

An open-label, randomized clinical trial to assess the immunomodulatory activity of a novel oligosaccharide compound in healthy adults

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ABSTRACT

Background: Rice Bran Arabinoxylan Compound (RBAC) is a nutritional supplement produced by enzymatic hydrolysis of hemicellulose B derived from rice bran. Several *in vitro* studies and clinical reports have shown RBAC to possess promising immunomodulating effects, specifically with respect to natural killer cell and cytokine activity. The concept of a true immunomodulator is an agent possessing a broad range of activity dependent upon the existing state of health and immunity in the individual host. The present study investigated the immunomodulatory effect of RBAC in a healthy adult human population over 60 days by assessing changes in natural killer cell cytotoxicity (NKCC) and cytokines and growth factors. Subjects participated in a two-group, randomized intervention, where one group (n=10) consumed 1 gram/day and the other (n=10) consumed 3 gram/day. Safety and tolerability of RBAC were assessed with total bilirubin, total protein, creatinine, and liver function tests.

Results: We found that both groups had similar responses for NKCC, cytokines, and growth factors. The NKCC peaked at 1 week, whereas interferon- γ , tumor necrosis factor- α , interleukins-1 α , -1 β , -8, and -10, and epidermal growth factor peaked at 30 days. All subjects tolerated the supplement without any adverse reactions.

Conclusions: Our results showed transient, bi-directional, immune marker effects consistent with true, multifactorial immunomodulation rather than simply immunostimulation or immunosuppression. Given our findings, the immunomodulatory activity of RBAC merits study

in conditions where the immune system is functionally compromised (e.g., otherwise-healthy smokers and HIV/AIDS or cancer patients). RBAC may not only help to destroy tumor cells and viruses directly, but also increase the activity of immune cells, thereby optimizing the immune system, especially NKCC, which can increase the chance and speed of host recovery.

Keywords: Rice bran, arabinoxylan compound, activity of immune cells, immunomodulation, HIV/AIDS, and cancer