Randomized, double-blind and placebo-controlled study of the immunomodulatory effects of Lingzhi in children with cancers


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Background: Lingzhi (Ganoderma lucidum) is a traditional Chinese medicine which is widely used to 'strengthen immunity' among patients with cancers. However, there is no published randomized controlled trial on its efficacity and anti-oxidative. Methods: This randomized, double-blind, placebo-controlled, parallel-group clinical trial recruited cancer patients aged 2–18 years from Children's Cancer Centre of a university-affiliated teaching hospital. These patients were recruited either during maintenance (for leukemias) or within weeks following (for solid tumors) chemotherapy. Stratified by underlying cancers, they were randomized to receive 4–6 capsules daily of Lingzhi or matched placebo, which were manufactured by our Institute of Chinese Medicine according to GMP standard, for 6 months. The changes in subjects' lymphoproliferative responses to mitogens during study were compared between Lingzhi and placebo groups. Results: 29 patients were assigned to each of Lingzhi or placebo groups, with mean (SD) age being 8.9 (4.4) years and 9.6 (5.2) years respectively (P=0.553). Sixteen subjects in Lingzhi group and 17 subjects in placebo group suffered from leukemias, and others had solid tumors (P=0.791). The mean (95% CI) changes in stimulation indices (SI) of purified peripheral blood mononuclear cells (PBMC) to phytohemagglutinin (PHA) and pokeweed mitogen (PWM) were 364 (42–687) and 83 (44–121) for Lingzhi group and -134 (-580–311) and -1 (-56–54) for placebo (P=0.046 for PHA and 0.028 for PWM). The result for lymphoproliferative response to concanavalin A was marginally significant (P=0.074). None of the subjects had significant hematologic or biochemical derangement. Patients were followed for a median of 2.9 years (IQR 2.3–3.8 years), and 20 from Lingzhi group and 21 from placebo remained disease-free. Conclusions: A 6-month treatment with Lingzhi augments mitogen-induced lymphoproliferative responses in immunocompromized children with cancers. Funding: Hong Kong Children's Cancer Foundation Peter Nash Pediatric Oncology Research Grant. This trial is registered with FDA under clinical trial number NCT00575926.

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