Novel Medical Food with SKRMs Offers Enhanced Support for Low-GL Diet in Improving Cholesterol Markers in Metabolic Syndrome

Nearly 50 million American adults (1 in 4) are affected by metabolic syndrome, characterized by a diagnosis of 3 or more of the following:[1]

- Abdominal obesity
- Dyslipidemia
- Elevated blood pressure
- Insulin resistance or glucose intolerance
- Prothrombotic state
- Proinflammatory state

Metabolic syndrome is a major risk factor for type 2 diabetes and coronary heart disease, as well as other diseases related to plaque buildup in artery walls. Leading health organizations and scientific studies now recommend therapeutic lifestyle changes (such as diet and exercise) as the first step in managing metabolic syndrome, type 2 diabetes, and other cardiovascular disease (CVD) risks.[2]

Medical foods can also be a part of this therapeutic plan. A medical food is formulated with macro- and micronutrients that are recognized by scientific principles to support the dietary management of a disease or condition, and contain nutrients that typically cannot be acquired through normal dietary measures.

Medical food support for the management of metabolic syndrome is not a new concept and has been in practice for almost 20 years in clinics worldwide. New to medical foods, however, are nutritional components that reflect breakthrough nutrigenomic research findings.

Several years ago a medical food was developed that featured a proprietary blend of soy protein and sterols—along with nutrients to promote the loss of fat while helping to maintain lean muscle tissue—in a low-glycemic-index beverage mix. Soy protein and plant sterols have both been recognized by the U.S. Food and Drug Administration for their ability to reduce the risk of CVD when complementing a healthy diet. This base formula was previously clinically tested and shown to complement a low-glycemic-load diet and exercise and have a greater effect on established CVD health markers than a standard dietary intervention from the American Heart Association that did not consider the glycemic load (GL) of recommended carbohydrates.[3]

Unlike the glycemic index (GI), which ranks foods according to their impact on blood sugar levels, the glycemic load (GL) is calculated by multiplying the glycemic index by the grams of carbohydrates in a serving. It is believed that the GL may be more beneficial, as it considers the amount of carbohydrate eaten in the context of an overall diet. Consumption of a low-GL diet has been associated with a lower risk of type 2 diabetes and CVD.[4,5]

New Medical Food Featuring SKRMs

Groundbreaking research suggests that certain food components can selectively modify kinase activity in favor of good health. These are referred to as selective kinase response modulators (SKRMs). Kinases are enzymes that translate dietary signals to positively or negatively influence numerous aspects of health. They function to chemically modify other proteins and regulate the majority of cellular pathways, especially those involved in the transmission of signals within the cell.

Acacia nilotica and reduced iso-alpha acids (RIAA) derived from *Humulus lupulus L*. (hops) are two such SKRMs shown to modulate kinase signaling in adipocytes—fat-storing cells involved in glucose utilization and insulin signaling. While hops and acacia have been utilized traditionally for centuries, nutrigenomic research has uncovered new applications for their use.[6,7] Components derived from hops, for example, have been shown to have anti-inflammatory properties.[8]

By supporting healthy kinase signaling, these SKRMs may help maintain healthy triglyceride levels. *In vitro* testing of these ingredients has also demonstrated inhibition of IL-6 cytokines that influence insulin function. In addition, RIAA and acacia have been clinically shown in a preliminary study at the Functional Medicine Research Center℠, the clinical research arm of Metagenics, to improve fasting insulin and lipid parameters.

Before adding SKRMs to the medical food formula containing soy protein and plant sterols, a clinical trial was designed to monitor the combined effects on what are considered to be stronger prognostic markers for coronary risk—apolipoprotein B (apoB) and the ratio of apoB to apolipoprotein A1 (apoB/apoA1). (A low-GL diet and exercise were held constant to better evaluate the combined effect of these nutrients.)

Apolipoproteins—Better CVD Predictors

ApoB is a component of low density lipoprotein (LDL or "bad") cholesterol that has been shown in studies to be superior to LDL or total cholesterol when predicting CVD risk because its measure reflects the total number of atherogenic particles (LDL can be calculated indirectly by measuring apoB). ApoA1, conversely, is the main component of high density lipoprotein (HDL or "good") cholesterol and has a central role in reverse cholesterol transport. An increasing number of studies suggest that the apoB/apoA1 ratio provides an accurate picture of the balance of good and bad cholesterol in the blood and is a superior risk indicator.[9-11]

Recent Study Results[12]

A 12-week open-labeled, randomized, 2-arm study conducted at the Functional Medicine Research Center—the clinical research arm of Metagenics—consisted of 44 subjects with at least 3 markers for metabolic syndrome (randomized to one of 2 arms) who completed at least 8 to 12 weeks participation.

Methodology. Participants received detailed dietary counseling on a low-GL diet with no caloric restriction and were asked to complete 150 minutes per week of moderate exercise. Subjects in one arm also received the soy protein/plant sterol medical food and a nutraceutical containing RIAA and acacia (the same combination of ingredients now featured in the second generation of this medical food formula). Blood was drawn at baseline, 8, and 12 weeks and analyzed for apoA1, apoB, and other risk markers.

The research team chose to pay particular attention to apoB/apoA1 ratio because it is "the most powerful predictor of all routine risk factors for coronary artery disease" and "significantly associated with metabolic syndrome and considered to be a stronger risk assessment tool than LDL-C." At baseline measurements, researchers noted that "Subjects with higher apoB/apoA1 ratios were older, were heavier, were more likely to have hypertension, and had on average greater mean values for waist circumference, triglycerides, fasting glucose, blood pressure levels, low-density lipoprotein, total cholesterol, and non-HDL cholesterol than subjects with lower apoB/apoA1 ratios."

Results. Despite no caloric restrictions, both groups experienced weight loss. The intervention group, however, showed remarkably better overall results: persistent lowering effects on both apoB and the apoB/apoA1 ratio. The medical food/SKRMs arm also showed statistically greater reductions in lipid parameters—including the total cholesterol, HDL cholesterol, triglycerides, and the calculated LDL cholesterol. In addition, this arm showed statistically greater reduction in serum homocysteine (an indicator of coronary artery disease) and a significant increase in HDL cholesterol. [*See Table 1.*]

Researchers concluded that the addition of a medical food containing SKRMs to a low-GL diet and exercise plan "significantly improves the apoB/ApoA1 ratio, a major risk factor in subjects with metabolic syndrome."

Measurement	Arm 1: Medical Food with SKRMs plus Low-GL Diet Plan & Exercise	Arm 2: Low-GL Diet Plan & Exercise Only
Total Cholesterol	-36.74*	-16.33*
Triglycerides	-89.39*	-30.89
HDL-C	2.65*	1.06
LDL-C	-28.38*	-15.06*
T Chol/HDL-C	-1.35*	-0.61*
TG/HDL	-3.01*	-1.01
ApoA1	-4.00	-8.44
ApoB	-25.70*	-15.06*
ApoB/ApoA1	-0.12*	-0.05*

* These results are statistically significant.

Table 1. *The arm that included the medical food and SKRMS showed significantly greater improvements in risk indicators apoB and apoB/apoA1.*

References

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