THE OFFICIAL JOURNAL OF THE BRITISH DIETETIC ASSOCIATION

Journal of Human Nutrition and Dietetics

Journal of Human Nutrition and Dietetics

RESEARCH PAPER

Effects of a 3-month supplementation with a novel soluble highly viscous polysaccharide on anthropometry and blood lipids in nondieting overweight or obese adults

M. Lyon,*† S. Wood,* X. Pelletier,‡ Y. Donazzolo,‡ R. Gahler§ & F. Bellisle¶

*Canadian Centre for Functional Medicine, United Boulevard, Coquitlam, BC, Canada
†University of British Columbia, Food, Nutrition and Health Program, Faculty of Land and Food Systems, Main Mall, Vancouver, BC, Canada
‡Optimed Clinical Research, 1 rue des Essarts, Gieres, France
§Factors Group of Nutritional Studies Inc. R 1 D, Bonneville Place, Burnaby BC, Canada
¶Département de Médecine Sociale et Préventive, Université Laval, Québec, Canada

Keywords
blood lipids, body weight control, high viscosity fibre, obesity, overweight.

Correspondence
F. Bellisle, Département de Médecine Sociale et Préventive, Université Laval, Québec G1V 0A6, Canada.
Tel/fax.: +1 450 616 1058
E-mail: france.bellisle@kin.msp.ulaval.ca

doi:10.1111/j.1365-277X.2011.01157.x

Abstract

Background: High viscosity fibre is known to exert many beneficial effects on appetite and metabolism. It could potentially help in weight management, in dieting or nondieting individuals. The present study investigated the effects of the daily intake of a novel high viscosity polysaccharide (HVP) over 3 months in nondieting obese or overweight men and women.
Methods: The study comprised a double-blind, randomised controlled clinical trial. Participants ingested 5–15 g per day of either HVP (n = 29, experimental group) or inulin (n = 30, control group) for 15 weeks. Changes in anthropometry (weight, waist and hip circumferences), blood lipids and glucose tolerance were studied from the beginning to the end of administration. Compliance and tolerance were examined.
Results: Differences appeared between HVP and inulin supplementation in female participants only. Mean (SD) decreases in body weight [1.6 (3.2) kg; approximately 2% of initial weight] and hip circumference [2.8 (3.6) cm] occurred in women of the HVP group but not in controls (Time × Group interactions, $P \leq 0.002$). Total, high-density lipoprotein and low-density lipoprotein-cholesterol were lower at the end of supplementation in the women of the HVP group compared to controls ($P \leq 0.021$). No effect appeared in waist circumference and triacylglycerol. No difference was noted in the number or severity of the adverse effects reported in both groups. Adverse effects were mild and agreed with commonly reported reactions to intake of dietary fibre.
Conclusions: Beneficial although modest effects appeared after several weeks of daily HVP intake in nondieting obese or overweight women. The effects of HVP should be investigated in the context of a weight loss programme.

Introduction

In the context of the global obesity epidemic, strategies to facilitate weight control and weight loss have been studied extensively in recent years. Drugs acting on the brain or peripheral appetite mechanisms have been proposed for the treatment of overweight and obese individuals (Blundell, 2002; Blundell & Finlayson, 2008). Besides their potential effects on weight loss, pharmacological agents capable of curbing appetite also appear to generate more or less severe adverse effects. Many have been withdrawn from the market on this account.

Another safer approach to weight control is the use of dietary substances that induce no or mild side effects, but can facilitate the control of food intake. One important control mechanism concerns satiety, the inhibition of

eating that follows food ingestion (Blundell *et al.*, 2002). Dietary fibre has many effects that can possibly improve satiety: fibre increases food volume and decreases energy density, thereby enhancing the cognitive cues that facilitate satiety sensations (Wansink, 2004; Wansink *et al.*, 2005); fibre increases gastric volume and retards gastric emptying, which maximises the gastric signals accompanying the early phases of satiety (Havel, 2001); fibre in a food lowers its glycaemic index (Jenkins *et al.*, 1978) and affects the secretion of satiety hormones in the gut (Cani *et al.*, 2004; Adam & Westerterp-Plantenga, 2005; Delzenne *et al.*, 2007; Wren & Bloom, 2007; Reimer & Russell, 2008). Besides enhancing satiety, dietary fibres have been shown to exert beneficial effects on blood lipids (Jenkins *et al.*, 2000). A high fibre diet can decrease total cholesterol (Brown *et al.*, 1999) and improve glucose tolerance (Jenkins *et al.*, 1978).

Different types of fibres have been studied for their impact on satiety. Soluble fibres that confer viscosity to a food can increase its satiating effects (Dikeman & Fahey, 2006). Highly viscous fibre reduces subsequent food intake more than medium or low viscosity fibre (Vuksan *et al.*, 2009).

Beyond immediate effects on intake, the critical test of a satiety-enhancing substance is the ultimate influence that it can exert on weight change over time. In a multistep proof of concept, it is important to assess whether the regular intake of a potential satiety agent can indeed affect weight or health in a significant fashion. Such an effect could be a useful contributor in the context of a weight loss programme, although it might also help weight management in nondieting individuals who do not make other deliberate changes to their lifestyle.

The present randomised controlled trial examined the effects of a daily intake of high viscosity polysaccharide (HVP) over 3 months in nondieting overweight or obese individuals. As a control, another fibre (inulin) was administered to a parallel group. Changes in body mass as well as waist and hip circumferences were quantified. Other secondary outcomes were changes in blood lipids and the insulin and glucose responses to an oral glucose tolerance test (OGTT). The hypothesis was that a daily intake of HVP over 3 months would improve these parameters in nondieting overweight or moderately obese men and women.

Materials and methods

Participants

Healthy men and women were recruited by the Optimed Research Centre in Gières (France) from a file of individuals willing to participate in biomedical studies. Prior to inclusion, potential participants were examined by the medical team. The examination included the measurement of height and weight, a questionnaire on medical and surgical history, and a pregnancy test in women. Individuals with a body mass index (BMI) in the range 27–35 kg m^{-2}, aged 18–50 years, with stable weight for at least 2 months, nonsmokers (or smokers of fewer than five cigarettes a day), without past or present conditions of metabolic or digestive diseases, and without current medication that could affect appetite, were selected and randomised into experimental (HVP: 15 men and 15 women) and control (Inulin: 13 men, 17 women) groups. All participants provided their written informed consent.

Experimental and control fibres

The experimental fibre was PolyGlycopleX® (Inovobiologic Inc., Calgary, Canada) (α-D-glucurono-α-D-manno-β-D-manno-β-D-gluco), (α-L-gulurono-β-D mannurono), β-D-gluco-β-D-mannan; Inovobiologic Inc.), a novel functional fibre complex (Abdelhameed *et al.*, 2010; Harding *et al.*, 2010) manufactured by a proprietary process (EnviroSimplex®; InovoBiologic Inc.) from three natural fibres (konjac, sodium alginate and xanthan gum) to form a highly viscous polysaccharide with high water holding and gel-forming properties. Following safety studies in rodents (Matulka *et al.*, 2009) and genotoxicity testing *in vitro* and *in vivo* (Marone *et al.*, 2009), the substance has been shown to be safe for ingestion in humans (Carabin *et al.*, 2009). The composition of this product is presented in Table 1. Recent studies have shown that this product is susceptible to affect satiety in many ways: it reduces post-prandial glycaemia in a dose-dependent manner (Jenkins *et al.*, 2010) and increases the fasting levels of the satiety hormone, peptide YY (PYY) (Reimer *et al.*, 2010). It was supplied by InovoBiologic Inc. The control fibre, Inulin, was provided by Gee Lawson (London, UK). Inulin is a plant-derived fructose polymer that is undigested in the human upper gastrointestinal tract (Niness, 1999), with beneficial effects on satiety (Archer *et al.*, 2004).

The International Drug Development Technopole (Dartilly, France) received both fibres and packaged them

Table 1 Composition of the high viscosity polysaccharide per 100 g

Carbohydrate (g)	82
Fibre (g)	87
Ash (g)	8
Protein (g)	1.4
Fat (g)	0.3
Arsenic	<0.5 p.p.m.
Lead	<1.0 p.p.m.
Sodium (g)	1.25
Potassium (g)	0.4

into identical neutral bottles. The powder bottles were kept at ambient temperature.

Anthropometry

Height was measured to the nearest cm using a stadiometer. Weight was measured to the nearest 100 g using a Tanita TBF300 electronic scale (Tanita Corp., Tokyo, Japan). BMI (kg m^{-2}) was computed from measured height and weight.

Waist and hip circumferences were measured according to standard procedures (Price *et al.*, 2006). Waist circumference was measured midway between the anterior superior iliac spine and the lower base of the last rib. Hip circumference was measured at the level of the upper limit of the iliac crest.

Blood lipids

Blood samples (3.5 mL) were collected for the analysis of blood lipids [triacylglycerol, total cholesterol, high-density lipoprotein (HDL)-cholesterol, low-density lipoprotein (LDL)-cholesterol] from a catheter (Insyte-W 18G, 32 mm; Becton Dickinson, Franklin Lakes, NJ, USA) implanted in the participant's antecubital vein. Blood lipids were determined using the Hitachi 912 multiparametric automated system (Hitachi, Tokyo, Japan) [coefficient of variation (CV) 5–8%]. Enzymatic colourimetric methods were used for determination of total and HDL-cholesterol and triacylglycerol (Trinder modified). LDL-cholesterol was computed using Friedewald's equation (Friedewald *et al.*, 1972).

OGTT

A classic OGTT was carried out. The stimulus was 75 g glucose dissolved in 250 mL of water. Through the implanted Becton Dickinson catheter, blood samples (5.5 mL) were drawn 15 and 10 min prior to the administration of the glucose solution, and 60 min (T_{60}) and 120 min (T_{120}) after. Glycaemia was assayed using a glycolysis inhibitor method (GOD-PAP enzymatic colourimetric Hitachi 912 multi-parametric automated system, CV 5%). Insulinaemia was determined on AXSYM Abbott multi-parametric automated system (Abbott Laboratories, Abbott Park, IL, USA), using a microparticle enzymatic immunoassay (CV 10%). Values obtained at T_{60} and T_{120} were compared with baseline (mean of two prestimulus values) recorded on the same test day.

Protocol

A randomisation list was established using the RANUNI function of SAS software, version 8.2 (SAS Institute Inc., Cary, NC, USA), by blocks of 10 subjects. Fibres (HVP and inulin) were randomly attributed a letter code (A or B). Subjects were successively assigned a subject/treatment number that was used for the labelling of fibre bottles by the supplier. This procedure insured blinding for participants, experimenters and the statistical team until data analysis was completed.

Participants were instructed to mix the fibre powder with 125 g of low fat yoghurt [commercial brand, 251 kJ (60 kcal), 6.9 g protein, 0.1 g fat, 7.9 g carbohydrate] immediately before intake. Yoghurt was supplied in ready-to-eat portions. During the first week, fibre (3 g) was ingested twice a day, with breakfast and dinner. Measuring scoops were provided. From the second week, larger scoops were used (5 g). The prescribed intake was twice a day during the second week, and then three times a day (with each main meal) from the third week.

On the first test day, participants arrived at the laboratory early in the morning, after an overnight fast. After voiding, participants were weighed in their underwear. Then the ante-cubital catheter was implanted and blood was drawn for assays of blood lipids. The OGTT procedure followed. Before leaving the laboratory, the participants were provided with the amount of powder and yoghurt required until their next test day. Diaries were supplied for the participants to record the intake (time and amount) of powder and yoghurt, as well as any occurrence of adverse effects. Participants were instructed not to diet or attempt to lose weight.

Seven more test days were scheduled. Figure 1 presents the time course of the protocol. On each successive test day, the participants were asked to return the unused powder. Compliance with intake instructions (times and amounts ingested) and the occurrence of any adverse effects were recorded. More powder and yoghurt were supplied in sufficient amounts for supplementation until the next visit.

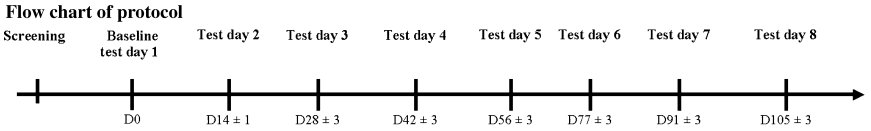
Anthropometric measurements were repeated on test days 3, 5 and 8 (following 4, 8, and 15 weeks of supplementation, respectively). On the last test day (following 15 weeks of supplementation), blood lipids and glucose tolerance (OGTT) were assessed.

Ethical considerations

The protocol was approved by the local Committee for the Protection of Persons participating in biomedical protocols and registered by French Health authorities (AFSSAPS No ID-RCB: 2008-A00674-51).

Statistical analysis

A power calculation based on expected changes in body weight (primary outcome) indicated that 22 subjects per



Screening: clinical examination, informed consent. urinary pregnancy test

Test day 1 (baseline): randomisation to control or test groups. Anthropometry, blood lipids, OGTT, yoghurt and powder delivery.

Test day 2: assessment of compliance and tolerance, yoghurt and powder delivery.

Test day 3: anthropometry, assessment of compliance and tolerance, yoghurt and powder delivery.

Test day 4: assessment of compliance and tolerance, yoghurt and powder delivery.

Test day 5: anthropometry, assessment of compliance and tolerance, delivery of yoghurt and powder.

Test day 6: assessment of compliance and tolerance, yoghurt and powder delivery.

Test day 7: assessment of compliance and tolerance, yoghurt and powder delivery.

Test day 8: anthropometry, blood lipids, OGTT, assessment of compliance and tolerance.

Figure 1 Schedule of experimental visits to the laboratory for the duration of the supplementation in participants of both groups.

group would allow the demonstration of a significant 2 kg between-group difference in body mass, with $P = 0.05$ and power at 90%. Allowing for a possible 20% dropout rate, it was decided to include 30 subjects per group.

Results are presented as the mean (SD). Participants' characteristics at baseline were compared between groups using analysis of variance (ANOVA) or Whitney–Wilcoxon tests for quantitative parameters, and chi-squared tests or Fisher's exact tests for qualitative ones. Effects of treatments over time were tested using repeated measures ANOVAS, with group (HVP versus Inulin), time of measurement and gender as fixed effects and the parameter baseline as a co-variable. In case of a significant group effect or Group × Time interaction, Tukey–Kramer tests were used for post-hoc comparisons. Whenever significant gender effects appeared, separate analyses were performed for men and women.

The number of participants reporting adverse effects was compared between groups using a chi-squared test or Fisher's exact tests. Data were analysed using SAS software, version 8.2.

Results

Participants

Individual characteristics of the participants are presented in Table 2. No difference in age, BMI, clinical or biochemical characteristics existed between groups at the beginning of the study.

One participant (a woman in the HVP group) withdrew from the study for personal reasons (moving to another town). Her data were deleted from the data set, leaving 15 men and 14 women in the HVP group.

Compliance

Based on the weight of the unused powder brought back by participants, actual intake was quantified. Compliance was estimated using the formula:

$$\%\ \text{compliance} = \text{weight of product ingested} / \text{prescribed weight of product} \times 100$$

Mean (SD) compliance was 93.7% (5.9%) in the HVP group and 94.0% (6.8%) in the control group ($P = 0.85$).

Anthropometry

Table 3 presents the anthropometric data obtained on test day 1 (baseline, before beginning of supplementation), and test days 3, 5 and 8 (following 4, 8, and 15 weeks of supplementation, respectively). No group effect ($P = 0.588$) appeared on body weight and the Group × Time interaction failed to reach statistical significance ($P = 0.051$). An analysis by gender showed that, in women only, a significant interaction occurred between group and time of measurement ($P = 0.016$). Weight did not change significantly over time in the Inulin group but, on the last test day, weights recorded in women of the HVP group were slightly lower than in controls ($P = 0.053$).

Hip circumference was not affected by group ($P = 0.533$), but a Group × Time interaction appeared ($P = 0.012$). A further analysis by gender revealed that, in women only, the Group × Time interaction was significant ($P = 0.029$). Although hip circumference remained stable in women of the Inulin group, a decrease was

Table 2 Baseline characteristics of participants in the high viscosity polysaccharide (HVP) and Inulin groups. No significant group difference existed at baseline

Group	HVP				Inulin			
	Men		Women		Men		Women	
	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)
n	15		15		13		17	
Age (year)	38.1	(7.2)	34.7	(10.4)	38.8	(7.1)	37.1	(10.8)
Weight (kg)	93.0	(8.4)	80.2	(8.7)	90.0	(9.0)	85.0	(11.1)
Height (cm)	176.7	(7.7)	163.7	(6.8)	173.4	(8.3)	163.7	(6.9)
Body mass index (kg m^{-2})	29.8	(1.2)	30.1	(2.5)	30.0	(1.5)	31.7	(1.8)

Table 3 Anthropometric measurements obtained after 0, 4, 8 and 15 weeks of daily supplementation with either high viscosity polysaccharide (HVP) or Inulin

Group	HVP				Inulin			
	Men		Women		Men		Women	
	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)
n	15		14		13		17	
Weight (kg)								
Test day 1	93.0	(8.4)	80.5	(9.0)	90.0	(9.0)	85.0	(11.1)
Test day 3	92.7	(9.1)	80.4	(9.6)	91.6	(9.0)	85.1	(10.7)
Test day 5	93.3	(9.4)	80.5	(9.9)	90.3	(9.2)	85.2	(11.0)
Test day 8	93.2	(10.6)	78.9*	(9.6)	90.9	(9.3)	85.2*	(10.6)
Hip circumference (cm)								
Test day 1	99.0	(3.4)	104.8	(7.8)	98.9	(4.5)	105.7	(8.5)
Test day 3	97.6	(3.4)	103.8	(8.2)	98.6	(5.3)	104.8	(7.3)
Test day 5	97.9	(3.2)	104.2	(8.1)	99.0	(5.6)	105.1	(7.4v
Test day 8	97.7	(4.4)	102.0*	(8.3)	99.4	(5.1)	105.2*	(7.5)
Waist circumference (cm)								
Test day 1	100.8	(4.4)	97.7	(9.1)	102.0	(6.3)	99.6	(8.6)
Test day 3	100.3	(5.1)	96.2	(8.3)	101.6	(6.1)	98.1	(7.7)
Test day 5	100.4	(5.0)	95.2	(7.7)	101.2	(5.7)	98.5	(7.2)
Test day 8	100.5	(4.6)	94.0	(7.6)	102.3	(5.8)	98.6	(7.1)

*Significant Time × Group interaction in women for weight ($P = 0.016$) and hip circumference ($P = 0.029$); last day hip circumference significantly lower in HVP than in Control group women ($P = 0.037$).

recorded on test day 8 in women of the HVP group. On test day 8, hip circumference was lower in women of the experimental group compared to controls ($P = 0.037$).

Waist circumference was not affected by group ($P = 0.89$) and there was no Group × Time interaction ($P = 0.128$).

Blood lipids

Blood lipid values are presented in Table 4. ANOVAS on total cholesterol revealed that, in women only, there was a significant group effect ($P < 0.001$) and a significant Group × Time interaction ($P < 0.001$). While no group difference existed on test day 1, total cholesterol values were significantly lower on test day 8 in the HVP than in the control group (Tukey–Kramer post-hoc test, $P < 0.001$).

The decrease in total cholesterol in women of the HVP group resulted from decreases in both LDL and HDL-cholesterol. For HDL-cholesterol, no main effect of group or time of test was revealed by the ANOVA, but a significant interaction ($P = 0.02$) showed that, although no difference between groups existed on test day 1, HDL-cholesterol on test day 8 was lower in women of the HVP group compared to controls (Tukey–Kramer post-hoc test, $P = 0.021$). For the LDL-cholesterol, group effect ($P = 0.007$) and the interaction Group × Time ($P = 0.007$) were significant. Although no group difference

Table 4 Blood lipids prior to and following 15-week supplementation with daily high viscosity polysaccharide (HVP) or Inulin

Group	HVP				Inulin			
	Men		Women		Men		Women	
	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)
n	15		14		13		17	
Total cholesterol (mmol l^{-1})								
Test day 1	5.24	(1.12)	4.88	(0.84)	5.89	(0.88)	4.93	(0.89)
Test day 8	5.06	(1.00)	4.45*	(0.69)	5.62	(0.83)	5.00*	(0.91)
HDL-cholesterol (mmol l^{-1})								
Test day 1	1.08	(0.23)	1.46	(0.38)	1.07	(0.25)	1.29	(0.27)
Test day 8	1.05	(0.24)	1.40*	(0.33)	1.06	(0.23)	1.34*	(0.22)
LDL-cholesterol (mmol l^{-1})								
Test day 1	3.48	(0.98)	2.95	(0.65)	3.78	(0.91)	3.19	(0.67)
Test day 8	3.29	(0.94)	2.56*	(0.68)	3.74	(0.82)	3.19*	(0.67)
Triacylglycerol (mmol l^{-1})								
Test day 1	1.48	(0.56)	1.03	(0.51)	1.99	(1.00)	0.99	(0.57)
Test day 8	1.57	(0.67)	1.07	(0.51)	1.82	(1.31)	1.01	(0.72)

*Significant Time × Group interaction. Significantly lower values in HVP than in control group women on day 8 ($P \leq 0.021$).

existed on test day 1, the last assays showed lower LDL values in women of the HVP group than in controls (Tukey–Kramer post-hoc test, $P = 0.001$). In men, neither main effect, nor interaction was observed.

Neither main effects, nor interactions significantly affected triacylglycerol values.

Oral glucose tolerance test

Table 5 presents the variations in blood insulin and glucose before and following a 75 g glucose load on test days 1 and 8. Pre- and post-load glycaemia values were not significantly different between groups.

Regarding insulinaemia, a statistically significant group effect appeared on the last test day, with higher values in the Inulin than in the HVP groups ($P < 0.001$). For the HVP group, no change was observed between the first and last test days.

Adverse events

The participants in both groups reported minor adverse effects. Sixty instances were reported, of which 38 were gastrointestinal disturbances: flatulence (12 reports in the Inulin group, four in the HVP group), diarrhoea (four in the Inulin group, 11 in the HVP group), nausea (one in the Inulin group, two in the HVP group), abdominal pain (one report in each group), gastrointestinal pain (one in the HVP group) and vomiting (one in the HVP group). Overall, 19 cases of gastrointestinal disorder were reported in each group. No difference between groups ($P = 0.796$) appeared for number of participants with at least one emergent adverse effect of gastrointestinal origin. Other types of adverse effects (e.g. headache) were mild and were reported equally often in both groups.

Table 5 Glucose and Insulin responses to an oral glucose load (oral glucose tolerance test) at the beginning and end of the study

Group	HVP		Inulin	
	Mean	(SD)	Mean	(SD)
n	29		30	
Glycaemia (mmol l^{-1})				
Fasting				
Test day 1	5.27	(0.38)	5.15	(0.47)
Test day 8	5.19	(0.48)	5.08	(0.46)
1 hour after glucose load				
Test day 1	7.42	(1.89)	7.35	(1.73)
Test day 8	6.99	(1.66)	7.24	(1.60)
2 hours after glucose load				
Test day 1	6.02	(1.59)	6.12	(1.36)
Test day 8	5.88	(1.48)	5.64	(1.35)
Insulin (mU l^{-1})				
Fasting				
Test day 1	8.29	(2.91)	8.64	(4.63)
Test day 8*	9.42	(4.28)	10.16	(6.26)
1 hour after glucose load				
Test day 1	61.73	(25.46)	70.41	(56.90)
Test day 8*	59.66	(32.68)	85.33	(69.98)
2 hours after glucose load				
Test day 1	42.92	(24.38)	55.36	(47.59)
Test day 8*	40.78	(28.77)	63.05	(74.80)

Discussion

The present study addressed the potential benefits of the daily intake of a high viscosity fibre supplement on

anthropometry and various health-associated parameters in nondieting overweight or moderately obese adults. The experimental product, a novel high viscosity polysaccharide, was compared with Inulin, a plant-derived polymer with demonstrated safety and beneficial effects on appetite. The daily administration of fibre was continued for 15 weeks so that the potential effects on body weight could be examined over a period of time that many meta-analyses of such effects consider meaningful (e.g. de la Hunty *et al.*, 2006). In agreement with previous literature (Jenkins *et al.*, 1978, 2000, 2010), other potential effects of the 15-week treatment were also investigated on blood lipids and glucose tolerance.

Over the course of the protocol, a few significant product (HVP versus Inulin) effects and a few product by time interactions were observed in women. No significant effect of group (HVP versus Inulin) was observed in male participants. The mechanism of the higher responsiveness of women remains unclear, although a simple hypothesis can be proposed to account for the gender difference. Because the daily amount of fibre to be ingested daily was the same for male and female participants, the amount of fibre per kg body mass was actually higher in women than men. The daily intake of fibre might have been insufficient to produce effects in men in the present study, simply because of their larger body mass. In line with this hypothesis, a recent report showed that the same HVP, administered at a fixed daily dose of 10 g, exerted a significant action on the satiety hormone PYY only in subjects with a BMI lower than 23 kg m^{-2}, regardless of gender (Reimer *et al.*, 2010). The adequate amount of HVP required to obtain beneficial effects might have to be individualised to the participant's own body mass. It cannot be ruled out that other gender-specific factors (i.e. physiological or psychological) might have contributed to the absence of effects in male participants.

The changes in the dependent variables included in the present protocol were modest, as expected in a group of nondieting overweight/obese women who were specifically instructed not to modify their lifestyle during the course of the study. In addition, the anthropometric effects of HVP were not linear over the course of the protocol but only the last day measurements showed a modest effect. This suggests that, in nondieting women, the daily intake of HVP must be continued for more than 2 months before any effects on anthropometry can be observed. Longer-term studies should confirm this hypothesis and clarify the time course of the anthropometric effects beyond 3 months.

It has often been stated that modest weight losses, representing 5–10% of initial weight, can confer many health benefits to overweight/obese individuals (Goldstein, 1992; Pasanisi *et al.*, 2001). Usually, such weight changes are achieved in the context of reducing diets or programmes. They are notoriously difficult to maintain. The 2% weight loss reported in the present study under HVP supplementation in nondieting women suggests that longer-term outcomes might be worth investigating, particularly if the early benefits proved to be cumulative.

In women of the HVP group, a decrease was observed in total cholesterol. Although this effect can be considered beneficial, it must be qualified by the fact that the net decrease was obtained from significant reductions in both HDL (favourable) and LDL (unfavourable) fractions. Glucose tolerance did not change following 15 weeks of daily intake of HVP. In the control situation, an increase in insulin response to the OGTT was observed following 15 weeks of daily intake of Inulin. This did not affect glycaemia before or following the glucose load. From this perspective, the insulin response to an OGTT appears better following 15 weeks on HVP than on Inulin, although the HVP treatment *per se* exerted no net beneficial effects.

The 15-week treatment with HVP and Inulin was well tolerated but induced minor digestive adverse effects, in agreement with previous data (Carabin *et al.*, 2009). The most often reported adverse effect associated with HVP intake was diarrhoea. The symptom was mild and transient. It remains to be demonstrated whether, over the long term, consumers would be willing to accept the mild adverse effects associated with a daily intake of HVP so as to improve body weight control or perhaps to obtain other benefits, such as a lowering of their blood cholesterol level.

In conclusion, the present randomised controlled trial of the effects of HVP suggests that a number of beneficial (although modest) changes appear after several weeks in nondieting women (lower body weight, hip circumference, and cholesterol). These effects of HVP on weight and health parameters should now be investigated over longer periods of administration and also in the context of weight loss programmes. The results obtained in the present study suggest that it might be important to adjust the amounts of daily HVP supplementation to individual body size.

Acknowledgments

The PolyGlycopleX® powder used in the protocol was a commercial grade product obtained from the producer (InovoBiologic Inc., Calgary, Canada). Inulin was obtained from Gee Lawson (UK). PGX®, PolyGlycopleX® and EnviroSimplex® are registered trademarks of InovoBio logic Inc. (Canada).

Conflict of interest, source of funding and authorship

The study was initiated and fully supported by InovoBiologic, Inc. (Canada). ML receives consulting fees from the Factors Group of Companies. SW receives consulting fees from InovoBiologic Inc. XP and YD are employees of the Optimed Clinical Research laboratory that received financial support from the sponsor. RG owns the Factors Group of Companies, which retains an interest in PolyGlycopleX®. FB participated in the analysis of the data and received financial support for the preparation of the manuscript.

This study was supported by a grant from InovoBiologic, Inc., Canada to Optimed Clinical Research.

ML, SW, XP, YD and RG designed the study, which was carried out by XP and YD at the Optimed Research Centre (Gières, France). All six authors participated in the analysis and interpretation of the data. FB wrote the article. All authors have read and approved the final version submitted for publication.

References

Abdelhameed, A.S., Ang, A., Morris, G.A., Smith, I., Lawson, C., Gahler, R., Wood, S. & Harding, S.E. (2010) An analytical ultracentrifuge study on ternary mixtures of konjac glucomannan supplemented with sodium alginate and xanthan gum. *Carbohydr. Polym.* **81**, 141–148.

Adam, T.C. & Westerterp-Plantenga, M.S. (2005) Glucagon-like peptide-1 release and satiety after a nutrient challenge in normal-weight and obese subjects. *Br. J. Nutr.* **93**, 845–851.

Archer, B.J., Johnson, S.K., Devereux, H.M. & Baxter, A.L. (2004) Effect of fat replacement by inulin or lupin-kernel fibre on sausage patty acceptability, post-meal perceptions of satiety and food intake in men. *Br. J. Nutr.* **91**, 591–599.

Blundell, J.E. (2002) A psychobiological approach to appetite and weight control. In *Eating Disorders and Obesity: A Comprehensive Textbook*. eds C.G. Fairburn & K.D. Brownell, pp. 43–49. New York, NY: Guilford Press.

Blundell, J.E. & Finlayson, G. (2008) Mechanisms and biomarkers of appetite control. *Focus on Obesity* **19**, 8–10.

Blundell, J.E., King, N.A. & Halford, J.C.G. (2002) Appetite control system and functional foods for the control of energy intake. Obesity and functional foods in Europe. In *COST Action 918*. eds A. Palou, M.L. Bonet & F. Serra, pp. 302–316. Luxembourg: European Communities.

Brown, L., Rosner, B., Willet, W.W. & Sacks, F.M. (1999) Cholesterol-lowering effects of dietary fiber: a meta-analysis. *Am. J. Clin. Nutr.* **69**, 30–42.

Cani, P.D., Dewever, C. & Delzenne, N.M. (2004) Inulin-type fructans modulate gastrointestinal peptides involved in appetite regulation (glucagon-like peptide-1 and ghrelin) in rats. *Br. J. Nutr.* **92**, 521–526.

Carabin, I.G., Lyon, M.R., Wood, S., Pelletier, X., Donazzolo, Y. & Burdock, G.A. (2009) Supplementation of the diet with the functional fiber PolyGlycopleX is well tolerated by healthy subjects in a clinical trial. *Nutr. J.* **8**, 9.

Delzenne, N.M., Cani, P.D. & Neyrinck, A.M. (2007) Modulation of glucagon-like peptide 1 and energy metabolism by inulin and oligofructose: experimental data. *J. Nutr.* **137**(Suppl), 2547S–2551S.

Dikeman, C.L. & Fahey, G.C. (2006) Viscosity as related to dietary fiber: a review. *Crit. Rev. Food Sci. Nutr.* **46**, 649–663.

Friedewald, W.T., Levy, R.I. & Fredrickson, D.S. (1972) Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. *Clin. Chem.* **18**, 499–502.

Goldstein, D.J. (1992) Beneficial health effects of modest weight loss. *Int. J. Obes. Relat. Metab. Disord.* **16**, 397–415.

Harding, S.E., Smith, I.H., Lawson, C.J., Gahler, R.J. & Wood, S. (2010) Studies on macromolecular interactions in ternary mixtures of konjac glucomannan, xanthan gum and sodium alginate. *J. Carbpol.* **10**, 1016–1020.

Havel, P.J. (2001) Peripheral signals conveying metabolic information to the brain: short-term and long-term regulation of food intake and energy homeostasis. *Exp. Biol. Med. (Maywood)* **226**, 963–977.

de la Hunty, A., Gibson, S. & Ashwell, M. (2006) A review of the effectiveness of aspartame in helping wiht weight control. *Br. Nutr. Found. Nutr. Bull.* **31**, 115–128.

Jenkins, D.J.A., Wolever, T.W., Leeds, A.R., Gassull, M.A., Haisman, P., Dilawari, J., Goff, D.V., Metz, G.L. & Alberti, K.G. (1978) Dietary fibres, fibre analogues, and glucose tolerance: importance of viscosity. *Br. Med. J.* **27**, 392–1394.

Jenkins, D.J., Kendall, C.W., Axelsen, M., Augustin, L.S. & Vuksan, V. (2000) Viscous and nonviscous fibres, nonabsorbable and low glycaemic index carbohydrates, blood lipids and coronary heart disease. *Curr. Opin. Lipidol.* **11**, 49–56.

Jenkins, A.L., Kacinik, V., Lyon, M.R. & Wolever, T.M.S. (2010) Reduction of postprandial glycemia by the novel viscous polysaccharide PGX, in a dose-dependent manner, independent of food form. *J. Am. Coll. Nutr.* **29**, 92–98.

Marone, P.A., Lyon, M., Gahler, R., Donath, C., Hofman-Huther, H. & Woods, S. (2009) Genotoxicity studies of PolyGlycopleX (PGX): a novel dietary fiber. *Int. J. Toxicol.* **28**, 318–331.

Matulka, R.A., Lyon, M.R., Wood, S., Marone, P.A., Merkel, D.J. & Burdock, G.A. (2009) The safety of PolyGlycopleX (PGX) as shown in a 90-day rodent feeding study. *Nutr. J.* **8**, 1.

Niness, R.R. (1999) Inulin and oligofructose: what are they? *J. Nutr.* **129**, S1402–S1406.

Pasanisi, F., Contaldo, F., de Simone, G. & Mancini, M. (2001) Benefits of sustained moderate weight loss in obesity. *Nutr. Metab. Cardiovasc. Dis.* **11**, 401–406.

Price, G.M., Uauy, R., Breeze, E., Bulpitt, C.J. & Fletcher, A.E. (2006) Weight, shape, and mortality risk in older persons: elevated waist-hip ratio, not high body mass index, is associated with a greater risk of death. *Am. J. Clin. Nutr.* **84**, 449–460.

Reimer, R.A. & Russell, J.C. (2008) Glucose tolerance, lipids, and GLP-1 secretion in JCR:LA-cp rats fed a high protein fiber diet. *Obesity (Silver Spring).* **16**, 40–46.

Reimer, R.A., Pelletier, X., Carabin, I.G., Lyon, M., Gahler, R., Parnell, J.A. & Wood, S. (2010) Increased plasma PYY levels following supplementation with the functional fiber PolyGlycopleX in healthy adults. *Eur. J. Clin. Nutr.* **64**, 1186–1191.

Vuksan, V., Panahi, S., Lyon, M., Rogovik, A.L., Jenkins, A.L. & Leiter, L.A. (2009) Viscosity of fiber preloads affects food intake in adolescents. *Nutr. Metab. Cardiovasc. Dis.* **19**, 498–503.

Wansink, B. (2004) Environmental factors that increase the food intake and consumption volume of unknowing consumers. *Annu. Rev. Nutr.* **24**, 55–479.

Wansink, B., Painter, J.E. & North, J. (2005) Bottomless bowls: why visual cues of portion size may influence intake. *Obes. Res.* **13**, 93–100.

Wren, A.M. & Bloom, S.R. (2007) Gut hormones and appetite control. *Gastroenterology* **132**, 2116–2130.