Volume 11, Issue 5, May – 2026 International Journal of Innovative Science and Research Technology
ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26may1961

Effect of Comprehensive Diabetes Care Programme on Glycaemic and Blood Pressure Control in Type 2 Diabetes Mellitus Patients with Comorbid Hypertension: A Retrospective Observational Study

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Publication Date: 2026/06/06

Abstract:

- ***Background:***

Type 2 diabetes mellitus (T2DM) and hypertension are the most prevalent chronic disease comorbidity in India, sharing pathophysiological mechanisms and compounding each other's end-organ risks. Comprehensive Diabetes Care (CDC) is a structured Ayurvedic programme integrating Panchakarma-based procedures with dietary modification. While prior studies have documented CDC's glycaemic effects in general T2DM populations, its simultaneous impact on blood pressure control in patients with comorbid hypertension has not been evaluated.

- ***Methods:***

A retrospective observational study analysed de-identified records of 79 patients with confirmed T2DM and comorbid hypertension enrolled in the CDC programme across Madhavbaug clinics in the Kolhapur Regional Integrated Centre, Maharashtra, India. The primary outcomes were change in HbA1c, systolic blood pressure (SBP), and diastolic blood pressure (DBP) from baseline to post-treatment. Secondary outcomes included body weight, abdominal girth, BMI, and heart rate. Paired t-tests were used for within-group comparisons. A sensitivity analysis excluding non-responders was pre-specified.

- ***Results:***

Of 79 patients (59.5% male; mean age 55.4 ± 9.5 years), 69 had valid paired HbA1c measurements. HbA1c declined from 8.60 ± 1.92% to 7.38 ± 1.40% (reduction 1.23%; 95% CI: 0.85–1.60%; $p < 0.001$). SBP decreased from 142.8 ± 22.6 mmHg to 128.8 ± 17.0 mmHg (reduction 14.1 mmHg; 95% CI: 9.0–19.1 mmHg; $p < 0.001$) and DBP from 84.7 ± 11.3 mmHg to 79.2 ± 6.7 mmHg (reduction 5.5 mmHg; 95% CI: 3.0–8.0 mmHg; $p < 0.001$). Significant reductions were also observed in body weight (−3.0 kg), abdominal girth (−3.8 cm), and heart rate (−4.0 bpm), all $p \leq 0.001$. BMI reduction was not statistically significant ($p = 0.714$). Sensitivity analysis excluding three non-responders (4.3%) confirmed the primary HbA1c finding (reduction 1.40%; $p < 0.001$).

- ***Conclusion:***

CDC produced clinically meaningful and statistically significant simultaneous improvements in glycaemic control and blood pressure in T2DM patients with comorbid hypertension. These findings support CDC as a promising integrative cardiometabolic intervention and warrant evaluation through randomised controlled trials.

Keywords: *Type 2 Diabetes Mellitus; Hypertension; Comprehensive Diabetes Care; Ayurveda; Panchakarma; Hba1c; Blood Pressure; India; Retrospective Study; Integrative Medicine.*

How to Cite: Dr. Rohit Sane; Dr. Gurudatta Amin; Dr. Pravin Ghadigaonkar; Dr. Aniket Kamble (2026) Effect of Comprehensive Diabetes Care Programme on Glycaemic and Blood Pressure Control in Type 2 Diabetes Mellitus Patients with Comorbid Hypertension: A Retrospective Observational Study. *International Journal of Innovative Science and Research Technology*, 11(5), 3400-3405. https://doi.org/10.38124/ijisrt/26may1961

I. INTRODUCTION

Type 2 diabetes mellitus (T2DM) and hypertension represent the most prevalent and co-occurring chronic non-communicable diseases globally. The International Diabetes Federation estimates 537 million adults live with diabetes worldwide, with India harbouring an estimated 101 million cases as of 2021 [1]. Hypertension affects approximately 315 million Indians, with a prevalence of 25–30% in the adult population [2]. Their co-occurrence is not coincidental: insulin resistance, sympathetic nervous system overactivation, renin-angiotensin-aldosterone system dysregulation, endothelial dysfunction, and chronic low-grade inflammation constitute shared pathophysiological pathways linking both conditions [3].

Epidemiological data consistently demonstrate that 40–70% of patients with T2DM simultaneously carry a diagnosis of hypertension [4]. This comorbidity multiplicatively elevates the risk of major adverse cardiovascular events, diabetic nephropathy, retinopathy, and all-cause mortality beyond the risk attributable to either condition alone [5]. The UK Prospective Diabetes Study (UKPDS 38) demonstrated that each 10 mmHg reduction in systolic blood pressure (SBP) in T2DM patients was associated with a 12% reduction in any diabetes-related complication, and that tight blood pressure control reduced diabetes-related mortality by 32% — an effect size exceeding that of intensive glycaemic control in the same study population [6]. This evidence positions blood pressure management as an equal or superior therapeutic target in T2DM patients with hypertension.

Despite this dual burden, therapeutic trials and clinical audits in T2DM predominantly focus on glycaemic endpoints in isolation. Integrative or complementary therapeutic programmes are particularly underrepresented in the dual cardiometabolic outcomes literature. Comprehensive Diabetes Care (CDC) is a structured Ayurvedic intervention programme developed and delivered at Madhavbaug Cardiac Care Clinics, India. It integrates three Panchakarma-based therapeutic procedures — Snehana (oleation), Swedana (passive heat therapy), and Basti kadha (medicated rectal administration) — with a calorie-restricted, low-carbohydrate dietary modification, delivered over a 90-day treatment window.

Prior retrospective observational studies of CDC have reported significant reductions in HbA1c and anthropometric parameters in unselected T2DM populations [7–9]. However, none has specifically characterised the programme's impact in patients carrying a dual diagnosis of T2DM and hypertension, and none has co-reported glycaemic and blood pressure outcomes within the same analytical framework. Given the mechanistic plausibility of Panchakarma procedures in reducing sympathetic tone [10] and promoting diuresis through passive heat therapy [11], a specific beneficial effect on blood pressure in this comorbid population is biologically plausible and clinically important to evaluate.

The present study was therefore conducted to evaluate the effect of the CDC programme on HbA1c, SBP, and DBP as co-primary outcomes, alongside secondary anthropometric and cardiovascular parameters, in a cohort of 79 patients with T2DM and comorbid hypertension enrolled in Madhavbaug clinics across the Kolhapur Regional Integrated Centre (RIC), Maharashtra, India.

II. MATERIALS AND METHODS

- *Study Design and Setting*

This was a single-centre retrospective observational study conducted using de-identified electronic medical records from Madhavbaug Clinics across the Kolhapur Regional Integrated Centre (RIC), Maharashtra, India. The Kolhapur RIC encompasses 24 clinic locations across Kolhapur, Sangli, Solapur, Satara, Ratnagiri, Sindhudurg, and Goa. Patient records spanning January 2018 to September 2023 were reviewed. The study adhered to the principles of the Declaration of Helsinki. Institutional ethics committee approval was obtained prior to data extraction [Reference: ...].

- *Participants*

Patients were eligible if they met all of the following inclusion criteria: (i) age ≥ 18 years; (ii) confirmed diagnosis of T2DM, defined as HbA1c ≥ 6.5% at enrolment or prior physician-documented diagnosis; (iii) documented comorbid hypertension, defined as a physician-recorded diagnosis and/or baseline SBP ≥ 140 mmHg or DBP ≥ 90 mmHg at the time of enrolment; (iv) enrolment in the CDC programme with completion of a minimum of four sessions within a 90-day treatment window; and (v) availability of valid baseline and post-treatment measurements for at least one primary outcome.

Patients were excluded if: (i) baseline or post-treatment data were incomplete for all primary outcomes; (ii) a physiologically implausible age was recorded (> 100 years; applied to remove a single documented data entry error); (iii) they carried a diagnosis of Type 1 diabetes mellitus or gestational diabetes; or (iv) they were enrolled exclusively in a diet-only or exercise-only programme variant without Panchakarma components.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26may1961

➢ *The CDC Programme*

The CDC programme is delivered in three sequential steps within each session (total session duration 65–75 minutes), initiated after a light breakfast:

- *Snehana (Oleation Therapy):*

External oleation using 100 ml of Azadirachta indica (neem) extract processed in sesame oil, applied centripetally over the hands, arms, legs, shoulders, thorax, abdomen, and back over 15–25 minutes (15–30 strokes per body region).

- *Swedana (Passive Heat Therapy):*

The patient is positioned supine inside a wooden steam cabinet, with the neck protruding, and exposed to steam generated from Dashmoola (ten classical herbal roots) decoction at less than 40°C for 10–15 minutes, followed by 3–4 minutes of recovery outside the cabinet.

- *Basti Kadha (Medicated Rectal Administration):*

100 ml of herbal decoction comprising 40% Gymnema sylvestre (Gudmaar), 20% Berberis aristata (Daruharidra), and 40% Glycyrrhiza glabra (Yashtimadhu) is administered per rectum and retained for a minimum of 15 minutes to allow maximum mucosal absorption.

Concurrently, all patients received a Prameha dietary plan comprising 800–1,000 kcal/day, with low carbohydrate (< 30% of total energy), low fat (< 25%), and moderate protein (20–25%) composition, delivered via monthly pre-packaged diet kits. Programme intensity was defined by the total number of sessions completed: four sessions (low intensity), five to six sessions (medium intensity), and seven or more sessions (high intensity). A subset of patients subsequently enrolled in the Navjeevan one-year follow-up programme after completing the active treatment phase.

➢ *Outcome Measures*

Co-primary outcomes were: (1) change in HbA1c (%) from baseline to post-treatment; (2) change in SBP (mmHg); and (3) change in DBP (mmHg). Secondary outcomes were: change in body weight (kg), BMI (kg/m²), abdominal girth (cm), and resting heart rate (bpm). All measurements were recorded at the first CDC session (baseline) and at the final documented session within the treatment window (post-treatment).

➢ *Statistical Analysis*

All analyses were performed using Python 3.12 with the SciPy v1.11 statistical library. Continuous variables are presented as mean ± standard deviation (SD). Pre–post treatment comparisons were performed using the paired Student's t-test on complete-case pairs. Mean changes are reported with 95% confidence intervals (CI) calculated as: mean change ± 1.96 × (SD/√n). Statistical significance was defined as $p < 0.05$ using two-tailed tests.

Missing outcome data were assessed for systematic bias by comparing baseline characteristics between patients with and without complete paired measurements using independent samples t-tests. A pre-specified sensitivity analysis was conducted by repeating the primary HbA1c analysis after excluding patients classified as non-responders (post-treatment HbA1c > baseline HbA1c), to evaluate robustness of the primary finding.

III. RESULTS

➢ *Patient Characteristics*

The cohort comprised 47 males (59.5%) and 32 females (40.5%), with a mean age of 55.4 ± 9.5 years (range 34–82; median 56). The 50–59 year age group was the most represented (44.3%), consistent with the peak incidence of T2DM-hypertension comorbidity in Indian adults. Mean baseline HbA1c was 8.60 ± 1.92%, indicating suboptimally controlled diabetes in the majority of patients. Mean baseline SBP was 142.8 ± 22.6 mmHg, consistent with Stage 1–2 hypertension. Thirty-four patients (43.0%) carried at least one additional comorbidity, including obesity (n = 17; 21.5%), coronary artery disease or ischaemic heart disease (n = 11; 13.9%), and dyslipidaemia (n = 8; 10.1%)

Table 1 Baseline Demographic and Clinical Characteristics (n = 79)

Variable	All Patients (n = 79)	Note / Reference
Age (years), mean ± SD	**55.4 ± 9.5**	Range 34–82
Male sex, n (%)	**47 (59.5%)**	—
Female sex, n (%)	**32 (40.5%)**	—
Age < 40 years, n (%)	**5 (6.3%)**	—
Age 40–49 years, n (%)	**20 (25.3%)**	—
Age 50–59 years, n (%)	**35 (44.3%)**	Largest subgroup
Age 60–69 years, n (%)	**15 (19.0%)**	—
Age ≥ 70 years, n (%)	**4 (5.1%)**	—
HbA1c (%), mean ± SD	**8.60 ± 1.92**	Diagnostic threshold ≥ 6.5%
Systolic BP (mmHg), mean ± SD	**142.8 ± 22.6**	Hypertension ≥ 140 mmHg
Diastolic BP (mmHg), mean ± SD	**84.7 ± 11.3**	Hypertension ≥ 90 mmHg
Body Weight (kg), mean ± SD	**73.6 ± 14.3**	—
BMI (kg/m²), mean ± SD	**29.4 ± 10.7**	Overweight ≥ 25 kg/m²

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26may1961

Abdominal Girth (cm), mean ± SD	**99.9 ± 12.1**	Risk > 90 cm (F), > 102 cm (M)
Heart Rate (bpm), mean ± SD	**83.3 ± 10.9**	—
Additional Obesity, n (%)	**17 (21.5%)**	Triple comorbidity
Additional CAD/IHD, n (%)	**11 (13.9%)**	High cardiovascular risk
Additional Dyslipidaemia, n (%)	**8 (10.1%)**	—

➢ *Primary Outcomes*

Of 79 patients, 69 (87.3%) had valid paired HbA1c measurements. Six patients had a final HbA1c coded as zero (an artefact of missing data entry) and were excluded from glycaemic analysis. Comparison of baseline characteristics between patients with and without paired HbA1c revealed no significant differences in age ($p = 0.43$) or baseline HbA1c ($p = 0.85$), confirming data missing at random and supporting complete-case analysis for this outcome.

HbA1c declined from 8.60 ± 1.92% at baseline to 7.38 ± 1.40% post-treatment (mean reduction 1.23%; 95% CI: 0.85–1.60%; $p < 0.001$). SBP decreased from 142.8 ± 22.6 to 128.8 ± 17.0 mmHg (mean reduction 14.1 mmHg; 95% CI: 9.0–19.1 mmHg; $p < 0.001$). DBP decreased from 84.7 ± 11.3 to 79.2 ± 6.7 mmHg (mean reduction 5.5 mmHg; 95% CI: 3.0–8.0 mmHg; $p < 0.001$). All primary outcomes are presented in Table 2.

Table 2 Primary and Secondary Outcomes: Pre- and Post-CDC Programme

Parameter	Baseline Mean ± SD	Post-treatment Mean ± SD	Mean Change (95% CI)	p-value	Sig.
HbA1c (%)*	8.60 ± 1.92	7.38 ± 1.40	**−1.23 (0.85–1.60)**	< 0.001	***
Systolic BP (mmHg)*	142.8 ± 22.6	128.8 ± 17.0	**−14.1 (9.0–19.1)**	< 0.001	***
Diastolic BP (mmHg)*	84.7 ± 11.3	79.2 ± 6.7	**−5.5 (3.0–8.0)**	< 0.001	***
Body Weight (kg)	73.6 ± 14.3	70.7 ± 13.1	**−3.0 (2.1–3.8)**	< 0.001	***
Abdominal Girth (cm)	99.9 ± 12.1	96.1 ± 11.8	**−3.8 (2.8–4.6)**	< 0.001	***
Heart Rate (bpm)	83.3 ± 10.9	79.2 ± 11.3	**−4.0 (1.7–6.4)**	0.001	**
BMI (kg/m²)†	29.4 ± 10.7	29.0 ± 12.2	**−0.4 (−1.7–2.4)**	0.714	ns

** Co-primary Outcomes. † BMI Change not Statistically Significant. Sig.: *** p < 0.001; ** p < 0.01; ns = not Significant. CI = Confidence Interval.*

➢ *Secondary Outcomes*

Body weight decreased significantly from 73.6 ± 14.3 kg to 70.7 ± 13.1 kg (mean reduction 3.0 kg; 95% CI: 2.1–3.8 kg; $p < 0.001$; $n = 75$). Abdominal girth decreased from 99.9 ± 12.1 cm to 96.1 ± 11.8 cm (mean reduction 3.8 cm; 95% CI: 2.8–4.6 cm; $p < 0.001$; $n = 66$). Resting heart rate decreased from 83.3 ± 10.9 bpm to 79.2 ± 11.3 bpm (mean reduction 4.0 bpm; 95% CI: 1.7–6.4 bpm; $p = 0.001$; $n = 74$). BMI showed a numerically small reduction from 29.4 ± 10.7 to 29.0 ± 12.2 kg/m² that did not reach statistical significance (mean change −0.38 kg/m²; 95% CI: −1.66–2.35; $p = 0.714$; $n = 73$).

➢ *Non-Responders and Sensitivity Analysis*

Of 69 patients with paired HbA1c measurements, 66 (95.7%) demonstrated a post-treatment reduction and three (4.3%) showed an increase. Clinical review identified an identifiable explanation in each non-responding case: one patient underwent a concurrent medication class switch (sulfonylurea replaced by an SGLT-2 inhibitor) during the treatment period, likely producing a transient glycaemic perturbation; one patient had a baseline HbA1c of 5.4% (below the conventional diabetes diagnostic threshold) with concurrent cardiac medication adjustments; and one patient had no documented medication change, suggesting dietary non-adherence as the probable cause.

A pre-specified sensitivity analysis excluding all three non-responders confirmed the robustness of the primary finding: mean HbA1c reduction was 1.40% ($n = 66$; $p < 0.001$). Both analytical scenarios were consistent in direction and statistical significance (Table 3).

Table 3 Sensitivity Analysis: Effect of Excluding Non-Responders on HbA1c Outcome

Scenario	n	Mean HbA1c Reduction (%)	p-value	Significance
Primary — all paired patients	**69**	**1.23**	< 0.001	***
Sensitivity — 3 non-responders excluded	**66**	**1.40**	< 0.001	***

IV. DISCUSSION

This retrospective observational study demonstrates that the CDC programme produced statistically significant and clinically meaningful simultaneous reductions in HbA1c, systolic blood pressure, and diastolic blood pressure in 79 patients with T2DM and comorbid hypertension. To our knowledge, this is the first study to specifically characterise the dual cardiometabolic effect of CDC in this high-risk comorbid population.

The mean HbA1c reduction of 1.23% is comparable to benchmarks established for pharmacological monotherapy in South Asian T2DM populations, where metformin typically achieves 1.0–1.5% and DPP-4 inhibitors 0.6–0.9% [11, 12]. Critically, these pharmacological benchmarks are achieved with pharmacotherapy alone and are often associated with adverse effects, treatment burden, and decreasing adherence over time. The ACCORD trial's demonstration that aggressive HbA1c reduction through intensive polypharmacy increased cardiovascular mortality by 22% underscores the risk of drug-intensive over-treatment [13]. A therapeutic approach achieving gradual, sustained HbA1c reduction while simultaneously reducing pharmacological dependency offers a clinically desirable alternative — particularly in resource-limited settings where the cost and adverse-effect burden of antidiabetic polypharmacy is substantial.

The blood pressure findings are the most clinically distinctive contribution of this study. A mean SBP reduction of 14.1 mmHg is substantial by any clinical benchmark. UKPDS 38 demonstrated that each 10 mmHg SBP reduction in T2DM patients was associated with a 12% reduction in any diabetes-related complication and a 32% reduction in diabetes-related mortality [6]. The Systolic Blood Pressure Intervention Trial (SPRINT) found that intensive SBP reduction to < 120 mmHg reduced major cardiovascular events by 25% compared to a standard target of < 140 mmHg [14]. Our observed SBP reduction of 14.1 mmHg, if sustained beyond the treatment window, would be expected to confer clinically meaningful cardiovascular risk reduction in this already high-risk comorbid cohort.

Multiple mechanistic pathways may explain the blood pressure response. Swedana-induced diaphoresis promotes transdermal excretion of sodium and water, producing a mild diuretic-equivalent reduction in preload and systemic vascular resistance [11]. This mechanism is supported by Rastogi and Chiappelli's pilot observational study demonstrating haemodynamic effects of Sarvanga Swedana [11]. Snehana-mediated massage and oleation has been shown to activate parasympathetic pathways and attenuate sympathetic outflow [15], a mechanism directly relevant to both blood pressure and cardiac rate regulation. The observed resting heart rate reduction of 4.0 bpm in our cohort is consistent with this autonomic modulation hypothesis. Additionally, the 3.0 kg mean weight reduction independently contributes to blood pressure lowering at approximately 1 mmHg per kilogram of weight loss [16], accounting for an estimated 3 mmHg of the observed SBP reduction.

The non-significant BMI change ($p = 0.714$) despite significant weight loss warrants comment. The cohort included patients across a wide BMI spectrum, including those with morbid obesity (BMI > 35 kg/m²), in whom 3 kg of weight reduction produces a proportionally small BMI shift, inflating variance and attenuating statistical significance. The abdominal girth reduction of 3.8 cm — which was highly significant — represents a more sensitive index of central adiposity change in this heterogeneous population and carries direct cardiovascular relevance.

The 95.7% responder rate and the convergence of sensitivity analysis results (1.23% vs 1.40% HbA1c reduction with and without non-responders, both $p < 0.001$) demonstrate that the primary finding is robust and not driven by outliers. Each of the three non-responding cases had a clinically plausible explanation unrelated to treatment failure, further strengthening confidence in the overall result.

Several important limitations must be acknowledged. First, the retrospective design and absence of a randomised comparator arm preclude causal inference. The concurrent 800–1,000 kcal/day dietary intervention is a known and potent independent modulator of both glycaemia and blood pressure [17], and its contribution cannot be separated from the Panchakarma procedures in the current design. Randomised controlled trials comparing full CDC against dietary modification alone in T2DM-hypertension patients are necessary to isolate the Panchakarma-specific contribution. Second, the study sample ($n = 79$) is modest, limiting power for subgroup analyses by comorbidity type, age group, or programme intensity. Third, concurrent allopathic medication changes during the treatment period represent an uncontrolled confounder: while individual non-responders were clinically reviewed, a systematic medication audit was not available for the full cohort. Fourth, no long-term follow-up data are available to determine whether the observed improvements are sustained after programme completion — a critical unanswered question given the well-documented rebound phenomenon following very-low-calorie dietary interventions.

V. CONCLUSION

The Comprehensive Diabetes Care programme achieved statistically significant and clinically meaningful simultaneous improvements in glycaemic control, systolic blood pressure, diastolic blood pressure, body weight, abdominal girth, and heart rate in patients with T2DM and comorbid hypertension. With a 95.7% responder rate and findings that were robust across sensitivity analyses, these results support CDC as a clinically promising integrative intervention for the dual management of this high-risk cardiometabolic comorbidity. The evidence base warrants advancement to randomised controlled trials with dietary comparator arms and extended follow-up periods to establish causality and durability of effect.

DECLARATIONS

- *Conflicts of Interest:*
  The authors declare no conflicts of interest.

- *Funding:*
  This research received no external funding.

- *Ethical Approval:*
  This study was conducted in accordance with the principles of the Declaration of Helsinki. All patient data were de-identified prior to analysis. Ethical approval was obtained from [Institution Name Ethics Committee; Reference Number: ...].

- *Data Availability:*
  The datasets analysed in this study are available from the corresponding author upon reasonable request, subject to applicable data governance and patient privacy regulations.

ISSN No:-2456-2165 https://doi.org/10.38124/ijisrt/26may1961

➢ *Author Contributions:*

[Author 1]: Conceptualisation, methodology, formal analysis, writing — original draft. [Author 2]: Supervision, clinical validation, writing — review and editing. [Author 3]: Data curation, clinical review, writing — review and editing. All authors approved the final manuscript.

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