## Protective effects of Panax ginseng against doxorubicin-induced cardiac toxicity in patients with non-metastatic breast cancer: a randomized, double blind, placebo controlled clinical trial

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## Abstract

BACKGROUND: Anthracycline-based chemotherapy increases the risk of cardiotoxicity in breast cancer patients. This prospective study evaluated the beneficial role of ginseng supplementation in alleviating doxorubicin-induced cardiotoxicity besides declining left ventricular ejection fraction (LVEF) in breast cancer patients. METHODS: Thirty women with non-metastatic, HER-2 negative early breast cancer were enrolled into the study. Participants received ginseng (1 g/day) or placebo in conjugation with standard anticancer therapy. Echocardiographic measurements were assessed at baseline, after the final cycle of anthracycline therapy (4th cycle), and at six months of chemotherapy (8th cycle). High-sensitive cardiac troponin I (hs-cTnI) was assessed at baseline and after the 4th cycle. Cardiotoxicity was defined as a drop in LVEF of [?] 10% from baseline in patients whose LVEF was [?] 50%. RESULTS: A significant difference in LVEF changes were observed from baseline to the 4th cycle (-1.3  $\pm$  1.1% vs. -5.27  $\pm$  0.8%, p-value = 0.006) and from baseline to the 8th cycle (0.8  $\pm$  1.3% vs. -7.3  $\pm$  1.4%, p-value < 0.001) between ginseng and placebo groups, respectively. None of the patients in the ginseng group developed cardiotoxicity during the study period. In contrast, 1(6.7%, p-value = 0.5) and 5 (33.3%, p-value = 0.02) patients in the placebo group developed cardiotoxicity after the 4th and 8th cycles, respectively. No significant difference was found regarding hs-cTnI levels between the two groups. CONCLUSIONS: According to our results, prophylactic use of ginseng supplement may provide protection against doxorubicin-induced early cardiotoxicity as well as early decline in LVEF in breast cancer patients.

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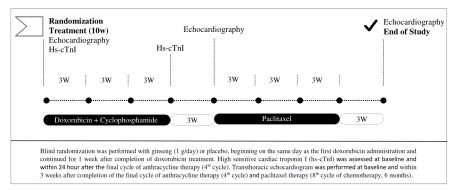


Figure 1 - Study Protocol

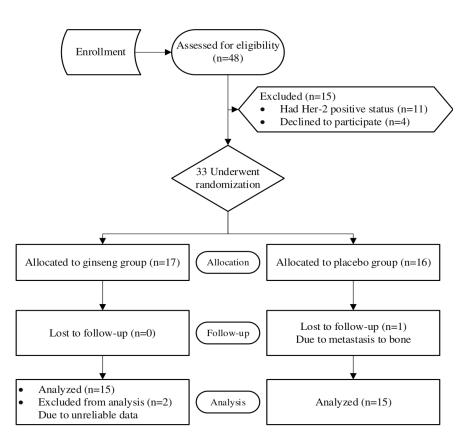


Figure 2 - CONSORT Flow Diagram

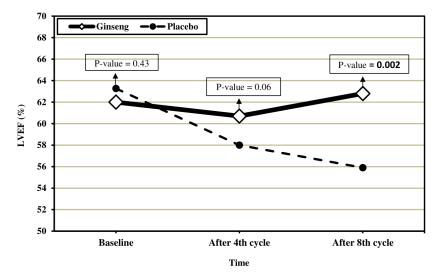


Figure 3 - Comparison of changes in mean left ventricular ejection fraction (LVEF) values between ginseng and placebo groups during six months follow-up

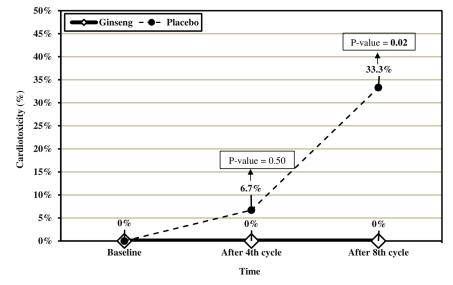


Figure 4 - Comparison of cardiotoxicity incidence between ginseng and placebo groups during six months follow- up