

A randomized double-blind placebo-controlled study of oral coenzyme Q10 to relieve self-reported cancer-treatment-related fatigue in newly diagnosed breast cancer patients.

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Abstract:

Background: Coenzyme Q10 (CoQ) is an antioxidant supplement with known cardioprotective effects and potential anticancer benefits. We performed a randomized, double-blind, placebo-controlled study of oral CoQ in female breast cancer patients to determine CoQ's effects on self-reported fatigue, depression and quality of life (QOL). **Methods:** Eligible women with newly diagnosed breast cancer and planned adjuvant chemotherapy were randomized to oral supplements of 300 mg CoQ or placebo, each combined with 300 IU Vitamin E, divided into three daily doses. Treatment was continued for 24 weeks. Participants were stratified by anthracycline (yes/no) and radiation therapy (yes/no). Blood tests, QOL measures, and serum CoQ and Vitamin E levels were obtained at baseline, 8, 16 and 24 weeks. Mixed effects models were used to assess treatment differences in outcomes over time. **Results:** Between 8/2004 and 3/2009, 236 women were enrolled. Treatment arms were well balanced with respect to age (range 28-85), PS (0, 1, 2) (91%, 8%, 4%), ethnicity (87% White/11%Black/2%Hispanic) and planned therapy (84% anthracycline; 61% RT). No serious adverse events were noted. At 24 weeks, there were no significant differences between the CoQ and placebo arms on the POMS-Fatigue (LS means 5.88 vs. 7.24, p=.27); FACIT-Fatigue (40.2 vs. 39.7, p=.77); FACT-B subscale (25.6 vs. 25.7, p=0.92); or CES-D (10.1 vs. 10.5, p=0.82). In the 86 pts with complete CoQ serum samples, baseline and 24 week CoQ levels in the CoQ and placebo arms were

0.72/1.98 and 0.77/0.82 $\mu\text{g/mL}$, respectively. In this subset, higher CoQ levels were modestly associated with less fatigue. **Conclusions:** Supplementation with conventional doses of CoQ led to sustained increases in serum CoQ levels, but did not result in improved self-reported fatigue or QOL after 24 weeks of treatment in women with breast cancer receiving adjuvant therapy. The modest association between higher CoQ levels and less fatigue in patients with complete assays suggests that further exploration of the relationship between CoQ dose and self-reported fatigue may be warranted. Supported by NIH/NCI/DCP grant 3 U10 CA081851.