Poster 311

Electronic Patient-Reported Outcomes With Vital Signs Monitoring Versus Usual Care During Trastuzumab Deruxtecan Treatment for Metastatic Breast Cancer: Updated Results From the PRO-DUCE Study

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Objective

- To evaluate the impact of ePROs with vital sign monitoring compared with routine follow-up care on the QoL of patients with HER2-positive mBC treated with T-DXd.

Conclusions

- The mean **change from baseline in EORTC QLQ-C30 GHS/QoL** (primary endpoint) was **significantly better** in the **monitoring group** vs. the usual care group at week 24, and this difference remained beyond week 24 (Figure 3).
- **The monitoring group was favored over the usual care group** across all (total, physical, and cognitive scores) **EORTC QLQ-FA12 (cancer-related fatigue** questionnaires) at week 24; this difference remained consistent beyond week 24 (Figure 5).
- **Survival outcomes** showed **no significant difference** between the monitoring group and the usual care group (Figure 6).
- Most any-grade TEAEs using PRO-CTCAE were reported in a higher proportion of patients in the monitoring group vs. the usual care group (Table 2).

Key message:
Long-term findings from the PRO-DUCE study suggest that integrating ePRO with vital signs monitoring, an approach inherently promoting active patient involvement in their care, is significantly effective in clinical practice for maximizing QoL for patients receiving T-DXd.

Plain language summary

Why did we perform this research?

- Figuring out how to make patients' quality of life (QoL) better is important because it can help improve care and support for people living with cancer.
- This study looked at how monitoring electronic patient-reported outcomes (ePROs) and vital signs, compared with usual care, affects the QoL of patients with HER2-positive metastatic breast cancer (mBC) who are being treated with trastuzumab deruxtecan (T-DXd).

How did we perform this research?

- The participants were adults with mBC who could receive T-DXd treatment, and they were randomly assigned to either a monitoring group or a usual care group.
- In the monitoring group, patients self-reported their symptoms and vital sign data regularly using electronic devices.
- We used statistical tests to compare the QoL scores between the monitoring group and the usual care group.

What were the findings of this research?

- A total of 111 patients from 38 hospitals in Japan were included in this study.
- Patients who used the electronic tools reported higher QoL scores regarding overall and cancer-related fatigue, with no notable difference in survival rates.

What are the implications of this research?

- This research shows that using electronic tools to track symptoms can help maintain or improve the QoL for patients receiving T-DXd.
- The results may help doctors and healthcare providers understand the advantages of using technology in cancer care.

Where can I access more information?

- For additional details about this study, please visit the jRCT website at identifier: jRCTs031200387.

Poster | Plain language summary | Supplementary material

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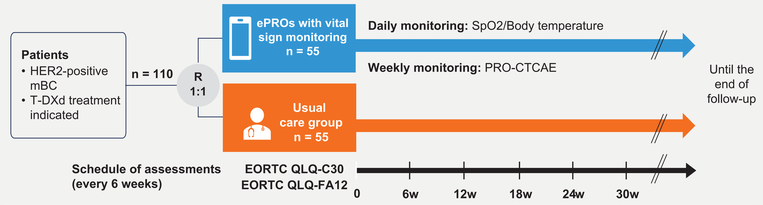
This study was sponsored by Daiichi Sankyo. In March 2019, AstraZeneca entered into a global development and commercialization collaboration agreement with Daiichi Sankyo for trastuzumab deruxtecan (T-DXd; DS-8201).
Poster presented at ASCO 2025 by Yuichiro Kikawa. Corresponding author email address: bj.u1ro@gmail.com

Background

- Trastuzumab deruxtecan (T-DXd) is associated with specific treatment-emergent adverse events with common ones including nausea, vomiting, and fatigue, while interstitial lung disease (ILD) is a notable adverse event of interest.[1-3]
- Patient-reported outcome (PRO) data enhance symptom control and quality of life (QoL), with some instruments linked to improved survival; European Society for Medical Oncology (ESMO) guidelines recommend digital symptom monitoring during systemic cancer treatment.[4,5]
- The PRO-DUCE study (jRCTs031200387), a multicenter, randomized controlled open-label study, evaluated the impact of monitoring (ePRO plus body temperature [BT]/oxygen saturation [SpO2] monitoring) vs. usual care on the quality of life (QoL) of patients with HER2-positive metastatic breast cancer (mBC) treated with T-DXd.
- The primary endpoint analyzed a mixed-effects model for repeated measures (MMRM) to assess the change in global health status/quality of life from baseline at week 24, with a two-sided alpha error <0.10 due to its exploratory nature.
- The primary results presented at American Society of Clinical Oncology (ASCO) 2024 showed that at week 24, ePROs with vital sign monitoring demonstrated significantly better results for global health status (GHS) than usual care, with a mean difference of **8.0 (90% confidence interval [CI] 0.2, 15.8; p = 0.091)** (Data cutoff: July 15, 2023).
- Here, we present additional effects on long-term QoL scores and overall survival (OS) from the PRO-DUCE study (Data cutoff: May 20, 2024).

Methods

Figure 1. PRO-DUCE Study Design



Stratification factors: ECOG PS (0/1-2), Age (≤ 59 years/≥ 60 years), Line of treatment after recurrence (≤ 3/≥ 4 line)

ePRO Monitoring Procedures

- Participants used the "Hibilog app" on personal devices for daily logging of body temperature and SpO2 (a pulse oximeter was provided for home SpO2 monitoring) and weekly reporting of selected PRO-CTCAE symptoms
- Investigators and healthcare providers had real-time access to PRO data via the app
- Alert notifications were triggered based on predefined symptom thresholds established by expert consensus

Primary Endpoint:

- Change from baseline in GHS/QoL at week 24

Secondary PRO Endpoints:

- Change in each domain from baseline at week 24 and from baseline to the end of the entire observation period
- Cancer-related fatigue
- OS, PFS, TTF
- Adherence with ePRO
- AEs

Results

Figure 2. CONSORT Diagram

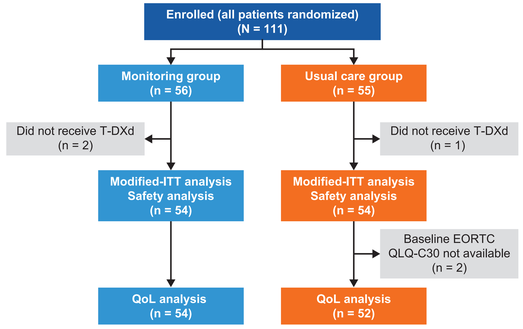
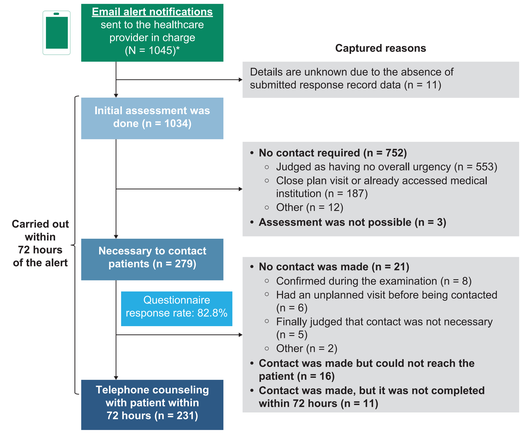


Figure 4. Actions Taken in Response to Alert Notifications Throughout the Entire Observation Period



Category	No. of Alerts	No. of Responses	Alerts/Responses	Alerts per Person
Body Temperature/SpO2	542	21709	2.5%	9.7
PRO-CTCAE	503	3275	15.4%	9.0
Total	1045	24984	4.2%	18.7

Table 1. Baseline Patient Characteristics

- Between March 2021 and January 2023, patients who enrolled across 38 hospitals in Japan were randomized into two treatment groups; baseline characteristics were similar between the two cohorts (Table 1)

Patient characteristic	Modified ITT analysis population (n = 108)	
	Monitoring group (n = 54)	Usual care group (n = 54)
Age, mean (SD), years	57.1 (9.7)	57.2 (12.3)
ECOG PS, n (%)		
0	33 (61.1)	32 (59.3)
1	21 (38.9)	19 (35.2)
2	0 (0.0)	3 (5.6)
T-DXd treatment line, n (%)		
≤ 3	32 (59.3)	34 (63.0)
≥ 4	22 (40.7)	20 (37.0)
Starting dose of T-DXd, n (%)		
5.4 mg/kg	52 (96.3)	53 (98.1)
4.4 mg/kg	2 (3.7)	1 (1.9)
Hormone receptor status, n (%)		
ER positive	35 (64.8)	33 (61.1)
ER negative	19 (35.2)	21 (38.9)
Education level, n (%)		
Below college level	47 (87.0)	48 (88.9)
College degree or above	7 (13.0)	6 (11.1)

Figure 3. Change from baseline in EORTC QLQ-C30 GHS/QoL

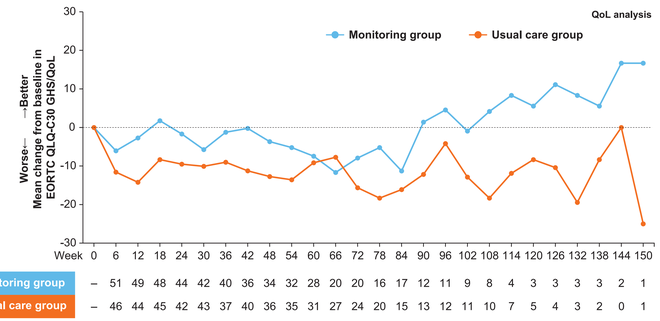
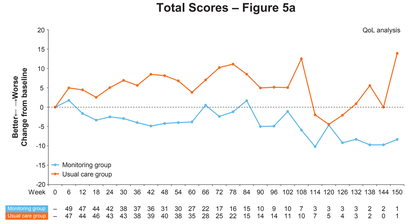
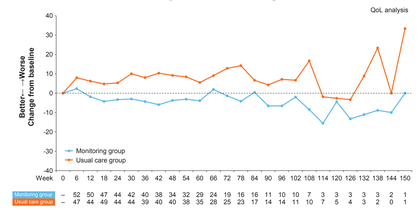


Figure 5. Change from baseline in EORTC QLQ-FA12 (cancer-related fatigue)

Total Scores – Figure 5a



Physical Scores – Figure 5b



Cognitive Scores –Figure 5c

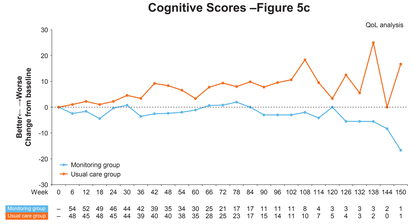
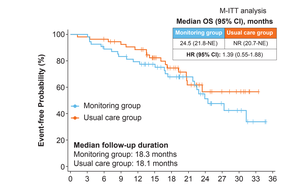
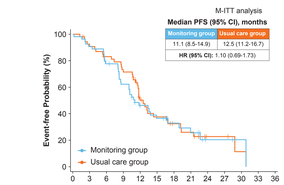


Figure 6. OS, PFS, TTF

OS – Figure 6a



PFS – Figure 6b



TTF – Figure 6c

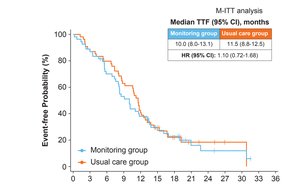


Table 2. Adverse Events

Safety analysis

	Monitoring group (n = 54)		Usual care group (n = 54)	
	Any grade	≥Grade 3	Any grade	≥Grade 3
AEs (PRO-CTCAE), n (%)				
Decreased appetite	27 (50.0)	2 (3.7)	22 (40.7)	0
Nausea	39 (72.2)	1 (1.9)	33 (61.1)	0
Vomiting	14 (25.9)	0	10 (18.5)	0
Diarrhea	24 (44.4)	1 (1.9)	13 (24.1)	1 (1.9)
Constipation	21 (38.9)	0	23 (42.6)	1 (1.9)
Shortness of breath	7 (13.0)	0	2 (3.7)	0
Pain	8 (14.8)	0	1 (1.9)	0
Insomnia	5 (9.3)	0	3 (5.6)	0
Fatigue	23 (42.6)	3 (5.6)	25 (46.3)	2 (3.7)
Anxiety	4 (7.4)	0	1 (1.9)	0
Cough	8 (14.8)	0	3 (5.6)	0
AEs of special interest, n (%)				
Interstitial lung disease	4 (7.4)	0	5 (9.3)	0

Abbreviations

AE, adverse events; BT, body temperature; CTCAE, Common Terminology Criteria for Adverse Events; CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; ePROs, electronic patient-reported outcomes; EORTC, European Organization for Research and Treatment of Cancer; ER; estrogen receptor; FA12, cancer-related fatigue; GHS, global health status; HER2, human epidermal growth factor receptor 2; HR, hazard ratio; ILD, interstitial lung disease; mBC, metastatic breast cancer; M-ITT, modified intention to treat; MMRM, mixed-effects model for repeated measures; NE, not estimable; NR, not reached; OS, overall survival; PFS, progression-free survival; PRO, patient-reported outcome; PRO-CTCAE, PRO version of the Common Terminology Criteria for Adverse Events; QLQ-C30, Quality of Life Core 30 questionnaire; QoL, quality of life; R, randomization; SD, standard deviation; SpO2, oxygen saturation; T-DXd, trastuzumab deruxtecan; TTF, time to treatment failure; w, weeks

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Disclosures

Yuichiro Kikawa: honoraria from Eisai, Chugai Pharma, Pfizer, Lilly Japan, Taiho Pharmaceutical, Novartis, AstraZeneca, and Daiichi Sankyo.

References

1. Modi S, et al. *N Engl J Med*. 2020 Feb 13;382(7):610-621.
2. Andre F, et al. *Lancet*. 2023 May 27;401(10390):1773-1785.
3. Cortés J, et al. *N Engl J Med*. 2022 Mar 24;386(12):1143-1154.
4. Basch E, et al. *J Clin Oncol*. 2016 Feb 20;34(6):557-565.
5. Di Maio M, et al. *Ann Oncol*. 2022 Sep;33(9):878-892.