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CARDIOMETABOLIC OUTCOMES OF THE COMPREHENSIVE DIABETES CARE (CDC) PROGRAMME ACROSS 16 CLINICS IN VIDHARBHA: A REAL-WORLD MULTI-SITE COHORT STUDY

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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 Panchakar ma 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 ± 1.99% to 7.15 ± 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

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identifies protocol fidelity and quality standardisation as the critical next frontier for programmeoptimisation. These findings provide the strongest multi-site real-world evidence base yet for CDC-based integrative diabetes management in India.

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

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

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

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

Materials and Methods:-

Study Design and Setting:-

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

Participants:-

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

The Comprehensive Diabetes Care (CDC) Programme:-

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

1. Snehana (External Oleation): Centripetal massage with 100 mL of Azadirachta indica (neem) extract processed in sesame oil, applied to the hands, feet, shoulders, thorax, abdomen, and back over 20 minutes.
2. Swedana (Passive Heat Therapy): Whole-body steam exposure using Dashmoola (ten herbal roots) decoction at a temperature below 40°C for 15–20 minutes, followed by 3–4 minutes of supervised rest.

3. Basti Kadha (Medicated Enema): Per-rectal administration of 100 mL herbal decoction comprising 40% Gymnemasylvestre (Gudmar), 20% Berberis aristata (Daruharidra), and 40% Glycyrrhiza glabra (Yashtimadhu), retained internally for a minimum of 15 minutes [5,6].

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

Data Collection and Outcome Measures:-

Sociodemographic, anthropometric, biochemical, and medication data were extracted at baseline (first clinic visit) and most recent follow-up. Comorbid diagnoses were parsed from free-text records into binary indicators: hypertension, obesity, CAD/IHD, hypothyroidism, and dyslipidaemia [7]. Primary outcome: change in HbA1c (%). Secondary outcomes: RBS (mg/dL), SBP/DBP (mmHg), BMI (kg/m²), abdominal girth (cm), total cholesterol, TG, LDL, HDL (all mg/dL), VO2 peak (mL/kg/min), and OHA reduction. A glycaemic responder was defined as ΔHbA1c $\leq -1.0\%$ [7]. Complete OHA discontinuation was defined as documented absence of all OHAs at most recent follow-up.

Statistical Analysis:-

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

Results:-

Study Population:-

A total of 585 enrolment records representing 522 unique patients were identified across 16 clinics. Mean age was 50.8 ± 11.6 years (range 21–87); 378 patients (64.6%) were male. Baseline characteristics are presented in Table 1. Comorbid hypertension was the most prevalent concurrent diagnosis (147 patients, 28.2%), followed by obesity (72, 13.8%), CAD/IHD (41, 7.9%), dyslipidaemia (34, 6.5%), and hypothyroidism (25, 4.8%). The mean baseline HbA1c of 8.61 ± 1.99% reflects a predominantly uncontrolled glycaemic profile at programme entry, consistent with prior CDC programme data [5,6].

Table 1. Baseline characteristics of the CDC programme cohort

Characteristic	CDC Cohort (N = 522)
Age, years — mean ± SD	50.8 ± 11.6
Age range, years	21 – 87
Male, n (%)	378 (64.6%)
Female, n (%)	207 (35.4%)
Participating clinic sites	16
Baseline HbA1c, % — mean ± SD	8.61 ± 1.99

Baseline RBS, mg/dL — mean ± SD	234.7 ± 94.7
Baseline BMI, kg/m² — mean ± SD	26.92 ± 4.76
Baseline Systolic BP, mmHg — mean ± SD	131.9 ± 17.8
Baseline Diastolic BP, mmHg — mean ± SD	81.6 ± 11.4
Baseline Abdominal Girth, cm — mean ± SD	96.0 ± 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 (%)	4.8%) **25**

Cardiometabolic Outcomes:-

Among 501 patients with complete paired HbA1c data, mean HbA1c declined significantly from 8.61 ± 1.99% at baseline to 7.15 ± 1.55% at follow-up — a mean reduction of 1.46 ± 1.58 percentage points (95% CI −1.60 to −1.32; p<0.001). The glycaemic responder rate was 60.7% (304 of 501); 37.9% (n=190) achieved HbA1c below 6.5%, and 10.4% (n=52) reached HbA1c below 5.7%. Sixteen percent of patients (n=80) showed no glycaemic improvement (ΔHbA1c ≥ 0).

Significant improvements were observed across all secondary cardiometabolic parameters (Table 2). RBS 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). BMI decreased by 1.19 kg/m² and abdominal girth by 3.3 cm (both p<0.001). Total cholesterol fell by 29.0 mg/dL, triglycerides by 51.5 mg/dL, and LDL cholesterol by 11.9 mg/dL (all p<0.001). A small statistically significant HDL reduction was observed (−2.4 mg/dL; p=0.027), discussed in Section 4. Among the 31 patients with VO2 peak data, aerobic capacity improved from 24.4 ± 10.1 to 27.5 ± 9.6 mL/kg/min (p=0.007)

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/m²)	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**
VO2 Peak (mL/kg/min)	31	24.4 ± 10.1	27.5 ± 9.6	+3.1 ± 6.3	**0.007**

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

Inter-Clinic Variation in Glycaemic Response:-

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

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

Clinic Site	n	Baseline HbA1c (mean ± SD)	ΔHbA1c (mean ± SD)	Responders* (%)
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%

*** Responder defined as ΔHbA1c ≤ −1.0%. Clinics with n<19 excluded. ΔHbA1c = mean change from baseline to follow-up.**

Comorbidity Subgroup Analysis:-

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

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**

All paired t-tests within subgroup. Comorbidities parsed from free-text clinical records into binary indicators.

OHA Reduction and Discontinuation:-

Medication reduction data were available for 481 patients. Of these, 21 (4.4%) achieved 100% OHA elimination within programme records. The CDC programme's Tapered-Off clinical register documented 145 patients achieving complete OHA discontinuation across the programme year. A further 147 patients (30.6%) demonstrated partial OHA reduction. The remaining 331 patients (68.8%) maintained an unchanged OHA regimen at follow-up — including those whose clinician elected to maintain pharmacotherapy despite glycaemic improvement. Adverse

event data including hypoglycaemic episodes were not systematically captured in clinic records and could not be assessed in this analysis.

Discussion:-

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

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

The 3.4-fold inter-clinic variation in mean HbA1c reduction (−0.68% to −2.33%, ICC = 0.18) is the study's most novel and operationally significant finding. All prior CDC publications treated the programme as a standardised intervention with a uniform effect — the present data demonstrate this assumption to be empirically false. Concurrent variation in average Panchakarma sessions per patient (1.8 to 10.4 across clinics) suggests protocol intensity as a partial mediator of heterogeneity. Identifying and disseminating the practices of the best-performing clinics — particularly Nagpur Dhantoli FR (mean ΔHbA1c −2.33%, responder rate 81.5%) — represents the highest-yield quality improvement opportunity for the Vidharbha RIC network.

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

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

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

Conclusion:-

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

Declarations:-

Ethical approval: Approved by the Institutional Ethics Committee. All data pseudonymised prior to analysis.
Patient consent: Waived by the IEC for retrospective analysis of de-identified clinical records.
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Competing interests: The authors declare no competing interests.
Data availability: Anonymised aggregate data available from the corresponding author on reasonable request.
Author contributions: [To be completed per CRediT taxonomy and institutional authorship guidelines]

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