CLINICAL TRIAL IN COOPERATION WITH THE LAIKO HOSPITAL

Objective: The effect on Metabolic Parameters in adults with Type 2 Diabetes Mellitus of consuming desserts from the Sweet & Balance range with a Low Glycemic Index and low Glycemic Load.

Subjects: A total of 25 people with Type 2 diabetes mellitus were studied. They received a stable dose of antidiabetic tablets for 3 months before the start of the dietary intervention and throughout the study, and acceptable glycemic control (HbA1C <8%) was observed. The Adults were studied at the Diabetes Center of the Athens University 1st Preventative Pathology Clinic, at the "Laiko" hospital.

Method: The subjects were randomly separated into two groups. One group of 17 people (the Sweet & Balance Group) followed a balanced, low calorie (500 kcal less than the reference) diet programme which was given to them for three months, (45% carbohydrates, 35% fats, 20% protein). Sweet & Balance products were included in the diet four times a week. The second group of 8 people, both men and women, (the Control Group) followed a balanced diet programme with the same proportions of carbohydrates, fats, and protein for three months. The food products being tested were not included in the diet. Frequent dietary monitoring was conducted at the same intervals on both groups. During the initial assessment and after the three month long intervention, weight, waist circumference, blood pressure, glucose, HbAIC, lipids, hepatic biochemistry and inflammation markers such as hsCRP TNF-α and Interleukin 6 (IL-6) were measured.

Results: The table describes the clinical and biochemical results (median) of the two groups. Specifically, a statistically significant body weight loss of 3 kg, a decrease in body mass index (BMI) ($p < 0.001$) and waist circumference ($p = 0.013$) were observed, and better glycemic control was achieved as both glucose fasting levels ($p = 0.063$) and HBA1C ($p = 0.074$) were reduced. Also, there was a significant reduction in blood pressure ($p = 0.021$), liver biochemistry markers associated with fatty liver filtration improved, and inflammation markers decreased. None of the 25 patients experienced any adverse reaction after consuming the food being studied.

Conclusions: Those who followed a diet that included Sweet & Balance desserts with a Low Glycemic Index and a Low Glycemic Load were able to follow their diet more easily and better and significant weight loss and better glycemic control were observed in this group.

Table 1. Clinical and laboratory results

Results	Initial Group Sweet & Balance	Final Group Sweet & Balance		Initial Group Control	Final Group Control	
Weight, Kg	87,1	84	p=0,000	86,8	84,4	p=0,042
BMI, Kg/m^2	32,5	31,1	p=0,000	31,4	30,8	p=0,066
Waist Circumference	103,9	101,6	p=0,013	109,6	107	p=0,098
Circumference of hips, cm	115,7	112,4	p=0,001	115,2	114,2	p=0,089
Systolic Blood Pressure (SBP), mmHg	129,9	121,8	p=0,021	130,6	131,4	p=0,587
Diastolic Blood Pressure (DBP), mmHg	76,2	70,6	p=0,009	78,6	74,8	p=0,099
Blood sugar mg/dl	142,6	132,2	p=0,063	144,2	122,6	p=0,294
Total Cholesterol, mg/dl	180	168,7	p=0,092	148,8	154,6	p=0,113
HBA1C	6,5	6,2	p=0,074	6,7	6,4	p=0,419