TOPIC: Health Policy & Regulatory - **DISEASE:** Oncology

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Use of Administrative Databases to Support Disease Registries in Oncology: A Model in the Setting of Metastatic Breast Cancer in Italy

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BACKGROUND AND OBJECTIVES

Recent evidence published in national and international literature shows how data collected in administrative databases could be used for cancer research purposes to supplement and support information from pathology registries.

OBJECTIVES: This analysis presents a model of implementation of this goal in breast cancer (BC) setting aimed at estimating and describing the epidemiology, distribution of molecular profiles, stage of disease, treatment patterns and the related outcomes in the real clinical practice.

METHODOLOGY

DATA SOURCE AND PATIENTS

- The analysis was conducted using the administrative flows of Italian entities of the project STREAM (***S**upporting with **T**he **R**eal-world **E**vidence the **A**ssessment of **M**edicines and Health-Technology*) with data available from 2009 to 2023 covering around 4 million women. Specifically, data were extracted to analyse the following parameters: stratification by BC subtype, presence of metastatic status, treatment patterns and disease progression.
- As described in **Figure 1**, the analysis was then focused on patients diagnosed with BC in metastatic status carrying the receptor subtype HR+/HER2- (**HR+/HER2- mBC)** included from January 2017 to March 2022.
- For HR+/HER2- patients identified between 2017 and March 2022, treatment patterns and disease progression (in terms of occurrence of a new metastasis or death) were investigated.

TIMEPOINTS OF THE ANALYSIS

Study period: from January 2009 to March 2023.
Inclusion period: from January 2017 to March 2022.
Index date: date of the first metastasis detection during the inclusion period.
Characterization period: all the available period before the index date, of at least 12 months of data availability.
Follow up period: all the available period after the index date, of at least 12 months of data availability.

DETAILED METHODOLOGY FOR IDENTIFYING THE STUDY POPULATION: PATIENTS WITH DIAGNOSIS OF HR+/HER2- MBC

- The **diagnosis of BC** was identified by the flow of hospitalizations (by the presence of primary or secondary hospital discharge diagnosis with the ICD-9-CM codes: 193-233.0-238.3) and by pharmaceutical database through the presence of drugs indicated for BC.
- **Receptor subtype** identification was proxied by the presence/absence of drugs tracing HR and HER2 status.
- **Metastases** were identified through the flow of hospitalizations (by the presence of primary or secondary hospital discharge diagnosis with the ICD-9-CM codes: 196-198) and by the presence of drugs indicated for metastatic status (mBC).

Figure 1. Detailed methodology for the selection of patients in analysis.

RESULTS

1. EPIDEMIOLOGY

- HR+/HER2- mBC subtype was found in 70-74% of mBC patients identified, consistent with literature (66-75%).[1-4]
- The estimated prevalence in 2021 was 115/100,000 women (**Figure 2**).
- Even in the absence of direct comparisons at national and international level, these findings appear to be consistent with published scientific evidence. Starting with Globocan data,[5] that reported a prevalence of BC of 719/100,000 women in Italy during year 2020, considering the frequency of 70-74% for HR+/HER2- and that the metastatic form occurs in 8-30% of the cases, the epidemiological range can be expected to range between 42 and 160 x 100,000 women.

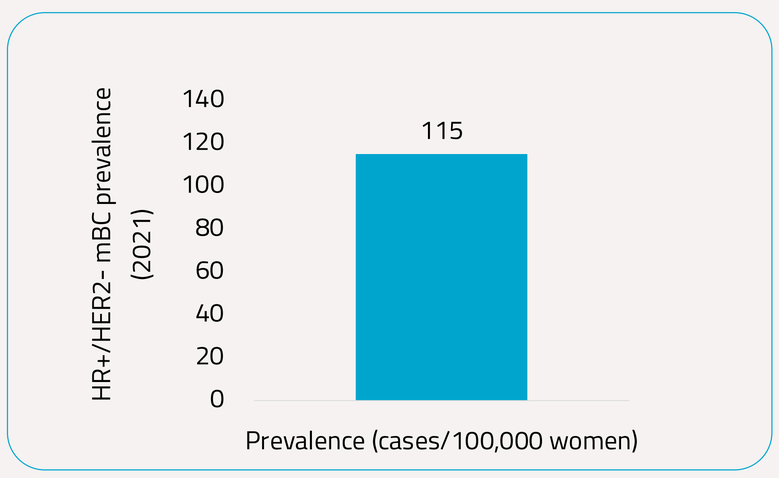

Figure 2. Estimated prevalence of HR+/HER2- mBC in the study population (year 2021).

2. TREATMENT PATTERNS

Among patients with at least one first-line metastatic therapy, 61% underwent second-line, 37% third-line therapy during the entire available follow-up (**Figure 3**).

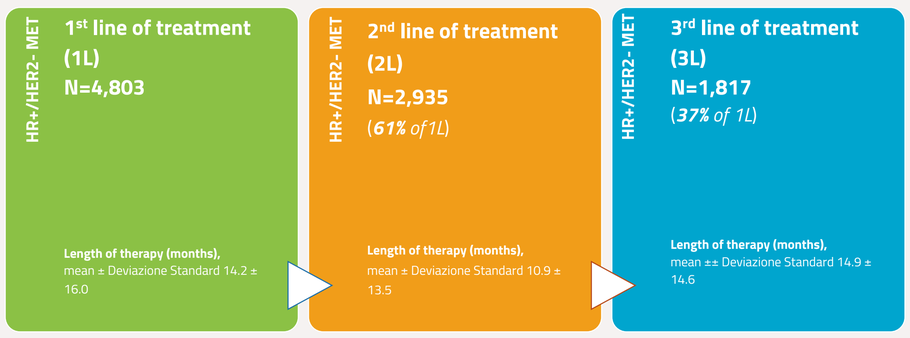

Figure 3. Details of treatment patterns in HR+/HER2- mBC patients.

3. DISEASE PROGRESSION

Disease progression was observed in 35% of the cases, on average (± SD) after 11.9 ± 13.2 months from metastasis detection (**Figure 4**).

Time to progression was defined as time (in months) from index date (date of the first metastasis) to the date of a subsequent metastasis different from the first at index date or the date of death.

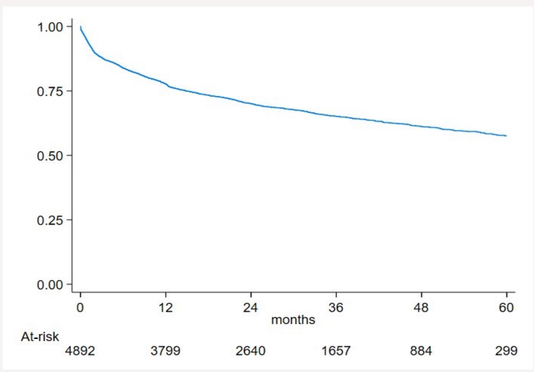

Figure 4. Progression free survival (PFS) in HR+/HER2- mBC patients.

MEDIAN SURVIVAL TIME, MONTHS			
	N	Median	95% CI
HR+/HER2- mBC	4,892	Not reached	[.-.]

NUMBER OF EVENTS				
	Censored	%	Progressed	%
HR+/HER2- mBC	3,185	65.1	1,707	34.9

CONCLUSIONS

This evidence generated in BC setting shows how administrative databases can be used to estimate the epidemiology and describe real-life clinical practice in oncology area, to support the information of pathology registries.

References

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