

Self-reported compliance compared to biomarker levels of vitamin E in breast cancer patients participating in a CoQ10 clinical trial.

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Abstract:

Background: Participant compliance in clinical trials is crucial as noncompliance leads to underestimation of treatment effect and loss of statistical power. Compliance is frequently assessed using diaries and pill counts and less frequently using biomarker measurements. This report compares self-reported and serum biomarker measures of compliance in one clinical trial.

Methods: A randomized, double-blind, placebo-controlled trial of CoQ10 (CoQ) was conducted to assess the supplement's effect on fatigue. Women with newly diagnosed breast cancer who had planned adjuvant chemotherapy were randomized to receive oral supplements of either 300mg CoQ per day or placebo, each with 300 IU Vitamin E (Vit E) to support absorption of CoQ, split into three daily doses over 24 weeks. Patients completed pill diaries. Blood samples were drawn at baseline, 8, 16, and 24 weeks. Patients were categorized into quartiles according to reported compliance and changes in serum levels of VitE. Crosstabs and correlations were used to determine the concordance between the two measures. **Results:** Women (N=236) ages 28- 85 were enrolled between 8/2004 and 3/2009. 113 Patients had complete sets of serum Vit E. Mean baseline and 24 week Vit E levels increased from 14.2 to 23.3, respectively; 14% had increases less than 1 ug/mL. Self-reported compliance in this subset was 88% (range: 29%-

100%). Association between measures was weak ($r=.15$, $p=.12$); 7 participants in the lowest quartile of self-reported compliance were in the highest quartile of serum Vit E and 5 in the highest quartile of self-reported compliance were in the lowest quartile of Vit E. **Conclusions:** Self-reported compliance was not strongly related to patient's biomarker levels, supporting the notion that self-reported compliance is overestimated. The addition of biomarker methods to self-report may assist in improving interpretation of this and other intervention studies. Supported by NCI grant 3 U10 CA081851.