- and middle-income countries (LMICs). Cost remains a major barrier to the adoption of advanced HER2-targeted agents, particularly innovator T-DM1, in Indian oncology practice.[11,12]

The current standard for patients with residual invasive HER2-positive disease after neoadjuvant chemotherapy is adjuvant T-DM1, as established by the phase 3 KATHERINE trial, which demonstrated a 50% reduction in the risk of invasive disease recurrence or death compared with trastuzumab alone, with 3-year invasive disease-free survival (iDFS) rates of 88.3% vs 77.0%.[4,13–15] Despite its efficacy, the high acquisition cost of innovator T-DM1 limits its accessibility in LMICs, often resulting in suboptimal treatment sequencing. Biosimilar formulations offer a cost-effective alternative and have demonstrated comparable efficacy and safety in metastatic HER2-positive breast cancer.[16] This retrospective single-center study was designed to evaluate the efficacy, measured by iDFS, and safety profile of Ujvira (Zydus Lifesciences), a trastuzumab emtansine biosimilar, in patients with high-risk early-stage HER2-positive breast cancer in India. The study aimed to address a critical gap in locally relevant evidence and support equitable access to effective therapy.

METHODS

Study design and setting

This was a retrospective, single-center, observational study conducted at Sunshine Global Hospital, Surat, India, between January 2022 and May 2024. The primary objective was to descriptively evaluate iDFS and safety outcomes following adjuvant therapy with a trastuzumab emtansine biosimilar product (UJVIRA, Zydus Lifesciences) in patients with early-stage HER2-positive breast cancer.

Study population

The study included 24 women with histologically confirmed HER2-positive stage II or III breast cancer who had completed neoadjuvant chemotherapy followed by definitive surgery. All included patients had residual invasive disease identified on postneoadjuvant surgical pathology. Eligible patients were initiated on adjuvant therapy with trastuzumab emtansine biosimilar.

Eligible patients were identified from medical records. Inclusion criteria were female sex, age 18 years or older, histologically confirmed HER2-positive breast cancer (immunohistochemistry [IHC] score 3+ or IHC 2+ with fluorescence in situ hybridization [FISH] confirmation), stage II or III disease without evidence of distant metastasis at baseline, and completion of standard neoadjuvant chemotherapy followed by definitive surgery. Patients were excluded if records indicated prior exposure to trastuzumab emtansine or receipt of investigational agents during the index treatment period, known hypersensitivity to components of trastuzumab emtansine, or significant baseline cardiac dysfunction (left ventricular ejection fraction [LVEF] < 50%).

Treatment protocol

Following surgery, patients received trastuzumab emtansine biosimilar administered intravenously at a standard dose of 3.6 mg/kg every 21 days. Treatment was planned for a total of 14 cycles, with a median of 11 cycles completed per patient. Dose modifications were permitted based on tolerability and adverse events, and 20.8% of patients required dose reduction.

Fixed starting doses (e.g., 200 mg or 160 mg) observed in the cohort reflected vial-based dose rounding and/or subsequent dose reductions due to tolerability, rather than protocol-defined flat dosing. Patients were monitored throughout treatment for hematological toxicity and cardiac function.

Data collection and end points

Baseline demographic and clinical data, including age, menopausal status, comorbidities, Eastern Cooperative Oncology Group (ECOG) performance status, tumor characteristics, and prior treatment details, were collected. Treatment-related variables such as the number of cycles completed, dose modifications, and treatment-emergent adverse events were recorded during follow-up.

The primary end point was iDFS, defined according to the KATHERINE trial as the time from initiation of adjuvant trastuzumab emtansine biosimilar to the first occurrence of invasive disease recurrence (local, regional, or distant) or death from any cause. Second primary malignancies and ductal carcinoma in situ events were censored.

Secondary end points included the site of recurrence, safety outcomes graded according to the Common Terminology Criteria for Adverse Events (CTCAE), treatment discontinuation, and cardiac function assessment, including decline in LVEF to less than 50%.

Statistical analysis

Descriptive statistics were used to summarize baseline characteristics, treatment patterns, and safety outcomes. Categorical variables were expressed as frequencies and percentages, while continuous variables were reported as mean (SD) or median (IQR), as appropriate.

Subgroup comparisons were performed using the log-rank test and were considered exploratory given the small sample size, limited number of events, and multiple testing. A 2-sided $P < 0.05$ was reported. All analyses were performed using SPSS software, version 25 (IBM). Patients without an iDFS event were censored at the date of last clinical follow-up.

RESULTS

Baseline characteristics

A total of 24 women with stage II or III HER2-positive breast cancer were included in this retrospective analysis. The median age was 60 years (mean [SD], 60.3 [8.5] years), and 83.3% were postmenopausal. At diagnosis, 79.2% of patients had stage III disease, and the predominant histology was invasive ductal carcinoma (79.2%). HER2 IHC was scored as 2+ in 50.0% and 3+ in 50.0% of patients, with FISH performed in all IHC 2+ cases.

Table 1. Baseline Demographic and Clinical Characteristics (N = 24)

Characteristic	No. (%) or Mean (SD)
Age, y, mean (SD)	60.3 (8.5) (range, 43–74)
Menopausal status	
Premenopausal	4 (16.7)
Postmenopausal	20 (83.3)
ECOG performance status	
1	6 (25.0)
2	18 (75.0)
HER2 IHC score	
2+	12 (50.0)
3+	12 (50.0)
FISH testing among IHC 2+ cases, positive	12 (100)
Tumor size before neoadjuvant therapy, cm, mean (SD)	3.35 (1.12)
Clinical stage at diagnosis	
II	5 (20.8)
III	19 (79.2)
Postneoadjuvant pathological stage	
ypT1N0	6 (25.0)
ypT1N1	13 (54.2)
ypT1N2	2 (8.3)
ypT2N1	3 (12.5)
Tumor histology	
Invasive ductal carcinoma	19 (79.2)
Invasive lobular carcinoma	5 (20.8)
Neoadjuvant chemotherapy cycles, median (IQR)	6 (6–8)
Trastuzumab emtansine cycles, median (IQR)	11 (10–12)
Hormone receptor status	
ER and/or PR positive	14 (58.3)
ER and PR negative	10 (41.7)
Comorbidities	
Any	16 (66.7)
Hypertension	12 (50.0)
Diabetes	11 (45.8)
Mode of payment	
Out of pocket	21 (87.5)
Insurance	3 (12.5)
Family history of HBOC	
Yes	2 (8.3)
No	22 (91.7)
Breast surgery	
Mastectomy	15 (62.5)
Breast-conserving surgery	9 (37.5)
Axillary surgery	
ALND	18 (75.0)
SLNB	4 (16.7)
None	2 (8.3)
Radiotherapy	
Yes	20 (83.3)
No	4 (16.7)
First-cycle dose	
200 mg	19 (79.2)
160 mg	5 (20.8)
Dose reduction required	
Yes	5 (20.8)
No	19 (79.2)

ALND, axillary lymph node dissection; ECOG, Eastern Cooperative Oncology Group; ER, estrogen receptor; FISH, fluorescence in situ hybridization; HBOC, hereditary breast and ovarian cancer; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; PR, progesterone receptor; SLNB, sentinel lymph node biopsy.

Comorbidities were present in 66.7% of patients, most commonly hypertension (50.0%) and diabetes (45.8%). The majority of patients underwent

mastectomy (62.5%) and axillary lymph node dissection (75.0%). The most frequently administered neoadjuvant regimen was docetaxel, carboplatin, and trastuzumab (TCH), received by 41.7% of patients. Baseline demographic and clinical characteristics are summarized in Table 1, and neoadjuvant treatment regimens are detailed in Table 2.

Clinical outcomes

At a median follow-up of 14 months, no deaths were observed. Five patients (20.8%) experienced invasive disease recurrence. The 12-month iDFS rate was 79.2%. Given the small number of events (n=5) and the short median follow-up of 14 months, estimation of median iDFS is not reported. The 12-month iDFS rate of 79.2% was reported for this study.

Subgroup comparisons were exploratory, performed without adjustment for multiple testing, and should be interpreted with caution. Numerically longer iDFS was observed in patients with stage III vs stage II disease, those who underwent mastectomy vs breast-conserving surgery, and those who received a 200-mg vs 160-mg starting dose; however, these observations are hypothesis generating and do not imply a causal or prognostic association. Menopausal status, ECOG performance status, hormone receptor status, and family history did not show a meaningful association with iDFS. A nonsignificant trend toward shorter iDFS was observed in patients with insurance-based payment compared with out-of-pocket payment.

Sites and patterns of recurrence

Among the five patients (20.8%) who experienced invasive disease recurrence, all relapses were distant metastases; no isolated locoregional recurrences were observed. The sites of recurrence were bone (n=2; 40%), brain (n=1; 20%), and liver (n=2; 40%). The site-specific recurrence data are summarized in Table 4.

Table 2. Neoadjuvant Systemic Therapy Regimens

Regimen	No. (%)
TCH (docetaxel + carboplatin + trastuzumab)	10 (41.7)
AC→TH (doxorubicin + cyclophosphamide → taxane + trastuzumab)	7 (29.2)
TH (taxane + trastuzumab)	3 (12.5)
TCHP (TCH + pertuzumab)	3 (12.5)
AC→THP (AC → taxane + trastuzumab + pertuzumab)	1 (4.2)

AC, doxorubicin and cyclophosphamide; H, trastuzumab; P, pertuzumab; T, taxane (docetaxel or paclitaxel); TCH, docetaxel, carboplatin, and trastuzumab; TCHP, docetaxel, carboplatin, trastuzumab, and pertuzumab.

Safety and tolerability

Treatment was generally well tolerated, with hematologic toxicities predominating. Thrombocytopenia was the most frequently observed adverse event, occurring in 95.8% of patients, with 20.8% experiencing grade 3 events. Neutropenia occurred in 79.2% of patients and was limited to grade 1 or 2 severity. Anemia was reported in 41.7%, predominantly grade 1 or 2.

Elevations in hepatic transaminases were observed in approximately one-third of patients, primarily grade 1. An asymptomatic decline in LVEF to less than 50% was noted in 20.8% of patients, with no associated clinical cardiac events. No grade 4 toxicities, treatment-related deaths, or permanent treatment discontinuations due to adverse events were observed. A summary of treatment-emergent adverse events is provided in Table 3, and the temporal distribution of selected toxicities is illustrated in Figure 1.

Table 3. Treatment-Emergent Adverse Events Observed With Trastuzumab Emtansine Biosimilar (N = 24)

Adverse Event	Grade 1, No. (%)	Grade 2, No. (%)	Grade 3, No. (%)	Grade 4, No. (%)
Thrombocytopenia	15 (62.5)	3 (12.5)	5 (20.8)	0 (0)
Neutropenia	12 (50.0)	7 (29.2)	0 (0)	0 (0)
Anemia	8 (33.3)	2 (8.3)	0 (0)	0 (0)
Elevated transaminases	8 (33.3)	0 (0)	0 (0)	0 (0)
LVEF decline to <50%	5 (20.8)	NA	NA	NA

LVEF, left ventricular ejection fraction; NA, not applicable.

[a]Adverse events were graded according to the *Common Terminology Criteria for Adverse Events* (*CTCAE*). No grade 4 toxicities or treatment-related deaths were observed. Decline in LVEF was asymptomatic in all affected patients. Grades are presented for the most clinically relevant toxicities; lower-grade events (grade 0–1) predominated for transaminase elevations and anemia.

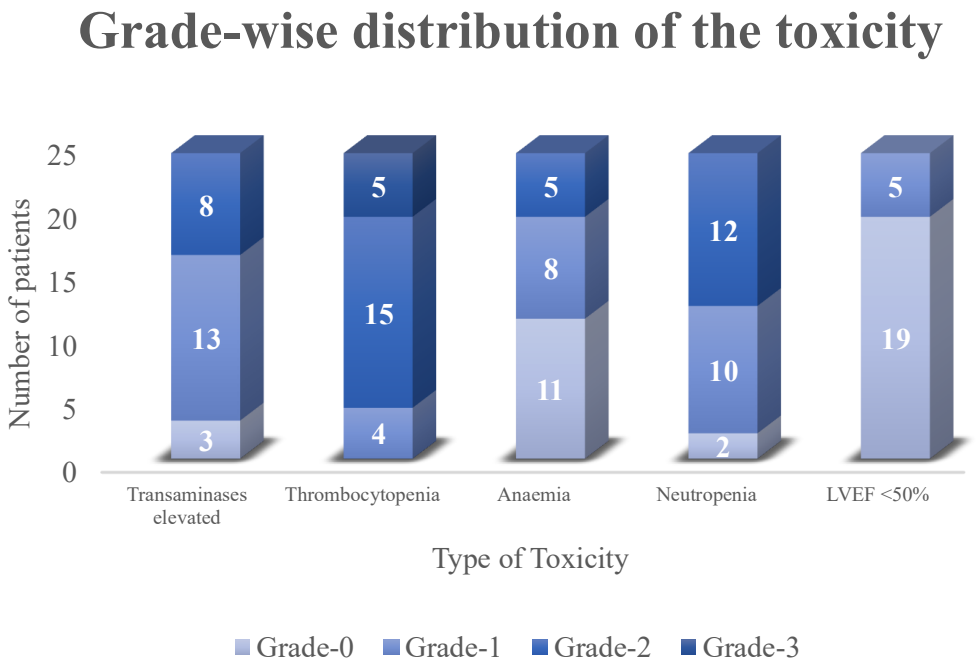

Figure 1. Grade-Wise Distribution of Treatment-Related Toxicities Among Patients Receiving Trastuzumab Emtansine

Table 4. Sites and Patterns of Recurrence Among Patients With Invasive Disease Recurrence (n = 5)

Site of recurrence	n	% of relapsed patients
Bone	2	40%
Brain (CNS)	1	20%
Liver	2	40%
Total distant recurrences	5	100%

Note: All 5 recurrences were distant metastases; no locoregional recurrences were observed. Percentages refer to the proportion among the 5 patients who relapsed. CNS, central nervous system.

DISCUSSION

This single-center retrospective study provides early real-world evidence for a trastuzumab emtansine (T-DM1) biosimilar as adjuvant therapy in Indian women with stage II or III HER2-positive breast cancer and residual disease after neoadjuvant therapy. The 12-month iDFS rate was 79.2%; given the short follow-up and the small number of events (n=5), median iDFS was not reported. In KATHERINE, adjuvant T-DM1 reduced the risk of invasive recurrence or death by 46% compared with trastuzumab alone; 7-year iDFS was 80.8% with T-DM1 vs 67.1% with trastuzumab, and overall survival also improved.[17] In the present cohort, 20.8% of patients relapsed, usually to bone, brain, or liver, and no deaths occurred during 14 months of follow-up. The observed relapse rate likely reflects the higher baseline risk profile of the cohort, including a predominance of stage III disease and the presence of comorbidities. Longer follow-up is needed to assess whether these early outcomes converge with those of the KATHERINE population.

The ATEMPT phase 2 trial explored T-DM1 in lower-risk stage I disease. After 5.8 years of follow-up, patients receiving T-DM1 had a 5-year iDFS of 97%, with only 5 recurrences, and a toxicity profile distinct from paclitaxel plus trastuzumab. These results, together with outcomes from the APT trial, demonstrate that excellent long-term disease control is achievable in patients with small, node-negative HER2-positive tumors.[18]

The present cohort, however, consisted of patients with residual invasive disease after neoadjuvant chemotherapy, a population with substantially higher recurrence risk. In this setting, adjuvant T-DM1 is supported by the KATHERINE trial and remains the only therapy with proven benefit in improving iDFS.[17] Trials such as KAITLIN and KRISTINE, which evaluated T-DM1 plus pertuzumab in place of standard taxane-based regimens, did not demonstrate improved outcomes, suggesting that T-DM1 should be reserved for patients with residual disease following neoadjuvant therapy.

In metastatic disease, the EMILIA and TH3RESA trials demonstrated improvements in progression-free and overall survival with T-DM1 compared with lapatinib plus capecitabine and physician's choice chemotherapy, respectively.[19] These findings, together with data from the KAMILLA safety study, established the manageable toxicity profile of T-DM1, including thrombocytopenia and transaminase elevations.[20] The current real-world findings are consistent with these reports: thrombocytopenia, neutropenia, and anemia were common but

predominantly grade 1 or 2, and declines in LVEF were asymptomatic.

A strength of this study is the exploration of potential prognostic factors beyond the primary end point. Exploratory analyses demonstrated numerically longer iDFS in patients with stage III disease and those undergoing mastectomy; however, these findings were counterintuitive. These observations likely reflect selection bias and limited statistical power, as only 5 patients had stage II disease. Patients initiating treatment at higher starting doses demonstrated numerically longer iDFS, although dose selection was influenced by clinical factors and vial-based rounding, limiting interpretability.

Hormone receptor status, ECOG performance status, and menopausal status did not show a meaningful association with iDFS. Socioeconomic factors showed trends: patients paying out of pocket had numerically longer iDFS than those with insurance. While not statistically significant, this observation highlights the potential impact of affordability and adherence. High out-of-pocket costs can adversely affect treatment persistence. A US cross-sectional study demonstrated reduced adherence to aromatase inhibitors with increasing copayments, and similar patterns have been reported for oral chemotherapy.[21,22]

In India, breast cancer treatment costs impose substantial financial burden. A retrospective study from Tata Memorial Centre estimated mean total treatment costs of ₹258 095 ($3531), with out-of-pocket expenditure accounting for the majority.[22] Financial toxicity may therefore contribute to dose delays or early discontinuation, potentially compromising outcomes.

Biosimilars offer an opportunity to improve access to HER2-targeted therapies by reducing costs. Real-world studies have demonstrated comparable efficacy and safety of trastuzumab biosimilars relative to the originator, with significant cost savings.[23] Our findings support the feasibility of delivering a T-DM1 biosimilar in a resource-constrained setting with acceptable safety and disease control. The median progression-free survival reported in an Indian retrospective study of a T-DM1 biosimilar in metastatic breast cancer is comparable to outcomes observed here, further supporting biosimilar use across disease stages.[24]

The study has important limitations, including its retrospective design, small sample size, single-center setting, short follow-up, and lack of a comparator arm. These factors limit generalizability and preclude adjusted analyses. Despite these limitations, this study contributes to the limited real-world literature on T-DM1 biosimilars in early-stage HER2-positive breast cancer. Future multicenter studies with larger cohorts, longer follow-up, and incorporation of patient-reported outcomes are needed to confirm these findings and evaluate long-term effectiveness and economic impact.

CONCLUSION

This retrospective real-world evaluation suggests that adjuvant trastuzumab emtansine biosimilar use in patients with high-risk early-stage HER2-positive breast cancer is feasible and associated with a manageable safety profile consistent with previously reported clinical trials and real-world data. Given the small sample size, short follow-up, and descriptive nature of this analysis, efficacy outcomes should be interpreted cautiously. Larger multicenter studies with longer follow-up, incorporation of patient-reported outcomes, and formal cost-effectiveness analyses are required to confirm these findings and to inform equitable implementation of biosimilar-based therapies in low- and middle-income countries.

ETHICAL CONSIDERATIONS

The study was conducted at Sunshine Global Hospital, Surat, and was approved by the Institutional Ethics Committee of Sunshine Global Hospital. Informed consent was waived due to the retrospective nature of the study.

DATA AVAILABILITY

The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

CONFLICT OF INTERESTS

None reported.

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AI DISCLOSURE

The authors declare that artificial intelligence–based tools were used for language editing and formatting of the manuscript to improve clarity and readability.

AUTHOR CONTRIBUTION

KP: Conceptualization, Methodology, Formal Analysis, Investigation, Resources, Writing – Original Draft, Writing – Review & Editing, Visualization, Supervision, Project Administration. VT: Conceptualization, Methodology, Formal Analysis, Investigation, Resources, Writing –

Original Draft, Writing – Review & Editing, Visualization, Supervision, Project Administration. PM: Conceptualization, Methodology, Formal Analysis, Investigation, Resources, Writing – Original Draft, Writing – Review & Editing, Visualization, Supervision, Project Administration.

REFERENCES

1. Li YW, Dai LJ, Wu XR, Zhao S, Xu YZ, Jin X, et al. Molecular characterization and classification of HER2-positive breast cancer inform tailored therapeutic strategies. *Cancer Res*. 2024;84(21):3669–3683. doi:10.1158/0008-5472.CAN-24-1176.
2. Prat A, Carey LA, Adamo B, Vidal M, Tabernero J, Cortés J, et al. Molecular features and survival outcomes of the intrinsic subtypes within HER2-positive breast cancer. *J Natl Cancer Inst*. 2014;106(8):dju152. doi:10.1093/jnci/dju152.
3. Rediti M, Venet D, Joaquin Garcia A, Maetens M, Vincent D, Majjaj S, et al. Identification of HER2-positive breast cancer molecular subtypes with potential clinical implications in the ALTTO clinical trial. *Nat Commun*. 2024;15:10402. doi:10.1038/s41467-024-53498-5.
4. Cronin KA, Harlan LC, Dodd KW, Abrams JS, Ballard-Barbash R. Population-based estimate of the prevalence of HER-2 positive breast cancer tumors for early stage patients in the US. *Cancer Invest*. 2010;28(9):963–968. doi:10.3109/07357907.2010.512598.
5. Erickson AW, Ghodrati F, Habbous S, Jerzak KJ, Sahgal A, Ahluwalia MS, et al. HER2-targeted therapy prolongs survival in patients with HER2-positive breast cancer and intracranial metastatic disease: a systematic review and meta-analysis. *Neurooncol Adv*. 2020;2(1):vdaa136. doi:10.1093/noajnl/vdaa136.
6. Li SG, Li L. Targeted therapy in HER2-positive breast cancer. *Biomed Rep*. 2013;1(4):499–505. doi:10.3892/br.2013.112.
7. Hunter FW, Barker HR, Lipert B, Rothé F, Gebhart G, Piccart-Gebhart MJ, et al. Mechanisms of resistance to trastuzumab emtansine (T-DM1) in HER2-positive breast cancer. *Br J Cancer*. 2020;122(5):603–612. doi:10.1038/s41416-019-0635-y.
8. Arnold M, Morgan E, Rumgay H, Mafra A, Singh D, Laversanne M, et al. Current and future burden of breast cancer: global statistics for 2020 and 2040. *Breast*. 2022;66:15–23. doi:10.1016/j.breast.2022.08.010.
9. Kulothungan V, Ramamoorthy T, Sathishkumar K, Mohan R, Tomy N, Miller GJ, et al. Burden of female breast cancer in India: estimates of YLDs, YLLs, and DALYs at national and subnational levels based on the national cancer registry programme. *Breast Cancer Res Treat*. 2024;205(2):323–332. doi:10.1007/s10549-024-07278-5.
10. Singh K, Grover A, Dhanasekaran K. Unveiling the cancer epidemic in India: a glimpse into GLOBOCAN 2022 and past patterns. *Lancet Reg Health Southeast Asia*. 2025;34:100951. doi:10.1016/j.lansea.2025.100951.
11. Nagarjun BR, Parikh B, Patel MN, Trivedi PJ, Patel DM. Indian data on HER2 fluorescence in situ hybridization in invasive breast cancer with immunohistochemically equivocal results as per 2018 ASCO/CAP guidelines. *South Asian J Cancer*. 2022;11(4):281–286. doi:10.1055/s-0042-1757758.
12. Baruah P, Sarma A, Bhattacharyya M, Saema P, Das BC, Sarma D, et al. Elevated FISH Her-2/neu amplification in ER positive, IHC Her-2 equivocal invasive breast cancer patients of North-East India. *Asian Pac J Cancer Care*. 2024;9(4):705–711. doi:10.31557/APJCC.2024.9.4.705-711.
13. Denkert C, Lambertini C, Fasching PA, Pogue-Geile KL, Mano MS, Untch M, et al. Biomarker data from the phase III KATHERINE study of adjuvant T-DM1 versus trastuzumab for residual invasive disease after neoadjuvant therapy for HER2-positive breast cancer. *Clin Cancer Res*. 2023;29(8):1569–1581. doi:10.1158/1078-0432.CCR-22-2803.
14. Geyer CE, Loibl S. Switching to T-DM1 remains justified in patients with HER2-negative residual invasive breast cancer after neoadjuvant therapy. *Breast*. 2025;81:104450. doi:10.1016/j.breast.2025.104450.
15. Conte P, Schneeweiss A, Loibl S, Mamounas EP, von Minckwitz G, Mano MS, et al. Patient-reported outcomes from KATHERINE: a phase 3 study of adjuvant trastuzumab emtansine versus trastuzumab in patients with residual invasive disease after neoadjuvant therapy for human epidermal growth factor receptor 2–positive breast cancer. *Cancer*. 2020;126(13):3132–3139. doi:10.1002/cncr.32862.
16. Thukral DG, Thummar DV, Mehta DP, Janagama DV, Khambhati K. Drug utilization pattern of world's first T-DM1 biosimilar (UJVIRA) for Her2+ breast cancer in first year of its availability–an Indian context. *Int J Med Sci Clin Invent*. 2023;10(02):6561–6568. doi:10.18535/ijmsci/v10i02.05.
17. Geyer CE Jr, Untch M, Huang CS, Mano MS, Mamounas EP, Wolmark N, et al. Survival with trastuzumab emtansine in residual HER2-positive breast cancer. *N Engl J Med*. 2025;392(3):249–257. doi:10.1056/NEJMoa2409646.
18. Kesireddy M, Krishnamurthy J. T-DM1: a promising adjuvant therapy option for stage I HER2-positive breast cancer—interpreting ATEMPT trial results from a clinical perspective. *Gland Surg*. 2025;14(4):785–790. doi:10.21037/gs-24-452.
19. Hurvitz SA, Martin M, Symmans WF, Jung KH, Huang CS, Thompson AM, et al. Neoadjuvant trastuzumab, pertuzumab, and chemotherapy versus trastuzumab emtansine plus pertuzumab in patients with HER2-positive breast cancer (KRISTINE): a randomised, open-label, multicentre, phase 3 trial. *Lancet Oncol*.

2018;19(1):115–126. doi:10.1016/S1470-2045(17)30716-7.
20. Wuerstlein R, Ellis P, Montemurro F, Antón Torres A, Delaloge S, Zhang Q, et al. Final results of the global and Asia cohorts of KAMILLA, a phase IIIB safety trial of trastuzumab emtansine in patients with HER2-positive advanced breast cancer. *ESMO Open*. 2022;7(5):100561. doi:10.1016/j.esmoop.2022.100561.
21. Neugut AI, Subar M, Wilde ET, Stratton S, Brouse CH, Hillyer GC, et al. Association between prescription co-payment amount and compliance with adjuvant hormonal therapy in women with early-stage breast cancer. *J Clin Oncol*. 2011;29(18):2534–2542. doi:10.1200/JCO.2010.33.3179.
22. Zullig LL, Peppercorn JM, Schrag D, Taylor DH Jr, Lu Y, Samsa G, et al. Financial distress, use of cost-coping strategies, and adherence to prescription medication among patients with cancer. *J Oncol Pract*. 2013;9(6 suppl):60s–63s. doi:10.1200/JOP.2013.000262.
23. Mamori T, Tanioka M, Takada K, Hamano H, Tsukioki T, Takahashi Y, et al. Real-World Comparative Analysis of Trastuzumab Originator and Biosimilars: Safety, Efficacy, and Cost Effectiveness. *BioDrugs*. 2025 Jan;39(1):131-142. doi: 10.1007/s40259-024-00686-x.

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