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Research

Sun-dried tomato powder reduces blood sugar levels and improves the lipid profile among people with type-2 diabetes: A randomized controlled trial

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Background

Diabetes mellitus is a complex metabolic disorder characterized by hyperglycaemia, leading to significant health complications and increased healthcare costs. The prevalence of type 2 diabetes mellitus (T2DM) is projected to rise dramatically by 2040, especially in India, where factors such as genetic predisposition, obesity, and lifestyle contribute to its high incidence. Treatment methods usually involve pharmacological interventions that carry side effects, prompting interest in non-pharmacological strategies.

Objective

This study investigates the effects of supplementation with sun-dried tomato powder, rich in antioxidants like lycopene, on glycaemic and lipid profiles in individuals with T2DM.

Methods

This is an open-label, single-centre, two-arm parallel group, prospective randomized controlled trial. A total of 100 T2DM patients were recruited from Army Welfare Housing Organization Society, Belagavi, Karnataka in the southern part of India and randomly assigned to receive for 60 days either sun-dried tomato powder (25g daily) or a control treatment of tepid water with ghee. The primary outcomes included fasting blood sugar (FBS), postprandial blood sugar (PPBS), and HbA1c levels, while the secondary outcomes focused on lipid profile. A group of 10 subjects was formed and divided into 10 cohorts. One cohort provided blood samples daily for 10 consecutive days for laboratory analysis.

Results

There was a significant reduction in FBS and PPBS, along with improvements in lipid profile, including HDL and VLDL, observed exclusively in the experimental group (EG) ($p<0.001$). Notably, the experimental group showed a significant difference in FBS and PPBS compared to the control group ($p<0.001$). However, HbA1c did not exhibit any significant changes ($p=0.347$).

Conclusions

Our findings indicate that sun-dried tomato powder effectively reduces blood sugar levels and improves lipid profiles in patients with type 2 diabetes mellitus (T2DM), offering a promising non-pharmacological intervention.

INTRODUCTION

Diabetes mellitus is a heterogeneous metabolic disease characterized by the presence of hyperglycaemia due to impairment of insulin secretion, defective insulin action or both (American Diabetes Association, 2010) The symptoms of hyperglycaemia are characterized by polyuria, weight loss, polydipsia and sometimes polyphagia and blurred vision (Canadian Diabetes Association Clinical Practice Guidelines Expert Committee et al. 2013).

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The complications of chronic hyperglycaemia are associated with significant long term microvascular and macrovascular complications (American Diabetes Association, 2010; Canadian Diabetes Association Clinical Practice Guidelines Expert Committee et al. 2013), which lead to increase medical care expenses (Kahn et al. 2014; Baena-Díez et al. 2016; Ye et al. 2023) and a negative impact on a person's quality of life and functional abilities, often leading to an early death (Khan et al. 2020; Ramtahal et al. 2015).

According to predictions made by the International Diabetes Federation, the global prevalence of diabetes will rise from 10.5% in 2021 to 11.3% by 2030 and 12.2% by 2040 (Magliano et al., 2021; Ye et al. 2023). According to the Indian Council of Medical Research the Indian prevalence of T2DM estimated to 10.1 crores (Nanditha et al. 2024). The global prevalence of T2DM estimated reach around 642 million by 2040 (Kaveeshwar and Cornwall 2014).

In India, the aetiology of diabetes is complex and involves both genetic predisposition and environmental factors, such as obesity, linked to rising living standards, frequent urban migration, unhealthy diet and sedentary lifestyle (Kaveeshwar and Cornwall 2014; Zheng et al., 2018) factors which also contribute to the current global epidemic (Zheng et al., 2018).

The two most common treatment modalities for type 2 diabetes are oral anti-diabetics and insulin both of which have side effects, particularly drug-induced hypoglycaemia, weight gain, and nutritional deficiencies (Chaudhury et al. 2017). The goal of conventional medicine for the treatment of type 2 diabetes has been to control blood glucose levels by dietary modifications, the use of oral medications and/or insulin, maintenance of a healthy body weight, frequent exercise, and self-monitoring of blood sugar levels (Radwan et al. 2020).

The primary goals of the management of diabetes are to reduce mortality, prevent or postpone the onset of late disease complications, prevent acute decline and maintain a high quality of life. Non-pharmacological interventions can satisfy all of these. Indeed, physical exercise and dietary approaches which lower blood sugar levels, are regarded as the primary therapeutic strategy for type 2 diabetes mellitus (Selvakumar et al. 2017).

Tomatoes have powerful antioxidants like lycopene, Saponins, ascorbic acid, carotene, flavonoids (such as kaempferol), tocopherol, folic acid, and other small bioactive compounds (Stewart et al. 2000) and also have a low glycaemic index, which is unique combination to help people with Diabetes (Shidfar et al. 2011). Carotenoids are strong antioxidants that may prevent the onset of type 2 diabetes because they contain many conjugated double bonds that can scavenge peroxyl radicals (Wang et al. 2006). Lycopene, the strongest antioxidant present in tomatoes, helps increase concentrations of adiponectin, a specific adipokine having an effect on insulin sensitization (Banihani 2018). It also reduces oxidative stress and thereby reduces inflammatory cytokines (Gouranton et al. 2011; P. Palozza et al. 2010).

Fasting blood sugar is an important indicator of diabetes mellitus and the lipid profile is an important indicator of the related cardiovascular diseases (CVDs) (Li et al. 2020). There are strong associations between lycopene and dyslipidaemia (Sugini 2020). Lycopene has a role in the lowering the arterial wall thickness (Kohlmeier et al. 1997) and also decreasing concentrations of low-density lipoprotein cholesterol (LDL-C) and increasing LDL resistance to oxidation (Silaste et al. 2007). It also improves high density lipoprotein cholesterol (HDL-C) (Cuevas-Ramos et al. 2013a), an important goal in preventing atherosclerosis and CVDs (Kohlmeier et al. 1997). In a systematic review and meta-analysis of randomized controlled trials, Li et al. (2020) found that tomato consumption had no significant effect on reducing FBS levels but did reduce total cholesterol, plasma triglyceride (TG), and LDL and increased HDL levels (Li et al. 2020).

The bioavailability of lycopene is higher in sun-dried tomatoes than in fresh ones (Karakaya and Yılmaz 2007). Yet there are no studies published on sun-dried tomato and its effect on FSB or lipid profiles. Hence, the present study examines whether the consumption of sun-dried tomato powder will have an effect on blood sugar levels and lipid profiles among individuals with type-II diabetes.

METHODS

STUDY DESIGN

This was an open labeled, single center, two-arm parallel group, prospective randomized control trail. It was conducted from April 2024 to September 2024 at the Army Welfare Housing Organization Society, Belagavi, Karnataka in the southern part of India. It was approved by the Ethics Committee of SDM College of Naturopathy and Yogic Sciences, Ujire, and registered on https://clinicaltrials.gov/ (identifier CTRI/2024/03/064798). Participants provided written informed consent.

SAMPLE SIZE

The sample size was calculated using G* power 3.1.9.4 by taking the results of a previous study (Cuevas-Ramos et al. 2013b), considering a 2-sided p-value with a level of significance of 0.05 and a power of 0.80. This resulted in a sample size of 86 ($n \geqslant 43$ for each group). To account for a potential dropout rate of 10%, we initially added 8 subjects, 4 to each group, resulting in a total sample size of 94 (n=47 per group). For convenience and to make the groups evenly rounded, we included an additional 3 subjects in each group, bringing the total sample size to 100 (n=50 per group).

RANDOMIZATION

Randomization was performed using the chit method. For every group of 4 to 8 participants recruited, their names were written on chits, which were then randomly drawn and allocated to either the experimental or control group in a 1:1 ratio. The allocation details were subsequently placed in sealed envelopes.

RECRUITMENT

The subjects were invited to participate in the study by phone calls and through personal visits to their residences. Patients that who were interested and eligible were further called for a screening visit. Fig. 1 presents participant flow by group.

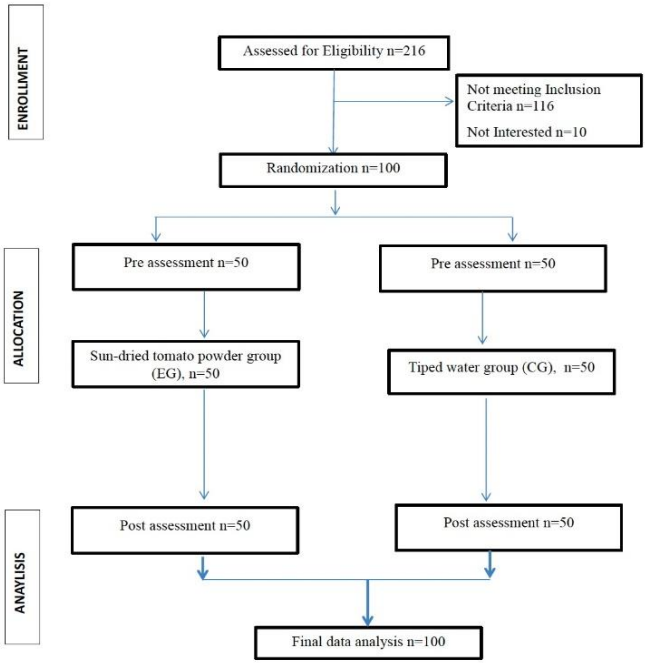

Figure 1. Consort flow chart

Eligible individuals were 30-60 years of age, both males and females, suffering from type 2 diabetes mellitus based on diagnoses meeting the American Diabetic Association diagnostic criteria, and on oral anti-diabetic therapy (Canadian Diabetes Association Clinical Practice Guidelines Expert Committee et al. 2013), whether or not they had dyslipidaemia. Individuals with chronic kidney or liver failure, pregnant or lactating women, those suffering from substance abuse, underweight or morbidly obese individuals, patients with coronary artery disease (CAD) or any vascular disorders, neurological or thyroid conditions, nutritional disorders, acute illnesses, or those on insulin therapy were excluded from the study.After screening, 100 patients were recruited and randomly assigned to the experimental group (EG, n = 50) or control group (CG, n = 50).

COLLECTION OF BLOOD

Blood samples were collected aseptically from participants following an overnight fast of at least 8–10 hours for FBS and lipid profile measurements. For PPBS, samples were collected two hours after a standard meal. HbA1c was measured using whole blood. Serum was separated by centrifuging samples at 3,000 rpm for 10 minutes for biochemical analysis.

FASTING BLOOD SUGAR (FBS) AND POSTPRANDIAL BLOOD SUGAR (PPBS)

Glucose levels were determined using the enzymatic glucose oxidase-peroxidase (GOD-POD) method on an automated biochemistry analyzer (Model: Roche Cobas c311, Manufacturer: Roche Diagnostics).

HBA1C

Glycated hemoglobin (HbA1c) was analyzed using high-performance liquid chromatography (HPLC) on an automated analyzer (Model: Bio-Rad D-10, Manufacturer: Bio-Rad Laboratories).

LIPID PROFILE

The lipid profile, including total cholesterol, triglycerides, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol, was assessed using enzymatic colorimetric assays on an automated biochemistry analyzer (Model: Beckman Coulter AU480, Manufacturer: Beckman Coulter)

We created groups of 10 subjects, resulting in 10 cohorts. Blood was drawn from one cohort every day. Blood for PPBS was collected two hours after a meal. Blood draws for all other indicators were done on an early morning on an empty stomach with a minimum of 8 hour of fasting.

INTERVENTION

PREPARATION, DISTRIBUTION, AND CONSUMPTION OF SUN-DRIED TOMATO POWDER

Ripe Roma tomatoes harvested after 70 days of planting were used for preparing the powder. Tomatoes were thoroughly washed and sliced into 4mm thick slices longitudinally. They were then sun dried for 20 days, receiving around 8 hours of direct sunlight every day. Then they were ground to a powder.

Sachets of 25g sun-dried tomato powder were made, using an electronic weighing scale. Every individual in the EG received 60 sachets on the day of baseline data collection, and were to instructed to consume each sachet in 100 ml tepid water along with a teaspoon of cow ghee every day for the duration of 60 days on an empty stomach. Participants in the CG were to take 100 ml of tepid water with a teaspoon of cow ghee every day on an empty stomach for 60 days.

OUTCOMES

Outcomes were evaluated at two time points: baseline (T_0) data were obtained 1 day before and post-intervention (T_1) 1 day after the 60 days.

1. Primary outcome variable: glycaemic profile (FBS, PPBS and HbA1c)
2. Secondary outcome variable: lipid profile (T.CHOL, TRI, HDL, LDL, VLDL)

Baseline Data and Post intervention data was collected from all subjects. FBS, PPBS, HbA1C, lipid profile was evaluated using laboratory investigation.

STATISTICAL ANALYSIS

Statistical analyses were performed using the Jamovi open statistical software (2022, version 2.3). Descriptive statistics were expressed as means ± standard deviations. All data were analysed for normality by Shapiro-wilk's test. Data not normally distributed were analysed using non-parametric tests. Between-group analysis was done using Man-Whitney test, and with-group analysis, Wilcoxon rank test. Statistical significance was set at $p < 0.05$.

RESULTS

A total of 216 adults with a type 2 diabetes mellitus diagnosis were assessed for eligibility for the study, and 150 were screened. 100 were found to be eligible and volunteered to participate in the study. The age mean±SD of the patients were 48.3 ±6.44 and 49.9±6.53 for the EG and CG respectively.

Table 1. Within the group and between the group comparison of glycaemic profile

Variables	EG			CG				Effect size
	Pre	Post	Within the group	Pre	Post	Within the group	Between the group	
	mean ± SD	mean ± SD	p value	mean ± SD	mean± SD	p value	p value	Cohen's d / Rank biserial correlation
FBS	184 ± 155	120 ± 33	< 0.001	136± 10	132 ± 13	0.861	< .001	0.6115
PPBS	225 ± 81	161 ± 60	<0.001	202 ± 16	204 ± 19	0.922	< .001	0.9683
HbA1c	8.7 ±1.7	7.5 ± 1.2	<0.001	7.5 ± 0.5	7.4 ± 0.5	0.190	0.347	0.109

EG: experimental group; CG: control group; FBS: Fasting blood sugar; PPBS: Postprandial blood sugar; HbA1c: Glycated haemoglobin; FBS is expressed in mg/dl; PPBS is in mg/dl and HbA1c is in %.

GLYCAEMIC PROFILE

There were statistically significant differences in the FBS, PPBS and HbA1c (p<.001) within the EG when compared to the CG. In addition, there was a highly significant difference seen in FBS and PPBS (p<.001) between groups. However, the HbA1c showed no significant difference between the groups (p=0.347). Table 1 and Figure 2 show the changes that occurred in the glycaemic profiles of the two groups.

LIPID PROFILE

There were statistically significant differences in the HDL and VLDL (p<.001) within the EG when compared to the CG. In addition, there was significant improvement in triglyceride (p<0.05) when compared to the CG. Between group comparisons in T.CHOL and LDL cholesterol were significant (p=0.05). Table 2 and Figure 3 show the changes in the lipid profile of the two groups.

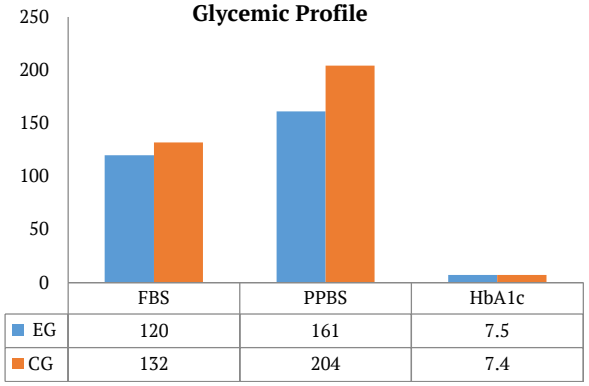

Figure 2: Changes in the Glycaemic profile between the experimental and control groups

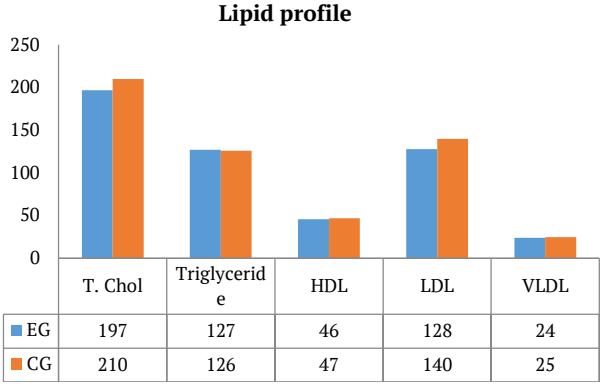

Figure 3. Changes in the lipid profile between EG and CG

Table 2. Within the group and between the group comparison of lipid profile

Variables	EG			CG				Effect Size
	Pre	Post	Within the group	Pre	Post	Within the group	Between the group	
	mean ± SD	mean ± SD	p value	Mean ± SD	Mean ± SD	P value	p value	Cohen's d / Rank biserial correlation
T.CHOL	203 ± 57	197 ± 58	0.097	211 ± 35	210 ± 35	0.534	0.017	0.278
TRI	183 ± 146	127 ± 59	0.003	126 ± 35	126 ± 36	0.826	0.383	0.102
HDL	41 ± 8	46 ± 10	< .001	47 ± 2	46 ± 2	0.089	0.051	0.226
LDL	131 ± 46	128 ± 49	0.178	140 ± 31	140 ± 31	0.133	0.009	0.302
VLDL	31 ± 15	24 ± 14	<.001	25 ± 7	25 ± 7	0.056	0.056	0.222

EG: experimental group; CG: control group; T.CHOL: Total cholesterol, TRI: Triglycerides, HDL: High-density lipoprotein cholesterol, LDL: Low-density lipoprotein cholesterol, VLDL: Very low-density lipoprotein cholesterol are expressed in mg/dl.

DISCUSSION

To the best of our knowledge, this is the first investigation to show that sun-dried tomato powder can lower blood sugar and improve lipid profiles among type-2 diabetic individuals.

We found a substantial statistically significant difference in the FBS, PPBS and HbA1c (p<.001) in within analyses. In between-group analysis, statistical significance was only seen in FBS and PPBS (p<.001).

In previous research, consumption of tomato supplements did not show significant improvement in fasting blood sugar and HbA1c (Bose and Agrawal 2006). This may due to the fact that the bioavailability of lycopene in tomato improves after being sun dried (Karakaya and Yılmaz 2007; Hussein et al., 2016).

Previous research providing 14 servings a week of raw tomato for 1 month showed a favourable effect on HDL-C (Cuevas-Ramos et al. 2013b). Another study 150 ml/day of a novel sauce (OsteoCol) from vine-ripened tomatoes for the period of 6 weeks found a reduction in the TC, TG, LDL-C and an improvement in HDL-C (Ferro et al. 2021). Consumption of at least 7 servings/week of lycopene-based products also decreased cardiovascular risk among post-menopausal women (Sesso et al. 2003). Supplementation with 500 ml/day of tomato juice vitamin E (800 U/day), and vitamin C (500 mg/day) for the period of 4 weeks increased plasma lycopene levels and the intrinsic resistance of LDL to oxidation which also decreases plasma levels of C-reactive protein, all useful in reducing the risk of myocardial infarction in patients with diabetes (Upritchard et al. 2000). A meta-analysis published on effect of lycopene on blood lipids and blood pressure, showed that it effectively reduces LDL cholesterol and total serum cholesterol when taken in doses higher than 25 mg daily and that it also reduces systolic blood pressure in hypertensives (Ried and Fakler 2011).

Lycopene supplementation is associated with a reduction in platelet aggregation (Dutta-Roy et al. 2001; Hsiao et al. 2005), a decrease LDL oxidation, prevention of atherosclerosis by preventing endothelial injury, and it reduces inflammatory responses, also useful in preventing CVDs (Ried and Fakler 2011; Paola Palozza et al. 2010). Thus, overall, the beneficial effects of tomato on cardiovascular health that we found is well described in the literature already. However, our study is the first to show simultaneous benefit on blood glucose parameters in type-2 diabetes.

STRENGTHS AND LIMITATIONS

To our best knowledge, this is the first ever study that was done on the effect of sun-dried tomato powder on blood sugar and lipid profile among T2DM patients. There were no dropouts in the study, and no adverse effects were observed during the entire duration of the study. The participants who participated in the study were middle-aged. The duration of the study was not long and adherence to daily consumption of the materials provided to the two groups was not assessed.

CONCLUSIONS

The present study showed that consumption of sun-dried tomato powder in type-2 diabetics resulted in a notable drop in blood sugar levels and an improvement in blood lipid levels. Hopefully further research will indicate if sun-dried tomato powder is a feasible and alternative therapy in reducing blood sugar and reducing lipid levels in these patients. A larger and longer robust randomized controlled trial could also examine the impact of dosage.

AUTHOR CONTRIBUTIONS

Author AA: Conceptualization, Methodology, Software, Data curation, Writing- original draft preparation. Author PS: Visualization, Investigation, Supervision. Author GBS: Software, Validation, Writing- Reviewing and Editing. All author contributed to the manuscript revision and approved the submitted version.

CONFLICT OF INTEREST

The authors declare that they have no other potential conflicts of interest.

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