Effectiveness and safety of an adjuvant phytoformula in the treatment of patients with type 2 diabetes mellitus.

Nidia Angélica García Espinoza (1), Hugo Morales Tello (1), Ricardo Sacchi Córdova (1), Nicasio Morales Sarabia (1), Jair Isaí Ortega Gaxiola (1), José Alfredo Primelles Gingele (1), María Magdalena Valencia Gutiérrez (2), Erick Ayala Calvillo (3), *Cesar Ochoa Martínez (4).

(1) SAPI de C.V. – División Elevate® (2) Escuela Superior de Medicina, Instituto Politécnico Nacional, CDMX, México, Especialista en Medicina Familiar IMSS/UNAM (Unidad de Medicina Familiar 187 del IMSS). (3) Facultad de Farmacia, Universidad Autónoma del Estado de Morelos. Cuernavaca, Morelos, México. (4) Center for Clinical Research, WesternU Medical Center at Western University of Health Sciences, Pomona, CA, USA

Introduction

Type 2 diabetes mellitus (T2DM)) is a "metabolic disorder of multiple etiology characterized by chronic hyperglycemia with alteration of carbohydrate metabolism, fat and proteins as a result of defects in insulin secretion, insulin action or both".(1) T2DM has been a public health problem associated to comorbidities and mortality.(2) Therefore, Terrabrio SAPI de CV developed the phytoformulation Elevaté® with several natural products (Figure 1).

Figure 1. Composition of fitoformulation

Common name	Scientific name	Compositon (% Weight)
Chaga	Inonotus obliquus	Hongo seco (20%)
Shilajit	Asphaltum punjabianum	Exudado (20%)
Moringa	Moringa oleifera	Hojas (20%)
Berberina	Berberis vulgaris	Hojas (8%)
Bayetilla	Hamelia patens Jacq	Hojas (32%)

Objective

Evaluate efficacy and safety of the phytoformulation Elevaté ® Body Balance as an adjuvant in the treatment of patients with T2DM.

Material and methods

A 90 days randomized double-blind placebo-controlled trial was conducted. 368 patients with T2DM without or on oral hypoglycemic agents were randomized. 269 in experimental group (1.5g/day of the phytoformulation) and 99 in control group (placebo; 50mg/ Vitamin C per day) In treatment for 90 days. Clinical, somatometric and biochemical parameters through previously and reported.

The sample size was calculated with the results of the study on the effects of Moringa Oleifera in patients with type II Diabetes by V. Veeranan Arun Giridhari et al., 2011 with the mean difference formula, 31 patients per group were required to obtain a power of 80% and a CI of 95%

Results

Results: In the experimental group, cholesterol decreases from 187(160.75-210) mg/dl to 164(119.25-190.50) mg/dl [reduction 25.5 mg/dl] and triglycerides of 174.5 (117-278) mg/ dl to 143.5 (80-208) mg/dl, with p <0.001 (figure 2). Possibly related adverse effects, dysgeusia related to sour taste (11.5%), pruritus (6.31%) and headache (1.4%)

Figure 2. Medical Follow-up at 0 and 3 months of patients with type 2 Diabetes mellitus in somatometric and biochemical variables by treatment group.

Variable	Experimental group n= 269			Control group n=99		
	Basaline	3 months	p	Basaline	3 months	p
BMI kg/m2 m±SD	28.76±6.43	28.6±6.33	0.001	28.15±4.17	28.33±3.75	0.044
	Biochemical variables					
Cholesterol, mg/dl, m(RIQ)	187 (160.75-210)	164(119.25-190.5)	0.001	207 (166-227)	185 (166-227)	0.012
Tryglicerides, mg/dl, m(p)	174.5 (117-278)	143.5 (80-208)	0.001	213(154-254)	180(151-282)	0.601
A1c m±SD	9.09±1.39	7.92±1.45	0.001	8.81±1.27	8.84±1.28	0.650
A1c** m(p)	8.88 (7.70-9.40)	7.70 (6.80-8.60)	0.001	9.58 (8.80-9.80)	9.60 (7.50-10.30)	0.063

BMI=Body index mass, m= meters, cm= centimeters, Kg = kilograms, kg/m2= kilograms/meters^2, **m(RIQ)= median, Interquartile range and Wilcoxon test, m±SD = media and standar desviation and t de student test,** N= subjects, A1c= glycosylated hemoglobin, **(without hypoglycemic agents), p≤0.05

A complementary evaluation was carried out in 86 patients from the experimental group, triglycerides decreased from 179mg/dl (129-255) to 158mg/dl (101.50-218.50) at 6 months with p<0.001. A1c decreased from 9.08±1.24% (0 months) to 8±1.27% (3 months) and 7.98±1.46% (6 months) with p<0.001 (Figure 3).

Figure 3. Medical follow-up at 0, 3 and 6 months of patients with with type 2 Diabetes mellitus in somatometric and biochemical variables by treatment group.

Variable	Experimental group N=86			p
	Basaline	3 months	6 months	
BM kg/m2 m±SD	26.91 (23.43-29.16)	27.02(23.68-29.47)	27.24(23.98-30.40)	0.012b
Waist cm m(RIQ)	98.01±13.73	96.43±11.81	96.80±12.38	0.612[a]
SBP mmHg m(RIQ)	130 (110-142.5)	130 (120-150)	130 (120-150)	0.941b
DBP mmHg m(RIQ)	75 (70-82.5)	80 (70-85)	80 (70-85)	0.976b
Cholesterol, mg/dl m(RIQ)	193.26 ±39.54	186.75±51.68	193.41±49.65	0.947[a]
Tryglicerides mg/dl m(RIQ)	179 (129-255)	180 (128.5-263)	158(101.50-218.50)	0.001b
A1c% m(RIQ)	9.08±1.24	8±1.27	7.98±1.46	0.001[a]

BMI=Body index mass, m= meters, cm= centimeters, Kg = kilograms, kg/m2= kilograms/meters2, SBP= Sistolyc blood pressure, DBP= diastolic blood pressure, mmHg= milimeters of mercury, m(RIQ)= median, Interquartile range, m±SD = media and standar desviation, N= subjects, %=percentage, A1c= glycosylated hemoglobin, a=ANOVA test, b=Friedman test, p≤0.05

Conclusion

The results show a potential effective and safe use of Shilajit, Chaga, Moringa, Berberina and Bayetilla in a phytoformulation as co-adjuvant in the glycemic control of patients with T2DM, which has a positive effect on the reduction of risk Cardiometabolic.

Key words: Type 2 diabetes mellitus, glycemic control, A1c, phytoformulation Elevate® Body Balance, mineral-herbalism.

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Contact information

Cesar Ochoa, MD, PhD – Center for Clinical and Translational Research at WestenU Medical Center, Western University of Health Sciences, Pomona, CA, USA cochoa@westernu.edu (909) 469-8412