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Title: Patient-reported endocrine symptoms, sexual functioning and quality of life (QoL) in the IBCSG SOFT trial: adjuvant treatment with tamoxifen (T) alone versus T plus ovarian function suppression (OFS) in premenopausal women with hormone receptor-positive (HR+) early breast cancer (BC)

Background: SOFT efficacy results reported at this SABCS show that T+OFS provides improved disease control compared with T for the cohort of patients (pts) who received prior chemotherapy (chemo), but relatively little is known about treatment-related endocrine symptoms, sexual function and QoL in premenopausal women receiving adjuvant T+OFS compared with T.

Methods: From Nov 2003 to Apr 2011, 1,722 premenopausal pts with HR+ BC were enrolled and included in the QoL analysis of the randomized phase III trial SOFT, to receive adjuvant treatment with 5 yrs T or T+OFS. A third group received exemestane+OFS and is not included in this report. SOFT enrolled two cohorts: pts who received no chemo, and those who received prior chemo with confirmed premenopausal estradiol levels within 8 mos of completing chemo. Pts completed a questionnaire consisting of global and symptom-specific indicators at baseline, every 6 mos for the first 24 mos, and annually yrs 3 to 6. Differences in change of QoL from baseline between the two treatments were tested at short-, intermediate-, and long-term (6, 24 and 60 mos post-randomization, respectively) for 13 symptoms and 4 global QoL indicators using mixed models with repeated measures, overall and by chemo stratum.

Results: Changes of global QoL indicators (mood, physical wellbeing) from baseline were small and similar between treatments over the whole observation period, but treatment differences were seen with respect to symptom-specific indicators, especially for patients in the no chemo cohort. Overall, pts on T+OFS were substantially more affected by hot flushes than pts on T alone at short- and intermediate-term (each p<.0001). The change of hot flushes from baseline improved for the T+OFS but not for the T alone group over the period of 60 mos. Pts on T+OFS reported more loss of sexual interest (p<.0001) and sleep problems (p<.0001) at short-term, and more vaginal dryness over the whole treatment period (each p<.01). Pts on T alone reported more vaginal discharge up to 60 mos (each p<.05), but only among those pts who did not receive prior chemo. Symptom-specific treatment differences (hot flushes, sleep problems, vaginal discharge) were less pronounced in pts who had received prior chemo. Although pts receiving no prior chemo had less improvement in coping and greater treatment burden with T+OFS vs. T (p<.05), no such treatment differences were seen for pts in the prior chemo cohort.

Conclusion: Global QoL (mood and physical wellbeing) did not differ between groups. Overall, pts receiving T+OFS experienced worse endocrine symptoms and sexual functioning than those receiving T alone during the first two years of treatment; most differences between treatments were no longer apparent thereafter. Differences between T+OFS and T with respect to impaired symptom-specific QoL, being burdened by treatment, and having delayed adaptation during the first two yrs of treatment were less pronounced for pts who received chemo prior to enrolling in SOFT, the cohort that benefited most from OFS in terms of disease control.

Authors:
1. Karin Ribi
2. Weixiu Luo
3. Jürg Bernhard
4. Prudence A. Francis
5. Meritxell Bellet
6. Harold J. Burstein
7. Lorenzo Pavesi
8. Vani Parmar
9. Carlo Tondini
10. Marilena Visini
11. Roberto Torres
12. Per Karlsson
13. Simon Spazzapan
14. Antoni Avella
15. Thomas Ruhstaller
16. Fabio Puglisi
17. Meredith M. Regan
18. Alan S. Coates
19. Richard D. Gelber
20. Gini F. Fleming