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Effectiveness Of A Structured Diabetes Care Program On Glycaemic Control And Cardiometabolic Parameters In Semi-Urban Maharashtra: A Pre-Post Interventional Pilot Study

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Abstract

Background: *India harbours the second-largest diabetes population globally, yet evidence on structured care outcomes from semi-urban settings remains scarce. We evaluated the effectiveness of a structured diabetes care program on glycaemic and cardiometabolic parameters among patients with type 2 diabetes mellitus (T2DM) at a semi-urban clinic in Solapur district, Maharashtra.*

Methods: *This single-centre, retrospective, pre-post interventional pilot study included 32 patients with T2DM enrolled in structured care programs (DM Packages, n = 27; Navjeevan Care Plan, n = 5) at a diabetes clinic in Akluj, Solapur district. Patients with genuinely paired baseline and follow-up measurements were analysed. The primary outcome was change in glycated haemoglobin (HbA1c). Secondary outcomes included random blood sugar (RBS), systolic and diastolic blood pressure (SBP, DBP), body weight, and resting heart rate. Pre-post comparisons were performed using the Wilcoxon signed-rank test.*

Results: *Mean HbA1c decreased significantly from 9.60 ± 2.53% to 7.96 ± 1.65% (Δ = −1.64%; 95% CI: 0.84–2.44; p < 0.001; n = 20; Cohen's d = 0.96). Glycaemic target achievement (HbA1c < 7%) more than doubled from 15.0% to 35.0%. RBS decreased from 257.55 ± 117.38 to 171.70 ± 44.59 mg/dL (p < 0.001; n = 20). Significant reductions were observed in SBP (−11.75 mmHg; p = 0.002; n = 24), DBP (−3.96 mmHg; p = 0.004; n = 24), body weight (−2.03 kg; p < 0.001; n = 27), and heart rate (−7.09 bpm; p = 0.042; n = 22). Blood pressure target achievement (< 140/90 mmHg) improved from 58.3% to 95.8%.*

Conclusion: *A structured diabetes care program in semi-urban Maharashtra achieved statistically significant improvements in glycaemic control, blood pressure, body weight, and heart rate, with large effect sizes. These pilot findings support the feasibility of systematic diabetes management in non-metropolitan Indian settings and warrant larger confirmatory studies.*

Keywords: *Type 2 diabetes mellitus; HbA1c; Glycaemic control; Cardiometabolic risk; Structured care; Semi-urban India; Pilot study*

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I. Introduction

India bears the second-largest burden of type 2 diabetes mellitus (T2DM) globally, with an estimated 101 million individuals affected [1]. The International Diabetes Federation projects this figure to reach 134 million by 2045, driven by epidemiological transition, urbanisation, and dietary shifts [1,2]. While metropolitan centres have benefited from specialist endocrinology services, semi-urban and rural regions—home to approximately 65% of India's population—continue to face fragmented, episodic diabetes care [3,4].

The ICMR-INDIAB study reported a national T2DM prevalence of 7.3%, with Maharashtra registering approximately 8.4%; however, most published evidence originates from urban tertiary centres, creating a critical evidence gap for non-metropolitan populations [5]. Globally, structured diabetes management programs integrating pharmacotherapy, glycaemic monitoring, and lifestyle counselling have demonstrated HbA1c reductions of 0.5–1.5% [6,7]. The UK Prospective Diabetes Study (UKPDS) established that each 1% HbA1c reduction is associated with a 21% reduction in diabetes-related deaths, 14% reduction in myocardial infarction, and 37% reduction in microvascular complications [8]. The Steno-2 study further demonstrated that multifactorial intervention addressing glycaemia, blood pressure, and lipids simultaneously yields superior cardiovascular risk reduction [9].

The present pilot study evaluates the effectiveness of structured diabetes care programs—DM Packages and the Navjeevan Care Plan—on glycaemic control and cardiometabolic parameters among T2DM patients at a diabetes clinic in Akluj, Solapur district, Maharashtra.

II. Materials And Methods

Study Design and Setting

This was a single-centre, retrospective, pre-post interventional pilot study conducted at a diabetes care clinic in Akluj, Solapur district, Maharashtra, India, operating under the Kolhapur Regional Integrated Centre (RIC). The clinic serves a predominantly semi-urban and rural catchment population.

Study Population

Thirty-two consecutive patients with T2DM enrolled in structured care programs between March 2025 and April 2026 were included. Patients were enrolled in either DM Packages (n = 27; 84.4%), a tiered comprehensive diabetes management program involving scheduled clinical visits, glycaemic monitoring, dietary counselling, physical activity guidance, and pharmacotherapy optimisation; or the Navjeevan Care Plan (n = 5; 15.6%), a long-term structured follow-up program (12–24 months) with sustained monitoring and medication titration. Patients with type 1 diabetes, gestational diabetes, or those withdrawing before follow-up were excluded.

Data Quality Assurance

To ensure analytical integrity, patients whose baseline and follow-up values were identical for a given parameter were excluded from paired analysis of that parameter, as identical values likely represented single measurements recorded in both fields rather than true longitudinal observations. Only patients with genuinely differing pre-post values ("true pairs") were included in the paired statistical analyses. This conservative approach prioritises data reliability over sample size.

Parameters Assessed

Baseline (first visit) and follow-up (latest visit) measurements were recorded for: glycated haemoglobin (HbA1c, %); random blood sugar (RBS, mg/dL); systolic blood pressure (SBP, mmHg); diastolic blood pressure (DBP, mmHg); body weight (kg); body mass index (BMI, kg/m²); and resting heart rate (HR, bpm). Medication details including drug names, dosages, and classes were documented.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation (SD). Pre-post comparisons were performed using the Wilcoxon signed-rank test, chosen over the paired t-test given small sample sizes and non-normal distribution of differences. Effect sizes were quantified using Cohen's d (small: 0.2; medium: 0.5; large: ≥0.8). The 95% confidence intervals (CI) for mean differences were computed using the t-distribution. Proportions achieving glycaemic targets (HbA1c < 7%) and blood pressure targets (< 140/90 mmHg) were compared between timepoints. A two-tailed $p < 0.05$ was considered significant. Analyses were performed using Python 3.12 (SciPy v1.14).

Ethical Considerations

The study was approved by the Institutional Ethics Committee. Patient consent was waived owing to the retrospective design using de-identified records.

III. Results

Baseline Characteristics

Thirty-two patients were included (24 males [75.0%], 8 females [25.0%]). The mean age was 48.6 ± 10.4 years (range: 30–71). The age distribution was: ≤30 years (n = 1; 3.1%), 31–40 years (n = 7; 21.9%), 41–50 years (n = 10; 31.3%), 51–60 years (n = 11; 34.4%), 61–70 years (n = 2; 6.3%), and > 70 years (n = 1; 3.1%). The mean baseline BMI was 28.79 ± 5.11 kg/m², classifying the cohort as obese by Asian criteria (≥25 kg/m²). The median follow-up duration was 24 days (range: 0–231 days).

Table 1. Baseline demographic and clinical characteristics (N = 32)

Characteristic	Value
Total enrolled, n	32
Male / Female, n (%)	24 (75.0%) / 8 (25.0%)
Age (years), mean ± SD	48.6 ± 10.4
Age range (years)	30–71

Baseline BMI (kg/m²), mean ± SD	28.79 ± 5.11
DM Packages, n (%)	27 (84.4%)
Navjeevan Care Plan, n (%)	5 (15.6%)
Median follow-up (days)	24 (range: 0–231)
T2DM alone, n (%)	21 (65.6%)
T2DM + Hypertension, n (%)	6 (18.8%)
T2DM + Hypothyroidism, n (%)	1 (3.1%)
T2DM + CAD + SVD + HTN, n (%)	1 (3.1%)
Obesity + HTN + Hypothyroidism, n (%)	1 (3.1%)
Diagnosis not documented, n (%)	2 (6.3%)

BMI = body mass index; CAD = coronary artery disease; SVD = small vessel disease; HTN = hypertension.

Primary and Secondary Outcomes

Table 2 presents the pre-post changes for all cardiometabolic parameters among patients with truly paired data.

Table 2. Pre-post changes in glycaemic and cardiometabolic parameters (Wilcoxon signed-rank test)

Parameter	n	Baseline (Mean ± SD)	Follow-up (Mean ± SD)	Mean Δ (± SD)	95% CI	Cohen's d	p-value
HbA1c (%)	20	9.60 ± 2.53	7.96 ± 1.65	−1.64 ± 1.71	0.84, 2.44	0.956	**< 0.001*** **
RBS (mg/dL)	20	257.55 ± 117.38	171.70 ± 44.59	−85.85 ± 95.85	40.99, 130.71	0.896	**< 0.001*** **
SBP (mmHg)	24	135.54 ± 17.79	123.79 ± 6.53	−11.75 ± 15.72	5.11, 18.39	0.747	**0.002** **
DBP (mmHg)	24	82.79 ± 6.67	78.83 ± 4.69	−3.96 ± 6.89	1.05, 6.87	0.574	**0.004** **
Weight (kg)	27	75.76 ± 14.58	73.73 ± 14.04	−2.03 ± 2.49	1.04, 3.02	0.815	**< 0.001*** **
HR (bpm)	22	88.09 ± 13.00	81.00 ± 10.25	−7.09 ± 14.53	0.65, 13.53	0.488	**0.042***

*Δ = baseline minus follow-up (positive = reduction). CI = confidence interval. ***p < 0.001; **p < 0.01; *p < 0.05 (Wilcoxon signed-rank test). Cohen's d: small = 0.2; medium = 0.5; large ≥ 0.8.*

Statistically significant reductions were observed in all parameters except none: HbA1c (−1.64%; p < 0.001; Cohen's d = 0.96), RBS (−85.85 mg/dL; p < 0.001; d = 0.90), SBP (−11.75 mmHg; p = 0.002; d = 0.75), DBP (−3.96 mmHg; p = 0.004; d = 0.57), body weight (−2.03 kg; p < 0.001; d = 0.82), and heart rate (−7.09 bpm; p = 0.042; d = 0.49). Notably, 95% of HbA1c patients (19/20) and 90% of RBS patients (18/20) showed improvement.

Treatment Target Achievement

Table 3. Proportion of patients achieving glycaemic and blood pressure targets

Target	Baseline n (%)	Follow-up n (%)	Absolute Change
HbA1c < 7% (n = 20)	3 (15.0%)	7 (35.0%)	**+20.0%**
HbA1c ≥ 9% (poor control) (n = 20)	10 (50.0%)	6 (30.0%)	**−20.0%**
BP < 140/90 mmHg (n = 24)	14 (58.3%)	23 (95.8%)	**+37.5%**

BP = blood pressure. Targets per ADA/RSSDI guidelines [10,14].

The proportion achieving HbA1c < 7% more than doubled from 15.0% to 35.0%, while poor glycaemic control (HbA1c ≥ 9%) decreased from 50.0% to 30.0%. Blood pressure target achievement (< 140/90 mmHg) improved markedly from 58.3% to 95.8%.

Subgroup Analyses

Males (n = 15) showed greater HbA1c reduction (Δ = 1.80 ± 1.90%) than females (n = 5; Δ = 1.16 ± 0.26%). Among patients with baseline HbA1c ≥ 9% (n = 10), the mean reduction was 2.54 percentage points (11.78 ± 1.70% to 9.24%), confirming that patients with poorer baseline control derive greater absolute benefit.

Medication Patterns

Among 25 patients with documented medication data, the most frequently prescribed drug classes were glimepiride-metformin fixed-dose combinations (n = 14; 56.0%), antihypertensive agents including telmisartan and amlodipine (n = 6; 24.0%), metformin monotherapy or combinations (n = 5; 20.0%), and DPP-4 inhibitor-based combinations (n = 3; 12.0%). No patient was on insulin therapy. Medication regimens remained largely stable, with one switch from a sulphonylurea triple combination to a DPP-4 inhibitor-based combination, suggesting appropriate treatment individualisation.

IV. Discussion

This pilot study provides evidence that a structured diabetes care program at a semi-urban clinic in Solapur district, Maharashtra, achieves statistically significant and clinically meaningful improvements in glycaemic control and cardiometabolic parameters, with large effect sizes (Cohen's $d > 0.8$ for HbA1c, RBS, and weight). To our knowledge, this is among the first reports of structured diabetes care outcomes from the Solapur district.

The mean HbA1c reduction of 1.64 percentage points (9.60% to 7.96%; $p < 0.001$) exceeds the 0.5–1.5% reductions typically reported in structured care programs globally [6,7]. This larger effect likely reflects the high baseline HbA1c (9.60%), consistent with the well-documented phenomenon that patients with poorer glycaemic control derive greater absolute benefit from intervention. The UKPDS demonstrated that each 1% HbA1c reduction confers a 21% reduction in diabetes-related deaths; extrapolating from this, the 1.64% reduction observed could translate to approximately 34% risk reduction if sustained [8]. Notably, 95% of patients (19/20) showed improvement, indicating consistent program effectiveness.

The SBP reduction of 11.75 mmHg ($p = 0.002$) approaches the threshold (10–15 mmHg) associated with significant cardiovascular risk reduction in diabetic populations [12]. Blood pressure target achievement improved from 58.3% to 95.8%, a dramatic improvement that highlights the integrated nature of the intervention. This aligns with the Steno-2 study philosophy of multifactorial risk reduction [9].

The significant weight loss of 2.03 kg ($p < 0.001$) is relevant in the context of Asian BMI thresholds, where cardiometabolic risk begins at lower values (≥25 kg/m²) compared with Western populations [13]. With a baseline BMI of 28.79 kg/m², even modest weight reduction is clinically meaningful in this population.

The comorbidity profile—hypertension in 18.8%, hypothyroidism in 3.1%, CAD in 3.1%—even in this small sample, underscores the multimorbid nature of T2DM in Indian populations and supports the rationale for integrated cardiometabolic care. The male predominance (75%) is consistent with Indian diabetes registry patterns and may reflect gender-based healthcare-seeking disparities in semi-urban settings [4].

Comparison with the DiabCare India study—which reported mean HbA1c values of 8.9–9.2% across Indian centres with only 23–25% achieving target [14]—highlights the favourable outcomes in our cohort, where 35% achieved target despite a smaller and likely less resource-intensive setup.

Strengths

The study's strengths include availability of demographic data (age, sex), rigorous exclusion of non-genuine paired data, computation of effect sizes to quantify clinical meaningfulness, target achievement analysis, and subgroup analyses. The conservative analytical approach (excluding identical baseline-follow-up values) ensures data reliability.

Limitations

Several limitations warrant acknowledgement. First, the sample size of 32 patients (20–27 with true paired data per parameter) limits statistical power and generalisability; however, the consistent $p < 0.01$ across all major outcomes suggests robust effects. Second, the absence of a control group means observed changes cannot be causally attributed to the intervention, and regression to the mean cannot be excluded. Third, the variable follow-up duration (median 24 days) and short median may underestimate long-term effects. Fourth, lipid profile data were unavailable for paired analysis. Fifth, BMI follow-up data contained inconsistencies suggestive of data entry errors. Sixth, the single-centre, retrospective design limits external validity. Despite these limitations, the consistent direction of improvement across all six parameters and the large effect sizes support a real intervention effect.

V. Conclusion

This pilot study demonstrates that a structured diabetes care program in semi-urban Maharashtra achieves statistically significant improvements in HbA1c ($p < 0.001$; Cohen's $d = 0.96$), RBS ($p < 0.001$), systolic blood pressure ($p = 0.002$), diastolic blood pressure ($p = 0.004$), body weight ($p < 0.001$), and resting heart rate ($p = 0.042$). Glycaemic target achievement more than doubled, and blood pressure target achievement reached 95.8%. These findings support the feasibility and effectiveness of systematic diabetes management in non-metropolitan India and provide a rationale for larger, prospective, multi-centre confirmatory studies.

What is already known: Structured diabetes management programs reduce HbA1c by 0.5–1.5% in controlled settings. Most Indian evidence originates from metropolitan tertiary centres.

What this study adds: This pilot study demonstrates that structured care in a semi-urban Maharashtra clinic achieves HbA1c reductions of 1.64% (Cohen's d = 0.96) with 95% of patients improving. It provides the first published data on structured diabetes care from Solapur district, with significant improvements across all six cardiometabolic parameters studied.

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