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Effectiveness of True Diabetes Reversal Program (TDRP) In Type-2 Diabetes Mellitus (T2DM): A Multicenter, Retrospective, Observational Study

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Abstract: Type 2 Diabetes Mellitus (T2DM) remains a major global health concern, with conventional therapies often presenting limitations in addressing the root cause. Ayurvedic therapies have shown promising potential in diabetes prevention and management. This retrospective, observational 12-week study evaluated the effectiveness of the True Diabetes Reversal Program (TDRP), a holistic regimen aimed at improving glycaemic control by targeting the underlying causes and promoting cellular repair. The primary outcome was the change in glycaemic parameters including HbA1c, fasting plasma glucose (FPG), and post-prandial plasma glucose (PPG). The study also assessed the proportion of patients achieving at least a 1% reduction in HbA1c and compared outcomes in diabetic and prediabetic subgroups. A total of 69% of patients achieved an HbA1c level of ≤7.0%, and 38.1% reached ≤5.7%. HbA1c was significantly reduced ($p<0.0001$), with 57% of patients showing at least a 1% drop. FPG improved significantly ($p=0.007$ overall; $p=0.004$ in diabetics), while both diabetics and prediabetics showed significant reductions in HbA1c ($p=0.001$). Furthermore, 26.2% of patients achieved target levels for both FPG and PPG. The highest mean reduction was observed in HbA1c (17.1%), followed by FPG (16.3%) and PPG (9.9%). TDRP demonstrated meaningful improvements in glycaemic control, suggesting its effectiveness in managing newly diagnosed and uncontrolled T2DM.

Index Terms **- True Diabetes Reversal Program, Type 2 Diabetes Mellitus, Fasting Plasma Glucose, Post-Prandial Plasma Glucose, Glycated Hemoglobin**

I. INTRODUCTION

The burden of diabetes mellitus (T2DM) in developing countries has increased manifold in recent years, with India becoming the diabetes capital of the world (1). In India, nearly 101 million patients with diabetes and 136 million cases of pre-diabetes have been recorded in a recent survey conducted by ICMR.(1) The repercussions on health and longevity of the disease also affect the economy and growth of the individual and collectively the country, making it an imminent and large-scale health issue.

T2DM is a chronic metabolic disease characterized by elevated blood sugar levels, affecting the heart, blood vessels, kidneys, eyes and nerves. Considering the growing concern and burden of T2DM, it is worth noting that conventional treatments are inherently associated with several adverse effects leading to the need for alternative approaches. Ayurveda offers a promising potential for diabetes management with a holistic strategy. However, there is a gap in research which can be filled by collaborations between Ayurvedic practitioners and contemporary healthcare professionals (2). Indigenous methods of controlling blood sugar levels in India have disappeared with the advancement of science and growing urban civilization. A general lack of awareness regarding lifestyle habits and dietary indulgence, mental stress, and unbalanced dietary practices form the base of this sudden upsurge in T2DM (3).

Ayurveda encompasses a multi-pronged approach to manage T2DM through lifestyle modifications, Ayurvedic detoxifying and purifying therapies (e.g., Panchakarma) and Ayurvedic formulations that have pancreatic and extra-pancreatic effects (4). Ayurveda has the potential to not only prevent the development of Diabetes but also preventing and treating its complications (5). For many in the Indian population, Ayurveda is part of their culture, and for T2DM patients do not prefer Western medicine due to their cost, safety concerns and mode of drug administration. Thus Ayurvedic treatments fare better in terms of acceptability and patient satisfaction (4).

There is a plethora of evidence to support the use of several Ayurvedic ingredients, such as Ashwagandha (*Withania Somnifera)* (6), Brahmi (*Bacopa monnieri)* (7), Guduchi (*Tinospora cordifolia)* (8), Shatavari (*Asparigus racemosus)* (9), Tulsi (10), *Curcuma longa*, Amalaki (*Emblica officinalis*) (11) etc in the treatment of T2DM and in preventing its complications. The True Diabetes Reversal Program (TDRP) represents a structured Ayurvedic intervention comprising detoxification therapies and standardized herbal formulations designed to restore metabolic balance and improve glycemic control. Given its basis in classical Ayurvedic principles and increasing patient preference for non-pharmacologic therapies, this program warrants clinical evaluation.

To explore the real-world effectiveness of the TDRP, a retrospective, multicentre observational study was conducted which evaluated the glycemic outcomes of patients with diagnosed T2DM who underwent TDRP regimen. The intervention included multi-herbal preparations, administered in phased visits, without any dietary restrictions and lifestyle recommendations. The objective was to assess the proportion of patients achieving clinically meaningful HbA1c reductions, normalization of plasma glucose levels.

By systematically capturing and analyzing real-world clinical data, this study seeks to provide evidence for the integrative role of Ayurveda in the holistic management of T2DM, potentially bridging traditional knowledge with modern healthcare practices.

II. METHODOLOGY

Study design

This was a multicenter, retrospective observational study conducted at 2 sites - Techclinic Connect Pvt. Ltd, Naupada, Thane and Tech Clinic Connect Pvt Ltd, Shimpoli Road, Borivali, Mumbai, Maharashtra, between January 2024 and November 2024.

Study data

Patients' data of either gender aged 40 to 85 years and diagnosed with Type 2 diabetes mellitus as per ADA guidelines were included in the study.(12,13)

Data from patients diagnosed with any other type of diabetes; poor glycemic control; ESRD (End stage renal disease), or ESLD (End-stage liver disease); auto-immune disorders; AIDS, Hepatitis B, patients on ART; pulmonary or extra pulmonary tuberculosis, pleural effusion, COPD, bronchial asthma, or severely compromised lung function; Hansen's disease or any other infectious disease that needs immediate and long-duration treatment; parkinsonism, Alzheimer's or any other neurodegenerative disease; congestive heart disease, ischemic heart disease and on regular antiplatelet therapy for cardiac disorders; under regular treatment with medication like corticosteroids, immunosuppressant; uncontrolled hypertension; pregnant or lactating mothers; solid tumor/ under treatment for any type of cancer or any life-limiting condition; unable to take oral medication due to any physical condition; addiction to substance-tobacco, alcohol, cigarettes or any other; extremely elevated liver enzymes or any other biological assessment measure that the investigator deems unfit for were excluded from the study.

Ethics statement

Ethical approval was obtained from an Institutional Ethics Committee (IEC) for Biomedical and Health Research D. Y. Patil Deemed to be University School of Medicine, Navi-Mumbai [Registration #: EC/NEW/INST/2019/473 (DHR, MOHFW, Govt. of India)] prior to data extraction and analysis. Patient's written informed consent was obtained wherever possible.

True Diabetes Treatment Regimen (TDRP)

The TDRP is a structured Ayurvedic intervention designed to promote metabolic balance and support glycemic control through detoxification, herbal supplementation, and lifestyle modification. The program was individualized and included the following key components: The treatment protocol began with detoxification using *Adyanta Shodhanam* and *Gandharva Haritaki* for gut cleansing, metabolic activation and nourishment through *Jeevanvardhini* and tailored churnas.

Data was collected from all patients who underwent the TDRP for a period of at least 12 weeks. The regimen comprises of multiple preparations, namely Adyanta shodhanam, Gandharva Haritaki, Satvik Shuddhi, MedWave, Tarush Meh, Ayurda, VivaZen syrup and Jeevanvardhini. Additionally, Pranayu was administered to emaciated patients and Amrutaveda was administered to patients only if the difference in FPG and PPG was more than 100 mg/dL. All the medication was made using multiple ayurvedic ingredients that have been proven to reduce glycaemic parameters – FPG, PPG and glycated hemoglobin (HbA1c). To achieve significant results from this treatment, adherence to the prescribed diet protocol and lifestyle routine, as recommended by the physicians, was essential. The TDRP offers a holistic approach to reduce glycemic parameters. The Program regimen is elaborated in table 1.

Table 1: True Diabetes Treatment Regimen

Sr.no.	Visit	Medication name	Dose	Regimen	Remarks
1.	Treatment Initiation (Day 1)	Adyanta shodhanam	3 Tablets thrice daily	After Meal	-
		Gandharva Haritaki	2 tablets twice a day	Before Meal	-
		Satvik Shuddhi	2 tablets thrice daily	Before Meal	-
		MedWave	2 tablets twice a day	After meal	-
		Tarush Meh	2 tablets twice daily	Before Meal	-
		Ayurda	2 tablets twice a day	At 8 am and 6 pm with warm milk/ warm water	-

		VivaZen	2 spoonsful	Before bedtime	Dosage to be increased or decreased as per requirement.
2.	Visit 2 (Week 4± 4 days)	Adyanta shodhanam	2 Tablets thrice daily	After Meal	-
		Gandharva Haritaki	2 tablets twice a day	Before Meal	-
		Satvik Shuddhi	2 tablets twice daily	Before Meal	-
		Tarush Meh	2 tablets twice daily	Before Meal	-
		VivaZen	2 spoonsful	Before bedtime	Dosage to be increased or decreased as per requirement.
		Ayurda	2 tablets twice a day	At 8 am and 6 pm with warm milk/ warm water	-
		Pranayu* (To be administered only to emaciated persons)	2 tablets daily twice	Before meal	*If patient has tendency to lose weight due to diabetes.
		Amrutaveda* (to be administered only is difference in Blood sugar levels- F and PP is more than 100 mg/dl)	2 tablets twice daily	After meal	*If there is difference of more than 100 between Fating and Post prandial blood sugar level in this visit.
3.	Visit 3 (Week 8± 4 days)	Adyanta shodhanam	2 Tablets twice daily	After Meal	-
		Gandharva Haritaki	2 tablets twice a day	Before Meal	-
		Satvik Shuddhi	2 tablets twice daily	Before Meal	-
		VivaZen	2 spoonsful	Before bedtime	Dosage to be increased or decreased as per requirement.
		Jeevanvardhini	2 tablets twice a day	Before meal	-
		Pranayu* (To be administered only to emaciated persons)	2 tablets daily twice	Before meal	*If patient has a tendency to lose weight due to diabetes.
		Amrutaveda* (to be administered only is a difference in Blood sugar levels- F and PP is more than 100 mg/dl)	2 tablets twice daily	After meal	*If there is a difference of more than 100 between Fasting and Postprandial blood sugar levels in this visit.

Study procedures

Data captured from eligible participants included demographic details (age, gender, weight, occupation, diagnoses, medication history, comorbid conditions, and glycemic parameters). Data about the post-treatment glycemic parameters were captured after the patient had received at least 12 weeks of treatment.

Study Outcomes

The primary endpoints of the study were the mean change in glycemic parameters from day 1 to week 12 (±4) days. The secondary endpoints included mean change in glycemic parameters in diabetic and pre-diabetic patients from day 1 to week 12 (±4) days; proportion of patients with improvement of HbA1c level by 1 (%) at week 12 (±4) days; proportion of patients with achievement of target HbA1c (≤5.7% and ≤7.0%) at week 12 (±4) days and proportion of patients with achievement of target plasma glucose (≤100 mg/dL FPG and ≤130 mg/dL PPG) at week 12 (±4) days.

Statistical analysis

As this was an exploratory study, the sample size was not based on any assumptions and calculations. Measurement data was presented as means with SD, whereas categorical and nominal data was presented as numbers and percentages (proportions). Confidence intervals (95% C.I.) were provided wherever applicable. Change in the scores and different parameters were calculated and expressed as means with SD. Post-hoc individual comparisons were done using t-test. Between groups comparisons of different sub-groups (gender, age group, comorbidities) were analyzed for differences in outcomes one-way ANOVA. All testing was done using two-sided tests at alpha 0.05.

III. RESULTS

Demographic and Clinical Characteristics

The study evaluated data from 42 (10 males and 32 females) patients with T2DM who underwent TDRP. Of these, 6 (14.3%) were treatment naïve and 36 (85.7%) had uncontrolled T2DM. Out of the patients evaluated 9 (21.4%) were prediabetic and remaining were diabetic. 37 (88.1%) patients had one or more comorbidities. The baseline characteristics of patients are summarized in Table 2.

Table 2: Demographic and Clinical Characteristics

Characteristics	Variable	Mean ±SD.	Range

Demography	Age (years)	63.07±8.39	41.00 - 82.00
	Weight (kg)	74.97±10.03	49.00 - 102.00
	-	No. (%)	-
Gender	Male	10 (23.8%)	-
	Female	32 (76.2%)	-
Medical Diagnosis	Newly diagnosed (Treatment naive)	6 (14.3%)	-
	Uncontrolled T2DM	36 (85.7%)	-
Diabetes Mellitus (years)	≤5 yrs.	39 (92.9%)	-
	>5 yrs.	3 (7.1%)	-
HbA1C Status	Prediabetic	9 (21.4%)	-
	Diabetic	33 (78.6%)	-
Duration of Therapy	10 to12 weeks	12 (28.6%)	-
	>12 to 16 weeks	23 (54.8%)	-
	>16 to 20 weeks	7 (16.7%)	-
Comorbid Condition status	Present	37 (88.1%)	-
	Absent	5 (11.9%)	-
No. of Comorbid Conditions	No Comorbidity	5 (11.9%)	-
	One Comorbidity	9 (21.4%)	-
	Two Comorbidities	13 (31.0%)	-
	Three Comorbidities	8 (19.0%)	-
	Four Comorbidities	3 (7.1%)	-
	Five Comorbidities	4 (9.5%)	-
	Total patients with comorbidity	37 (88.1%)	-
Comorbid Conditions	Hypertension	23 (54.8%)	-
	Osteoarthritis	13 (31.0%)	-
	Rheumatoid Arthritis	9 (21.4%)	-
	Hypothyroidism	8 (19.0%)	-
	Dyslipidemia	7 (16.7%)	-
	Coronary Artery Disease	4 (9.5%)	-
	Others	9 (21.4%)	-
Concomitant Medication	Metformin	15 (35.7%)	-
	Sulfonylureas	4 (9.5%)	-
	Glimepiride + Metformin	4 (9.5%)	-
	Gliptin	4 (9.5%)	-
	Statin	6 (14.3%)	-
	Angiotensin II Receptor Blocker (ARB)	5 (11.9%)	-
	Anti-platelet	4 (9.5%)	-
	Beta blockers	3 (7.1%)	-
	Calcium Channel Blocker (CCB)	3 (0.07	-
	Alpha-glucosidase inhibitor	1 (2.4%)	-
	Insulin	1 (2.4%)	-
	Proton Pump Inhibitor (PPI)	1 (2.4%)	-
	Thyroxine	1 (2.4%)	-
	Trazodone	1 (2.4%)	-
	Upadacitinib	1 (2.4%)	-
	Dexamethasone	1 (2.4%)	-

**Other comorbid Conditions: Benign Prostatic Hyperplasia (BPH); chronic kidney disease (CKD); Fatty Liver and Total Knee Replacement (TKR); Gout; Hyperlipidaemia; Lumbar Spondylosis; Parkinson's and Post Cholecystectomy; Post PCTA; Urinary Tract Infection (UTI).*
SD: Standard deviations; No.: Number of participants.

Glycemic parameters

Table 3 results indicate significant improvements in glycemic parameters post-treatment. The mean FPG level significantly decreased from 142.66 ± 51.09 mg/dL pre-treatment to 119.46 ± 38.40 mg/dL post-treatment ($p = 0.007$). The postprandial glucose (PPG) level also reduced from 159.19 ± 64.37 mg/dL to 143.48 ± 42.30 mg/dL, but this change was not statistically significant ($p = 0.179$). Additionally, the HbA1c levels significantly decreased from 8.00 ± 1.83% to 6.63 ± 1.32% post-treatment ($p < 0.0001$). The changes from pre-treatment showed a reduction in FPG by -23.20 ± 53.23 mg/dL, in PPG by -15.71 ± 74.53 mg/dL, and in HbA1c by -1.37 ± 0.87%. These findings highlight the effectiveness of the treatment in improving glycemic control.
There was a 17.1% reduction in HbA1c, a 16.3% reduction in FPG and a 9.9% reduction in PPG from baseline (Figure 1). Of the 42 patients, 69% achieved a target HbA1c of ≤7.0% and 38.1% achieved a target HbA1c of ≤5.7%, with 57.1% of patients having a reduction of HbA1c level by 1%. Additionally, with the 12-week TDRP treatment, 26.2% of patients achieved a target of FPG of ≤100 mg/dl and a similar 26.2% achieved a target of PPG of ≤130mg/dl as illustrated in Table 3 and fig.1, 2.

Table 3: Glycemic parameters of participants (n=42)

Parameter	Pre-Treatment	Post Treatment	Change from Pre-Treatment	P* value
FPG level (mg/dL)	142.66±51.09 (80.00 - 317.00)	119.46±38.40 (60.00 - 293.00)	-23.20±53.23 (-189.00 - 116.00)	0.007
PPG level (mg/dL)	159.19±64.37 (94.00 - 427.00)	143.48±42.30 (65.00 - 307.68)	-15.71±74.53 (-255.00 - 115.68)	0.179
HBA1c level (%)	8.00±1.83 (6.00 - 13.70)	6.63±1.32 (5.20 - 10.80)	-1.37±0.87 (-3.60 - -0.20)	<0.0001

Data is represented as *Mean ±SD* (Range). * *Pre-treatment vs post-treatment.* Data was analyzed by within group - *paired t test.*

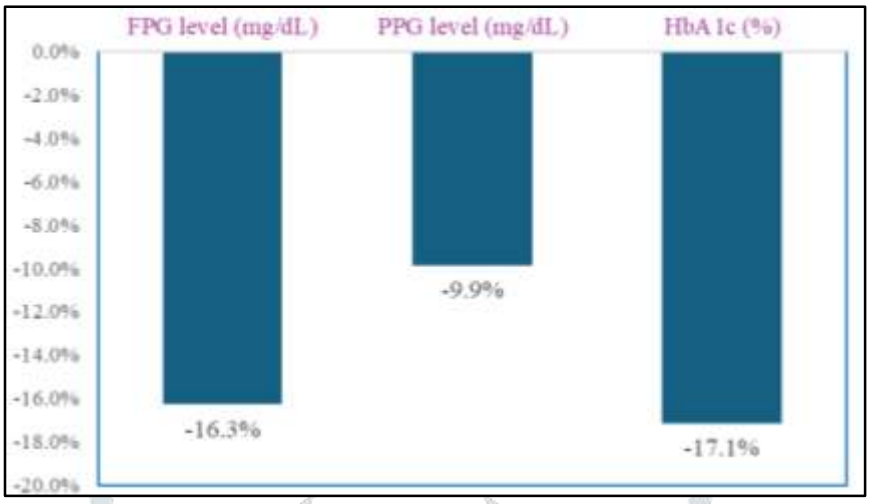

Figure 1: Percentage change from pre-treatment to post-treatment in participants (n=42)

Category-wise glycemic parameters of participants

The subgroup analysis was based on the patient categories presented in Table 4. The categories were diabetes status (prediabetic or diabetic), number of years with diabetes (≤5 years or >5 years' duration), treatment duration (10-12 weeks, >12-16 weeks or >16-20 weeks) and comorbid conditions (whether present or absent). In this study, it was found that with TDRP, the reduction from pre-treatment in FPG in diabetic patients was 35.13 ± 65.80 mg/dl which was statistically significant (p = 0.04). The change in HbA1c from pre-treatment showed a significant reduction in both diabetic (reduction by 1.60 ± 0.85%) as well as in prediabetic (reduction by 1.50 ± 0.91%) patients (p = 0.01 in both groups).

A significant reduction in FPG from baseline was seen in patients who were treated with TDRP for >12-16 weeks (p=0.03). The reduction from pre-treatment in HbA1c was 1.18 ± 0.98 % at 10-12 weeks, 1.42 ± 0.78 % at >12-16 weeks and 1.53 ± 1.04 % at >16-20 weeks of therapy, all of which were significant (p = 0.02, 0.01 and 0.08 respectively).

A significant reduction in FPG of 22.52 ± 56 mg/dl was seen in patients with other comorbid conditions (p=0.02). The reduction from baseline in HbA1c was 1.31 ± 0.82 % in patients with comorbidities and 1.84 ± 1.18 % in those without comorbidities, both of which were significant (p= 0.01 and 0.025 respectively). These findings highlight the effectiveness of TDRP in reducing FPG and HbA1c specifically in various categories of patients as illustrated in Table 4 and fig.2.

The reduction from pre-treatment in FPG in patients with diabetes for ≤5 years was by 26.88 ± 50.33 mg/dL, though not statistically significant (p = 0.107). The reduction in HbA1c from baseline was by 1.40 ± 0.90% in patients with diabetes for ≤5 years (p = 0.413) and 0.97 ± 0.60% in patients with diabetes for >5 years (p = 0.427) (Table 5).

Table 4: Category-wise glycemic parameters of participants (n=42)

Glycemic	Status	Pre-Treatment			Post Treatment			Change from Pre-Treatment			
Parameter		*No*	*Mean ±SD.*	**p*	*No*	*Mean±SD.*	**p*	*No.*	*Mean±SD.*	**p*	*#p*
FPG level (mg/dL)	Pre-diabetic	9	108.44±15.47	-	23	112.27±24.15	-	23	13.35±38.91	-	0.501
	Diabetic	33	151.99±53.53	-	19	28.15±50.00	-	19	35.13±65.80	-	0.004
PPG level (mg/dL)	Pre-diabetic	9	138.78±30.23	-	23	136.36±32.94	-	23	8.33±53.65	-	0.891
	Diabetic	33	164.76±70.22	-	19	152.09±51.05	-	19	24.65±94.77	-	0.165
HBA1c level (%)	Pre-diabetic	9	6.14±0.14	-	23	5.68±0.34	-	23	1.26±0.85	-	0.001
	Diabetic	33	8.50±1.75	-	19	7.77±1.14	-	19	1.50±0.91	-	0.001
Duration of Therapy (weeks)											
FPG level (mg/dL)	10 to 12 weeks	12	146.50±48.29	-	12	116.28±15.28	-	12	30.22±56.01	-	0.088
	>12 to 16 wks.	23	137.20±46.62	-	23	118.79±32.11	-	23	18.41±38.11	-	0.030
	>16 to 20 wks.	7	154.00±72.80	0.723	7	127.09±76.02	0.840	7	26.91±89.92	0.815	0.459

PPG level (mg/dL)	10 to 12 weeks	12	134.30±39.27	-	12	142.43±15.41	-	12	8.13±50.73	-	0.590
	>12 to 16 wks.	23	156.45±51.53	-	23	147.21±50.28	-	23	9.24±64.37	-	0.498
	>16 to 20 wks.	7	210.86±106.62	0.038	7	133.01±48.35	0.745	7	77.84±110.68	0.039	0.112
HBA1c level (%)	10 to 12 weeks	12	7.51±2.15	-	12	6.33±1.48	-	12	1.18±0.98	-	0.002
	>12 to 16 wks.	23	8.00±1.47	-	23	6.58±1.16	-	23	1.42±0.78	-	0.001
	>16 to 20 wks.	7	8.83±2.28	0.325	7	7.30±1.51	0.298	7	1.53±1.04	0.664	0.008
Comorbid Condition status											
FPG level (mg/dL)	Present	37	141.69±54.08	-	37	119.28±40.79	-	37	22.42±56.00	-	0.020
	Absent	5	149.80±19.06	0.744	5	120.80±11.65	0.935	5	29.00±27.76	0.799	0.080
PPG level (mg/dL)	Present	37	161.22±65.06	-	37	143.35±45.04	-	37	17.86±75.58	-	0.159
	Absent	5	144.20±63.66	0.585	5	144.40±9.21	0.959	5	0.20±71.94	0.617	0.995
HBA1c level (%)	Present	37	7.97±1.87	-	37	6.66±1.35	-	37	1.31±0.82	-	0.001
	Absent	5	8.22±1.73	0.775	5	6.38±1.17	0.663	5	1.84±1.18	0.204	0.025

**p: Between group comparisons (ANOVA); #p: Within group- paired t test.*
No. Number of patients; FPG: Fasting plasma glucose; PPG: Postprandial plasma glucose test; HbA1C: Hemoglobin A1C; SD: Standard deviation.

Table 5: Comparison of glycemic control based on the duration of type 2 diabetes mellitus.

Diabetes Mellitus (years)										
Parameter	**Duration**	**n**	**Pre treatment**	**n**	**Post treatment**	**#p**	**n**	**Change in pre & post**	***p (Between initial)**	***p (Between Final-initial)**
FPG level (mg/dL)	≤5 yrs.	39	142.45±52.57	39	115.57±27.64	<0.001	39	26.88±50.33	0.926	0.107
	>5 yrs.	3	145.33±31.50	3	170.00±107.64	-	3	24.67±79.10	0.016	
PPG level (mg/dL)	≤5 yrs.	39	161.03±66.07	39	141.67±42.93	0.390	39	19.36±75.38	0.512	0.258
	>5 yrs.	3	135.33±33.01	3	167.00±27.71	-	3	31.67±48.01	0.324	
HBA1c level (%)	≤5 yrs.	39	8.07±1.87	39	6.67±1.35	<0.001	39	-1.40±0.90	0.334	0.413
	>5 yrs.	3	7.00±0.87	3	6.03±0.84	-	3	-0.97±0.06	0.427	

**p is between group comparisons and #p is within group comparisons. Data is represented in mean ± SD. Data was analysed for within group by using Wilcoxon and student t dependent test; and between group was analysed by student t independent test, n is the number of participants.*

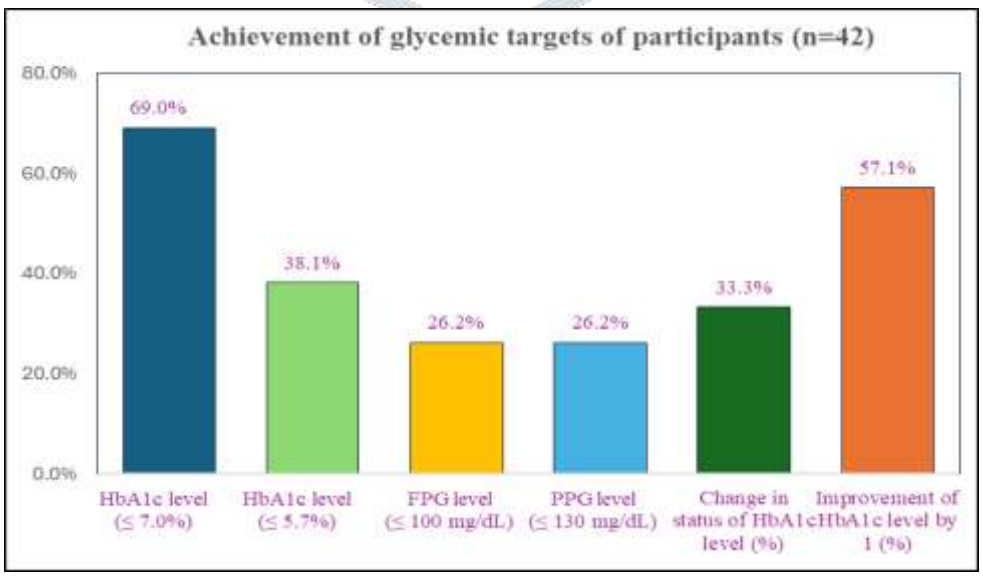

Figure 2: Achievement of glycemic targets and improvement in HbA1c level in participants (n=42)

IV. DISCUSSION

Diabetes Mellitus, also known as *Madhumeha*, has been described in ayurveda, as a multifactorial, complex metabolic disease which has genetic variations (14). Ayurvedic treatments are hypothesised to have both pancreatic and extra-pancreatic effects. Postulated mechanisms of action include – delaying gastric absorption and carbohydrate absorption, inhibition of glucose transport, increased glycogenesis, insulin secretion modification, and reduction of glycogenesis through enzyme inhibition (such as glucose-6-phosphatase, fructose-1, and 6-bisphosphatase) (15).

Traditionally, ayurvedic treatments comprise polyherbal formulations and the combined effect of the phytoconstituents in the herbs is responsible for their therapeutic efficacy. Thus, the ayurvedic management of diabetes mellitus is a multifaceted approach (16). TDRP is designed to control blood sugar levels by addressing the underlying metabolic derangement.

This study found that the TDRP was effective in patients with T2DM. Patients who were treated with TDRP had a significant improvement in their FPG ($p=0.007$) and their HbA1c ($p<0.0001$). The improvement in HbA1c was extremely significant in both diabetic as well as prediabetic groups. While significant improvement in FPG was seen only in recently diagnosed patients (within past 5 years), improvement in HbA1c was seen in all patients. The improvement in FPG and HbA1c was noted even in patients with comorbidities. Thus, it can be understood that TDRP can be an effective treatment option to reduce HbA1c specifically in both prediabetic as well as diabetic patients, and regardless of the presence of comorbid conditions.

A significant portion of patients (69%) achieved the HbA1c target level of ≤7.0%, while 38.1% reached the target level of ≤5.7%. Additionally, 57% of patients exhibited a 1% improvement in HbA1c levels. More than a quarter of patients met the target levels for both fasting and post-prandial plasma glucose. Following 12 weeks of TDRP treatment, the most notable improvement was observed in HbA1c (17.1%), followed by FPG (16.3%) and PPG (9.9%). These findings further support the use of TDRP regimen in T2DM as it can reduce all glycaemic parameters, in newly diagnosed patients as well as patients with T2DM uncontrolled with conventional treatment.

Similar studies are limited but promising. In a case study by Kumari et al, in 2021, where a patient was treated with Panchakarma procedures, oral medicines, ayurvedic Pathyahara and yoga intervention, it was found that the FPG reduced from 174 to 85 mg/dl, PPG reduced from 208 to 102 mg/dl and HbA1c reduced from 8.8% to 6% after 1 year of treatment with no adverse effects reported. Additionally, the patient reported a healthy weight loss and improvements in her energy levels (17).

In a case report published by Thomas et al, 2023, it was found that the Ayurvedic intervention significantly improved his glycaemic parameters, especially his HbA1c (reduction from 14.87% to 6.05%) after about 8 months of treatment (18). In a study published in 2024 by Khobarkar et al, a randomized control trial comparing an ayurvedic formulation Vidangadi Lauha with Metformin, it was found that both treatments were equally effective in reducing FPG, PPG, HbA1c and Body Mass Index (BMI) in obese patients with T2DM over a 3-month period. It was also found that Vidangdi Lauha was more effective in improving additional parameters such as waist-hip ratio, cholesterol, Quality of Life (QoL) and bowel symptoms (19). These results also resonate with the global shift toward non-pharmacologic, lifestyle-based interventions, such as the use of diet, intermittent fasting, yoga, and circadian rhythm optimization, in the management of type 2 diabetes. As a holistic system, Ayurveda inherently integrates these aspects, and programs like TDRP may offer a culturally aligned, sustainable alternative or adjunct to conventional therapies, particularly in resource-limited or medication-averse populations.

A systematic review and meta-analysis conducted by Chattopadhyay et al, 2022, concluded that the current evidence is in favour of the benefit of a range of ayurvedic medicines in improving glycemic control in T2DM patients while calling for more evidence-based research and high-quality randomized controlled trials to confirm the findings (4).

However, this study has several limitations such as retrospective design, the absence of a control group and other confounding factors such as physical activity, dietary adherence, and stress levels were not systematically recorded.

Despite these limitations, the study provides valuable real-world evidence supporting the feasibility and potential efficacy of individualized TDRP in diabetes management. Given the chronic nature and rising prevalence of type 2 diabetes in India, there is an urgent need to explore integrative care models that are culturally relevant, cost-effective, and aligned with patients' beliefs and values. To build upon these findings, prospective randomized controlled trials (RCTs) with larger sample sizes are warranted.

V. CONCLUSION

This retrospective, real-world study demonstrates the effectiveness of an individualized Ayurvedic diabetes reversal protocol (TDRP) in improving glycemic parameters among middle-aged and elderly patients with type 2 diabetes. Notably, the intervention was associated with a significant reduction in HbA1c, fasting plasma glucose (FPG), and postprandial glucose (PPG) over a 12-week period. While limited by its retrospective design and absence of a control group, these findings offer promising evidence supporting Ayurveda's integrative framework in managing chronic metabolic disorders. Future well-controlled clinical trials are essential to validate these outcomes, elucidate mechanisms, and position TDRP as a complementary strategy in diabetes care. As the global burden of type 2 diabetes escalates, culturally aligned, holistic, and sustainable interventions like TDRP warrant serious consideration within public health paradigms.

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VIII. ETHICS APPROVAL

Each site received an ethics committee approval from D.Y.Patil Deemed to be University School of Medicine, Navi Mumbai before initiating the study.

IX. CONFLICT OF INTEREST

Dr. Sandip Mali is associated with Techclinic Connect Private Limited. All other author declares no conflict of interest.

X. DATA AVAILABILITY

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

XI. AUTHORSHIP AND CONTRIBUTION

SMK, SSD, MS, SM, GG; Acquisition, analysis, or interpretation of data, drafting and critical review of the manuscript. All authors have read and agreed to the published version of the manuscript.

XII. REFERENCES

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