NON-INTERVENTIONAL STUDY REPORT ABSTRACT

Title: Demographics and treatment patterns of Turkish female HR (+) HER2 (-) mBC patients in real life setting

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Keywords: HR (+) HER2 (-) breast cancer patients, retrospective study, treatment patterns, real-life data, observational.

Rationale and background: The age-standardized incidence rate of breast cancer among women is 47.7 /100,000 according to the national cancer statistics in Turkey. Hormone receptor (HR) and human epidermal growth factor receptor (HER2) status are the key points in the management of BC. HR+/HER2-, associated with improved survival compared with other subtypes in metastatic patients, is the most common molecular subtype of BC. Moreover, demographic characteristics are associated with treatment choices and patient outcomes.

Current treatment for (HR+/HER2-) advanced (locally or metastatic) BC include endocrine therapy or anti-estrogen aimed at increasing overall survival, delaying disease progression, and improving or maintaining the quality of life

Research question and objectives: To describe demographics, clinical and disease characteristics and treatment patterns of HR (+) HER2 (-) locally advanced and mBC women treated in routine practice setting in Turkey.

Primary objective is determining chemotherapy and endocrine therapy rates for HR (+) HER2 (-) mBC patients. Secondary objectives are to evaluate response to treatments used in routine clinical practice in mBC patients in Turkey, demographics, treatment pattern, baseline BC characteristics, clinical characteristics and reasons for switching to another therapy and/or discontinue to treatment in follow-up period of treated HR (+) HER2 (-) mBC patients.

Study design: This study was designed as a retrospective, multicenter, non-interventional, observational study.

Setting: Hospitals archives were screened for all patients who fulfilled eligibility criteria defined in the study protocol and who started the first line, second line and third line

treatment for mBC between the dates of 01 January 2019 – 31 December 2020 in the study centers.

Subjects and study size, including dropouts: A total of 823 patients were screened for the study, and 758 patients were found eligible for analysis.

Variables and data sources: Data source for this trial is the Case Report Forms including demographic information, family and medical history, treatment pattern, responses to treatments, survival status, baseline BC characteristics, clinical characteristics and reasons for switching to another therapy and/or discontinue to treatment in follow-up period filled by the investigators.

Results: 758 (median age 56 years) out of 823 women screened were included in the analyses. The median follow-up duration was 12.0 12.2 and 19.3 months for the 1st, 2nd, 3rd lines of treatment. Metastatic disease was present in 57% at diagnosis, most commonly in bones (71%), distant lymph nodes (24%), and lungs (19%). The most common pathology was invasive ductal carcinoma (67%). CDK4/6 inhibitors (CDK4/6i) plus endocrine therapy (ET) rates before and after May 2020, the date of reimbursement in Turkey, were 14% vs. 71% in the 1st line, 14% vs. 61% in the 2nd line, and 15% vs. 56% in the 3rd line. Meanwhile, ET as monotherapy rates decreased from 37% to 8%, 43% to 11%, and 29% to 5%, whereas chemotherapy rates decreased from 49% to 21%, 44% to 28%, and 57% to 39% in 1st to 3rd lines of treatment, respectively. The median progression-free survival (PFS) increased from 10 months before May 2020 to 17.5+ months after May 2020 for 1st line treatment. Dose reduction during CDK4/6i+ET was 5.3%, 9.4%, and 6.6% in the treatment lines, and the most frequent toxicity leading to dose reduction was neutropenia. The best response rate assessments for CDK4/6i+ET showed an objective response rate of 62.7%, 57.5%, and 63.9% and a disease control rate of 71.3%; 63.2%, and 65.6% in the 1st, 2nd and 3rd lines of treatment. Moreover, overall ORR independent of treatment lines for CDK4/6i+ET was found as 61.1%.

Discussion: The results showed the current treatment preferences and treatment efficiencies of a large sample of HR+/HER2- mBC patients in real-life in Turkey. Additionally, epidemiological characteristics identified will serve as a basis for detecting the changes in patient characteristics over time and determining the best candidates for specific treatments.

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