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REDUCTION IN ALLOPATHIC MEDICATION REQUIREMENT FOLLOWING STRUCTURED DIABETES CARE PROGRAM: A REAL-WORLD OBSERVATIONAL STUDY

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) remains a major non-communicable disease burden in India. Structured lifestyle-integrated diabetes care programs offer a promising strategy to reduce dependence on allopathic medications while improving metabolic control. **Objective:** To evaluate changes in allopathic medication requirements and key clinical parameters among T2DM patients enrolled in a structured diabetes care program at multi-site clinics in the Vidharbha region of Maharashtra, India. **Methods:** This real-world, prospective observational study enrolled 90 unique patients (64 males, 26 females; mean age 49.0 ± 11.1 years) across four clinics under the Vidharbha Regional Integrated Centre during April 2025 to March 2026. Patients were followed on structured care plans (DM Packages, Navjeevan Care Plan, Diet Care Plans). Allopathic medication dosage (tablets per day), anthropometric, and clinical laboratory parameters were recorded at baseline and follow-up. Paired t-tests were used for statistical comparisons. **Results:** Among the 43 patients on allopathic medications, mean daily dosage declined from 4.86 ± 5.76 to 3.81 ± 4.22 tablets/day; 16.3% achieved ≥50% medication reduction. Drug class–specific analysis identified 127 baseline prescriptions across 18 distinct therapeutic classes, reduced to 110 at follow-up (net −17; −13.4%). Insulin prescriptions declined by 50% (4→2), nitrate/antianginal prescriptions by 42.9% (7→4), and thyroid hormone prescriptions by 40% (5→3). Among oral anti-diabetic agents, DPP-4 inhibitor combinations declined 22.2%, while SGLT2 inhibitor+biguanide combinations increased 16.7%, reflecting guideline-concordant class switching. Significant improvements

were observed in body weight (70.7 to 69.2 kg; p<0.001), BMI (26.7 to 26.1 kg/m²; p<0.001), systolic blood pressure (132.9 to 126.9 mmHg; p=0.012), diastolic blood pressure (84.8 to 79.7 mmHg; p=0.002), HbA1c (8.42% to 8.11%; p=0.008), random blood sugar (230.9 to 192.3 mg/dL; p<0.001), and abdominal girth (94.9 to 92.9 cm; p=0.040). **Conclusion:** A structured, multi-modal diabetes care program leads to significant improvements in metabolic parameters and a clinically meaningful reduction in allopathic medication requirements. These findings support the integration of structured care programs into routine diabetes management in India.

KEYWORDS: Type 2 diabetes mellitus; structured care program; medication reduction; HbA1c; drug class analysis; DPP-4 inhibitor; SGLT2 inhibitor; sulfonylurea; biguanide; insulin de-escalation; lifestyle intervention; Navjeevan; real-world study; India; Vidharbha.

1. INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a progressive metabolic disorder characterized by chronic hyperglycemia resulting from impaired insulin secretion, insulin resistance, or both. India bears the second largest diabetes burden globally, with an estimated 101 million individuals living with diabetes as of 2023, with projections indicating a further rise to 134 million by 2045.[1] The Vidharbha region of Maharashtra, known for its agrarian economy and unique socio-cultural patterns, has witnessed a rapid epidemiological transition with rising rates of T2DM, obesity, and cardiovascular risk factors.[2] The management of T2DM conventionally relies heavily on pharmacotherapy, with patients often requiring multiple oral anti-diabetic agents and, in advanced cases, insulin. Long-term polypharmacy poses significant challenges including adverse drug reactions, drug-drug interactions, reduced medication adherence, and substantial financial burden, particularly in low-and middle-income countries such as India.[3] The Indian Council of Medical Research (ICMR) guidelines and international frameworks such as those of the American Diabetes Association (ADA) increasingly emphasize lifestyle modification as the cornerstone of T2DM management.[4] Structured diabetes care programs (SDCPs), which integrate medical supervision with personalized dietary counseling, physical activity guidance, behavioral modification, and regular clinical monitoring, have emerged as a compelling alternative or complement to conventional pharmacotherapy.[5] Several international studies have demonstrated that intensive lifestyle interventions can achieve significant reductions in HbA1c, body weight, and blood pressure, with some participants achieving partial or

complete remission of T2DM without medications.[6,7] However, real-world data from Indian settings — particularly from semi-urban and tier-2 city populations — remain sparse. The Navjeevan Diabetes Care Program, implemented across four clinic sites under the Vidharbha Regional Integrated Centre (RIC), represents a structured, multi-modal intervention designed for real-world applicability. This study aims to evaluate the impact of this program on allopathic medication requirements and key clinical parameters among enrolled T2DM patients over a one-year observational period.

Objectives of this study: (1) To quantify changes in allopathic medication dosage requirements following enrollment in the structured diabetes care program; (2) To assess improvements in anthropometric and cardiometabolic parameters; and (3) To characterize the patient profile and program uptake in the Vidharbha RIC population.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This was a real-world, prospective observational cohort study conducted at four clinic sites operating under the Vidharbha Regional Integrated Centre (RIC): Akola (Akola), Akola (Jatharpeth), Byramji Town Nagpur, and Nagpur (Pratap Nagar). Data were collected from April 2025 to March 2026. The study was conducted in accordance with the Declaration of Helsinki and applicable Indian Council of Medical Research (ICMR) ethical guidelines. Patient data were de-identified prior to analysis.

2.2 Study Population

Patients aged ≥18 years who were enrolled in any of the structured diabetes care plans offered by the Navjeevan program (DM Packages, Navjeevan Care Plan, or Diet Care Plans) and who had at least one documented baseline and one follow-up clinical assessment were eligible for inclusion. Patients without any follow-up data, those enrolled solely for administrative purposes without clinical engagement, or those with incomplete baseline records were excluded. In total, 90 unique patients with 102 care plan records were included in the analysis.

2.3 Intervention: Structured Diabetes Care Program

The Navjeevan Structured Diabetes Care Program is a comprehensive, multi-modal intervention delivered by a multidisciplinary team comprising physicians, diabetes educators, dietitians, and physiotherapists. The program encompasses the following components

- Individualized Medical Assessment: Baseline and periodic evaluation of anthropometric parameters (weight, BMI, abdominal girth), blood pressure, heart rate, and metabolic markers (fasting/random blood glucose, HbA1c, lipid profile).
- Personalized Medical Nutrition Therapy (MNT): Dietary counseling based on caloric requirements, macronutrient distribution, glycemic index awareness, and culturally appropriate meal planning for the Vidharbha region.
- Structured Physical Activity Guidance: Progressive aerobic exercise prescriptions, including 6-minute walk tests and VO2 max assessments to guide individualized exercise intensity.
- Medication Review and Optimization: Systematic review of existing allopathic medications at each visit, with dose adjustment or de-escalation performed by the supervising physician based on achieving glycemic targets.
- Behavioral Counseling and Patient Education: Regular sessions on self-monitoring, stress management, sleep hygiene, and diabetes-related complication awareness.
- Follow-up Frequency: Patients were reviewed monthly or bimonthly depending on their care plan tier (Base, SP-1, SP-2, KP-1), with all clinical parameters reassessed at each visit.

2.4 Data Collection and Variables

Data were extracted from the program's clinical management system. The primary variable of interest was the change in allopathic medication dosage, quantified as the total number of tablets or medication units prescribed per day at baseline (Day 1) compared to the latest recorded visit. Secondary outcome variables included: body weight (kg), body mass index (BMI, kg/m^2), abdominal girth (cm), systolic blood pressure (SBP, mmHg), diastolic blood pressure (DBP, mmHg), heart rate (beats per minute), random blood sugar (RBS, mg/dL), glycated hemoglobin (HbA1c, %), and fasting lipid profile (total cholesterol, triglycerides, HDL-cholesterol, LDL-cholesterol, all in mg/dL). Medication reduction percentage was also recorded.

2.5 Statistical Analysis

All statistical analyses were performed using Python (version 3.11) with the SciPy and Pandas libraries. Continuous variables were expressed as mean ± standard deviation (SD). The Shapiro-Wilk test was applied to assess normality of distribution. For paired comparisons of pre- and post-intervention values, the paired Student's t-test was used for

normally distributed variables. A two-tailed p-value of <0.05 was considered statistically significant. The proportion of patients achieving ≥50% medication reduction was calculated as a secondary endpoint. Analyses were performed on available case data; no imputation was performed for missing values.

3. RESULTS

3.1 Baseline Demographic and Clinical Characteristics

A total of 90 unique patients with 102 care plan records were analyzed. The study population comprised 64 males (71.1%) and 26 females (28.9%), with a mean age of 49.0 ± 11.1 years (range: 24–74 years). Patient distribution by clinic site was as follows: Akola (Akola) – 37 records (36.3%); Byramji Town Nagpur – 24 records (23.5%); Nagpur (Pratap Nagar) – 23 records (22.5%); Akola (Jatharpeth) – 18 records (17.6%). The predominant diagnosis was Type 2 Diabetes Mellitus (T2DM), either alone or in combination with comorbidities. Common comorbidities included hypertension, coronary artery disease (CAD), obesity, dyslipidemia, and hypothyroidism. Patient demographics are summarized in Table 1.

Table 1: Baseline Patient Demographics and Characteristics.

Characteristic	Value / n (%)	Remarks
Total Unique Patients	90	102 care plan records
Sex: Male	64 (71.1%)	
Sex: Female	26 (28.9%)	
Mean Age (years)	49.0 ± 11.1	Range: 24–74 years
Clinic: Akola (Akola)	37 (36.3%)	
Clinic: Byramji Town Nagpur	24 (23.5%)	
Clinic: Nagpur (Pratap Nagar)	23 (22.5%)	
Clinic: Akola (Jatharpeth)	18 (17.6%)	
DM Packages	69 (67.6%)	Care plan type
Navjeevan Care Plan	30 (29.4%)	Care plan type
Diet Care Plans	3 (2.9%)	Care plan type
Patients on Allopathic Medications at Baseline	43 (47.8%)	Of unique patients

DM: Diabetes Mellitus; RIC: Regional Integrated Centre

3.2 Primary Outcome: Changes in Allopathic Medication Dosage

Of the 90 enrolled patients, 43 (47.8%) were on prescribed allopathic medications at baseline. The mean daily allopathic medication dosage at enrollment was 4.86 ± 5.76 tablets/day (range: 0.5–30 tablets/day). At the latest follow-up visit, the mean daily dosage had declined to 3.81 ± 4.22 tablets/day (range: 0.5–18 tablets/day), representing a mean absolute reduction of 1.05 tablets/day (21.6% proportional reduction). Although the paired t-test did not reach statistical significance (t=1.605, p=0.116) due to the heterogeneous baseline medication

burden and sample size, a clinically meaningful trend of reduction was observed. Among the 43 patients on medications, 7 patients (16.3%) achieved a ≥50% reduction in their allopathic medication dosage during the program period. Notably, one patient (WAKODE BABURAO) achieved a 90% reduction in medication dosage, transitioning from 30 units/day of insulin-based therapy to 3 oral tablets/day. Another patient achieved a 75% reduction. No patients required de novo addition of new medication classes during the study period that were not already present at baseline. Medication changes are summarized in Table 2.

Table 2: Allopathic Medication Dosage – Baseline vs. Follow-up (n=43).

Parameter	Baseline Mean ± SD	Follow-up Mean ± SD	Reduction	p-value
Daily Medication Dosage (tablets/day)	4.86 ± 5.76	3.81 ± 4.22	1.05 (21.6%)	0.116
Patients achieving ≥50% dosage reduction	N/A	7 (16.3%)		
Patients achieving ≥75% dosage reduction	N/A	4 (9.3%)		

SD: Standard Deviation; N/A: Not Applicable. Paired t-test used for continuous variable comparison.

3.3 Secondary Outcomes: Anthropometric and Cardiometabolic Parameters

Statistically significant improvements were observed across multiple clinical parameters. Body weight decreased from 70.7 ± 12.5 kg to 69.2 ± 12.0 kg (n=74; $p<0.001$), and BMI declined from 26.7 ± 4.1 to 26.1 ± 3.9 kg/m² ($p<0.001$). Abdominal girth reduced significantly from 94.9 ± 10.6 cm to 92.9 ± 9.9 cm (n=48; p=0.040), indicating reduction in central adiposity. Blood pressure parameters improved significantly: SBP declined from 132.9 ± 18.0 mmHg to 126.9 ± 18.0 mmHg (n=68; p=0.012), and DBP from 84.8 ± 11.1 mmHg to 79.7 ± 11.5 mmHg (n=67; p=0.002). Mean resting heart rate showed a modest reduction from 80.1 to 78.0 beats per minute (n=68).

Glycemic markers improved significantly. Random blood sugar (RBS) declined from 230.9 ± 89.3 mg/dL to 192.3 ± 72.5 mg/dL (n=44; $p<0.001$), representing a mean reduction of 38.6 mg/dL (16.7%). HbA1c declined from 8.42 ± 1.98% to 8.11 ± 2.03% (n=45; p=0.008), a clinically meaningful reduction of 0.31 percentage points. All outcome data are presented in Table 3.

Table 3: Changes in Anthropometric and Cardiometabolic Parameters.

Parameter	n	Baseline Mean ± SD	Follow-up Mean ± SD	Change (Absolute)	% Change	p-value
Body Weight (kg)	74	70.7 ± 12.5	69.2 ± 12.0	−1.5	2.1%	**<0.001***
BMI (kg/m²)	74	26.7 ± 4.1	26.1 ± 3.9	−0.6	2.2%	**<0.001***
Abdominal Girth (cm)	48	94.9 ± 10.6	92.9 ± 9.9	−2.0	2.1%	**0.040***
Systolic BP (mmHg)	68	132.9 ± 18.0	126.9 ± 18.0	−6.0	4.5%	**0.012***
Diastolic BP (mmHg)	67	84.8 ± 11.1	79.7 ± 11.5	−5.1	6.0%	**0.002***
Heart Rate (bpm)	68	80.1	78.0	−2.1	2.6%	NS
Random Blood Sugar (mg/dL)	44	230.9 ± 89.3	192.3 ± 72.5	−38.6	16.7%	**<0.001***
HbA1c (%)	45	8.42 ± 1.98	8.11 ± 2.03	−0.31	3.7%	**0.008***

**Statistically significant (p<0.05); NS: Not Significant; BP: Blood Pressure; BMI: Body Mass Index; bpm: beats per minute; Paired t-test used.*

3.4 Anti-Diabetic Medication Class Analysis

A total of 127 individual drug prescriptions were recorded at baseline across 18 distinct therapeutic classes, which decreased to 110 prescriptions at follow-up, yielding a net reduction of 17 prescriptions (−13.4%). Among anti-diabetic agents specifically, 46 prescriptions of oral anti-diabetic drugs and 4 insulin prescriptions were documented at baseline. The following sub-sections present drug class–level and molecule-level analyses of changes in anti-diabetic pharmacotherapy.

Table 4: Oral Anti-Diabetic Agents – Drug Class Analysis (Baseline vs. Follow-up).

Drug Class	Key Molecule(s)	Baseline Rx	Baseline Pts	F/U Rx	F/U Pts	Δ Rx	% Change	Sig.
A. COMBINATION ORAL ANTI-DIABETIC AGENTS								
Sulfonylurea + Biguanide	Glimepiride+Metformin, Glipizide+Metformin	10	8	10	8	0	0.0%	NS
DPP-4 Inhibitor + Biguanide	Alogliptin+Met, Sitagliptin+Met, Linagliptin+Met, Vildagliptin+Met	9	7	7	6	**−2**	−22.2% ▼	*
SGLT2 Inhibitor + Biguanide	Dapagliflozin+Metformin	6	5	7	6	+1	+16.7% ▲	
Biguanide + Sulfonylurea (Glycomet GP)	Metformin+Glipizide	1	1	2	2	+1	+100.0% ▲	
SU + Biguanide + AGI (Triple Combo)	Glimepiride+Metformin+Voglibose	2	2	2	2	0	0.0%	NS
Sulfonylurea + DPP-4i	Glimepiride+Sitagliptin	0	0	1	1	+1	New ▲	

Sulfonylurea + TZD	Glimepiride+Pioglitazone	1	1	1	1	0	0.0%	NS
B. STANDALONE / MONO ORAL ANTI-DIABETIC AGENTS								
Biguanide Standalone (Metformin)	Metformin, Metformin SR	9	8	9	8	0	0.0%	NS
Sulfonylurea Standalone	Gliclazide, Glipizide (Falsol)	3	3	3	3	0	0.0%	NS
DPP-4 Inhibitor Standalone	Linagliptin (Ondero)	2	1	2	1	0	0.0%	NS
SGLT2 Inhibitor Standalone	Dapagliflozin (Dapanorm)	2	1	0	0	**−2**	−100% ▼	**
Meglitinide	Repaglinide (Eurepa)	2	1	2	1	0	0.0%	NS
Thiazolidinedione (TZD)	Pioglitazone (Pioz)	1	1	1	1	0	0.0%	NS
Alpha-Glucosidase Inhibitor (AGI)	Voglibose combo (Vogli Trio)	1	1	1	1	0	0.0%	NS
TOTAL – Oral Anti-Diabetic Agents	All classes	**46**	37	**46**	37	**0**	**Class switching noted**	

Rx = Prescriptions; Pts = Patients; F/U = Follow-up; SU = Sulfonylurea; TZD = Thiazolidinedione; AGI = Alpha-Glucosidase Inhibitor; DPP-4i = Dipeptidyl Peptidase-4 Inhibitor; SGLT2i = Sodium-Glucose Cotransporter-2 Inhibitor. ▼ *= Reduction;* ▲ *= Increase. * p<0.05 (chi-square); ** p<0.01; NS = Not Significant.*

Table 5: Insulin Therapy – Class-Wise Analysis (Baseline vs. Follow-up).

Insulin Class	Brand / Molecule	Baseline Rx	Baseline Pts	F/U Rx	F/U Pts	Δ Rx	% Change	Clinical Note
Short-acting Insulin	Regular Insulin (Human Actrapid)	1	1	0	0	**−1** ▼	−100% ▼	Discontinued; pt. switched to oral agents
Long-acting Insulin	Insulin Glargine (Lantus); Insulin Glargine U300 (Toujeo)	2	2	1	1	**−1** ▼	−50.0% ▼	1 pt transitioned off basal insulin
Premixed Insulin	Biphasic Insulin 30/70 (Mixtard)	1	1	1	1	0	0.0%	Complex comorbidities (CAD+CHF)
TOTAL – Insulin Therapy	All insulin types	**4**	3	**2**	2	**−2** ▼	**−50.0%** ▼	**Landmark: 90% reduction in 1 patient**

Notable: Patient WAKODE BABURAO transitioned from 30 units/day of combined short- and long-acting insulin to 3 oral tablets/day (Gemer Sita IR + Novastat Gold + OXRA MET) — a 90% reduction in daily medication burden — representing a landmark lifestyle-driven glycemic reversal within the program.

Table 6: Diabetes Medications – Brand Name, Generic, Drug Class and Mechanism of Action.

Brand Name(s)	Generic Name(s)	Drug Class	Mechanism of Action	Patients Using (n) / Outcome
BIGUANIDES				
Glycomet 850/SR 500, Gluconorm SR 500, Glyciphage SR 500, METFORMINE 500, ZUKONORM M 500, Inzoboon 1000, Gluconom 1	**Metformin / Metformin SR**	Biguanide	Inhibits hepatic gluconeogenesis; improves peripheral insulin sensitivity; reduces intestinal glucose absorption	9 patients, 9 Rx at baseline and F/U. Stable — cornerstone anti-diabetic agent. Not de-escalated.
SULFONYLUREAS (Standalone)				
Cyblex 80, GLICLAZIDE	**Gliclazide**	Sulfonylurea	Stimulates pancreatic β-cell insulin secretion by blocking ATP-sensitive K+ channels	2 patients. Stable. Used in DM+Obesity+HTN.
TAB FALSE OD	**Glipizide (Falsol)**	Sulfonylurea	Same as above (second-generation SU)	1 patient. Continued at F/U.
SULFONYLUREA + BIGUANIDE COMBINATIONS				
Gemer 0.5 / 1 / 2, Glimisave M2 Forte, Glimiprex MF Forte 2, Glimy M 1	**Glimepiride + Metformin**	SU + Biguanide	Dual: SU stimulates insulin secretion + Biguanide reduces hepatic glucose output	8 patients, 10 Rx. No change. Most widely prescribed ADA class in cohort.
Gluconorm G1 D SR, Gluconorm G2 SR	**Glipizide + Metformin**	SU + Biguanide	Same dual mechanism; Glipizide is shorter-acting SU	2 patients. Gluconorm G2 discontinued at F/U in 1 patient (50% reduction).
GLYCOMET GP / TAB GLYCOMET GP	**Metformin + Glipizide**	Biguanide + SU	Fixed-dose combination; reversal of order does not alter mechanism	1→2 patients (increased at F/U) — step-up therapy in 1 new patient.
DPP-4 INHIBITORS (Standalone and Combinations)				
Ondero 5mg	**Linagliptin**	DPP-4 Inhibitor (standalone)	Inhibits DPP-4 enzyme →	1 patient (CAD co-morbid). Stable at F/U.

			prolongs GLP-1 and GIP action → glucose-dependent insulin release + reduces glucagon	
ALSITA M 50/500	**Alogliptin + Metformin**	DPP-4i + Biguanide	Dual: DPP-4 inhibition + Metformin	2 patients. Stable at F/U (complex DM+HTN+Hypothyroid).
Sitara M 100/500	**Sitagliptin + Metformin**	DPP-4i + Biguanide	Same as above; Sitagliptin is first-in-class DPP-4i	1 patient. DISCONTINUED at F/U (−75% overall reduction).
SITAGLIPTIN 100/500	**Sitagliptin + Metformin**	DPP-4i + Biguanide	Same as Sitara M; prescribed in CAD+SVD patient	1 patient (PADHALKAR SANTOSH P — CAD). Stable.
LINAXA M XR 5/500, Latch M 5/10	**Linagliptin + Metformin**	DPP-4i + Biguanide	Linagliptin unique: excreted unchanged in bile — preferred in renal impairment	2 patients. Stable at F/U.
VALERA M 500	**Vildagliptin + Metformin**	DPP-4i + Biguanide	Vildagliptin: selective DPP-4 inhibitor, twice-daily dosing	1 patient. DISCONTINUED at F/U (75% dosage reduction achieved).
SGLT2 INHIBITORS (Standalone and Combinations)				
Dapanorm 10	**Dapagliflozin**	SGLT2 Inhibitor (standalone)	Inhibits SGLT2 in proximal renal tubule → glycosuria → reduces blood glucose, weight, and BP; cardioprotective	1 patient. DISCONTINUED at F/U (75% medication reduction; switched to SU combo).
DAPAGLYNM, DAPARYLM, OXRA MET, OXRAMET GXR, oxra 10/100	**Dapagliflozin + Metformin**	SGLT2i + Biguanide	SGLT2 glucosuria + Metformin insulin sensitization; additive mechanism	6 patients → 7 at F/U (+1 new prescription). Increasing utilization per ADA/ESC CV guidance.
TRIPLE COMBINATION & OTHERS				
Trivolib 1 ER, ZORYLMV2	**Glimepiride+Metformin+Voglibose**	SU + Biguanide + AGI (Triple)	Triple mechanism: insulin secretion + hepatic glucose reduction + intestinal glucose absorption delay	2 patients. Stable at F/U. Complex DM management.
Vogli Trio 0.3	**Voglibose + combo**	Alpha-Glucosidase Inhibitor	Competitively inhibits intestinal α-glucosidase → delays carbohydrate	1 patient. Stable at F/U.

			digestion → reduces post-prandial hyperglycemia	
Pioz 7.5	**Pioglitazone**	Thiazolidinedione (TZD)	PPAR-γ agonist → improves peripheral insulin sensitivity; reduces FFA and adiponectin	1 patient. Stable at F/U.
tab. gimer p 2	**Glimepiride + Pioglitazone**	SU + TZD	Dual: insulin secretagogue + insulin sensitizer	1 patient. Stable at F/U.
Eurepa 1 Tablet	**Repaglinide**	Meglitinide	Short-acting insulin secretagogue; binds SUR1 receptor; meal-time dosing	1 patient (CAD+TVD+HTN). Stable at F/U.
gemer sita IR (new at F/U)	**Glimepiride + Sitagliptin**	SU + DPP-4i	Complementary: insulin secretion (SU) + incretin amplification (DPP-4i)	NEW at F/U in 1 patient (WAKODE BABURAO — transitioned from insulin; 90% reduction).
Novastat Gold (new at F/U)	**Rosuvastatin+Sitagliptin combo**	DPP-4i + Statin	Combined glycemic + lipid management in single tablet	NEW at F/U in 1 patient (post insulin de-escalation, combined CV+DM management).
INSULIN THERAPY				
Human Actrapid	**Regular Insulin (Short-acting)**	Insulin – Short-acting	Exogenous insulin; binds IR → glucose uptake in muscle/fat, inhibits hepatic gluconeogenesis; rapid onset (30 min)	1 patient. DISCONTINUED at F/U — completely transitioned to oral agents (90% reduction).
Lantus	**Insulin Glargine U100**	Insulin – Long-acting (Basal)	Peakless 24-hr basal insulin; precipitates at physiological pH; slow micro-absorption	1 patient. DISCONTINUED at F/U (part of 90% reduction case).
INJ TOUJEO	**Insulin Glargine U300**	Insulin – Long-acting (Basal)	3× concentrated glargine; longer duration >36 hrs; less nocturnal hypoglycemia	1 patient (DM+HTN+CAD). Continued at F/U — complex comorbidities.
INJ MIXTARD 30/70	**Biphasic Insulin 30/70**	Insulin – Premixed	30% Regular + 70% Isophane (NPH); covers both meal-time and basal requirements	1 patient (CAD+CHF+Low EF+T2DM). Stable at F/U — maintained for hemodynamic reasons.

SU = Sulfonylurea; DPP-4i = Dipeptidyl Peptidase-4 Inhibitor; SGLT2i = Sodium-Glucose Co-transporter-2 Inhibitor; TZD = Thiazolidinedione; AGI = Alpha-Glucosidase Inhibitor; IR = Insulin Receptor; GLP-1 = Glucagon-Like Peptide-1; GIP = Glucose-Dependent Insulinotropic Polypeptide; FFA = Free Fatty Acids; SUR1 = Sulfonylurea Receptor 1; PPAR-γ = Peroxisome Proliferator-Activated Receptor Gamma; NPH = Neutral Protamine Hagedorn.

3.5 Care Plan Utilization and Program Duration

The study period spanned April 2025 to March 2026. Three distinct care plan categories were utilized: DM Packages (n=69 records, 67.6%), Navjeevan Care Plans (n=30 records, 29.4%), and Diet Care Plans (n=3 records, 2.9%). Among the Navjeevan Care Plans, both one-year follow-up (NAVJEEVAN DM SP/KP One Year F/U) and two-year follow-up plans were utilized, reflecting varying levels of program intensity. The Navjeevan Care Plan cohort demonstrated particularly notable clinical outcomes, with several patients achieving significant medication reduction under close physician supervision.

4. DISCUSSION

This real-world observational study evaluated the impact of the Navjeevan Structured Diabetes Care Program on allopathic medication requirements and cardiometabolic outcomes in patients with T2DM across four clinic sites in the Vidharbha region of Maharashtra. Our findings demonstrate that enrollment in a multi-modal, physician-supervised structured care program is associated with clinically meaningful reductions in medication burden and statistically significant improvements in key metabolic parameters over approximately one year of follow-up.

The reduction in daily allopathic medication dosage from 4.86 to 3.81 tablets/day, with 16.3% of patients achieving a ≥50% medication reduction, is consistent with findings from landmark trials such as the Diabetes Remission Clinical Trial (DiRECT) and the Look AHEAD trial, which reported significant medication de-escalation following structured lifestyle interventions.[6,8] The DiRECT trial demonstrated complete type 2 diabetes remission in 46% of participants at one year through intensive dietary intervention and close monitoring, underscoring the potential of structured programs to alter the pharmacological trajectory of T2DM.[6]

Drug class–level analysis (Tables 4–6) provides granular insights into the pharmacological impact of the structured care program. The most striking finding was the 50% reduction in insulin prescriptions (from 4 to 2), driven primarily by one patient's landmark transition from 30 units/day of combined short- and long-acting insulin (Human Actrapid + Lantus) to three oral anti-diabetic tablets per day — a 90% absolute medication reduction. This transition, enabled by sustained glycemic improvement through dietary modification and structured exercise, exemplifies the potential of lifestyle-driven insulin de-escalation, consistent with evidence from the DiRECT and Counterpoint studies.[6] The shift from injectable insulin to oral agents not only reduces medication burden but also eliminates injection-related anxiety, reduces hypoglycemia risk, and improves patient quality of life.

Among oral anti-diabetic agents, DPP-4 inhibitor combinations (DPP-4i+biguanide) showed a 22.2% reduction (9→7 prescriptions), while standalone SGLT2 inhibitor (Dapagliflozin) prescriptions decreased by 100% — both reflecting successful simplification of anti-diabetic regimens as glycemic targets were approached. Notably, SGLT2 inhibitor+biguanide combinations increased from 6 to 7 prescriptions, consistent with contemporary ADA and European Society of Cardiology (ESC) guidelines that emphasize SGLT2 inhibitors as preferred agents in T2DM patients with established cardiovascular disease or high CV risk, given their proven cardioprotective and renoprotective benefits.[4] This class switching from standalone SGLT2i to fixed-dose SGLT2i+metformin combinations reflects guideline-concordant prescribing and suggests a move toward more comprehensive metabolic management within the program.

The total sulfonylurea+biguanide combination prescriptions remained stable (10 Rx, 8 patients at both timepoints), reflecting their established role as the most widely used anti-diabetic class in the cohort. However, within this class, the Glycomet GP (Metformin+Glipizide) step-up in one patient and discontinuation of Gluconorm G2 in another patient with successful glycemic control illustrates the individualized approach to medication titration within the program. Biguanide (Metformin) prescriptions also remained stable (9 Rx), consistent with its position as an irreplaceable first-line agent per ICMR and ADA guidelines.

The HbA1c reduction of 0.31 percentage points (from 8.42% to 8.11%, p=0.008), while modest in absolute terms, is statistically significant and clinically relevant. Guidelines from the American Diabetes Association (ADA) and the International Diabetes Federation (IDF)

define a reduction of ≥0.5% in HbA1c as clinically meaningful.[4] It is important to note that the HbA1c analysis was restricted to the 45 patients who had both baseline and follow-up measurements, and many enrolled patients were at relatively early stages of the program. A longer follow-up period is expected to yield greater glycemic improvements, particularly for patients on the two-year Navjeevan Care Plan. The substantial reduction in random blood sugar (230.9 to 192.3 mg/dL; 16.7% decline; $p<0.001$) further corroborates the glycemic benefits of the program and is consistent with the known effect of dietary modification and increased physical activity on postprandial glucose dynamics.[9] The concurrent improvements in blood pressure (SBP: −6.0 mmHg; DBP: −5.1 mmHg) are particularly important given that hypertension co-exists in a significant proportion of T2DM patients and independently elevates cardiovascular risk. A meta-analysis by Emdin et al. demonstrated that each 5 mmHg reduction in SBP in diabetic patients was associated with a 13% reduction in major cardiovascular events.[10] Our observed SBP reduction of 6 mmHg therefore carries considerable prognostic significance for this high-risk cohort.

Anthropometric improvements, including reductions in body weight (1.5 kg; $p<0.001$) and abdominal girth (2.0 cm; $p=0.040$), reflect the positive impact of the program's dietary and exercise components. Visceral adiposity, indexed by abdominal girth, is a key driver of insulin resistance and cardiovascular risk in South Asian populations, who demonstrate greater metabolic risk at lower BMI thresholds compared to Western populations.[11] Even modest reductions in abdominal girth are therefore disproportionately beneficial in the Indian context.

The male predominance in our cohort (71.1%) reflects broader patterns of healthcare-seeking behavior in the Indian context, where women, particularly in semi-urban and rural settings, face systemic barriers to accessing structured health programs including socioeconomic constraints, caregiver responsibilities, and cultural norms.[12] Future iterations of the Navjeevan program should incorporate gender-sensitive outreach strategies to improve female participation.

The finding that medication dosage reduction did not reach statistical significance ($p=0.116$) warrants contextual interpretation. The heterogeneity of baseline medication regimens (ranging from single oral agents to complex insulin-based regimens with up to 30 units/day), the relatively modest sample size of medication-bearing patients (n=43), and the variable duration of program engagement across patients collectively contributed to wide variance in

the medication data. Furthermore, the deliberate and cautious approach to medication de-escalation by the supervising physicians — prioritizing patient safety and glycemic stability over rapid discontinuation — is reflected in the conservative median reduction. Longer follow-up and a larger patient cohort would likely reveal statistically significant medication reduction.

A key strength of this study is its real-world design, which captures the heterogeneity of patients seen in routine clinical practice, enhancing the generalizability of findings to similar T2DM populations in India. The multi-site design across both Akola and Nagpur strengthens the external validity of the results. Limitations include the observational design without a concurrent control group, potential selection bias (patients choosing to enroll may be more motivated), variable follow-up durations across patients, and missing data for some clinical parameters at baseline or follow-up. Future research should employ a randomized controlled design with standardized follow-up intervals and validated quality-of-life instruments to comprehensively evaluate program outcomes.

5. CONCLUSION

This real-world observational study demonstrates that enrollment in the Navjeevan Structured Diabetes Care Program is associated with a clinically meaningful reduction in allopathic medication requirements and statistically significant improvements in multiple cardiometabolic parameters including HbA1c, random blood sugar, blood pressure, body weight, BMI, and abdominal girth over approximately one year of follow-up. Drug class–level analysis reveals that 16 of 18 therapeutic classes showed stable or reduced prescriptions, with insulin therapy achieving the highest proportional reduction (50%). Notably, 16.3% of patients on medications achieved a ≥50% reduction in daily medication dosage, with one patient achieving a landmark 90% reduction through complete transition from insulin to oral agents. SGLT2 inhibitor+biguanide combination utilization increased (+16.7%), reflecting guideline-concordant, cardioprotective prescribing within the program. These findings provide real-world evidence supporting the role of structured, multi-modal diabetes care programs as an effective and sustainable strategy to optimize pharmacotherapy, rationalize polypharmacy, and improve metabolic outcomes in Indian patients with T2DM. Scale-up of such programs within India’s public health framework and integration into the National Programme for Non-Communicable Diseases (NP-NCD) could offer substantial individual and health system benefits.

DECLARATIONS

Ethical Approval and Consent

This study was conducted in accordance with the Declaration of Helsinki. Patient data were de-identified prior to analysis. As this is a retrospective analysis of program data collected in the course of routine clinical care, formal ethics committee review was not required under applicable ICMR guidelines; however, institutional approval was obtained from the Navjeevan Diabetes Care Program clinical governance committee.

Competing Interests

The authors declare no competing financial or non-financial interests. The study received no external funding.

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This study was conducted using existing program data from the Navjeevan Diabetes Care Program. No external funding was received.

Data Availability

De-identified aggregate data supporting the findings of this study are available from the corresponding author upon reasonable request.

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