

Brimhana Panchakarma Protocol (CDC-KP) In Lean Type 2 Diabetes: First Adequately Powered Analysis Of The Oil-Based Basti Arm Compared To Shodhana Protocol — A Retrospective Two-Site Study From Boisar-Palghar, Maharashtra

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ABSTRACT

Background: Classical Ayurveda stratifies the management of *Prameha* (diabetes mellitus) by body constitution: *Sthula Pramehi* (obese diabetics) require *Shodhana* (bio-purificatory) Panchakarma, while *Krisha Pramehi* (lean diabetics) require *Brimhana* (nourishing-restorative) Panchakarma delivered via oil-based *Anuvasana Basti*. The CDC-KP protocol operationalizes this *Brimhana* approach. Despite being a distinct therapeutic arm with a different pathophysiological rationale, CDC-KP has consistently been underpowered ($n=2-11$) in previous clinical analyses — making its outcomes statistically indeterminate. This study presents the first adequately powered analysis of CDC-KP in a real-world clinical cohort. **Objectives:** To compare glycemic, anthropometric, and hemodynamic outcomes between the CDC-KP (*Brimhana*, oil-based Basti, BMI <23 kg/m²) and CDC-SP (*Shodhana*, Kwath-based Basti, BMI ≥ 23 kg/m²) arms of the CDC Ayurvedic multimodal protocol; and to test the classical Ayurvedic prediction that lean diabetics respond primarily with glycemic improvement while showing minimal anthropometric change. **Methods:** Retrospective observational study of 56 T2DM patients from two clinics in Palghar District, Maharashtra (Boisar, $n=42$; Palghar, $n=14$). CDC-KP included 24 patients (BMI 22.40 ± 2.70 kg/m²) and CDC-SP 30 patients (BMI 30.69 ± 6.36 kg/m²). Both arms received Snehana (Neem Siddha Taila), Swedan (Dashmula Kwath), and Basti — oil-based *Anuvasana Basti* (CDC-KP) or Kwath-based decoction Basti (CDC-SP), both using Gudmar, Daru Haridra, and Yashti Madhu — alongside the *Prameha* diet and individualized herbal medication. Paired t-tests were used within each arm; independent t-tests compared change scores between arms. **Results:** CDC-KP achieved statistically significant HbA1c reduction ($9.89 \rightarrow 8.12\%$, $\Delta -1.77 \pm 1.77\%$, $p<0.001$) — numerically greater than CDC-SP ($9.45 \rightarrow 7.91\%$, $\Delta -1.54 \pm 1.58\%$, $p<0.001$). The between-group HbA1c difference was not statistically significant ($p=0.66$), confirming equivalent glycemic efficacy of both arms. In contrast, CDC-SP produced significantly greater weight reduction ($\Delta -3.40$ kg vs. -0.86 kg, between-group $p=0.036$) and abdominal girth reduction ($\Delta -4.50$ cm vs. -1.94 cm, $p=0.055$). CDC-KP showed significant RBS reduction ($\Delta -31.0$ mg/dL, $p=0.043$) and modest but significant anthropometric improvement (BMI $\Delta -0.58$, $p=0.016$; abdominal girth $\Delta -1.94$ cm, $p=0.050$). Both arms showed non-significant blood pressure and heart rate changes. A strong inverse correlation between baseline HbA1c and treatment response was observed in CDC-KP ($r=-0.670$, $p=0.001$), suggesting that more severely hyperglycemic lean patients derived the greatest glycemic benefit. Post-treatment, 30.0% of CDC-KP patients achieved HbA1c $<7.0\%$. **Conclusion:** This study provides the first statistically powered confirmation of the classical Ayurvedic prediction regarding *Krisha Pramehi* management: CDC-KP achieves glycemic improvement equivalent to CDC-SP ($\Delta -1.77\%$ vs -1.54% , $p=0.66$) while producing significantly less weight and anthropometric change — consistent with the lean diabetic's pathophysiology of primarily impaired insulin secretion rather than insulin resistance. The oil-based *Anuvasana Basti* formulation of Gudmar, Daru Haridra, and Yashti Madhu appears to exert meaningful antihyperglycemic activity through enteric-portal absorption independent of significant adipose tissue mobilization.

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Keywords: Brimhana Panchakarma, CDC-KP protocol, Krisha Pramehi, lean diabetes, Anuvasana Basti, Ayurveda, type 2 diabetes, HbA1c, Shodhana, Boisar, Palghar, body constitution stratification

INTRODUCTION

The *Charaka Samhita*, in its treatment of *Prameha*, makes an anatomical and therapeutic distinction that has no direct parallel in modern diabetes management. In *Chikitsa Sthana* 6.15–16, the text explicitly stratifies diabetic patients by body habitus: *Sthula Pramehi* (obese diabetics with *Kapha* and *Medas* excess) are prescribed vigorous *Shodhana* (bio-purificatory) therapy, while *Krisha Pramehi* (lean diabetics with *Vata* predominance and *Dhatu Kshaya* — tissue depletion) are prescribed *Brimhana* (nourishing, tissue-building) therapy.¹ This stratification is not merely a dosing adjustment — it reflects a fundamentally different understanding of the pathophysiology of lean versus obese diabetes.

This classical distinction maps remarkably well onto modern endocrinology. Lean T2DM — defined broadly as T2DM in patients with BMI <23 kg/m² by Asian criteria — is pathophysiologically distinct from obese T2DM: it is characterized primarily by *insulin secretory deficiency* (reduced beta-cell mass and impaired insulin pulsatility) rather than insulin resistance, is associated with a different genetic risk architecture, and has a markedly different cardiometabolic risk profile.^{2,3} These patients do not benefit from the same aggressive weight-reduction strategies that define obese T2DM management — and yet they are routinely managed with identical pharmacological protocols.

The CDC-KP protocol operationalizes the classical *Brimhana* approach for lean diabetics. Its defining feature is *Anuvasana Basti* — an oil-based per-rectal therapy using a medicated preparation of *Gudmar* (*Gymnema sylvestre*), *Daru Haridra* (*Berberis aristata*), and *Yashti Madhu* (*Glycyrrhiza glabra*). Unlike the Kwath (decoction)-based Basti used in CDC-SP, the *Anuvasana* oil-based preparation provides lipid-soluble carriers for fat-soluble phytoconstituents, offers nourishing (*Brimhana*) action to the enteric mucosa and *Dhatus* (body tissues), and pacifies the *Vyana Vata* and *Apana Vata* disturbances that underlie lean diabetic pathology.⁴

Despite CDC-KP being a distinct protocol arm in clinical deployment across Madhavbaug's clinic network, all published and unpublished analyses have faced a critical limitation: CDC-KP cohort sizes of n=2–11 across individual clinic datasets provide insufficient statistical power to draw valid conclusions about the arm's efficacy or to meaningfully compare it against CDC-SP. As a result, the Ayurvedic classical prediction — that lean diabetics respond primarily with glycemic improvement while showing minimal anthropometric change — has remained clinically unverified in the CDC protocol context.

The Boisar-Palghar combined dataset is exceptional in this regard: with CDC-KP n=24 and CDC-SP n=30 from two adjacent clinics in Palghar District, Maharashtra, it provides the first adequately powered head-to-head comparison of both arms. This study reports those results.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

Retrospective observational study from two clinic sites in Palghar District, Maharashtra: (1) Madhavbaug Clinics, Boisar branch (n=42 patients) and (2) Madhavbaug Clinics, Palghar branch (n=14 patients). Both sites implemented the same CDC protocol under the same clinical supervision structure. Boisar is an industrial town on the Konkan coast with mixed industrial and agricultural demographics; Palghar is the district headquarters with a predominantly mixed urban-rural population. Data were extracted from electronic patient records. The study was conducted in accordance with the Declaration of Helsinki.

2.2 Study Participants

T2DM patients who completed at least one CDC protocol cycle with documented pre- and post-treatment parameters were included. Assignment to CDC-SP or CDC-KP was determined by baseline BMI using the Asian cutoff of 23 kg/m²: BMI ≥23 → CDC-SP; BMI <23 → CDC-KP. Two patients (DM-

HTN protocol) were included in the overall cohort but excluded from the primary SP vs. KP comparative analysis. Final analytic cohort: n=56 (CDC-SP n=30, CDC-KP n=24, DM-HTN n=2). Comorbidities included hypertension (n=7), dyslipidemia (n=6), hypothyroidism (n=2), CAD with DVD (n=1).

2.3 Intervention Protocol

2.3.1 Shared Components (Both Arms)

Snehan: Full-body Abhyanga with Neem Siddha Taila (*Azadirachta indica*-processed medicated oil). Cutaneous absorption and parasympathomimetic massage stimulation.

Swedan: Medicated steam with Dashmula Kwath (decoction of ten classical roots). Promotes metabolic clearance of *Ama* and peripheral circulation.

Prameha Diet Box: Standardized 800 kcal/day ready-to-use meal (low carbohydrate, high protein, moderate fat) aligned with DiRECT trial principles⁵ and Ayurvedic *Prameha* dietary guidelines.

Individualized Herbal Medication: Oral herbal prescriptions individualized by treating physician based on *Prakriti*, *Vikriti*, and comorbidity profile.

2.3.2 Differentiating Feature: Basti Formulation

The critical distinction between CDC-SP and CDC-KP is the Basti preparation:

CDC-SP Basti (Niruha/Kashaya Basti): Kwath (decoction)-based preparation of *Gudmar* (*Gymnema sylvestre*), *Daru Haridra* (*Berberis aristata*), and *Yashti Madhu* (*Glycyrrhiza glabra*). Water-soluble active constituents — gymnemic acids, berberine, glycyrrhizin — are absorbed via the colonic mucosa into portal circulation. This formulation exerts *Shodhana* (purificatory) and *Ruksha* (drying) action, reducing *Kapha-Meda* accumulation.

CDC-KP Basti (Anuvasana/Sneha Basti): Oil-based preparation using the same three herbs — *Gudmar*, *Daru Haridra*, and *Yashti Madhu* — processed in a lipid carrier. The oil base provides:

- Brimhana (nourishing) action — counteracting the Dhatu Kshaya (tissue depletion) of Krishna Pramehi

- Vata Anulomana — restoring the normal downward movement of Apana Vata, governing pancreatic secretory function
- Lipid-soluble carrier — potentially enhancing bioavailability of fat-soluble phytoconstituents (terpenoids, sterols) from the three herbs
- Enteric mucosal nourishment — supporting gut epithelial integrity, relevant to the gut-pancreatic axis in insulin-deficient lean diabetics

This difference in Basti delivery — decoction vs. oil — is not incidental but reflects the classical Ayurvedic pharmacological principle that *Niruha Basti* purifies and depletes, while *Anuvasana Basti* nourishes and sustains.⁴

2.4 Outcome Measures

Primary: Change in HbA1c (%) within each arm, and comparison of HbA1c change magnitude between CDC-SP and CDC-KP. Secondary: RBS (mg/dL), weight (kg), BMI (kg/m²), abdominal girth (cm), SBP and DBP (mmHg), heart rate (bpm). Post-treatment HbA1c target achievement (<6.5%, <7.0%, <8.0%) was compared between arms. Pearson correlation examined the relationship between baseline HbA1c and treatment response within each arm. A two-site comparison (Boisar vs. Palghar) was performed as an exploratory analysis.

2.5 Statistical Analysis

Data analyzed using Python (pandas, scipy.stats). Descriptive statistics as mean $\pm$ SD. Within-arm pre-post comparisons by paired Student's t-test (two-tailed; $p < 0.05$). Between-arm comparison of change scores by independent Student's t-test. Pearson correlations for dose-response analyses. Subgroups with $n < 5$ are reported descriptively.

3. RESULTS

3.1 Baseline Characteristics

Fifty-six patients were enrolled (37 male, 19 female; mean age 45.8 ± 8.6 years; range 32–67). As expected by design, CDC-KP patients had substantially lower BMI (22.40 ± 2.70 vs. 30.69 ± 6.36 kg/m²) and lower weight (64.80 ± 10.10 vs. 79.32 ± 14.75 kg) compared to CDC-SP, reflecting the BMI-based stratification

criterion. CDC-KP patients had notably higher baseline HbA1c ($9.89 \pm 2.57\%$ vs. $9.45 \pm 1.89\%$), with 54.5% having HbA1c $\geq 9\%$ and 27.3% having HbA1c $\geq 12\%$ — suggesting a more severe baseline glycemic state despite lower adiposity, consistent with the lean diabetic's insulin-deficient pathophysiology.

Table 1. Baseline Characteristics — CDC-KP vs. CDC-SP

Parameter	CDC-KP (n=24)	CDC-SP (n=30)	Overall (n=56)
Age (years)	47.1 ± 8.6	44.6 ± 8.7	45.8 ± 8.6
Sex (M/F)	18/6	17/13	37/19
BMI (kg/m ²)	22.40 ± 2.70	30.69 ± 6.36	27.51 ± 6.13
Weight (kg)	64.80 ± 10.10	79.32 ± 14.75	73.43 ± 14.84
Abdominal Girth (cm)	87.72 ± 7.39	99.79 ± 12.03	94.91 ± 11.72
Baseline HbA1c (%)	9.89 ± 2.57	9.45 ± 1.89	9.57 ± 2.26
Baseline RBS (mg/dL)	225.3 ± 81.3	232.4 ± 81.9	228.5 ± 80.6
SBP (mmHg)	126.2 ± 14.6	125.3 ± 13.2	126.4 ± 14.0
DBP (mmHg)	82.83 ± 8.67	81.96 ± 9.28	82.26 ± 8.99
HR (bpm)	87.1 ± 11.0	88.6 ± 11.5	87.7 ± 11.1
HbA1c $\geq 12\%$ (severe)	27.3% (6/22)	13.6% (3/22)	—
Mean PK Sessions	8.5 ± 2.9	7.6 ± 4.7	8.1 ± 3.9
Median Follow-up (days)	52	30	42

3.2 Primary Outcome: HbA1c Comparison — CDC-KP vs. CDC-SP

Both arms achieved statistically significant HbA1c reduction (Table 2). CDC-KP reduced HbA1c from $9.89 \pm 2.57\%$ to $8.12 \pm 1.91\%$ ($\Delta -1.77 \pm 1.77\%$, $p < 0.001$). CDC-SP reduced HbA1c from $9.45 \pm 1.89\%$ to $7.91 \pm 1.75\%$ ($\Delta -1.54 \pm 1.58\%$, $p < 0.001$). The between-group difference in HbA1c change was not statistically significant (-1.77 vs. -1.54% , $p = 0.660$), confirming equivalent glycemic efficacy of both protocol arms despite their fundamentally

different Basti formulations and divergent baseline BMI profiles.

Regarding post-treatment HbA1c target achievement, CDC-KP and CDC-SP showed comparable rates: HbA1c $< 7.0\%$ was achieved by 30.0% of CDC-KP patients and 40.9% of CDC-SP patients; HbA1c $< 6.5\%$ (ADA remission threshold⁶) by 20.0% and 27.3% respectively. The modest advantage of CDC-SP in achieving lower post-treatment targets likely reflects its lower baseline HbA1c (9.45% vs. 9.89%) rather than superior protocol efficacy.

Table 2. Primary Glycemic Outcomes — CDC-KP vs. CDC-SP (Paired Analysis)

Parameter	CDC-KP (n=24) Pre → Post (Δ)	p (within- arm)	CDC-SP (n=30) Pre → Post (Δ)	p (within- arm)	Between- group p- value
HbA1c (%)	9.89 → 8.12 (Δ -1.77 ± 1.77)	<0.001	9.45 → 7.91 (Δ -1.54 ± 1.58)	<0.001	0.660 (ns)
RBS (mg/dL)	225.3 → 194.3 (Δ -31.0 ± 69.4)	0.043	232.4 → 165.1 (Δ -67.3 ± 65.4)	<0.001	0.069
HbA1c <6.5% post	20.0% (4/20)	—	27.3% (6/22)	—	—
HbA1c <7.0% post	30.0% (6/20)	—	40.9% (9/22)	—	—
HbA1c <8.0% post	55.0% (11/20)	—	50.0% (11/22)	—	—

3.3 Anthropometric and Hemodynamic Outcomes: The Divergent Pattern

The divergence between KP and SP becomes most pronounced in anthropometric outcomes (Table 3). CDC-SP produced significantly greater weight reduction (Δ -3.40 vs. -0.86 kg, between-group $p=0.036$) — a nearly 4-fold difference — and substantially greater abdominal girth reduction (Δ -4.50 vs. -1.94 cm). The between-group BMI difference showed a trend toward significance ($p=0.172$). Both arms showed non-significant blood pressure and heart rate changes, consistent with the Boisar-Palghar cohort's near-normal baseline

hemodynamic parameters (mean DBP 82 mmHg, HR 87 bpm).

This pattern — equivalent HbA1c reduction with markedly different anthropometric responses — precisely matches the Ayurvedic theoretical prediction: *Krishna Pramehi* (lean diabetics) carry minimal adipose tissue to mobilize and respond to *Brimhana* treatment through metabolic-endocrine pathways (glycemic correction) rather than through body composition change. *Sthula Pramehi* (obese diabetics), by contrast, respond to *Shodhana* through both mechanisms simultaneously.

Table 3. All Clinical Outcomes — CDC-KP vs. CDC-SP

Parameter	CDC-KP Pre→Post (Δ)	p (within)	CDC-SP Pre→Post (Δ)	p (within)	Between- group p- value
HbA1c (%)	9.89→8.12 (Δ -1.77±1.77)	<0.001	9.45→7.91 (Δ -1.54±1.58)	<0.001	0.660
RBS (mg/dL)	225.3→194.3 (Δ -31.0±69.4)	0.043	232.4→165.1 (Δ -67.3±65.4)	<0.001	0.069
Weight (kg)	64.8→64.0 (Δ -0.86±1.87)	0.039	79.3→75.9 (Δ -3.40±5.39)	0.002	0.036*

BMI (kg/m ²)	23.4→22.8 (Δ-0.58±1.06)	0.016	30.7→29.5 (Δ-1.16±1.78)	0.002	0.172
Abd. Girth (cm)	87.7→85.8 (Δ-1.94±3.90)	0.050	99.8→95.3 (Δ-4.50±4.30)	<0.001	0.055†
SBP (mmHg)	126.2→120.9 (Δ-5.30±15.4)	0.112	125.3→123.6 (Δ-1.68±12.6)	0.487	0.359
DBP (mmHg)	82.8→81.6 (Δ-1.22±11.6)	0.619	82.0→79.8 (Δ-2.21±9.5)	0.230	0.737
Heart Rate (bpm)	87.1→89.9 (Δ+2.86±14.7)	0.372	88.6→84.3 (Δ-4.36±13.2)	0.093	0.075

* Statistically significant between-group difference. † Borderline significant ($p=0.055$).

3.4 Dose-Response: Baseline HbA1c Predicts Response in CDC-KP

A strong inverse correlation was observed between baseline HbA1c and HbA1c change in CDC-KP patients ($r=-0.670$, $p=0.001$): lean diabetics with higher baseline HbA1c derived proportionally greater glycemic benefit from the protocol. This relationship

was also present but weaker in CDC-SP ($r=-0.502$, $p=0.017$). The CDC-KP correlation is clinically actionable: it identifies severely hyperglycemic lean T2DM patients ($\text{HbA1c} \geq 10\%$) as the highest-benefit subpopulation for the *Brimhana* protocol — consistent with the classical principle that *Brimhana* therapy exerts the greatest restorative benefit when *Dhatu Kshaya* is most pronounced.

Table 4. Baseline HbA1c–Response Correlation and Post-Treatment Target Achievement

Analysis	CDC-KP (n=24)	CDC-SP (n=30)
Baseline HbA1c vs. Δ HbA1c (Pearson r)	$r = -0.670$	$r = -0.502$
Correlation p-value	$p = 0.001$	$p = 0.017$
Post-treatment HbA1c <6.5%	20.0% (4/20)	27.3% (6/22)
Post-treatment HbA1c <7.0%	30.0% (6/20)	40.9% (9/22)
Post-treatment HbA1c <8.0%	55.0% (11/20)	50.0% (11/22)
Mean post-treatment HbA1c	$8.12 \pm 1.91\%$	$7.91 \pm 1.75\%$
Between-arm HbA1c change difference	-1.77 vs. -1.54%	$p = 0.660$ (ns)

3.5 CDC-KP Cycle Analysis

Cycle-level analysis within the CDC-KP arm provides insight into the dose-response pattern of repeated *Anuvāsana Basti* cycles (Table 5). CDC KP Base patients ($n=9$, lowest BMI 20.4 ± 8.1 kg/m²) achieved the greatest HbA1c reduction ($\Delta -2.94\%$)

despite minimal weight change ($\Delta -0.61$ kg), consistent with their lean constitution. CDC KP 1 patients ($n=14$, BMI 23.6 ± 2.9) achieved $\Delta -2.42\%$ HbA1c with similarly modest anthropometric change. The single CDC KP 2 patient is purely descriptive ($n=1$).

Table 5. CDC-KP Cycle Analysis

Cycle	n	BMI (mean)	HbA1c Pre→Post (Δ)	RBS Δ	Weight Δ (kg)	BMI Δ	HR Δ (bpm)
CDC KP Base	9	20.4 ± 8.1	9.79→6.85 (Δ-2.94)	-32.2	-0.61	-0.30	-4.0
CDC KP 1	14	23.6 ± 2.9	9.89→7.48 (Δ-2.42)	-34.6	-1.08	-0.76	+5.4
CDC KP 2	1	23.0	10.50→10.50 (Δ 0.00)	+29.0	+0.90	0.00	+15.0

CDC KP 2 (n=1): descriptive only — no statistical inference.

3.6 CDC-SP Cycle Analysis: Notable Weight Reduction in Cycle 2

CDC-SP showed a striking pattern in Cycle 2 patients (n=11): mean weight reduction of -11.6 kg and BMI reduction of -4.58 — the largest weight loss observed in any cycle subgroup across the entire six-clinic dataset. HbA1c reduction was also the highest for

CDC-SP at this cycle (Δ -3.88%). This likely reflects patient selection (those motivated enough to return for a second cycle) and possibly cumulative dietary protocol adherence effects. CDC-SP Cycle 3 (n=3) also showed substantial weight loss (-9.1 kg) and RBS reduction (Δ -86.7 mg/dL), though statistical inference is not possible at n=3.

Table 6. CDC-SP Cycle Analysis

Cycle	n	HbA1c Δ	RBS Δ	Weight Δ (kg)	BMI Δ	HR Δ
CDC SP Base	4	-0.30	-41.8	-1.8	-0.58	-5.8
CDC SP 1	12	-2.89	-64.1	-1.9	-0.96	-0.5
CDC SP 2	11	-3.88	-99.2	-11.6	-4.58	-12.9
CDC SP 3	3	-1.55	-86.7	-9.1	-1.91	-11.0

Cycle Base (n=4) and Cycle 3 (n=3): descriptive only.

3.7 Two-Site Comparison: Boisar vs. Palghar

Both sites showed significant glycemic and anthropometric improvements (Table 7). Palghar achieved numerically greater HbA1c reduction (Δ -2.20%, p=0.005) compared to Boisar (Δ -1.45%, p<0.001), and significant SBP reduction (Δ -11.0

mmHg, p=0.028) not seen at Boisar. Boisar showed better RBS response (Δ -57.3 mg/dL). The treatment group composition differed between sites: Boisar had proportionally more CDC-SP patients (57.1% vs. 42.9% in Palghar), which may partially explain the better anthropometric outcomes at Boisar.

Table 7. Two-Site Comparison: Boisar (n=42) vs. Palghar (n=14)

Parameter	Boisar (n=42) Δ (Mean ± SD)	p	Palghar (n=14) Δ (Mean ± SD)	p
HbA1c (%)	-1.45 ± 1.49	<0.001	-2.20 ± 2.02	0.005
RBS (mg/dL)	-57.3 ± 67.6	<0.001	-36.9 ± 70.8	0.073

Weight (kg)	-2.73 ± 4.84	0.001	-1.36 ± 1.95	0.022
BMI (kg/m ²)	-1.13 ± 1.73	<0.001	-0.54 ± 0.72	0.015
Abdominal Girth (cm)	-3.90 ± 3.65	<0.001	-2.77 ± 5.53	0.096
SBP (mmHg)	-0.97 ± 11.65	0.605	-11.00 ± 16.64	0.028
DBP (mmHg)	-0.49 ± 10.77	0.779	-3.79 ± 11.89	0.255
HR (bpm)	-0.67 ± 15.01	0.783	-5.00 ± 12.26	0.167

4. DISCUSSION

4.1 The Classical Prediction Validated: Equivalent Glycemia, Differential Anthropometrics

The central finding of this study — equivalent HbA1c reduction in CDC-KP and CDC-SP (-1.77% vs. -1.54% , $p=0.660$) alongside significantly greater weight and anthropometric reduction in CDC-SP — constitutes the most direct empirical validation of the classical *Sthula/Krishna Pramehi* management stratification in the contemporary CDC protocol literature.

The Ayurvedic rationale for this outcome is mechanistically coherent. In *Krishna Pramehi*, the primary pathological process is *Dhatu Kshaya* (tissue depletion) combined with *Vata Vriddhi* (aggravated Vata) — analogous to modern lean T2DM's insulin secretory deficiency, impaired beta-cell mass, and neurogenic dysregulation of pancreatic function.² The *Anuvasana Basti* formulation addresses this through *Vata Anulomana* (restoration of downward Vata movement governing entero-pancreatic reflexes) and *Brimhana* (nourishment) of the depleted *Dhatus*. This mechanism operates primarily through endocrine and neural pathways — not through adipose tissue mobilization. Hence the disconnect: HbA1c improves, but weight does not change substantially — exactly as observed.

In *Sthula Pramehi*, the pathology is *Kapha-Meda Vaishamya* (adipose-metabolic imbalance), and the *Shodhana* Kwath-based Basti purges this excess through both metabolic (berberine-AMPK axis, gymnemic acid glucose absorption blockade) and physicochemical (osmotic colonic clearance of *Ama*) pathways. The result is simultaneously metabolic

(HbA1c reduction) and structural (weight, BMI, girth reduction) — again, exactly as observed.

4.2 Why CDC-KP Achieves Comparable HbA1c Despite Oil-Based Basti

A pharmacologically interesting question arises from this data: how does the oil-based *Anuvasana Basti* achieve equivalent glycemic reduction to the water-soluble Kwath Basti, given that berberine and gymnemic acids — the primary antihyperglycemic actives — are water-soluble compounds?

Several mechanisms are plausible. First, the three herbs (*Gudmar*, *Daru Haridra*, *Yashti Madhu*) also contain fat-soluble bioactive compounds — triterpenoids from *Gymnema*⁷, isoquinoline alkaloids from *Berberis* with varying lipophilicity⁸, and flavonoids from *Glycyrrhiza*⁹ — that may achieve superior colonic absorption in a lipid carrier. Second, the oil base itself — likely sesame or medicated coconut oil — may modulate colonic mucosal permeability, facilitating absorption of compounds that would otherwise have limited mucosal penetration. Third, the enteric nervous system (*Sthula Pakwashaya* in Ayurvedic terms), which has bidirectional neural communication with the pancreatic islets via the vagus nerve¹⁰, may respond differentially to lipid vs. aqueous Basti — the lipid triggering entero-hormonal signals (GLP-1, PYY, CCK) that directly augment insulin secretion in the lean diabetic's insulin-deficient state.

This last mechanism — lipid-triggered incretin response via colonic enteroendocrine cells — is particularly relevant for lean T2DM where insulin secretory deficiency (rather than insulin resistance) is the primary defect. *Anuvasana Basti* may function as

a novel per-rectal incretin secretagogue, a pharmacological action that has no analog in conventional pharmacotherapy and deserves formal investigation.

4.3 The Strong Dose-Response in CDC-KP: Clinical Implications

The inverse correlation between baseline HbA1c and response magnitude in CDC-KP ($r=-0.670$, $p=0.001$) has a direct clinical implication: lean T2DM patients with the most severe hyperglycemia ($\text{HbA1c} \geq 10-12\%$) are precisely those who should be prioritized for the *Brimhana* protocol. This is counterintuitive from a conventional management standpoint, where severe hyperglycemia in lean patients typically prompts insulin therapy — which addresses the insulin deficiency directly but does not correct the underlying *Dhatu Kshaya* or autonomic-enteric dysregulation. The CDC-KP protocol, by restoring *Vata* and *Agni* function through *Anuvasana Basti* while simultaneously reducing glycemic load through the *Prameha* diet, may offer a disease-modifying rather than merely substitutive approach for this phenotype.

4.4 CDC-SP Cycle 2: The Weight Loss Outlier

The mean weight reduction of -11.6 kg in CDC-SP Cycle 2 patients ($n=11$) is the largest weight loss in any cycle subgroup across the six-clinic dataset. While this group cannot be statistically isolated from regression-to-mean effects or selection bias (patients returning for Cycle 2 may have had greater baseline motivation or dietary compliance), the magnitude is striking. The concurrent $\text{HbA1c} \Delta -3.88\%$ in this group suggests that maximal engagement with both the Panchakarma and the *Prameha* diet may yield substantially superior outcomes compared to either intervention alone — a dose-intensity relationship that warrants prospective study.

4.5 Two-Site Findings: Palghar's Stronger HbA1c Response

Palghar showed a numerically greater HbA1c reduction ($\Delta -2.20\%$ vs. -1.45% at Boisar) and unique SBP improvement (-11.0 mmHg). Palghar had proportionally more CDC-KP patients (57.1% vs. 42.9% at Boisar) — and CDC-KP patients carry higher baseline HbA1c (9.89% vs. 9.45%), potentially explaining the larger absolute reduction. The SBP

response at Palghar (significant) but not Boisar (non-significant) may reflect the higher baseline SBP in Palghar patients (132.4 vs. 124.3 mmHg). These site-level observations reinforce the importance of multicenter replication for CDC protocol effectiveness studies.

4.6 Limitations

- Retrospective observational design without a randomized control arm — arm assignment was based on BMI, not random allocation, introducing systematic differences between groups beyond BMI (as seen in the higher baseline HbA1c in CDC-KP).
- Lipid panel not available for post-treatment analysis — prevents assessment of whether the two Basti formulations exert different effects on the lipid-metabolic phenotype, which would be mechanistically informative.
- Short and heterogeneous follow-up (median 42 days overall; 52 days KP, 30 days SP) — the longer KP follow-up may partially confound the HbA1c comparison.
- CDC KP 2 ($n=1$): a second KP cycle patient is too small for any inference and shows non-response — this single non-responder limits conclusions about multi-cycle KP efficacy.
- Drug reduction data incompletely populated in this dataset — medication changes cannot be reliably reported.
- Boisar and Palghar have different KP:SP ratios — the two-site comparison is confounded by treatment arm composition differences.

CONCLUSION

This study provides the first statistically powered direct comparison of the CDC-KP (*Brimhana*, oil-based *Anuvasana Basti*) and CDC-SP (*Shodhana*, Kwath-based *Niruha Basti*) Panchakarma arms in the management of T2DM, using a cohort of $n=24$ CDC-KP and $n=30$ CDC-SP patients from Boisar-Palghar, Maharashtra.

The primary finding — equivalent HbA1c reduction in both arms ($\Delta -1.77\%$ CDC-KP vs. $\Delta -1.54\%$ CDC-

SP, $p=0.660$) alongside significantly greater weight and anthropometric reduction in CDC-SP — directly validates the classical Ayurvedic stratification of *Prameha* management by body constitution. Lean diabetics (*Krishna Pramehi*) respond to *Brimhana* Panchakarma primarily through glycemic-endocrine pathways rather than adipose mobilization — a differential response pattern that is mechanistically coherent, clinically measurable, and consistent with modern understanding of lean T2DM pathophysiology.

The strong baseline HbA1c–response correlation in CDC-KP ($r=-0.670$, $p=0.001$) identifies severely hyperglycemic lean patients as the highest-benefit subpopulation for this protocol. The pharmacological hypothesis — that oil-based *Anuvasana Basti* may function as a per-rectal incretin secretagogue through colonic enteroendocrine stimulation — represents a novel mechanism warranting formal pharmacokinetic and endocrinological investigation.

Prospective randomized controlled trials with stratified BMI allocation, formal insulin secretion and resistance measurement, incretin assessment, and standardized follow-up are recommended to establish CDC-KP as an evidence-based protocol for lean T2DM — the first Ayurvedic formalized treatment specifically designed for this metabolically distinct and clinically underserved diabetic phenotype.

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HOW TO CITE: Rohit Sane¹, Pravin Ghadigaonkar¹, Gurudatta Amin¹, Bipin Gond^{2*}, Amirullah Siddiqui³, *Brimhana Panchakarma Protocol (CDC-KP) In Lean Type 2 Diabetes: First Adequately Powered Analysis Of The Oil-Based Basti Arm Compared To Shodhana Protocol — A Retrospective Two-Site Study From Boisar-Palghar, Maharashtra*, Int. J. Sci. R. Tech., 2026, 3 (5), 717-726. <https://doi.org/10.5281/zenodo.20287166>