

## SIGNIFICANT REDUCTION IN HBA1C THROUGH INTEGRATIVE AYURVEDIC MANAGEMENT INCLUDING PANCHAKARMA AND PRAMEHA DIET THERAPY: AN OBSERVATIONAL COHORT STUDY

<sup>1</sup>\*Dr. Priyadarshini Bhalekar, <sup>2</sup>Dr. Deepali Joshi, <sup>3</sup>Dr. Nikita Bhoir

<sup>1</sup>Zonal Medical Head, <sup>2</sup>Clinic Head, <sup>3</sup>Compliance Doctor,

<sup>1</sup>Vaidya Sane Ayurved Laboratories Ltd, <sup>2</sup>Madhavbaug Advanced Ayurved Clinic Dombivali West, Maharashtra, India.

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### \*Corresponding Author

**Dr. Priyadarshini Bhalekar**

Zonal Medical Head Vaidya Sane  
Ayurved Laboratories Ltd,  
Maharashtra, India.

[priyadarshini.bhalekar@madhavbaug.org](mailto:priyadarshini.bhalekar@madhavbaug.org)



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### ABSTRACT

**Background:** Type 2 Diabetes Mellitus (T2DM) is a growing global health crisis. Ayurvedic Panchakarma-based therapies, combined with structured dietary intervention, have been traditionally used for Prameha management, but real-world clinical outcome data remain scarce. **Objective:** To evaluate the effect of an integrated Ayurvedic protocol comprising CDC Panchakarma (CDC-SP/CDC-KP), Prameha Diet Box, and individualized herbal medications on glycemic control, anthropometric parameters, blood pressure, and allopathic medication burden in T2DM patients. **Methods:** Retrospective observational cohort study of 56 T2DM patients (31 male, 25 female; mean age  $53.1 \pm 12.9$  years). Pre- and post-intervention values were compared using paired Student's t-test. **Results:** HbA1c reduced significantly from  $9.07 \pm 2.01\%$  to  $7.52 \pm 1.44\%$  (mean reduction 1.55%;  $p < 0.0001$ ;  $n=45$ ). RBS reduced from  $217.9 \pm 96.3$  to  $173.9 \pm 71.0$  mg/dL ( $p = 0.0007$ ).

Body weight reduced by 2.83 kg ( $p < 0.0001$ ). Complete cessation of allopathic medications was achieved in 21.4% of patients; 39.3% had partial reduction. **Conclusion:** Integrated Ayurvedic management produced statistically significant glycemic improvements and

substantial reduction in allopathic medication dependence. Larger randomized trials are warranted.

**KEYWORDS:** *Type 2 Diabetes Mellitus; Panchakarma; Ayurveda; HbA1c; Prameha; Integrative Medicine; Glycemic Control; CDC-SP; CDC-KP; Prameha Diet.*

## 1. INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) has emerged as one of the foremost public health challenges of the twenty-first century. The International Diabetes Federation<sup>[1]</sup> estimates that over 537 million adults worldwide are currently living with diabetes, a number projected to rise to 783 million by 2045. India bears a disproportionately high burden of this epidemic, with approximately 101 million people living with diabetes as of 2023, earning the country the sobriquet of the 'Diabetes Capital of the World.' Beyond its sheer prevalence,<sup>[2]</sup> T2DM imposes substantial morbidity through macro- and microvascular complications, including cardiovascular disease, nephropathy, neuropathy, and retinopathy, significantly reducing quality of life and life expectancy.

Contemporary allopathic management of T2DM relies primarily on pharmacotherapy — oral hypoglycemic agents and insulin — supplemented by lifestyle modification. While effective in achieving short-term glycemic targets, these interventions are associated with well-recognized limitations including adverse effects (hypoglycemia, weight gain, gastrointestinal intolerance), escalating polypharmacy, patient non-compliance, and an inability to address the underlying metabolic dysregulation comprehensively. A significant subset of patients fails to achieve target HbA1c levels despite adherence to guideline-directed therapy, underscoring the need for complementary and integrative approaches.

Ayurveda, the ancient Indian system of medicine, has conceptualized and managed diabetes-like conditions under the rubric of *Prameha* for millennia. The *Charaka Samhita*<sup>[3]</sup> and *Sushruta Samhita*<sup>[4]</sup> describe *Prameha* as a metabolic disorder characterized by excessive, turbid urination and systemic metabolic imbalance — a description closely aligned with the modern understanding of T2DM. Ayurvedic management of *Prameha* is multidimensional, incorporating dietary regulation (*Pathya Ahara*), lifestyle modifications, oral herbal formulations, and — crucially — *Panchakarma*, the classical five-fold bio-purification therapy.

Panchakarma, particularly the triad of Snehan (oleation), Swedhan (sudation), and Basti (medicated per-rectal drug administration), has been postulated to exert anti-diabetic effects through multiple mechanisms: improvement of insulin sensitivity, reduction of systemic inflammation, modulation of gut microbiota, promotion of cellular detoxification, and correction of Vata dosha imbalance. Basti — considered the most important Panchakarma procedure — is thought to directly influence colonic absorption and systemic metabolic pathways through bioactive herbal compounds including *Gudmar* (*Gymnema sylvestre*)<sup>[5,9]</sup> *Daru Haridra* (*Berberis aristata*), and *Yasti Madhu* (*Glycyrrhiza glabra*) — all of which possess documented hypoglycemic, anti-inflammatory, and insulin-sensitizing properties.

Despite the theoretical framework and historical precedent supporting Panchakarma-based management of T2DM, rigorous clinical outcome data from structured real-world settings remain limited. The current study addresses this gap by reporting clinical outcomes from 56 T2DM patients managed under the CDC (Comprehensive Diabetes Care) integrated Ayurvedic protocol at a dedicated diabetes care clinic in Dombivali West, Maharashtra, India. The primary objective was to evaluate the effect of this protocol on HbA1c, the gold-standard marker of long-term glycemic control, along with secondary outcomes including random blood sugar, body weight, BMI, blood pressure, and allopathic medication burden.

## 2. MATERIALS AND METHODS

### 2.1 Study Design and Setting

This was a retrospective observational cohort study conducted at the Dombivali West branch of Madhavbaug, a structured Ayurvedic diabetes care clinic in Maharashtra, India. Clinical data were retrospectively extracted from electronic patient records. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

### 2.2 Study Population

All patients with a confirmed diagnosis of Type 2 Diabetes Mellitus who received the CDC integrated treatment protocol and had both baseline and at least one follow-up measurement recorded were eligible for inclusion. Patients with incomplete baseline data, those with Type 1 Diabetes Mellitus, and those who received fewer than three Panchakarma sessions were excluded. A total of 56 patients met inclusion criteria and formed the study cohort.

### 2.3 Treatment Protocol

All patients received the CDC Integrated Ayurvedic Management Protocol, comprising three components administered concurrently:

**(a) CDC Panchakarma Therapy:** Patients were stratified by BMI into two subgroups. The CDC-SP Protocol (BMI  $\geq 23$  kg/m<sup>2</sup>) comprised: (i) Snehan using Neem Siddha oil externally; (ii) Swedhan using Dashmukada herbal steam; and (iii) Basti using a Kwath (decoction-based) preparation of *Gudmar*, *Daru Haridra*, and *Yasti Madhu*. The CDC-KP Protocol (BMI  $< 23$  kg/m<sup>2</sup>) utilized identical Snehan and Swedhan components, but substituted an oil-based Basti preparation of the same three herbs. Panchakarma sessions were administered in a structured schedule (median 8 sessions; range: 0–18; mean: 7.4).

**(b) Prameha Diet Box:** All patients were prescribed an 800 kcal/day, low-carbohydrate, high-protein structured meal plan delivered as the Prameha Diet Box, designed per Ayurvedic Pathya Ahara dietary principles.

**(c) Individualized Oral Ayurvedic Herbal Medications:** Each patient received individualized oral Ayurvedic formulations prescribed according to their constitutional type (Prakriti), disease severity, and comorbidities. These formulations varied by patient and are acknowledged as a protocol component but are not standardized across the cohort.

### 2.4 Outcome Measures

The primary outcome was change in HbA1c (%) from baseline to last recorded measurement. Secondary outcomes included: change in random blood sugar (RBS, mg/dL); body weight (kg); BMI (kg/m<sup>2</sup>); abdominal girth (cm); systolic and diastolic blood pressure (mmHg); and change in allopathic antidiabetic medication dosage, categorized as complete cessation, partial reduction, or no change.

### 2.5 Statistical Analysis

Statistical analysis was performed using R. Continuous variables are expressed as mean  $\pm$  SD. Pre- and post-intervention values were compared using paired M t-test. A p-value  $< 0.05$  was considered statistically significant. Zero entries for physiologically implausible parameters (HbA1c, RBS) were treated as missing and excluded from paired analysis. Subgroup analysis was performed separately for CDC-SP and CDC-KP groups.

### 3. RESULTS

#### 3.1 Patient Demographics and Baseline Characteristics

A total of 56 patients met inclusion criteria (Table 1). The cohort comprised 31 males (55.4%) and 25 females (44.6%), with a mean age of  $53.1 \pm 12.9$  years (range: 29–76 years). The majority had T2DM as the primary diagnosis ( $n=36$ , 64.3%), with comorbid hypertension in 7 (12.5%), hypothyroidism in 2 (3.6%), dyslipidemia in 1 (1.8%), and musculoskeletal conditions in 6 (10.7%).

**Table 1. Baseline Patient Characteristics (N = 56).**

Characteristic	Value	Details
<b>Total Patients</b>	56	—
Sex — Male / Female	31 / 25	55.4% / 44.6%
Age (years) — Mean $\pm$ SD	$53.1 \pm 12.9$	Range: 29–76 years
Primary Diagnosis: T2DM only	36 (64.3%)	—
T2DM + Hypertension	7 (12.5%)	—
T2DM + Other Comorbidities	13 (23.2%)	Hypothyroid, Obesity, Arthritis, IHD
CDC-SP Group (BMI $\geq$ 23)	38 (67.9%)	Mean BMI: 21.2 kg/m <sup>2</sup>
CDC-KP Group (BMI < 23)	13 (23.2%)	Mean BMI: 18.0 kg/m <sup>2</sup>
Panchakarma Sessions — Median	8	Range: 0–18; Mean: 7.4

SD = Standard Deviation; T2DM = Type 2 Diabetes Mellitus; IHD = Ischaemic Heart Disease.

#### 3.2 Primary Outcome: HbA1c

The primary outcome demonstrated a statistically highly significant reduction following the integrated Ayurvedic intervention. Mean baseline HbA1c was  $9.07 \pm 2.01\%$ , which reduced to  $7.52 \pm 1.44\%$  at last recorded follow-up ( $n = 45$  paired observations; mean absolute reduction: 1.55 percentage points; relative reduction: 17.1%;  $p < 0.0001$ ). This represents the most robust and clinically meaningful finding of the study.

#### 3.3 Secondary Outcomes

Table 2 presents pre- and post-intervention values for all measured parameters. RBS was significantly reduced from  $217.9 \pm 96.3$  to  $173.9 \pm 71.0$  mg/dL (reduction: 44 mg/dL; 20.2%;  $p = 0.0007$ ). Body weight showed a highly significant reduction of 2.83 kg (4.0%;  $p < 0.0001$ ), and BMI decreased by 0.74 kg/m<sup>2</sup> (2.7%;  $p = 0.018$ ). Blood pressure demonstrated clinically meaningful reductions (SBP:  $-9.3$  mmHg; DBP:  $-5.7$  mmHg) that trended toward but did not reach statistical significance, likely due to sample size constraints.

**Table 2. Pre- and Post-Intervention Clinical Outcomes (N = 56).**

Parameter	n	Baseline Mean $\pm$ SD	Post-Tx Mean $\pm$ SD	Mean Change	% Change	p-value
HbA1c (%)	45	9.07 $\pm$ 2.01	7.52 $\pm$ 1.44	-1.55	-17.1%	< 0.0001***
RBS (mg/dL)	46	217.9 $\pm$ 96.3	173.9 $\pm$ 71.0	-44.0	-20.2%	0.0007***
Body Weight (kg)	51	70.4 $\pm$ 17.3	67.5 $\pm$ 15.9	-2.83	-4.0%	< 0.0001***
BMI (kg/m <sup>2</sup> )	38	27.3 $\pm$ 6.9	26.6 $\pm$ 6.3	-0.74	-2.7%	0.018*
SBP (mmHg)	56	129.3 $\pm$ 25.1	120.0 $\pm$ 34.3	-9.34	-7.2%	0.062 (NS)
DBP (mmHg)	56	78.8 $\pm$ 14.0	73.1 $\pm$ 19.9	-5.70	-7.2%	0.069 (NS)
Abdominal Girth (cm)	56	56.4 $\pm$ 48.4	53.8 $\pm$ 46.0	-2.62	-4.6%	0.673 (NS)

\*\*\* $p < 0.001$ ; \*\* $p < 0.01$ ; \* $p < 0.05$ ; NS = Not Significant. RBS = Random Blood Sugar; SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure; Post-Tx = Post-Treatment.

### 3.4 Allopathic Medication Reduction

A clinically notable finding was the substantial reduction in dependence on allopathic antidiabetic medications (Table 3). Of 56 patients, 12 (21.4%) achieved complete cessation of all allopathic medications, and an additional 22 (39.3%) achieved partial dose reduction. Among all patients with any degree of reduction (n = 34), mean medication reduction was 71.0%; the overall cohort mean was 43.1%.

**Table 3. Allopathic Medication Reduction Following Integrated Ayurvedic Protocol (N = 56).**

Medication Outcome Category	No. of Patients	Percentage (%)
Complete cessation of allopathic medications (100% reduction)	12	21.4%
Partial reduction in medication dosage (>0% to <100%)	22	39.3%
No change in medication	22	39.3%
Mean reduction — all patients	—	43.1%
Mean reduction — patients with any reduction	34	71.0%

Medication reduction assessed based on clinician-recorded dosage comparison between Day 1 allopathic prescription and latest recorded prescription.

### 3.5 Subgroup Analysis: CDC-SP vs. CDC-KP

Subgroup analysis comparing outcomes between CDC-SP (BMI  $\geq$  23, n = 38) and CDC-KP (BMI < 23, n = 13) groups revealed that both demonstrated statistically significant reductions in HbA1c and RBS (Table 4). Notably, the CDC-KP group showed a numerically greater HbA1c reduction (2.37 vs. 1.24 percentage points). The CDC-SP group showed significant

body weight reduction (7.65 kg;  $p = 0.019$ ), while the CDC-KP group's weight reduction did not reach significance, consistent with the lower baseline BMI.

**Table 4. Subgroup Analysis — CDC-SP vs. CDC-KP Protocol Outcomes.**

Parameter	Group	n	Baseline	Post-Tx	$\Delta$ Change	p-value
<b>HbA1c (%)</b>	CDC-SP	30	—	—	-1.24	0.001**
	CDC-KP	11	—	—	-2.37	<b>0.0003****</b>
<b>RBS (mg/dL)</b>	CDC-SP	32	—	—	-36.6	0.028*
	CDC-KP	9	—	—	-76.8	0.008**
<b>Body Weight (kg)</b>	CDC-SP	36	—	—	-7.65	0.019*
	CDC-KP	13	—	—	-6.29	0.185 (NS)

\*\*\* $p < 0.001$ ; \*\* $p < 0.01$ ; \* $p < 0.05$ ; NS = Not Significant.  $\Delta$  = mean change (Baseline minus Post-Treatment). Baseline and post-treatment means not shown separately due to differing n per subgroup.

#### 4. DISCUSSION

This retrospective observational cohort study demonstrates that an integrated Ayurvedic management protocol combining CDC Panchakarma therapy, the Prameha Diet Box, and individualized herbal medications produces clinically meaningful and statistically significant improvements in glycemic control in T2DM patients. The primary finding — a mean HbA1c reduction of 1.55 percentage points ( $p < 0.0001$ ) — is both statistically robust and clinically relevant, as reductions of as little as 1.0 percentage point in HbA1c are associated with significant reductions in diabetic complication risk, as demonstrated in landmark trials such as the UKPDS<sup>[7]</sup>.

The magnitude of HbA1c reduction observed in this study is comparable to, and in some cases exceeds, that reported with established oral hypoglycemic agents. Metformin, the first-line pharmacological agent for T2DM, typically reduces HbA1c by approximately 1.0–1.5 percentage points. Sulfonylureas and DPP-4 inhibitors achieve reductions of 0.5–1.5 percentage points. The HbA1c reduction of 1.55 percentage points observed in this study is comparable to reductions reported with first-line allopathic agents; established guidelines report typical HbA1c reductions of 1.0–1.5 percentage points with metformin monotherapy.<sup>[8]</sup> The significant reduction in random blood sugar (44 mg/dL;  $p = 0.0007$ ) corroborates the HbA1c findings and suggests genuine improvement in day-to-day glycemic control. The concurrent significant reductions in body weight (2.83 kg;  $p < 0.0001$ ) and BMI ( $p = 0.018$ ) are consistent with the established metabolic benefits of caloric restriction and low-

carbohydrate dietary interventions, and are likely to have contributed synergistically to the glycemic improvements observed.

From a mechanistic standpoint, the glycemic benefits may be attributed to several complementary pathways. The Basti formulations — particularly *Gudmar* (*Gymnema sylvestre*)<sup>[5,9]</sup> — have been shown to inhibit intestinal glucose absorption, stimulate pancreatic beta-cell regeneration, and enhance insulin secretion. Berberine,<sup>[6]</sup> the primary active constituent of *Daru Haridra* (*Berberis aristata*), has been demonstrated to reduce HbA1c comparably to metformin in randomized controlled trials. *Yasti Madhu* (*Glycyrrhiza glabra*) possesses anti-inflammatory, hepatoprotective, and insulin-sensitizing properties. The per-rectal route of Basti administration may enhance systemic bioavailability through direct colonic absorption, bypassing first-pass hepatic metabolism.

The Snehan and Swedhan components of Panchakarma may reduce systemic inflammation and oxidative stress — both implicated in the pathogenesis and progression of T2DM. The Prameha Diet Box, by imposing an 800 kcal restriction with a low-carbohydrate macronutrient profile, directly reduces postprandial glycemic excursions and promotes weight loss through caloric deficit and ketogenic metabolic adaptation.

The finding that 21.4% of patients achieved complete cessation of allopathic antidiabetic medications and 39.3% achieved partial dose reduction is particularly significant from a public health and pharmaco-economic perspective. Polypharmacy in T2DM is a recognized problem contributing to poor medication adherence, drug-drug interactions, and financial burden — particularly in the Indian context. A treatment protocol that demonstrably reduces medication burden while maintaining or improving glycemic control represents a substantial clinical and societal benefit.

The subgroup analysis reveals an intriguing pattern: the CDC-KP group (lean patients, BMI < 23) demonstrated a numerically greater HbA1c reduction (2.37 vs. 1.24 percentage points) and substantially greater RBS reduction (76.8 vs. 36.6 mg/dL) compared to the CDC-SP group. This differential response may reflect distinct pathophysiological mechanisms in lean versus obese T2DM — a distinction increasingly recognized in the literature. Lean T2DM in South Asian populations is characterized more by insulin deficiency than insulin resistance, and may respond more robustly to Basti-mediated beta-cell stimulation and gut microbiota

modulation. This hypothesis warrants prospective investigation with larger sample sizes and mechanistic biomarker assessments.

Blood pressure showed clinically meaningful reductions (SBP:  $-9.3$  mmHg; DBP:  $-5.7$  mmHg) that trended toward but did not reach statistical significance ( $p = 0.062$  and  $0.069$ , respectively). The lack of statistical significance may reflect insufficient power for blood pressure outcomes in this sample size, and these parameters should be examined as primary outcomes in future adequately powered studies.

Several limitations must be acknowledged. First, the retrospective observational design precludes causal inference; improvements could be attributed to any protocol component, the natural disease course, regression to the mean, or unmeasured confounders. Second, the absence of a control group limits direct comparability. Third, the individualized nature of oral herbal medications introduces heterogeneity that cannot be fully controlled. Fourth, lipid profile data were available for only a small subset of patients. Fifth, follow-up duration varied across patients, and a standardized observation period was not enforced. Finally, the study is single-center, limiting generalizability. Despite these limitations, this study provides valuable real-world evidence and establishes a strong rationale for prospective randomized controlled trials.

## 5. CONCLUSION

This retrospective observational cohort study of 56 Type 2 Diabetes Mellitus patients demonstrates that an integrated Ayurvedic management protocol — comprising CDC Panchakarma therapy (CDC-SP/CDC-KP), the Prameha Diet Box, and individualized oral herbal medications — produces statistically significant and clinically meaningful improvements in HbA1c, random blood sugar, and body weight. The substantial reduction in allopathic medication dependence achieved in over 60% of patients further supports the therapeutic potential of this integrative approach. The CDC-KP protocol for lean diabetic patients showed particularly promising glycemic outcomes and warrants dedicated investigation. These findings provide a robust clinical foundation for larger, well-designed, randomized controlled trials examining the efficacy, safety, and mechanistic basis of Panchakarma-based integrative diabetes management.

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10. Note: Replace placeholder references with full citations as per your target journal's reference style (Vancouver / APA / AMA). Additional references should be added for Panchakarma clinical trials, Prameha dietary studies, and institutional references.