CLINICAL SUMMARY

Evaluation of a Combination Formula that includes Chromium, Green Tea, Cinnamon, and Alpha-Lipoic Acid in Patients with Metabolic Syndrome and Diabetes: Summary of Case Studies

Introduction

An estimated 16 million Americans have type 2 diabetes, and as many as 47 million individuals are at an increased risk to develop type 2 diabetes because of metabolic syndrome—also known as insulin resistance syndrome.[1,2] The prevalence of metabolic syndrome has increased dramatically over the past several decades. As the number of individuals with blood sugar metabolism disorders rises, so does the need for safe agents that assist with blood sugar management and reduce the risk of further health complications.

It is now clear that these disorders of blood sugar metabolism are associated with a cluster of cardiovascular disease (CVD) risk factors including obesity, hypertension (HTN), suppressed high-density lipoprotein cholesterol (HDL-C), and high total cholesterol (tChol) and triglycerides (TG). Although not all are known causal factors, this collection of health complications is present in an overwhelming majority of individuals in which the underlying issue is reduced insulin sensitivity—or insulin resistance.

In cases of insulin resistance, the body attempts to maintain control over high glucose levels as the pancreas secretes larger and larger amounts of insulin, producing a state of hyperinsulinemia. Over time, the pancreas may become less capable of maintaining this high level of insulin secretion, leading to reduced glucose control, and ultimately, the development of type 2 diabetes. Dysregulation of blood sugar metabolism is also associated with reduced antioxidant defenses and increased generation of reactive oxygen species (i.e., oxidative stress), which is a major contributing factor to the late-stage complications of type 2 diabetes, such as CVD.

Fortunately, positive lifestyle changes—such as dietary supplementation to support blood glucose homeostasis, consuming a low-glycemic load diet, and getting regular exercise—can help reduce the health risks associated with these disorders. Based on published clinical research of specific ingredients, scientists have developed an advanced dietary supplement as support for individuals with reduced insulin sensitivity and resulting poor blood glucose control. Clinical observations have shown that when combined with other positive lifestyle changes, this formula is successful for the management of complications associated with metabolic syndrome and type 2 diabetes.

This unique combination formula contains alpha-lipoic acid, cinnamon, green tea catechins, chromium, and targeted antioxidants that may help reverse insulin resistance, support glucose control, and protect against oxidative stress (Table 1).

Table 1. **Main ingredients and their actions in the combination formula for glucose management support.**

Nutrient(s)	Action
Alpha-Lipoic Acid	A potent antioxidant shown to help improve insulin sensitivity, regulate blood glucose levels, and prevent diabetic polyneuropathy.[3,4]
Cinnamon	A dietary ingredient shown to reduce serum glucose, triglycerides, LDL cholesterol, and total cholesterol in individuals with type 2 diabetes.[5]
Green Tea Catechins	Flavonoids from green tea that have been reported to have insulin-like effects in type 2 diabetic patients and provide antioxidant protection.[6]
Chromium	A trace mineral that plays a role in the metabolic action of insulin and may help reduce blood lipids.[7]
Vitamins C & E, Zinc, Manganese, Selenium	A blend of antioxidant nutrients to help protect against oxidative stress and degenerative complications associated with poor glucose control.[8]

The six case studies below show how nutritional support with this unique combination can positively influence insulin sensitivity, blood glucose control, and CVD risk factors when combined with healthy dietary and lifestyle changes.

Case Study #1

A 54-year-old female presented with a history of weight gain, beginning at adolescence, and was currently at her heaviest weight ever. She reported symptoms of hypoglycemia following consumption of high carbohydrate meals, along with feeling sluggish and lethargic. Her height was 68", weight was 247 lb, BMI* was 37.6 kg/m^2, and blood pressure (BP) was 140/78. Significant laboratory findings included elevated insulin, TG, and tChol. The assessment was metabolic syndrome, obesity, HTN, and hyperlipidemia.[9]

The patient was instructed to begin the combination formula including chromium, green tea, cinnamon, and alpha-lipoic acid, along with a low-glycemic-load dietary program with no caloric restrictions and a minimum of 100 to 150 minutes per week of aerobic activity. Over the course of 8 weeks, the patient's fasting insulin and TG levels improved, suggesting improved insulin sensitivity (Figures 1 & 2). She had lost 27 lb, her BMI was 33.4 kg/m^2, and her BP was under control at 112/72.

32% Reduction in Triglyceride Levels

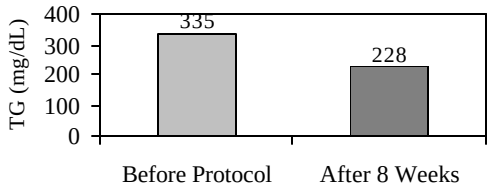

Figure 1. The patient's triglyceride (TG) levels decreased from 335 mg/dL to 228 mg/dL after 8 weeks on the program (reference range: 10-175 mg/dL), indicating a substantial improvement in TG.

40% Decrease in Fasting Insulin

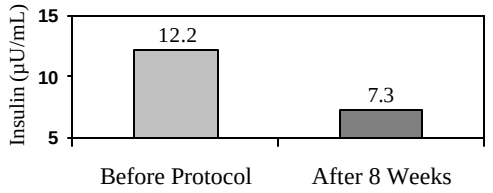

Figure 2. After 8 weeks, the patient's fasting insulin improved from 12.2 µU/mL to 7.3 µU/mL (reference range: 3-30 µU/mL). Taken into account with the reduction in TG, this finding suggests a considerable improvement in insulin sensitivity.

Case Study #2

A 58-year-old male presented with a steady weight gain over the previous 20 years, and elevated BP and gout, which were controlled with medication. His height was 72.25", weight was 287 lb, BMI* was 38.9 kg/m^2, and BP was 138/70. Significant laboratory findings included elevated low-density lipoprotein cholesterol (LDL-C), tChol, insulin, and TG. The assessment indicated metabolic syndrome, hyperlipidemia, and obesity.[10]

The patient was instructed to start the combination formula including chromium, green tea, cinnamon, and alpha-lipoic acid and a low-glycemic-load dietary program with no caloric restrictions, along with an aerobic exercise plan working up to a minimum of 150 minutes per week. After 13 weeks, the patient demonstrated substantial improvements in tChol and LDL-C (Figures 3 & 4). Moreover, his TG had normalized.

22% Reduction in Total Cholesterol

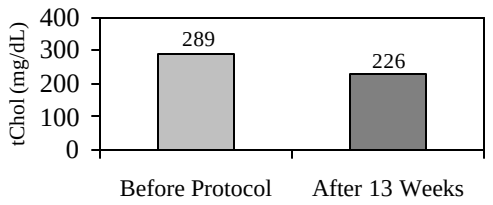

Figure 3. The patient's total cholesterol decreased from 289 mg/dL to 226 mg/dL after 13 weeks on the program (reference range: 110-200 mg/dL), indicating a notable improvement in tChol levels.

26% Improvement in LDL Cholesterol

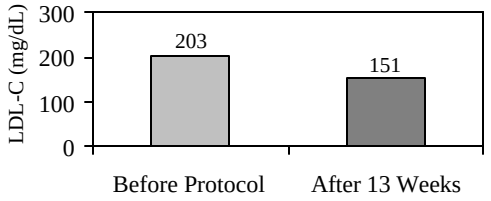

Figure 4. After 13 weeks, the patient's LDL-C decreased from 203 mg/dL to 151 mg/dL (reference range: 95-130 mg/dL). This result indicates the patient's LDL-C substantially improved.

Case Study #3

A 51-year-old male presented with concerns about his weight, BP, and paternal family history of cardiac arrest. His height was 69", weight was 255 lb, BMI* was 39.5 kg/m^2, and BP was 154/97. Significant laboratory findings included an abnormal lipid profile and elevated C-reactive protein (hsCRP) and homocysteine (HCys). The assessment was metabolic syndrome, obesity, HTN, and hyperhomocysteinemia.[11]

The patient was instructed to begin the combination formula including chromium, green tea, cinnamon, and alpha-lipoic acid, a medical food for hyperlipidemia featuring soy protein and phytosterols, and 6:1 EPA/DHA supplement, along with a low-glycemic-load dietary program with no caloric restrictions and 100 to 150 minutes of aerobic activity weekly. After 30 weeks, the patient had lost 33 lb, his BMI* had decreased to 32.7 kg/m^2, and his HTN, blood lipids (Figures 5 & 6), and HCys were all brought under control.

34% Improvement in Total Cholesterol

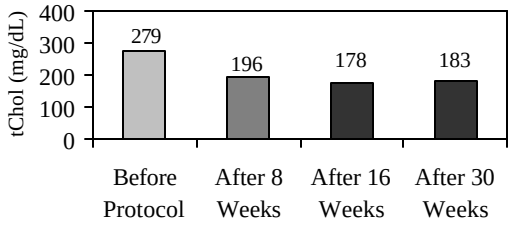

Figure 5. The patient's total cholesterol (tChol) decreased from 279 mg/dL to 183 mg/dL over the course of 30 weeks (reference range: 110-200 mg/dL), indicating his tChol had normalized.

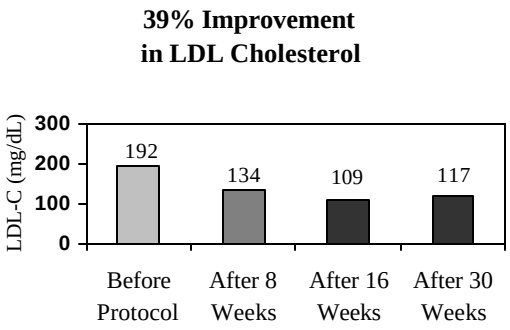

Figure 6. After 30 weeks, the patient's LDL-C decreased from 192 mg/dL to within normal range at 117 mg/dL (reference range: 95-130 mg/dL).

Case Study #4

A 43-year-old male presented with obesity and increased fatigue. His height was 70.75", weight was 278 lb, and BMI* was 38.8 kg/m^2. His physical exam revealed some edema in the calves, bilateral pitting edema in the ankles, and tingling and some numbness in 3 toes of the left foot. Significant laboratory findings included elevated glucose, tChol, and TG.[12]

The patient was instructed to begin the combination formula including chromium, green tea, cinnamon, and alpha-lipoic acid and a medical food for altered body composition, along with a low-glycemic-load dietary program with no caloric restrictions and aerobic exercise (at least 20 minutes) 3 to 4 times per week. After 10 weeks, the patient's blood glucose had substantially improved, tChol had normalized (from 238 to 172 mg/dL), and TG had also normalized (from 506 to 137 mg/dL). (Figures 7 & 8).

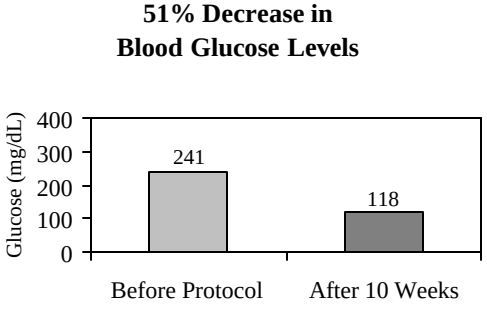

Figure 7. Over the course of 10 weeks, the patient's fasting blood glucose levels decreased from 241 mg/dL to within reference range at 118 mg/dL (reference range: 65-120 mg/dL). This result indicates a considerable improvement in blood glucose levels.

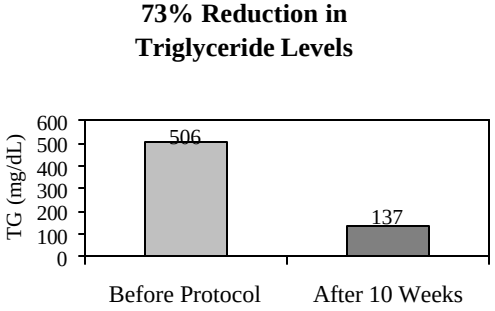

Figure 8. The patient's TG levels were reduced from a very high level of 506 mg/dL to within normal range at 137 mg/dL (reference range: 10-175 mg/dL), indicating a substantial improvement in his TG.

Case Study #5

A 28-year-old female presented with progressive weight gain since age 15, along with amenorrhea and fatigue. She had recently been diagnosed with insulin resistance by her gynecologist and was prescribed metformin and depoprovera. She was interested in trying a more natural approach and had not filled her prescriptions yet. Her height was 64", weight was 242 lb, and BMI* was 41.5 kg/m^2. Significant laboratory findings included elevated TG and TG/HDL-C ratio.[13]

The patient was advised to begin the combination formula including chromium, green tea, cinnamon, and alpha-lipoic acid and a medical food for altered body composition, combined with a low-glycemic-load dietary program with no caloric restrictions and aerobic exercise working up to a minimum of 100-150 minutes per week. At the patient's 28-week visit, her TG and TG/HDL-C ratio had normalized (Figures 9 & 10).

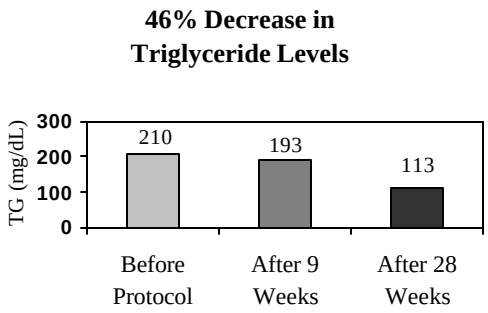

Figure 9. At the patient's 28-week visit, her TG reduced from 210 mg/dL to within the normal range at 113 mg/dL (reference range: 10-175 mg/dL), indicating a considerable improvement in TG.

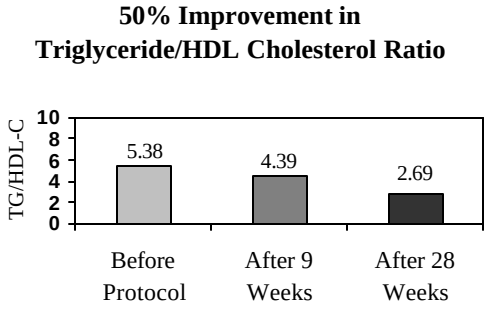

Figure 10. After 28 weeks, the patient's TG/HDL-C ratio decreased from 5.38 to 2.69 (reference range: < 3.0). This result suggests a noteworthy improvement in blood lipid levels.

Case Study #6

A 44-year-old female presented with concerns about her weight and a history of type 2 diabetes, for which she had been prescribed metformin 5 years earlier. Over the previous 3 years, she had made dietary and exercise modifications and lost about 50 lbs. She weighed 190.5 lbs, her BMI* was 33.7 kg/m^2, body fat was 37.6%, and lean mass was 62.4%. Significant laboratory findings indicated elevated tChol, LDL-C, and TG.[14]

The patient was advised to start the combination formula including chromium, green tea, cinnamon, and alpha-lipoic acid and a medical food for hyperlipidemia, combined with a low-glycemic load diet with no caloric restrictions. She was

also instructed to continue on metformin and increase aerobic exercise activity to 5 times per week. After 13 weeks, the patient's BMI* had decreased to 31.4. She also demonstrated improvements in blood lipid levels and other parameters associated with type 2 diabetes (Figures 11 & 12).

23% Decrease in Total Cholesterol

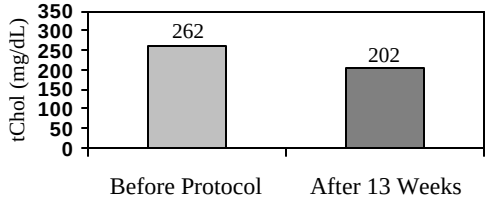

Figure 11. Over the course of 13 weeks, the patient's total cholesterol (tChol) decreased from 262 mg/dL to near normal range at 202 mg/dL (reference range: 110-200 mg/dL), indicating a noteworthy improvement in tChol.

45% Decrease in Triglyceride Levels

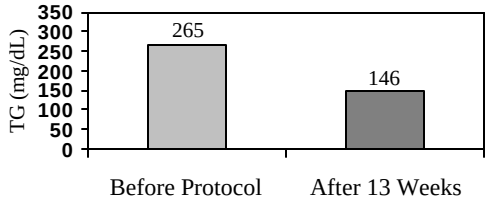

Figure 12. The patient's TG decreased from 265 mg/dL to within normal range at 146 mg/dL (reference range: 10-175 mg/dL), indicating a considerable improvement in TG.

Conclusion

Statistics indicate that metabolic syndrome and type 2 diabetes are on the rise, suggesting the need for effective interventions that help to normalize insulin sensitivity and reduce the risk of further health complications.[1,2] Safe, natural agents that are scientifically formulated can play an important role as part of a healthy lifestyle program to restore blood glucose control.

This evaluation of six patients with blood sugar metabolism disorders suggests that a combination formula—including chromium, green tea, cinnamon, and alpha-lipoic acid—along with healthy dietary and lifestyle changes can improve insulin sensitivity, blood sugar control, and markers of CVD risk.[9-14]

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12. A Case Study Evaluating the Effects of a Combination Formula including Chromium, Green tea, Cinnamon and Alpha-lipoic Acid and a Medical Food for Altered Body Composition in an Obese Male with Type 2 Diabetes. Metagenics, Inc; 077DM205.
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Note

The information provided in each case study describes the results of one patient under the care of a licensed healthcare practitioner and may not be a typical response. Patients treated with medications should be carefully monitored by their healthcare practitioner during any changes to their medication and/or dietary regimens.

These studies were conducted under the supervision of the Functional Medicine Research Center[SM] (FMRC), the clinical research arm of Metagenics, Inc. Dan Lukazcer, ND, is the Director of Clinical Research at the FMRC.

*Body Mass Index (BMI) is computed by the weight (kg) divided by the square of the height (m).

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