

<b>PRO0917</b>
<i>Effect of pulses on glycemic control and cardiovascular disease risk factors in type 2 diabetes: a dose response study</i>
<b>INVESTIGATORS</b>
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<b>STUDY SPONSORS</b>
Agricultural Bioproducts Innovation Program (ABIP): PUREnet (Pulse Research Network) Saskatchewan Pulse Growers
<b>TYPE OF STUDY</b>
Health Outcome: Clinical trial-dose response study
<b>OBJECTIVES</b>
To determine if pulses improve glycemic control in non-insulin dependent diabetes, as assess by hemoglobin A <sub>1c</sub> (HbA <sub>1c</sub> ) and to assess whether these outcomes relate to improvements in cardiovascular health (i.e. serum lipids and measures of oxidative stress and inflammatory markers).
<b>WHY STUDY NEEDED</b>
Incidence of type 2 diabetes mellitus (DM) is increasing rapidly and is associated with an increase of cardiovascular disease, kidney disease, and blindness. Dietary changes could make a significant contribution to the treatment of those with type 2 DM. Legumes, including beans, chickpeas, and lentils have been recommended in national DM guidelines but never used specifically to lower the glycemic index (GI) of a diet. A meta-analysis of randomized clinical trials investigating effects of pulses on glycemic control found that pulses alone or as part of a low glycemic index (GI) or high-fibre diet could improve markers of long term glycemic control. A previous study had shown that including pulses as part of a low glycemic index diet resulted in improved glycemic control and coronary heart disease (CHD) risk and with greater weight loss than a control high-fiber diet. The researchers wanted to further investigate these results through a large clinical study of type 2 DM patients.
<b>HYPOTHESIS</b>
Pulses have been found to have a low GI. It is believed pulse flours could displace high GI carbohydrate foods in the diet thus lowering the dietary glycemic load and resulting in improved blood glucose control in type 2 DM and improved CHD risk factors. It is anticipated that legume treatment will result in a reduction of HbA <sub>1c</sub> and fasting blood glucose with

improvements in inflammatory biomarkers (C-reactive protein and total: HDL-C ratio).
<b>STUDY DESIGN</b>
<p>A total of 121 participants with type 2 DM were randomized to either a low-GI legume diet that encouraged participants to increase legume intake by at least 1 cup (~190 g or 2 servings) per day or to increase insoluble fiber by consumption of whole wheat products (breads, cereals, brown rice, etc.) for three months. The primary outcome was a change in hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) values with calculated CHD risk score as a secondary outcome.</p> <p>Adherence to diet were assessed from seven day food records at week zero visit and the mean of the last three visits (weeks, 8, 10 and 12).</p>
<b>FINDINGS</b>
<p><sup>35</sup><sub>17</sub> Participant completion was 93.3% (56 of 60) for the low-GI legume diet arm and 95.1% (58 of 61) for the high wheat fibre diet arm</p> <p><sup>35</sup><sub>17</sub> The low-GI legume diet reduced HbA<sub>1c</sub> values by 0.5% and the high wheat fibre diet reduced HbA<sub>1c</sub> values by 0.3%. A reduction of 0.3% to 0.4% in HbA<sub>1c</sub> is considered to be therapeutically meaningful by the U.S. Food and Drug Administration (FDA)</p> <p><sup>35</sup><sub>17</sub> There was significant body weight reductions seen on both the low-GI legume diet (-2.7Kg) and high-wheat fibre diets (-2.0 kg)</p> <p><sup>35</sup><sub>17</sub> The low GI legume diet produced significant reductions in total cholesterol level and triglyceride levels with no significant change in HDL-C levels. The high fibre diet resulted in significant increases in HDL-C levels</p> <p><sup>35</sup><sub>17</sub> Both blood pressure (BP) and heart rate were reduced on the low-GI legume diet relative to the high wheat fibre diet</p> <p><sup>35</sup><sub>17</sub> In the completer analysis, relative to the wheat high fibre diet, the low GI legume diet resulted in a greater reduction in total cholesterol level and high-density lipoprotein cholesterol (HDL-C) levels; lower blood pressure and heart rate. There was a reduction in the calculated absolute CHD risk on a legume diet, relative to the wheat high fibre diet</p>
<b>SIGNIFICANCE OF STUDY</b>
<p>Incorporation of legumes as part of a low-GI diet improved both glycemic control and reduced calculated CHD risk score in type 2 DM.</p> <p>Study results provide support to offer legumes as a specific food option to lower the dietary GI in type 2 DM and further supports the recommendations of many national diabetes associations to increase consumption of low GI foods containing legumes.</p> <p>The lack of association between change in HDL-C and legume consumption on the low-GI</p>

diet does not support an effect of beans in lowering HDL-C.

The study demonstrated a number of findings not previously seen:

- 1) First study to specifically use legumes to lower the GI of a diet
- 2) First to demonstrate a reduction in blood pressure with legume consumption in type 2 DM although the mechanisms are not known
- 3) First to assess the effect of bean consumption on heart rate and one of the few to determine effect of dietary intervention

#### **PUBLICATIONS, PRESENTATIONS, EDUCATION MATERIALS PRODUCED**

Results of the study published online October 22, 2012 in Arch. Intern Med (172 (21): 1653-1660. "Effect of legumes as part of a low glycemic index diet on glycemic control and cardiovascular risk factors in type 2 diabetes mellitus". Jenkins et al., 2012.

#### **VALUE TO PRODUCERS**

Contributes to growing body of knowledge of health benefits of pulse consumption. An increased awareness of the positive effects of eating legumes may encourage the health professions to promote pulses as healthy foods to be included as part of a healthy diet.