

SUMMARY REPORT ON RELIV STUDY

Background

Almost 700,000 people die annually in the US from heart disease. Heart disease is the number one cause of death in the US and diagnosed heart disease occurs in 11% of non-institutionalized adults. Diabetes is the 6th leading cause of death and becoming an epidemic due to the obese and aging population.

People with no history of heart attack or stroke are twice as likely to die of cardiovascular disease if they have 2 or more uncontrolled risk factors (such as elevated cholesterol or blood pressure). They have almost the same risk of death from cardiovascular disease as people with a history of heart attack or stroke (American Heart Association story "Ignored cardiovascular risk factors costs billions" 9/2/04). The subjects in this study have 3 problems; elevated lipids, elevated blood pressure and elevated glucose.

Reliv Study

The product taken daily is effective in significantly reducing two risk factors for heart disease and stroke; elevated cholesterol and elevated glucose. The product taken every other day significantly reduced only systolic blood pressure, which is also a risk factor. The product is more effective for lipids and glucose when given daily than when given every other day so the discussion in the numbered items below is mostly for that dosing regimen.

Individuals taking statin drugs had a slight overall beneficial effect on cholesterol and LDL with the product (daily or every other day) and also experienced a reduction in the risk factor (cholesterol/HDL). Triglycerides were increased in this group but not significantly. The statin group also experienced a slight decrease in glucose. Thus the product does not interfere with the action of statins but in fact adds to the benefit of taking statins. The baseline average cholesterol level of the statin group was 210 mg/dL which is similar to the average cholesterol level of the US population. Statistically 35% of coronary heart disease events occur in people with < 200 mg/dL cholesterol. The fact that "normal" cholesterol levels were decreased by the product taken daily or every other day indicates a possible beneficial for people with normal cholesterol to experience a lowering of cholesterol with the product. Only a supplement study with a normal population can prove this hypothesis.

One effect that was consistent throughout all the groups and dosages was the antioxidant effect of Reliv on measures of lipid oxidative damage. The every day regimen and the every other day regimen significantly and reduced the damage for both the statin group and the non-statin group. (33-63% reduction). Lipid oxidation damage is a measure of oxidative stress and is elevated in hypercholesterolemic subjects and those with heart disease. Lipid oxidation is predictive of cardiovascular events and lowering it, as was done with Reliv, indicates a decreased risk of heart disease in the subjects.

1. Lipids (Non-Statins group)

The average cholesterol at baseline was 243 mg/dL, LDL was 164 and triglycerides were 165, all elevated. HDL was 48, which was normal. Cholesterol, LDL and triglycerides were decreased in this study. For the every day regimen, the average heart disease risk factor [cholesterol/HDL] decreased significantly 10% and every other day decreased it a non-significant 3%. *The ratio of bad to good cholesterol (LDL/HDL), another heart disease risk factor, declined 13% in the every day group. This reduction is greater than the 10% decrease produced by successful obese or overweight dieters who lost an average of 5% of their body weight after 12 months of any of the 4 popular diets studied and reported in JAMA, January 2005.* For the every day regimen, subjects were classified initially as having an undesirable ratio (5.5), and after supplementation (4.9) were in the desirable range (5.0 or less). Cholesterol was lowered 7% and LDL 9% (both significant), which translates from Framingham Study data to a decrease in risk of cardiovascular disease of 7-18%. HDL increased 4% and this calculates to a reduced risk of 12%. Triglycerides were decreased 13% with the every day regimen and only 4% with every other day. The change from 162 to 141, a drop of 20 points in the every day group indicates a risk reduction of 50% for ischemic heart disease as determined by the Quebec Cardiovascular Study [New Engl. J. Med., 1996]. The subjects before supplementation were classified as having borderline- high triglycerides but after supplementation were classified as normal. Increased triglycerides are part of the metabolic syndrome that increases heart disease risk. The average subject in the study possessed 2 of the necessary 3 classification parameters for metabolic syndrome, elevated triglycerides and elevated BMI (29). In fact 28/42 subjects were either overweight or obese at entry. The regimen did not affect body weight.

The every day regimen was significantly more efficacious than every other day for lowering cholesterol and LDL.

2. Blood pressure (Non-Statins group) Every other day regimen

Systolic (upper number) was significantly lowered after supplementation with the every other day regimen. The reduction was 7%. Subjects were initially classified as pre-hypertensive (Systolic between 120-139 mm) with the average of 126 before treatment, which decreased to 117 after supplementation. Paradoxically the daily dose caused no change in systolic blood pressure.

3. Glucose (Non-Statins group)

The fasting glucose significantly decreased 6% following treatment with the regimen taken every day but with every other day it increased 3%, non-significant. Subjects were pre-diabetic at entry, 101 mg/dL (2004 classification by the American Diabetic Association). After daily supplementation they fell into the normal range at 95 mg/dL. This decrease in glucose calculates into a 38% reduction in risk in developing diabetes according to a 2001 epidemiological study. Since diabetes is an independent

risk factor for heart disease, the benefit of this reduction is considerable. Using a recent epidemiological study [Hypertension, 2004], it can be calculated that the risk of heart disease is reduced 64% in hypertensives by the glucose lowering magnitude of the product. Although the subjects were not all hypertensives, the average value classified them as pre-hypertensives.

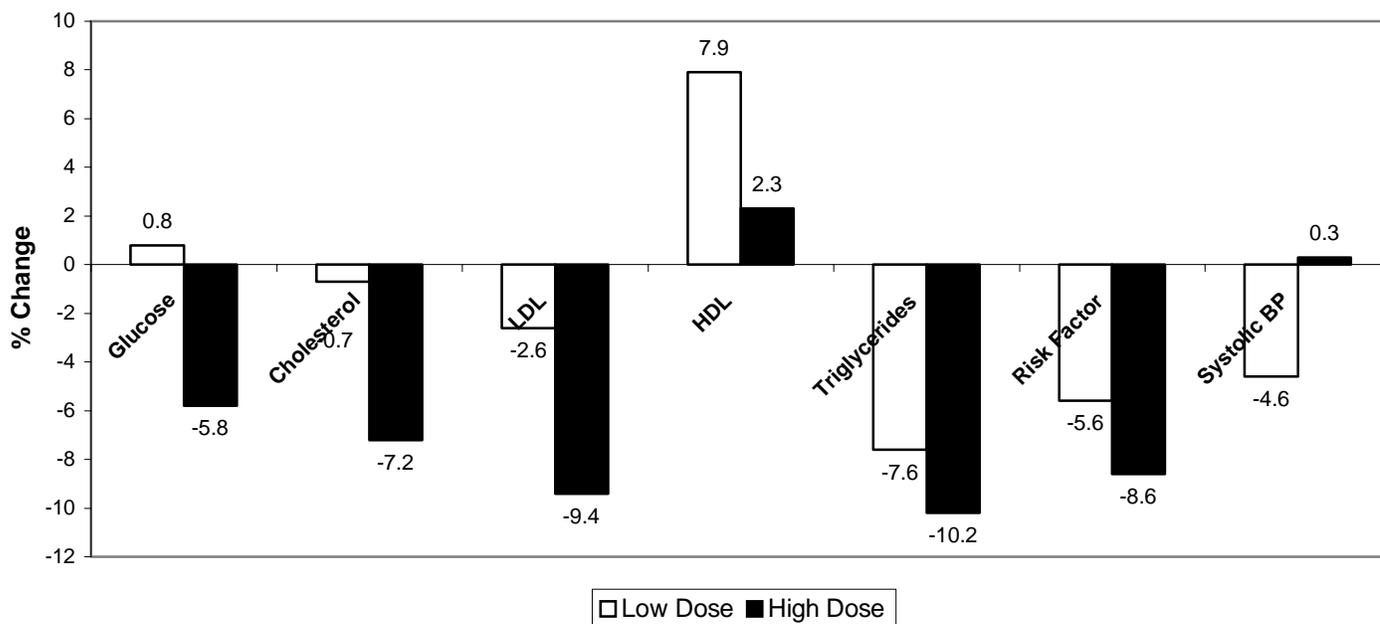
4. Safety

Small but significant changes occurred with every day use of Reliv supplement in the non-Statin group for RBC, MCV, MCH, RDW-CV, sodium, and creatinine. The group average was in the normal range for these parameters before and after the supplementation. There was a very large increase in homocysteine in both every day (16%) and every other day (32%) supplementation. However the homocysteine values stayed well within the normal range. There was also a large but non-significant increase in high sensitivity C-reactive protein after every day use in the Statin (90%) and non-Statin group (27%). These subjects had elevated CRP on entry to the study. There were no significant changes in renal function or in levels of liver-associated enzymes in any of the treated groups. Thus the product is safe to use for both people on statins or those who are hypercholesterolemic.

5. Dose-Response (Non-Statin group)

In general there was a dose-response effect on the parameters studied and thus the every day regimen was superior to the every other day. The exceptions were HDL and systolic blood pressure, which were significantly improved by the every other day regimen but were not by every day. The comparisons are shown in the figure below.

% Change in Heart Disease Risk Factors



Summary for Heart Disease Risk

A simple calculation of the effect of supplementation in this study is to use the National Cholesterol Education Program Adult Treatment Panel III 10 year risk assessment test. Inputting the data for a 50-year old male in this study (average starting and ending cholesterol, HDL and systolic BP), the 10-year risk of developing cardiovascular disease decreases **29%** and for a 50-year old female the risk decreases **from 1% to less than 1%**. For a 60-year old male in the study the risk declines **9%** and for a 60-year old female decreases **33%**. For a 40-year old male the risk reduction is **33%**. See the graph below.



CARDIOVASCULAR RISK REDUCTION WITH RELIV

% reduction in 10-year heart disease risk

