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MS-Adjunctive Use of Garlic (Allium sativum), Tinospora cordifolia (Giloy)Leaves and Pomegranate (Punica granatum) Juice in Patients with Type 2 Diabetes Mellitus and Hypertension: A Prospective Observational Cohort Study

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ABSTRACT:

Background. Type 2 diabetes mellitus (T2DM) and hypertension frequently coexist and confer substantial cardio metabolic risk. Food-derived bioactive compounds from garlic (Allium sativum), pomegranate (Punica granatum) and Tinospora cordifolia (giloy) have been investigated for metabolic and antioxidant properties, yet evidence for their combined real-world use as a dietary adjunct remains limited.

Objective. To evaluate the association between regular adjunctive consumption of raw garlic, fresh T. cordifolia leaves and freshly prepared pomegranate juice and changes in glycemic, lipid and selected biochemical parameters among adults with T2DM and hypertension receiving conventional therapy.

Methods. Prospective observational cohort study of 125 adults (age 45–65 years) with established T2DM and hypertension attending outpatient departments at MVJ Medical College & Research Hospital, Hoskote (Bangalore Rural) and Department of Biochemistry, BLDE (Deemed to be University), Shri B M Patil Medical College and

Research Centre, Vijayapura, Karnataka 586103, India between January 2026 to April 2026. Participants continued prescribed antidiabetic and antihypertensive therapy and consumed a standardized dietary adjunct: two medium-sized raw garlic cloves (4–6 g) at night, approximately 10 fresh T. cordifolia leaves (5–8 g) in the morning, and 150–200 mL unsweetened pomegranate juice in the afternoon. Baseline and 12-week biochemical measurements were compared. Primary outcomes were change in HbA1c and serum triglycerides. Reporting followed STROBE recommendations.

Results. Mean age was 55.1 ± 6.0 years; 68 (54.4%) were male; mean BMI 27.6 ± 3.2 kg/mZ. Significant improvements were observed: HbA1c decreased from 9.7 ± 1.3% to 7.5 ± 1.0% (mean change C2.2%, 95% CI C2.4 to C2.0, P < 0.001); triglycerides from 598 ± 156 mg/dL to 295 ± 98 mg/dL (mean change C303 mg/dL, 95% CI C335 to C271, P < 0.001). Fasting and postprandial glucose, total cholesterol and LDL-C declined significantly; HDL-C increased. Malondialdehyde decreased and vitamin D rose modestly. Liver-and renal-function tests remained stable. Mild transient gastrointestinal discomfort occurred in 9 participants (7.2%); no serious adverse events were recorded.

Conclusion. In this prospective observational cohort of 125 adults, adjunctive use of garlic, Tinospora cordifolia leaves and pomegranate juice was associated with clinically meaningful improvements in glycaemic control, triglyceride levels and selected oxidative-stress parameters, with good tolerability. The findings are hypothesis-generating; adequately powered randomized controlled trials are required to establish causality and component-specific effects.

1. INTRODUCTION

Type 2 diabetes mellitus is a chronic metabolic disorder characterized by hyperglycemia arising from insulin resistance, progressive -cell dysfunction and altered glucose, lipid and protein metabolism. Hypertension frequently accompanies T2DM and substantially increases the risk of atherosclerotic cardiovascular disease, heart failure, chronic kidney disease and stroke. Contemporary diabetes care therefore emphasizes integrated management of glycaemia, blood pressure, lipid abnormalities, body weight, kidney risk and other cardiovascular risk factors rather than glucose control alone [1–3].

Diabetic dyslipidemia commonly includes elevated triglycerides, reduced high-density lipoprotein cholesterol (HDL-C) and qualitative abnormalities in low-density lipoprotein (LDL) particles. Persistent hyperglycemia and insulin resistance are also associated with increased oxidative stress, endothelial dysfunction and lipid peroxidation. These interrelated processes may amplify cardio metabolic risk and provide a biological rationale for investigating adjunctive dietary strategies.

Garlic (*Allium sativum*) contains organosulfur compounds, including allicin and related metabolites (S-allyl cysteine, diallyl disulphide). Multiple systematic reviews and meta-analyses of randomized controlled trials have demonstrated modest but statistically significant reductions in fasting plasma glucose, HbA1c, total cholesterol and LDL-C, together with small increases in HDL-C. Effects on triglycerides have been less consistent across meta-analyses [4–7].

Pomegranate (*Punica granatum*) is rich in hydrolysable tannins (punicalagins), ellagic acid and anthocyanins. Clinical trials and recent meta-analyses indicate favorable effects on triglyceride levels, HDL-C, markers of oxidative stress (including malondialdehyde) and, in some studies, blood pressure. Effects on HbA1c have been more variable [8–12].

Tinospora cordifolia (giloy), a climbing shrub widely used in Ayurveda medicine, contains protoberberine alkaloids (berberine, palmatine), diterpenoid lactones and polysaccharides. Preclinical and limited clinical data support antidiabetic, antidyslipidaemic and antioxidant activity; however, the volume and methodological quality of randomized evidence remain substantially lower than for garlic or pomegranate. Importantly, reports of herb-induced liver injury temporally associated with giloy use make botanical authentication and safety monitoring essential in clinical research [13–15].

The rationale for the present study was therefore to evaluate a pragmatic combined dietary regimen in routine outpatient practice across two tertiary centres in Karnataka. Because all participants continued conventional therapy and no concurrent control group was used, the objective was to assess temporal associations rather than establish causal efficacy.

2. AIM AND OBJECTIVES

2.1 Aim

To evaluate changes in glycaemic control, lipid profile and selected biochemical parameters following adjunctive consumption of garlic, *T. cordifolia* leaves and fresh pomegranate juice among patients with T2DM and hypertension receiving conventional treatment.

2.2 Primary objectives

To assess change in HbA1c and serum triglycerides from baseline to approximately 12-week follow-up.

2.3 Secondary objectives

To assess changes in fasting and postprandial blood glucose, total cholesterol, HDL-C, LDL-C, malondialdehyde (MDA), vitamin D, cortisol (where available), liver-function tests, renal-function tests and clinically relevant adverse events.

3. MATERIALS AND METHODS

3.1 Study design

Prospective observational cohort study, reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [1].

3.2 Study setting and period

The study was conducted during diabetic screening camps organized through the outpatient departments of Biochemistry at two tertiary-care medical institutions: (i) MVJ Medical College and Research Hospital, Hoskote, Bengaluru Rural, Karnataka, and (ii) BLDE (Deemed to be University), Shri B. M. Patil Medical College and Research Centre, Vijayapura, Karnataka. Participant recruitment and follow-up were carried out from 15 January 2026 to 20 April 2026.

3.3 Participants

One hundred and twenty-five consecutive eligible adults aged 45–65 years with established T2DM and hypertension were enrolled (approximately balanced across the two centers). Participants continued their prescribed conventional therapy throughout the observation period.

3.4 Inclusion criteria

Age 45–65 years; documented T2DM with concurrent hypertension; stable conventional antidiabetic and antihypertensive treatment; ability to attend baseline and follow-up laboratory assessment; willingness to follow the dietary regimen; and written informed consent.

3.5 Exclusion criteria

Type 1 diabetes; acute metabolic decompensation; severe hepatic or significant renal impairment; known allergy or intolerance to garlic, pomegranate or *T. cordifolia*; pregnancy or lactation; active severe systemic illness; concurrent participation in another interventional trial; and use of other herbal preparations expected to influence primary outcomes.

3.6 Sample size

One hundred and twenty-five participants were recruited on the basis of available outpatient volume across both centers and feasibility of prospective follow-up during the 3-month recruitment window. No formal a priori effect-size-based power calculation was performed. This limitation is acknowledged transparently and should be addressed in future controlled research.

3.7 Dietary adjunct

Participants were advised to consume: (i) two medium-sized raw garlic cloves (approximately 4–6 g) at night; (ii) approximately 10 fresh *T. cordifolia* leaves (approximately 5–8 g fresh weight) in the morning; and (iii) 150–200 mL freshly prepared unsweetened pomegranate juice in the afternoon. No protocol-mandated change to prescribed pharmacotherapy was made.

3.8 Botanical authentication

T. cordifolia was authenticated by a botanical expert at the University of Agricultural Sciences, College Viayapura ,Karnataka voucher specimens were retained (voucher specimens retained; authentication records available from the corresponding author). Garlic and pomegranate were obtained from local

markets; *T. cordifolia* leaves were harvested from verified cultivated sources.

3.9 Study procedure

Demographic and clinical information was recorded at enrolment. Baseline fasting venous samples were obtained for glycaemic, lipid, oxidative-stress, hepatic, renal and selected endocrine measurements. Participants were counselled regarding the dietary regimen and followed prospectively. Biochemical reassessment was undertaken at approximately 12 weeks. Adherence was assessed by patient diary and verbal report.

3.10 Laboratory analysis

Venous samples were collected after overnight fast (and 2-hour postprandial where applicable) using standard procedures and analyzed on validated automated platforms with manufacturer-recommended reagents, daily internal quality control and external proficiency testing. MDA was measured by the thiobarbituric-acid reactive substances (TBARS) method. Reference intervals followed institutional laboratory standards. Analyses were performed on institutional automated platforms under routine quality-control procedures.

3.11 Safety assessment

Participants were monitored for gastrointestinal symptoms, hypoglycemia, allergic reactions and other adverse events. Serial liver and renal biochemical measurements were reviewed. Because *T. cordifolia*-associated liver injury has been reported in multicenter Indian data, structured hepatotoxicity assessment was included [14,15].

3.12 Statistical analysis

Continuous variables are summarized as mean ± standard deviation (SD) when approximately normally distributed or median (interquartile range) otherwise. Baseline-to-follow-up comparisons used the paired *t*-test or Wilcoxon signed-rank test as appropriate. Mean differences are presented with 95% confidence intervals (CI) and exact two-sided *P*-values. $P < 0.05$ was considered statistically significant. Analyses were performed on complete cases (n = 125). Analyses were performed with standard statistical software. Missing data and protocol deviations, if any, are reported.

4. RESULTS

4.1 Participant characteristics

A total of 125 participants were enrolled and all completed the approximately 12-week follow-up assessment (100% retention). Recruitment was distributed across the two centers during January–December 2026.

Table 1. Baseline demographic and clinical characteristics (n = 125)

Characteristic	Value
Number enrolled / analysed	125 / 125
Age, years (mean ± SD)	55.1 ± 6.0
Male, n (%)	68 (54.4%)
Female, n (%)	57 (45.6%)
Duration of diabetes, years (mean ± SD)	7.4 ± 3.5
Duration of hypertension, years (mean ± SD)	6.0 ± 3.0

BMI, kg/mZ (mean ± SD)	27.6 ± 3.2
Baseline HbA1c, % (mean ± SD)	9.7 ± 1.3
Baseline triglycerides, mg/dL (mean ± SD)	598 ± 156
Recruitment period	January 2026 – December 2026
Study centers	MVJ MC&RH, Hoskote; BLDE University Research Centre Vijayapur

BMI = body-mass index; SD = standard deviation.

4.2 Biochemical outcomes

Baseline and follow-up values for primary and secondary biochemical parameters are presented in Table 2. Statistically significant improvements were observed for HbA1c, fasting and postprandial glucose, triglycerides, total cholesterol, LDL-C, HDL-C, MDA and vitamin D. Liver enzymes (AST, ALT) and serum creatinine showed no clinically or statistically significant change.

Table 2. Baseline and approximately 12-week follow-up biochemical parameters (n = 125)

Parameter	Baseline (mean ± SD)	Follow-up (mean ± SD)	Mean change (95% CI)	P-value
HbA1c (%)	9.7 ± 1.3	7.5 ± 1.0	C2.2 (C2.4 to C2.0)	<0.001
FBS (mg/dL)	262 ± 45	148 ± 31	C114 (C126 to C102)	<0.001
PPBS (mg/dL)	305 ± 51	182 ± 38	C123 (C138 to C108)	<0.001
Triglycerides (mg/dL)	598 ± 156	295 ± 98	C303 (C335 to C271)	<0.001
Total cholesterol (mg/dL)	225 ± 34	189 ± 28	C36 (C44 to C28)	<0.001
HDL-C (mg/dL)	39 ± 7	46 ± 8	+7 (+5 to +9)	<0.001
LDL-C (mg/dL)	130 ± 29	109 ± 23	C21 (C28 to C14)	<0.001
Vitamin D (ng/mL)	18.1 ± 6.4	23.6 ± 7.3	+5.5 (+3.9 to +7.1)	<0.001
MDA (nmol/mL)	4.7 ± 1.2	3.0 ± 0.9	C1.7 (C2.0 to C1.4)	<0.001
AST (U/L)	29 ± 10	27 ± 9	C2 (C4 to +0.5)	0.12
ALT (U/L)	33 ± 12	30 ± 10	C3 (C6 to 0)	0.07
Creatinine (mg/dL)	0.93 ± 0.19	0.90 ± 0.17	C0.03 (C0.06 to +0.01)	0.11

FBS = fasting blood sugar; PPBS = postprandial blood sugar; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol; MDA = malondialdehyde; AST = aspartate aminotransferase; ALT = alanine aminotransferase; CI = confidence interval. Paired comparisons used paired t-test (normally distributed variables) or Wilcoxon signed-rank test. Two-sided P < 0.05 considered statistically significant.

Cortisol (subset, n = 62) showed a modest non-significant decline. No participant developed laboratory evidence of hepatic or renal toxicity.

4.3 Safety and tolerability

No serious adverse events occurred. Mild transient gastrointestinal discomfort (mild flatulence or garlic aftertaste) was reported by 9 participants (7.2%) and resolved without discontinuation of the regimen. No hypoglycemic episodes requiring medical attention, allergic reactions or clinically significant laboratory abnormalities attributable to the adjunctive regimen were observed. Liver- and renal-function tests remained within or returned to normal reference ranges throughout the observation period.

5. DISCUSSION

In this prospective observational cohort of 125 adults with established T2DM and hypertension recruited from two tertiary outpatient centers in Karnataka between January and December 2026, regular consumption of two raw garlic cloves, approximately 10 fresh *Tinospora cordifolia* leaves and 150–200 mL fresh pomegranate juice for approximately 12 weeks was associated with statistically and clinically significant improvements in glycaemic control, lipid profile and an oxidative-stress marker, while liver and renal function tests remained stable and no serious adverse events were recorded.

5.1 Glycaemic control

The mean reduction in HbA1c of 2.2 percentage points is clinically relevant because current American Diabetes Association (ADA) Standards of Care identify an HbA1c goal of <7% for many non-pregnant adults, while emphasizing individualization [2]. However, the magnitude of any observed change cannot be attributed specifically to the dietary adjunct. Regression to the mean, improved medication adherence, dietary counselling, physical-activity changes and alterations in background pharmacotherapy may all influence HbA1c. The observed effect size substantially exceeds typical pooled estimates for garlic monotherapy (approximately 0.5–0.7 percentage points) [4,5]; therefore additive or synergistic contributions, concurrent lifestyle improvements or optimized adherence to background therapy remain plausible explanations that cannot be disentangled in an uncontrolled design.

5.2 Garlic and glycaemic metabolism

Garlic has been evaluated in randomized clinical trials and meta-analyses, generally demonstrating modest effects on glucose and HbA1c. Proposed mechanisms include enhancement of insulin sensitivity, inhibition of hepatic gluconeogenesis and improvement of peripheral glucose uptake. The larger magnitude observed here should not be interpreted as proof of synergy from this uncontrolled design.

5.3 Pomegranate and glycaemic outcomes

Pomegranate contains polyphenols with antioxidant and metabolic effects, including inhibition of intestinal

-amylase and

-glucosidase and reduction of oxidative stress that impairs insulin signaling. Clinical meta-analyses have reported variable effects on fasting glucose, HbA1c and insulin-resistance indices. Differences in juice versus extract, dose, duration, baseline metabolic status and study quality may explain heterogeneity. The present regimen therefore provides a hypothesis for prospective controlled evaluation rather than proof of efficacy.

5.4 Tinospora cordifolia

Preclinical literature supports possible antidiabetic and antioxidant actions of *T. cordifolia*, but high-quality clinical evidence is limited. Prior work by our group has demonstrated favorable effects of giloy (Tinospora cordifolia) herbal extracts, including combinations with mangiferin, on glycaemic control and insulin secretion in type 2 diabetes mellitus [31]. Its inclusion should therefore be described as exploratory, building on these preliminary observations. Rigorous taxonomic authentication is important because reports of liver injury have raised concerns regarding giloy products and possible botanical substitution [14,15].

5.5 Triglycerides and lipid profile

The mean reduction in serum triglycerides of approximately 300 mg/dL is particularly noteworthy given the markedly elevated baseline values characteristic of poorly controlled diabetic dyslipidemia. Parallel declines in total cholesterol and LDL-C, together with a rise in HDL-C, are directionally consistent with the lipid-modulating effects of both garlic and pomegranate reported in meta-analyses. Elevated triglycerides and adverse TG/HDL-C ratios are recognized early cardiovascular risk markers in hypertensive and diabetic populations; prior observations from our centers have highlighted the utility of triglyceride-glucose index, TG/HDL-C ratio and lipoprotein(a) for risk stratification [32,33]. Improvement in glycaemic control itself can reduce triglycerides, so direct lipid-lowering attribution to the botanical regimen alone is not justified [3]. in meta-analyses. Improvement in glycaemic control itself can reduce triglycerides, so direct lipid-lowering attribution to the botanical regimen alone is not justified [3].

5.6 Oxidative stress

The observed decrease in MDA is biologically compatible with reduced lipid peroxidation. Garlic organosulfur compounds and pomegranate polyphenols possess radical-scavenging and Nrf2-activating properties. Nevertheless, TBARS-based MDA assays have analytical limitations and should not be interpreted as a definitive measure of systemic oxidative stress. Future work should incorporate validated complementary redox biomarkers.

5.7 Vitamin D

An increase in vitamin D should be regarded as exploratory because vitamin D status is affected by sunlight exposure, supplementation, diet, season, adiposity and other factors. Gender-based endocrine variations in vitamin D, cortisol and sex hormones have been reported in T2DM populations from related cohorts [34], underscoring the need for stratified analyses. A direct effect of the dietary regimen should not be inferred without controlling these variables.

5.8 Cardiovascular and blood-pressure relevance

Patients with T2DM and hypertension have elevated cardiovascular risk. Current ADA guidance recommends individualized blood-pressure targets and comprehensive cardiovascular risk management [3]. Any antihypertensive effect of pomegranate or the combined regimen would require pre-specified blood-pressure measurements and appropriate analysis; the present design cannot establish such an effect.

5.9 Safety

Stable liver and renal biochemical parameters over approximately 12 weeks are reassuring. However, they do not establish long-term safety. A multicenter Indian study identified cases of liver injury temporally associated with giloy use, including autoimmune-like features [14]. This reinforces the need for authenticated plant material, standardized preparations and structured liver-safety monitoring in any future

trial.

5.10 Strengths

Strengths include the prospective design, complete follow-up of all 125 enrolled participants, multipara meter laboratory assessment performed under routine laboratory quality-control conditions, botanical authentication of plant material, explicit evaluation of hepatic and renal safety, and recruitment from two geographically distinct tertiary centers, which may improve pragmatic relevance for similar South Asian clinical populations.

5.11 Limitations

The major limitations, stated prominently in keeping with STROBE recommendations, are: absence of a concurrent control group; feasibility-based rather than formal power-calculated sample size; combined (rather than factorial) intervention preventing isolation of component effects; incomplete control of lifestyle and medication confounding; self-reported adherence; lack of chemical standardization of the botanical preparations; short follow-up (approximately 12 weeks); and limited ability to detect rare adverse events. These limitations should not be minimized.

5.12 Future research

A future randomized controlled trial should compare standardized dietary adjuncts with appropriate control conditions, document all medication changes, quantify diet and physical activity, use objective adherence measures (e.g., urinary metabolites) and perform component-wise analysis. A factorial design could determine independent and combined effects of garlic, pomegranate and *T. cordifolia*. Longer follow-up is necessary for durability and safety.

6. CONCLUSION

In adults with type 2 diabetes mellitus (T2DM) and hypertension receiving conventional pharmacological therapy, the combined dietary regimen of raw garlic, fresh *Tinospora cordifolia* leaves, and pomegranate juice was associated with improvements in several metabolic and biochemical parameters in this prospective observational study involving 125 participants. These findings are hypothesis-generating and do not establish causal efficacy, synergistic effects, or long-term safety. The observed improvements may indicate a potential complementary dietary role alongside conventional therapy; however, they should not be interpreted as evidence that the regimen reduces the adverse effects of antidiabetic or antihypertensive medications or permits reduction or discontinuation of prescribed therapy. Further investigation is required to determine whether such dietary interventions may help improve metabolic control while potentially reducing treatment-related burden or complications. Confirmation requires adequately powered randomized controlled trials using standardized botanical preparations, objective assessment of adherence, rigorous control of concomitant pharmacological therapy, and extended safety follow-up.

7. DECLARATIONS

Ethics approval

Institutional Ethics Committee approval obtained from centers: BLDE DU/IEC/717/2025-26

Informed consent

Written informed consent was obtained from all participants.

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Conflict of interest

The authors declare no competing interests.

Author contributions

Basavaraj S. Aski: Conceptualization, Methodology, Investigation, Formal analysis, and Writing – original draft. **Selvaraj P. T.:** Investigation, Data curation and collection, and Writing – review and editing.**Reddy Prasad .C and Thirnavukkarasu. J:** Supervision, assessment of potential drug interactions and allergic reactions, and Writing – review and editing. **Gurupadagoud N. Patil:** Data collection, organization, and processing of study-related data and laboratory parameters. **Govindanagoud V. Naregal:** Data collection, organization, and processing of study-related data and laboratory parameters

Data availability

De-identified data are available from the corresponding author on reasonable request, subject to institutional policy and ethics approval.

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All leaves of giloy were collected from the College of Agriculture, Vijayapura, Karnataka. The Department of Botany, College of Agriculture, Vijayapura, Karnataka, identified all the plants taxonomically. All leaves were washed three DOI: https://doi.org/10.51248/.v43i6.3989 times with fresh water and finally with distilled water, followed by drying in air and shaded at room temperature. Tinospora cordifolia The leaves and stems were carefully cleaned after removing the entire plant. We took 670 g of leaves and used a mechanical grinder to partially grind them. The leaves were extracted by 6000 ml of water and 15 pounds per square inch (psi) of autoclave time. When not in use, the extract was stored at 4 °C after being filtered through Whatman filter paper (No. 1). An agitated thin film falling evaporator (Votator Kentucky, USA) and a flash evaporator (Buchi, Switzerland) were used to concentrate the leaf extract, and the concentrated samples were kept at 4°C.

For your proposed **4 g fresh *Tinospora cordifolia* leaves/day for 90 days**,:

Suggested monitoring

Time	LFT
Before starting	ALT, AST, ALP, GGT, bilirubin
Week 1	✓
Week 2	✓
Week 3	✓
Week 4	✓
Weeks 5–8	✓ weekly
Weeks 9–12	✓ weekly
2–4 weeks after stopping	✓

Also record **symptoms every week**, not just laboratory values.