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Oat Ingestion Reduces Systolic and Diastolic Blood Pressure in Patients with Mild or Borderline Hypertension: A Pilot Trial

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- OBJECTIVES: We assessed the short-term antihypertensive effects of soluble fiber-rich whole oat cereals when added to a standard American diet. In addition, multiple assessments of insulin sensitivity were conducted.
- STUDY DESIGN: This was a randomized, controlled, parallel-group pilot study designed to compare an oat cereal group (standardized to 5.52 g/day beta-glucan) to a low-fiber cereal control group (less than 1.0 g/day total fiber) over 6 weeks.
- POPULATION: A total of 18 hypertensive and hyperinsulinemic (⩾10 µU/mL) men and women completed the trial.
- OUTCOMES MEASURED: Primary study outcomes were changes in systolic blood pressure (SBP) and diastolic blood pressure (DBP). Secondary outcomes included blood lipid, fasting glucose, and insulin levels and side effects related to elevated blood pressure and increased dietary fiber intake.
- RESULTS: The oat cereal group experienced a 7.5 mm Hg reduction in SBP ($P < .01$) and a 5.5 mm Hg reduction in DBP ($P < .02$), while there was virtually no change in either SBP or DBP in the control group. In the oat cereal group, a trend was observed for a lower total insulin response to a glucose load, suggesting improved insulin sensitivity. However, this could not be confirmed using estimates from the Bergman Minimal Model, perhaps because of our small sample size. As expected and reported in previous trials, the oats group experienced a significant reduction in both total cholesterol (9%) and low-density lipoprotein cholesterol (14%).
- CONCLUSIONS: The addition of oat cereals to the normal diet of persons with hypertension significantly reduces both systolic and diastolic blood pressure. Soluble fiber-rich whole oats may be an effective dietary therapy in the prevention and adjunct treatment of hypertension.

key words **Hypertension; insulin; whole grain oats; beta-glucan; soluble fiber. (J Fam Pract 2002; 51:369)**

Interest is growing in the use of nonpharmacologic methods for the prevention and management of hypertension. Specifically, the effect of dietary fiber on the incidence and treatment of hypertension has been explored. Epidemiologic studies show that the amount of dietary fiber ingested is inversely related to the incidence of hypertension as well as to systolic blood pressure (SBP) and diastolic blood pressure (DBP) in both hypertensive and normotensive patients.[1–5] The results obtained from clinical trials, however, are inconsistent; some report modest blood pressure reductions after increased fiber intake,[6–12] while others fail to demonstrate any effect of dietary fiber on blood pressure.[13–16] Some animal trials[17,18] and human trials[19,20] have shown a consistent lowering of blood pressure upon consumption of larger amounts of soluble fiber, suggesting that the antihypertensive effects of fiber may be caused by the soluble fraction and that these effects may be contingent upon the intake of a sufficiently large quantity.

Hypertension often occurs in association with obesity, impaired glucose tolerance, and dyslipidemia. Hyperinsulinemia and insulin resistance are thought to be key pathogenic links among these disturbances.[21–23] Studies show that soluble fiber from oats reduces both postprandial blood glucose and insulin levels.[24–27] Therefore, we conducted the following pilot trial to investigate the antihypertensive and insulin-modifying effects of oat cereal supplementation in a population of mild and borderline hyperinsulinemic and hypertensive men and women.

METHODS

Study protocol

The study participants in this 6-week, randomized, parallel-group, active-controlled pilot trial were recruited by means of local community screenings and mass media advertising. The study protocol was reviewed and approved by the University of Minnesota Institutional Review Board. All participants provided informed consent before official enrollment in the study. One hundred nine men and women aged 20 to 70 were screened for eligibility with a physical exam, medical history, and chemistry and lipid profile (see **Table 1** for exclusion criteria). Only generally healthy, untreated hypertensives with average SBP of 130 to 160 mm Hg and DBP of 85 to 100 mm Hg and with at least 1 reading greater than 140/90 as well as moderately elevated levels of fasting insulin (⩾10μU/mL) were considered for enrollment. Participants were determined to be eligible only after 2 sets of hypertensive (SBP > 130, DBP > 85) baseline blood pressure readings had been taken 7 days apart and only if all inclusion criteria were fulfilled.

Ultimately, 22 men and women were randomized to either an oat cereal treatment group (standardized to 5.52 g/day beta-glucan) or a low fiber cereal control group (<1 g/day total fiber). Four of these individuals (1 in the treatment and 3 in the control group) discontinued participation because of time constraints. Eighteen healthy, nonsmoking men and women aged 27 to 59 years (44 ± 18; mean, SD) completed the trial. Cereal treatments were isocaloric. Participants were instructed to consume all their cereal (treatment, 137 g; control, 146 g) daily for the next 6 weeks but were allowed to prepare and consume the cereal however and whenever they wished.

Cereal compliance was determined by participant self-report in a daily cereal calendar. In addition, dietary intake was reviewed both at baseline and at the end of the 6-week intervention, using 3-day food records. Side effect data were gathered from participants at baseline and the end of the intervention. Side effects were assessed via a questionnaire consisting of 21 items relating to potential side effects from increased fiber intake (eg, loose stools, flatulence) or hypertension (eg, headaches, dizziness). Participants reported the frequency at which they experienced these side effects on a scale ranging from “never” to “very frequently” (event occurring once or more per day). Each response was assigned a numerical value. Prestudy and post study averages were used in analyses.

Blood Pressure, Plasma Lipid Concentrations, Glucose Metabolism, and Insulin Sensitivity

Blood pressure was measured weekly for each participant for the duration of the study. Each participant reported to the Hypertension and Cholesterol Research Clinic located at the University of Minnesota Medical School at approximately the same time for each blood pressure reading. All readings were obtained in the morning after participants had rested quietly, seated, for at least 5 minutes in an examination room. An examiner who was blinded to the treatment groups took readings on the right arm using a mercury column sphygmomanometer (Korotkoff phase V for DBP). Standard cuff

size was used unless upper arm circumference exceeded 31 cm, in which case the examiner used a large cuff with 15 x 35-cm bladders. Measurements were repeated 4 times in 2-minute intervals. The mean of the last 3 readings was calculated and used in analyses.

To determine plasma lipid concentrations (total, high-density lipoprotein [HDL], and low-density lipoprotein [LDL] cholesterol and triglycerides), pretreatment and posttreatment blood samples were drawn. A 75-g, 3-hour oral glucose-tolerance test (OGTT) was administered before and after treatment to assess participants' glucose tolerance and insulin response. Whole blood sampling occurred at -30, 0, 30, 60, 90, 120, 150, and 180 minutes. A measure of insulin sensitivity was assessed within 48 hours after the OGTT by means of the modified frequently sampled intravenous glucose tolerance test (FSIGT).[28] The glucose and insulin data derived from this test were used to calculate the insulin sensitivity index (SI) employing the minimal-model method developed by Bergman.[29]

Statistical methods

Reported results are expressed in terms of means ± SD or means SE. Student's t test for independent samples was used to compare the 2 treatment groups at baseline and to compare mean change scores between the 2 groups. Additionally, area-under-the-curve analyses were performed to compare OGTT insulin curves. All analyses were performed on data from an intent-to-treat population, which included all randomized participants. Statistical tests were 2 sided, performed at the 5% level of significance, and conducted with Statistical Analysis System software (SAS Institute, Cary, N.C.).

RESULTS

No statistically significant differences in baseline characteristics occurred between the groups, although this comparison is limited by the small sample size **Table 2**. LDL cholesterol and total cholesterol levels and blood pressure were somewhat higher in the treatment group. The blood pressure measurements in the treatment group resulted in an average SBP of 143 ± 3.7 mm Hg before intervention and 135 ± 2.6 mm Hg after intervention (an average of the last 2 study visits, P < .01) **Table 3**. No significant change in SBP was observed in the control group. A significant difference between the treatment and control groups was observed for the change in SBP (P < .02). DBP dropped from 93 ± 1.9 mm Hg to 87 ± 2.2 mm Hg after the oat fiber intervention (P = .02), with no significant change in the control group (P = .94). A borderline significant trend was noted for the change scores of DBP between groups (P = .055).

Changes in fasting insulin, insulin sensitivity (S_I), and insulin curves derived from the oral glucose tolerance tests were assessed. Fasting insulin values **Table 3** were taken from the OGTT (preglucose infusion values). Neither the control group (P = 1.00) nor the treatment group (P = .753) showed a significant change in fasting insulin levels. The Bergman minimal model method was used to estimate insulin sensitivity and showed no significant change in either group. Area-under-the-curve analysis of the insulin data derived from the OGTTs before and after treatment with oat cereal (**Figure 1** and **Figure 2**) suggested a trend toward significance in terms of less insulin required to clear a glucose load (top of graphs, P = .093), with no significant changes in the control group (bottom).

Total cholesterol concentrations dropped 16.2 ± 6.3 mg/dL in the oat cereal group (P = .030), with a slight (nonsignificant) increase in the control group (P = .48). Additionally, a comparison of the changes in total cholesterol between the 2 groups revealed a significant mean difference of 21.1 ± 9.1 mg/dL (P = .035). LDL cholesterol was also reduced significantly after the oat cereal intervention by 15.8 ± 5.9 mg/dL (P = .025). The nonsignificant increase in LDL cholesterol in the control group (P = .231) combined with the significant reduction in the treatment group resulted in a significant difference between the groups after intervention (P < .015). Neither group experienced significant changes in HDL cholesterol or triglyceride concentrations.

An analysis of the side effect data showed no significant difference in the occurrence of side effects between groups. There was an overall decrease in the frequency of dietary fiber-related and hypertension-related side effects in both groups, with a more substantial reduction occurring in the oat cereal group (P = .11). Total body weight did not change significantly in either group. Additionally, both groups were very compliant (approximately 90%) in terms of cereal

consumption **Table 3**.

DISCUSSION

The results of this pilot study suggest that the inclusion of oats into the standard American diet of people with borderline or mild hypertension may reduce both SBP and DBP. In persons consuming 5.52 g/day of beta-glucan soluble fiber from oat cereal for 6 weeks, we found a statistically and clinically significant decrease in both SBP and DBP (7.5 mm Hg and 5.5 mm Hg, respectively) and a trend toward improved OGTT-determined insulin sensitivity. These findings warrant a large-scale clinical trial to explore further the relationship between whole-grain oat consumption and blood pressure, especially considering the limitations of this pilot study.

As with all small-scale trials, this one lacked sufficient power to detect true changes in both primary and secondary outcome variables. It is possible that regression to the mean explains at least part of the treatment effect, since participants in the oats group began the study with higher SBP, DBP, and LDL cholesterol levels than controls. In addition, it is possible that the reported blood pressure changes could have been caused by “other” undetected dietary change made by members of the oats group. Future trials will need to collect and analyze dietary data carefully; feeding trials should be considered. Such dietary analyses may indicate that certain micronutrients partially explain the hypotensive effects of whole-grain oat consumption. The DASH trial and others have consistently demonstrated that diets rich in certain micronutrients can reduce blood pressure.[30,31]

Soluble fiber-rich oat cereals may affect blood pressure by modulating changes in insulin metabolism. The mechanism of action is thought to involve the slowed absorption of macronutrients from the gut, resulting in a flattening of the postprandial glycemic curve.[29] These lower postprandial blood glucose levels elicit a lower insulin response to accommodate its clearance from the plasma. This process may lead to improved insulin sensitivity if the lower circulating insulin levels lead eventually to upregulation of the insulin receptors in peripheral tissues. A recent animal trial demonstrated that soluble fiber feeding improved insulin sensitivity by increasing skeletal muscle plasma membrane GLUT-4 content.[32] Findings in this pilot suggest that over time, oat ingestion may reduce the amount of insulin needed to clear a glucose load. However, the study was underpowered to detect significant differences in more sensitive measures of insulin resistance. The causal mechanistic relationship among whole grain oat consumption, blood pressure, and insulin resistance might be best studied using a long-term feeding study design.

Alternate mechanisms, such as attenuation in endothelial function, may have affected blood pressure responses in this study.[33] Drugs specific to endothelial cell receptors mediating vasodilation are known to lower blood pressure.[34] Moreover, plasma cholesterol reductions are associated with improvements in endothelium-mediated vasodilation.[35,36] In addition, preliminary evidence in animals supports a direct relationship between changes in plasma cholesterol concentrations and blood pressure.[37] In the present study, plasma cholesterol levels were significantly reduced in participants who ingested whole grain oat-based cereals compared to a more refined grain wheat, corn, and rice control. Thus, it is possible that the blood pressure reduction observed in the subjects consuming oats resulted in part from improved endothelial function due to a drop in plasma cholesterol. Additional research is needed to fully investigate this pathway.

From a practical standpoint, improvements in SBP and DBP such as those observed in this study would be a useful contribution to the clinical management of hypertension. The cereal feeding intervention was well tolerated. Participants were very compliant for the 6-week treatment period. Substantial improvements in blood lipids could serve as an added incentive for patients to maintain long-term compliance with feeding recommendations.[18,19] Since treatment of hypertension is a lifelong process for most patients, future studies would need to assess the effectiveness of oat cereals to maintain blood pressure benefits over a longer time. Such studies may need to consider dietary options such as soluble fiber-rich fruits in addition to cereal consumption in efforts to deliver the desired quantity of soluble fiber. Future trials will have to investigate the antihypertensive effect of whole oats in other populations, such as people with diabetes, and to study not only surrogate endpoints such as blood pressure but also patient-oriented outcomes such as mortality and morbidity.

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