JOURNAL OF GERIATRIC ONCOLOGY 7 (2016) 154–157

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Editorial

Poor persistence with hormonal therapy among women with breast cancer

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(Editorial accompanies Jacob et al. "Age-related differences in persistence in women with breast cancer treated with tamoxifen or aromatase inhibitors in Germany")

ARTICLE INFO

Article history:
Received 10 April 2016
Accepted 10 April 2016
Available online 28 April 2016

Tamoxifen and aromatase inhibitors are essential medications for patients with non-metastatic and metastatic hormone-receptor positive (HR+) breast cancer (BC). In early stage non-metastatic BC, five-years of tamoxifen therapy reduces the 15-year risk of a BC recurrence by 40% and BC mortality by 30%.[1] In postmenopausal women with early stage non-metastatic BC, aromatase inhibitors are even more efficacious than tamoxifen.[2] In the metastatic setting, tamoxifen and aromatase inhibitors are the backbone for treating HR+ BC and have been shown to both prolong life and the quality of life.[3] These drugs are among the most efficacious cancer medications. Despite their importance, lack of compliance is a common issue. Like many oral medications for chronic conditions, patients may fail to initiate therapy (non-initiation), take the drug as prescribed (nonadherence defined as a medication possession ratio or MPR <80%) or may stop taking the medication entirely before completing a full course of treatment (nonpersistence or discontinuation).

In the current issue "Age-related differences in persistence in women with breast cancer treated with tamoxifen or aromatase inhibitors in Germany" by Jacob et al. characterizes the persistence of patients with non-metastatic and metastatic BC to these anti-estrogen therapies at 5 years after the start of therapy with a focus on age-differences. By combining patients with curable non-metastatic BC and those with metastatic BC (MBC), their population was heterogeneous. Among women with MBC, there are many clinical scenarios where cessation of hormonal therapy (HT) may be indicated. For example, patients with MBC may have disease progression on HT requiring treatment with either chemotherapy or targeted therapy, sometimes in a clinical trial setting. Often in these situations, HT is stopped. The study used claims data from a subset of clinical practices in Germany including both general and gynecological practices. A portion of patients who may have initiated their HT in these practices may have transferred their oncology care elsewhere and as a result were captured in this dataset as patients who discontinued their tamoxifen or AI therapy at 5 years. Importantly, younger women may be more likely to change care than older women and this could have affected the study's findings.

Despite these limitations, this study is noteworthy for many reasons. It is the first of its kind to investigate this issue in a large cohort of German women with BC and it focused on understanding persistence with HT among older women.[4] One of the first studies investigating HT adherence in a BC population examined women diagnosed between 1990 and 1996 and found that although 77% of patients filled prescriptions to achieve a

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http://dx.doi.org/10.1016/j.jgo.2016.04.002

Table 1 – Landmark studies assessing adherence and/or persistence to tamoxifen (Tam) and aromatase inhibitor (AI) therapy.[5–8,14,20,21].
Abbreviations: BC = breast cancer, HR + =hormone-receptor positive, and f/u = follow-up.

Study	Years	Location	Age	Inclusion criteria	Exclusion criteria	N	Metric/primary endpoint	Outcome
Owusu et al.	1990–1994	Delivery systems within the Cancer Research Network, US	≥65	Stage I–IIB ER+ or indeterminant receptor BC with long-term f/u	Died during study period	961	Discontinued therapy if 60 days elapsed from prior prescription without a refill over 5 years.	49% discontinued therapy.
Partridge et al.	1990–1996	US, New Jersey	≥18	Primary breast cancer and provided a prescription for Tam	Died during study period or had metastatic disease	2378	Adherence to therapy as MPR ≥80% at year 1 and 4.	77% were adherent at year 1. 50% were adherent at year 4.
Hershman et al.	1996–2007	US, Kaiser Permanente of California	All ages	HR+ Stage I-III BC who filled one prescription for Tam, AI or both within 1 year of diagnosis	–	8769	Discontinued therapy if 180 days elapsed from prior prescription without a refill over 4.5 years. Adherence was assessed as MPR ≥80%.	32% discontinued therapy. Of those who continued on therapy, 72% were fully adherent.
Huiart et al.	1998–2008	UK	All ages	BC patients who received a prescription for Tam or an AI within 1 year of diagnosis	Metastatic at diagnosis or became metastatic within 6 months	13,479	Adherence to therapy as MPR ≥80% at year 5.	29.8% were adherent at 5 years: 31% of Tam users and 18.9% of AI users.
Partridge et al.	2002–2004	US, three commerical datasets	All ages	Early stage BC and initiated an AI	–	12,391	Adherence to therapy as MPR ≥80% at year 1 and 3.	78–86% were adherent at year 1. 62–79% were adherent at year 3.
Riley et al.	2003–2005 (diagnosed with BC) Outcomes measured between 5/2006 and 12/2007.	US SEER-Medicare data	≥65	Invasive HR+ BC who underwent mastectomy or lumpectomy	Unknown stage or spent >10% of time in a hospital or skilled nursing facility.	15,542 were in the initiation analysis. 9446 were in the adherence analysis.	Percent who initiated HT. Adherence to therapy as MPR ≥80% at ~5 years of follow-up.	22% initiated treatment with Tam, 52% with an AI and 26% neither. 20–30% were nonadherent to therapy.
Jacob et al.	2004–2013	Germany	≥18	Non-metastatic and metastatic BC who received a prescription for Tam or an AI	–	29,245	Discontinued therapy if 90 days elapsed from prior prescription without a refill at 5 years.	88.8% of women <70 and 82% of women ≥70 discontinued therapy by 5 years.