GLUCOMANNAN (PROPOL®) DIETARY FIBER ACTION IN BODY WEIGHT LOSS AND IN THE REGULATION OF LIPIDEMIA VALUES IN OVERWEIGHT PATIENTS

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Summary

The present study's objective was to determine the effects of Propol* (Glucomannan) ingestion as an adjuvant element in weight reduction program in overweight patients, as well as to determine the variations of lipidemia and glycemia values in that group of patients. It was a prospective, double-blind, parallel, cross-over, random study with two Propol dose (3 grams/day and 4 grams/day) versus a placebo. 60 Female patients from the Cardiology Department of the "Carlos Arvelo" Military Hospital in Caracas, who fulfilled the inclusion and exclusion criteria were included in the study. The patients were divided in groups of 15 each and assigned to four treatments by a random distribution table. The total treatment time was 12 weeks, divided in two phases in relation to the placebo. When grouping the patients receiving Propol 3g/day, we observed a variation percentage of the final weight with respect to the initial one of –5.04% and BMI –5.44% in 5 weeks of treatment. With Propol 4 g/day, the variations between the beginning and the end of the treatment, was body weight –5.1% and BMI –5.54%. In contrast, variations in the placebo phases were –1.93% in weight and –1.97% in BMI. We observed a total cholesterol (TChol) decrease of between 11.95% and 13.86% with a LDL cholesterol predominance. The triglycerides decrease is between 15.14% and 19.26%. As to glycemia, we observed that by using Propol 4 g/day the decrease was of 10.73% from the initial values but, when using 3 gram/day, the result was similar to the placebo, about 6%. We can affirm that adding Propol dietary fiber to the regular diet of overweight patients favors body weight reduction in the order to 5% to 6%. Moreover, total cholesterol (TChol) is reduce at the expense of LDL, increasing HDL. Triglycerides are also significantly reduced and glycemia, in our study, decreased only to the dose of 4 gram/day Propol. We came to the conclusion that the administration of Propol as a dietary supplement contributes to body weight and lipidemia decrease in overweight and hypercholesterolemic patients.

The ideal or desirable weight is the one associated to a minor morbimortality within a specific population. The values above the desirable value is considered as overweight and obesity (1) Overweight is a body weight increase above any arbitrary rule, defined in relation to height, the body mass index (BMI) being on of the most employed parameters(1). Obesity is a multi-factorial condition in which genetic, behavioral and psychosocial factors contribute to energetic imbalance that is translated into an increase of adipose tissue, as a consequence of a caloric intake higher than consumption (2).

Overweight and obesity have been associated as risk factors of large amounts of pathologies considered within the main causes of morbimortality, including: hypertension, arteriosclerosis, coronary arteropathy, diabetes mellitus, orthopedic and traumatologic disturbances, which translates into a decrease in life expectancy and quality for these groups of individuals (3).

The weight and height tables published by the Metropolitan Life Association in New York shows that a high percentage of the population in industrialized countries is overweight. Epidemiologic studies have suggested the existence of an association between a diet with scarce amounts of vegetal residues and diseases of high incidence in western countries: obesity, arteriosclerosis, in fact, diabetes mellitus, hypercholesterolemia, constipation and colonic neoplasias (4).

Over-refined meals have become the principal products of western diets, with a considerable fiber loss in the diet to the point that, nowadays, obesity is one of the diseases affecting western societies (5).

Up to now, countless and different procedures, medicaments, techniques and recommendations have been established by health sciences trying to diminish the incidence of these conditions. Nutritional studies have reported the advantages in this sense, which result from the modification of alimentary habits, including the increase in fiber consumption (2).

The integration of vegetal fiber to the diet can particularly and favorably influence the evolution of some glucose and lipid metabolism alterations acting on cardiovascular risk factors. The benefits of adding fiber to the diet include: 1) Fiber provides volume but not calories. 2) Volume allows a faster meal transportation through the digestive system, therefore reducing the opportunity of overabsorption of bile acids, thus reducing lipid and glucose absorption (4).

The fibers, including guar gum, pectin and oat, chickpea and different fruit derivatives, vegetables and tubercles, have shown to possess an effect in lipidemia decrease. The fiber action mechanism, in this sense, is not year clear. In fact, bran derived from different cereals, decreases lipids in a very variable way, even through the fundamental components of fiber, such as lignin, cellulose and hemicellulose may be represented in qualitatively similar proportions or with very small differences. In order to obtain an important effect in cholesterol decrease, the type of fiber used to integrate seems to be fundamental: cellulose seems to be inefficient, while it has been proven that fiber gels derived from pectin decrease the plasmatic levels of the total cholesterol (6).

Propol is a potent glucomannan, and a component of Amorphophallus Konjac tubercules, which is extensively diffused tree in the Far East. It is a polysaccharide of high molecular weight with similar chemical characteristics to those of cellulose, but with the advantage of being able to absorb large quantities of water and, thus, turn into a gel. It is made up of glucose and mannose molecules, the cohesion of the same making the presence of linkages of the beta 1-4 type (6).

Clinical studies using glucomannan in obese patients have been done in prestigious research centers. A group of obese patients, who were administered Propol or placebo 3gr/day during four weeks of treatment, was studies in the Research Department of the General Nutrition Corporation, in Fargo, North Dakota. Those patients receiving glucomannan lost weight and reduced their cholesterol (Chol), triglycerides (Tg) and low density lipoproteins (LDL) (4).

This study's objective was to determine the effects of Propol ingestion as an adjuvant element in weight reduction programs in overweight patients, thus determining the variations of glycemia and lipidemia values in said group of patients.

Material and Methods

This was a prospective, double-blind, parallel, cross-over, random study with two dose of Propol (3g/day and 4 g/day) versus a placebo. 60 Female patients from the Cardiology Department of the "Carlos Arvelo" Military Hospital, Caracas, were included, who fulfilled the following inclusion criteria: 1) Age between 18 and 65 years; 2) Body Mass Index (BMI) calculated as weight/height2 between 25 and 30; 3) Cholesterolemia higher than 200mg%. The exclusion criteria were the following: 1) Younger than 18 and older than 65 years; 2) BMI higher than 30; 3) Other concomitant pathologies: diabetes mellitus, infections, chronic renal failure, oncologic pathologies, bad absorption syndrome, hypovitaminosis.

The patients were divided in groups of 15 each, assigned to four treatments by a random distribution table. The total treatment time was 12 weeks, dividend in three phases: two 5-week phases and one of 2 weeks. In phase I, patients according to the random distribution received Propol or placebo. In phase II, as washing or cross-over treatment phase, all patients received placebo for two weeks, and in phase III, patients received Propol or placebo, opposite to phase I. Table 1 shows the treatment distribution by group and phase.

Propol, as well as placebo, was administered to the patients in from of capsules. Patients receiving 3g/day were given 500mg capsules, of which they had to take 2 before each meal. Those patients who received 4 g/day were administered 650mg capsules, taking 2 capsules before each meal. Placebo, a powdered gel, was administered in capsules organoleptically similar to Propol. The capsules had to be taken with a glass of water.

Table 1

Treatment Phases

	Phase I 5 weeks	Phase II 2 weeks(washing)	Phase III 5 weeks
A	Propol 3g/day	Placebo	Placebo
B	Placebo	Placebo	Propol 3g/day
C	Placebo	Placebo	Propol 4g/day
D	Propol 4g/day	Placebo	Placebo

Table 2

Age (years) by the group of treatment

Variable	Mean	D.S.	E.E.	Amplitude
A group	40.73	11.85	3.06	28-59
B group	38.00	8.38	2.16	23-53
C group	41.87	9.23	2.38	29-56
D group*	39.86	12.80	3.42	22-66
Total**	40.12	10.50	1.37	22-66

Table 3

Body weight (kg) by the group of treatment and by the phases

	Phase I			Phase II			Phase III	
Week	0	2	4	5	7	9	11	12
A	66.6	65.3	63.8	64.2	64.9	64.7	64.5	64.3
B	70.8	69.6	68.8	68.7	68.7	68.4	66.4	64.2
C	68.3	67.0	66.3	65.9	66.7	65.5	63.9	61.3
D	69.9	68.9	67.4	67.8	68.3	68.4	68.3	67.9

The following parameters: body weight, heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP) were recorded at baseline (week 0) and in weeks 2, 4, 5, 7, 9, 11 and 12. Height was measured for BMI calculation only at the baseline.

Total cholesterol (Tchol), HDL, LDL, VLDL, triglycerides (Tg) and glycemia were the performed laboratory tests. The initial and final days of each phase, i.e. weeks of 0, 5, 7, and 12 were

determined.

Statistical analysis was performed by frequency analysis and by the t-Student test, with a statistical significance of $p<0.05$ and $p<0.001$.

Results

Out of the 60 patients included in the study, 59 finished the three phases; one patient was withdrawn from the study because she presented a gynecologic pathology that needed surgical intervention.

The patients' average age was 40.12 years $\pm$10.5. Table 2 shows the average ages of each group with standard deviation (SD), mean standard error (MSE) and amplitude.

Body weight variations can be assessed in Table 3 by treatment groups, and with the average weight by weeks of treatment.

Table 4 shows BMI variations at the beginning and the end of each phase and by treatment. Initial and final mean value of each phase, the t-Student test and the exact "p" value can also be assessed. Body weight and BMI variation percentages in patients using Propol 3 grams/day and Propol 4 g/day and placebo can be assessed in Figure 1.

The assessed cardiovascular variables were heart rate and the systolic and diastolic blood pressures of each group at the beginning and the end of each phase, as can be observed in Table 5.

The laboratory tests performed on the patients were total cholesterol (Tchol), HDL, LDL, VLDL, triglycerides (Tg), glycemia. The results are seen in Tables 6, 7, 8, and 9 according to the treatment they received, with the mean value at the beginning and the end, numerical differences between those values and the statistical significance.

Table 4

Body Mass Index (BMI) by the treatment phases

		Mean	T	P	Significance
A group Propol 3g	Start	26.86	5.20	0.0001	Significant
	Final	25.90			
A group Placebo	Start	26.15	1.36	0.2	N.S
	Final	25.96			
B group – Placebo	Start	27.49	5.78	0.0001	Significant
	Final	26.68			
B group Propol 3g	Start	26.68	5.92	0.0001	Significant
	Final	24.94			
C group – Placebo	Start	27.48	7.05	0.0001	Significant
	Final	26.55			
C group – Propol 4g	Start	26.86	7.58	0.0001	Significant
	Final	24.70			
D group – Propol 4g	Start	28.26	5.36	0.0001	Significant
	Final	27.42			
D group – Placebo	Start	27.61	1.16	0.27	N.S.
	Final	27.44			

Table 5

Heart rate (Hr), systolic blood pressure(SBP) and diastolic (DBP) by group of treatment

	Beginning		Week5		Week7		Week12	
	Hr	SBP/DBP	Hr	SBP/DBP	Hr	SBP/DBP	Hr	SBP/DBP
A	76.1	124/76	75.2	117/72	77.9	121/77	75.2	119/76
B	80.0	120/72	77.0	121/75	74.0	122/75	75.4	121/72
C	73.3	122/77	72.4	119/74	74.5	123/78	73.5	118/72
D	78.9	113/75	73.1	116/71	74.3	116/71	76.0	114/69

No side effects arose during the trial; one patient was withdrawn from the test because of gynecological causes alien to the same.

Discussion

The present evidences suggest that diets with a high fiber content and soluble fiber supplements improve the carbohydrate metabolism and decrease the total cholesterol (Tchol), cholesterol joined to low density lipoprotein (LDL), reduce weight and body mass index (BMI) in overweight, hypercholesterolemic and diabetic patients (7). For this reason, we proposed the performance of a clinical trial with a soluble dietary fiber – Propol glucomannan - which has proven effectiveness in weight reduction plans in addition the regulation of lipidemia (5), (6), (8). A total of 59 overweight patients with cholesterolemia values over 200mg% were studied at the "Carlos Arevalo" Military Hospital in Caracas. The patients' average age was 40.12 years, corresponding to the fifth life decade where the incidence of cardiovascular risk factors must be greater. The patients were crossed-over in phases so that each one was to receive placebo as well as Propol at any moment of the trial.

Table 6

Laboratory test (Group A)

	Propol 3g			Placebo		
	Phase I			Phase III		
	Before	After	Differ.	Before	After	Differ.
Total cholesterol	222.7	192.7*	-30	230.6	206.6**	-24
HDL-C	35.9	48.5*	12.6	43.3	46.1ns	2.8
LDL-C	157.4	120.1*	-37.3	155	135.8ns	-19.2
VLDL-C	29.3	23.9ns	-5.4	28.5	23.3ns	-5.2
Triglycerides	135.3	115.9ns	-19.4	141.6	131.8ns	-9.8
Glycemia	80.9	82.3ns	1.4	86.7	84.3ns	-2.4

*P<0.0001 **P<0.05 N.S=Not significant

Table 7

Laboratory test (Group B)

	Placebo			Propol 3g		
	Phase I			Phase III		
	Before	After	Differ.	Before	After	Differ.
Total cholesterol	207.6	194.4**	-13.2	202.4	173.4*	-29
HDL-C	38.3	44.9ns	6.6	43.3	54.9*	16.6
LDL-C	143.3	127.9ns	-15.4	132.3	107.9**	-24.4
VLDL-C	26.1	25.9ns	-0.2	26.6	16.4ns	-10.2
Triglycerides	123.8	121ns	-2.8	124.6	104.6ns	-20
Glycemia	85.4	78.6ns	-6.8	87.3	75.4*	-11.9

*P<0.0001 **P<0.05 N.S=Not significant

Table 8

Laboratory test (Group B)

	Placebo			Propol 3g		
	Phase I			Phase III		
	Before	After	Differ.	Before	After	Differ.
Total cholesterol	194.7	200.6ns	5.9	211.8	190.9ns	-20.9
HDL-C	41.6	45.4*	3.8	46.8	49.2ns	2.4
LDL-C	131.8	132.5ns	0.7	144.8	117.3**	-27.5
VLDL-C	22.5	22.4ns	-0.1	25.4	19.2ns	-6.2
Triglycerides	113.1	121.5ns	8.4	137.9	95*	-42.9
Glycemia	84	81.5ns	-2.5	86.3	75.8*	-10.5

*P<0.0001 **P<0.05 N.S=Not significant

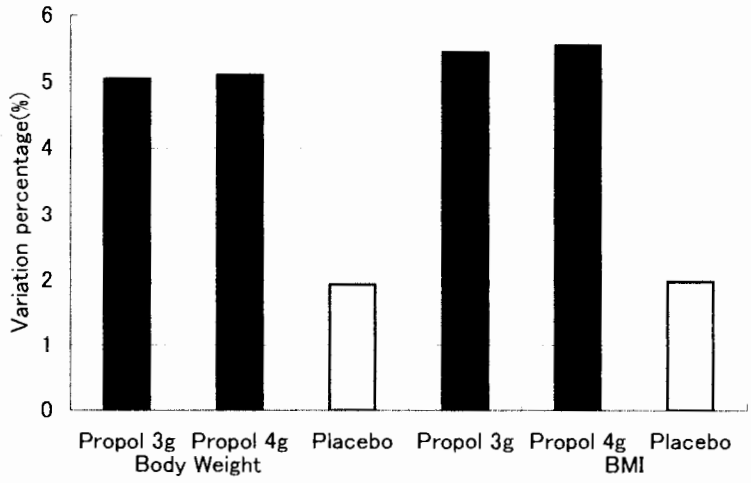
Table 9

Laboratory test (Group B)

	Propol 4g			Placebo		
	Phase I			Phase III		
	Before	After	Differ.	Before	After	Differ.
Total cholesterol	223.8	192.6*	-31.2	205.1	225ns	19.9
HDL-C	35.6	46.9*	11.3	41.4	39.5ns	-1.9
LDL-C	160.9	126.6*	-34.3	143.2	163.1ns	19.9
VLDL-C	29.8	19.1**	-10.7	30.3	22.4ns	-7.9
Triglycerides	158	101**	-57	131.1	116ns	-15.1
Glycemia	81.3	73.8**	-7.5	84.9	77.3*	-7.6

*P<0.0001 **P<0.05 N.S=Not significant

Body Weight-B.M.I Propol 3g & 4g



We observed a body weight and body mass index (BMI) decrease in the patients receiving Propol either in the 3 g/day or the 4 g/day phase in relation to the phases where they received a placebo. We assessed that all patients decreased weight in phase I possibly because patients, when admitted to a weight reduction program, followed the indicated basic dietary rules such as: not to eat between meals, not to drink alcoholic beverages, not to increase the daily ingestion and to drink, at least, 8 glasses of water a day. But in the third test phase, when motivation decreased, we appreciate that only those patients in the Propol groups within this phase, reduced weight with a highly significant difference, while the patients from the placebo group did not modify either the weight or the body mass index. When grouping the patients receiving Propol 3 g/day we observed a variation percentage of the final weight, compared to the initial one, of –5.04% and –5.44% in the BMI. On the other hand, variations within the placebo phases were –1.93% in weight and –1.97% in BMI. This data agrees with other performed clinical trials where the weight decrease percentage with Propol varies between 5% and 10% from the initial weight, in the 8-week treatment (8). Better results in weight and BMI decreases were obtained with the administration of Propol in 4 g/day in relation to Propol 3 g/day, the same as in the Giacosa et al., test, where they concluded that the effects of Propol are dose-related and that the intake of 4 g of Propol per day guarantees a significant effect on weight loss and reduction of the risks of overweight relapse (9).

In relation to cardiovascular variables, recorded during the study, we can observe how the important clinical variations of heart rate, SBP and DBP within the four groups were not assessed in any of the treatment phases. When comparing this clinical study with the one of Dr. Reffo et al., where these cardiovascular variables were recorded, we found similar results as to the heart rate and DBP. SBP, in that study, decreased to a statistically significant degree, but with no clinical importance, since it varied from 144.6 mmHg to 137.3 mmHg in the average. (10).

It is widely known that soluble fibers seem to have reducing effects on cholesterol. Between 6% and 15%, also decreasing LDL-cholesterol and triglycerides (7). In our studied group we observed a decreased of cholesterol between 11.95% and 13.86%, in predominance of LDL cholesterol – results similar to those obtained by Venter and other researchers, where the cholesterol decrease was of 13.3% (3), (8). A HDL-cholesterol increase between 16.63% and 30.52% from the initial values, assessed with both Propol dose, catches our attention. The cause of this is not yet known, though this fact has been observed by other researchers (10). A decrease of triglycerides is in the order of 15.14% to 19.26%, similar to what was observed in other clinical studies where Reffo et al. obtained a triglycerides decrease between 14% and 36% (5). We observed that, by using Propol 4 g/day, decrease in glycemia was 10.73% from the initial values, but, with Propol 3 g/day, the results were similar to placebo, about 6%.

From all previously observed, as well as the data contributed by international literature (5), (6),

(9), we can affirm that adding Propol dietary fiber to the overweight patients' regular diet favors body weight reduction in the order of 5% to 6%. It also decreased the total cholesterol at the expense of LDL, increasing HDL. Triglycerides are significantly reduced and glycemia decreased in our study only within the group of patients receiving Propol 4 g/day. We can conclude that the administration of Propol as a dietary supplement contributes to body weight reduction and the control of dislipidemias.

* Propol® used in the study was obtained from Shimizu Chemical Corporation, Japan.

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