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Efficacy and Safety of a Traditional Herbal Combination in Patients with Type II Diabetes Mellitus: A Randomized Controlled Trial

Saeed Mehrzadi ¹, Reza Mirzaei ², Mojtaba Heydari ³, Maryam Sasani ⁴, Bahman Yaqoobvand ⁵, Hasan Fallah Huseini ⁵

Affiliations

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Abstract

Background: *Capparis spinosa*, *Rosa canina*, *Securidaca securigera*, *Silybum marianum*, *Urtica dioica*, *Trigonella foenum-graecum* and *Vaccinium arctostaphylos* are used traditionally as an herbal combination for treatment of diabetic patients in Iran. Despite the clinical evidence supporting their use in solitary form, no controlled human study has determined the efficacy and safety of their combination in treatment of diabetic patients.

Methods: A total 150 type II diabetic patients of both sexes under the oral anti-hyperglycemic drugs treatment (maximum 10 mg glyburide and 1000 mg metformin daily) were randomly assigned to three groups. The patients in each group received either herbal combination or placebo or metformin capsule daily for three months, without any change in their previous oral anti-hyperglycemic drugs dosage. Herbal combination, placebo and metformin capsules matched by shape and color were prepared in the Institute of Medicinal Plants Karaj, Iran. To assess the efficacy and safety of the treatments, the patients fasting plasma glucose, HbA1c, lipid profile, liver enzymes and renal function were determined at the beginning of the study and after three months.

Results: Results showed that after three months, the fasting plasma glucose, HbA1c and cholesterol levels in herbal combination were decreased significantly as compared to placebo group (20% and 12% respectively) and also compared to base line (25% and 15% respectively). The herbal combination was as effective as metformin in reduction of FPG ($p = 0.001$, $p = 0.001$) and HbA1c ($p = 0.028$ and $p = 0.050$ respectively) compared to placebo. No notable hepatic, renal and gastrointestinal side effects were observed in the trial groups.

Conclusion: The results suggest that traditional herbal combination may safely improve glycemic control in type II diabetic patients with no significant adverse effect. [Formula: see text].

Keywords: Anti-hyperglycemic; complementary medicine; diabetes; polyherbal combination; traditional Persian medicine.

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