Issues Surrounding Health Claims for Barley

Nancy P. Ames* and Camille R. Rhymer

Cereal Research Centre, Agriculture and Agri-Food Canada, Winnipeg, Manitoba R3T 2M9, Canada

Abstract

Government-approved health claims support dietary intervention as a safe and practical approach to improving consumer health and provide industry with regulatory guidelines for food product labels. Claims already allowed in the United States, United Kingdom, Sweden, and The Netherlands for reducing cholesterol through consumption of oat or barley soluble fiber provide a basis for review, but each country may have different criteria for assessing clinical evidence for a physiological effect. For example, the FDA-approved barley health claim was based on a petition that included 39 animal model studies and 11 human clinical trials. Since then, more studies have been published, but with few exceptions, clinical data continue to demonstrate that the consumption of barley products is effective for lowering total and LDL cholesterol. More research is needed to fully understand the mechanism of cholesterol reduction and the role of β-glucan molecular weight, viscosity, and solubility. In an assessment of the physiological efficacy of a dietary intervention, consideration should also be given to the potential impact of physical and thermal food-processing treatments and genotypic variation in the barley source. New barley cultivars have been generated specifically for food use, possessing increased β-glucan, desirable starch composition profiles, and improved milling/processing traits. These advances in barley production, coupled with the establishment of a government-regulated health claim for barley β-glucan, will stimulate new processing opportunities for barley foods and provide consumers with reliable, healthy food choices. J. Nutr. 138: 1237S–1243S, 2008.

Introduction

There are 2 major reasons for advocating the consumption of barley and barley β-glucan through the establishment of a government-regulated health claim. The first relates to the food and agriculture industry, and the second relates to the health of consumers. This article discusses health claims for high-β-glucan barley foods including relevance to industry and consumers, status of current claims, clinical evidence of cholesterol reduction, and the potential influence of intrinsic barley properties and processing conditions.

New barley research: why is there interest in barley as a food?

Although barley is grown throughout Canada, the majority of the production is in western Canada and is utilized primarily in the malting industry or as a livestock feed. Barley, which is a source of dietary fiber, β-glucan, and antioxidants, has been used as a staple food in several areas of the world for centuries (1,2). The history of food uses of barley was recently reviewed (3). Traditional barley foods such as roasted barley flour, called tsampa, and roasted puffed barley are widely consumed in Tibet and provide an important source of dietary fiber in diets consisting primarily of animal-based products (4). The average North American consumer has had little exposure to barley food products with the exception of pot or pearled barley, which is often used in soup. Replacement of refined grains such as white rice or refined wheat flour by barley whole-grain products would help consumers meet Canadian Food Guide recommendations for 3–4 daily servings of whole grains (5).

Over the last 15 y, research efforts associated with food barley have increased significantly, revealing a number of unique cultivar-specific functional characteristics that affect both human health and functionality in food processing. New barley cultivars have been generated specifically for food use, possessing increased β-glucan, desirable starch composition profiles, and improved milling/processing traits (6–8). Recently, barley flour and whole-grain products have been formulated in food research laboratories to increase the diversity of barley food
products available and to improve the utilization potential of this healthful grain (1). These innovations have proven that barley-based foods succeed as an alternative to wheat-based foods, and barley does not need to be considered only as a minor ingredient. There are a variety of foods that can be made from suitable cultivars of barley, and modern technology offers the means of overcoming any previous limitations in palatability or acceptability. The wide range in sensory and functional properties offered by diverse barley sources provides food manufacturers with unlimited product opportunities that span multiple market sectors including breakfast cereals, snack foods, pasta, beverages, bakery goods, and more. Strong industry interest in the future of barley warranted a workshop held in Minneapolis, describing recent advances in barley food research (9).

Another motivation for advancing barley research and product development is the potential for barley foods to improve consumer health and reduce the risk of prevalent diseases such as cardiovascular disease (CVD) or heart disease. The risk factors associated with CVD include high total cholesterol levels and high levels of LDL cholesterol. Modifying risk factors through dietary intervention offers great potential for reducing the incidence of CVD. The consumption of dietary fiber, especially water-soluble fiber, has been shown to be inversely associated with coronary heart disease (10,11). The heart-healthy diet proposed by the Canadian Heart and Stroke Foundation recommends consumption of 21 to 38 g/d of fiber and suggests that inclusion of soluble fiber may help lower cholesterol and blood sugar (12). The National Cholesterol Education Program and the National Academy of Sciences in the United States follow similar dietary fiber guidelines, recommending 20–30 g/d of dietary fiber and at least 5–10 g/d of soluble fiber (13). Barley foods could help consumers achieve these dietary goals.

The role of barley β-glucan in reducing risk factors associated with CVD (e.g., high cholesterol) is the focus of many studies. The ability of barley β-glucan soluble fiber to lower serum cholesterol is thought to occur through a combination of factors and mechanisms. Suggested mechanisms of cholesterol reduction after increased soluble fiber consumption include delayed intestinal absorption of glucose and lipids and inhibition of absorption and reabsorption of cholesterol and bile acids accompanied by increased excretion of bile acids (14–16). The reduced absorption may be caused by the high viscosity of β-glucan solutions, which increases the viscosity of the intestinal contents (17–20). Other factors may also be important, such as the fermentation of β-glucan in the colon, resulting in production of short-chain fatty acids, which impede cholesterol biosynthesis (15).

**Linking research and consumers: benefits of a barley health claim**

Increasing fiber through dietary intervention is a safe and practical approach to improving health. Aller et al. (21) showed that a modest increase in soluble fiber intake (4 g) as part of a normal diet reduced LDL cholesterol levels by 12.8% in healthy humans. These authors suggested that nutritional recommendations to increase the intake of soluble fiber must be made to the general public to reduce the impact of CVD. Government-approved health claims can help educate and improve the health of consumers as well as help to develop regulatory guidelines for the food industry in utilizing claims on product labels. A health claim should provide the consumer with information regarding proven health benefits associated with a specific functional food or component including details on the target group and effective dose-response relation. Health claims can also serve the food industry as advertising or marketing tools to increase purchase and consumption of food products. In the case of barley, such marketing strategies could stimulate development of new food products to increase the production and utilization of barley. Barley food products are not widely available or consumed in North America, so development of new food products may be important to consumers who want to increase their barley consumption.

Numerous studies have shown that β-glucan soluble fiber from oat and barley can lower total and LDL cholesterol and thus play a role in both the prevention and management of CVD (22,23). Although the majority of the studies examining the effect of β-glucan on CVD focused on oats, there is a significant body of research literature relating food barley or barley fractions to cholesterol lowering and reduced risk of CVD (22,23). Recently, the U.S. FDA allowed a claim for β-glucan soluble fiber from whole-grain barley and certain barley milling fractions for reducing plasma cholesterol levels and reducing the risk of heart disease (24). The claim for barley β-glucan is an extension to an existing U.S. FDA claim for oat soluble fiber in lowering cholesterol because both cereal grains are believed to contain soluble fiber with similar physiological effects (25). Similar oat soluble fiber claims exist in the United Kingdom, Sweden, and The Netherlands (26–28). The corresponding barley soluble fiber claim was introduced into the Swedish Code in 2006 (27).

**Evidence supporting U.S. health claim: barley foods reduce risk of coronary heart disease**

The FDA concluded that daily consumption of 3 g of soluble β-glucan from whole-grain barley or certain dry milled barley products would produce the same cholesterol-lowering effect as oat products (lowering plasma total cholesterol by 5–8%). The required dosage for a single food is 0.75 g in a single serving (24). The FDA approval was based on a petition submitted by the National Barley Food Council (29), which included 39 animal model studies and 11 human clinical trials. Because 6 of the human trials were excluded from the review, the claim for barley β-glucan lowering the risk of heart disease is based on 5 human clinical trials (30–34).

McIntosh et al. (32) showed that a 4-wk diet enriched with barley foods containing 8 g β-glucan per day reduced total and LDL cholesterol in moderately cholesterolemic men by 6.0 and 6.8%, respectively, compared with wheat foods containing 1.5% β-glucan. Both the wheat and barley foods consumed in this study contained 38.4 g total dietary fiber (TDF). Another wheat-barley comparison showed 12 and 14% reductions in total and LDL cholesterol, respectively, when 14 normal cholesterolemic men were fed whole-grain barley flour products containing 9.6% β-glucan per day for 4 wk, where both barley and control groups consumed equivalent levels of TDF per day (33). Furthermore, Li et al. (34) compared a barley whole-grain diet with 8.9 g soluble fiber added to rice with 3.9 g soluble fiber in a 12-wk crossover study in normal cholesterolemic females. This barley diet resulted in 14.5 and 21% reductions in total and LDL cholesterol. Two studies conducted by Behall et al. (30,31) represent the most recent studies assessed in the FDA claim. In 1 study by Behall et al. (31), 7 men and 18 women were given test diets providing 0, 3, or 6 g/d of barley β-glucan with equivalent levels of TDF. Following both the 3 g/d and 6 g/d diet periods, serum total cholesterol was reduced 5 and 6%, respectively, and LDL cholesterol 10 and 13%, respectively.

**Initiating a barley health claim: new scientific evidence for consideration**

Although the FDA oat-barley β-glucan soluble fiber health claim does not extend to other countries, it does provide a basis for
review and discussion. Most countries review the same scientific information but may have different criteria for assessing evidence, determining study quality, and inclusion and exclusion criteria. In addition, since the U.S. FDA barley petition was received, several additional animal and human clinical studies have been reported, and any new petitions must include these studies in the overall assessment. Preparing a health claim petition involves following a systematic process to first identify all relevant research studies and then selecting from these based on defined inclusion criteria (e.g., human subjects, barley tested, cholesterol/lipid response measured) (35). The selected studies are further rated based on several aspects of study design. Studies with acceptable quality scores are then examined by a panel of expert reviewers, who make recommendations based on overall evidence for a health claim including such aspects as dose-response relations, consistency of observations, feasibility of consuming the effective dose, and target populations for the proposed claim.

A recent systematic review of the scientific evidence for a barley β-glucan/cholesterol reduction claim is currently being coordinated by the author (unpublished data) following the assessment criteria identified through the Health Canada guidelines (35). Nine search engines were used to identify published studies on the effects of barley or barley β-glucan on cholesterol and clinical studies done using barley. Key words searched included but were not limited to β-glucan, barley, clinical, cholesterol, and coronary heart disease. Of 257 relevant barley studies, 58 were specifically related to the effects of barley fiber on plasma cholesterol or other blood lipid levels. Of these, 37 studies involved assessment with animal models, and 21 included human clinical trials. The relevant human studies were then subjected to evaluation using stepwise inclusion and exclusion criteria to create a final summary table of 16 acceptable studies (Table 1) for final review, and 12 of these include statements of β-glucan soluble fiber content. These studies include the 5 human studies used to assess the evidence in the recent U.S. barley petition.

There is a large amount of additional evidence to consider in a health claim petition, including several new studies conducted since the U.S. claim. For example, Pins et al. (49) and Keenan et al. (41) conducted randomized, controlled human studies to determine the cholesterol-lowering effects of different doses of isolated barley β-glucan extracts added to food products. These studies showed a greater reduction in cholesterol with 5 g/d than with 3 g/d of β-glucan, but both doses reduced LDL cholesterol by 14% and 9%, respectively. A recent Swedish study (44) showed a 5% reduction in LDL cholesterol when mildly cholesterolemic subjects ate packages of a processed barley flour product containing 1 g β-glucan, 3 times each day, for a total of 3 g/d for 4 wk. A study with Japanese male prisoners showed a significant reduction in total cholesterol when they ate a boiled rice and barley mixture, known as Mugimeshi (46). Furthermore, Bourdon et al. (47) measured lipid responses in 11 men consuming high-fiber barley pasta containing 5.2 g of barley β-glucan or traditional wheat pasta with 0.3 g β-glucan. They showed that total cholesterol dropped below fasting levels 4 h after consumption of barley but remained unchanged after the subject ate the wheat pasta.

Not all studies involving barley β-glucan have shown significant reductions in cholesterol. For example, Keogh et al. (42) reported small but not significant reductions in total (1.3%) and LDL (3.8%) cholesterol in 12 mildly cholesterolemic men when β-glucan-enriched barley, Glucagel, was added to their diets, which contained 38% energy from fat. In another study, Biorklund et al. (45) added a milled, enzyme-treated, barley product, with insoluble fibers removed, to a drink and showed no effect on cholesterol levels. The low molecular size associated with Glucagel and the enzyme-treated product may be partially responsible for the lack of significant effects (44,50), although a recent review by Kim et al. (51) on β-glucan from various sources suggests that molecular size differences alone cannot explain inconsistencies. In a recent German study, translated to English, a diet containing a barley extrudate with 7.2% β-glucan was fed to 11 healthy subjects for 4 wk (48). Although plasma cholesterol levels were reduced only slightly, excretion of bile acids was significantly higher (25%). In addition, fecal cholesterol content decreased as fecal cholesterol metabolites increased, suggesting that β-glucan did reduce bile acid reabsorption. Inconsistencies in human data may have a variety of causes, including amount of β-glucan intake, the type of diet or supplement, physiochemical differences in β-glucan as a result of extraction or processing, molecular weight and viscosity, baseline cholesterol level, study duration, target group, dietary control, sample size, and dose of treatment.

Properties of barley β-glucan with potential influence on cholesterol reduction

Aside from clinical study design parameters, there are several intrinsic properties of the barley food and soluble fiber component itself that can affect experimental outcomes. For example, the β-glucan content of Canadian barley grain grown in western Canada can range from 3 to 10% depending on the cultivar and the growing environment (1,52,53). Also, hull-less cultivars tend to contain higher levels of β-glucan soluble fiber than hulled types. Hull-less barley types can be further separated into groups of normal, high, and low amylose, waxy barley, based on starch amylose content (52). The β-glucan soluble fiber levels in barley foods have been reported in a number of studies and ranged from ~3 to 7.5% for whole-grain and pearled products and from 2.7 to 23% for various types of flour products (1,53–57). Variation in β-glucan among flour samples is also dependent on the method of flour extraction or sieving and particle size (1,53,55,56,58).

Although total β-glucan content in a product would be important for meeting health claim criteria, properties of β-glucan such as molecular weight, extractability or solubility, and viscosity could also potentially influence physiological response (52,59–65). Clinical evidence for a role of viscosity in mediating physiological effects is strongly established for glycomic response but is less clear for cholesterol lowering (66). The importance of viscosity is often cited as the probable mechanism for the beneficial effects of β-glucan, yet few clinical studies have included data on viscosity (67). There are a few recent studies that have looked beyond the content of β-glucan in products and considered physiochemical characteristics of β-glucan such as solubility and molecular weight. For example, Kalra and Jood (68) compared cultivars of barley differing in β-glucan content and showed that quantity and solubility of barley β-glucan were strong predictors of cholesterol-lowering ability in rats. However, Wilson et al. (15) showed that both high-molecular-weight and low-molecular-weight β-glucan concentrates from barley lowered cholesterol to similar levels and through similar mechanisms in hamsters. In addition, Pins et al. (49) and Keenan et al. (41) conducted randomized, controlled, human studies to determine the cholesterol-lowering effects of isolated barley β-glucan when low- (50–400 kDa) vs. high-molecular-weight (1000 kDa) β-glucan was added to food products. Although a dose response was evident, 9–15% reduction in LDL cholesterol, molecular weight did not significantly affect cholesterol lowering.
<table>
<thead>
<tr>
<th>Diet containing barley β-glucan, food matrix, quantity, process</th>
<th>Subjects</th>
<th>Physiological response: cholesterol, glucose, insulin&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activated barley in packages, 3 g/d β-glucan</td>
<td>Mildly hypercholesterolemic men and women</td>
<td>C: LDL cholesterol decreased by 5%</td>
<td>Aman (44)</td>
</tr>
<tr>
<td>Diets containing 0.3, 3, or 6 g/d of β-glucan from barley in pancakes, bars, hot cereal, etc.</td>
<td>Mildly hypercholesterolemic men</td>
<td>C: Total cholesterol decreased 14, 17, and 17%; LDL cholesterol 17, 17, and 24%, respectively. Soluble fiber from barley can reduce cardiovascular risk factors.</td>
<td>Behall et al. (30)</td>
</tr>
<tr>
<td>Diets containing 3 or 6 g/d of β-glucan from barley in pancakes, bars, hot cereal, etc.</td>
<td>Mildly hypercholesterolemic men and women</td>
<td>C: decrease in total and LDL cholesterol, the higher intake in particular, more so in postmenopausal women and men.</td>
<td>Behall et al. (31)</td>
</tr>
<tr>
<td>Beverage containing 5 or 10 g/d barley β-glucan</td>
<td>Mildly hypercholesterolemic men and women</td>
<td>C: decrease in total and LDL cholesterol, but not significant, possibly because of low MW.</td>
<td>Biorklund et al. (45)</td>
</tr>
<tr>
<td>Complete meal containing pasta enriched with high-β-glucan barley, 5 g/d</td>
<td>Healthy normolipemic men</td>
<td>G/I: no change in insulin response. C: decrease in total cholesterol. G/I: change in insulin but not glucose response.</td>
<td>Bourdon et al. (47)</td>
</tr>
<tr>
<td>Extruded whole-grain barley meal containing 7.2 g/d β-glucan to supplement usual diet</td>
<td>Mildly hypercholesterolemic men and women</td>
<td>C: LDL cholesterol decreased by 6%</td>
<td>Dongowski et al. (48)</td>
</tr>
<tr>
<td>Cooked rice and barley mixture (7:3 ratio) containing 18.7 g/d soluble fiber</td>
<td>Diabetic male prisoners</td>
<td>C: total cholesterol decreased by 9.7%. G/I: fasting plasma glucose levels dramatically decreased.</td>
<td>Hinata et al. (46)</td>
</tr>
<tr>
<td>Cooked barley and rice mixture containing 6.1 g/d dietary fiber</td>
<td>Healthy normolipemic men Hyperlipidemic men Hypercholesterolemic menopausal women</td>
<td>C: significant reduction in cholesterol for hypercholesterolemic subjects. Normolipemic subjects unaffected.</td>
<td>Ikekami et al. (37)</td>
</tr>
<tr>
<td>Portfolio diet of high plant sterols plus 10 g/d viscous fiber: 1000-kcal (4.184 MJ) diet consisting of 4.2 g oats, 1.4 g barley, 4.2 g psyllium</td>
<td></td>
<td>C: cholesterol reduction from a combination of food components in portfolio diet</td>
<td>Jenkins et al. (36)</td>
</tr>
<tr>
<td>Diets containing 3 or 5 g LMW or 3 or 5 g HMW barley β-glucan concentrate in cereal, juice beverage</td>
<td>Mildly hypercholesterolemic men and women</td>
<td>C: decrease in LDL cholesterol by 9, 13, 9, and 15%, respectively.</td>
<td>Keenan et al. (41)</td>
</tr>
<tr>
<td>Extracted barley β-glucan incorporated into snacks and food products, 9.9 g/d β-glucan</td>
<td>Mildly hypercholesterolemic men</td>
<td>C: no significant reduction in total or LDL cholesterol. G/I: no significant change in fasting or postprandial glucose.</td>
<td>Keogh et al. (42)</td>
</tr>
<tr>
<td>Cooked rice and barley mixture (7:3 ratio) containing 8.9 g/d soluble fiber</td>
<td>Healthy normolipemic women</td>
<td>C: significant decrease in total and LDL cholesterol. G/I: no significant decrease in glucose tolerance.</td>
<td>Li et al. (34)</td>
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<td>Buns consumed at meals containing 12.4 g/d barley β-glucan</td>
<td>Ileostomy subjects, men and women</td>
<td>C: significant increase in cholesterol excretion</td>
<td>Lia et al. (38)</td>
</tr>
<tr>
<td>Barley bran flour from distillers’ grain in packages to supplement meals, 20 g/d dietary fiber</td>
<td>Moderately hypercholesterolemic men and women</td>
<td>C: LDL cholesterol decreased by 6.5%</td>
<td>Lupton et al. (39)</td>
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<tr>
<td>Diets containing daily β-glucan from barley flakes and bran in bread, muesli, spaghetti, and biscuits</td>
<td>Mildly hypercholesterolemic men</td>
<td>C: reduction in plasma total and LDL cholesterol</td>
<td>McIntosh et al. (32)</td>
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<td>Chapattis consumed at meals containing 100 g/d barley flour</td>
<td>Mildly hypercholesterolemic men and women</td>
<td>C: HDL cholesterol increased.</td>
<td>Narain et al. (40)</td>
</tr>
<tr>
<td>Diets containing 12.9 g/d of β-glucan from barley in muffins, bars, bread, etc.</td>
<td>Healthy men</td>
<td>G/I: decrease in area under glucose curve</td>
<td>Newman et al. (33)</td>
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<tr>
<td>Diets containing 40 g/d of dietary fiber from barley in muffins, bars, bread, etc.</td>
<td>Mildly hypercholesterolemic men and women</td>
<td>C: decrease in total and LDL cholesterol</td>
<td>Newman et al. (43)</td>
</tr>
<tr>
<td>Diets of rice and pearled barley (1:1) containing 7.0 g/d β-glucan</td>
<td>Hypercholesterolemic men</td>
<td>C: decrease in total and LDL cholesterol</td>
<td>Shimizu et al. (8)</td>
</tr>
</tbody>
</table>

<sup>1</sup> C, cholesterol; G/I, glucose or insulin; HMW, high molecular weight; LMW, low molecular weight.
Effects of processing on barley β-glucan

The physiochemical properties of barley β-glucan such as viscosity and solubility, as well as their determinant factors, molecular weight and concentration, affect the functionality of these components in food systems (69,70). Although the high viscosity of β-glucan soluble fiber is implicated as a contributing factor to health benefits (50,51), addition of high levels of viscous barley flour can present a challenge to food product developers. Processing barley into food involves a wide range of techniques including milling, extraction, fermentation, boiling, pasteurizing, salting, and drying, all of which could affect β-glucan functionality. It has been reported that processing methods can alter molecular structure and viscosity of β-glucan without affecting β-glucan content (20,63,70,71). Similarly, barley product development research conducted at the Cereal Research Centre, Winnipeg, has shown that both processing and genotype influence β-glucan extractability, and heat treatments increased viscosity (1). Table 2 shows the effect of heat treatments on the viscosity and solubility of barley flour from several barley genotypes. As information accumulates on the range of potentially beneficial physiological effects associated with barley, the food industry is challenged to develop products with desirable sensory properties while ensuring that the physiological effects of the β-glucan are retained.

Reducing the incidence of CVD through dietary intervention is a major focus of health organizations worldwide. With few exceptions, published clinical data demonstrate that the consumption of barley products is an effective dietary approach for lowering total and LDL cholesterol. Although details on the physiological mechanisms of barley β-glucan require further elucidation, the information currently available provides evidence of a human health benefit that should be made available to consumers.

Acknowledgment

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Other articles in this supplement include references (72–81).

Literature Cited


### Table 2

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Untreated</th>
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<th>Untreated</th>
<th>Heat treated</th>
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<td>CDC Candle</td>
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<td>7.10</td>
<td>0.1049</td>
<td>0.9494</td>
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<td>CDC Dawn</td>
<td>4.32</td>
<td>4.08</td>
<td>0.0071</td>
<td>0.0257</td>
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<td>SBB9497</td>
<td>6.52</td>
<td>6.51</td>
<td>0.0277</td>
<td>0.7067</td>
</tr>
</tbody>
</table>

1 At 2.651/s shear stress.


52. Storsley JM, Jardorcyz MS, You S, Biliaderis CG, Rossnagel B. Structural and physicochemical properties of beta-glucans and arabinoxylans isolated from hull-less barley. Food Hydrocoll. 2003;17:831–44.


