Features of HER2+ metastatic patients pts) from a prospective registry of Advanced Breast Cancer (ABC), GEACIM/2014-3 (RegistEM)

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INTRODUCTION

Breast Cancer (BC) is the most frequent cancer diagnosed in women. Several BC subtypes have been described according to immunohistochemical (IHC) or in situ hybridization (ISH) definition (1). Advanced (A) BC continues being an incurable disease, with a median survival of 3 years and a 5-year survival of 25% (9). Its management is complex and the involvement of all appropriate professionals in a multidisciplinary team is essential.

The RegistEM study is a non-interventional study that is providing prospective data from around 1,900 ABC pts. diagnosed with advanced disease between 01/Jan/2016 and 31/Dec/2019. After recurrence or at 14th diagnosis, all the Spanish sites representative of the national territory and whose investigators are GEACIM members (ClinicalTrials.gov Identifier: NCT0219882).

OBJECTIVE

In this exploratory analysis (cut-off date 10/May/2021, database is ongoing), we describe the features of 279 pts. with HER2+ tumors at any time of their ABC diagnosis. This subgroup has been evaluated because of the interest from a clinical perspective.

MATERIALS AND METHODS

This study is a prospective, multicenter, non-interventional, observational study designed to develop a Spanish registry in Unresectable Locally Advance Breast Cancer (ULABC) and Metastatic Breast Cancer (MBC) pts. For this subset of pts, HER2 positivity was defined by immunohistochemistry (IHC) > 3+ or IHC 2+ in situ hybridization [ISH]+, according to the valid American Society of Clinical Oncology/College of American Pathologists guideline.

INCLUSION CRITERIA:

• Patients (females or males) diagnosed with ULABC or MBC (either after a disease recurrence or as a first diagnosis) from January 2016 to December 2019.
• Patients who died are allowed to be included.
• Patients who are able and willing to provide written informed consent.

Age ≥ 18 years.

Access to medical records and all data related to disease management.

STATISTICAL CONSIDERATIONS:

This study is estimated to recruit 1,867 patients [1,305 (70%) Luminal, 336 (18%) HER2+ and 226 (12%) TN, based on the expected distribution of BC subtypes] in 38 Spanish sites throughout the country.

The analyses will be exploratory and primarily make use of descriptive statistical methods (i.e. number, mean, median, standard deviation and range).

Multivariate Cox proportional hazard models were constructed with variables that were either continuous or categorical and were statistically significant in the univariate analysis. In order to avoid overfitting, the number of variables that were included in the model was limited by the number of patients. The models were checked for their assumptions and for the consistency of the results.

RESULTS

Table 1. Characteristics of HER2+ ABC by HR status and stage at diagnosis.

Table 2. Other relevant data according to HR status and type of ABC.

Table 3. Overall Survival by RH status.

CONCLUSIONS

• In this cohort of HER2+ pts. de novo ABC was presented in 50% of cases.
• de novo ABC was associated with better OS compared to recurrent ABC. Younger age was also associated with better OS.
• HR status and menopausal status at ABC diagnosis were not prognostic factors for OS.

REFERENCES


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