

**CLINICAL TRIAL IN COOPERATION WITH
"AGIA SOPHIA" CHILDREN'S HOSPITAL
AND THE ENDOCRINOLOGY, METABOLISM
AND DIABETES UNIT OF THE "EVGENIDEIO CLINIC"**

Objective: To investigate the effect of consuming food from the **Sweet & Balance** range with a Low Glycemic Index / Glycemic Load (DG / GF), on the improvement in Metabolic Syndrome parameters and inflammatory markers in **overweight or-obese children**.

Subjects: 29 teenage girls (10-14 years), with a body mass index (BMI) \geq 85th percentile in the development curves for children in Greece were studied. The children were studied at the Endocrinology Unit of the First Pediatric Clinic of the University of Athens, at the Children's Hospital «Agia Sophia» and the Endocrinology, Metabolism and Diabetes Unit of the "Evgenideio Clinic".

Method: The subjects were randomly separated into two groups. One group of 15 children (**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 14 children (**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, but subjects in the Control Group were given the opportunity to eat a sweet of their choice once a week. Frequent dietary monitoring was conducted on both groups. During the initial assessment and after the three-month intervention, indicators related to Metabolic Syndrome and Chronic Inflammation were measured (Cholesterol, Triglycerides, HDL, LDL, Uric acid, SGOT, SGPT, γ Gt, glucose, HbA1C, Insulin, Cortisol, Leptin, RBP4, LpPL2, Systainin C, Antiponectin, hsCRP, TNF- α , Interleukin 6)

Statistical Analysis: Intermediate value control was used for independent Mann Whitney samples and Wilcoxon dependent samples. The statistics analysis was performed with the statistical package SPSS 16.0 and was defined as a statistical level of significance p-value <0.05 .

Results: Table 1 describes the clinical and biochemical results (median) of the two groups. There was a statistically significant improvement in the group of children who consumed the new Sweet & Balance products with low GI / GF in relation to the control group children when comparing their median values of changes in the following parameters: i) **Body Weight** ($p = 0.001$), ii) **BMI** ($p = 0.037$), iii) **Systolic Arterial Pressure** ($p = 0.027$), iv) **Fasting insulin** ($p = 0.004$), v) **HOMA Index** ($p = 0.009$).

Conclusions: Dietary regimes which include sweets with low GI/GL help overweight-obese children to follow the diets fully, with the ultimate goal of improving the clinical and laboratory parameters of the Metabolic Syndrome.

Table 1. Clinical and laboratory results

Results	Initial Group Sweet & Balance	Final Group Sweet & Balance		Initial Group Control	Final Group Control	
Weight, kg	77,5	73,4	p=0,001	60,1	60,4	p=0,091
BMI, Kg/m ²	30,7	29,2	p=0,001	27,1	25,9	p=0,011
Waist to Hip Ratio (WHR)	0,9	0,87	p=0,138	0,91	0,88	p=0,125
Systolic Blood Pressure (SBP), mmHg	120	110	p=0,011	110	110	p=0,25
Diastolic Blood Pressure (DBP), mmHg	75	75	p=0,562	75	70	p=0,031
Fasting Glucose, mg/dl	92	94	p=0,989	90	91	p=0,377
Insulin, μ [^] /ml	17,6	13,9	p=0,021	13,2	15,5	p=0,083
HOMA Index	3,7	3,2	p=0,078	3,2	3,4	p=0,083