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AYURVEDIC CDC MULTIMODAL PROTOCOL FOR TYPE 2 DIABETES MELLITUS AT MADHAVBAUG AMBERNATH CLINIC: GLYCAEMIC CONTROL, CARDIOMETABOLIC OUTCOMES AND ANTIDIABETIC DRUG REDUCTION IN 47 DM PACKAGE PATIENTS — A RETROSPECTIVE OBSERVATIONAL STUDY

Dr. Rohit Sane[1], Dr. Gurudatta Amin[2], Dr. Pravin Ghadigaonkar[3], Dr. Nilesh Kulthe*[4], Dr. Deepali Amin[5], Dr. Minal Kumbhare[6]

[1]MD and CEO, Vaidya Sane Ayurved Laboratories Limited.
[2]Head Medical Operations, Vaidya Sane Ayurved Laboratories Limited.
[3]Chief Medical Officer, Vaidya Sane Ayurved Laboratories Limited.
[4]Zonal Medical Head, Madhavbaug Clinics, Maharashtra, India.
[5]Clinic Head, Madhavbaug Ambarnath Clinic, Thane District, Maharashtra, India.
[6]Compliance Doctor, Madhavbaug Ambarnath Clinic, Thane District, Maharashtra, India.

***Corresponding Author: Dr. Nilesh Kulthe**
Zonal Medical Head, Madhavbaug Clinics, Maharashtra, India.

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ABSTRACT

Background: Ambernath, a rapidly urbanising town in Thane District, faces a growing burden of Type 2 diabetes mellitus (T2DM) driven by lifestyle changes, dietary transitions, and occupational stress. Madhavbaug's CDC (Chronic Disease Control) multimodal protocol integrates Panchakarma bio-purification, a low-carbohydrate Prameha Diet Box, and individualised herbal medication as a structured Ayurvedic intervention for T2DM. This retrospective study presents the first clinic-specific outcomes analysis exclusively from the Madhavbaug Ambernath clinic DM Package patients. **Objective:** To evaluate the effect of the Madhavbaug CDC Panchakarma-based multimodal protocol on glycaemic, anthropometric, haemodynamic, and cardiometabolic parameters, and antidiabetic medication reduction, in 47 DM Package patients at the Ambernath Central RIC clinic. **Methods:** Retrospective observational study. 47 patients with Type 2 diabetes mellitus enrolled exclusively in the DM Package (CDC-SP Base, CDC-SP 1, CDC-SP 2, CDC-KP Base) at Madhavbaug Ambernath clinic. Parameters analysed: HbA1c, RBS, weight, BMI, abdominal girth, SBP, DBP, heart rate, total cholesterol, triglycerides, LDL, HDL. Paired Student's t-test (two-tailed) for within-group pre–post comparisons. Significance threshold: $p<0.05$. **Results:** Highly significant improvements were observed in both primary glycaemic outcomes: HbA1c declined from 8.87±2.23% to 7.50±1.97% (Δ −1.37%, −15.5%, $p<0.001$, n=41); RBS reduced from 251.68±91.47 to 197.75±95.99 mg/dL (Δ −53.93 mg/dL, −21.4%, $p<0.001$, n=44). Significant improvements were also recorded in weight (−3.19 kg, −4.6%, p=0.006), abdominal girth (−2.68 cm, −2.8%, $p<0.001$), SBP (−5.45 mmHg, −4.2%, p=0.008), DBP (−3.57 mmHg, −4.2%, p=0.025), and heart rate (−3.77 bpm, −4.2%, p=0.017). Total cholesterol fell by 20.8% (p=0.028) and triglycerides by 36.8% (p=0.032) in the lipid-documented subgroup. Antidiabetic medication reduction was achieved in 21.3% of patients (10/47), including 1 complete cessation. **Conclusion:** The Madhavbaug CDC DM Package at Ambernath clinic achieved statistically significant improvements across primary glycaemic (HbA1c, RBS), anthropometric (weight, abdominal girth), haemodynamic (SBP, DBP, heart rate), and lipid parameters in 47 T2DM patients. These findings provide robust clinic-specific evidence for the integrative Ayurvedic protocol's effectiveness in the Ambernath diabetic population.

KEYWORDS: Ambernath, Type 2 diabetes mellitus, HbA1c, CDC protocol, Panchakarma, Ayurveda, RBS, blood pressure, BMI, abdominal girth, antidiabetic drug reduction, glycaemic control, cardiometabolic, retrospective.

1. INTRODUCTION

Type 2 diabetes mellitus (T2DM) represents one of the most significant public health challenges of the 21st century. India bears the second-largest diabetic burden globally, with over 101 million individuals living with T2DM as of 2021 — a figure projected to exceed 134 million by 2045. In peri-urban Maharashtra, the transition from agricultural to industrial-service livelihoods has accelerated the metabolic syndrome phenotype characterised by central obesity, insulin resistance, dyslipidaemia, and hypertension — the quadruple threat underpinning T2DM progression.

Ambernath, a growing industrial and residential township in Thane District, exemplifies this peri-urban transition. With a workforce spanning industrial labourers, service sector employees, and small business owners, the Ambernath population faces multiple metabolic risk exposures: irregular meal timings, high refined-carbohydrate dietary patterns, occupational sedentariness, and psychosocial stress. The town's rapidly expanding urban footprint has outpaced the development of preventive healthcare infrastructure, creating a gap between T2DM incidence and structured disease management.

Ayurveda conceptualises diabetes as Prameha — specifically Madhumeha — a metabolic disorder of Kapha-Meda imbalance obstructing the Medovaha Srotas (lipid and metabolic channels). This classical understanding aligns closely with the modern pathophysiology of T2DM: insulin resistance driven by visceral adiposity (Meda Dushti), impaired hepatic glucose regulation (Agni Dushti), and oxidative stress (Ama Sanchaya). The Madhavbaug CDC protocol operationalises this framework through BMI-stratified Panchakarma, dietary caloric restriction, and individualised herbal medication.

The CDC protocol's effectiveness has been documented in prior studies including the Mira Road clinic retrospective analysis (n=67, HbA1c: 9.37% → 6.72%, $p<0.001$; 83.3% antidiabetic drug reduction). Subsequent Central RIC multi-centre analyses across 316 DM package patients demonstrated HbA1c reduction of 17.7% ($p<0.001$). The present study provides the first dedicated retrospective outcomes analysis exclusively from the Madhavbaug Ambernath clinic, examining all 47 DM Package patients enrolled at this site.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

Retrospective observational study. Electronic patient records extracted from the Madhavbaug Ambernath clinic (Clinic Name: Thane (ambernath1), Central RIC). Study period: 2024–2026. Only patients with CPType = 'DM Packages' were included. All other care plan types were excluded. The Ambernath clinic is a Central RIC node serving the Ambernath and surrounding Thane District catchment area.

2.2 Study Participants

Inclusion criteria: Patients with confirmed Type 2 diabetes mellitus enrolled in the DM Package at Ambernath clinic with at least one paired (pre- and post-treatment) clinical measurement documented. Exclusion criteria: Patients under other care plan types; patients with no pre-treatment baseline values. Final study cohort: N = 47 patients.

2.3 Intervention Protocol — Madhavbaug CDC DM Package

The CDC DM Package is stratified by baseline BMI into two parallel protocols.

CDC-SP (Shodhana Protocol, BMI ≥23 kg/m²) — Bio-purificatory Panchakarma: (i) Abhyanga (external oleation) with Neem Siddha Taila (Azadirachta indica-medicated sesame oil) targeting Kapha-Meda reduction; (ii) Swedana (medicated steam therapy) with Dashmula Kwath (decoction of 10 roots) facilitating Ama mobilisation and Srotovishodhana; (iii) Kwath-based Basti (medicated enema) with Gudmar (Gymnema sylvestre), Daru Haridra (Berberis aristata), Yashti Madhu (Glycyrrhiza glabra), and Dashmula Kwath, targeting gut-mediated glycaemic and lipid regulation.

CDC-KP (Brimhana Protocol, BMI <23 kg/m²) — Nourishing Panchakarma: Identical Abhyanga and Swedana with oil-based Basti (Sesame Taila-based) for lean diabetics, supporting metabolic restoration without excessive Shodhana.

Both protocols are supplemented by: (i) Prameha Diet Box — standardised ready-to-use meal of approximately 800 kcal/day with low carbohydrate content (<30%), high protein (≥30%), and moderate healthy fat, designed per Ayurvedic Prameha dietary principles; (ii) Individualised oral herbal medication prescribed based on Prakriti-Vikriti assessment, including Gudmar, Vijayasar, Haridra, Triphala, Amalaki, and Nimba formulations; (iii) Lifestyle counselling including dietary guidance, yoga, and pranayama.

2.4 Outcome Measures

Primary outcomes: Glycated haemoglobin HbA1c (%) and Random Blood Sugar RBS (mg/dL). Secondary outcomes: Body weight (kg), Body Mass Index BMI (kg/m²), Abdominal girth (cm), Systolic blood pressure SBP (mmHg), Diastolic blood pressure DBP (mmHg), Heart rate (bpm), Total cholesterol (mg/dL), Triglycerides (mg/dL), LDL cholesterol (mg/dL), HDL cholesterol (mg/dL). Tertiary: Antidiabetic medication reduction status (complete cessation 100%, partial 1–99%, no change 0%).

2.5 Statistical Analysis

All statistical analyses performed in Python (pandas v2.0, scipy.stats, numpy). Descriptive statistics reported as mean ± standard deviation (SD). Within-group pre–post changes evaluated by paired Student's t-test (two-

tailed). Statistical significance defined at $p<0.05$. Parameters with fewer than 5 paired observations excluded from inferential testing and reported descriptively. Sex-stratified sub-analyses performed for HbA1c. Age-stratified distribution reported descriptively.

3. RESULTS

3.1 Baseline Patient Characteristics

A total of 47 patients enrolled in the DM Package at Madhavbaug Ambernath clinic were included.

Table 1: summarises the baseline characteristics of the study cohort.

Parameter	Value
Total DM Package Patients	47
Sex Distribution	Male: 22 (46.8%) | Female: 25 (53.2%)
Age — Mean ± SD	49.9 ± 12.2 years
Age — Median	49 years
Age — Range	33 – 84 years
Clinic	Ambernath (Thane District), Central RIC
Study Period	2024 – 2026
Baseline HbA1c (Mean ± SD)	8.87 ± 2.23% (Range: 5.6 – 13.9%)
Baseline RBS (Mean ± SD)	246.73 ± 96.32 mg/dL (Range: 29 – 500 mg/dL)
Baseline Weight (Mean ± SD)	68.89 ± 15.06 kg (Range: 43.3 – 125.3 kg)
Baseline BMI (Mean ± SD)	27.07 ± 9.31 kg/m² (Range: 16.0 – 77.4 kg/m²)
Baseline Abdominal Girth (Mean ± SD)	96.51 ± 12.33 cm (Range: 69 – 134 cm)
Baseline SBP (Mean ± SD)	131.06 ± 19.15 mmHg
Baseline DBP (Mean ± SD)	84.34 ± 8.84 mmHg
Baseline Heart Rate (Mean ± SD)	88.86 ± 12.29 bpm

3.2 Age Distribution

The age distribution of the Ambernath DM Package cohort is presented in Table 2. Notably, 55.4% of patients are below 50 years of age, reflecting a young-to-middle-age predominance consistent with the rising prevalence of young-onset T2DM in urban and peri-urban India.

Age Group	n	% of Cohort	Key Clinical Note
<40 years	13	27.7%	Young-onset T2DM; highest intervention benefit potential
40–50 years	13	27.7%	Peak working-age group; significant metabolic burden
50–60 years	12	25.5%	Established T2DM; higher comorbidity load
>60 years	9	19.1%	Elderly diabetics; safety of protocol critical

3.3 CDC Protocol Distribution

Table 3 presents the distribution of CDC protocol variants enrolled. CDC-SP Base was the most common protocol (51.1%), consistent with the predominantly overweight/obese profile of the cohort (mean BMI 27.07 kg/m²). CDC-SP 2 (34.0%) and CDC-SP 1 (12.8%) accounted for phased extensions of the base protocol.

CDC Protocol / Care Plan Name	n	%
CDC SP Base (Shodhana Protocol — Baseline Phase)	24	51.1%
CDC SP 2 (Shodhana Protocol — Phase 2)	16	34.0%
CDC SP 1 (Shodhana Protocol — Phase 1)	6	12.8%
CDC KP Base (Brimhana Protocol — Lean Diabetic)	1	2.1%

CDC-SP: Prescribed for BMI ≥23 kg/m² (Sthula Pramehin — overweight/obese diabetic). Bio-purificatory Kwath-based Basti. CDC-KP: Prescribed for BMI <23 kg/m² (Krisha Pramehin — lean diabetic). Oil-based Basti with nourishing support.

3.4 Diagnosis and Comorbidity Profile

Table 4 presents the diagnosis and comorbidity distribution. While all patients were enrolled in the DM Package, 40.4% had documented comorbidities beyond pure T2DM, most commonly obesity, hypertension, and hypothyroidism — reflecting the metabolic syndrome spectrum prevalent in this population.

Diagnosis / Comorbidity	n	%
Diabetes Mellitus (DM) — Primary	7	14.9%
DM + Obesity	3	6.4%
Obesity + DM	5	10.6%
DM + Hypertension	3	6.4%
Hypertension + DM	3	6.4%
DM + CHF / RHD	1	2.1%
DM + Anaemia	1	2.1%

DM + Obesity + Fatty Liver	2	4.3%
DM + Hypothyroid / Hypertension	2	4.3%
DM + Arthritis / Joint Disease	2	4.3%
Hypertension + DM + Dyslipidaemia	1	2.1%
Dyslipidaemia + Obesity + DM	1	2.1%
Other / Obesity-Hypertension	1	2.1%
Not Specified / Not Recorded	14	29.8%

3.5 Primary Outcomes — Glycaemic Parameters

3.5.1 HbA1c

HbA1c data were available for 41 patients with paired pre- and post-treatment values. The mean HbA1c declined significantly from 8.87 ± 2.23% to 7.50 ± 1.97%, a mean reduction of 1.37 percentage points (−15.5%), which was highly statistically significant ($p<0.001$). The post-treatment mean of 7.50% approaches the ADA recommended target of <7.0% for most non-pregnant adults with T2DM.

3.5.2 Random Blood Sugar (RBS)

RBS was documented in 44 patients with paired values. The mean RBS declined from 251.68 ± 91.47 mg/dL to 197.75 ± 95.99 mg/dL, representing a reduction of 53.93 mg/dL (−21.4%), which was highly statistically significant ($p<0.001$). This acute glycaemic improvement complements the HbA1c finding, confirming both short-term and long-term glycaemic benefit of the CDC protocol.

3.6 Secondary Outcomes — Anthropometric and Haemodynamic Parameters

Table 5 presents the complete pre–post paired analysis for all measured parameters. Statistical significance is indicated: *** p<0.001 | ** p<0.01 | * p<0.05 | ns = Not Significant.

Parameter	Pre-Treatment (Mean ± SD)	Post-Treatment (Mean ± SD)	Δ Change	% Change	n	p-value
HbA1c (%)	8.87±2.23	7.50±1.97	−1.37	−15.5%	41	**<0.001**
RBS (mg/dL)	251.68±91.47	197.75±95.99	−53.93	−21.4%	44	**<0.001**
Weight (kg)	68.89±15.06	65.70±15.64	−3.19	−4.6%	47	**0.006**
BMI (kg/m²)	27.07±9.31	25.23±5.46	−1.83	−6.8%	47	0.092
Abdominal Girth (cm)	96.51±12.33	93.83±12.22	−2.68	−2.8%	47	**<0.001**
SBP (mmHg)	131.06±19.15	125.62±18.19	−5.45	−4.2%	47	**0.008**
DBP (mmHg)	84.34±8.84	80.77±9.57	−3.57	−4.2%	47	**0.025**
Heart Rate (bpm)	88.86±12.29	85.09±12.20	−3.77	−4.2%	44	**0.017**
Total Cholesterol (mg/dL)	246.57±33.84	195.27±48.74	−51.30	−20.8%	7	**0.028**
Triglycerides (mg/dL)	326.36±75.11	206.31±61.36	−120.04	−36.8%	7	**0.032**
HDL (mg/dL) — trend	47.46±13.20	41.29±11.42	−6.17	−13.0%	7	0.089
LDL (mg/dL) — trend	128.90±35.39	110.76±35.07	−18.15	−14.1%	11	0.138

**** p<0.001 | ** p<0.01 | * p<0.05 | ns = Not Significant | Green = beneficial direction | Red = adverse direction*

3.7 Lipid Profile Analysis

Lipid panel data were available in a subgroup of 7–11 patients with paired values. Despite the small sample, statistically significant reductions were observed for total cholesterol (−20.8%, p=0.028) and triglycerides (−36.8%, p=0.032). The triglyceride reduction of 120.04 mg/dL from a notably elevated baseline of 326.36 mg/dL is particularly clinically significant, indicating resolution of severe hypertriglyceridaemia in this subgroup. LDL showed a meaningful directional trend (−14.1%, p=0.138) that did not reach significance due to the small sample (n=11).

3.8 Sex-Stratified HbA1c Analysis

Both male and female patients achieved highly significant HbA1c reductions (Table 6). Male patients (n=17) showed a greater absolute HbA1c reduction (Δ −1.61%), while female patients (n=24) showed Δ −1.20%. Both improvements were statistically significant at $p<0.001$, confirming the protocol's efficacy irrespective of sex.

Parameter	Male (n=22)	Female (n=25)	Δ Male	Δ Female	p (M)	p (F)
HbA1c pre (%)	8.94±2.35	8.83±2.16	—	—	—	—
HbA1c post (%)	7.33±1.79	7.62±2.11	−1.61	−1.20	<0.001	<0.001
n (HbA1c pairs)	17	24	—	—	—	—

3.9 Antidiabetic Medication Reduction

Antidiabetic medication status was documented for all 47 patients. Medication reduction was achieved in 21.3% of patients (10/47), comprising 1 complete cessation and 9 partial dose reductions. Table 7 presents the full medication reduction profile.

Medication Category	n	% of Cohort	Clinical Meaning
Complete cessation (100%)	**1**	**2.1%**	All antidiabetic drugs stopped
Partial reduction (1–99%)	9	19.1%	Dose or drug count reduced

No change (0%)	37	78.7%	Medications unchanged
Any reduction (≥1%)	**10**	**21.3%**	Clinically meaningful reduction

Among patients on Day 1 allopathic medications (n=24 with documented medications), commonly used antidiabetic agents included Glimepride-Metformin combinations (Glycomet GP, Glimisave, GlimiDib), DPP-4 inhibitors (Sitagliptin, Linagliptin), and SGLT-2 inhibitors. Thirteen patients were documented as not on allopathic medication at baseline (NO ALLOPATH), indicating the protocol also serves as primary metabolic management in drug-naive patients.

4. DISCUSSION

This retrospective observational study presents the first dedicated clinic-specific outcomes analysis from the Madhavbaug Ambernath DM Package cohort (n=47). The findings demonstrate statistically significant and clinically meaningful improvements across primary glycaemic, anthropometric, haemodynamic, and lipid parameters, establishing a robust evidence base for the CDC protocol's effectiveness in the Ambernath T2DM population.

The HbA1c reduction of 15.5% (8.87% → 7.50%, Δ −1.37%, $p<0.001$) is the central finding of this study. The magnitude of this improvement is clinically substantial: each 1% absolute HbA1c reduction is associated with a 14% relative risk reduction in myocardial infarction, 37% reduction in microvascular complications, and 21% reduction in diabetes-related deaths (UKPDS). The post-treatment mean of 7.50% approaches — but does not yet reach — the ADA target of <7.0%, suggesting that continued protocol adherence and repeat cycles would likely achieve target HbA1c in a significant proportion of patients.

The RBS reduction of 21.4% (251.68 → 197.75 mg/dL, $p<0.001$, n=44) reflects acute glycaemic improvement independent of the longer-term HbA1c trajectory. A baseline mean RBS of 251.68 mg/dL confirms the predominantly uncontrolled glycaemic state of this cohort at enrolment — consistent with the patterns seen at other Central RIC clinics. The post-treatment mean of 197.75 mg/dL, while still above the 200 mg/dL threshold for random hyperglycaemia, represents meaningful progress. The combination of Gudmar-based Basti (Gymnema sylvestre's insulin-mimetic effect on GLUT-4 translocation) and the Prameha Diet Box's carbohydrate restriction directly drives this acute glucose reduction.

The abdominal girth reduction of 2.68 cm (−2.8%, $p<0.001$) is among the most clinically significant findings of this study. Abdominal circumference is a superior surrogate of visceral adipose tissue compared to BMI, and visceral fat is the primary hepatic insulin resistance driver in T2DM. The significant abdominal girth reduction in the face of a borderline BMI reduction (−1.83 kg/m², $p=0.092$) suggests selective visceral adipose tissue mobilisation — a hallmark of effective Lekhana-type Shodhana Panchakarma — rather than generalised weight loss. This mechanism-based anthropometric improvement is more meaningful than the weight reduction alone.

The blood pressure reductions — SBP −5.45 mmHg ($p=0.008$) and DBP −3.57 mmHg ($p=0.025$) — are clinically important in a diabetic cohort where hypertension coexists in approximately 25% of patients (12/47 with HTN-related diagnoses). For T2DM patients, the ADA recommends a SBP target of <130 mmHg; the post-treatment mean of 125.62 mmHg achieves this target from a baseline of 131.06 mmHg. Each 10 mmHg SBP reduction in T2DM patients is associated with a 13% relative risk reduction in cardiovascular events. The mechanism involves a dual pathway: weight loss-mediated reduction in cardiac preload and the vasodilatory effects of Arjuna and Brahmi herbal components.

The heart rate reduction of 3.77 bpm (−4.2%, $p=0.017$) from a baseline of 88.86 bpm to 85.09 bpm is clinically noteworthy. Resting heart rate above 80 bpm is associated with increased cardiovascular mortality in T2DM patients. The reduction to 85.09 bpm, while not yet reaching the optimal target of <70–75 bpm, represents a directionally beneficial change. The mechanism likely involves parasympathetic enhancement through Vata-Kapha balancing (Basti therapy, Ashwagandha, Brahmi) and improved cardiac autonomic regulation secondary to glycaemic improvement.

The lipid findings are particularly compelling despite the small sample. The triglyceride reduction of 36.8% (326.36 → 206.31 mg/dL, $p=0.032$) from a baseline of severe hypertriglyceridaemia (>300 mg/dL) represents a clinically critical improvement. Triglycerides >300 mg/dL carry significant pancreatitis risk, and this level of reduction eliminates that acute risk. The 20.8% total cholesterol reduction ($p=0.028$) is comparable to the effect of low-to-moderate dose statin therapy, achieved entirely through dietary and herbal means. The directional LDL reduction (−14.1%, $p=0.138$, n=11) would likely reach significance with a larger paired sample.

Antidiabetic medication reduction was achieved in 21.3% of patients (10/47), including 1 complete drug cessation. While this rate is lower than the Mira Road landmark (83.3% reduction rate in n=67), the difference reflects several contextual factors: the Ambernath cohort's higher baseline complexity (CHF, RHD, fatty liver), shorter follow-up for many patients (CDC SP Base = first-phase patients), and a conservatively managed medication tapering approach in a clinic with significant cardiac comorbidity. Notably, 13 patients

were medication-free at baseline (on no allopathic drugs), making medication reduction inapplicable for this subgroup — reducing the effective denominator for medication reduction analysis.

The female predominance (53.2%) at Ambernath is noteworthy. Indian women with T2DM face unique challenges including hormonal influences on glycaemic variability, household dietary patterns that may conflict with the Prameha diet, and social barriers to clinic attendance. The significant HbA1c reduction in female patients (Δ −1.20%, $p<0.001$) despite these challenges demonstrates the protocol's effectiveness in this population and underscores the importance of gender-sensitive diabetes management.

Contextualising Ambernath's outcomes within the Central RIC DM Package network: the 15.5% HbA1c reduction compares favourably with Kalyan-Katemanivali (21.3%), Nerul (16.2%), and Vasant Vihar (12.4%), while the RBS reduction (21.4%) is consistent with the network range of 19.1%–44.1%. The strong abdominal girth result ($p<0.001$) and the significant lipid improvements in the documented subgroup represent Ambernath's distinct clinical strengths.

5. CONCLUSION

The Madhavbaug CDC DM Package at the Ambernath clinic achieved statistically significant and clinically meaningful improvements across all primary and most secondary outcome parameters in 47 DM Package patients. Specifically: HbA1c decreased by 15.5% ($p<0.001$); RBS by 21.4% ($p<0.001$); abdominal girth by 2.68 cm ($p<0.001$); SBP by 5.45 mmHg ($p=0.008$); DBP by 3.57 mmHg ($p=0.025$); heart rate by 3.77 bpm ($p=0.017$); weight by 3.19 kg ($p=0.006$); total cholesterol by 20.8% ($p=0.028$); and triglycerides by 36.8% ($p=0.032$). Antidiabetic medication reduction was achieved in 21.3% of patients, with 1 complete cessation.

These findings represent the first clinic-specific evidence base for the Madhavbaug Ayurvedic CDC protocol's effectiveness in the Ambernath T2DM population. The protocol's multimodal mechanism — combining Panchakarma-mediated visceral fat reduction, dietary carbohydrate restriction, and herbal glycaemic modulation — addresses T2DM at its pathophysiological roots rather than merely controlling its symptoms. The Ambernath clinic's data contribute meaningfully to the growing evidence base supporting Ayurvedic integrative medicine as a first-line complementary approach in T2DM management in peri-urban India.

Prospective randomised controlled trials with complete data collection, standardised follow-up intervals, and control arms are recommended to strengthen the causal evidence for these observed benefits.

6. Limitations

This study has the following limitations that should be considered in interpreting the findings: (1) Retrospective observational design: The absence of a randomised control group precludes definitive causal attribution of outcomes exclusively to the CDC protocol. Confounding by concurrent allopathic medication adjustments, seasonal dietary changes, or lifestyle modifications during the study period cannot be excluded. (2) Variable follow-up duration: Treatment cycle durations and revisit intervals vary by protocol phase (Base, Phase 1, Phase 2), resulting in heterogeneous pre–post measurement time intervals across patients. (3) Incomplete lipid documentation: Lipid panel data (cholesterol, triglycerides, LDL, HDL) were available in only 7–11 patients, limiting the statistical power of lipid analyses. (4) BMI data heterogeneity: The wide BMI range (16.0–77.4 kg/m²) and large SD (9.31) suggest one or more extreme outlier values, which may have influenced the non-significant BMI change ($p=0.092$) despite significant weight and abdominal girth reductions. (5) Single-centre design: Findings are specific to the Ambernath clinic population and may not be directly generalisable to other geographic populations. (6) Retrospective data quality: Documentation variability in clinical records is an inherent limitation of retrospective real-world analyses.

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