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Beanblock® (standardized dry extract of Phaseolus vulgaris) in mildly overweight subjects: a pilot study

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Abstract. – OBJECTIVE: This study evaluates the efficacy of Beanblock®, a standardized extract of Phaseolus vulgaris L., on weight control in healthy overweight subjects on a weight management plan that combined lifestyle and dietary advice.

PATIENTS AND METHODS: Sixty overweight (BMI 25-30 kg/m^2) healthy subjects were enroled. All subjects were instructed to follow a weight management plan, accompanied by dietary advice. Thirty subjects used Beanblock® for at least 12 weeks (50 mg tablets, two times daily). The remaining 30 subjects did not receive any supplementation (management-only). The main endpoints were changes in body weight and waist circumference, with plasmatic oxidative stress, satiey and appetite being also evaluated.

RESULTS: At week 12, the supplementation with Beanblock® was associated with a reduction in body weight (from 82.8 ± 9.1 kg to 78.8 ± 8.9 kg; $p < 0.0001$) and a decrease of waist circumference from 94.4 ± 10.3 cm to 88.2 ± 10.0 cm ($p < 0.0001$). Conversely, only marginal changes were observed in the control group. Oxidative stress was also significantly decreased with Beanblock® (from 380.4 ± 14.8 to 340.7 ± 14.8 Carr Units; $p < 0.0001$). Satiety and appetite improved in the supplement group. No side effects were observed and compliance was optimal.

CONCLUSIONS: Beanblock®, in association with a health management plan, was useful for weight control in mildly overweight healthy subjects.

Key Words:
Overweight, BMI, Dry extract of Phaseolus Vulgaris, Waist circumference, Oxidative stress.

Introduction

The control of body weight helps prevent a number of disorders by controlling metabolic and cardiovascular risk factors particularly in asymptomatic subjects[1-3]. Indeed, the control of risks associated to increased weight, particularly metabolic and cardiovascular conditions, is possibly – at the moment – one of the most important objectives for medicine in industrialized countries given the high number of individuals with this problem[4-8].

Many approaches are available to progressively reach body weight reduction and/or control without resorting to unrealistically restrictive diets or unrealistically intensive physical exercise, whose long-term efficacy is questionable. Furthermore, some subjects cannot rely – i.e. for physical disabilities – on intense exercise prescription, while the safety of high-protein diets, a quick way to promote weight loss, is a growing medical concern. Many "natural" new supplements are introduced into the market based not on a mainstream pharmacological action, such as, for example, the modulation of aminergic brain systems, but rather on the physiological modulation of the absorption of high-calory food, and especially easily absorbed sugars[3,9,10]. These supplementations may help reach a control of body weight in a progressive and "soft" manner, and are particularly useful in asymptomatic, otherwise healthy subjects.

Beanblock®, a standardized dry extract of *Phaseolus vulgaris*, has been recently validated in a placebo-controlled study for its efficacy in reducing post-prandial glucose, insulin and C-peptide excursions in healthy subjects. This study also duplicated in a human context several previous observations on satiety and the release of gastrointestinal hormones made with Beanblock® in animal studies[11-13]. Beanblock® is obtained from a selected bean variety (Italian Borlotto Lamon), doubly standardized for α-amylase inhibition (1400 U/mg) and a hemagglutinating activity (16 units/mg) to combine efficacy and tolerability[14,15]. Beanblock® acts like a nutritional modulator of

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the absorption of sugars and the appetite/satiety balance[11,16-20], but additional clinical data are necessary to translate the data on glucose and appetite control into an effective weight management. With this aim, we have investigated the effect of Beanblock® to complement a health-management plan aimed at weight control.

Patients and Methods

Study Design and Patients

This was a registry, supplement study (see[21] for a definition and a description of such studies). In total, 60 individuals (aged between 45 and 65 years, 27 males), with body mass index (BMI) between 25 and 30 kg/m^2 were included in the registry after a full clinical examination to exclude any pathological condition. In addition, subjects who used any slimming product were not considered for inclusion, and subjects on a special diet (e.g. vegetarian) were also excluded. All subjects were followed by personal monitors for at least 12 weeks.

The Registry

All subjects received instructions to follow a health management plan; dietary recommendations, without specific or absolute diet restrictions, were provided and all individuals were free to follow their normal lifestyle. At the moment of inclusion this approach was considered the best sustainable long term management to control the increase of body weight.

The proposed health plan included mild routine exercise such as repeated walking whenever possible, limiting the use of lifts, performing mild efforts in association with main working and free-time activities (e.g. moving heavy objects at work). The exercise plan was left to personal preference (however including at least 5 periods of 15 minutes per week). The suggestions included also wearing running/walking shoes during most of the day.

The briefing also suggested regular meals (with no between-meal snacks) and 'mild' caloric restrictions (avoid use of sugar and dietary salt when possible, using nothing or sugar- and salt replacements), reduction of full fat milk (no more than 100 ml day) and alcohol (no more than half a glass of wine or beer per day or drinking beer without alcohol); avoidance of soft drinks; adequate rest and sleep. The individuals did not modify their main eating habits or times, or initiate any specific physical training plan aimed at reducing their body weight.

Subjects were briefed about the potential effects of the supplementation with Beanblock®, and spontaneously decided whether or not to take this supplementation, providing feedback on their decision to the registry monitors.

When a total of 30 individuals decided to take Beanblock® (administered in tablet form; each tablet contained 50 mg of *Phaseolus vulgaris* dry extract) the registry was closed. Subjects were instructed to take Beanblock® 15-30 minutes before the main meals, taking two tablets per meal with half a glass of water. The supplement is available over-the-counter in the market without prescription and could be voluntarily acquired by the registry subjects. A quantity of product was made freely available for underprivileged subjects.

Compliance was monitored by evaluating the number of tablets correctly used at the end of the evaluation period.

Registry Endpoints

The main endpoints of the registry were body weight and waist circumference, self-measured before initiating the supplementation period and at 12 weeks. These endpoints were selected as they can be easily self-measured. Study subjects were specifically instructed on how to measure their body weight and waist circumference.

The weight was defined as the average of 3 measurements made by the registry subjects in the morning before breakfast. All subjects were provided the same digital scale (A Digital, personal scale Etekcity®, 2310 SE Delaware Ave Suite G 243, Ankeny, IA, USA) to measure body weight.

Oxidative stress was assessed by measuring plasma hydroxyperoxide and plasma free radicals (PFR) by the d-ROMS test[17], using a FRAS equipment (Diacron, Parma, Italy; supplied by Corcon, Milan) used according with manufacturer's instructions. Only subjects with an increased oxidative stress (>350 Carr units) in association with increased weight were evaluated (12 subject in the treatment group and 14 in the control group). Study subjects were asked to report satiety and appetite – as felt in the week before the evaluation – at the beginning and at the end of the registry period using a Visual Analogue Scale (10 cm)

Blood pressure and essential laboratory tests (hematocrit, fasting sugar, lipids, hepatic and liver function tests, and urine analysis) were measured at inclusion and at 12 weeks.

Statistical Analysis

All data were reviewed by an external, independent statistician and were analyzed by descriptive statistics. The outcomes reported in subjects taking Beanblock® were compared with those observed in the other individuals. Based on previous studies a number of at least 20 subjects in each group was considered necessary to evaluate differences in weight and waist circumference given the variability of there measurements (<4%) in these study conditions.

Differences between the two treatments were evaluated by the Student *t* test or the Mann-Whitney U-test, as necessary. A *p*-value < 0.05 was considered statistically significant.

Results

Table I summarizes the different study parameters in the two groups. All individuals completed the registry period, with a mean follow-up of 93.3±2.1 days in the supplement group and 92.2±3.2 days in the management-only group. The two groups were comparable for age, gender distribution, weight and abdominal circumference at inclusion.

The weight management plan was correctly observed by 94% of all control subjects; the compliance to the supplement was 97.7%.

Bowel movements and minor, temporary gastrointestinal symptoms – not requiring medical treatment – were observed and spontaneously reported by three subjects in the Beanblock® group and two in the management-only group. No other adverse events were reported.

At 12 weeks, subjects on Beanblock® reported a significant reduction in body weight when compared with baseline values (-4.1 kg; $p < 0.0001$). This reduction was greater than that observed in the management-only group (-0.15 kg; $p < 0.05$ vs Beanblock® subjects).

Waist circumference was significantly reduced in the supplement group (-6.3 cm; $p < 0.0001$); there was a non-significant decrease (-1.4 cm) in the management-only group.

A significant reduction in plasma free radicals versus baseline values (-39.7 Units; $p < 0.0001$) was observed in the subjects using the supplement; a non-significant variation (+4.8 Carr Units) was observed in controls. The difference in PFR between groups was significant ($p < 0.001$).

Beanblock® supplementation was also associated with a reduction in appetite and with an in-

Table I. Outcomes reported in the Beanblock® group (B; n=30) and in the management-only group (M; n=30).

Parameter	Group	t_0	t_{12}	Difference	*p*
Males,	B	13			
number	M	14			
Age,	B	47 ± 4			
years	M	48 ± 3			
Body weight,	B	82.8 ± 9.1	78.8 ± 8.9	-4 kg	< 0.0001
kg	M	81.2 ± 8.32	81.3 ± 8.32	-0.1 kg	ns
Waist circumference,	B	94.4 ± 10.3	88.2 ±10.0	-6.2 cm	< 0.0001
cm	M	92.5 ± 9.5	91.1 ± 9.3	-1.4 cm	ns
Appetite	B	7.6 ± 1.2	5.0 ± 1.1	-2.66	< 0.0001
(0-10 VAS)	M	7.4± 1.4	7.3 ± 1.0	-0.2	ns
Satiety	B	5 ±1.1	7.6 ± 1.2	2.7	< 0.0001
(0-10 VAS)	M	5.5 ± 1.3	5.7 ± 1.4	-0.2	ns
Glucose	B	92 ± 9.3	93 ± 6.6		ns
(mg/dl)	M	91 ± 8.2	91 ± 7.6		ns
HbA1c	B	4.9 ± 1.10	4.84 ± 0.94		ns
%	M	5.02 ± 0.79	5.03 ± 0.62		ns
Syst art. pressure	B	122 ± 8.0	123 ± 5.8		ns
mm Hg	M	126 ± 8.3	128 ± 7.2		ns
Diast art. pressure	B	73 ± 5.8	73 ± 6.2		ns
mm Hg	M	76 ± 6.5	77 ± 5.0		ns
Heart rate	B	80 ± 6.5	79 ± 5.8		ns
b/min	M	80 ± 4.4		80± 4.3	ns
d-ROMs test	B	380.4 ± 14.8	340.7 ± 14.8	-39.7	< 0.0001
U.CARR	M	382.3 ± 16.2	387.1 ± 14.5	4.8	< 0.001

crease in the sensation of satiety. These effects were not observed or were minimal (not significant) in the management-only group.

Blood pressure values ≥130/85 mmHg were reported at the inclusion in seven individuals of the supplement group and 11 individuals of the management-only group. Pressure levels were normalized in all subjects at the end of the study period. No variations in the laboratory data were reported.

Discussion

In this registry study, supplementation with Beanblock® of a weight management plan over a 12 week period was associated with a significant reduction of body weight (-4%) and waist circumference in healthy mildly overweight subjects, without any relevant adverse event or alteration in blood pressure and laboratory parameters. Since a placebo arm was not present, and the study was open also in terms of recruitment, the possibilities of a treatment bias and or a recruitment bias exist.. That is, the volunteers willing to take Beanblock® supplementation were likely more motivated than the controls and might have been psychologically influenced by the concomitant administration of the tablets to follow more stricly the dietary and lifestyle recommendations. On the other hand, the differences observed are more pronounced than those associated with a simple placebo and/or recruitment bias effect in studies of this type[22], and, therefore, it does not seem unreasonable to associate the results with a specific activity of Beanblock®.

If so, one first factor involved might be the inhibitory action of a-amylase[14,15], that slows down the hydrolysis of food starch, increasing their colonic load, where they are used by the metaboloma for its own growth and the production of energy. A second factor might be a specific reduction of food consumption linked to increased satiety and decreased appetite, and this view is, indeed, backed up by the data observed in the study on these parameters, although their subjective nature should be also considered[14].

Subjects using Beanblock® showed also a reduction in plasma free-radicals. A higher oxidative stress is usually associated with a number of risk factors including reduced exercise level, increase in lipids level, increased caloric intake, and with hypertension. It has been shown that the decrease in PFRs associated to the control of lipids reduces atherosclerosis progression that is not completely improved by lipid-lowering treatment alone[23]. Therefore, the effects on PFR – which need re-evaluation in subjects at higher risks – may be also an important target of investigation for this type of supplementation.

Importantly, supplementation with Beanblock® was not associated with a clinically-relevant modification of blood pressure, or other laboratory parameters. On the other hand, the subjects enrolled were healthy, and the effects of Beanblock® in subjects with concomitant conditions were not investigated in the present study. Noteworthy, a high compliance to both the health plan and the administration of Beanblock® was reported, given also that the subjects included were left free to follow the indications given by the monitors.

This 'soft' approach described capitalizes on relatively simple lifestyle instructions and supplementation, and does not involve any forced, restrictive diet or stressing physical exercise, and might, therefore, be easily accepted by mildly overweight subjects. Furthermore, the reduction in the selected endpoints – i.e. body weight and waist circumference – is immediately appreciated, reinforcing compliance to the health management plan. It must be remarked that the management plan alone tends to decrease waist circumference, marginally improving the muscular tone, and that most subjects may feel better, without, however, a substantial decrease in weight. On the other hand, supplementation may help achieve also weight loss in addition to the decreased waist circumference, and a harsher regimen associated to supplementation might produce more marked effects.

Given the overall limited number of patients and the short follow-up of this registry, its results are preliminary. Larger and controlled studies with a longer follow-up are in preparation. In these investigations, the potential interaction of Beanblock® with commonly-prescribed drugs (e.g. anti-hypertensives, anti-platelet agents) will also be evaluated, since higher-risk (cardiovascular, metabolic) subjects require a more complex approach.

Conclusions

In this supplement registry study, Beanblock® associated with a weight management plan was effective in inducing weight reduction in healthy

mildly overweight people without the need of particularly harsh or prolonged diet restriction or a significant increase in physical exercise. Beanblock® appears to be potentially useful in subjects who may have problems in markedly increasing the intensity of physical activity or severely reducing their daily global food intake, but who, nevertheless, can still comply with a health management plan that combines moderate changes in lifestyle and diet. Given the open nature of the study, it is not possible to dissect the effects of Beanblock® in terms of specific pharmacological activity, increased compliance with the weight management plan, or a combination of both.

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Conflict of Interest

The Authors declare that they have no conflict of interests.

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