Patient-reported outcomes with adjuvant exemestane versus tamoxifen in premenopausal women with early breast cancer undergoing ovarian suppression (TEXT and SOFT): a combined analysis of two phase 3 randomised trials


BACKGROUND
The combined efficacy analysis of the TEXT and SOFT trials showed a significant disease-free survival benefit with exemestane plus ovarian function suppression (OFS) compared with tamoxifen plus OFS. We present patient-reported outcomes from these trials.

METHODS
Between Nov 7, 2003, and April 7, 2011, 4717 premenopausal women with hormone-receptor positive breast cancer were enrolled in TEXT or SOFT to receive unmasked adjuvant treatment with 5 years of exemestane plus OFS or tamoxifen plus OFS. Gonadotropin-releasing hormone analogue triptorelin, bilateral oophorectomy, or bilateral ovarian irradiation were used to achieve OFS. Chemotherapy use was optional. Randomisation with permuted blocks was done with the International Breast Cancer Study Group's internet-based system and was stratified by chemotherapy use and status of lymph nodes. Patients completed a quality of life (QoL) form comprising several global and symptom indicators at baseline, every 6 months for 24 months, and then every year during years 3 to 6. Differences in the change of QoL from baseline between the two treatments were tested at 6 months, 24 months, and 60 months with mixed-models for repeated measures for each trial with and without chemotherapy and overall. The analysis was by intention to treat. At the time of analysis, the median follow-up was 5.7 years (IQR 3.7-6.9); treatment and follow-up of patients continue. The trials are registered with ClinicalTrials.gov, as NCT00066703 (TEXT) and NCT00066690 (SOFT).

FINDINGS
Patients on tamoxifen plus OFS were more affected by hot flushes and sweats over 5 years than were those on exemestane plus OFS, although these symptoms improved. Patients on exemestane plus OFS reported more vaginal dryness, greater loss of sexual interest, and difficulties becoming aroused than did patients on tamoxifen plus OFS; these differences persisted over time. An increase in bone or joint pain was more pronounced, particularly in the short term, in patients on exemestane plus OFS than patients on tamoxifen plus OFS. Changes in global QoL indicators from baseline were small and similar between treatments over the 5 years.

INTERPRETATION
Overall, from a QoL perspective, there is no strong indication to favour either exemestane plus OFS or tamoxifen plus OFS. The distinct effects of the two treatments on the burden of endocrine symptoms need to be addressed with patients individually.

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