

Non-interventional, Real-world Study of Patients with Early Stage, Human Epidermal Growth Factor Receptor 2 (HER2) Positive Breast Cancer Receiving Biosimilar Trastuzumab

Objective



The objectives of this study were to understand the utilization patterns and safety profile of trastuzumab-qyyp and examine the healthcare resource use in patients prescribed trastuzumab-qyyp in a real-world setting.

Conclusions



- The current study showed that treatment utilization patterns and the safety profile of trastuzumab-qyyp among patients who initiated neoadjuvant or adjuvant treatment were consistent with the product label and the clinical recommendations.
- Healthcare resource use was substantial in this patient population, consistent with the substantial economic burden associated with breast cancer.

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Background

- Trazimera® (trastuzumab-qyyp) is a biosimilar to Herceptin® (trastuzumab) and is currently approved by the United States Food and Drug Administration¹ and the European Medicines Agency.²
- It is the fourth biosimilar to Herceptin® in Europe.
- In a randomized, non-inferiority, double-blind study, trastuzumab-qyyp was shown to be comparable to its originator in terms of the primary endpoint of pathological complete response as well as grade 3-4 adverse events.³
- However, there are no studies evaluating the treatment patterns and outcomes associated with trastuzumab-qyyp in a real-world setting.
- The objectives of this study were to understand the utilization of trastuzumab-qyyp and its benefits and risks in a real-world setting.

Results

Patient Demographics and Clinical Characteristics

- A total of 102 patients were included; 74 (72.6%) received trastuzumab-qyyp, 26 (25.5%) switched from Herceptin to trastuzumab-qyyp and 3 switched from other trastuzumab biosimilars.
- Demographic and clinical characteristics are presented in Table 1.

Table 1. Patient Demographics and Clinical Characteristics

Variable	Statistic or Category	All Patients (N=102)
Age (years)	Mean (SD)	56.3 (11.9)
Body Mass Index	Mean (SD)	26.8 (5.6)
Charlson comorbidity index	Mean (SD)	0.32 (0.96)
Healthcare coverage, N (%)	Public/Government	49 (48.0%)
	Private	31 (30.4%)
	Unknown	22 (21.6%)
Smoking status, N (%)	Current smoker	7 (6.9%)
	Former smoker	20 (19.6%)
	Never smoked	59 (57.8%)
	Unknown	16 (15.7%)
Family history of breast cancer, N (%)	Yes	36 (35.3%)
Menopausal status, N (%)	Premenopausal	27 (26.5%)
	Postmenopausal (due to LH-RH analog or oophorectomy)	3 (2.9%)
	Postmenopausal (not due to LH-RH analog or oophorectomy)	55 (53.9%)
	Unknown	17 (16.7%)
ER/PgR status, N (%)	ER + (>50% positive) / PgR +	51 (50.0%)
	ER + (<50% positive) / PgR +	1 (1.0%)
	ER + (>50% positive) / PgR -	16 (15.7%)
	ER + (<50% positive) / PgR -	4 (3.9%)
	ER - / PgR +	1 (1.0%)
	ER - / PgR -	29 (28.4%)
HER2 status, N (%)	HER2 positive (no further info. given)	39 (38.2%)
	HER2 positive: 2+ and CISH/FISH positive	16 (15.7%)
	HER2 positive: 3+	47 (46.1%)

Utilization of trastuzumab-qyyp

- The median trastuzumab-qyyp initial dose was 8.0 mg/kg, with dose change occurring in 78 (76.5%) patients. (Table 2)

Methods

Study Design

An observational, multi-site study conducted in adult patients who received trastuzumab-qyyp as neoadjuvant or adjuvant therapy for the treatment of BC in Norway and the Netherlands was conducted.

Inclusion Criteria

- Patients with stage 0-3 HER2 positive breast cancer at the time of diagnosis or trastuzumab-qyyp initiation
- Initiated treatment with trastuzumab-qyyp for the neoadjuvant or adjuvant treatment of their disease and/or received at least 3 months of trastuzumab-qyyp treatment

Exclusion Criteria

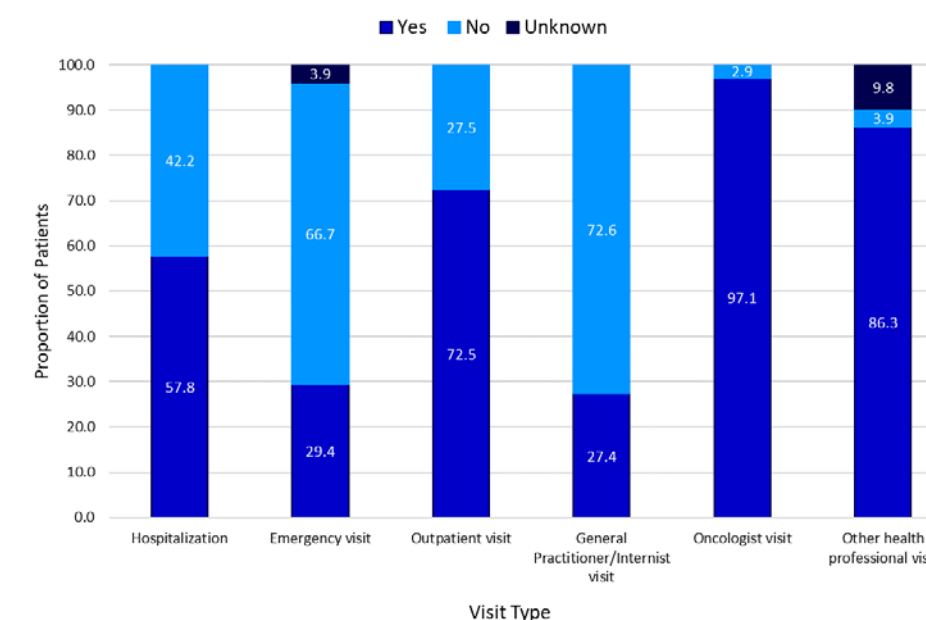
- Age <18 years
- Stage 4 HER2 positive breast cancer at the time of diagnosis or trastuzumab-qyyp initiation

- Trastuzumab-qyyp was part of combination therapy in 100 (98%) patients, where 38 (37.2%) combination regimens included platinum-based drugs and 40 (39.2%) regimens included pertuzumab. (Table 2)
- Further details on trastuzumab-qyyp utilization can be found in Table 2.

Table 2. Utilization and Patterns of trastuzumab-qyyp

Variable	Statistic or Category	All Patients (N=102)
Initial dose (mg/kg)	Mean (SD)	6.4 (1.9)
	Median (Q1-Q3)	8.0 (6.0–8.0)
Initial duration (minutes)	Mean (SD)	65.1 (47.6)
	Median (Q1-Q3)	35.0 (30.0 to 90.0)
Treatment duration (days)	Mean (SD)	245.6 (107.2)
Combination therapy, N (%)	Yes	100 (98.0%)
Type of combination therapy, N (%)	Chemotherapy	76 (74.5%)
	Hormone therapy	35 (34.3%)
	Immunotherapy	3 (2.9%)
	Radiation therapy	2 (2.0%)
	Chemotherapy + Immunotherapy	15 (14.7%)
Dose change, N (%)	Chemotherapy + Radiation	1 (1.0%)
	Hormone therapy + Radiation	8 (7.8%)
	Yes	78 (76.5%)

Figure 1. Healthcare Resource Utilization Among Patients



- active malignant disease requiring treatment with trastuzumab or currently on trastuzumab-emtansine

Data Source

- The patient's medical record served as the primary data source.

- Data was collected from 1 site in Norway and 6 sites in the Netherlands from February 2020 to July 2021.

Statistical Analysis

- Trastuzumab-qyyp treatment patterns, patient demographics, clinical characteristics, tolerability and healthcare resource utilization (HCRU) were assessed and presented descriptively.
- Healthcare resource utilization was assessed from 6 months prior to biosimilar initiation through to the informed consent date or the end of data collection period.

Healthcare Resource Utilization

- Over 50% of the patients were hospitalized for a mean of 7.7 days.
- Reasons for hospitalization were breast cancer surgery including reconstructions (32.7%), PICC line/port-a-cath procedures (15.8%), fever (13.9%), ablation (5.9%), and other unspecified surgery (5.9%).
- Further details on the HCRU are presented in Figure 1.

Adverse Events and Cardiac Monitoring

- A total of 66 adverse events occurred and 38 (57.6%) were mild.
- Results associated with adverse events are presented in Table 3.
- Heart monitoring was conducted in 95 (93.1%) patients; 237 heart monitoring events recorded.
- Of 237 heart monitoring events, 221 (93.2%) had normal findings; trastuzumab-qyyp was stopped temporarily during 7 events and permanently during 1 event.

Table 3. Adverse Events During trastuzumab-qyyp Treatment (Event Level)

Variable	Statistic or Category	All Patients (N=102)
Severity/Grade, N (%)	Mild	38 (57.6%)
	Moderate	24 (36.4%)
	Severe	4 (6.1%)
trastuzumab-qyyp-Related, N (%)	Definitely	6 (9.1%)
	Probably	13 (19.7%)
	Unlikely	11 (16.7%)
	Unrelated	36 (54.6%)
	Serious, N (%)	Yes
Action Taken for trastuzumab-qyyp, N (%)	Withdrawn	16 (24.2%)
	Dose not changed	43 (65.1%)
	Not applicable	7 (10.6%)
Adverse Event Treatment, N (%)	None	30 (45.4%)
	Treatment with medications	32 (48.5%)
	Treatment without medication	4 (6.1%)
Outcome, N (%)	Resolved/recovered	58 (87.9%)
	Resolved/recovered with sequelae	4 (6.1%)
	Not resolved/not recovered	4 (6.1%)
	Fatal	0 (0.0%)