

## HR+/HER2- METASTATIC BREAST CANCER IN A LARGE ITALIAN DATABASE: INCIDENCE, PRESCRIPTION PATTERNS, DISEASE PROGRESSION AND DIRECT COSTS

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**Introduction:** Breast cancer is the second incident neoplasm and the second leading cause of cancer death worldwide, accounting for the highest healthcare costs in European countries. The epidemiology knowledge of different breast cancer types is crucial for planning and funding effective health services. This holds particularly for metastatic breast cancer (MBC) where information on its epidemiology are scarce. The aim of this study was to estimate the burden of HR+/HER2- metastatic breast cancer (MBC) in Italy, in terms of incidence, prescription patterns, healthcare resource utilisation and costs for the National Health System (NHS).

**Methods:** A cohort study based on healthcare administrative data (Fondazione ReS database), covering >10 millions of Italians, was performed. Incident cases of HR+/HER2- MBC were identified among adult women, at 2013. A woman was defined affected by MBC if she was hospitalized with concomitant diagnosis of "Malignant neoplasm of female breast" and "Secondary and malignant neoplasms". Incident cases were identified by excluding women responding to these criteria in the previous year. The cohort was followed-up for 24 months to describe healthcare utilisation and integrated costs (pharmaceuticals, hospitalisations and outpatients visits and services) paid by NHS. Prescription patterns were described in terms of first-line choice (active substance, monotherapy or combination therapy) and therapeutic changes (switches, drug addition or removal). Specific changes in drug therapy were used as proxies of disease progression. A survival analysis was performed to estimate the time from diagnosis to first disease progression.

**Results:** Out of a population of 5,174,723 adult women, 355 new cases of HR+/HER2- MBC were selected, with an incidence of 6.9 per 100,000. These women generated an average cost of €3,888 for the hospitalization required to entry in the cohort. During the first follow-up year, they generated an average cost of €7,543, whereas €4,834 in the second year. The 85.9% of the cohort received a monotherapy, whereas the remaining 14.1% a combination therapy. The most commonly used monotherapy was nonsteroidal aromatase inhibitors (45.9%), while the most prescribed combination therapy was tamoxifen + luteinizing hormone releasing hormone analogues (6.2%). Therapeutic changes occurred in 45.4% of the cohort, especially from chemotherapy to nonsteroidal aromatase inhibitors, after on average 276.8 days from the first treatment. Disease progression was identified in 22.5% of patients and it occurred after a mean of  $13 \pm 6$  months from diagnosis.

**Conclusions:** The study provided a detailed picture of HR+/HER2- MBC. Real-world data were used to describe the current management of this type of breast cancer and related direct costs paid by NHS. These findings could be helpful in health technology assessment and expenditure forecasts of future therapeutic strategies for HR+/HER2- MBC, particularly in the field of "precision medicine" or "personalized medicine".