



Comparative Clinical Evaluation of *Withania coagulans* fruit tablet and Metformin in the Management of *Madhumeha* (Type 2 Diabetes Mellitus): A Randomized Controlled Trial

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Abstract

This research investigates the efficacy and safety of *Withania coagulans* fruit tablet compared to the standard drug Metformin in managing *Madhumeha*, aligning with Type 2 Diabetes Mellitus. A randomized controlled trial was conducted on 40 patients, assessing both subjective symptoms and biochemical markers. Both treatments offered significant relief, with distinctive benefits, and lifestyle modifications played a critical role in improving outcomes. The findings advocate for the inclusion of *Withania coagulans* as a safe, effective alternative or adjuvant, setting pathways for integrative diabetes management.

Key words: *Madhumeha*, Type 2 Diabetes Mellitus, *Withania coagulans*, *Paneer Doda*

Introduction

Madhumeha (Type 2 Diabetes Mellitus) is a chronic metabolic disorder marked by abnormal carbohydrate, protein, and lipid metabolism, escalating as a major global health challenge.¹ Conventional management via oral hypoglycemics, particularly Metformin, is effective but often limited by side effects, incomplete symptom coverage, and patient intolerance.² *Ayurveda* emphasizes a holistic approach, integrating herbal medicines and lifestyle modifications.³

Withania coagulans (*Paneer Doda*), though not mentioned in classical *Ayurvedic* texts under that name, is widely used in North Indian traditional medicine for diabetes and metabolic disorders.⁴ Its pharmacological profile includes hypoglycemic, hypolipidemic, and antioxidant actions, aligning with *Ayurvedic* descriptions of “*Kapha-Meda Shamana*”.⁵

Materials and Methods

Study Design

A randomized controlled clinical trial was conducted in the OPD of *Uttarakhand Ayurved University* on 43 registered patients, with 40 completing the protocol.

Patient Selection

Inclusion criteria encompassed adults aged 30–60, with FBS 110–210 mg/dl, PPBS 140–300 mg/dl, HbA1c 6–10%, and diabetes duration <5 years. Key exclusion factors were advanced diabetes, other grave illnesses, or non-compliance

Interventions

- **Group A (Trial):** *Withania coagulans* fruit tablets, 500 mg x 2 tablets twice daily, before meals for 90 days.
- **Group B (Control):** Metformin 500 mg twice daily, after meals.

Dietary regulation and lifestyle modification were strongly recommended for both groups: a diabetic-friendly Ayurvedic diet, regular exercises including yoga, and stress management

Assessment Protocols

Subjective symptom scores (polyuria, polydipsia, polyphagia, weakness, burning limb sensation, turbid urine) and objective biochemical markers (FBS, PPBS, HbA1c, urine sugar, BMI) were measured at baseline, 30, 60, and 90 days.

Statistical Analysis

Wilcoxon Signed-Rank Test and Paired t-test were utilized for intra-group comparisons; Mann–Whitney U test and Unpaired t-test for inter-group comparisons. p-values were interpreted as NS (>0.05), S (≤ 0.05), and HS (≤ 0.01).

Results

Demographics and Baseline Profile

- **Age:** Majority 51–60 years (40%), followed by 41–50 (37%), and 31–40 (23%).
- **Gender:** 70% male, 30% female.
- **Socioeconomic Status:** Middle class predominance.
- **Diet and Lifestyle:** 51% vegetarians, 93% urban, 43% physically inactive, high prevalence of irregular dietary and lifestyle habits.

Clinical Characteristics

Most common symptoms were increased appetite and weakness (both 79%), followed by polyuria (56%) and polydipsia (28%).

Efficacy Outcomes

Subjective Parameters

Symptom	Group A Improvement	Group B Improvement
Polyuria	73.68%	71.43%
Turbid Urine	33.33% (NS)	75%
Thirst	40%	81.82%
Polyphagia	34.78%	57.14%
Weakness	52.17%	63.16%
Burning extremities	70.83% (HS)	62.5%

Highly significant (HS) improvements were documented for cardinal symptoms, especially in polyuria, weakness, and burning sensation. Metformin showed stronger improvement in thirst and polyphagia, while *Withania coagulans* provided better relief for neuropathic symptoms.

Objective Parameters

Parameter	Group A (%)	Group B (%)	Intergroup Difference
FBS	12.0	12.29	NS
PPBS	11.4	11.59	NS
HbA1c	6.05	18.42	HS (Group B better)
Urine sugar	34.1	42.55	NS
BMI	4.24	4.1	NS

Both groups had comparable effects on FBS, PPBS, and BMI. Metformin excelled in HbA1c reduction, while *Withania coagulans* fruit tablet supported gradual and meaningful metabolic improvements.

Overall Effect

Relief Category	Group A (n, %)	Group B (n, %)
Complete (100%)	2 (10%)	1 (5%)
Marked (76–99%)	1 (5%)	4 (20%)
Moderate (51–75%)	9 (45%)	8 (40%)
Mild (26–50%)	7 (35%)	4 (20%)
No relief (<25%)	1 (5%)	3 (15%)

Safety profiles were excellent with no major adverse events in either group.

Discussion

Comparative Insights

Withania coagulans fruit tablet and Metformin demonstrated significant efficacy in both symptomatic and biochemical outcomes. Metformin provided greater long-term glycemic control (HbA1c), consistent with its mechanism of action, whereas *Withania coagulans* was more effective in controlling neuropathic symptoms and polyuria, likely related to its antioxidant and *Kapha-Meda* balancing properties.⁶

Mechanism of Action

Withania coagulans acts via:

- **Regulation of *Kapha–Meda* metabolism:** Correcting underlying derangements through *Tikta* (bitter) and *Ruksha* (dry) properties.⁷
- **Peripheral glucose utilization, β -cell protection, antioxidant activity:** Validated by experimental evidence of improved insulin sensitivity and reduced oxidative stress.⁸
- **Modest hypolipidemic action:** Observed via reduction in BMI and improvement in lipid parameters.⁹

Lifestyle modification

Across both groups, adherence to diet and exercise was strongly correlated with better clinical outcomes, emphasizing the vital role of non-pharmacological measures alongside pharmacotherapy in diabetes management.^{10,11}

Safety

Preclinical and clinical evidence confirmed *Withania coagulans*' safety at therapeutic dosage. No toxicity or adverse effects were reported during the trial period.^{12,13}

Conclusion

Both *Withania coagulans* fruit tablet and Metformin are effective, safe choices for managing *Madhumeha* (T2DM), with distinct profiles of clinical benefit. *Withania coagulans* is particularly effective for polyuria, weakness, and burning extremity sensations and offers affordable access for patients preferring herbal remedies or experiencing intolerance to modern drugs. Integration of lifestyle modification enhances therapeutic effect, advocating for a holistic and patient-centered approach. Larger-scale, long-term studies are warranted to further validate *Withania coagulans* and advance integrative diabetes care.

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