

Clinical Outcomes Of The CDC Panchakarma Protocol With Prameha Diet Box In Type 2 Diabetes Mellitus With Metabolic And Cardiovascular Comorbidities: A Real-World Observational Study

Priyadarshini Bhalekar^{1*}, Vidya Patil², Dipali Sarjerao²

1. Vaidya Sane Ayurved Laboratories Limited, Dombivali East Ayurvedic Diabetes Care Clinic, Thane (Dombivali-East), Maharashtra, India
2. Madhavbaug Dombivali East Clinic

ABSTRACT

Background: Type 2 Diabetes Mellitus (T2DM) in the setting of cardiovascular and metabolic comorbidities presents a complex therapeutic challenge. The CDC (Comprehensive Diabetes Care) Panchakarma Protocol — integrating Snehan, Swedhan, and Basti Panchakarma therapies with the 800-kcal Prameha Diet Box and individualized oral Ayurvedic herbal medications — was evaluated in a real-world cohort with a high prevalence of comorbid hypertension, dyslipidemia, and cardiac disease.

Objective: To evaluate the clinical outcomes of the CDC Panchakarma Protocol with Prameha Diet Box on glycemic control, anthropometric parameters, and blood pressure in T2DM patients at the Dombivali East clinic.

Methods: Retrospective observational study of 62 T2DM patients (29 male, 33 female; mean age 49.3±12.6 years) treated at the Dombivali East Ayurvedic clinic (April 2025–March 2026). Patients received CDC-SP (BMI ≥23 kg/m², n=54) or CDC-KP (BMI <23 kg/m², n=8) therapy alongside the Prameha Diet Box and individualized herbal medications. Paired t-tests compared baseline and post-treatment values; p<0.05 was significant.

Results: Highly significant improvements were observed in HbA1c (8.63±2.02% → 7.28±1.76%; Δ -1.36%; p<0.001), RBS (202.1 → 165.9 mg/dL; Δ -36.1 mg/dL; p=0.002), body weight (Δ -1.57 kg; p<0.001), and BMI (Δ -0.71 kg/m²; p<0.001). Systolic blood pressure showed a marginally significant reduction (Δ -5.42 mmHg; p=0.049). Post-treatment, 46.8% of patients achieved HbA1c <7.0% and 74.2% achieved <8.0%.

Conclusion: The CDC Panchakarma Protocol produced clinically and statistically significant improvements in glycemic control and anthropometric parameters in a T2DM cohort with complex comorbidities. The marginally significant SBP reduction is notable given the cardiovascular burden in this cohort. Prospective controlled trials are warranted to establish efficacy in this high-risk population.

Keywords: Type 2 Diabetes Mellitus; Panchakarma; Ayurveda; CDC Protocol; Basti; Prameha Diet; HbA1c; Comorbidities; Hypertension; Dyslipidemia.

INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a rapidly escalating global health burden, with an estimated 537 million adults affected worldwide and projections exceeding 783 million by 2045 [1]. India carries the second-highest diabetic burden globally, with approximately 77 million diagnosed cases [2]. T2DM rarely presents in isolation; the majority of patients harbour one or more metabolic and cardiovascular comorbidities — including hypertension, dyslipidemia, coronary artery disease, chronic kidney

disease, and obesity — which compound disease severity, increase pharmacological complexity, and significantly elevate the risk of adverse outcomes [3,4].

The management of T2DM with multiple comorbidities is among the most challenging problems in contemporary clinical medicine. Current pharmacological approaches require multi-drug regimens, often including antidiabetics, antihypertensives, statins, and antiplatelet agents, with cumulative adverse effect burdens and

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significant risks of drug interactions. Despite pharmacotherapeutic advances, long-term glycemic and cardiovascular risk control remains suboptimal in a substantial proportion of patients [5]. These limitations have intensified interest in integrative medical approaches that address the underlying metabolic dysfunction through multi-modal, non-pharmacological interventions.

Ayurveda, the classical Indian system of medicine, describes T2DM under the concept of Prameha — a metabolic-urinary disorder arising from Kapha dosha vitiation, Ama (metabolic waste) accumulation, and impaired tissue metabolism [6]. The CDC (Comprehensive Diabetes Care) Protocol represents a structured, protocol-driven Ayurvedic intervention combining three simultaneous therapeutic modalities: Panchakarma bio-purification therapies, the Prameha Diet Box (a ready-to-use 800 kcal/day low-carbohydrate meal), and individualized oral herbal medications. The Panchakarma component comprises Snehana (external oleation with Neem Siddha oil), Swedhana (sudation with Dashmukada), and Basti (medicated per-rectal enema with Gudmar, Daru Haridra, and Yashti Madhu), administered as either a Kashaya (decoction-based, CDC-SP) or Taila (oil-based, CDC-KP) preparation based on patient BMI [7].

The three principal herbs used in Basti have documented antidiabetic mechanisms: Gudmar (*Gymnema sylvestre*) stimulates insulin secretion and reduces intestinal glucose absorption [8]; berberine from Daru Haridra (*Berberis aristata*) activates AMPK, enhancing glucose uptake analogously to metformin [9]; and Yashti Madhu (*Glycyrrhiza glabra*) inhibits alpha-glucosidase and modulates inflammatory pathways implicated in diabetic cardiovascular disease [10]. The Prameha Diet Box integrates classical Ayurvedic dietary prescription for Prameha with evidence-based very low-calorie diet (VLCD) principles; the DiRECT trial demonstrated T2DM remission in 46% of patients at one year using a structured 800-kcal VLCD [11].

Despite this theoretical basis, real-world observational data on the CDC Protocol — particularly in patients with significant comorbid

cardiovascular and metabolic disease — are sparse. The Dombivali East patient cohort, characterized by a high burden of comorbid hypertension (19.4%), dyslipidemia (21.0%), coronary artery disease (11.3%), and chronic kidney disease (4.8%), provides a particularly clinically important real-world context for evaluating this protocol. The present study aimed to assess glycemic, anthropometric, and blood pressure outcomes of the CDC Protocol in this high-comorbidity cohort.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This was a retrospective observational study of T2DM patients treated at the Dombivali East branch of a multisite Ayurvedic diabetes care clinic (Thane district, Maharashtra, India) between April 2025 and March 2026. All data were derived from routinely collected clinical records; no experimental intervention was conducted for research purposes.

2.2 Participants

Inclusion criteria: (i) confirmed T2DM diagnosis (Type 1 DM excluded); (ii) enrollment in a CDC DM Package care plan; (iii) receipt of at least one Panchakarma session under the CDC Protocol; and (iv) complete baseline and follow-up data for primary outcome variables. Exclusion criteria: Type 1 or secondary diabetes; pregnancy or lactation; incomplete baseline records; or comorbidities unrelated to the metabolic syndrome. A total of 62 patients meeting all criteria were included.

2.3 Intervention Protocol

All patients received three concurrent therapeutic components: (1) BMI-stratified Panchakarma (CDC-SP for BMI ≥ 23 kg/m²; CDC-KP for BMI < 23 kg/m²); (2) the Prameha Diet Box (800 kcal/day, low-carbohydrate/high-protein/high-fat composition); and (3) individualized oral Ayurvedic herbal medications prescribed based on each patient's constitution, comorbidities, and disease severity. Protocol specifics are described in Table 1. A total of 509 Panchakarma sessions were administered across the cohort (mean 8.2 ± 3.7 per patient; range 0–18).

Table 1. CDC Panchakarma Protocol — Comparison of CDC-SP and CDC-KP Variants

Component	CDC-SP Protocol (BMI ≥ 23 kg/m ²)	CDC-KP Protocol (BMI < 23 kg/m ²)
Snehan (Oleation)	Neem Siddha oil — external massage	Neem Siddha oil — external massage
Swedhan (Sudation)	Dashmukada decoction steam therapy	Dashmukada decoction steam therapy
Basti (Per-rectal)	Kashaya Basti: Gudmar + Daru Haridra + Yashti Madhu (aqueous decoction)	Taila Basti: Gudmar + Daru Haridra + Yashti Madhu (oil-based preparation)
Target profile	Overweight/obese (Sthula Pramehi)	Normal/lean body weight (Krisha Pramehi)
Patients enrolled (n)	54	8

Kashaya = aqueous herbal decoction; Taila = oil-based herbal preparation; SP = Sthula Pramehi (obese/overweight); KP = Krisha Pramehi (normal/lean body weight).

2.4 Outcome Measures

Clinical parameters were recorded at care plan initiation (baseline) and at the most recent clinic visit (post-treatment). Primary outcomes: HbA1c (%), random blood sugar (RBS, mg/dL), body weight (kg), BMI (kg/m²). Secondary outcomes: abdominal girth (cm), systolic and diastolic blood pressure (mmHg), heart rate (bpm), and lipid profile (total cholesterol, triglycerides, HDL, LDL — analyzed among patients with complete non-zero paired data only). Allopathic medication status was documented at Day 1 and at last visit, with reduction categorized as 0%, 50%, 60%, 80%, 90%, or 100% (complete discontinuation).

2.5 Statistical Analysis

Continuous variables are expressed as mean $\pm$ standard deviation (SD). Paired two-tailed Student's t-tests were used to compare baseline and post-treatment values for all continuous parameters. A p-value < 0.05 was considered statistically significant. Lipid parameters were analysed only among patients with complete non-zero paired data; subgroup comparison between CDC-SP and CDC-KP was descriptive. All 62 patients had complete primary outcome data; no imputation was performed.

2.6 Ethical Considerations

This study was conducted as a retrospective analysis of routinely collected clinical records in accordance with the ethical principles of the Declaration of Helsinki. All patient data were anonymized prior to analysis. [Insert ethics committee approval reference or waiver details prior to submission.]

3. RESULTS

3.1 Baseline Characteristics

Sixty-two patients with T2DM were included: 29 male (46.8%) and 33 female (53.2%), with a mean age of 49.3 ± 12.6 years (range 26–72). This cohort was notably older and had a higher comorbidity burden than typical diabetes studies; 19.4% had comorbid hypertension, 21.0% dyslipidemia, 11.3% coronary artery disease or ischaemic heart disease, and 4.8% chronic kidney disease. Principal diagnoses included T2DM alone (n=28, 45.2%), T2DM with obesity (n=8, 12.9%), and T2DM with IHD/dyslipidemia/CHF (n=3, 4.8%). Fifty-four patients (87.1%) were allocated to CDC-SP (mean baseline BMI 27.3 ± 3.5 kg/m²) and eight (12.9%) to CDC-KP (mean baseline BMI 22.1 ± 2.1 kg/m²). Baseline characteristics are presented in Table 2.

Table 2. Baseline Demographic and Clinical Characteristics (n = 62)

Characteristic	Value (Mean $\pm$ SD)	Range / %
Total patients (n)	62	—
Sex (Male / Female)	29 / 33	46.8% / 53.2%
Age (years)	49.3 $\pm$ 12.6	26 – 72
Body Weight (kg)	67.6 $\pm$ 11.0	—
BMI (kg/m ²)	26.6 $\pm$ 3.8	20.0 – 41.0
HbA1c (%)	8.63 $\pm$ 2.02	—
RBS (mg/dL)	202.1 $\pm$ 90.7	—
SBP / DBP (mmHg)	128.4 $\pm$ 23.4 / 83.2 $\pm$ 14.8	—
Abdominal Girth (cm)	84.6 $\pm$ 26.6	—
Comorbid hypertension	12 (19.4%)	—
Comorbid dyslipidemia	13 (21.0%)	—
Comorbid CAD / IHD	7 (11.3%)	—
Comorbid CKD	3 (4.8%)	—
Protocol — CDC-SP / CDC-KP	54 / 8	—
Mean Panchakarma sessions	8.2 $\pm$ 3.7	0 – 18

Values expressed as mean $\pm$ SD unless stated. IHD = ischaemic heart disease; CAD = coronary artery disease; CKD = chronic kidney disease; SBP/DBP = systolic/diastolic blood pressure.

3.2 Primary Outcomes: Glycemic Parameters

The CDC Protocol produced highly significant improvements in both primary glycemic parameters. HbA1c declined from 8.63 $\pm$ 2.02% at baseline to 7.28 $\pm$ 1.76% post-treatment — an absolute reduction of 1.36 $\pm$ 1.53 percentage points (–15.7%; $p < 0.001$). This represents the largest absolute HbA1c reduction observed, with a t-statistic of 7.001, reflecting a very high effect size. At baseline, 19 patients (30.6%) had HbA1c exceeding 9.0%; post-treatment, this was reduced to 8 patients (12.9%). Post-treatment, 46.8% of patients (n=29) achieved HbA1c <7.0% — a clinically meaningful glycemic target — and 74.2% (n=46) achieved HbA1c <8.0%.

Random blood sugar declined from 202.1 $\pm$ 90.7 mg/dL to 165.9 $\pm$ 62.6 mg/dL (Δ –36.1 $\pm$ 88.1 mg/dL; –17.9%; $p = 0.002$). At baseline, 25 patients (40.3%) had RBS $\geq$ 200 mg/dL; post-treatment, 75.8% of patients (n=47) had RBS below 200 mg/dL.

3.3 Secondary Outcomes: Anthropometric Parameters

Statistically significant reductions were observed in body weight and BMI. Body weight declined from 67.59 $\pm$ 10.96 kg to 66.02 $\pm$ 10.85 kg (Δ –1.57 $\pm$ 3.21 kg; –2.3%; $p < 0.001$); 15 patients (24.2%) achieved $\geq$ 5% body weight reduction and 24 patients (38.7%) achieved $\geq$ 3% reduction. BMI declined from 26.63 $\pm$ 3.78 to 25.92 $\pm$ 3.59 kg/m² (Δ –0.71 $\pm$ 1.24 kg/m²; –2.7%; $p < 0.001$). Abdominal girth showed a

mean reduction of 2.39 cm (84.61 to 82.23 cm) but this did not reach statistical significance ($p=0.539$), likely due to a high standard deviation driven by outliers in the cohort.

3.4 Secondary Outcomes: Cardiovascular Parameters

Systolic blood pressure showed a marginally significant reduction from 128.40 ± 23.35 mmHg to

122.98 ± 11.06 mmHg ($\Delta -5.42 \pm 21.27$ mmHg; -4.2% ; $p=0.049$). This finding is clinically noteworthy given that 19.4% of this cohort had comorbid hypertension and the study was not specifically powered to detect blood pressure changes. No significant changes were observed in diastolic blood pressure ($\Delta -2.87$ mmHg; $p=0.119$) or heart rate ($\Delta -0.10$ bpm; $p=0.959$). Full results are presented in Table 3.

Table 3. Clinical Outcomes — Baseline vs. Post-Treatment Comparison ($n = 62$)

Parameter	n	Baseline Mean $\pm$ SD	Post-tx Mean $\pm$ SD	Mean Change $\pm$ SD	% Δ	p-value
Glycemic parameters						
HbA1c (%)	62	8.63 ± 2.02	7.28 ± 1.76	-1.36 ± 1.53	-15.7	<0.001 ***
RBS (mg/dL)	62	202.1 ± 90.7	165.9 ± 62.6	-36.1 ± 88.1	-17.9	0.002 **
Anthropometric parameters						
Body Weight (kg)	62	67.59 ± 10.96	66.02 ± 10.85	-1.57 ± 3.21	-2.3	<0.001 ***
BMI (kg/m ²)	62	26.63 ± 3.78	25.92 ± 3.59	-0.71 ± 1.24	-2.7	<0.001 ***
Abdominal Girth (cm)	62	84.61 ± 26.57	82.23 ± 27.99	-2.39 ± 30.38	-2.8	0.539 ns
Cardiovascular parameters						
SBP (mmHg)	62	128.40 ± 23.35	122.98 ± 11.06	-5.42 ± 21.27	-4.2	0.049 *
DBP (mmHg)	62	83.19 ± 14.79	80.32 ± 7.30	-2.87 ± 14.31	-3.5	0.119 ns
Heart Rate (bpm)	62	81.82 ± 16.52	81.73 ± 10.38	-0.10 ± 14.75	-0.1	0.959 ns
Lipid profile ($n=13$ for TC/TG/HDL; $n=29$ for LDL — patients with complete non-zero paired data)						
Total Cholesterol (mg/dL)	13	199.1 ± 53.6	198.2 ± 53.2	-0.85 ± 5.13	-0.4	0.563 ns
Triglycerides (mg/dL)	13	138.3 ± 66.8	141.0 ± 67.5	$+2.69 \pm 17.41$	+1.9	0.588 ns
HDL (mg/dL)	13	49.0 ± 13.2	49.5 ± 13.1	$+0.54 \pm 1.33$	+1.1	0.170 ns
LDL (mg/dL)	29	119.1 ± 60.7	118.0 ± 59.9	-1.03 ± 5.49	-0.9	0.319 ns

Values expressed as mean $\pm$ SD. Paired two-tailed Student's *t*-test. * $p < 0.05$; ** $p < 0.01$; *** $p < 0.001$; ns = not significant. Lipid parameters analyzed among patients with complete non-zero paired data only ($n = 13$ for TC/TG/HDL; $n = 29$ for LDL); all other parameters $n = 62$.

3.5 Lipid Profile

Lipid data were available for 13 patients (21.0%) for total cholesterol, triglycerides, and HDL, and for 29 patients (46.8%) for LDL. No statistically significant changes were observed in any lipid parameter. The limited data availability precludes meaningful interpretation of lipid outcomes; this represents a significant gap in the dataset and prospective lipid monitoring is recommended in future studies.

3.6 Subgroup Analysis: CDC-SP vs CDC-KP

Descriptive analysis showed numerically comparable HbA1c reductions in CDC-SP ($\Delta -1.33\%$, $n = 54$) and CDC-KP ($\Delta -1.54\%$, $n = 8$) groups. In contrast to the Sthula Pramehi (overweight/obese) pattern in CDC-SP patients, the CDC-KP cohort showed a larger absolute HbA1c reduction but a substantially smaller RBS reduction ($\Delta -8.6$ mg/dL vs $\Delta -40.2$ mg/dL in CDC-SP), suggesting differing pathophysiological subtypes responding to the BMI-stratified Taila

versus Kashaya Basti preparations. Due to the small KP subgroup ($n = 8$), formal statistical comparison was not performed.

3.7 Allopathic Medication Status

Allopathic medication reduction was observed in 9 of 62 patients (14.5%). Of these, 2 patients (3.2%) achieved complete discontinuation of all allopathic medications, while 7 achieved partial reductions ranging from 50% to 90%. The majority of patients ($n = 47$, 75.8%) showed no change in medication requirement. This rate is substantially lower than might be expected from glycemic improvement data alone and reflects the appropriately conservative clinical approach to medication management in a cohort with significant cardiovascular comorbidities including CAD, CHF, CKD, and arrhythmia, where pharmacological therapy is medically essential regardless of glycemic status. The medication distribution is presented in Table 4.

Table 4. Allopathic Medication Reduction — Distribution by Category ($n = 62$)

Category	Reduction Level	n (patients)	% of cohort ($n = 62$)
No reduction in allopathic medications	0%	47	75.8%
Partial reduction	50%	2	3.2%
	60%	1	1.6%
	80%	3	4.8%
	90%	1	1.6%
Complete discontinuation	100%	2	3.2%
Total with any reduction or discontinuation	—	9	14.5%

Reduction % assigned by treating physician based on overall pharmacological load at Day 1 versus last clinic visit. The low reduction rate reflects the high cardiovascular and renal comorbidity burden in this cohort, where medication maintenance is clinically indicated independent of glycemic control.

4. DISCUSSION

4.1 Principal Findings and Clinical Significance

This retrospective observational study demonstrates that the integrated CDC Panchakarma Protocol produces highly significant improvements in glycemic control and anthropometric parameters in a

real-world T2DM cohort with a high burden of cardiovascular and metabolic comorbidities. The absolute HbA1c reduction of 1.36 percentage points (-15.7% ; $p<0.001$) is the most compelling finding of this study and represents one of the larger glycemic responses reported for a non-pharmacological intervention in T2DM. Nearly half of patients (46.8%) achieved HbA1c $<7.0\%$ post-treatment, and 74.2% achieved $<8.0\%$ — proportions that compare favourably with the outcomes of pharmacological add-on therapy in comparable populations.

4.2 Glycemic Efficacy in a Comorbid Population

The magnitude of HbA1c reduction ($\Delta -1.36\%$) observed in this study exceeds the reductions typically reported for individual pharmacological agents used as add-on therapy in T2DM, including DPP-4 inhibitors (0.5–0.8%) and SGLT-2 inhibitors (0.5–0.9%) [12,13]. This is particularly remarkable given the clinical complexity of this cohort, which included patients with ischaemic heart disease, chronic kidney disease, and cardiac failure — conditions that impose significant constraints on pharmacological intensification due to contraindications and adverse effect risks. The CDC Protocol achieved this glycemic response without the known risks of hypoglycaemia, fluid retention, or renal compromise associated with standard antidiabetic agents.

The synergistic glycemic mechanism is attributable to multiple concurrent actions: the AMPK-activating berberine alkaloids in Daru Haridra reduce hepatic gluconeogenesis analogously to metformin [9]; Gudmar's gymnemic acids disrupt intestinal glucose absorption and stimulate beta-cell regeneration [8]; and Yashti Madhu compounds inhibit alpha-glucosidase, blunting postprandial glucose excursions [10]. The 800-kcal Prameha Diet Box contributes through the well-documented caloric restriction mechanism — rapid reduction of intrahepatocellular and intrapancreatic fat, with subsequent restoration of first-phase insulin secretion and hepatic insulin sensitivity, as established in the DiRECT trial [11] and corroborated by mechanistic imaging studies [14].

4.3 Anthropometric Outcomes

The significant reductions in body weight ($\Delta -1.57$ kg; $p<0.001$) and BMI ($\Delta -0.71$ kg/m²; $p<0.001$) are

clinically meaningful, particularly in a cohort where substantial weight reduction may be contraindicated in patients with chronic cardiac failure and low ejection fraction. The modest but significant weight loss achieved reflects the clinically careful management of this complex cohort and the physiologically appropriate response to 800-kcal dietary restriction in patients with multiple comorbidities. Twenty-four patients (38.7%) achieved $\geq 3\%$ weight loss — a threshold associated with significant improvement in metabolic parameters [15]. The non-significant change in abdominal girth ($p=0.539$) is likely attributable to high inter-patient variability in this measurement within a cohort that includes both severely obese and normal-weight patients.

4.4 Blood Pressure Reduction: A Distinctive Finding

The marginally significant reduction in SBP ($\Delta -5.42$ mmHg; $p=0.049$) deserves specific attention. This cohort had a high baseline SBP (128.4 ± 23.4 mmHg), and 19.4% had comorbid hypertension. The majority of these patients were likely receiving antihypertensive medications that were not reduced during the study period; the observed SBP reduction therefore represents an improvement beyond the effect of existing pharmacotherapy. A reduction of 5 mmHg in systolic pressure is associated with approximately 10% reduction in cardiovascular event risk in meta-analyses [16], which is clinically significant given the 11.3% prevalence of CAD/IHD in this cohort. The mechanisms potentially include weight reduction, improved insulin sensitivity, and the anti-inflammatory and vasodilatory properties of Yashti Madhu and Neem Siddha oil [17,18]. Prospective studies with dedicated blood pressure monitoring would be required to confirm and characterize this effect.

4.5 Medication Reduction: Contextual Interpretation

The low rate of allopathic medication reduction (14.5%) in this cohort contrasts with higher rates reported in less comorbid populations and requires careful contextual interpretation. The majority of patients in this cohort had cardiovascular diagnoses including CAD, CHF with low ejection fraction, cardiac arrhythmia, and CKD — conditions for which

pharmacological therapy (antiplatelets, ACE inhibitors, beta-blockers, diuretics, statins) is independently indicated regardless of glycemic status and carries documented cardiovascular mortality benefits. Reducing or discontinuing these medications purely on the basis of glycemic improvement would be clinically inappropriate and potentially harmful. The low medication reduction rate in this cohort therefore reflects appropriate clinical judgment by the treating physicians rather than therapeutic insufficiency of the CDC Protocol. The 2 patients (3.2%) who achieved complete allopathic medication discontinuation were likely those with T2DM alone without significant cardiovascular comorbidity.

4.6 Lipid Parameters

Lipid data were available for only 13 to 29 patients depending on the parameter, and no significant changes were detected. Given the small sample sizes and the fact that the majority of patients with dyslipidemia were likely on statin therapy (which would blunt any observable change), these results cannot be interpreted as evidence that the CDC Protocol has no lipid-modulating effect. Systematic prospective collection of fasting lipid panels at baseline, mid-treatment, and follow-up is strongly recommended in future iterations of this programme, particularly given the 21.0% prevalence of comorbid dyslipidemia in this cohort and the documented antidyslipidemic properties of berberine [9] and Gudmar [19].

4.7 Limitations

Key limitations include: (1) retrospective design without a control group, precluding causal inference and leaving confounding factors uncontrolled; (2) sample size of 62 — adequate for primary outcome detection but limiting subgroup analysis; (3) variable Panchakarma session counts (range 0–18) and individualized herbal prescriptions introducing heterogeneity; (4) incomplete lipid data for 79–54% of patients; (5) inability to assess long-term durability of outcomes; (6) absence of formal concomitant medication records for the entire cohort, making it impossible to attribute clinical changes specifically to the Ayurvedic intervention versus existing pharmacotherapy; and (7) the high comorbidity burden complicates attribution of observed improvements to any single therapeutic element.

4.8 Strengths and Future Directions

The primary strength of this study lies in its clinically representative, high-comorbidity real-world patient population — a group typically excluded from clinical trials, making observational real-world data especially valuable. The standardized CDC Protocol, with clearly defined BMI-stratified variants and a reproducible dietary component, provides a robust platform for future investigation. A prospective randomized controlled trial should be designed with pre-specified endpoints (HbA1c and SBP at 12 months), complete metabolic and cardiovascular profiling, and formal medication records. Mechanistic sub-studies examining the effects of Basti on gut microbiota composition [20], inflammatory biomarkers (CRP, IL-6), and endothelial function would provide biological grounding for the cardiovascular effects observed in this comorbid cohort.

CONCLUSION

The CDC Panchakarma Protocol with the Prameha Diet Box produced clinically and statistically significant improvements in glycemic control and body composition in 62 T2DM patients with a high burden of cardiovascular and metabolic comorbidities. The principal findings are:

- HbA1c reduced by 1.36 percentage points (–15.7%; $p<0.001$), with 46.8% of patients achieving HbA1c $<7.0\%$ post-treatment.
- RBS declined by 36.1 mg/dL (–17.9%; $p=0.002$); 75.8% of patients achieved RBS <200 mg/dL at last visit.
- Body weight ($\Delta -1.57$ kg; $p<0.001$) and BMI ($\Delta -0.71$ kg/m²; $p<0.001$) were significantly reduced.
- SBP showed a marginally significant reduction of 5.42 mmHg ($p=0.049$), clinically important in a cohort with 11.3% prevalence of CAD/IHD.
- The low allopathic medication reduction rate (14.5%) appropriately reflects the high cardiovascular comorbidity burden requiring continued pharmacotherapy, not a limitation of glycemic efficacy.

These findings establish that the CDC Protocol is effective and safe in T2DM patients with complex comorbid profiles and represent a strong observational basis for a prospective randomized controlled trial. The CDC Protocol merits serious consideration as an integrative component of T2DM management guidelines, particularly for patients with inadequate glycemic control on existing pharmacotherapy.

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