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Original Article

Sesame oil exhibits synergistic effect with anti-diabetic medication in patients with type 2 diabetes mellitus

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SUMMARY

Background & aims: Recently, studies have reported that sesame oil lowered blood pressure and improved antioxidant status in hypertensive and diabetic-hypertensive patients. The aim of this study was to evaluate the effectiveness of sesame oil with anti-diabetic (glibenclamide) medication as combination therapy in mild-to moderate diabetic patients.

Methods: This open label study included sixty type 2 diabetes mellitus patients divided into 3 groups, receiving sesame oil ($n = 18$), 5 mg/day (single dose) of glibenclamide ($n = 20$), or their combination ($n = 22$). The patients were supplied with sesame oil [BNB Sesame oil^{TM}] except glibenclamide group, and instructed to use approximately 35 g of oil/day/person for cooking, or salad preparation for 60 days. 12 h-fasting venous blood samples were collected at baseline (0 day) and after 60 days of the experiment for various biochemical analysis.

Results: As compared with sesame oil and glibenclamide alone, combination therapy showed an improved anti-hyperglycemic effect with 36% reduction of glucose ($P < 0.001$ vs before treatment, $P < 0.01$ vs sesame oil monotherapy, $P < 0.05$ vs glibenclamide monotherapy) and 43% reduction of HbA_{1c} ($P < 0.001$ vs before treatment, $P < 0.01$ vs sesame oil monotherapy, $P < 0.05$ vs glibenclamide monotherapy) at the end point. Significant reductions in the plasma TC, LDL-C and TG levels were noted in sesame oil (20%, 33.8% and 14% respectively vs before treatment) or combination therapies (22%, 38% and 15% respectively vs before treatment). Plasma HDL-C was significantly improved in sesame oil (15.7% vs before treatment) or combination therapies (17% before treatment). Significant ($P < 0.001$) improvement was observed in the activities of enzymatic and non-enzymatic antioxidants in patients treated with sesame oil and its combination with glibenclamide.

Conclusions: Sesame oil exhibited synergistic effect with glibenclamide and can provide a safe and effective option for the drug combination that may be very useful in clinical practice for the effective improvement of hyperglycemia.

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1. Introduction

The pervasiveness of Type 2 diabetes mellitus (T2DM) is rising radically in developing countries because of flourishing economics and changing life styles. A recent survey has alarmed that number of people with diabetes is expected to reach 370 million worldwide by the year 2030.[1] Primary defects in insulin secretion and the development of insulin resistance contribute to the etiology of type 2 diabetes. Impaired postprandial insulin secretion resulting from both functional defects and the loss of surviving pancreatic β-cells leads to hyperglycemia and a decline in insulin sensitivity.[3,4] Although many drugs have been developed and used for the treatment of diabetes, most patients' therapeutic goals are still not achieved. The need for efficient new therapeutic strategies for the treatment of T2DM is obvious.[2] Among the anti-diabetic agents used for glycemic control, sulfonylureas are most widely prescribed because of its superior postprandial anti-hyperglycemic effect. In general, sulfonylureas are safe, well tolerated, and highly efficient in insulin secretion due to their potent insulinotropic action, as supported by numerous studies.[5,6]

Patients with T2DM characteristically have fasting hypertriglyceridemia and exaggerated lipemia.[7] Therefore, a diet reducing lipids concentrations should be useful in preventing atherosclerosis

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like cardiovascular events associated with T2DM. Dietary saturated fatty acids (SFA) increase the risk for cardiovascular disease, whereas monounsaturated fatty acids (MUFA) and polyunsaturated fatty acids (PUFA) decrease those risks by modification of lipids.[8] We have recently reported that sesame oil, an edible oil rich in mono and polyunsaturated fatty acids, lowered blood pressure and lipids in hypertensive patients medicated with calcium channel blockers.[9,10] In another study, we have reported that sesame oil exhibits additive effect with anti-diabetic medication by beneficially modulating blood sugar and lipids in diabetic-hypertensive patients.[11] Sesame seeds and oil have long been categorized as traditional health food in India and other East Asian countries. Sesame oil has been found to contain considerable amounts of the sesame lignans: sesamin, sesamol, episesamin, and sesamolin. Sesame oil also contains vitamin E (40 mg/100 g oil), 43% of polyunsaturated fatty acids, and 40% monounsaturated fatty acids. The lignans present in sesame oil are thought to be responsible for many of its unique chemical and physiological properties, including its antioxidant, anti-diabetic and antihypertensive properties.[11–15]

Because of its unique action and safety record, sesame oil is an ideal candidate for the combination therapy with sulfonylurea to treat T2DM. The present study investigated the effect of treatment with combination of sesame oil and glibenclamide, an anti-diabetic drug, in mild-to moderate diabetic patients to explore the potential of the novel combination therapies.

2. Materials and methods

2.1. Patients

Sixty outpatients (32 male and 28 female), who were diagnosed with T2DM at Prof. Maniarasan Memorial Poly Hospital, were enrolled in this study. Participants (1) were nonsmokers and non-alcoholics; (2) had no prior cardiovascular, hepatic, or renal disease, or other diseases; (3) had not changed the dose of anti-diabetic agent during the 4 weeks preceding the study; (5) were men or women; (6) had similar socio-economic background.

2.2. Study design

This study was an open label, 3-arm parallel randomized dietary intervention. The patients were randomly divided into 3 groups, receiving sesame oil ($n = 18$), or single dose (5 mg/day) of glibenclamide ($n = 20$), or their combination ($n = 22$). The patients were supplied with sesame oil except glibenclamide group, and were instructed to use approximately 35 g of oil/day/person for cooking, or salad preparation for 60 days. The study protocol, which was approved by the Rajah Muthiah Institute of Health Sciences, Annamalai University and Vinayaka Missions University, was fully explained to the patients; and all the patients gave their oral informed consent before enrollment into the study.

2.3. Sample collection

On the mornings of the first day of the study (0 day) and the day at the end of the study (60th day); 12 h-fasting venous blood samples were collected between 7:00 and 8:00 a.m., and the subject's weight and height were recorded.

2.4. Laboratory procedures

Venous blood was collected into EDTA tubes as well as in plain tubes. Plasma and serum samples were separated by centrifugation at 3000 rpm for 10 min from the respective tubes and stored at 4 °C until analysis. A known volume of erythrocyte was lysed with hypotonic phosphate buffer at pH 7.4. The hemolysate was separated by centrifugation at 10,000 rpm for 15 min at 20 °C and the supernatant was used for the estimation of superoxide dismutase and glutathione peroxidase. Plasma glucose was measured with Bayer RA-50 clinical autoanalyser (Bayer Diagnostics, Mumbai, India) using commercial kit (Merck, India). Blood concentration of glycated hemoglobin (HbA_{1c}) was measured by a commercially available kit (Glycated hemoglobin HbA_{1c} kit, Bio-SupplyUK, UK). Plasma concentrations of total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C) and triglycerides (TG) were assayed with standardized enzymatic method by using commercial kits (GenXBio, India). Low-density lipoprotein cholesterol (LDL-C) was calculated using Friedewald's equation.[16] LDL-C = TC − (HDL-C + TG/5).

2.5. Assay of antioxidant enzymes

Superoxide dismutase (SOD) was assayed by the inhibition of formation of NADH-phenazine methosulphate nitroblue tetrazolium formazan.[17] The reaction was initiated by the addition of NADH and after incubation for 90 s the reaction was stopped by the addition of glacial acetic acid. The colour formed at the end of the reaction was extracted into the butanol layer and measured at 520 nm. One unit of activity was taken as the enzyme concentration, which gave 50% inhibition of nitroblue tetrazolium (NBT) reduction in 1 min.

Glutathione peroxidase (GPx) was estimated by the method of Rotruck et al.[18] A known amount of hemolysate was allowed to react with H_2O_2 in the presence of glutathione (GSH) for a specified time period, then the remaining GSH content was allowed to react with 5,5′-dithio-bis-2-nitro benzoic acid (DTNB) and the yellow colour developed was measured at 412 nm. One unit of activity was expressed as μg of GSH consumed/min/mg Hb.

Catalase (CAT) was assayed colorimetrically by the method of Sinha.[19] Dichromate in acetic acid was converted to perchromic acid and then to chromic acetate when heated in the presence of H_2O_2. The chromic acetate formed was measured at 620 nm. The catalase preparation was allowed to split H_2O_2 for different periods of time. The reaction was stopped at different time intervals by the addition of a dichromate–acetic acid mixture and the remaining H_2O_2 was determined colorimetrically as chromic acetate. One unit of activity was expressed as μmole of H_2O_2 consumed/min/mg protein.

2.6. Assay of non-enzymatic antioxidants

Plasma vitamin C was estimated by the method of Roe et al.[20] The ascorbic acid was converted to dehydroascorbic acid by mixing the plasma samples with acid washed norit, which was then coupled with 2, 4-dinitrophenyl hydrazine (DNPH) in the presence of thiourea, a mild reducing agent. The coupled dinitrophenyl hydrazine was then converted into an orange red coloured complex when treated with sulphuric acid, which was read colorimetrically at 520 nm.

Plasma α-tocopherol was estimated by the method of Baker et al.[21] This method involved the reduction of ferric ions to ferrous ions by α-tocopherol and the formation of a red coloured complex with 2, 2′-dipyridyl. Absorbance of the chromophore was measured at 520 nm.

Plasma β-carotene was determined by the method of Bradely.[22] Proteins were precipitated with ethanol and the carotenes were extracted into light petroleum. The intensity of the yellow colour due to carotene was read directly at 450 nm using a violet filter.

Reduced glutathione (GSH) in plasma was measured according to the method of Ellman.[23] This method was based on the development of a yellow colour when DTNB was added to compounds containing sulfhydryl groups.

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