

Effect of natural blend of plant extracts on waist circumference in overweight and obese people: open-labelled observation

Abstract

Aim: Obesity and its metabolic consequences are major health problems. The lifestyle changes are insufficient or often fail. We have studied a proprietary blend of plant extracts and minerals (Cinnamomum zeylanicum, Trigonella foenum-graecum, Coffee Arabica, Magnesium citrate and Chromium picolinate; BM Nutraceuticals, Sofia) aiming to determine effects on body composition in obese and overweight NAFLD patients.

Material and methods: We have prospectively studied 53 (40 females) subjects with BMI ≥ 25 kg/m² mean aged 45 years (range 27-68) and ultrasound features of fatty liver disease. The participants were given one capsule of the nutraceutical blend twice daily for 8 weeks and were advised to keep their usual lifestyle, diet and physical activity. Measured outcomes were efficacy (anthropometric parameters, BMI, body fat percentage) and safety (adverse events, laboratory tests and vital signs).

Results: The natural blend supplementation was associated with significant decrease of the waist circumference. The mean reduction at week four was 3.3 cm (95% CI: 2.6 to 4.0), and 6.2 cm at week eight (95% CI: 5.0 to 7.5, $p < 0.0001$ for all comparisons). Mean change in hips circumference at week 8 was -4.1 cm (95% CI: 2.9 to 5.2, $p < 0.0001$). At the end of week eight was observed significant decrease in BMI (mean 29.3 vs 28.4 kg/m²) and body fat percentage ($p < 0.001$ for both). All participants reported substantial decrease in sugar cravings. There were no serious adverse events reported.

Conclusion: Supplementation with a proprietary blend of plant extracts efficiently decreases waist and hip circumference, WHR and BMI with favorable tolerability. Further long term controlled studies are needed to underline the place of the plant extracts blend in weight loss programmes in metabolic syndrome patients.

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Victor Kamburov,¹ Maria Nikolova,² Petya Spassova,³ Mihaela Petrova¹

¹Balkanmed Medical Center, Sofia, Bulgaria

²Department of Hygiene, Medical Ecology and Nutrition, Medical University, Bulgaria

³UMHATEM "N.I. Pirogov", Bulgaria

Correspondence: Mihaela Petrova, Balkanmed Medical Center, Sofia, Bulgaria, Email mpetrova@gmail.com

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Background

The prevalence of obesity increases worldwide in the last several decades affecting up to 30% of adults in some of the EU countries.¹ Obesity is a major risk factor for type 2 diabetes, non-alcoholic fatty liver disease, dyslipidemia, hypertension, cardiovascular disease, sleep apnea, and gall bladder disease.² Recent reports alarm that even metabolically healthy obese persons are in risk of developing metabolic syndrome within 10 years, suggesting increased health risks of obesity.³

The most common definition for overweight and obesity is based on Quetelet's formula or the body mass index (kg/m²). Overweight person is defined as having BMI greater than or equal to 25; and obesity is a BMI greater than or equal to 30.^{4,5} Measures of central obesity such as waist circumference (WC) and waist to hip ratio (WHR) provide more robust information than isolated BMI according to overall obesity-related health risk. Currently, general advice on nutrition and diet is the first step in the management of obesity and overweight.⁶ NAFLD is one of the features of the metabolic syndrome and its prevalence parallels the prevalence of obesity, metabolic syndrome and its components. Clinical practice guidelines advise measures aimed at lifestyle changes towards healthy diet and habitual physical activity as a first and only treatment in uncomplicated fatty liver disease.⁷

In the last decades a large amount of nutritional supplements aimed

to benefit obesity were placed on the market. Cinnamon (*Cinnamomum zeylanicum*) may activate thermogenic and metabolic responses in subcutaneous adipocytes supporting anti-obesity effects in humans.⁸ Chlorogenic Acid (CGA, 3-CQA) is one of the most important isomers which can be naturally found in green coffee extracts. CGA is a biologically active dietary polyphenol, exerting antioxidant, antibacterial, hepatoprotective, cardioprotective, anti-inflammatory, anti-obesity activity, and free radicals scavenger. It might modulate lipid metabolism and glucose in metabolic related disorders. In recent years CGA is used as a natural food supplement in overweight people.⁹ 4-Hydroxyisoleucine (4-OHIL), an amino acid isolated from fenugreek (*Trigonella foenum-graecum*) seeds, exhibits different effects on insulin resistance related to obesity. It might influence the regulation of blood glucose, plasma triglycerides, total cholesterol, free fatty acid levels, and to improve of liver function.¹⁰ On this background from the published evidences, we aimed to evaluate the effect of a proprietary blend of natural plants extracts in overweight and obese people with features of metabolic syndrome (fatty liver disease and visceral obesity).

Material and methods

We have prospectively studied 53 (40 females) subjects with BMI ≥ 25 kg/m² mean aged 45 years (range 27-68) and ultrasound features of fatty liver disease. The participants were given one capsule of the nutraceutical blend twice daily for 8 weeks and were advised to keep their usual lifestyle.

Everyone was followed up prior to inclusion for a month and served as a control subject for further intervention. Measured outcomes were efficacy (anthropometric parameters, BMI, body fat percentage) and safety (adverse events, laboratory tests and vital signs).

Each capsule contain extracts from cinnamon zeylonicum, green coffee and trigonella fenugreek in addition to chromium picolinate and magnesium citrate in a single capsule (excipients under 2%). Each participant after being consented underwent an assessment according to EASO algorithm. The primary objective was to determine the effect of the blend on waist circumference, WHR and secondly to weight loss, assessed by BMI. We have also evaluated safety signals. Patients with diabetes and ongoing diabetic medication, history of syncope, anticoagulant therapy, decompensated concomitant disease, weight loss in the last two months, pregnant and lactating women and subjects younger than 18 years were not included in the observation. We recorded demographics, medical history, height, weight and anthropometry measurements of body composition at baseline, at fourth and at eight week of follow up.

Results

We have initially screened 53 persons (40 females) and the study was completed by 40 participants. Eleven participants dropped out due to loss for follow up and two persons stopped taking the supplement because of adverse events. The natural blend supplementation was associated with significant decrease of the waist circumference. The mean reduction at week four was 3.3cm (95% CI: 2.6 to 4.0), and 6.2cm at week eight (95% CI: 5.0 to 7.5, $p < 0.0001$ for all comparisons, paired t-test). Mean change in hips circumference at week 8 was -4.1cm (95% CI: 2.9 to 5.2, $p < 0.0001$, paired t-test). At the end of week eight was observed significant decrease in BMI (mean 29.3 vs 28.4kg/m²) and body fat percentage ($p < 0.001$ for both; paired t-test).

All participants reported substantial decrease in sugar cravings. There were no serious adverse events reported and no change in the laboratory variables. Two female participants reported breast tension during the first four weeks of taking the supplement and were excluded of further treatment. They were however followed up for safety up to the end of the observation and three months later and were without safety signals up to the end of the follow up (Table 1) (Figure 1).

Table 1 Dynamics of changes as paired comparisons baseline vs week 8

	Baseline	Week 4	Week 8	p*
Waist (mean, SD)	94.8 (16.34)	90.8 (15.60)	88.5 (14.83)	<0.0001
Hip (mean, SD)	110.4 (10.50)	107.2 (10.65)	106.3 (10.31)	<0.0001
WHR (mean, SD)	0.849 (0.107)	0.839 (0.105)	0.828 (0.106)	<0.0001
BMI (mean, SD)	29.3 (5.28)	28.8 (5.186)	28.4 (5.713)	<0.0001

*Paired t-test baseline vs week 8

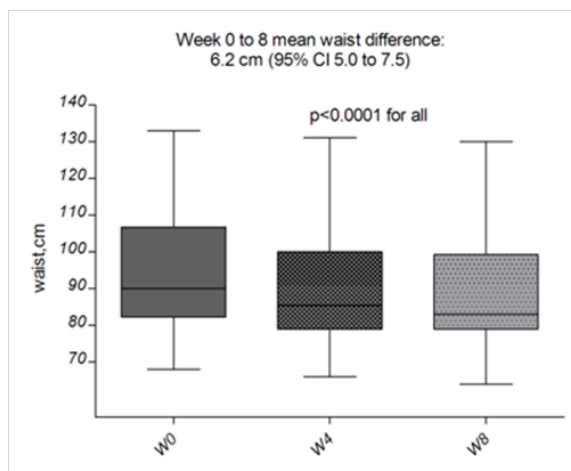


Figure 1 Change in waist circumference.

Comments

We evaluated an herbal blend which consists of cinnamon zeylonicum, green coffee and trigonella fenugreek in addition to chromium picolinate and magnesium citrate in a single capsule in overweight and obese people while following their usual lifestyle and without further diet modifications. In our study we used abdominal obesity and fatty liver disease as surrogate markers of insulin resistance and showed that this proprietary formula of plant extracts and minerals improves abdominal obesity. Increasing evidence suggests that polyphenols have a significant potential in the prevention and treatment of risk factors associated with metabolic syndrome.

Previous study showed a considerable beneficial effect of cinnamon supplementation on Asian Indians with metabolic syndrome as evident from a decrease in hyperglycemia, body weight, total adiposity, abdominal adiposity and serum lipid levels.¹¹ Beneficial effects of cinnamon were reported on normal subjects, as well as on those with prediabetes, T2DM and polycystic ovarian disease (PCOD). Various studies revealed that cinnamon is related to reduced post prandial blood glucose levels and decreased gastric emptying rate, reduced levels of postprandial insulin and increased glucagon-like peptide-1 (GLP-1) levels, which may explain the overall improvement in glycemic parameters and to some extent weight loss and decrease of waist circumference in the present study.¹² Indeed, if cinnamon acts at the cellular level in improving insulin resistance, it could be of benefit to overweight subjects with metabolic syndrome.

There are several mechanisms proposed for the beneficial effect of fenugreek extract on insulin responses and obesity. 4-Hydroxyisoleucine (4-OHile), a nonprotein amino acid isolated from fenugreek (*Trigonella foenum-graecum*) seeds, exhibits effects on insulin resistance related to obesity. It increases glucose-induced insulin release, and the insulin response mediated by 4-OHile depends on glucose concentration. The beneficial effects observed are related to the regulation of blood glucose, plasma triglycerides, total cholesterol, free fatty acid levels, and the improvement of liver function.¹⁰

Recent publications discussed that chlorogenic acid, one of the major compounds in the green coffee extract can perform crucial roles in lipid and glucose metabolism regulation and thus to benefit many disorders such as hepatic steatosis, cardiovascular disease, and obesity as well.⁹ Previous study found significant reductions in body weight, body mass index and waist circumference after few months of treatment with blend containing chlorogenic acid, inulin and other compounds in patients with metabolic syndrome.¹³ Recent systematic

review summarized the biological properties of CGA in addition to its antioxidant and anti-inflammatory effects. It found that CGA is able to exert pivotal roles on glucose and lipid metabolism regulation and on the related disorders, e.g. diabetes, cardiovascular disease (CVD), obesity, cancer, and hepatic steatosis.¹⁴

Despite the lack of control group and open labelled design, our study showed in a prospective manner that nutraceutical supplement might have beneficial role in supporting obesity treatment. It was reasonably safe and was tolerated very well, with significant reduction in anthropometric variables. It may be worthwhile to further investigate the dynamics in metabolic biomarkers and the effects of the blend on cardiovascular function. The drop-out rate might be attributed to the lack of tools of augmenting compliance like availability of free meals, phone calls, diary, etc. as we aimed not to change the usual daily activity of the participants.

The main findings of this observation were that the herbal blend, when provided together with a standard diet and without modifications of the lifestyle, promoted a significant reduction of BMI, waist circumference and WHR as compared to the baseline and the period before starting the intervention.

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Conflicts of Interest

Authors received no funding for this study; MN and PS have no potential financial interests; MP and VK own shares in BM Nutraceuticals Ltd.

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