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Case Study

A PROSPECTIVE CARE-COMPLIANT CASE SERIES ON *WITHANIA COAGULANS* MONOTHERAPY IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT

Withania coagulans Dunal is described in Ayurvedic literature for the management of *Madhumeha*, yet systematically documented clinical evidence in Type 2 diabetes mellitus (T2DM) remains limited despite supportive preclinical data. This prospective, single-centre case series evaluated the clinical effects and safety of *Withania coagulans* fruit powder administered as *Ekala Dravya* (single-drug) monotherapy over 60 days in 23 patients with T2DM. Authenticated dried fruit powder was given orally at a dose of 5g twice daily before meals. Glycaemic parameters, including fasting blood sugar (FBS) and postprandial blood sugar (PPBS), were assessed at baseline, day 30, and day 60, along with anthropometric and laboratory safety parameters. All participants completed the study with good compliance. Mean FBS decreased from 151.83±26.10mg/dL at baseline to 87.73±10.86mg/dL at day 60 ($p<0.0001$), while mean PPBS decreased from 220.00±50.46mg/dL to 111.91±19.01mg/dL ($p<0.0001$). A modest but significant reduction in body weight and body mass index was observed. No adverse events were reported, and haematological, hepatic, and renal parameters remained within normal limits. These findings suggest that *Withania coagulans* monotherapy may provide effective short-term glycaemic control with good tolerability in T2DM, warranting further evaluation through controlled clinical studies.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a chronic metabolic disorder characterized by persistent hyperglycaemia resulting from insulin resistance with relative insulin deficiency. Its prevalence is increasing globally, contributing substantially to cardiovascular, renal, neurological, and microvascular complications. Contemporary management emphasizes dietary regulation, physical activity, and pharmacotherapy, with metformin widely recommended as first-line treatment owing to its efficacy, safety profile, and cardiometabolic benefits.[1] Nevertheless, a considerable proportion of patients fail to achieve adequate glycaemic control on monotherapy, experience adverse effects, or express concerns regarding long-term drug dependence, prompting interest in alternative or complementary approaches.[2]

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Ayurveda describes a clinical entity termed *Madhumeha*, classified under *Prameha*, which shares several phenotypic features with diabetes mellitus, including polyuria, metabolic derangement, and progressive tissue depletion. Classical Ayurvedic texts advocate individualized management through *Ahara* (diet), *Vihara* (lifestyle), and *Aushadha* (pharmacotherapy), with emphasis on correction of *Kapha* and *Meda* vitiation.[3] While *Madhumeha* is not directly equated with T2DM, the conceptual overlap permits cautious clinical correlation and rational therapeutic exploration.

Withania coagulans Dunal (family- Solanaceae), known as *Rasna* among *Sindhi Vaidyas,* is distributed in Sindh, Punjab, Baluchistan, and Afghanistan. Its dried fruits, called Panir-ja-phota, coagulate milk and are used as vegetable rennet for cheese preparation.[4] Some scholars consider it a variety of *Ashwagandha*.[5] Upadhyay et al. mentioned *W. coagulans* as Rishyagandha and reported significant anti-hyperglycaemic effects in *Prameha* (T2DM).[6] *Rishyagandha* is mentioned in *Charaka Samhita* under *Brimhaniya Mahakashaya* and *Madhura Skandha*

Dravya,[7] and its fruits are traditionally used for treating *Prameha* in northern India.[8]

Experimental studies have demonstrated antihyperglycemic activity of *W. coagulans* through mechanisms relevant to T2DM pathophysiology, including stimulation of insulin secretion, enhancement of peripheral glucose utilization, inhibition of intestinal α-glucosidase enzymes, and reduction of oxidative stress. Animal models of experimental diabetes have consistently shown reductions in fasting blood glucose and improvement in lipid parameters, along with protective effects on pancreatic β-cells.[9-11] However, translation of these findings into clinical practice has been limited by a paucity of systematically documented human studies.

Available clinical evidence on *W. coagulans* in diabetes is sparse and largely confined to small, open-label studies with methodological limitations.[6] In this context, prospectively documented case series adhering to standardized reporting frameworks, such as the CARE (CAse REport) guidelines, and clinical research protocol of CCRAS provide valuable preliminary clinical evidence and help inform the design of future controlled trials.[12,13]

The present prospective case series was therefore undertaken to document the clinical effects and safety profile of *Withania coagulans* dried fruit powder administered as *Ekala Dravya* monotherapy in patients with T2DM over a 60-day period. The primary objective was to evaluate changes in fasting and postprandial blood glucose levels, while secondary objectives included assessment of anthropometric parameters and laboratory safety indices.

METHODS

Study Design and Setting

This prospective, single-centre uncontrolled interventional case series was conducted over 60 days in the outpatient department of the Institute of Post Graduate Ayurvedic Education and Research (IPGAER), Kolkata, India from February through July 2025, under supervision of the corresponding author. Clinical documentation followed the CARE (CAse REport) guidelines to ensure transparency in participant selection, intervention standardization, outcome assessment, and safety monitoring.[12] *Withania coagulans* fruit powder was administered as *Ekala Dravya* therapy for *Madhumeha*.

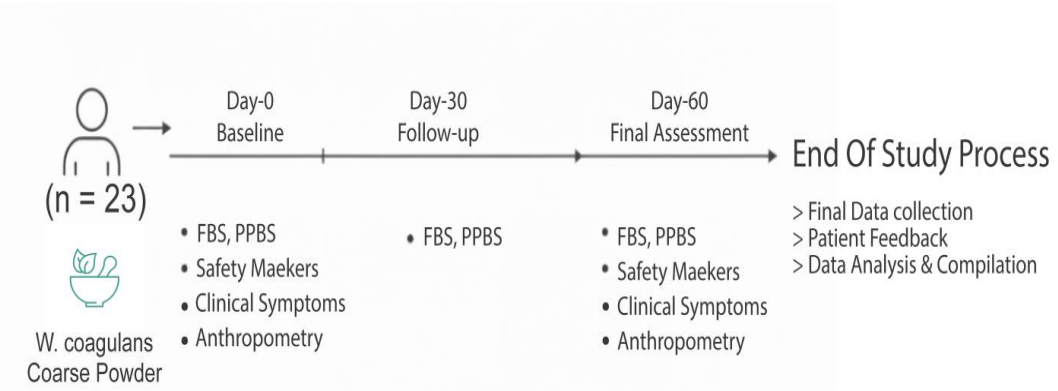

Figure 1: Study design and assessment schedule. The flow diagram outlines the 60-day intervention in 23 participants, including evaluation of fasting blood sugar (FBS), postprandial blood sugar (PPBS), safety parameters (CBC, LFT, KFT, lipid profile, urine analysis), and anthropometric measurements.

Ethical Considerations

The study protocol, patient information sheet, informed consent form, and case documentation were prepared according to the research guidelines of the Central Council for Research in Ayurvedic Sciences (CCRAS).[13] Written informed consent was obtained from all participants prior to enrolment. The study adhered to the ethical principles of the Declaration of Helsinki (2013 revision).[14]

Study Duration

Participants were followed for 60 days, with assessments at baseline (day 0), day 30, and day 60.

Participants Recruitment and Screening

Participants were recruited from the outpatient population with confirmed T2DM seeking Ayurvedic management. Eligibility was assessed through clinical history, physical examination, and laboratory investigations. Only patients meeting all inclusion criteria and none of the exclusion criteria were enrolled.

Diagnostic Criteria

T2DM diagnosis was based on documented clinical diagnosis supported by fasting blood sugar (FBS) and postprandial blood sugar (PPBS) values consistent with standard diagnostic criteria.[15] Ayurvedic assessment for features of *Madhumeha* was performed for descriptive correlation[13] but was not used as the primary diagnostic criterion.

Inclusion Criteria

Participants meeting the following criteria were included:

- Age 30–65 years
- Confirmed Type 2 diabetes mellitus.
- Elevated fasting and postprandial blood glucose levels at baseline.
- Willingness to receive *Withania coagulans* monotherapy and follow dietary advice and scheduled visits.
- Provision of written informed consent.

Exclusion Criteria

Participants were excluded if they had:

- Type 1 diabetes or secondary diabetes.
- Renal impairment (serum creatinine >1.5mg/dL or eGFR <30mL/min/1.73 m^2)
- Hepatic dysfunction (ALT or AST >2× upper limit of normal).
- Pregnancy or lactation
- Known hypersensitivity to *Withania coagulans.*
- Concurrent use of antidiabetic drugs or herbal formulations.
- Acute diabetic complications (e.g., ketoacidosis, hyperosmolar state).
- Uncontrolled endocrine disorders.
- Severe systemic illness affecting participation.

Withdrawal Criteria

Participants were withdrawn if serious adverse events occurred, conventional anti-diabetic therapy became necessary, or consent was withdrawn. No participant required withdrawal during the study.

Sample Size

As an exploratory case series, formal sample size calculation was not performed. Twenty-three consecutive eligible patients were enrolled to generate preliminary clinical evidence in accordance with CARE recommendations.[12]

Intervention

Study Drug and Authentication

The intervention consisted of *Withania coagulans* Dunal (family Solanaceae). Mature fruits were procured from a licensed herbal market (Barabazar, Kolkata) and botanically authenticated at the Quality Testing Laboratory, Institute of Post Graduate Ayurvedic Education and Research (IPGAER), Kolkata. Voucher specimens were preserved in the Quality Testing Laboratory, IPGAER, Kolkata.

Drug Preparation

The fruits were cleaned, shade-dried, and powdered using a mechanical grinder. The powder was stored in airtight containers under dry conditions to maintain stability.

Dose and Administration

Withania coagulans fruit powder was administered orally as *Ekala Dravya Chikitsā*.

- Dose: 5 g
- Frequency: Twice daily
- Adjuvant: Lukewarm water
- Timing: 30 minutes before meals
- Duration: 60 days

Participants were advised dietary moderation, avoidance of refined sugars, and daily physical activity (approximately 30 minutes walking). Use of other antidiabetic medications or herbal formulations during the study period was not permitted.

Table 1: Intervention Details

Intervention	Dose	Route	Adjuvant	Frequency	Timing	Duration
W. coagulans course powder	5 g	Orally	Lukewarm water	Twice a day	Before meal	60 days

Compliance Monitoring

Compliance was assessed during follow-up visits through patient self-report and sachet count.

Outcome assessment

Assessment Schedule

Evaluations were conducted at baseline (day 0), day 30, and day 60.

Primary Outcomes

Primary outcomes were changes in glycaemic parameters:

- Fasting Blood Sugar (FBS)
- Postprandial Blood Sugar (PPBS)

Blood samples were collected after overnight fasting, and PPBS was measured two hours after a standard meal using standard laboratory methods.

Secondary Outcomes

Secondary outcomes included, anthropometric parameters

- Body weight
- Body mass index (BMI)

Safety parameters

- Complete blood count (CBC)
- Liver function tests (bilirubin, AST, ALT, alkaline phosphatase)
- Renal function tests (urea, creatinine)

- Lipid profile (total cholesterol, triglycerides, HDL, LDL, VLDL)

Adverse events

Any untoward medical occurrence reported by participants during follow-up was recorded. Vital signs were monitored at each visit.

HbA1c Assessment

Baseline HbA1c was measured to characterize glycaemic status. Repeat estimation was not performed due to the short duration of the study.[16]

Safety Monitoring and Withdrawal

Participants were withdrawn if serious adverse events occurred, conventional anti-diabetic therapy became necessary, or consent was withdrawn. No participant met withdrawal criteria.

Statistical Analysis

Data were expressed as mean ± standard deviation. Changes from baseline were analyzed using within-group comparisons, with $p<0.05$ considered statistically significant. Statistical analysis was performed using standard statistical software.

RESULTS

Participant Flow and Compliance

A total of 23 patients fulfilling the eligibility criteria were enrolled in the study and all completed the 60-day intervention period. There were no withdrawals or protocol deviations during the study. Drug compliance was satisfactory in all participants, as assessed by sachet count and patient self-reporting. No participant required rescue medication or initiation of conventional antidiabetic therapy during the study period.

Baseline Characteristics

Baseline demographic and clinical characteristics of the study participants are summarized in Table 2. The mean age of participants was 44.17±8.33 years, with a female predominance (female: 13; male: 10). The mean duration of diabetes was 0.58±0.91 years. Fourteen participants were newly diagnosed, while nine participants had a prior history of metformin use but had discontinued conventional therapy before enrolment.

At baseline, the mean fasting blood sugar (FBS) was 151.82±26.10mg/dL, and the mean postprandial blood sugar (PPBS) was 220.00±50.46mg/dL. The mean baseline HbA1c was 7.63±0.85%. Mean body weight and body mass index (BMI) were 62.86± 5.24kg and 25.22±1.57kg/m^2, respectively.

Table 2: Baseline Characteristics of Study participants (n=23)

Characteristics	Baseline data (N=23)
Age (years)	44.17±8.33
Gender (M/F)	Female-13, Male-10
Diabetes duration (years)	0.58±0.91
Past medicine history	Prior history of metformin use- 9 patients; newly diagnosed-14 patients
Weight (kg)	62.86±5.24
BMI (kg/m^2)	25.22±1.57
Baseline FBS (mg/dl)	151.82±26.10
Baseline PPBS (mg/dl)	220±50.46
Baseline HbA1c (%)	7.63±0.85

Primary Outcome: Glycaemic Parameters

A statistically significant and progressive reduction in glycaemic parameters was observed during the study period.

Fasting Blood Sugar

Mean FBS decreased from 151.83±26.10mg/dL at baseline to 109.39±18.9mg/dL at day 30 and further to 87.73±10.86mg/dL at day 60. Repeated-measures ANOVA demonstrated a statistically significant reduction across time points ($p<0.0001$). The mean absolute reduction in FBS from baseline to day 60 was 64.09mg/dL (95% confidence interval [CI]: 49.89 to 78.28).

Table 3: Mean Value of Glycaemic Changes Over Treatment Period

Glycaemic parameters	Day-0 (Mean ± SD)	Day-30 (Mean ± SD)	Day-60 (Mean ±SD)
FBS (mg/dl)	151.83 ±26.10	109.39 ±18.91	87.73 ±10.86
PPBS (mg/dl)	220 ±50.46	140.83 ±28.50	111.91 ±19.01

Postprandial Blood Sugar

Mean PPBS showed a similar pattern of improvement, decreasing from 220.00±50.46mg/dL at baseline to 140.83±28.50mg/dL at day 30 and to 111.91±19.01mg/dL at day 60. This reduction was statistically significant (p <0.0001). The mean absolute reduction in PPBS from baseline to day 60 was 108.10mg/dL (95% CI: 82.63 to 133.50).

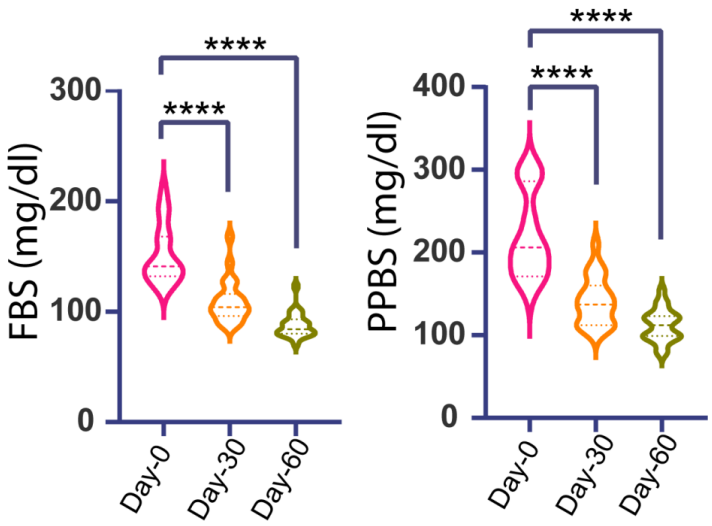

Figure 1: Fasting Blood Sugar (FBS) and Postprandial Blood Sugar (PPBS) showed a progressive reduction from Day-0 to follow-up and Day-60

Subgroup Analysis: Participants with Prior Metformin Exposure

Among the 23 participants, nine had a documented history of metformin use prior to enrolment but had discontinued conventional therapy before initiating *Withania coagulans* monotherapy. In this subgroup, mean FBS decreased by 70.89mg/dL (95% CI: 49.21 to 92.56), and mean PPBS decreased by 117.10mg/dL (95% CI: 75.48 to 158.70) at day 60 compared to baseline. These reductions were statistically significant (p<0.005), and the direction and magnitude of response were comparable to those observed in the overall cohort.

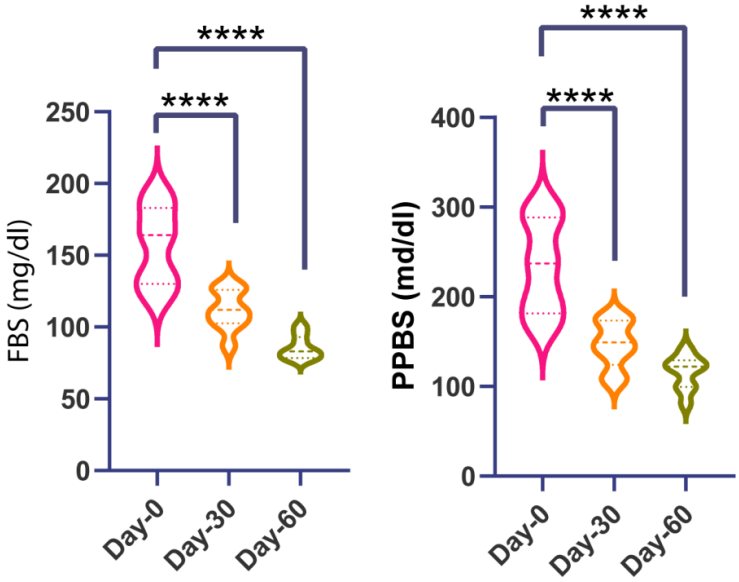

Figure 3: Sub-group of 9 patient's Fasting Blood Sugar (FBS) and Postprandial Blood Sugar (PPBS), showed a progressive reduction from Day-0 to follow-up and Day-60

Secondary Outcomes: Anthropometric Parameters

A modest but statistically significant reduction in body weight and BMI was observed over the study period. Mean body weight decreased from 62.86±5.24kg at baseline to 61.83±5.31kg at day 60, corresponding to a mean reduction of 1.03kg (95% CI: −1.45 to −0.61; p<0.0001). Mean BMI decreased proportionately, indicating improvement in overall anthropometric status.

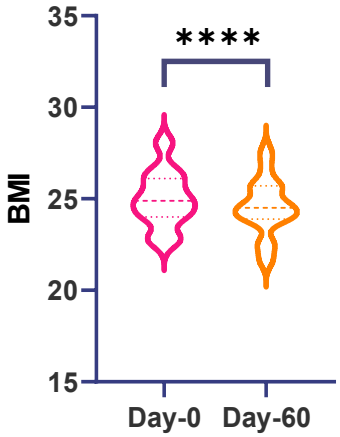

Figure 4: BMI Changes of all 23 patients

Safety and Tolerability

No adverse events were reported by any participant during the study period. Vital signs remained stable throughout follow-up. Hematological parameters, including hemoglobin concentration, total leukocyte count, differential count, and erythrocyte sedimentation rate, remained within normal reference ranges with no clinically significant changes from baseline to day 60. Renal function parameters (blood urea and serum creatinine) and hepatic function parameters (serum bilirubin, AST, ALT, and alkaline phosphatase) showed no statistically or clinically significant alterations during the intervention period, indicating good tolerability of the study drug. A favourable trend was observed in lipid profile parameters, including reductions in total cholesterol, triglycerides, and very-low-density lipoprotein (VLDL) cholesterol, along with a modest increase in high-density lipoprotein (HDL) cholesterol. These changes were not subjected to inferential statistical testing and are presented descriptively.

Table 4: Haematological and biochemical parameters of all patients (n=23)

Haematological and biochemical parameters	Before Treatment	After treatment
HB%	12.08 ±0.93	12.19 ±0.96
RBC	4.82 ±0.41	4.86 ±0.41
WBC	5.24 ±0.55	5.12 ±0.51
Neutrophil	61.69 ±10.47	58.30 ±8.77
Lymphocyte	23.30 ±4.43	23.86 ±3.31
Monocyte	4.08 ±1.16	4.08 ±2.24
Eosinophil	2.17 ±1.16	2.08 ±1.17
Besophil	1.04 ±0.95	1.04 ±0.90
ESR	11.13 ±1.75	10.95 ±1.48
Urea	20.32 ±3.43	19.80 ±3.77
Creatinine	0.95 ±0.16	0.90 ±0.22
Cholesterol	169.13 ±39.26	152.21 ±29.94
Triglyceride	150.69 ±26.22	137.95 ±18.60
HDL	54.62 ±9.06	56.28 ±8.85
LDL	120.91 ±20.56	118.60 ±17.91
VLDL	35.23 ±6.96	33.25 ±6.31
Bil.	1.01 ±0.20	0.96 ±0.26
SGOT	27.69 ±4.52	27.39 ±4.54
SGPT	33.93 ±5.99	33.50 ±5.93
Alk. Phosphate	72.96 ±40.39	74.14 ±24.21

* Data are represented as Average ± Standard Error

Summary

All participants demonstrated improvement in glycaemic parameters at the end of the 60-day intervention. No safety concerns or treatment-limiting adverse effects were observed. The findings indicate consistent short-term glycaemic improvement and acceptable tolerability of *Withania coagulans* administered as *Ekala Dravya* monotherapy.

DISCUSSION

This prospective case series evaluated the short-term clinical effects of *Withania coagulans* Dunal administered as *Ekala Dravya Chikitsā* in patients with Type 2 diabetes mellitus (T2DM). Over a 60-day intervention period, significant reductions in fasting blood sugar (FBS) and postprandial blood sugar (PPBS) were observed, without reported adverse events or laboratory evidence of hepatic or renal toxicity. These findings provide preliminary clinical support for the traditional use of *W. coagulans* in *Madhumeha* and contribute to the limited body of systematically documented clinical evidence for this medicinal plant. The magnitude of glycaemic improvement observed in this study is clinically meaningful. Mean reductions of approximately 64mg/dL in FBS and 108mg/dL in PPBS were recorded during the intervention period. While direct comparison with conventional pharmacotherapy is not appropriate due to the uncontrolled study design, these improvements are comparable to short-term outcomes reported for first-line oral hypoglycaemic agents in early T2DM.[1,2] Importantly, the decline in glycaemic parameters was progressive, with measurable improvement at day 30 and further reduction by day 60, suggesting a sustained therapeutic response rather than a transient effect.

From an Ayurvedic perspective, *Madhumeha* is described as a chronic metabolic disorder involving derangement of *Kapha*, *Meda*, and *Vata*, leading to impaired metabolic regulation and abnormal urinary excretion. Classical Ayurvedic texts recommend therapeutic agents with *Pramehaghna* and *Medohara* properties, along with dietary and lifestyle regulation.[3] The modest reduction in body weight and body mass index (BMI) observed in the present series is consistent with this conceptual framework and supports the metabolic corrective role attributed to *W. coagulans* in traditional Ayurvedic practice.

The subgroup of participants previously exposed to metformin also demonstrated glycaemic improvement following initiation of *W. coagulans* monotherapy. Although interpretation must remain cautious due to the small sample size and lack of a washout-controlled design, this observation suggests that *W. coagulans* may have potential utility in individuals who are unable or unwilling to continue conventional oral hypoglycaemic therapy. Similar clinical observations have been reported in earlier exploratory studies, although those investigations lacked standardized outcome assessment and systematic safety monitoring.[6] The favourable safety profile observed in this study is particularly noteworthy. No adverse events were reported during the study period, and haematological, hepatic, and renal parameters remained within normal reference ranges. This observation is consistent with experimental toxicology and pharmacological studies indicating good tolerability of *W. coagulans* at therapeutic doses.[9]

Biological plausibility for the antihyperglycemic effect of *W. coagulans* is supported by preclinical evidence. Experimental studies suggest that the plant exerts glucose-lowering activity through multiple mechanisms, including stimulation of insulin secretion, enhancement of peripheral glucose uptake, inhibition of intestinal α-glucosidase activity, and reduction of oxidative stress in pancreatic tissue.[9–11] Such multimodal pharmacological activity may be particularly relevant in T2DM, which involves complex interactions among metabolic, inflammatory, and endocrine pathways. Despite these encouraging findings, several limitations must be acknowledged. The observational design, absence of a control group, relatively small sample size, and short duration limit causal inference and generalizability. HbA1c could not be reassessed at the end of the study because the intervention period was insufficient to reflect meaningful changes in long-term glycaemic control. In addition, lifestyle modification advice provided to participants may have contributed to the observed improvements and cannot be entirely separated from the pharmacological effect of the study drug.

Nevertheless, carefully documented case series adhering to CARE reporting guidelines play an important role in Ayurvedic clinical research by generating preliminary clinical evidence and informing the design of future controlled studies.[12] The present study contributes to this evidence base by providing structured documentation of intervention standardization, outcome assessment, and safety monitoring. Overall, these findings suggest that *Withania coagulans*, administered as *Ekala Dravya* monotherapy, may provide short-term glycaemic improvement with good tolerability in patients with T2DM. Further well-designed randomized controlled trials with longer duration and comparative arms are required to confirm these findings and clarify its therapeutic role in diabetes management.

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