Anastrozole is superior to tamoxifen as first-line therapy in hormone receptor positive advanced breast carcinoma

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BACKGROUND: Two randomized, double-blind trials have compared tamoxifen 20 mg daily and the selective, nonsteroidal aromatase inhibitor anastrozole 1 mg daily as first-line therapy for advanced breast carcinoma (ABC) in postmenopausal women. The trials were prospectively designed to allow for combined data analyses. METHODS: The combined study population included 1021 postmenopausal women (median age, 67 years [range, 30-92]) with ABC whose tumors were either estrogen and/or progesterone receptor positive or of unknown receptor status. Primary endpoints were time to progression (TTP), objective response, and tolerability. RESULTS: At a median duration of follow-up of 18.2 months, anastrozole was at least equivalent to tamoxifen in terms of median TTP (8.5 and 7.0 months, respectively; estimated hazard ratio [tamoxifen relative to anastrozole], 1.13 [lower 95% confidence level, 1.00]). In a retrospective subgroup analysis, anastrozole was superior to tamoxifen with respect to TTP (median values of 10.7 and 6.4 months for anastrozole and tamoxifen, respectively, two-sided P = 0.022) in patients with estrogen and/or progesterone receptor positive tumors (60% of combined trial population). In terms of objective response, 29.0% of anastrozole and 27.1% of tamoxifen patients achieved either a complete response (CR) or a partial response (PR). Clinical benefit (CR + PR + stabilization of ≥ 24 weeks) rates were 57.1% and 52.0% for anastrozole and tamoxifen, respectively. Both anastrozole and tamoxifen were well tolerated. Anastrozole led to significantly fewer venous thromboembolic (P = 0.043; not adjusted for multiple comparisons) events, and vaginal bleeding was reported in fewer patients treated with anastrozole than with tamoxifen. CONCLUSIONS: In postmenopausal women with hormonally sensitive ABC, anastrozole should be considered as the new standard first-line treatment.