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Original Research

Influence of side-effects on early therapy persistence with letrozole in post-menopausal patients with early breast cancer: Results of the prospective EvAluate-TM study

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Side-effects;
Adverse events

Abstract ***Background:*** Endocrine treatment (ET) with an aromatase inhibitor (AI) is the treatment of choice in post-menopausal patients with hormone receptor–positive early breast cancer (EBC). However, adverse events (AEs) often lead to treatment discontinuation. This analysis aimed to identify side-effects that lead to patients failing to persist with letrozole treatment.

Patients and methods: Post-menopausal hormone receptor–positive EBC patients starting ET with letrozole were enroled in EvAluate-TM, a non-interventional study. Information regarding treatment compliance and persistence was gathered in months 6 and 12. Persistence was defined as the time from 30 d after the start to the end of treatment. The influence on persistence of musculoskeletal syndrome, menopausal disorder, sleep disorder and other AEs within the first 30 d was analysed using Cox regression analyses.

Results: Among 3887 patients analysed, the persistence rate after 12 months was >85%. In all, 568 patients (14.6%) discontinued the treatment, 358 of whom (63.0%) did so only because of side-effects. The main AEs influencing persistence were musculoskeletal symptoms (hazard ratio [HR] 2.55; 95% confidence interval [CI], 1.90–3.42), sleep disorders (HR 1.95; 95% CI, 1.41–2.70) and other AEs (HR 2.03; 95% CI, 1.51–2.73). Menopausal disorder was not associated with non-persistence (HR 1.17; 95% CI, 0.74–1.84).

Conclusions: These results suggest that side-effects of AIs such as musculoskeletal syndrome and sleep disorder lead to ET discontinuation within the first treatment year in significant numbers of EBC patients. Compliance programmes adapted for subgroups that are at risk for early non-persistence might help to ensure the recommended therapy duration.

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