Effect of Dietary Soy Protein Supplement in Dyslipidemic South Indian Population: A Randomized, Double-Blind, Placebo Controlled, Parallel-Group Trial

Natesan Chidambaram1, Subramaniyam Sethupathy1, Nadanam Saravanan2*, Toshiya Toda1, Mari Mori1, Yukio Yamori1, Arun Kumar Garg4 and Arun Chockalingam2

1Rajah Muthiah Medical College and Hospital, Annamalai University, Chidambaram, India
2Rani Meyyammai College of Nursing, Annamalai University, Chidambaram, India
3Institute for World Health Development, Mukogawa Women’s University, Nishinomiya, Japan
4Laboratory Medicine and Pathology at Fraser Health Authority, New Westminster, BC, Canada
5Dalla Lana Faculty of Public Health, University of Toronto, Toronto, Canada

Abstract

Forty subjects identified as dyslipidemic were assigned randomly to either soy powder (Soy) or red bean powder (Placebo). The soy group received daily a sachet of 18.1 g soy powder containing 85 Kcal and the placebo group received daily placebo sachet (23.1 g) of red bean powder containing 85.5 Kcal in addition to the usual diet for four weeks. Intake of soy/placebo powder was assessed by measurement of 24-hour urinary isoflavone excretions at baseline and at the end of the intervention period. Relative to placebo, soy powder has significant effect over some Cardiovascular Disease (CVD) markers and Metabolic Syndrome (MetS) indices including abdominal circumference, triglycerides, HbA1c and insulin. These data support that the dietary consumption of soy has the property to reduce risk factors for CVD and MetS.

Keywords: Dyslipidemia; South India; Soy

Introduction

Dyslipidemia and obesity are emerging as a major public health challenge in South Asian countries. The prevalence of obesity is more in urban areas than rural. There is greater accumulation of fat at “ectopic” sites, namely the liver and the skeletal muscles. This feature leads to higher magnitude of insulin resistance, and its concomitant metabolic disorders (the metabolic syndrome) including atherogenic dyslipidemia.

Metabolic Syndrome (MetS) is a plausible precondition for type II diabetes and Cardiovascular Diseases (CVD). MetS is characterised by symptoms of obesity, insulin resistance, hypertension, dyslipidemia and diabetes mellitus. The pathophysiological mechanisms involved in MetS are complex and involved dysregulation of many biochemical and physiological regulatory mechanisms of the body. Elevated levels of Very Low Density Lipoprotein (VLDL), and Low Density Lipoprotein (LDL) with reduction of High Density Lipoprotein (HDL) seen in patients with MetS contribute to atherogenic dyslipidemia. MetS and its components are associated with increased risk of stroke and CVD.

Further, the incidence of Coronary Artery Disease (CAD) is increasing in India. Our previous findings in the South India indicated the poor dietary habits of consuming excessive carbohydrates, fats, oils and salt as well as not enough fruits, vegetables, pulses and nuts which leads to hypertension and CAD [1]. Recent data suggesting insulin resistance can predict CVD independently of the other risk factors, such as hypertension, visceral obesity, or dyslipidemia [2]. The excess burden of coronary heart diseases among Indians appears to be primarily due to dyslipidemia that is characterized by high levels of triglycerides (TG), borderline high levels of LDL and low levels of HDL [3].

Soybean is the most important nutrient of the legume family. Asian populations who consume soy foods in their daily diet have a lower incidence of CVD than those who consume a typical Western diet [4]. It was also reported that soy protein and/or isoflavones improve lipid profiles [5] and exert antiatherogenic effects [6]. Soy protein isolate is known to reduce the risk of heart disease by lowering serum TC and TGL levels. Soybean is a rich source of vegetable protein, complex carbohydrates, polyunsaturated fat, soluble fibres, and phytoestrogens (isoflavones) that may be beneficial in the prevention of diabetes also [7]. In vitro studies suggest that isoflavones have antidiabetic properties such as the inhibition of the intestinal brush border uptake of glucose, α-glucosidase inhibitor actions, and tyrosine kinase inhibitory properties [8,9]. Several observational studies have also suggested that soy intake was associated with improved glycemic control or lowered risk of diabetes [10-13].

We hypothesize that the daily intake of soybean products as a dietary supplement may reduce lipid levels among dyslipidemic people whose daily consumption of soy products is low/nil. In an intervention study, the beneficial effects of a soybean diet on CVD risk factors in Japanese immigrants living in Hawaii are well proved [14]. Therefore, in the present study, we designed an intervention study to investigate the effects of soy protein on lipid levels such as Total Cholesterol (TC), TGL, cholesterol fractions, CVD risk factors such as blood pressure (BP), weight, abdominal circumference, body mass index and MetS indices such as fasting plasma glucose, HbA1C, Insulin and HOMA-IR among dyslipidemic South Indian population.

*Corresponding author: Dr. Nadanam Saravanan, Division of Biochemistry, Rani Meyyammai College of Nursing, Faculty of Medicine, Annamalai University, Annamalai Nagar - 608 002, Tamil Nadu, India, Tel: 91-4144-237225; E-mail: saravanan_74@rediffmail.com

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Subjects

A total of 40 dyslipidemic people identified at random from age-gender registers of Rajah Muthiah Medical College Hospital, Annamalai Nagar, Tamil Nadu, India. They are recruited by letter to participate in a health survey. Inclusion criteria as dyslipidemia is set as serum TGL>200 mg/dl or HDL-C<40 mg/dl or LDL-C>130 mg/dl [15]. Exclusion criteria included the presence of any other chronic illness that could affect blood lipid concentration or limit the individual’s ability to participate in the study, and the use of cholesterol-lowering drugs and any medication known to affect lipid concentrations. The study design was approved by the Institutional Ethical Committee, Annamalai University, India and written informed consent was obtained from each participant.

Study Design

The study was performed as a 4-week randomized, double-blind, placebo controlled, parallel-group trial with a follow-up examination at the end of the study. During the health survey, anthropometric measurements were measured for height, weight, abdominal circumference and BP. Height and weight were measured in bare feet and in right clothing. BP was measured at the right arm after 10 minutes rest in a seated position using an automated BP measurement system (HEM-970; OMRON, Kyoto, Japan) and these measurements were repeated three times. Five ml of overnight fasting blood samples were collected, and lipid profile was measured using ERBA SMARTLAB automated biochemistry Analyser. Twenty four-hour urine specimens were collected using a standard aliquot cup that allowed the participants to repeatedly collect an exact portion of voided urine [16,17]. These urine specimens were used for the analyses of isoflavones using high-performance liquid chromatography (HPLC) and for creatinine [16]. The analytical methods used for isoflavones were described by Uesugi et al. [18]. A structured questionnaire to obtain information about demographic characteristics, medical history and medication use were used for face-to-face interviews [16].

Forty subjects identified as dyslipidemic were assigned randomly to either soy powder (Soy) or red bean powder (Placebo). The soy group received daily a sachet of 18.1 g soy powder containing 85 K cal and the placebo group received daily placebo sachet (23.1 g) of red bean powder containing 85.5 K cal, in addition to the usual diet for four weeks. Intake of soy/placebo powder was assessed by measurement of 24-hour urinary isoflavone excretions at baseline and at the end of the intervention period. Randomization was done based on chance by which study participants are assigned to a treatment group to minimize differences among groups by equally distributing people with biochemical characteristics among the two groups before intervention. The researchers did not know which treatment is better. A double-blind procedure was used to guard against both experimenter bias and placebo effects. The subjects of the experiment and the persons administering the experiment did not know the critical aspects of the experiment. Table 1 shows the percentage compositions of nutrients in soy powder and placebo powder.

Table 1: Contents of Soy and bean powders.
Table 2. Baseline values of the analysed parameters after randomisation.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Parameter</th>
<th>Placebo powder Group (n=20)</th>
<th>Soy Powder Group (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Systolic BP (mm Hg)</td>
<td>130.55 ± 3.83</td>
<td>126.45 ± 5.16</td>
<td>0.240</td>
</tr>
<tr>
<td>2</td>
<td>Diastolic BP (mm Hg)</td>
<td>80.20 ± 2.50</td>
<td>72.95 ± 3.02</td>
<td>0.902</td>
</tr>
<tr>
<td>3</td>
<td>Heart rate (BPM)</td>
<td>81.45 ± 3.13</td>
<td>81.30 ± 2.29</td>
<td>0.428</td>
</tr>
<tr>
<td>4</td>
<td>Weight (Kg)</td>
<td>67.48 ± 2.47</td>
<td>65.05 ± 2.35</td>
<td>0.701</td>
</tr>
<tr>
<td>5</td>
<td>Abdominal circumference (cm)</td>
<td>89.00 ± 1.96</td>
<td>94.70 ± 2.11</td>
<td>0.611</td>
</tr>
<tr>
<td>6</td>
<td>Body mass index</td>
<td>25.51 ± 0.86</td>
<td>25.82 ± 0.73</td>
<td>0.850</td>
</tr>
<tr>
<td>7</td>
<td>Serum cholesterol (mg/dl)</td>
<td>169.20 ± 6.86</td>
<td>181.30 ± 11.51</td>
<td>0.340</td>
</tr>
<tr>
<td>8</td>
<td>Serum triglyceride (mg/dl)</td>
<td>188.40 ± 10.07</td>
<td>169.95 ± 10.87</td>
<td>0.932</td>
</tr>
<tr>
<td>9</td>
<td>Serum HDL (mg/dl)</td>
<td>41.60 ± 0.76</td>
<td>43.05 ± 0.75</td>
<td>0.980</td>
</tr>
<tr>
<td>10</td>
<td>Serum LDL (mg/dl)</td>
<td>92.95 ± 6.25</td>
<td>94.75 ± 6.40</td>
<td>0.723</td>
</tr>
<tr>
<td>11</td>
<td>Isoflavone by creatinine</td>
<td>1.04 ± 0.45</td>
<td>1.20 ± 0.48</td>
<td>0.441</td>
</tr>
<tr>
<td>12</td>
<td>Fasting blood sugar (mg/dl)</td>
<td>156.05 ± 14.89</td>
<td>164.95 ± 18.28</td>
<td>0.772</td>
</tr>
<tr>
<td>13</td>
<td>HbA1C (%)</td>
<td>7.08 ± 0.25</td>
<td>7.35 ± 0.27</td>
<td>0.475</td>
</tr>
<tr>
<td>14</td>
<td>Insulin (µ IU/mL)</td>
<td>23.10 ± 3.05</td>
<td>15.53 ± 1.48</td>
<td>0.021*</td>
</tr>
<tr>
<td>15</td>
<td>HOMA IR</td>
<td>8.50 ± 1.14</td>
<td>5.56 ± 0.43</td>
<td>0.009**</td>
</tr>
</tbody>
</table>

Values are expressed as mean ± SEM. * indicates p<0.05

Table 3. Effects of the Soy powder and the placebo powder on the analysed parameters after the intervention (4 weeks).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Placebo Group (n=20)</th>
<th>Soy Group (n=20)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Std. Error Mean</td>
<td>Mean</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>130.55</td>
<td>3.83</td>
<td>128.98</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td>80.20</td>
<td>2.50</td>
<td>77.70</td>
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<td>77.70</td>
</tr>
<tr>
<td>Weight (Kg)</td>
<td>67.48</td>
<td>2.47</td>
<td>67.04</td>
</tr>
<tr>
<td>Abdominal circumference (cm)</td>
<td>89.00</td>
<td>1.96</td>
<td>86.40</td>
</tr>
<tr>
<td>Body mass index</td>
<td>25.51</td>
<td>0.86</td>
<td>25.60</td>
</tr>
</tbody>
</table>

Significance: *** p<0.001 compared with the baselines.

Table 4. Effects of the Soy powder and the placebo powder on systolic blood pressure (BP), diastolic BP, heart rate, weight, abdominal circumference, body mass index.

Discussion

The results of this study demonstrate a protective role of soy protein on some CVD markers and some MetS indices following four-week supplementation to the dyslipidemic people. The change in 24-hour urinary isoflavone excretion indicates that subjects consumed the Soy/placebo well with the prescribed sachets.
As regard the limitation of this study, the number of subjects enrolled, no differences were observed in SBP, DBP, HR, weight and BMI between and within groups, but this may be due to the short treatment period, which reduced the statistical significance of the outcomes.

Four-week supplementation of Soy in dyslipidemic subjects significantly decreased the serum TGL level, which reduced the statistical significance of the outcomes.

Significance: * p<0.05, ** p<0.01 and *** p<0.001 compared with the baselines.

Table 5: Effects of the Soy powder and the placebo powder on serum cholesterol, serum triglyceride, serum high density lipoprotein (HDL), serum (low density lipoprotein (LDL)) and isoflavone by creatinine.

Table 6: Effects of the Soy powder and the placebo powder on fasting blood sugar, HbA1C, insulin and HOMA-IR.

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Conflict of Interest
None

References