Beneficial Effects of a Soy-Based Dietary Supplement on Lipid Levels and Cardiovascular Risk Markers in Type 2 Diabetic Subjects

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OBJECTIVE — Consumption of soy protein has recently been shown to improve the blood lipid levels in nondiabetic subjects. The purpose of this study was to evaluate if a dietary supplement of soy protein, isoflavones, and cotyledon fiber (Abalon) affects cardiovascular risk markers, blood glucose, and insulin levels in type 2 diabetic subjects.

RESEARCH DESIGN AND METHODS — Twenty type 2 diabetic subjects participated in a crossover trial. They were randomized to double-blind supplementation for 6 weeks with Abalon (soy protein [50 g/day] with high levels of isoflavones [minimum 165 mg/day] and cotyledon fiber [20 g/day]) or placebo (casein [50 g/day] and cellulose [20 g/day]), separated by a 3-week wash-out period.

RESULTS — The results are expressed as means ± SD. The percentage mean treatment difference between Abalon and placebo demonstrated significantly lower mean values after Abalon for LDL cholesterol (10 ± 15%, P < 0.05), LDL/HDL ratio (12 ± 18%, P < 0.05), apolipoprotein (apo) B100 (30 ± 38%, P < 0.01), triglycerides (22 ± 10%, P < 0.05), and homocysteine (14 ± 21%, P < 0.01), whereas the total cholesterol value tended to be less significant but still lower (8 ± 15%, P < 0.08). No change occurred in HDL cholesterol, apo B100/apo A1 ratio, plasminogen activator inhibitor 1, factor VIIc, von Willebrand factor, fibrinogen, lipoprotein(a), glucose, HbA1c, or 24-h blood pressure.

CONCLUSIONS — These results indicate beneficial effects of dietary supplementation with Abalon on cardiovascular risk markers in type 2 diabetic subjects. This improvement is seen even in individuals with near-normal lipid values.

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Coronary artery disease (CAD) is much more prevalent among adults with type 2 diabetes than in the general population (1,2) with a four- to sixfold greater cardiovascular mortality (3). A two to three times higher CAD risk is seen in diabetic subjects at every level of total cholesterol (4). The serum lipid abnormalities in type 2 diabetes are characterized by decreased HDL cholesterol and hypertriglyceridemia, whereas total cholesterol and LDL cholesterol levels are similar to those in nondiabetic subjects. Also, altered coagulation with increased concentrations and activity in blood of procoagulants including fibrinogen, coagulation factor VIIc, and von Willebrand factor, as well as attenuated fibrinolysis, with increased plasminogen activator inhibitor 1 (PAI-1) activity may contribute indirectly and directly to macrovascular disease (5,6). Both clinical and experimental studies have suggested that mild increases in plasma homocysteine may be an independent risk factor for CAD (7,8). A recent study in type 2 diabetes also demonstrated a clear relationship between increased homocysteinemia and increased risk of CAD (9). Hyperhomocysteinemia may be an even stronger risk factor for CAD in subjects with type 2 diabetes than in nondiabetic subjects (10).

In recent years, approaches to control CAD have largely focused on drug therapy in people with CAD. Still, lifestyle modifications including changed dietary pattern and increased exercise play an important role. The intake of diets low in fat and high in complex carbohydrates from grains, fruits, and vegetables is associated with a lower risk of cardiovascular disease (11). A diet with a high content of dietary fiber and low glycemic load is also associated with reduced incidence of type 2 diabetes (12,13). Dietary recommendations for type 2 diabetic subjects largely target reducing total and saturated fat and replacing the fat with complex carbohydrates (14). This dietary therapy is also generally recommended for lowering plasma cholesterol before resorting to drug treatments. Interestingly, the major components of soybean flour (i.e., soy proteins, soy cotyledon fiber, and isoflavones) appear to independently decrease serum cholesterol (15). A recent meta-analysis of 38 controlled clinical trials indicated that soy protein was effective in lowering plasma cholesterol, LDL cholesterol, and triglyceride concentrations (16). In a small acute study, supplementation of soy fibers for obese type 2 diabetic subjects also seemed to reduce the rise of postprandial plasma triglycerides and mildly lower the blood glucose response without affecting the insulin lev-
sulfonylureas and metformin). They took the prescribed medicine throughout the study and, with the exception of one patient who increased the metformin dose 8 days before the last visit, all other subjects kept an unchanged dose of medicine. None were taking insulin, hypolipidemic agents, β-blocking agents, or acetylsalicylic acid. Subjects were asked to maintain their habitual diet and level of physical activity throughout the study. All were in good general health and had normal liver and renal function. The experimental protocol was approved by the local ethical committee of Aarhus County. Informed written consent was obtained from each subject. The study was monitored by the Good Clinical Practice (GCP) unit of Aarhus University Hospital.

**RESEARCH DESIGN AND METHODS**

**Subjects**

Of the 25 individually randomized type 2 diabetic subjects, 20 completed the study. Two subjects receiving control did not complete the study for the following reasons: one subject developed headaches and vertigo, and one did not tolerate phlebotomia. Three subjects in the soy product phase did not complete for the following reasons: one subject had diarrhea after the first visit, one subject developed headaches and vertigo, and one did not tolerate phlebotomia. Two subjects receiving control did not complete the study. After a 6-week treatment with placebo. After a 6-week treatment, all other subjects kept an unchanged dose of medicine. None were taking insulin, hypolipidemic agents, β-blocking agents, or acetylsalicylic acid. Subjects were asked to maintain their habitual diet and level of physical activity throughout the study. All were in good general health and had normal liver and renal function. The experimental protocol was approved by the local ethical committee of Aarhus County. Informed written consent was obtained from each subject. The study was monitored by the Good Clinical Practice (GCP) unit of Aarhus University Hospital.

**Study design**

A controlled double-blind crossover study was conducted on outpatients. Twelve patients were randomly allocated to a 6-week treatment with Abalon and 8 patients to a 6-week treatment with placebo. After a 3-week wash-out period, the participants received the alternative treatment for 6 weeks. The soy product (Abalon; Nutri Pharma ASA, Oslo, Norway) provided a daily amount of 50 g isolated soy protein (Supro; Protein Technologies, St. Louis, MO) with a high isoflavone content (total isoflavones >165 mg) and 20 g soy cotyledon fiber (Supro). The control provided a daily amount of 50 g casein and 20 g cellulose. Both products containing low-energy flavoring (aspartame, maltodextrin, and cacao taste) were packaged in foils. This was conducted after an overnight fasting from 0800 on the last day of the 6-week treatment with Abalon and the control supplement.

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**Table 1—Subject characteristics of 20 type 2 diabetic subjects (14 men and 6 women) at the start of and after 6 weeks treatment**

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th></th>
<th>Abalon</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Start</td>
<td>6 weeks</td>
<td>Start</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>88.3 ± 11.8</td>
<td>89.0 ± 12.3</td>
<td>88.7 ± 11.9</td>
<td>89.3 ± 11.9</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>30.1 ± 4.2</td>
<td>30.3 ± 4.2</td>
<td>30.2 ± 4.2</td>
<td>30.4 ± 4.2</td>
</tr>
<tr>
<td>Waist (cm)</td>
<td>103.1 ± 8.7</td>
<td>103.5 ± 8.7</td>
<td>102.9 ± 8.9</td>
<td>103.6 ± 8.6</td>
</tr>
<tr>
<td>Waist-to-hip ratio</td>
<td>0.96 ± 0.07</td>
<td>0.97 ± 0.07</td>
<td>0.96 ± 0.07</td>
<td>0.97 ± 0.07</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>130 ± 9</td>
<td>129 ± 10</td>
<td>130 ± 9</td>
<td>130 ± 9</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>78 ± 6</td>
<td>77 ± 6</td>
<td>78 ± 5</td>
<td>77 ± 7</td>
</tr>
<tr>
<td>Pulse rate</td>
<td>79 ± 11</td>
<td>79 ± 9</td>
<td>76 ± 10</td>
<td>77 ± 9</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>6.7 ± 1.3</td>
<td>6.9 ± 1.7</td>
<td>6.6 ± 1.2</td>
<td>6.6 ± 1.2</td>
</tr>
<tr>
<td>Plasma glucose (mmol/l)</td>
<td>7.0 ± 2.0</td>
<td>7.7 ± 2.9</td>
<td>6.9 ± 2.3</td>
<td>7.3 ± 2.8</td>
</tr>
<tr>
<td>Insulin (pmol/l)</td>
<td>72 ± 30</td>
<td>68 ± 41</td>
<td>68 ± 37</td>
<td>74 ± 45</td>
</tr>
</tbody>
</table>

Data are means ± SD.
**Soy, diabetes, and cardiovascular risk markers**

**Analytical methods**

Plasma and urinary glucose levels were measured by the glucose oxidase method. Serum insulin was determined by an enzyme-linked immunosorbent assay (ELISA) method (19). HbA1c was measured by a commercial kit (Bio-Rad, Richmond, CA) (normal 3.5–5.5%). Free fatty acids were determined by a standard enzymatic colorimetric assay method using a commercial kit (Boehringer Mannheim, Mannheim, Germany). Triglycerides, total cholesterol, and HDL were measured on a Roche/Hitachi 917 Automatic Analyzer (Roche Diagnostics, Mannheim, Germany). LDL cholesterol was calculated. The functional activity of factor VII was determined by a coagulation procedure (20) and the functional concentration of fibrinogen with a modified Clauss assay (21). The protein concentration of fibrinogen was determined with an ELISA method from American Diagnostica (Greenwich, CT). PAI-1 was determined with the Imulysel PAI kit from Biopool International (Uppsala, Sweden).

The incremental areas over the 240-min determination, whereas measures of glucose in the blood sample measurements, and urine determinations, whereas measures of glucose and insulin responses were made by analysis of variance with repeated measurements (SAS software, Cary, NC). P < 0.05 was considered statistically significant. **RESULTS** — There were no significant differences in clinical characteristics before the Abalon and control treatments (Table 1). As seen, no difference occurred at the end of the two 6 weeks in weight, BMI, waist, WHR, BP, or pulse rate. On both treatments, the patients had a minor significant weight increase averaging 0.6 kg. Similar HbA1c, fasting plasma glucose, and fasting plasma insulin levels were obtained as seen in Table 1. No statistically significant difference in 24-h urinary excretion of sodium, potassium, calcium, creatinine, or glucose was observed during the day the 24-h blood pressure was estimated (K.H., M.S., L.H., unpublished data).

**Table 2—Composition of the diets of 20 type 2 diabetic subjects at the start of and after 6 weeks treatment**

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Abalon</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Start</td>
<td>End</td>
</tr>
<tr>
<td>Total energy (kcal/day)</td>
<td>2,021 ± 533</td>
<td>2,369 ± 550</td>
</tr>
<tr>
<td>Carbohydrate (% of energy)</td>
<td>48 ± 6</td>
<td>43 ± 7</td>
</tr>
<tr>
<td>Fat (% of energy)</td>
<td>30 ± 5</td>
<td>28 ± 5</td>
</tr>
<tr>
<td>Protein (% of energy)</td>
<td>19 ± 2</td>
<td>26 ± 4</td>
</tr>
<tr>
<td>Alcohol (% of energy)</td>
<td>4 ± 5</td>
<td>3 ± 4</td>
</tr>
<tr>
<td>Fiber (g/day)</td>
<td>27 ± 10</td>
<td>42 ± 11</td>
</tr>
<tr>
<td>Cholesterol (mg/day)</td>
<td>327 ± 106</td>
<td>319 ± 220</td>
</tr>
</tbody>
</table>

Data are means ± SD.

**Fasting blood lipids and other cardiovascular risk factors**

Lipid profiles and other cardiovascular risk markers before and after 6 weeks of each dietary supplementation are summarized in Table 3. There were no significant differences at the beginning of each dietary supplementation (baseline) between plasma lipid concentrations, indicating that the wash-out period was sufficient. Abalon supplementation resulted in significantly lower levels of total cholesterol than placebo (5.11 ± 0.78 vs. 5.45 ± 0.88 mmol/l; P < 0.01), LDL cholesterol (3.01 ± 0.68 vs. 3.33 ± 0.72 mmol/l; P < 0.01), and apo B100 (0.86 ± 0.19 vs. 0.98 ± 0.23 g/l; P < 0.05), whereas similar HDL cholesterol (1.38 ± 0.35 vs. 1.33 ± 0.34 mmol/l; NS) and apo A1 (1.29 ± 0.06 vs. 1.36 ± 0.05 g/l; NS) were obtained. The percentage mean treatment difference between Abalon and the control treatment assessed by Wilcoxon's test demonstrated significantly lower mean values after Abalon for LDL cholesterol (10 ± 15%; P < 0.05), triglycerides (22 ± 43%; P < 0.05), and apo B100 (30 ± 38%; P < 0.01), whereas total cholesterol did not reach statistical significance (8 ± 15%; P = 0.08). Also, the ratio of LDL cholesterol to HDL cholesterol was reduced by 12 ± 18% (P < 0.05), whereas the ratio between apo B100 and A1 was not significantly reduced (3 ± 11%; P = 0.07) by the soy supplementation.

As shown in Table 3, there was no change for the von Willebrand factor, factor VIIc, fibrinogen, or PAI-1. Interestingly, homocysteine was lower after Abalon compared with the control treatment both in absolute terms (11.6 ± 4.0 vs. 12.7 ± 4.7 µmol/l; P < 0.01) as well as in percentage treatment difference (14 ± 21%; P < 0.01), respectively.

**Glucose and insulin responses**

Glucose and insulin responses to Abalon compared with that from the control supplement (half-day dose) obtained during the test menu served the last day of the two 6-week periods showed similar response areas (above basal) during the 4-h observation periods for plasma glucose (533 ± 351 vs. 581 ± 333 mmol/l × 240 min) and serum insulin (51.2 ± 46.9 vs. 55.7 ± 45.8 mmol/l × 240 min).

**CONCLUSIONS** — In type 2 diabetic subjects, treatment with the soy-based dietary supplement Abalon for 6 weeks resulted in a significant (10%) reduction in LDL cholesterol, a 12% reduction in the LDL/HDL ratio, a nonsignificant (8%) reduction in total cholesterol, a 30% reduction in apo B100, and a 22% reduction in triglyceride levels; HDL cholesterol, how-
ever, remained unchanged. These results are fairly consistent with those in a recent meta-analysis with nondiabetic subjects (16). Thus, an average daily soy protein intake of 47 g induced a percentage reduction in total cholesterol of 9%, in LDL cholesterol of 13%, and in triglycerides of 11%. The initial serum cholesterol concentrations had a powerful effect on changes in total and LDL cholesterol concentrations in the group of subjects in the meta-analysis (16) of which many had moderate or severe hypercholesterolemia (>6.5 mmol/l). The lipid changes we observed included lower levels also of the ratio of LDL/HDL cholesterol and apo B100 after 6 weeks on Abalon. Such changes in lipid levels have been shown to be associated with less CAD (24–26). Because apo B is independently associated with cardiovascular disease and identifies high-risk phenotypes in normocholesterolemic type 2 diabetic patients (27), the 30% reduction induced by Abalon is noteworthy. It could be argued that the apparent difference in change in apo B100 versus the change in LDL cholesterol is enigmatic because there is one apo B molecule in the LDL particle. One explanation could be that the LDL particles have changed to larger less atherogenic particles during soy treatment. Another matter is that the LDL levels, in contrast to the apo B100 levels, are calculated not measured, which may have led to an underestimation in LDL cholesterol change and to some extent explain the apparent difference. Lp(a) is a cholesterol-carrying particle in the blood that is structurally similar to LDL, with the addition of the apoprotein(a) moiety. Increasing evidence has indicated that Lp(a) is also an independent risk factor for coronary heart disease (28). Despite its resemblance to the LDL particle, Lp(a) levels in the blood are not responsive to most conventional diet approaches to lowering LDL cholesterol. In line with this, we did not show any significant impact of Abalon on Lp(a). Table 3 shows a few inconsistencies in statistical significance between the percentage mean treatment differences and the absolute values of which the percentage of mean differences is considered most relevant.

It is puzzling that the weight increase during the two study periods only accounts for 0.6 kg on average considering the extra energy intake recorded. The most likely explanation is that the subjects are less likely to underreport at the end rather than at the start of the study periods because of the tight weight control during the study periods. Concomitantly with an increased protein and energy intake with Abalon, patients should be encouraged to reduce dietary fat and protein in their habitual diet. It appears that the wash-out period between dietary supplement periods was adequate because our subjects had returned to their basal lipid levels and weights before the second 6-week period. Compliance with the dietary supplement was good in our study.

The mechanisms for the lipid-lowering effect of Abalon are not known. There is persuasive evidence to implicate soy protein in the cholesterol-lowering effect. Thus, soy products provide a large amount of protein with high-quality amino acids, which seems to upregulate LDL receptors directly by 50% or more (29). The question of the mechanism involved is important, because selection of the protein source plays a critical role in the development of products with a greater or lesser likelihood of reducing serum cholesterol in humans. There is abundant evidence that both purified viscous soluble fiber and soluble fiber in foods reduce serum cholesterol levels (30). The action of soluble fiber seems to relate to an increase in fecal bile acid loss (31). That dietary soluble fiber in large amounts can result in a modest decrease in total and LDL cholesterol without changing HDL cholesterol also in people with diabetes has been demonstrated in several studies (32,33). Lo (34) reviewed data on soy fiber and reported that the addition of soy cotyledon fiber to diets of hypercholesterolemic individuals is effective in reducing total and LDL cholesterol. The combination of soy protein and cotyledon fiber therefore may be additive in cholesterol-lowering effects. The meta-analysis of Anderson et al. (16), however, indicated that a considerable proportion of the effect of soy products on serum cholesterol might be linked to the effects of isoflavones. The amount of isoflavones in Abalon is high (minimum 165 mg/50 g soy protein) because of the type of processing used to produce the product. Since isoflavones are compounds that have structure similar to estrogens and bind to estrogen receptors, it has been postulated

Table 3—Effects of a soy-based dietary supplement on cardiovascular risk markers in 20 type 2 diabetic subjects

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>6 weeks*</th>
<th>Abalon</th>
<th>6 weeks†</th>
<th>Abalon vs. control</th>
<th>Mean treatment difference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cholesterol (mmol/l)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>5.59 ± 0.81</td>
<td>5.45 ± 0.88</td>
<td>5.68 ± 0.84</td>
<td>5.11 ± 0.78</td>
<td>0.0041</td>
<td>-8 ± 15</td>
</tr>
<tr>
<td>LDL</td>
<td>3.64 ± 0.80</td>
<td>3.33 ± 0.72</td>
<td>3.63 ± 0.78</td>
<td>3.01 ± 0.68</td>
<td>0.0044</td>
<td>-10 ± 16</td>
</tr>
<tr>
<td>HDL</td>
<td>1.28 ± 0.29</td>
<td>1.33 ± 0.34</td>
<td>1.31 ± 0.22</td>
<td>1.38 ± 0.35</td>
<td>0.2024</td>
<td>0 ± 20</td>
</tr>
<tr>
<td>Triglycerides (mmol/l)</td>
<td>1.70 ± 1.49</td>
<td>1.79 ± 1.17</td>
<td>1.70 ± 1.17</td>
<td>1.63 ± 0.97</td>
<td>0.3632</td>
<td>-22 ± 43</td>
</tr>
<tr>
<td>Apo B100 (g/l)</td>
<td>0.95 ± 0.26</td>
<td>0.98 ± 0.25</td>
<td>1.09 ± 0.21</td>
<td>0.86 ± 0.19</td>
<td>0.0249</td>
<td>-30 ± 38</td>
</tr>
<tr>
<td>Lp(a) (U/l)</td>
<td>32.3 ± 37.5</td>
<td>32.4 ± 39.8</td>
<td>29.5 ± 29.9</td>
<td>33.9 ± 37.7</td>
<td>0.3488</td>
<td>8 ± 34</td>
</tr>
<tr>
<td>LDL/HDL ratio</td>
<td>2.95 ± 1.02</td>
<td>2.52 ± 0.62</td>
<td>2.82 ± 0.75</td>
<td>2.20 ± 0.61</td>
<td>0.0007</td>
<td>-12 ± 18</td>
</tr>
<tr>
<td>Apo B100/apo A1 ratio</td>
<td>0.82 ± 0.17</td>
<td>0.73 ± 0.17</td>
<td>0.80 ± 0.17</td>
<td>0.68 ± 0.16</td>
<td>0.0056</td>
<td>-3 ± 11</td>
</tr>
<tr>
<td>von Willebrand factor (%)</td>
<td>127 ± 31</td>
<td>124 ± 33</td>
<td>126 ± 27</td>
<td>124 ± 34</td>
<td>0.3251</td>
<td>-1 ± 23</td>
</tr>
<tr>
<td>Factor VIIc (%)</td>
<td>105 ± 20</td>
<td>111 ± 20</td>
<td>104 ± 22</td>
<td>106 ± 18</td>
<td>0.0875</td>
<td>-3 ± 17</td>
</tr>
<tr>
<td>Fibrinogen (µmol/l)</td>
<td>10.2 ± 2.6</td>
<td>10.0 ± 2.0</td>
<td>9.7 ± 1.8</td>
<td>9.8 ± 1.6</td>
<td>0.3632</td>
<td>-1 ± 21</td>
</tr>
<tr>
<td>PAI-1 (ng/ml)</td>
<td>24 ± 15</td>
<td>23 ± 13</td>
<td>24 ± 13</td>
<td>21 ± 12</td>
<td>0.4973</td>
<td>-1 ± 63</td>
</tr>
<tr>
<td>Homocysteine (µmol/l)</td>
<td>10.6 ± 2.6</td>
<td>12.7 ± 4.7</td>
<td>11.2 ± 3.9</td>
<td>11.6 ± 4.0</td>
<td>0.0040</td>
<td>-14 ± 21</td>
</tr>
</tbody>
</table>

Data are means ± SD, unless otherwise indicated. *Treated with control supplement; †treated with Abalon; ‡significance of differences in Abalon and control treatments at week 6; §significance of mean treatment differences (%).
that this may be responsible for the effects soy protein has on serum lipids (35). Two proposed mechanisms for a hypocholes-
terolemic impact of isoflavones are the up-regulation of LDL receptors and/or inhibi-
tion of endogenous cholesterol synthesis. A reduction in total cholesterol has been observed after consumption of 45 mg isoflavones/day relative to levels during a control period with isoflavone-free products (35). However, in other studies, the choles-
terol-lowering soy products were low in phyto-oestrogens, questioning this mecha-
nism of action (28).

Whereas Abalon caused no change in the procoagulants fibrinogen, factor VIIc, and von Willebrand factor or in the fibrinolytic marker PAI-1 in the type 2 diabetic subjects, it is noteworthy that it reduced the level of homocysteinemia by 14% compared with control. Thus, many significant studies indicate an effect by elevated homocysteine on CAD occurrence, progression, and recur-
rence that is independent of traditional risk factors (7,8). Also in type 2 diabetic subjects, a strong correlation with CAD has been demonstrated (9,10). This differential effect of homocysteinemia observed may at least in part be ascribed to the higher methionine content in casein compared with isolated soy protein (3.0 vs. 1.0 g/100-g product).

A very modest improvement in blood glucose attributed to fiber intake from soy beans has been reported in type 2 diabetic subjects both in some acute (17) and some more long-term experiments (36), while this was not seen in other studies (37). No change in insulin levels occurred (17,38). In the present study, similar results were obtained both regarding fasting blood glu-
cose and insulin levels as well as in response to test meal with Abalon.

In conclusion, these results indicate beneficial effects of dietary supplementation with Abalon on cardiovascular risk markers in type 2 diabetic subjects. This improve-
ment is seen even in individuals with near-
normal lipid values. Ingestion of soy products has been shown to further improve the effectiveness of low-fat diets in nondia-
betic subjects (38–40). Thus, a dietary sup-
plementation with Abalon in type 2 diabetic patients may provide an acceptable and effective option for blood lipid control, thereby postponing the requirement for drug therapy for these patients.

Acknowledgments — This study was sup-
ported by grants from Aarhus University and

Nutri Pharma ASA, Oslo, Norway, which also provided the Abalon and placebo.

We thank Tove Skramsgaard and Kirsten Eriksen for excellent technical assistance and Eva Pedersen, RD, for diet preparation and moni-
toring and calculating the food records.

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