

# Determining the Role of Food/Environmental Sensitivities in Reducing Risk Factors in Patients with NIDDM

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## **Abstract**

The role of functional lymphocyte response assays in predicting patient-specific food/environmental sensitivities in the pathogenesis and treatment of Non-Insulin Dependent Diabetes Mellitus (NIDDM)/Type II Diabetes has not been studied despite accumulating evidence that the condition is autoimmune and often exists concurrently with other autoimmune diseases in a given individual. Further, early exposure to cow's milk antigenic digestive remnants during the maturing process of the neonatal intestinal tract is linked to a higher risk of Insulin Dependent Diabetes Mellitus (IDDM)/Type I Diabetes in adulthood. The role of cow's milk and other immunogenic digestive remnants in individuals with NIDDM was studied for the first time in this pilot research study. The research protocol assigned subjects to one of two groups (n = 13 in each): Treatment [T] (*i.e.*, a dairy-free alkaline diet that substitutes for items found reactive by LRA by ELISA/ACT LRA<sup>®</sup> plus supplementation with metabolic intermediates, cofactors, and antioxidants to enhance repair competence) or Control [C] (*i.e.*, their usual lifestyle and standard diabetic diet). These programs were followed for six months to determine whether the T group would show improvement in specific objective risk factors [e.g., 2- hour post-prandial glucose, insulin, and glycohemoglobin as hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>)] thought to predict clinical outcomes in NIDDM. Both groups met biweekly for support and education. Table 1 presents the general characteristics of the two groups. The groups are not significantly different from each other.

**Table 1: Characteristics of Patients with Type II Diabetes**

<b>Characteristics</b>	<b>Treatment = T (n = 13)</b>	<b>Control = C (n = 13)</b>
Age (years)	55.0 ± 2.1	58.7 ± 2.5
Gender (# Women/# Men)	6/7	9/4
Height (inches)	67.5 ± 1.2	64.4 ± 1.0
Weight (lbs)	204 ± 11.6	190 ± 12.8

**Table 1: Characteristics of Patients with Type II Diabetes**

<b>Characteristics</b>	<b>Treatment = T (n = 13)</b>	<b>Control = C (n = 13)</b>
Duration of Diabetes (years)	2.6 ± 0.3	2.7 ± 0.4
Number of Sensitivities (of 57)	6.0 ± 0.6	4.9 ± 0.3
Most Common Health Concern	High Blood Cholesterol	Arthritis
Most Common Dietary Concern	Appetite Regulation	Appetite Regulation

The most common immune reactants were cow dairy products (8/26), followed by MSG (6/26), saccharine (6/26), and organophosphate cholinesterase inhibiting biocides (6/26).

Blood glucose measurements, obtained in the fasting state and two hours after a 50 gm glucose challenge, are presented in Figure 1. Subjects who had been in the T group showed a progressive ↓ in both the fasting and 2-hour challenge glucose levels. No such ↓ was noted in C. In addition to glucose, concurrent levels of HbA<sub>1c</sub> were determined. A ↓ in the HbA<sub>1c</sub> glycosylated hemoglobin was noted among T (Figure 2), but not among C subjects. Recent studies indicate that the use of fasting plasma glucose and HbA<sub>1c</sub> may be the most clinically relevant methods of predicting patient clinical outcome or treatment-requirements: patients with a HbA<sub>1c</sub> value < 7% should be treated with diet and exercise whereas those with values ≥ 7% should be treated more aggressively. Interestingly, whereas 9 and 8 subjects in the C and T groups, respectively, began with HbA<sub>1c</sub> values > 7%, only 5 T subjects had values ≥ 7% after six months whereas 9 C still had values at or above that value. This ↓ in HbA<sub>1c</sub> indicates clinical improvement for at least one-third of the T group.

In summary, six months of substituting other foods in place of dairy products and various immunoreactive substances resulted in clinical improvement in blood glucose control. Such changes were not found in the T group with nutrition education alone. The LRA by ELISA/ACT program may prove to be a low-cost, effective way to manage persons with NIDDM.

### ELISA/ACT Program Controls

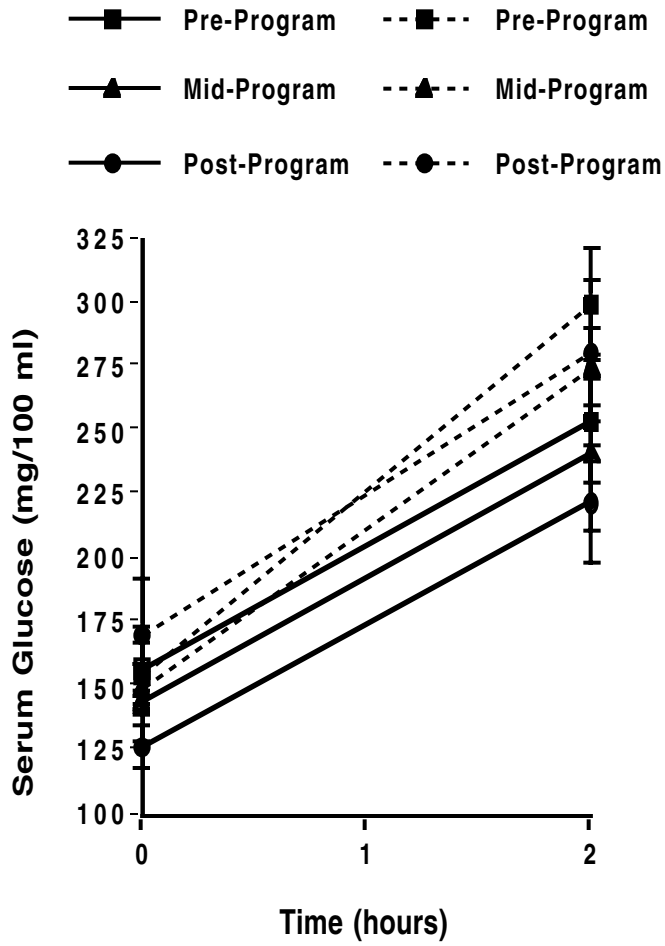


Figure 1. Blood glucose concentrations after a 12-hr fast and 2-hr post glucose challenge: at entry (Pre), after 3 (Mid) and 6 (Post) months for E/A (solid line) and Control (dotted line) groups.

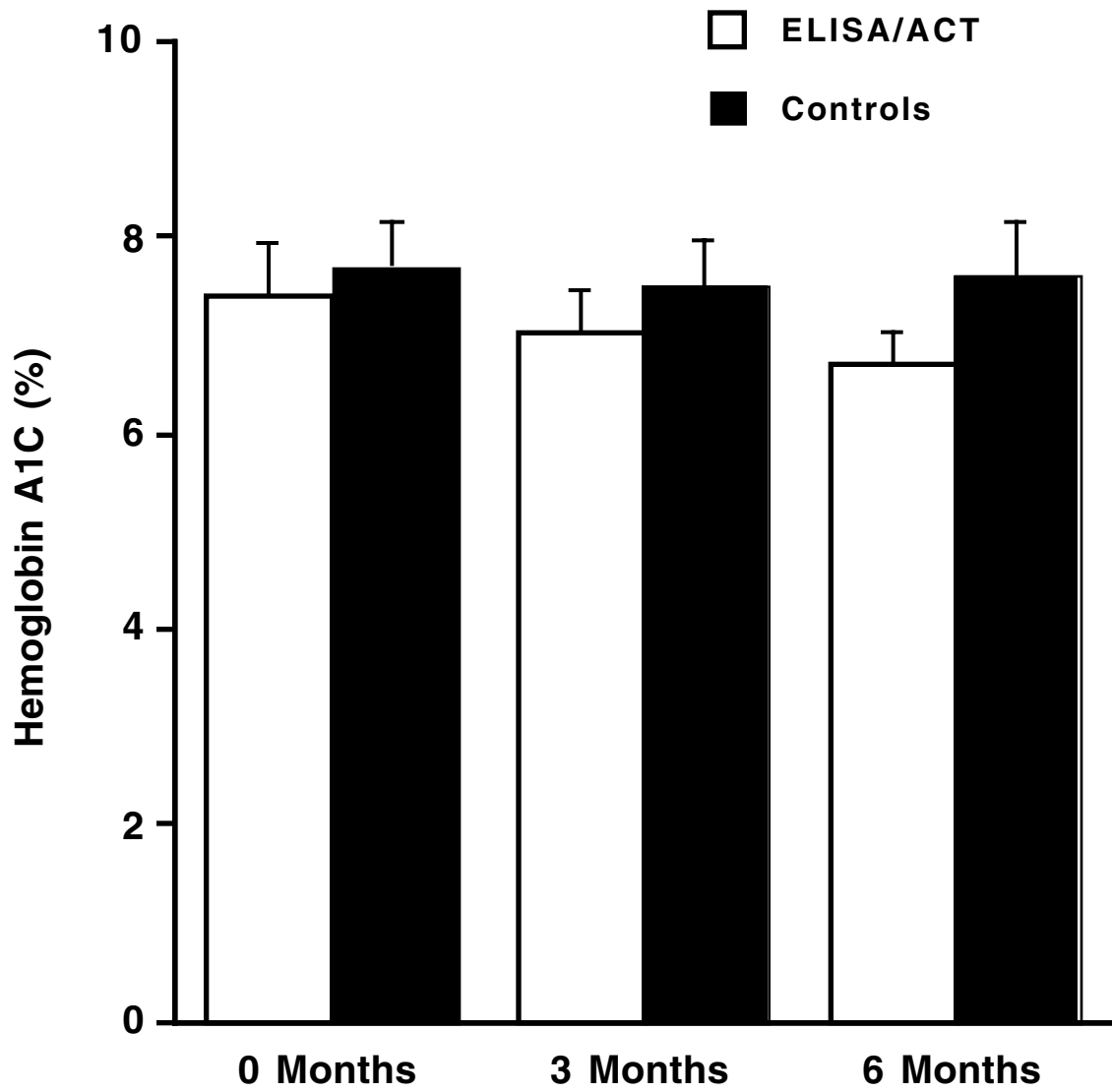


Figure 2. Hemoglobin A1C Values at Entry (0) , after 3 and 6 months, upon completion of study for T (open bars) and C (solid bars) groups.