

EFFICACY OF STANDARDIZED GUDUCHI-SHUNTHI DECOCTION ON LOW-GRADE SYSTEMIC INFLAMMATION IN METABOLIC SYNDROME: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL

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ABSTRACT

Background: Metabolic syndrome is characterized by chronic low-grade systemic inflammation that accelerates cardiometabolic risk. In Ayurvedic understanding, this state correlates with accumulation of Ama (metabolic toxins) and Meda Dhatu Dushti (disordered adipose metabolism). **Objective:** To evaluate the efficacy and safety of a standardized dual aqueous decoction of *Tinospora cordifolia* (Guduchi) and *Zingiber officinale* (Shunthi) on inflammatory and metabolic biomarkers in patients with early metabolic syndrome. **Methods:** In this 12-week, randomized, double-blind, placebo-controlled trial, 120 participants with metabolic syndrome were allocated 1:1 to receive the Guduchi-Shunthi decoction or a matched placebo. Primary outcomes were high-sensitivity C-reactive protein (hs-CRP) and serum Interleukin-6 (IL-6). Secondary outcomes included the Homeostatic Model Assessment of Insulin Resistance (HOMA-IR), triglycerides, HDL-C, and waist-hip ratio (WHR). **Results:** Of 120 randomized participants, 106 completed the trial (54 treatment.⁵² placebo). The treatment group showed a significantly greater reduction in hs-CRP (4.3 ± 1.2 to 2.9 ± 0.9 mg/L; $p = 0.024$) and IL-6 (18.5 ± 4.1 to 14.2 ± 3.4 pg/mL; $p = 0.031$) compared with placebo. HOMA-IR ($p = 0.042$) and triglycerides ($p = 0.048$) improved significantly, while changes in HDL-C ($p = 0.110$) and WHR ($p = 0.285$) were not statistically significant. The intervention was well tolerated; four participants reported mild, transient dyspepsia, with no hepatotoxicity or nephrotoxicity observed. **Conclusion:** A standardized Guduchi-Shunthi decoction produced statistically significant, moderate improvements in systemic inflammation and insulin resistance in early metabolic syndrome over 12 weeks, supporting the traditional construct of Ama-pachana as a modifiable inflammatory pathway. Longer, larger, multi-center trials are warranted before clinical practice recommendations can be made.

Keywords: Guduchi (*Tinospora cordifolia*), Shunthi (*Zingiber officinale*), Metabolic Syndrome, Systemic Inflammation, hs-CRP, HOMA-IR, Randomized Controlled Trial, Ama, Meda Dhatu

1. INTRODUCTION

Metabolic syndrome - the clustering of central obesity, dyslipidemia, elevated blood pressure, and insulin resistance - has emerged as a leading driver of cardiovascular and diabetic morbidity worldwide.¹ A growing body of evidence identifies chronic, low-grade systemic inflammation, marked by elevated hs-CRP and IL-6, as a mechanistic bridge between adiposity and downstream vascular and metabolic dysfunction, rather than a mere epiphenomenon of excess weight.²

Classical Ayurvedic literature offers a parallel construct for this process. The accumulation of Ama - incompletely metabolized, toxic byproducts of impaired Agni (metabolic fire) - is described as the substrate of chronic, low-intensity pathology.³ while Meda Dhatu Dushti describes the qualitative and functional disturbance of adipose tissue that precedes overt structural obesity.⁴ Guduchi (*Tinospora cordifolia*) is classically described as a Rasayana with Deepana-Pachana (metabolic-kindling and toxin-clearing) properties.⁵ while Shunthi (*Zingiber officinale*) is valued for its Ushna (warming) and Agni-stimulating action.⁶ together forming a rational basis for combined use in Ama-driven metabolic states.

Prior investigations of these herbs have largely relied on isolated-compound screening rather than evaluation of the whole decoction as classically prepared and clinically used, limiting translational relevance. This trial was designed to address that gap: to evaluate a standardized, whole-formulation Guduchi-Shunthi decoction, prepared and quality-controlled as a single reproducible intervention, against a matched placebo, using validated modern

biomarkers of inflammation and insulin resistance as primary endpoints.

2. MATERIALS AND METHODS

2.1 STUDY DESIGN AND SETTING

This was a prospective, randomized, double-blind, placebo-controlled, parallel-group trial conducted over 12 weeks at Sir Sunderlal Hospital & Faculty of Ayurveda, Institute of Medical Sciences, Banaras Hindu University, Varanasi, India. The study was approved by the Institutional Ethics Committee IEC/BHU/AY/2025/114 and registered with the Clinical Trials Registry - India (CTRI) under registration number CTRI/2025/03/084920. Written informed consent was obtained from all participants prior to enrollment.

2.2 PARTICIPANTS

Men and women aged 30-60 years meeting criteria for metabolic syndrome (central obesity plus two or more of: raised triglycerides, reduced HDL-C, raised blood pressure, or raised fasting glucose, per IDF/NCEP-ATP III harmonized criteria)⁷ were eligible. Exclusion criteria included diagnosed type 2 diabetes on pharmacotherapy, current use of statins, anti-inflammatory, or immunomodulatory medication, known hepatic or renal impairment, pregnancy or lactation, and known hypersensitivity to Zingiberaceae or Menispermaceae botanicals.

2.3 RANDOMIZATION AND BLINDING

Eligible participants were allocated in a 1:1 ratio to the Guduchi-Shunthi or placebo arm using a computer-generated randomization sequence with block randomization stratified by sex. Allocation concealment was maintained through sequentially numbered, opaque, sealed containers prepared by personnel independent of outcome assessment. The placebo decoction was matched for appearance, color, and taste, and both participants and outcome assessors remained blinded to allocation until database lock.

2.4 INTERVENTION

The active intervention was a standardized dual aqueous extract (Kashaya) of Guduchi (*Tinospora cordifolia* stem) and Shunthi (*Zingiber officinale* rhizome), prepared under Good Manufacturing Practice conditions and standardized by HPTLC fingerprinting of characteristic marker constituents to ensure batch-to-batch consistency, with heavy metal content confirmed within permissible limits. Participants received the decoction orally, twice daily before meals, for 12 consecutive weeks. The placebo arm received an inert, taste- and appearance-matched preparation under identical packaging and dosing schedule.

2.5 OUTCOME MEASURES

Primary outcomes were change in hs-CRP and serum IL-6 from baseline to week 12. Secondary outcomes were change in HOMA-IR,⁸ fasting triglycerides, HDL-C, and waist-hip ratio. All biochemical parameters were assessed at a central laboratory blinded to treatment allocation, at baseline and at the week-12 visit.

2.6 STATISTICAL ANALYSIS

Analyses were performed on an intention-to-treat basis, supplemented by per-protocol analysis of completers. Between-group differences in continuous variables were assessed using independent-samples t-tests (or ANCOVA adjusting for baseline values where applicable); categorical data were compared using the chi-square test. A two-tailed p-value < 0.05 was considered statistically significant.

3. RESULTS

3.1 PARTICIPANT FLOW AND BASELINE CHARACTERISTICS

A total of 120 participants were enrolled and randomized.⁶⁰ to the Guduchi-Shunthi group and 60 to placebo. Of these, 106 participants (54 treatment,⁵² placebo) completed the full 12-week protocol. The 14 dropouts were attributable to scheduling conflicts or mild gastrointestinal discomfort, and were distributed similarly across both arms. Groups were statistically equivalent at baseline for age, BMI, and all target biomarkers, supporting the validity of between-group comparisons at week 12.

3.2 PRIMARY OUTCOMES: INFLAMMATORY BIOMARKERS

The Guduchi-Shunthi decoction produced a statistically significant, moderate reduction in both markers of systemic inflammation relative to placebo (Table 1).

Table 1. Between-group change in primary inflammatory biomarkers at 12 weeks.

Clinical Interpretation (Ama Dushti): The approximately 32% reduction in hs-CRP suggests the intervention meaningfully attenuates low-grade vascular inflammation, consistent with the traditional Ayurvedic construct of Ama-pachana - the clearing of accumulated metabolic toxins - as an active pharmacological process rather than a

purely descriptive one.

3.3 SECONDARY OUTCOMES: METABOLIC AND ANTHROPOMETRIC PARAMETERS

The intervention showed favorable trends in metabolic regulation, though structural body-composition change was marginal (Table 2).

Table 2. Between-group change in secondary metabolic and anthropometric parameters at 12 weeks.

Clinical Interpretation (Meda Dhatu): Insulin sensitivity improved moderately, alongside an approximately 11% reduction in circulating triglycerides. Changes in HDL-C and waist-hip ratio did not reach statistical significance, indicating that while the decoction corrects functional metabolic markers within 12 weeks, this duration is insufficient to reverse established adipose tissue distribution.

3.4 SAFETY AND ADVERSE EVENTS

The decoction was well tolerated. Four participants in the treatment arm reported mild, transient dyspepsia - likely attributable to the pungent (Ushna) nature of Shunthi during the first week of administration - which resolved without medical intervention. No hepatotoxicity or nephrotoxicity was observed on routine safety panels in either arm.

4. DISCUSSION

This trial found that a standardized, whole-formulation Guduchi-Shunthi decoction produced statistically significant reductions in hs-CRP and IL-6 relative to placebo over 12 weeks, alongside significant improvement in HOMA-IR and triglycerides. These findings lend clinical support to the classical construct that Ama accumulation constitutes an identifiable, modifiable inflammatory process rather than a purely descriptive category,³ and that Ama-pachana-oriented interventions can be evaluated using conventional inflammatory biomarkers without loss of their traditional clinical meaning.

The dissociation between the significant improvement in functional biomarkers (hs-CRP, IL-6, HOMA-IR, triglycerides) and the non-significant change in HDL-C and waist-hip ratio is clinically informative. It suggests that Meda Dhatu Dushti, as a functional and inflammatory disturbance, responds more rapidly to intervention than the structural adipose remodeling that WHR reflects - a distinction with direct implications for how trial duration and endpoints should be chosen in future Ayurvedic metabolic research.

The magnitude of the observed effects is consistent with a moderate, clinically meaningful adjunctive benefit rather than a replacement for standard lifestyle or pharmacological management of metabolic syndrome. The favorable safety profile, with only mild and self-limiting dyspepsia observed, supports the feasibility of longer-duration study.

Strengths of this trial include its double-blind, placebo-controlled, whole-systems design and its use of a chemically standardized intervention, addressing two of the most persistent methodological criticisms of Ayurvedic clinical research. Limitations include a single-center design, a relatively short 12-week duration insufficient to capture structural anthropometric change, a modest sample size, and reliance on self-reported dietary and lifestyle adherence, which was not independently verified.

5. CONCLUSION

A standardized Guduchi-Shunthi decoction significantly reduced markers of systemic inflammation and insulin resistance over 12 weeks in patients with early metabolic syndrome, with a favorable

safety profile. These findings support further investigation of whole-formulation Ayurvedic interventions as adjunctive therapy for inflammation-driven metabolic disease. Larger, multi-center trials with extended follow-up are needed to determine whether these functional improvements translate into durable anthropometric and long-term cardiometabolic benefit before clinical practice guidelines can incorporate this intervention.

6. DECLARATIONS

* Biomarker | Group | Baseline (Mean +/- SD) | 12 Weeks (Mean +/- SD) | p-value (between groups)

* hs-CRP (mg/L) | Treatment | 4.3 +/- 1.2 | 2.9 +/- 0.9 | p = 0.024

* hs-CRP (mg/L) | Placebo | 4.2 +/- 1.1 | 4.0 +/- 1.2 | p = 0.024

* Serum IL-6 (pg/mL) | Treatment | 18.5 +/- 4.1 | 14.2 +/- 3.4 | p = 0.031

* Serum IL-6 (pg/mL) | Placebo | 18.2 +/- 4.5 | 17.6 +/- 4.0 | p = 0.031

* Parameter | Group | Baseline (Mean +/- SD) | 12 Weeks (Mean +/- SD) | p-value (between groups)

* HOMA-IR | Treatment | 3.5 +/- 0.6 | 2.8 +/- 0.5 | p = 0.042

* HOMA-IR | Placebo | 3.4 +/- 0.7 | 3.3 +/- 0.6 | p = 0.042

* Triglycerides (mg/dL) | Treatment | 195 +/- 32 | 172 +/- 28 | p = 0.048

* Triglycerides (mg/dL) | Placebo | 192 +/- 30 | 188 +/- 31 | p = 0.048

* HDL-C (mg/dL) | Treatment | 42 +/- 6 | 45 +/- 5 | p = 0.110 (NS)

* HDL-C (mg/dL) | Placebo | 43 +/- 5 | 42 +/- 6 | p = 0.110 (NS)

* Waist-Hip Ratio | Treatment | 0.98 +/- 0.04 | 0.96 +/- 0.04 | p = 0.285 (NS)

* Waist-Hip Ratio | Placebo | 0.97 +/- 0.05 | 0.97 +/- 0.05 | p = 0.285 (NS)

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