LONGTERM – LONG-TIME RESPONSE (>18 months) IN HER2-POSITIVE METASTATIC BREAST CANCER

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ABSTRACT

Progression-free survival (PFS) and overall survival (OS) have significantly improved in patients with HER2-positive metastatic breast cancer (mBC) due to advances in targeted therapies.

The current standard first-line treatment includes dual antibody therapy with trastuzumab and pertuzumab combined with chemotherapy, as established in the CLEOPATRA trial. This real-world data (RWD) analysis, conducted by the German Association of Private Practice-Based and Outpatient Gynecologic Oncologists (BNGO), retrospectively examined patients with a PFS >18 months.

INTRODUCTION

The prognosis of patients with HER2-positive metastatic breast cancer (mBC) has been fundamentally transformed over the past two decades through the introduction of HER2-targeted therapies. Dual HER2 blockade with trastuzumab and pertuzumab in combination with a taxane has become the established first-line standard, providing durable responses and extending median overall survival to more than five years in the pivotal CLEOPATRA trial[1].

Nevertheless, data from controlled studies may not fully reflect the diversity of patient characteristics, comorbidities, and treatment approaches observed in daily clinical practice. Real-world evidence is therefore essential to complement trial results and to evaluate the long-term effectiveness of anti-HER2 regimens outside controlled conditions. The LONGTERM project, initiated by the German BNGO network, was designed to identify and characterize patients treated in routine outpatient care. By analyzing clinical data from 23 centers between 2010 and 2020, the study aimed to describe baseline characteristics, therapeutic patterns, and disease course in individuals achieving a PFS > 18 months. This analysis provides a real-world perspective on durable disease control in HER2-positive mBC and its relevance for current treatment algorithms.

METHODS AND MATERIAL

This retrospective, multicenter study included patients with newly diagnosed HER2-positive metastatic or inoperable breast cancer documented between 1 Jan 2010 and 31 Jul 2020 across BNGO centers. Data collection was performed retrospectively from 1 Mar 2022 to 31 Dec 2023 using existing electronic medical records; no additional information was generated. Source data were pseudonymized and transferred into an electronic case report form (eCRF) developed and hosted by HERACLIN GmbH, the CRO of the BNGO network.
Eligible patients had confirmed HER2 IHC 3+ and/or ISH-positive status, received anti-HER2 therapy as first-line treatment, and achieved progression-free survival > 18 months by clinical or radiological assessment (RECIST 1.1). Patients without confirmed HER2-positive status or with progression within 18 months after first diagnosis were excluded. Patient, tumor, and therapy characteristics were analyzed descriptively.

RESULTS

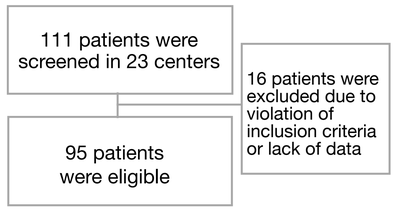


Figure 1. Study enrollment

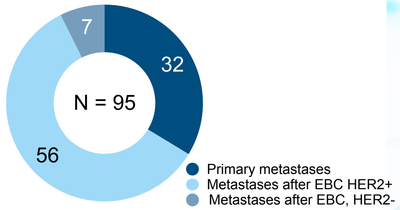


Figure 2. State at 1st-line therapy start

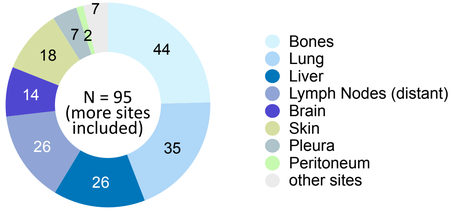
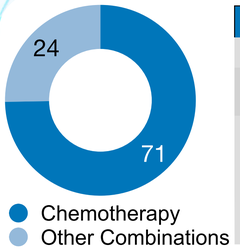


Figure 3. Distribution of metastatic sites at 1st-line therapy start



Chemotherapy	n (%)
Docetaxel	39 (41 %)
Paclitaxel	28 (29,5 %)
Epirubicin, Cyclophosphamide, Capecitabine, Vinorelbine, Eribulin, Carboplatin	5 (5,3 %)

Figure 4. 1st-line combinations with Anit-HER2-therapy

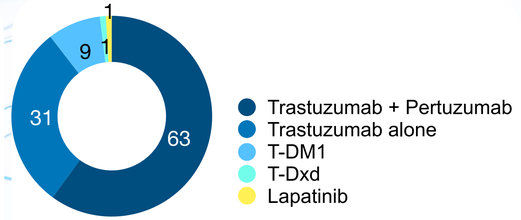


Figure 5. 1st-line combinations with Anit-HER2-therapy

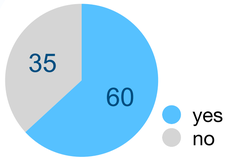


Figure 6. Antihormonal therape, simultaniously to Anti-HER2-therapy

DISCUSSION

The analyses show the characteristics of long-time-responders (> 18 months until progression, death or withdrawal of therapy.) This description of characteristics of the cohort can help to predict the outcome of the disease before the start of the therapy in patients treated in future. Described drugs in this analysis are a mirror of therapy evolution during the observation period. Based on the CLEOPATRA-Trial the approval für pertuzumab in combination with trastuzumab and taxan containing chemotherapy was given in 2013 in Europe. All patients in this cohort analysis get an anti-HER2-therapy, most in a combination of trastuzumab and pertuzumab. When the hormonal receptor status was positive, an antihormonal therapy was given in most cases, sequentially after chemotherapy. Initial chemotherapy and a longterm anti-HER2 therapy provide the patients a good life quality for a long term. New developed anti-HER2 drugs, such as trastuzumab-deruxtecan for the 1st-line treatment have to be compared in with the current standard. A good compliance to the given drugs in the chronic stadium is the challenge of future therapies.

Used drugs in the BNGO network are on the current level of international therapy guidelines in the observation period, such as ASCO, NCCN and AGO (Germany). The BNGO network Germany is able to describe patient characteristics and therapies comparable to international standards.

CONCLUSION

The LONGTERM analysis describes patients with HER2-positive metastatic or inoperable breast cancer who achieved a progression-free survival of more than 18 months after first-line therapy in routine German outpatient practice. Most patients received a trastuzumab-based regimen, frequently with pertuzumab and a taxane, consistent with national and international treatment standards. Endocrine therapy was often added in hormone receptor–positive cases. The findings confirm that long progression-free intervals are reproducible in everyday clinical care and largely mirror results reported from clinical trials. No unexpected treatment patterns were identified. New therapeutic options, including ADCs, must measure up against this established therapy.

The study further demonstrates the feasibility of retrospective documentation within the BNGO network for evaluating long-term outcomes in real-world settings.

References

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