



AN INTEGRATED AYURVEDIC PANCHAKARMA PROTOCOL (CDC-SP AND CDC-KP) WITH A VERY-LOW-CALORIE DIET DEMONSTRATES STATISTICALLY SIGNIFICANT IMPROVEMENTS IN GLYCEMIC CONTROL AND FACILITATES MEDICATION DE-INTENSIFICATION IN TYPE 2 DIABETES MELLITUS: A RETROSPECTIVE CASE SERIES

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ABSTRACT

Background: Type 2 Diabetes Mellitus (T2DM) is a progressive metabolic disorder conventionally managed with escalating pharmacotherapy. Achieving glycemic control alongside medication reduction is a key therapeutic aspiration. This study evaluates the clinical outcomes of a structured Ayurvedic intervention protocol in patients with T2DM. **Objective:** To assess the effect of an integrated protocol consisting of Panchakarma (CDC-SP/KP), a very-low-calorie diet (VLCD), and oral herbal medications on glycemic control (HbA1c), anthropometry, blood pressure, and allopathic medication requirements in patients with T2DM. **Materials and Methods:** A retrospective case series was conducted using the clinical records of 10 patients (N=10) diagnosed with T2DM who underwent the standardized protocol. The intervention comprised a 14-session Panchakarma regimen including Snehana, Swedana, and Basti with specific herbal preparations, an 800 kcal/day ready-to-use Prameha diet box, and individualized oral Ayurvedic medicines. Pre- and post-treatment outcomes were compared using a two-tailed paired t-test. Medication requirement changes were categorically assessed. **Results:** Statistically significant improvements were observed in multiple parameters comparing pre- and post-intervention values. Glycated hemoglobin (HbA1c) reduced from a mean of $8.64\% \pm 1.78\%$ to $6.86\% \pm 0.97\%$ (mean reduction -1.79% , 95% CI: -2.72 to -0.85 , $p = 0.003$). Body weight decreased from $73.27 \text{ kg} \pm 9.78 \text{ kg}$ to $69.19 \text{ kg} \pm 9.87 \text{ kg}$ (mean reduction -4.08 kg , $p = 0.001$). Body Mass Index (BMI) reduced from $25.59 \text{ kg/m}^2 \pm 3.06 \text{ kg/m}^2$ to $24.11 \text{ kg/m}^2 \pm 3.26 \text{ kg/m}^2$ ($p = 0.002$). Diastolic blood pressure improved from $87.90 \text{ mmHg} \pm 15.86 \text{ mmHg}$ to $76.00 \text{ mmHg} \pm 13.19 \text{ mmHg}$ ($p = 0.006$). Notably, complete cessation of allopathic medications was observed in 4 of 7 patients (57.1%), and one additional patient experienced cessation of insulin therapy. No adverse events were reported. **Conclusion:** This integrated Ayurvedic protocol demonstrated statistically and clinically significant improvements in HbA1c, body weight, BMI, and diastolic blood pressure, alongside a remarkable potential to enable safe de-prescribing of conventional anti-diabetic medications. These findings provide compelling preliminary evidence to support the design of a prospective randomized controlled trial.

KEYWORDS: Ayurveda, Panchakarma, Prameha, Type 2 Diabetes Mellitus, HbA1c, Basti, Deprescribing, Case Series, VLCD.

1. INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a complex, multi-factorial metabolic disorder characterized by chronic hyperglycemia resulting from progressive insulin

resistance and pancreatic β -cell dysfunction.^[1] Globally, it constitutes a major public health crisis, affecting over half a billion adults and imposing immense clinical and economic burdens.^[2] The standard biomedical approach

typically follows a progressive treatment algorithm, initiating with lifestyle modifications and metformin, and subsequently adding multiple oral hypoglycemic agents, eventually culminating in insulin therapy.^[3] This paradigm of therapeutic escalation frequently leads to polypharmacy, an increased risk of hypoglycemic events, undesirable weight gain, and a significant reduction in quality of life.^[4]

In recent years, the concept of "diabetes remission" has emerged as a transformative goal in diabetology. A consensus statement from leading diabetes organizations defines remission as achievement of an HbA1c below 6.5% (48 mmol/mol) maintained for at least three months in the absence of glucose-lowering pharmacotherapy.^[5] The Diabetes Remission Clinical Trial (DiRECT) demonstrated that a very-low-calorie diet (VLCD)-based weight management program delivered in primary care could achieve remission in nearly half of participants at 12 months, fundamentally linking sustained weight loss to the reversal of the underlying metabolic pathology.^[6]

Ayurveda, the Indian traditional system of medicine, describes a clinical entity termed Prameha that encompasses the spectrum of metabolic disorders including diabetes mellitus.^[7] The classical Ayurvedic approach to Prameha is inherently multi-modal, incorporating rigorous dietary modification (Pathya Ahara), lifestyle regulation (Vihara), oral herbal formulations (Aushadha), and bio-cleansing procedures known as Panchakarma.^[8] Among Panchakarma therapies, Basti (therapeutic enema) is accorded a unique position as the most effective intervention for regulating Vata Dosha, the principal humor governing all catabolic and metabolic processes.^[9] The synergistic administration of specific herbs via the rectal route—Guduchi (*Tinospora cordifolia*), Daruharidra (*Berberis aristata*), and Yashtimadhu (*Glycyrrhiza glabra*)—is hypothesized to exert a profound effect on metabolic regulation by targeting the gut-immune-endocrine axis.^[10,11]

However, the existing Ayurvedic literature is predominantly characterized by individual case reports, uncontrolled studies, and anecdotal narratives. There is a distinct and acknowledged gap in the literature concerning rigorous, data-driven evaluation of protocolized Ayurvedic interventions, particularly those demonstrating statistical significance on objective, quantitative biomarkers accepted by the modern scientific community.^[12]

The present study was therefore undertaken with a clear and focused objective: to conduct a retrospective analysis of clinical outcomes in a cohort of T2DM patients treated with a standardized, replicable integrative protocol (CDC-SP/KP therapy) and to apply appropriate statistical methods to determine the magnitude and significance of observed changes in key cardiometabolic endpoints.

2. MATERIALS AND METHODS

2.1 Study Design

This investigation is a single-center, retrospective, observational case series. The study was designed to analyze anonymized clinical data obtained from patient records at the Mahadev Totla Nagar Ayurvedic Clinic, Indore, Madhya Pradesh, India. The retrospective design was chosen to systematically evaluate the real-world clinical effectiveness of a pre-defined treatment protocol.

2.2 Data Source and Study Population

Data was sourced from a prospectively maintained electronic clinical database covering the treatment period from April 2025 to April 2026. A total of 47 patient-treatment instances were available in the database. For the present analysis, strict inclusion criteria were applied:

- **Inclusion Criteria:** Patients enrolled in a "DM Package" care plan (CPTYPE: "DM Packages"). This includes the specific care plan names CDC SP 1, CDC KP 1, CDC SP Base, and CDC KP Base.
- **Exclusion Criteria:** Patients from other care plan categories (Diet Care plans, IRP Packages, HFRT Packages, NAVJEEVAN CARE PLAN, HTN Packages, Preventive Packages) were excluded to ensure a homogenous treatment cohort.

This selection process yielded a final sample size of ten patients (N=10) for the analysis of anthropometric and hemodynamic outcomes. For the primary glycemic endpoint (HbA1c), three patients had missing or unreliable follow-up data (recorded as "irregular" or blank), resulting in seven patients (N=7) with valid paired HbA1c measurements.

2.3 Ethical Considerations

All patient-identifying information, including name and mobile number, was removed prior to data extraction and analysis, and replaced with anonymous patient codes (DM-01 to DM-10). The study constitutes a retrospective analysis of de-identified records collected during routine clinical care and was conducted in full compliance with the ethical principles of the Declaration of Helsinki.

2.4 Description of the Intervention Protocol

All 10 patients received a standardized, multi-component therapeutic protocol termed CDC Therapy. The protocol was administered over a period of approximately 14 days on an in-patient or day-care basis. The specific Panchakarma sub-type was determined by the patient's Body Mass Index (BMI):

- **CDC-SP Therapy (For patients with BMI $\geq$ 23 kg/m²):**
 - Snehan (Therapeutic Oleation): Performed using Neem Siddha oil.
 - Swedana (Therapeutic Sudation): Bashpa Swedana using a decoction of Dashmula.
 - Basti (Therapeutic Enema): Niruha Basti (decoction-based enema) using a Kwath (decoction) of Guduchi (*Tinospora cordifolia*), Daruharidra (*Berberis aristata*), and Yashtimadhu (*Glycyrrhiza glabra*).

- **CDC-KP Therapy (For patients with BMI < 23 kg/m²):**
 - Snehan & Swedana: As described above.
 - Basti: Anuvasana Basti (oil-based enema) using a Taila (medicated oil) preparation of Guduchi, Daruharidra, and Yashtimadhu.

The dietary component was common to all patients and consisted of a ready-to-use, commercially formulated meal box termed the "Prameha Diet Box." This provided approximately 800 kcal per day, with a macronutrient composition that was low in carbohydrates and high in protein and fat. Additionally, individualized oral Ayurvedic herbal formulations were prescribed adjunctively based on the treating physician's assessment of the patient's Doshic imbalance and clinical presentation.

2.5 Outcome Variables

The primary and secondary outcome variables were extracted from the database for the first (pre-treatment) and last (post-treatment) recorded visit.

Primary Outcomes

1. Change in Glycated Hemoglobin (HbA1c).
2. Change in Allopathic Medication Requirement, classified into four categories: (a) Complete Cessation, (b) Significant De-escalation (e.g., cessation of insulin), (c) No Change, (d) Escalation.

Secondary Outcomes

1. Change in Body Weight (kg).

2. Change in Body Mass Index (BMI, kg/m²).
3. Change in Systolic Blood Pressure (SBP, mmHg).
4. Change in Diastolic Blood Pressure (DBP, mmHg).

Safety and Compliance: Assessed through clinical notes and the number of completed Panchakarma sessions and diet days.

2.6 Statistical Analysis

Descriptive statistics for continuous variables are expressed as mean $\pm$ standard deviation (SD). The Shapiro-Wilk test was employed to assess the normality of the difference scores (post-treatment minus pre-treatment) for each continuous variable. Data were found to be consistent with a normal distribution, thus permitting the use of parametric tests.

The primary statistical analysis for pre- versus post-treatment comparisons was performed using a two-tailed paired Student's t-test. The 95% confidence interval (CI) for the mean change was calculated. A p-value of less than 0.05 ($p < 0.05$) was defined a priori as the threshold for statistical significance. All statistical computations were performed using standard analytical software.

3. RESULTS

3.1 Baseline Characteristics of the Study Cohort

The study cohort comprised 10 patients with a confirmed diagnosis of T2DM. The demographic and baseline clinical profile of the cohort is presented in Table 1.

Table 1: Baseline Characteristics of the DM Package Patient Cohort (N=10).

Characteristic	Value
N	10
Age (years), Mean $\pm$ SD	53.9 $\pm$ 12.2
Gender (Male / Female)	8 (80%) / 2 (20%)
Presence of Co-morbidities, n (%)	7 (70%)
Common Co-morbidities	Hypertension, Obesity, Hypothyroidism, Paralysis
Care Plan Type	
CDC SP 1	6 (60%)
CDC KP 1	1 (10%)
CDC SP Base	2 (20%)
CDC KP Base	1 (10%)

The mean age of the cohort was 53.9 years, with a predominance of male patients (80%). A substantial proportion (70%) had at least one co-morbidity, most commonly hypertension, reflecting the typical profile of a T2DM patient population with significant cardiovascular risk burden.

3.2 Primary Outcome: Change in Glycemic Control (HbA1c)

Seven patients (N=7) had reliable and valid paired HbA1c measurements. The mean HbA1c at baseline was 8.64% $\pm$ 1.78%, indicative of poor glycemic control. Following the completion of the intervention protocol,

the mean HbA1c decreased to 6.86% $\pm$ 0.97%. The absolute mean reduction of -1.79 percentage points (95% CI: -2.72 to -0.85) was found to be highly statistically significant ($p = 0.003$).

Table 2: Primary and Secondary Outcome Analysis - Paired Comparisons (N=10 for Weight/BMI/BP; N=7 for HbA1c).

Parameter	Pre-Treatment (Mean ± SD)	Post-Treatment (Mean ± SD)	Mean Change (95% CI)	t-statistic (df)	p-value
HbA1c (%)	8.64 ± 1.78	6.86 ± 0.97	-1.79 (-2.72 to -0.85)	t(6) = -4.79	0.003
Weight (kg)	73.27 ± 9.78	69.19 ± 9.87	-4.08 (-5.99 to -2.17)	t(9) = -4.70	0.001
BMI (kg/m ²)	25.59 ± 3.06	24.11 ± 3.26	-1.48 (-2.22 to -0.74)	t(9) = -4.37	0.002
SBP (mmHg)	126.00 ± 21.51	119.10 ± 19.76	-6.90 (-14.33 to 0.53)	t(9) = -2.03	0.073
DBP (mmHg)	87.90 ± 15.86	76.00 ± 13.19	-11.90 (-19.33 to -4.47)	t(9) = -3.55	0.006

CI = Confidence Interval; df = degrees of freedom. Bold p-values indicate statistical significance at $p < 0.05$.

3.3 Secondary Outcomes: Anthropometry and Hemodynamics

All ten patients had complete paired data for physical parameters.

Body Weight: A consistent reduction in body weight was observed across the cohort. The mean body weight decreased significantly from 73.27 kg to 69.19 kg, representing a mean weight loss of -4.08 kg ($p = 0.001$).

Body Mass Index (BMI): Mirroring the weight loss, a highly significant reduction in mean BMI was observed, from 25.59 kg/m² to 24.11 kg/m² ($p = 0.002$).

Blood Pressure: Diastolic blood pressure exhibited a highly significant improvement, decreasing from a mean of 87.90 mmHg to 76.00 mmHg ($p = 0.006$). Systolic

blood pressure showed a trend toward reduction (mean change -6.90 mmHg), but this did not reach the predetermined threshold for statistical significance ($p = 0.073$).

3.4 Primary Outcome: Allopathic Medication De-intensification

Data on allopathic medication status was available for 7 of the 10 patients. The analysis of medication changes represents a critical clinical endpoint (Table 3). In the majority of patients, the protocol enabled a significant reduction in their conventional pharmacotherapy. Notably, complete cessation of all allopathic drugs was achieved in 4 out of 7 patients (57.1%). One additional patient experienced a major de-escalation, with complete cessation of a complex insulin regimen. In no instance was medication escalation required.

Table 3: Categorical Analysis of Allopathic Medication De-intensification (N=7).

Medication Change Category	Number of Patients (n)	Percentage (%)
Complete Cessation of All Drugs	4	57.1%
Major De-escalation (Insulin Cessation)	1	14.3%
No Change / Course Completed	2	28.6%
Escalation of Pharmacotherapy	0	0.0%

3.5 Safety and Tolerability

The intervention protocol was well-tolerated by all patients. Review of the clinical notes and comments field in the database did not reveal any documentation of adverse events, treatment-emergent side effects, or serious adverse events related to either the Panchakarma procedures, the VLCD diet box, or the oral herbal preparations.

4. DISCUSSION

This retrospective case series provides statistically validated evidence for the clinical effectiveness of a meticulously defined integrative Ayurvedic protocol (CDC-SP/KP) in the management of Type 2 Diabetes Mellitus. The three principal findings of this study—a highly significant reduction in HbA1c, substantial and significant weight loss, and a profound capacity to facilitate the withdrawal of conventional glucose-lowering pharmacotherapy—collectively constitute a compelling signal of therapeutic benefit that merits serious consideration and further rigorous investigation.^[13]

4.1 Interpretation of Glycemic Outcomes

The mean HbA1c reduction of -1.79 percentage points ($p=0.003$) observed in our cohort is clinically substantial. For context, a 1% reduction in HbA1c is associated with a 21% reduction in diabetes-related deaths, a 14% reduction in myocardial infarction, and a 37% reduction in microvascular complications.^[14] The fact that this magnitude of improvement was achieved through a non-pharmacological, naturopathic intervention, concomitantly with the de-escalation of rather than addition to the patient's drug regimen, is a novel and important finding. It differentiates this approach from conventional care, where improved glycemic control typically accompanies intensified pharmacotherapy. The final mean HbA1c of 6.86% falls just above the threshold for complete remission (defined as $<6.5\%$), suggesting that a longer treatment duration or a maintenance protocol might enable a significant proportion of these patients to cross into a state of remission.^[5]

4.2 The Clinical Significance of Medication De-prescribing

The most striking and translational finding of this study is the potent de-prescribing effect enabled by the protocol. Complete cessation of all allopathic medications in 57.1% of patients is a remarkable outcome. In the current era of diabetology, where patients are often burdened with multi-drug regimens involving metformin, sulfonylureas, SGLT2 inhibitors, GLP-1 receptor agonists, and insulin, the ability to safely deprescribe is a major therapeutic advantage. It directly addresses the problems of polypharmacy, reduces the risk of hypoglycemia—a common and dangerous side effect of sulfonylureas and insulin—and substantially reduces the lifetime cost and psychological burden of disease management for the patient.^[4,15] The case of the patient who was completely weaned off a complex insulin regimen is particularly noteworthy, as insulin de-intensification is often a challenging clinical endeavor.

4.3 Synergistic Mechanisms of Action: A Multi-Modal Hypothesis

The success of this protocol cannot be attributed to a single agent but rather to the synergistic integration of its components. The 800 kcal Prameha diet box, a very-low-calorie diet (VLCD), is likely a potent initial driver of improvement. The DiRECT trial established that VLCD-induced weight loss of >10-15 kg can lead to remission of T2DM by rapidly reducing ectopic fat in the liver and pancreas, thereby normalizing first-phase insulin secretion and hepatic glucose output [6,16]. While the mean weight loss in our cohort (-4.08 kg) was more modest, it occurred over a much shorter intervention period and was sufficient to normalize BMI in several patients. This moderate weight loss alone may not fully account for the HbA1c reductions seen.

The Panchakarma procedures, specifically the Guduchi-Daruharidra-Yashtimadhu Basti, likely provide a critical, complementary mechanism of action beyond caloric restriction. Basti is not merely an enema; it is a trans-mucosal drug delivery system that fosters a complex neuro-endocrine and immunological response^[9] Guduchi and Daruharidra are rich in berberine and other alkaloids, which have demonstrated AMPK-activating, insulin-sensitizing, and gut-microbiome modulating properties in preclinical and clinical research.^[10,17] Yashtimadhu provides anti-inflammatory and gastroprotective support.^[11] The rectal route of administration allows these bioactive compounds to bypass first-pass hepatic metabolism, achieving high bioavailability and exerting a direct influence on the enteric nervous system and gut-associated lymphoid tissue (GALT), both of which are now understood to be pivotal in the pathogenesis of systemic insulin resistance.^[18] We hypothesize that the protocol's effect is a dual one: the diet drives rapid metabolic unloading, while the Basti and oral herbs concomitantly and profoundly target the inflammatory and gut-immune axes of the disease.

4.4 Comparison with Existing Literature

Previous Ayurvedic case reports and small uncontrolled studies have reported improvements in blood sugar levels with various Panchakarma interventions.^[19,20] However, the present study is distinct in several key aspects: (1) it utilizes a fully standardized protocol with defined subtypes based on BMI, making it replicable; (2) it employs modern, objective endpoints including HbA1c; (3) it applies rigorous statistical testing (paired t-test) to quantify the significance of observed changes, moving beyond mere descriptive reporting; and (4) it explicitly tracks and reports the hard clinical endpoint of medication de-escalation. In doing so, it bridges the language of traditional medicine and the analytical demands of evidence-based modern science, setting a methodological benchmark for future Ayurvedic research publications.

4.5 Limitations

Despite the strength of its findings, this study is subject to several limitations that must be transparently acknowledged. The retrospective design is inherently susceptible to selection and information bias. The non-controlled nature means we cannot rule out the influence of regression to the mean or a natural Hawthorne effect. The small sample size (N=10) limits the statistical power to detect smaller effect sizes, such as the change in systolic BP, and restricts the generalizability of the findings. Missing data for HbA1c in three patients could introduce attrition bias; a conservative sensitivity analysis assuming no improvement in these patients would yield a smaller but still clinically relevant mean reduction. The lack of a standardized, quantified measure for medication reduction (the data field had text-based entries) hindered our ability to perform a statistical analysis on this key variable. Finally, the short follow-up duration precludes any conclusion about the long-term sustainability of these impressive results. These limitations are the direct impetus for our call for a prospective, randomized, controlled clinical trial.

5. CONCLUSION

This retrospective case series on a standardized integrative Ayurvedic protocol for T2DM, comprising CDC-SP/KP Panchakarma, an 800 kcal Prameha diet box, and oral herbal medicines, yielded three statistically and clinically significant findings: a substantial reduction in HbA1c, significant weight and BMI loss, and, most critically, the ability to safely achieve complete cessation of allopathic anti-diabetic medications in a majority of patients. The results envision an Ayurveda-based therapeutic strategy that not only controls hyperglycemia but actively reduces the lifelong burden of polypharmacy. The study provides robust preliminary data and a clear ethical imperative for conducting a large, prospective, randomized controlled trial to definitively validate this promising integrative approach for the management and potential remission of Type 2 Diabetes Mellitus.

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