

Oxidant/Antioxidant Modulating Activity of Bio-Normalizer (Fermented Product of *Carica Papaya*) and its Clinical Efficacy

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It has long been established that an oxidant/antioxidant imbalance in an organism caused numerous damages to biomolecules and cellular structures that resulted in the development of a variety of pathologic states. Nutritional approach could be assumed as a remedy for "free radical" human pathologies. To combat them, the functional food should be a well-balanced complex mixture of compounds capable providing the optimal adaptive response to any changes in oxidant/antioxidant balance. Bio-Normalizer (BN) is a functional food produced by proprietary yeast (Sun-O strain) and bacterial fermentation of *Carica papaya* and some tropical herbs (Sun-O Internat., Gifu, Japan). BN consists of oligo- and monosaccharides, oligopeptides and aminoacids, SH-containing compounds, retinoic acid, and so on. In a number of experimental studies BN was found to be a free radical scavenger, inhibitor of lipid peroxidation, chelator of transition metals, and suppressor of free radical-associated pathologies in animals. Since BN was approved as a healthy food additive in Russia and Ukraine, we have performed several clinical trials attempting to show a correlation between the BN beneficial clinical effects and its capacity to modulate oxidant/antioxidant balance in the body. The vast majority of clinical studies were accounted as double blind, randomized and case-controlled ones, in which either BN or placebo were given to patients in dosage 3-9 g a day daily for 4 weeks. It was shown that along with entire safety and remarkable clinical efficiency BN suppressed significantly lipid peroxidation in both blood plasma and erythrocyte membranes of patients with virus and toxic hepatitis and insulin-dependent diabetes mellitus (IDDM) as well as in patients subjected to therapeutic or accidental irradiation. The short-term BN therapeutic course resulted in normalization of GSH levels in irradiated patients. It led also to induction of catalase and MnSOD in circulating white blood cells of patients suffered from tumors, hepatitis and IDDM. We found out a dramatic difference in nitric oxide (NO) production by granulocytes of healthy donors, patients with IDDM and insulin-independent diabetes mellitus (IIDM) (11.2 ± 1.3 ; 2.4 ± 0.7 and 20.7 ± 1.4 nmol/ 10^6 cells/ hour, respectively). BN administration induced critically suppressed NO-synthase in granulocytes of IDDM patients that in turn led to normalization of NO production (9.8 ± 0.9). The clinical trial on BN safety and clinical efficacy in patients with chronic lead intoxication showed that BN induced the lead release from bone storage, improvement of hemoglobin metabolism, and induction of metallothionein in white blood cells.

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PROGRAM & ABSTRACTS

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