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The effects of concentrated barley β-glucan on blood lipids in a population of hypercholesterolaemic men and women

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Barley, like oats, is a rich source of the soluble fibre β-glucan, which has been shown to significantly lower LDL-cholesterol (LDL-C). However, barley foods have been less widely studied. Therefore, we evaluated the LDL-C-lowering effect of a concentrated barley β-glucan (BBG) extract as a vehicle to deliver this potential health benefit of barley. In a 10-week blinded controlled study, subjects were randomized to one of four treatment groups or control. Treatment groups included either high molecular weight (HMW) or low molecular weight (LMW) BBG at both 3 and 5 g doses. Treatment was delivered twice per day with meals in the form of two functional food products: a ready-to-eat cereal and a reduced-calorie fruit juice beverage. Levels of total cholesterol, LDL-C, HDL-cholesterol (HDL-C), and TAG were determined at baseline and after 6 weeks of treatment. The study group comprised 155 subjects. All treatments were well tolerated and after 6 weeks of treatment the mean LDL-C levels fell by 15 % in the 5 g HMW group, 13 % in the 5 g LMW group and 9 % in both the 3 g/d groups, versus baseline. Similar results were observed for total cholesterol. HDL-C levels were unchanged by treatment. Concentrated BBG significantly improves LDL-C and total cholesterol among moderately dyslipidaemic subjects. Food products containing concentrated BBG should be considered an effective option for improving blood lipids.

Soluble fibre: Barley: LDL-cholesterol: CVD

CVD is the leading cause of morbidity and mortality for both men and women in the USA with over 1·4 million deaths and 865 000 myocardial infarctions each year (American Heart Association, 2005). The National Cholesterol Education Program's Adult Treatment Panel III (ATP III) has developed guidelines for reducing the risk of CVD which strongly urge lifestyle modification, including dietary changes, as the foundation and initial intervention for persons at risk for CVD (National Cholesterol Education Program, 2001). An important component of the lifestyle modification is a 'heart-healthy' diet, which specifically includes a recommendation for consumption of at least 5–10 g viscous soluble fibre (VSF) per day. As much as 10–25 g/d can provide additional LDL-lowering effects in some individuals. The current average intake of VSF in the USA is well below that at about 3–4 g/d (Bazzano *et al.*, 2003).

The ATP III guidelines emphasize attainment of a healthy level of LDL-C as the primary goal in CVD risk reduction. Clinical trials using VSF treatments have shown the potential for a 10–15 % reduction in LDL-C when it is added to a 'heart-healthy' diet (Bell *et al.*, 1990; Behall *et al.*, 2004*a*, b). VSF is found naturally in some grains, especially oats and barley, in select fruits, such as apples, guava and pears, and in most legumes (e.g. peas and pinto beans). It can also be consumed as a dietary supplement (e.g. psyllium). Despite recommendations for increased intakes of VSF in the diet, most individuals do not meet the recommended levels due, in part, to poor palatability of some fibres and the need to consume a relatively large amount of naturally high-fibre foods in order to achieve the desired level.

In an effort to increase consumption of VSF, concentrated extracts of β-glucan VSF have been added to foods and have been effective in modifying CVD risk (Behall *et al.*, 1997). Recently, a process has been developed for extracting the β-glucan from barley to achieve a barley β-glucan (BBG) concentrate with weight-average molecular weight in the range of 50–400 kDa. This represents a reduction in molecular weight from native (high molecular weight (HMW)) BBG, with weight-average molecular weight of 1000 kDa. This reduction in molecular weight improves BBG sensory properties and performance in foods. Food scientists have successfully incorporated it into foods (e.g. cereals, juices and baked goods) to produce palatable food products which are high in VSF.

The present paper reports the results of a clinical trial of concentrated BBG extract in human subjects. The paper

Abbreviations: ATP III, National Cholesterol Education Program's Adult Treatment Panel III; BBG, barley β-glucan; HDL-C, HDL-cholesterol; HMW, high molecular weight; LDL-C, LDL-cholesterol; LMW, low molecular weight; VSF, viscous soluble fibre; TAG, triglycerides; CVD, Cardiovascular Disease; CHD, Coronary Heart Disease.

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focuses on the blood lipid results of this intervention. Additional manuscripts are in review or preparation that will report results on insulin sensitivity, adipocytokines, and other CVD risk factors. The aim of the present study was to evaluate the efficacy of a diet augmented with food products (cereal and juice beverage) that were enriched with BBG to increase their VSF content. The study population included subjects at moderate CVD risk who would be considered candidates for the ATP III therapeutic lifestyle changes. The primary variable of interest was the change in LDL-C using two different doses (3 and 5 g) of both low molecular weight (LMW) and HMW forms of BBG. Of particular interest was the percentage of subjects who attained their personal risk-adjusted LDL-C goal using this daily therapy.

Methods

Subjects

The study group comprised men ($n = 75$) and women ($n = 80$) aged 25–73 years who met the National Cholesterol Education Program ATP III criteria for diet therapy due to elevated LDL-C. From September 2003 to October 2004, subjects were recruited from the University of Minnesota-Twin Cities and the greater Twin Cities area. The study was approved by the University of Minnesota Institutional Review Board, and all subjects gave informed consent. Inclusion criteria were: LDL-C between 1300 and 1900 mg/l; TAG $<$ 400 mg/l; fasting glucose $<$ 1260 mg/l. Individuals were excluded if they had diabetes, cancer, secondary hyperlipidaemia, CVD or other chronic medical conditions; TAG $>$ 4000 mg/l; BMI $\geq$ 40; or a large or unexplained weight change within the previous 6 months. In addition, individuals were excluded if they were taking lipid-altering medications or dietary supplements (2 months prior to screening) which might affect blood lipids; consumed greater than two alcoholic beverages per day on a regular basis; were allergic to aspirin, grain products or any ingredients used in the treatment foods; were following a special diet; or had smoked within the past year. Pregnant and lactating women were also excluded.

Study design

This randomized, double-blind, controlled, five-arm parallel group trial consisted of a 4-week diet stabilization phase followed by a 6-week treatment period. Individuals meeting all inclusion criteria as determined at an initial screening visit were eligible to enter diet stabilization (Fig. 1). These participants attended a group education class in which they were given dietary instruction to consume a diet low in saturated fat and trans-fats ($<$10 % of kJ/d) and to discontinue any lipid-altering dietary supplements. Participants who still met all inclusion criteria after the diet period were randomly allocated using a block randomization scheme to receive one of five treatments: low-dose (3 g) LMW BBG, high-dose (5 g) LMW BBG, low-dose HMW BBG, high-dose HMW BBG or control. Subjects were instructed to continue following the low saturated and trans-fat diet and to maintain other lifestyle habits throughout the study. Subjects returned to the clinic for evaluation of side-effects and compliance after 3 and 6 weeks of treatment. Blood pressure, blood lipids, blood apo and other CVD risk markers were evaluated at baseline and at the end of treatment.

Treatment

Two food products were chosen as vehicles to deliver the BBG (Barliv™ barley β-glucan concentrate; Cargill Health and Food Technologies, Wayzata, MN, USA): ready-to-eat cornflakes breakfast cereal and a low-energy tropical juice beverage containing 5 % fruit juice. The foods were formulated such that their nutritional profiles were consistent with FDA heart health claim requirements. Prior to the study, an informal screening exercise was conducted to confirm the sensory acceptability of the treatment foods.

The cereal and juice were packaged in single-serving packages (one cup of cereal or juice per serving) and subjects received a 3-week supply of treatment at baseline and after 3 weeks of treatment. They were instructed to consume two packages of juice beverage and one package of cereal with meals each day (Table 1). Subjects were instructed to save all used and unused cereal and juice containers. These were collected and counted at weeks 3 and 6 as a measure of compliance.

Clinical and laboratory measurements

All visits were conducted at the University of Minnesota General Clinical Research Center. At the screening visit a general medical history was obtained; blood pressure, height and weight were measured; and blood samples were collected to assess fasting chemistry and lipid values. Fasting lipids and lipoproteins were reassessed after the diet stabilization period. Scheduled visits during the treatment period were at baseline and weeks 3 and 6. At all treatment visits, blood pressure and weight were measured and side-effects were assessed. At baseline and week 6, blood was drawn to assess total cholesterol, HDL-C, LDL-C, and TAG.

All blood draws and clinical measurements were performed by University of Minnesota General Clinical Research Center medical staff. Weight and height measurements were obtained with subjects wearing indoor clothing and no shoes. Blood pressure measurements were obtained with an automatic Colin® blood pressure monitor (Pressmate® BP/8800C; Medical Instruments Corp., San Antonio, TX) after subjects had rested in a seated position for at least 5 min. Measurements were repeated four times at 1 min intervals, and the mean of the last three readings was used in analyses. All blood samples were obtained using standard venepuncture techniques after subjects had fasted for 12 h. All laboratory analysis was done using standard automated technology at the Quest Diagnostics® Laboratory (Wood Dale, IL) branch laboratory (certified and accredited laboratory by the Clinical Laboratory Improvement Amendment of 1988 and the College of American Pathologists) or at the University of Minnesota. Specifically, total cholesterol, LDL-C and TAG concentrations were determined using enzymatic methods with Olympus reagents, with automated spectrophotometry performed on Olympus AU5400®. HDL-C was determined directly using Roche reagents on the Olympus AU5400®.

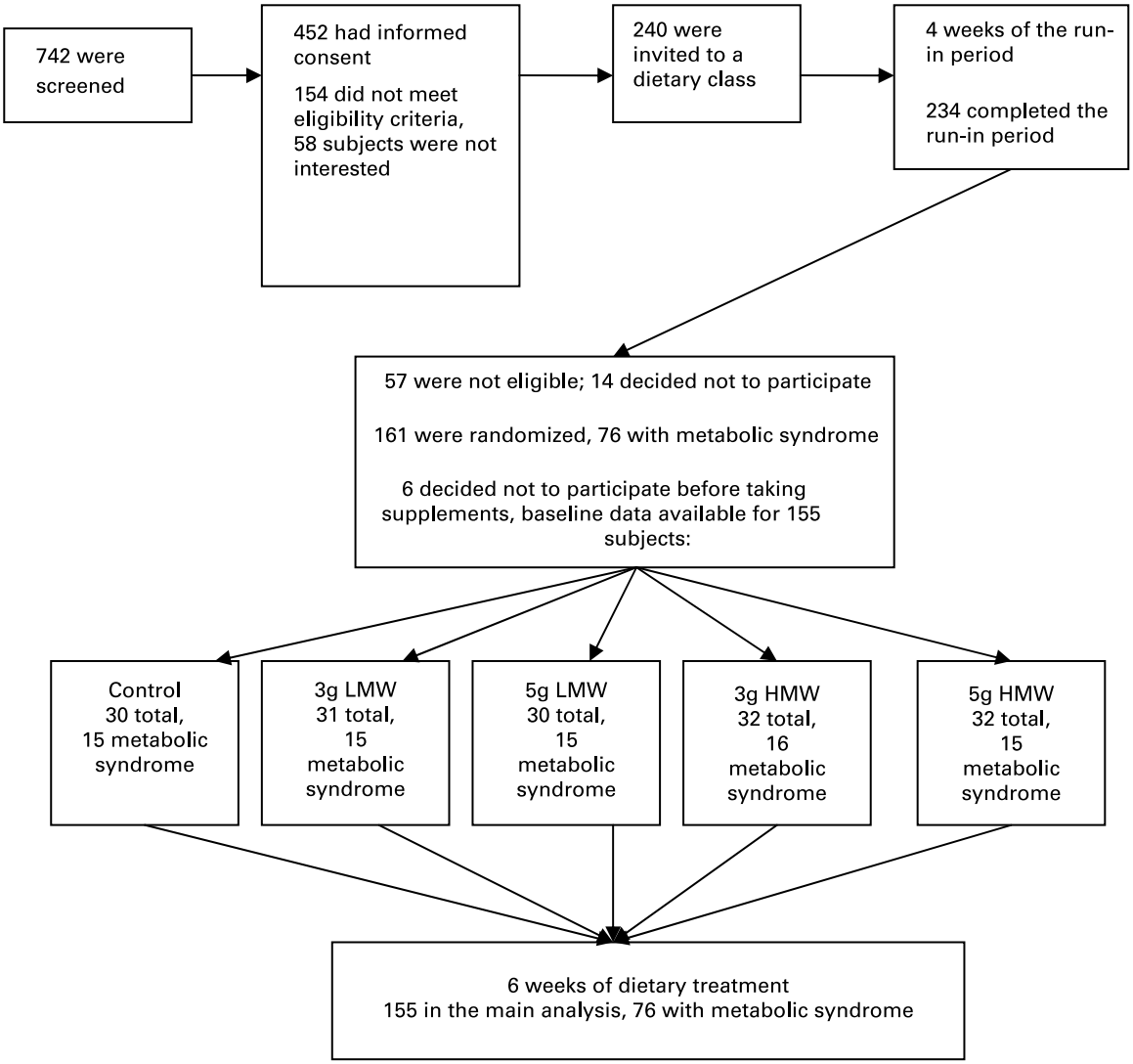

Fig. 1. Flow diagram of study eligibility for concentrated barley β-glucan extract trial. HMW, high molecular weight; LMW, low molecular weight.

Dietary data were collected during the treatment period to monitor diet compliance and consistency. Each subject completed a 3 d food record during the first and last week of treatment and returned them at weeks 3 and 6. Research staff reviewed the records for completeness and clarity during the study visits. Food records were analysed for energy, macronutrient and micronutrient intake using Nutrition Data System for Research software version 5·0_35 (NDS-R; Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN, USA).

Study-related side-effects were assessed by a thirteen-question side-effect questionnaire completed at baseline and subsequent treatment visits. Participants were asked to check the category that best represented their symptoms over the last month at baseline or since their last study visit at each subsequent visit. The categorical options for each symptom were 'Not at all', 'Somewhat', 'Moderately', 'Very much' or 'Extremely'. Frequency counts were used in the analyses and were categorized in two ways: (1) dichotomized as 'Any' *v.* 'No' side-effects or (2) the top two categories were collapsed and were used to indicate the presence of side-effects. Analyses were conducted using both methods of determining side-effects.

Statistical analysis

Differences in baseline demographic and clinical variables among the treatment groups were compared using ANOVA for continuous variables and the χ^2 test for categorical variables. The treatment effect was based on the measurement and comparison of the mean levels of lipids and lipoproteins among treatment groups using ANOVA. The GENMOD procedure of SAS version 8 (SAS Institute Inc., Cary, NC, USA) was used to perform the analyses. In addition, a χ^2 test was performed comparing all side-effect counts (frequencies) at baseline, mid-study and post-study visits. Regression analysis using a general linear model was used to determine the differences in side-effects over time and between the treatment groups and the control group. Test of independent proportions was used to compare the percentage of subjects who attained their LDL-C goal in the treatment groups versus the control

Table 1. Treatment schedule by group

	Juice†		Cereal‡		
Treatment group	Servings consumed	BBG consumed (g)	Servings consumed	BBG consumed (g)	Total BBG consumed (g)
Control (0 BBG/d)	Two cups/d at 0 g BBG/serving	0	One cup/d at 0 g BBG/serving	0	0
High dose HMW (5 g HMW BBG/d)	Two cups/d at 1·0 g BBG/serving	2·0	One cup/d at 3·0 g BBG/serving	3·0	5·0
High dose LMW (5 g LMW BBG/d)	Two cups/d at 1·0 g BBG/serving	2·0	One cup/d at 3·0 g BBG/serving	3·0	5·0
Low dose HMW (3 g HMW BBG/d)	Two cups/d at 0·75 g BBG/serving	1·5	One cup/d at 1·5 g BBG/serving	1·5	3·0
Low dose LMW (3 g LMW BBG/d)	Two cups/d at 0·75 g BBG/serving	1·5	One cup/d at 1·5 g BBG/serving	1·5	3·0

BBG, barley β-glucan; HMW, high molecular weight; LMW, low molecular weight.
† Subjects consumed two juice drinks per day: one with breakfast and the other with their largest meal.
‡ Subjects consumed one cereal per day as part of their breakfast and in lieu of their usual cereal.

group. Statistical significance adjustments were made using Dunnett's test for multiple comparisons.

Results

All baseline variables were similar among the treatment groups (Tables 2 and 3). The mean age overall was 55 years (age range 25–73 years). The ratio of men to women was similar in each treatment arm. The mean BMI between the groups was similar, with each group being borderline obese by National Institutes of Health and WHO standards. The proportion of subjects in each group that had a positive family history of CHD (as defined by the ATP III guidelines) was similar between the treatment groups. Each treatment group was block stratified on metabolic syndrome status resulting in an even distribution of metabolic and non-metabolic syndrome subjects in each group. Metabolic syndrome status was determined according to the ATP III guidelines (elevated TAG, low HDL-C, elevated blood pressure or blood pressure medication, elevated glucose and/or elevated waist girth) and meeting at least three of the five criteria. All study subjects were determined to be generally healthy at baseline and without history of CHD; 38 % had two or more CHD risk factors while 62 % had 0–1 CHD risk factors. For all study participants the mean baseline levels for blood lipids and lipoproteins were as follows (in mg/l): LDL-C, 1540 (range 1100–2200); total cholesterol, 2350 (range 1840–3270); HDL-C, 500 (range 270–1040); TAG, 1600 (range 440–4680).

The mean changes in total cholesterol, LDL-C, TAG and TC/HDL-C for the different treatment groups are shown in Table 3. After 6 weeks of treatment, total cholesterol dropped significantly in all treatment groups compared to control. Specifically, total cholesterol was reduced by 12 % in the 5 g HMW group, a decrease that was slightly more than the other treatment groups: 5 g LMW group, 11 % reduction; 3 g HMW group (−190 mg/l), 8 % reduction; 3 g LMW group, 7 % reduction. LDL-C levels were significantly reduced from baseline in all treatment groups compared to control. The 5 g HMW group experienced a 15 % drop in LDL-C where LDL-C was reduced by 13 % in the 5 g LMW group, 9 % in the 3 g HMW group and 9 % in the 3 g LMW group.

Table 2. Subject characteristics at baseline by treatment group and overall totals†

	Control ($n = 30$)		5 g, HMW ($n = 32$)		5 g, LMW ($n = 30$)		3 g, MW ($n = 32$)		3 g, LMW ($n = 31$)		Total ($n = 155$)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age	53·7	12·5	58·6	10·6	52·8	11·9	53·9	10·2	55	10·1	54·8	11·1
BMI	30·8	4·0	28·9	6·7	28·9	5·3	29·6	5·9	28·1	4·3	28·8	5·3
Body weight (kg)	82·8	15·1	81·7	19·8	80·7	16·8	86·4	19·4	80·7	14·9	82·5	17·2
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
CHD family history	6	20	11	34·4	9	30	10	31·3	9	29	45	29
Metabolic syndrome‡	15	50	15	46·9	15	50	16	50	15	48·4	76	49
Gender												
Male	17	56·7	15	46·9	11	36·7	16	50·0	16	51·6	75	48·4
Female	13	43·3	17	53·1	19	63·3	16	50·0	15	48·4	80	51·6
Race												
Caucasian	30	100	29	90·6	28	93·3	30	93·8	29	93·5	146	94·2

HMW, high molecular weight; LMW, low molecular weight.
† For details of treatment groups, see Table 1. χ^2 tests of association between groups were performed for gender and ANOVA. *F* tests were performed for age and BMI. *P* values were not significant ($P > 0{\cdot}09$).
‡ Each group was block stratified on metabolic syndrome status as defined by the National Cholesterol Education Program's Adult Treatment Panel III guidelines.

Table 3. Blood lipids results at baseline (Pre) and after 6 weeks of treatment (Post) by treatment group†

	Control ($n = 30$)		5 g, HMW ($n = 32$)		5 g, LMW ($n = 30$)		3 g, HMW ($n = 32$)		3 g, LMW ($n = 31$)	
Variable	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
TC										
Pre	234·0	22·7	235·1	25·3	238·0	27·6	233·6	22·8	235·9	23·0
Post	231·3[a]	26·9	205·9*[b]	25·1	211·6*[b]	20·2	214·5*[b]	21·6	218·8*[b]	20·1
TAG										
Pre	153·9	75·4	158·3	79·2	166·7	91·7	164·7	88·7	154·9	61·7
Post	158·8[a]	64·7	133·7*[b]	47·4	145·7*[a]	62·7	152·5[a]	55·8	142·2*[a]	49·2
HDL-C										
Pre	50·5	14·4	50·8	14·2	50·4	13·7	47·9	10·7	49·6	14·8
Post	49·9	13·8	51·9	12·7	49·7	12·8	47·4	11·2	50·8	15·8
TC/HDL-C										
Pre	4·9	1·2	4·9	1·3	5·0	1·4	5·1	1·2	5·0	1·2
Post	5·0[a]	1·4	4·2*[b]	1·0	4·5*[b]	1·2	4·8[a]	1·1	4·6*[b]	1·3
LDL-C										
Pre	152·7	13·9	154·5	16·5	154·6	19·9	152·8	18·1	153·9	15·1
Post	150·9[a]	24·3	132·0*[b]	11·4	134·3*[b]	12·8	138·8*[b]	20·3	140·5*[b]	15·1

HDL-C, HDL-cholesterol; HMW, high molecular weight; LDL-C, LDL-cholesterol; LMW, low molecular weight; TC, total cholesterol.
[a,b] Mean values within a row with unlike superscript letters were significantly different (with adjustments for multiple comparisons; $P < 0·05$).
Mean values were significantly different from those of the baseline (paired Student's *t*-tests): *$P < 0·05$.
† For details of treatment groups, see Table 1. ANOVA *F* tests were done for each variable. No significant differences were found between groups at baseline ($P > 0·60$).

Fasted TAG levels were reduced from baseline in all treatment groups except the 3 g HMW group (Table 3), while the control group experienced a modest increase. However, after adjusting for multiple comparisons only the 5 g HMW group experienced a significant drop in TAG levels compared to control. Fasted TAG level was reduced by 16 % in the 5 g HMW group. There were no significant changes from baseline in any of the treatment groups regarding HDL-C.

Table 3 shows the decrease in the total cholesterol/HDL-C ratio in all the treatment groups at the final study visit. The ratio of total cholesterol/HDL-C was significantly changed by treatment in all the treatment groups except the 3 g HMW group. The 5 g HMW group experienced a 15 % drop in the total cholesterol/HDL-C ratio while this ratio was reduced by 10 % in the 5 g LMW group and 9 % in the 3 g LMW group. The 3 g HMW group also experienced a reduction in the total cholesterol/HDL-C ratio from baseline but this change was not significantly different from the control group after adjusting for multiple comparisons.

Diet was unchanged throughout the study in both the treatment groups and the control group. All treatment groups (but not the control group) attained the ATP III guidelines goal of ≥ 10 g VSF/d when the dose of the treatment fibre was added to the background dietary soluble fibre intake. Body weight was unchanged over the duration of the study in all study groups.

The treatment was well tolerated by most subjects, with excellent compliance (average treatment compliance by group: control, 96 %; 5 g HMW, 95 %; 5 g LMW, 97 %; 3 g HMW, 94 %; 3 g LMW, 97 %). The fact that there were no study dropouts further indicates the tolerability of the study treatments. Moreover, adverse events were monitored at all study visits and none were reported. Treatment-related side-effects were also assessed at each study visit. There were no differences in the frequency of side-effects at baseline between any of the study treatment groups or the control group. Additionally, there was no change in the frequency of side-effects from baseline to the mid-study visit or to the final study visit in any of the treatment groups when compared to the control group except for the frequency of intestinal gas. In all groups except the control group the frequency of intestinal gas increased over the first 3 weeks of the study and persisted over the final 3 weeks of treatment. However, the change in frequency of intestinal gas only reached statistical significance in the 5 g HMW group (at week 3 and week 6 of treatment) when all treatment groups were compared to the control group ($P < 0·05$).

Table 4. LDL-cholesterol goal attainment at baseline and week 6 by number of CHD risk factors†

Treatment group	Zero or one CHD risk factors at baseline	Zero or one CHD risk factors at week 6	Two or more CHD risk factors at baseline	Two or more CHD risk factors at week 6
Total ($n = 154$)	66/95	80/95	2/59	20/59
Control ($n = 30$)	19/22	15/22	0/8	0/8
5 g HMW ($n = 32$)	12/17	15/17	1/15	8/15
5 g LMW ($n = 29$)‡	15/21	20/21	0/8	4/8
3 g HMW ($n = 32$)	9/18	15/18	1/14	7/14
3 g LMW ($n = 31$)	11/17	15/17	0/14	1/14
Any BBG treatment ($n = 124$)	47/73	65/73	2/51	20/51

BBG, barley β-glucan; HMW, high molecular weight; LDL-C, LMW, low molecular weight.
† For details of treatment groups, see Table 1. CHD risk factors as defined by National Cholesterol Education Program's Adult Treatment Panel III guidelines.
‡ One subject was left out of analysis (5 g LMW group) because we were unable to get all risk factor data.

The National Cholesterol Education Program ATP III guidelines were applied to each study participant to determine his or her LDL-C goal of therapy based on level of CHD risk (Table 4). A greater percentage of individuals in the treatment groups attained their LDL-C goal compared to the control group. At study conclusion 89 % of those with zero or one CHD risk factors who received any study treatment had attained their LDL-C treatment goal compared to 68 % in the control group. Similarly, among the subjects with two or more CHD risk factors, 39 % (20/51) who received any of the study treatments attained their LDL-C goal compared to 0 % (0/8) in the control group ($P<0{\cdot}05$).

Discussion

The aim of the present study was to assess the impact of BBG-enriched foods on CVD risk factors, specifically LDL-C and other blood lipid levels, in human subjects with moderate dyslipidaemia. The present study demonstrated that both HMW and LMW BBG, when added at either 3 or 5 g/d, reduced the primary study variable, LDL-C, with significant reductions at both the 3 g and 5 g daily dose. Reductions were 9 % for the 3 g dose and 15 % or 13 % for the 5 g dose (HMW and LMW, respectively). Additionally, total cholesterol was significantly reduced among all treatment groups, while the ratio TC/HDL was more significantly reduced among the 5 g/d groups. The present findings demonstrate that the efficacy of a BBG-enriched diet in modifying blood lipid CVD risk factors is at least comparable to previous clinical trials of VSF-enriched diets. As important, the LMW BBG which has even greater therapeutic potential because of its improved sensory properties and performance in foods demonstrated comparable efficacy to the HMW BBG in blood lipid improvement.

An important study outcome that is a corollary to the LDL-C reduction is the number of subjects who were able to attain their personal LDL-C goal as established by the ATP III guidelines. The ATP III guidelines use a system of assessing core CVD risk factors to establish the LDL level or cut point at which an individual can consider their efforts at risk reduction successful (National Cholesterol Education Program, 2002). If a person does not reach their goal with lifestyle changes, then they will generally need to progress to more aggressive interventions such as pharmacotherapy. It is an additional important measure of the efficacy of the BBG intervention that 69 % of the subjects in the treatment groups were able to attain their LDL-C goal as opposed to 50 % of the control group on a 'heart-healthy' diet alone. Of particular note is the fact that all treatment groups, both the 3 g and 5 g LMW and HMW groups, showed a substantial increase in persons reaching their ATP III goal for LDL-C. The study subjects were only moderately dyslipidaemic; 40 % of the subjects in the treatment groups and 63 % of the control group had already achieved their LDL-C goal on the run-in diet. Nevertheless, LDL-C is a continuous risk variable and additional improvement in LDL-C levels with the BBG intervention further enhanced their CVD risk reduction and maintenance of healthy lipid levels.

Overall compliance with study treatments and the lack of significant study-related side-effects demonstrated excellent acceptance and tolerance of BBG. As is common with an increase in fibre intake, subjects on active treatment did report an initial increase in intestinal gas, but for most subjects this side-effect did not increase over the duration of the study. Three-day food records obtained at baseline and at the end of the study indicated that subjects were generally compliant with overall diet recommendations and there were no significant changes in energy consumption or specific nutrient intake over the 6-week period. Of note, all subjects within the four treatment groups attained the ATP III goal of consumption of 10–25 g VSF/d when the treatment dose of BBG was added to their background VSF consumption on the 'heart-healthy' diet.

To date, most of the human studies investigating the hypocholesterolaemic effects of β-glucan have utilized diets rich in oat and oat products. However, human clinical trials have been conducted using barley foods as the source of β-glucan as well. (McIntosh *et al.* 1991) conducted one of the first trials comparing diets rich in barley versus wheat in a cross-over design. Compared to the wheat period, the barley diet period resulted in a 6 % lower total cholesterol level and a 7 % lower LDL-C level. In 2004, Behall *et al.* reported that adding 6 g soluble fibre from barley per day for 5 weeks in addition to a Step 1 diet resulted in a 24 % reduction in LDL-C (Behall *et al.*, 2004*b*). However, not all studies investigating the cholesterol-altering effects of barley have reported a treatment effect. (Keogh *et al.* 2003) reported that adding β-glucan-enriched barley to the diets of hypercholesterolaemic men containing 38 % of kJ from fat did not significantly reduce total or LDL-C levels.

To date, there have been even fewer studies investigating the cholesterol-altering effects of extracted β-glucan. There have been a few studies showing the benefit of oat β-glucan extract in CVD risk reduction (Behall *et al.*, 1997). However, there has only been one previous study reporting a dietary intervention using β-glucan extracted from oats with molecular weight modification (Frank *et al.*, 2004): the study used 6 g/d oat β-glucan extract (both LMW and HMW) for 3 weeks and failed to show a significant effect on blood lipids, specifically LDL-C. Compared to the findings in the present trial, the results of (Frank *et al.* 2004) would suggest that the extent of the molecular weight reduction of the β-glucan fibre could significantly alter its hypocholesterolaemic action. Additionally, it is apparent from a review of the literature that not all soluble fibre forms and sources have comparable effects on CVD risk factors (Truswell, 1995).

Experts contend that the LDL-C-lowering effects of high-VSF foods, such as oats and barley, are due to the action of VSF in the gastrointestinal tract. VSF has been shown to increase the elimination of bile salts, and secondarily, bacterial fermentation products (SCFA) have been shown to suppress hepatic cholesterol biosynthesis (Marlett *et al.*, 1994). There is a substantial body of knowledge supporting these mechanisms of action, and this persuaded the (US Food & Drug Administration 1993) to grant the first health claim for reduced risk of heart disease in 1993 to foods rich in soluble fibre from oats.

Lowering the molecular weight of β-glucan does improve sensory properties and performance in foods, but it can also reduce the viscosity of the fibre, thus the tradeoff can be a decrease in efficacy. This appears to be the reason that some previous studies of other LMW β-glucans in animals and man had reduced efficacy (Yamada *et al.*, 1999; Frank *et al.*,

2004). In addition, some feel that any β-glucan extract, even a concentrated source, loses some of the important components, such as polyphenolics and antioxidants, present in whole-grain products and thereby may be less effective in overall CVD risk reduction. (Jacobs & Gallaher 2004) have reviewed a number of prospective trials and have concluded that consumption of whole-grain products reduces CVD risk. The present study of foods enriched with extracted BBG demonstrates their efficacy in reducing LDL-C, a major surrogate marker for CVD, and gives support to the position that extracted VSF can significantly reduce CVD risk.

A study of longer duration may be helpful to show maintenance of the benefit. Further, in order to generalize the results to a broader, more diverse population, it may be helpful to study certain subgroups and other population groups over the age of 65.

Conclusion

The present study demonstrates the efficacy and excellent tolerance of a dietary intervention using BBG-enriched foods to reduce CVD risk, specifically LDL-C. All subjects in BBG treatment groups were able to reach the ATP III dietary goal of consumption of 10–25 g/VSF d. An important finding in the present study was that LMW BBG had comparable efficacy gram for gram when compared to native HMW BBG. This is clinically important because the improved sensory properties and performance in foods of LMW BBG make it a more viable food ingredient for broader applications. An additional important outcome of the present study was that a greater number of BBG-treated subjects versus control attained their ATP III goal for LDL-C. The findings of the present study have clear clinical benefits in CVD risk reduction and significant healthcare cost benefits due to reduced need for pharmacotherapy if the results can be sustained long term.

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