

A European, Observational Study of Endocrine Therapy Administration in Patients With an Initial Diagnosis of Hormone Receptor-Positive Advanced Breast Cancer

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Abstract

In this observational study we estimated the proportion of postmenopausal breast cancer patients initially diagnosed with hormone receptor (HR)-positive locally advanced or metastatic breast cancer (LA/MBC), using data from 6 European cancer registries (n = 244,268 with known HR status and disease stage). Approximately 19,002 patients (7.8%) received an initial diagnosis of HR-positive LA/MBC; 74.5% (n = 14,157) of these received subsequent endocrine therapy as per guideline recommendations.

Background: Despite guideline recommendations, reports suggest that a proportion of patients with hormone receptor (HR)-positive locally advanced or metastatic breast cancer (LA/MBC) might not receive endocrine therapy. The aims of this study were to estimate the proportion of postmenopausal patients with an initial (primary) diagnosis of HR-positive LA/MBC in Europe, and to assess the administration of endocrine treatment in these patients.

Materials and Methods: Fourteen national and regional cancer registries across Europe were invited to participate in this observational study. Six registries each provided anonymized clinical information on > 5000 postmenopausal women with breast cancer diagnosed between January 2000 and December 2014, including age at diagnosis, estrogen and/or progesterone receptor status, disease stage, and receipt of endocrine therapy. The proportion of patients with an initial diagnosis of HR-positive LA/MBC and, of these, the proportion who received endocrine therapy, was calculated. **Results:** Registries from Belgium, England, Ireland, Norway, The Netherlands, and Munich, Germany provided data. In total, 316,680 postmenopausal women were diagnosed with breast cancer, including 244,268 with known HR status and disease stage. Of these patients, 19,002 (7.8%) had a primary diagnosis of HR-positive LA/MBC. This proportion ranged from 5.4% (N = 4484) in England to 12.7% (N = 4085) in Germany. Most of these patients (n = 14,157; 74.5%) received endocrine treatment, ranging from 55.5% (n = 445) in

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Norway to 88.1% (n = 443) in Belgium. **Conclusion:** These results indicate that a sizeable proportion of postmenopausal patients in Europe received a primary diagnosis of HR-positive LA/MBC, and that almost three-quarters received subsequent endocrine therapy as per guideline recommendations.

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Introduction

Breast cancer is one of the most prevalent cancers among women,¹ and most breast cancers are classified as hormone receptor (HR)-positive at diagnosis.² Endocrine therapy is the current standard treatment for patients with HR-positive breast cancer, in the adjuvant setting as well as for advanced disease, in the absence of rapidly progressive disease or proven endocrine resistance.³⁻⁵ Therefore, only a small proportion of patients with locally advanced (LA) or metastatic breast cancer (MBC) might be expected to be endocrine therapy-naïve. This patient subgroup might comprise patients who received an initial (primary) diagnosis of HR-positive LA/MBC, and patients with recurrence or metastasis from an early stage breast cancer who did not receive endocrine therapy for their previous disease. There are limited data reporting the prevalence of these patient subgroups.

Studies of small retrospective databases have reported that of all patients with known HR status, approximately 13% to 17% had a primary diagnosis of HR-positive advanced disease (LA/MBC).⁶⁻⁸ However, these studies did not assess subsequent therapy in this patient group, and, to our knowledge, a comprehensive evaluation of the size of this patient population has not been performed.

The aims of this study were to ascertain the proportion of postmenopausal women with HR-positive LA/MBC at primary diagnosis, and to calculate the proportion of these patients who received endocrine therapy.

Materials and Methods

Study Population

This was an observational, retrospective study conducted by the European Registration of Cancer Care collaboration, which recruited patients from national and regional cancer registries across Europe. Participating registries provided anonymized data on postmenopausal women diagnosed with breast cancer, and only registries that provided data on > 5000 patients were included in the analysis.

Patients who met the following inclusion criteria were eligible for inclusion in the study: female sex, postmenopausal (55 years of age or older), and diagnosed with invasive breast cancer according to the *International Classification of Diseases for Oncology* (third edition)⁹ breast cancer criteria between January 2000 and December 2014. The population-based cohort included all patients fulfilling the inclusion criteria. For this type of study, ethical approval and informed consent were not required.

Data Collection

Anonymized data were collated from the cancer registries, which employ trained registrars to collect data from patient hospital files

after notification by pathology laboratories, or from other sources such as radiation facilities and hospital inpatient databases. Most registries recorded the first line of treatment prescribed within a year of diagnosis.

Patient clinical information requested included: date of diagnosis, age of patient, and tumor, node, metastasis [TNM] stage of tumor at diagnosis (clinical stage) and pathological stage. LA breast cancer was defined as TNM stage IIIb or IIIc (according to the *TNM Classification of Malignant Tumours*, sixth and seventh editions^{10,11}); MBC was defined as TNM stage IV. Estrogen receptor (ER) and progesterone receptor (PR) status (positive, negative, or unknown) was obtained, along with information on subsequent endocrine therapy (yes or no). HR-positive status was defined as having pathologically confirmed ER-positive and/or PR-positive breast cancer. Patients with known HR status were selected for inclusion in further analyses. Missing data (stage and HR status) for patients were classified as unknown; these patients were initially included in the cohort.

Data Analysis

Using the pooled as well as country-specific data, the proportion of patients with HR-positive LA/MBC at primary diagnosis was calculated, as well as the proportion of patients who received subsequent endocrine treatment. Descriptive results are presented; no formal statistical analyses were performed, because raw data were not provided by all registries.

Results

Patient Population

Fourteen cancer registries in Europe were invited to participate in the study. Five national registries (Belgium, England, Ireland, Norway, and The Netherlands) and 1 regional registry (Munich, Germany), who each contributed data from > 5000 patients, participated in this study. Registries that did not participate either did not respond to the invitation, or did not record the relevant data in the format required.

Data received (January 2000 to December 2014) were analyzed in November 2016. Data from Belgium were included for 2008 only, because this was the only year for which HR status was available. At the time of this analysis, not all diagnosed patients in England for 2014—or in Ireland for 2013 and 2014—were registered in the cohort.

In total, data for 316,680 postmenopausal women with breast cancer were collected (Table 1). Median patient age at diagnosis ranged across countries from 67.0 years in Ireland to 69.0 years in England and Belgium.

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