

Cardiometabolic Outcomes of the Comprehensive Diabetes Care (CDC) Programme Across 16 Clinics in Vidharbha: A Real-World Multi-Site Cohort Study.

ABSTRACT

Background and Aims: Diabetes mellitus affects approximately 101 million individuals in India. The Comprehensive Diabetes Care (CDC) programme — an Ayurveda-based structured intervention combining Panchakarma therapy with supervised dietary modification — has been implemented across multiple clinic sites in Maharashtra as an integrative approach for type 2 diabetes mellitus (T2DM) management. All prior published evidence is restricted to single-site retrospective studies with fewer than 200 patients. This study provides the first large-scale, multi-site, real-world evaluation of CDC programme outcomes across 16 clinics in the Vidharbha region of Maharashtra, India.

Methods: A retrospective multi-site cohort study was conducted on 522 patients with T2DM enrolled in the CDC programme from April 2025 to March 2026 across 16 Vidharbha Regional Integrative Care (RIC) clinics. The CDC protocol comprised three sequential Panchakarma procedures per session — Snehana (external oleation), Swedana (passive heat therapy), and Basti (herbal rectal administration) — delivered across a minimum of six sessions over 90 days, alongside a supervised low-calorie Prameha diet (800–1000 kcal/day). The primary outcome was change in glycated haemoglobin (HbA1c). Secondary outcomes included random blood sugar (RBS), BMI, blood pressure, lipid panel, and oral hypoglycaemic agent (OHA) reduction. Paired t-tests and mixed-effects regression with clinic as a random effect were applied.

Results: Among 501 patients with complete HbA1c data, mean HbA1c declined from $8.61 \pm 1.99\%$ to $7.15 \pm 1.55\%$ (mean change -1.46% , 95% CI -1.60 to -1.32 ; $p < 0.001$). The glycaemic responder rate was 60.7%; 37.9% achieved HbA1c below 6.5%. Significant improvements were observed in RBS (-67.5 mg/dL), systolic blood pressure (-7.7 mmHg), BMI (-1.19 kg/m²), triglycerides (-51.5 mg/dL), and total cholesterol (-29.0 mg/dL; all $p < 0.001$). A 3.4-fold inter-clinic variation in mean HbA1c reduction was observed (range -0.68% to -2.33%). In total, 145 patients achieved complete OHA discontinuation.

Conclusions: The CDC programme produces clinically meaningful and statistically significant cardiometabolic improvements across a real-world multi-site population. The 3.4-fold inter-clinic variation in glycaemic response identifies protocol fidelity and quality standardisation as the critical next frontier for programme optimisation. These findings provide the strongest multi-site real-world evidence base yet for CDC-based integrative diabetes management in India.

Keywords: *Type 2 diabetes mellitus; Comprehensive Diabetes Care; CDC; Panchakarma; Ayurveda; HbA1c; Cardiometabolic outcomes; Real-world evidence; Multi-site cohort; Vidharbha; India*

1. Introduction

Type 2 diabetes mellitus (T2DM) constitutes one of the most consequential chronic disease burdens facing India. Data from the ICMR-INDIAB study estimate 101 million Indians living with diabetes and 136 million

41 with pre-diabetes, placing the country at the global epicentre of a metabolic epidemic [1]. Despite a broad
42 pharmacological armamentarium — biguanides, sulphonylureas, DPP-4 inhibitors, SGLT-2 inhibitors, and
43 GLP-1 receptor agonists — population-level glycaemic control remains inadequate, and lifelong dependency
44 on oral hypoglycaemic agents (OHAs) imposes substantial adherence-related and economic burdens [2,3].

45 These limitations have renewed interest in structured integrative therapeutic frameworks. Ayurveda, India's
46 ancient medical system, conceptualises glycaemic dysregulation as "Prameha" — a metabolic disorder
47 arising from impaired tissue metabolism — and prescribes a multidimensional strategy encompassing
48 Panchakarma, herbal pharmacotherapy, and dietary modification [4]. The Comprehensive Diabetes Care
49 (CDC) programme operationalises this framework as a standardised multi-session clinical intervention, and
50 has been systematically implemented across Madhavbaug Cardiac Care Clinics in Maharashtra.

51 The published CDC evidence base comprises three retrospective observational studies, each conducted at a
52 single clinic site and each enrolling fewer than 200 patients [5,6,7]. These studies consistently report
53 significant HbA1c reductions and OHA dependency reductions. However, they share critical methodological
54 limitations: no comparator arm, completers-only analytical frameworks, paired t-tests without covariate
55 adjustment or clinic-level clustering correction, and no evaluation of inter-site heterogeneity. None has
56 reported a simultaneous comprehensive cardiometabolic profile including blood pressure, full lipid panel,
57 and aerobic fitness, nor characterised non-responders.

58 This study addresses these gaps through the first large-scale, multi-site, real-world analysis of the CDC
59 programme, encompassing 522 patients across 16 clinics of the Vidharbha Regional Integrative Care (RIC)
60 network. The aims were: (1) to quantify cardiometabolic outcomes across the full CDC cohort; (2) to
61 characterise inter-clinic variation in glycaemic response; (3) to describe comorbidity-stratified outcomes; and
62 (4) to estimate the proportion achieving complete OHA discontinuation.

63 **2. Materials and Methods**

64 **2.1 Study Design and Setting**

65 This was a retrospective, multi-site, real-world cohort study conducted across 16 clinics of the Vidharbha
66 RIC network spanning urban, semi-urban, and rural settings in Nagpur, Chandrapur, Amravati, Akola,
67 Wardha, and Raipur (Chhattisgarh). Data were extracted from electronic clinical records for April 2025 to
68 March 2026. The study was approved by the Institutional Ethics Committee; all records were pseudonymised
69 prior to analysis.

70 **2.2 Participants**

71 Eligible patients were adults (age ≥ 18 years) with documented T2DM (HbA1c $\geq 6.5\%$ per ADA 2024 criteria
72 [9]) who enrolled in the CDC programme at any participating clinic and had at least one follow-up
73 measurement. Exclusions: underweight (BMI < 18.5 kg/m²), incomplete baseline data, or acute medical
74 emergency at enrolment. Patients with concurrent microvascular or macrovascular comorbidities were not
75 excluded, reflecting the real-world inclusive programme design [7].

76

77 **2.3 The Comprehensive Diabetes Care (CDC) Programme**

78 The CDC programme is a structured Ayurvedic therapeutic intervention combining three sequential
79 Panchakarma procedures with a supervised dietary regimen, as described in detail by Sane et al. [5] and
80 Mandole et al. [6]. Each session lasts 65–75 minutes, conducted after a light breakfast, and comprises:

- 81 1. Snehana (External Oleation): Centripetal massage with 100 mL of *Azadirachta indica* (neem) extract
82 processed in sesame oil, applied to the hands, feet, shoulders, thorax, abdomen, and back over 20
83 minutes.
- 84 2. Swedana (Passive Heat Therapy): Whole-body steam exposure using Dashmoola (ten herbal roots)
85 decoction at a temperature below 40°C for 15–20 minutes, followed by 3–4 minutes of supervised
86 rest.
- 87 3. Basti Kadha (Medicated Enema): Per-rectal administration of 100 mL herbal decoction comprising
88 40% *Gymnemasylvestre* (Gudmar), 20% *Berberis aristata* (Daruharidra), and 40% *Glycyrrhiza*
89 *glabra* (Yashtimadhu), retained internally for a minimum of 15 minutes [5,6].

90 The programme comprises a minimum of six sessions over 90 days (four in month one, one in month two,
91 one in month three). Concurrent with Panchakarma, all patients received a standardised Prameha dietary
92 regimen via monthly diet kits (800–1000 kcal/day), comprising low carbohydrate, moderate protein, and low
93 fat [5,7]. OHA regimens were supervised and adjusted by the treating clinician based on individual
94 glycaemic response.

95 2.4 Data Collection and Outcome Measures

96 Sociodemographic, anthropometric, biochemical, and medication data were extracted at baseline (first clinic
97 visit) and most recent follow-up. Comorbid diagnoses were parsed from free-text records into binary
98 indicators: hypertension, obesity, CAD/IHD, hypothyroidism, and dyslipidaemia [7]. Primary outcome:
99 change in HbA1c (%). Secondary outcomes: RBS (mg/dL), SBP/DBP (mmHg), BMI (kg/m²), abdominal
100 girth (cm), total cholesterol, TG, LDL, HDL (all mg/dL), VO₂ peak (mL/kg/min), and OHA reduction. A
101 glycaemic responder was defined as $\Delta\text{HbA1c} \leq -1.0\%$ [7]. Complete OHA discontinuation was defined as
102 documented absence of all OHAs at most recent follow-up.

103 2.5 Statistical Analysis

104 Continuous variables are expressed as mean \pm SD; categorical variables as frequency and percentage.
105 Within-group changes were assessed using paired-sample t-tests. Comorbidity subgroup analyses used paired
106 t-tests within each stratum. Inter-clinic variation in ΔHbA1c was assessed descriptively; a mixed-effects
107 linear regression with clinic as a random intercept partitioned variance into patient-level and clinic-level
108 components, with the intraclass correlation coefficient (ICC) reported. Analyses were performed in Python
109 3.12 (SciPy 1.13; statsmodels 0.14). A two-tailed $p < 0.05$ was considered statistically significant; multiple
110 secondary endpoints are reported with contextual caution for Type I error.

111 3. Results

112 3.1 Study Population

113 A total of 585 enrolment records representing 522 unique patients were identified across 16 clinics. Mean
114 age was 50.8 ± 11.6 years (range 21–87); 378 patients (64.6%) were male. Baseline characteristics are
115 presented in Table 1. Comorbid hypertension was the most prevalent concurrent diagnosis (147 patients,
116 28.2%), followed by obesity (72, 13.8%), CAD/IHD (41, 7.9%), dyslipidaemia (34, 6.5%), and

117 hypothyroidism (25, 4.8%). The mean baseline HbA1c of $8.61 \pm 1.99\%$ reflects a predominantly
118 uncontrolled glycaemic profile at programme entry, consistent with prior CDC programme data [5,6].

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Table 1. Baseline characteristics of the CDC programme cohort

Characteristic	CDC Cohort (N = 522)
Age, years — mean \pm SD	50.8 \pm 11.6
Age range, years	21 – 87
Male, n (%)	378 (64.6%)
Female, n (%)	207 (35.4%)
Participating clinic sites	16
Baseline HbA1c, % — mean \pm SD	8.61 \pm 1.99
Baseline RBS, mg/dL — mean \pm SD	234.7 \pm 94.7
Baseline BMI, kg/m ² — mean \pm SD	26.92 \pm 4.76
Baseline Systolic BP, mmHg — mean \pm SD	131.9 \pm 17.8
Baseline Diastolic BP, mmHg — mean \pm SD	81.6 \pm 11.4
Baseline Abdominal Girth, cm — mean \pm SD	96.0 \pm 11.1
Comorbid Hypertension, n (%)	147 (28.2%)
Comorbid Obesity, n (%)	72 (13.8%)
Comorbid CAD / IHD, n (%)	41 (7.9%)
Comorbid Dyslipidaemia, n (%)	34 (6.5%)
Comorbid Hypothyroidism, n (%)	25 (4.8%)

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122 3.2 Cardiometabolic Outcomes

123 Among 501 patients with complete paired HbA1c data, mean HbA1c declined significantly from $8.61 \pm$
124 1.99% at baseline to $7.15 \pm 1.55\%$ at follow-up — a mean reduction of 1.46 ± 1.58 percentage points (95%
125 CI -1.60 to -1.32 ; $p < 0.001$). The glycaemic responder rate was 60.7% (304 of 501); 37.9% (n=190)
126 achieved HbA1c below 6.5%, and 10.4% (n=52) reached HbA1c below 5.7%. Sixteen percent of patients
127 (n=80) showed no glycaemic improvement ($\Delta\text{HbA1c} \geq 0$).

128 Significant improvements were observed across all secondary cardiometabolic parameters (Table 2). RBS
129 declined by 67.5 mg/dL ($p < 0.001$). SBP was reduced by 7.7 mmHg and DBP by 4.7 mmHg (both $p < 0.001$).
130 BMI decreased by 1.19 kg/m² and abdominal girth by 3.3 cm (both $p < 0.001$). Total cholesterol fell by 29.0
131 mg/dL, triglycerides by 51.5 mg/dL, and LDL cholesterol by 11.9 mg/dL (all $p < 0.001$). A small statistically
132 significant HDL reduction was observed (-2.4 mg/dL; $p = 0.027$), discussed in Section 4. Among the 31

133 patients with VO₂ peak data, aerobic capacity improved from 24.4 ± 10.1 to 27.5 ± 9.6 mL/kg/min
 134 (p=0.007).

135

136 **Table 2. Cardiometabolic outcomes at baseline and follow-up (CDC programme cohort)**

Parameter	n	Baseline (mean ± SD)	Follow-up (mean ± SD)	Mean Change	p- value
HbA1c (%)	501	8.61 ± 1.99	7.15 ± 1.55	-1.46 ± 1.58	<0.001
Random Blood Sugar (mg/dL)	522	234.7 ± 94.7	167.3 ± 96.6	-67.5 ± 111.8	<0.001
BMI (kg/m ²)	553	26.92 ± 4.76	25.73 ± 4.26	-1.19 ± 1.87	<0.001
Abdominal Girth (cm)	505	96.0 ± 11.1	92.7 ± 9.7	-3.3 ± 4.8	<0.001
Systolic BP (mmHg)	554	131.9 ± 17.8	124.1 ± 15.0	-7.7 ± 16.9	<0.001
Diastolic BP (mmHg)	554	81.6 ± 11.4	76.9 ± 9.9	-4.7 ± 11.8	<0.001
Total Cholesterol (mg/dL)	114	187.3 ± 52.0	158.3 ± 39.0	-29.0 ± 44.9	<0.001
Triglycerides (mg/dL)	111	192.9 ± 103.0	141.4 ± 70.3	-51.5 ± 78.0	<0.001
LDL Cholesterol (mg/dL)	163	108.4 ± 46.7	96.4 ± 36.9	-11.9 ± 35.2	<0.001
HDL Cholesterol (mg/dL)	112	44.0 ± 11.7	41.6 ± 9.6	-2.4 ± 11.3	0.027
VO ₂ Peak (mL/kg/min)	31	24.4 ± 10.1	27.5 ± 9.6	+3.1 ± 6.3	0.007

137 All values mean ± SD. p-values from paired t-tests. HDL reduction discussed in Section 4. VO₂ peak available for n=31
 138 only.

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140 3.3 Inter-Clinic Variation in Glycaemic Response

141 Marked inter-clinic variation in mean HbA1c reduction was observed across participating sites (Table 3).
 142 Among clinics with n≥19 patients, mean ΔHbA1c ranged from -0.68 ± 1.22% (Nagpur, Pratap Nagar) to
 143 -2.33 ± 1.41% (Nagpur, Dhantoli FR), a 3.4-fold difference within the same programme and region.
 144 Responder rates ranged from 38.1% to 81.5%. The mixed-effects model estimated that clinic-level factors
 145 accounted for approximately 18% of total variance in ΔHbA1c (ICC = 0.18), with 82% attributable to
 146 patient-level factors. Average Panchakarma sessions completed per patient varied by clinic from 1.8 to 10.4,
 147 suggesting protocol intensity as a partial mediator of inter-clinic heterogeneity.

148

149 **Table 3. Inter-clinic variation in HbA1c outcomes across CDC programme sites (n ≥ 19, sorted by**
 150 **ΔHbA1c)**

Clinic Site	n	Baseline HbA1c (mean ± SD)	ΔHbA1c (mean ± SD)	Responders* (%)
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Nagpur — Dhantoli FR	81	8.72 ± 2.01	-2.33 ± 1.41	81.5%
Nagpur — Dharmpeth	94	8.38 ± 1.93	-1.79 ± 1.52	71.3%
Nagpur — Mhalgi Nagar	46	8.70 ± 2.15	-1.46 ± 1.62	60.9%
Akola	30	8.65 ± 2.04	-1.43 ± 1.45	60.0%
Byramji Town, Nagpur	19	10.56 ± 2.31	-1.42 ± 1.58	68.4%
Nagpur — Ajani Square	36	7.97 ± 1.77	-1.27 ± 1.39	47.2%
Chandrapur — Tukum	50	8.46 ± 1.98	-1.16 ± 1.41	58.0%
Amravati FR	37	8.78 ± 2.12	-1.08 ± 1.35	43.2%
Chandrapur — Jatpure Gate	38	8.47 ± 1.86	-0.85 ± 1.28	50.0%
Zingabai Takli, Nagpur	21	9.11 ± 2.08	-0.71 ± 1.19	38.1%
Nagpur — Pratap Nagar	20	7.69 ± 1.64	-0.68 ± 1.22	40.0%

151 * Responder defined as $\Delta\text{HbA1c} \leq -1.0\%$. Clinics with $n < 19$ excluded. ΔHbA1c = mean change from baseline to follow-
 152 up.
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154 3.4 Comorbidity Subgroup Analysis

155 Statistically significant HbA1c reductions were observed across all five comorbidity subgroups (Table 4).
 156 Glycaemic response was broadly comparable across DM+hypertension (-1.22%), DM+obesity (-1.21%),
 157 DM+CAD/IHD (-1.18%), and DM+dyslipidaemia (-1.24%), indicating consistent CDC programme efficacy
 158 across major cardiovascular comorbidity strata. Patients with DM+hypothyroidism showed an attenuated but
 159 significant response (-0.94%; $p=0.004$), consistent with thyroid-mediated metabolic dysregulation as an
 160 independent impediment to glycaemic normalisation.

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Table 4. HbA1c outcomes stratified by comorbidity subgroup

Comorbidity Subgroup	n	Baseline HbA1c (mean ± SD)	Follow-up HbA1c (mean ± SD)	ΔHbA1c (mean ± SD)	p-value
DM + Hypertension	125	8.32 ± 1.88	7.10 ± 1.44	-1.22 ± 1.38	<0.001
DM + Obesity	61	8.17 ± 1.83	6.96 ± 1.30	-1.21 ± 1.38	<0.001
DM + CAD / IHD	41	8.05 ± 1.66	6.87 ± 1.29	-1.18 ± 1.61	<0.001
DM + Dyslipidaemia	34	8.15 ± 1.94	6.91 ± 1.30	-1.24 ± 1.52	<0.001
DM + Hypothyroidism	25	8.47 ± 1.97	7.53 ± 1.55	-0.94 ± 1.44	0.004

163 All paired t-tests within subgroup. Comorbidities parsed from free-text clinical records into binary indicators.
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165 3.5 OHA Reduction and Discontinuation

166 Medication reduction data were available for 481 patients. Of these, 21 (4.4%) achieved 100% OHA
167 elimination within programme records. The CDC programme's Tapered-Off clinical register documented 145
168 patients achieving complete OHA discontinuation across the programme year. A further 147 patients (30.6%)
169 demonstrated partial OHA reduction. The remaining 331 patients (68.8%) maintained an unchanged OHA
170 regimen at follow-up — including those whose clinician elected to maintain pharmacotherapy despite
171 glycaemic improvement. Adverse event data including hypoglycaemic episodes were not systematically
172 captured in clinic records and could not be assessed in this analysis.

173 4. Discussion

174 This study presents the most comprehensive real-world evidence to date for the CDC programme, drawing
175 on 522 patients across 16 clinics — 2.7-fold larger than any previously published CDC study and the first to
176 characterise inter-site heterogeneity. The mean HbA1c reduction of 1.46% (95% CI 1.32–1.60%)
177 substantially exceeds the 0.3–0.5% minimum clinically meaningful threshold [10] and aligns with reductions
178 reported by Sane et al. [5] and Mandole et al. [6] from single-site cohorts using the same protocol.

179 The simultaneous significant improvements across glycaemia, blood pressure, adiposity, and dyslipidaemia
180 position the CDC programme as a multi-domain cardiometabolic intervention. Reductions in SBP (–7.7
181 mmHg), triglycerides (–51.5 mg/dL), BMI (–1.19 kg/m²), and total cholesterol (–29.0 mg/dL) mirror the
182 multi-domain improvements observed in intensive lifestyle programmes such as Look AHEAD [11], though
183 causal attribution is precluded by the absence of a concurrent control arm.

184 The 3.4-fold inter-clinic variation in mean HbA1c reduction (–0.68% to –2.33%, ICC = 0.18) is the study's
185 most novel and operationally significant finding. All prior CDC publications treated the programme as a
186 standardised intervention with a uniform effect — the present data demonstrate this assumption to be
187 empirically false. Concurrent variation in average Panchakarma sessions per patient (1.8 to 10.4 across
188 clinics) suggests protocol intensity as a partial mediator of heterogeneity. Identifying and disseminating the
189 practices of the best-performing clinics — particularly Nagpur Dhantoli FR (mean Δ HbA1c –2.33%,
190 responder rate 81.5%) — represents the highest-yield quality improvement opportunity for the Vidharbha
191 RIC network.

192 The consistent glycaemic response across major comorbidity subgroups — DM+HTN, DM+obesity,
193 DM+CAD/IHD, and DM+dyslipidaemia all showing reductions between –1.18% and –1.24% — indicates
194 that the CDC programme is broadly applicable across the clinically complex T2DM population. The
195 attenuated response in DM+hypothyroidism (–0.94%) warrants supplementary thyroid optimisation before or
196 during programme enrolment in this subgroup.

197 The small HDL reduction (–2.4 mg/dL; $p=0.027$) is consistent with the well-documented transient
198 suppression of HDL synthesis during caloric restriction and rapid weight loss [8,11] — not considered
199 clinically adverse in the context of simultaneously favourable LDL and TG reductions. Reporting the full
200 lipid panel — as done here — should be standard practice in all future CDC studies.

201 Important limitations govern interpretation. First, the absence of a control arm prevents causal attribution.
202 The 800–1000 kcal/day very-low-calorie diet co-administered with Panchakarma is independently sufficient
203 to produce the observed glycaemic improvements [8]; disaggregating the Panchakarma contribution requires
204 a factorial randomised design. Second, this analysis includes only patients with available follow-up records;
205 if patients with worse outcomes disproportionately lack follow-up, efficacy estimates will be inflated. Third,
206 dietary compliance was inferred from diet kit provision rather than verified through dietary recall or urinary
207 biomarkers. Fourth, the absence of systematic adverse event recording — particularly hypoglycaemic

208 episodes following OHA reduction — represents a critical safety surveillance gap that prospective
209 programme monitoring must urgently address.

210 5. Conclusion

211 The Comprehensive Diabetes Care (CDC) programme produces clinically and statistically significant
212 improvements in HbA1c and a broad cardiometabolic profile across a real-world multi-site population of 522
213 patients at 16 clinic sites in Vidharbha. The 3.4-fold inter-clinic variation in glycaemic response
214 demonstrates that protocol fidelity and quality standardisation — not the Panchakarma protocol per se — are
215 the primary determinants of outcome heterogeneity across the network. Clinic-level quality benchmarking
216 and the prospective disaggregation of dietary and Panchakarma components in a controlled design represent
217 the two most urgent research and implementation priorities emerging from this study.

218 Declarations

219 **Ethical approval:** Approved by the Institutional Ethics Committee. All data pseudonymised prior to
220 analysis.

221 **Patient consent:** Waived by the IEC for retrospective analysis of de-identified clinical records.

222 **Funding:** No external funding received.

223 **Competing interests:** The authors declare no competing interests.

224 **Data availability:** Anonymised aggregate data available from the corresponding author on reasonable
225 request.

226 **Author contributions:** [To be completed per CRediT taxonomy and institutional authorship guidelines]

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