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Research Article

Type 2 Diabetes Mellitus

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Evaluation of Long-Term Glycemic Outcomes Following Ayurvedic Panchakarma Therapy and Lifestyle Intervention in Patients with Type 2 Diabetes Mellitus: A One-Year Follow-Up Study

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Background: Diabetes mellitus is a chronic condition marked by high blood sugar - the side effects of long-term allopathic treatment highlight the need for exploring safer, integrative therapies.

Methods: A retrospective, observational, single-centre study was conducted in Maharashtra, India between October 2021 and April 2024. Patients aged 18 years and above with a diagnosis of diabetes mellitus (HbA1c ≥6%) according to the American Diabetes Association and adherent to oral hypoglycemic agents who underwent treatment with the Comprehensive Diabetic Care Program were included in this analysis.

Results: Mean age of the study patients was 53.78 ± 11.08 years, of which 34 (68%) patients were male. Mean weight (day 1: 72.43 ± 12.38 kg, day 30: 70.45 ± 12.33 kg, day 60: 69.41 ± 12.15 kg, day 90: 69.15 ± 12.34 kg, and 1 year: 70.38 ± 12.26, p=0.00), body mass index (day 1: 27.51 ± 3.68, day 30: 26.76 ± 3.83, day 60: 26.43 ± 3.78, day 90: 26.31 ± 3.90, and 1 year: 26.78 ± 3.94, p=0.00), and abdominal girth (day 1: 96.54 ± 8.74 cm, day 30: 93.80 ± 8.98 cm, day 60: 92.14 ± 8.56 cm, day 90: 91.72 ± 8.59 cm, and 1 year: 92.84 ± 8.61 cm, p=0.00) improved at the follow-ups. Glycated hemoglobin (HbA1c) (day 1: 8.28 ± 2.10%, day 30: 7.22 ± 1.45%, day 60: 6.83 ± 1.02%, day 90: 6.55 ± 0.84%, and 1 year: 6.74 ± 0.81, p=0.00) also improved significantly at the follow-ups.

Conclusion: Integrated Ayurvedic management of type 2 diabetes mellitus over a 90-day period has proven highly effective in maintaining long-term glycemic control, even after 1-year of follow-up, whilst significantly reducing dependence on allopathic medications.

Keywords: Ayurveda, Panchakarma, Hyperglycemia, Metabolic syndrome, Glycemic control, HbA1c, Lifestyle modification, Diabetic neuropathy, Cardiovascular risk, Prameha, Madhumeha, Santarpanajanya Vyadhi

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Introduction

Diabetes is a chronic long-term disease that occurs when the body produces insufficient insulin or when the insulin produced is not used in the body, leading to a persistent metabolic disorder.[1] India has emerged as an epicentre of the global diabetes mellitus pandemic. The International Diabetes Federation states that over 415 million individuals suffer from diabetes mellitus worldwide and is projected to rise to an estimated 642 million by 2024.[2] Rapid socioeconomic development, demographic shifts, and the inherent susceptibility of Indian individuals have driven a sharp rise in diabetes mellitus prevalence in India over the past four decades.[3] Moreover, there are macrovascular complications (cardiovascular disease, perivascular disease), microvascular complications (retinopathy, neuropathy, and nephropathy), diabetic foot ulcers, and infections are associated with diabetes mellitus. These complications are a major contributor to early morbidity and mortality in individuals with diabetes, resulting in a shorter life expectancy and substantial financial and other costs, placing a significant economic strain on the Indian healthcare system.[4] The management of diabetes mellitus poses a significant challenge in India due to various factors such as absence of a multisectoral approach, limited surveillance data, low awareness about the disease, its risk factors, and complications, as well as restricted access to healthcare facilities and affordable medications.

Ayurveda, including Panchakarma therapies, offers a holistic approach to managing diabetes mellitus by addressing the root causes and aiming to restore metabolic balance naturally. The current study aimed to investigate the impact of the Comprehensive Diabetic Care (CDC) program on glycemic control in patients with type 2 diabetes mellitus.

Materials and Methods

This was retrospective, observational, single-centre study conducted in India between October 2021 and April 2024. Patients aged 18 years and above with diagnosis of diabetes mellitus (HbA1c ≥6%) according to American Diabetes Association[5] & adherent to oral hypoglycemicagents who underwent treatment with Comprehensive CDC program were included in this analysis. Patients with (i) age below 18 years, (ii) type 1 diabetes mellitus, (iii) pregnancy or lactation, (iv) concurrent severe illness, (v) treatment non-compliance, (vi) contraindication to *Panchakarma* therapy or (vii) incomplete or missing data were excluded from analysis. All patients provided written informed consent for collection and analysis of data for research purposes.

Comprehensive Diabetic Care Program

CDC program is 3-step procedure and each session lasts for approximately 65–75 mins. This procedure was performed on patients after light breakfast. First procedure, *Snehana* was external oleation with Neem (*Azadirechta Indica*) oil massaged on hands, legs, shoulders, thorax, abdomen and back in centripetal manner with upward strokes directed to heart. Duration of this massage was 25–30 mins. Second procedure, *Swedana* was passive heat therapy with Dashmoola (group of 10 herbal roots) decoction at 40°C. Duration of this therapy was 15–20 mins. Third procedure, Basti is per rectal drug administration. Gudmar (*Gymnema sylvestre*), 20% Daruharidra (*Berberis aristate*), and 40% Yashtimadhu (*Glycyrrhiza glabra*). Duration of this procedure was 10 mins. CDC program encompassed total of 8-10 sessions extending over duration of 90 days. Patients were restricted to diet plan of 800–1000 calories intake daily. Diet plan comprised of low carbohydrates, moderate proteins, and low fats. CDC program is demonstrated in Table 1.

Table 1: Treatment table

Steps involved	Product	Mechanism of action	Duration (mins/sitting)	Probable adverse effects
Snehan	Neem oil	Topical application of neem oil helps improve circulation. In diabetic patients, it reduces intramyocellular fat deposition and insulin resistance, thereby protecting the skin from infections and promoting the healing of minor bruises and soreness	30 mins	Rash on body
Swedan	Dashmool Kwath	Dashmool Kwath, when used for Swedana, facilitates the excretion of metabolic waste through sweat. It also helps calm an overactive sympathetic nervous system	15–20 mins	Rash on body
Basti	Gudmar, Daruharidra, Yashtimadhu	**Gudmar** possesses Tikta Rasa, Katu Vipak, and Shita Virya attributes. It is known for its ability to promote the regeneration of pancreatic islet cells. **Daruharidra** is effective in balancing Kapha and Pitta doshas and helps alleviate Abhishyanda. **Yashtimadhu** has Madhura and Tikta Rasa, is Guru and Snigdha in quality, and pacifies Kapha and Pitta doshas. It acts as a potent Rasayana, supporting overall vitality and balance.	10 mins	No

Data collection

Data for patient demographics, anthropometrics, laboratory findings, and medications were collected and analyzed from the patients' medical records. On day 1 of the CDC program, a detailed patient history was taken, anthropometric measurements were recorded and the fasting serum HbA1c levels were measured.

This activity was repeated on day 30, 60, 90, and after 1 year of the CDC program. Data of day 1 was compared with data of the follow-ups. Data of only those patients who had completed a total of 6 sessions was collected and analyzed.

Statistical analysis

Categorical data are expressed as number (percentage) and continuous data are expressed as mean ± standard deviation. Paired t test was used to determine the difference between baseline and follow-up at 90days. P value ≤0.05 was considered as statistically significant. R Version 3.4.1 software was used to analyze the data

Results

Baseline demographic and laboratory details

Mean age of the study patients was 53.78 ± 11.08 years of which 34 (68%) patients were male. Mean weight (day 1: 72.43 ± 12.38 kg, day 30: 70.45 ± 12.33 kg, day 60: 69.41 ± 12.15 kg, day 90: 69.15 ± 12.34 kg, and 1 year: 70.38 ± 12.26, p=0.00), body mass index (day 1: 27.51 ± 3.68, day 30: 26.76 ± 3.83, day 60: 26.43 ± 3.78, day 90: 26.31 ± 3.90, and 1 year: 26.78 ± 3.94, p=0.00), abdominal girth (day 1: 96.54 ± 8.74 cm, day 30: 93.80 ± 8.98 cm, day 60: 92.14 ± 8.56 cm, day 90: 91.72 ± 8.59 cm, and 1 year: 92.84 ± 8.61 cm, p=0.00), systolic blood pressure (day 1: 132.98 ± 17.97 mmHg, day 30: 125.30 ± 12.35 mmHg, day 60: 126.32 ± 13.17 mmHg, day 90: 128.90 ± 12.70 mmHg and 1 year: 128.52 ± 13.29 mmHg, p=0.09), and diastolic blood pressure (day 1: 81.96 ± 8.07 mmHg, day 30: 76.78 ± 8.20 mmHg, day 60: 78.88 ± 8.70 mmHg, day 90: 81.02 ± 7.28 mmHg, and 1 year: 81.18 ± 10.71 mmHg, p=0.40 decreased at the follow-ups). HbA1c (day 1: 8.28 ± 2.10%, day 30: 7.22 ± 1.45%, day 60: 6.83 ± 1.02%, day 90: 6.55 ± 0.84%, and 1 year: 6.74 ± 0.81, p=0.00). The baseline demographic and laboratory details are demonstrated in Table 2.

Table 2: Baseline demographic and laboratory details

Variable	Day 1	Day 30	Day 60	Day 90	1 Year	p value
Age, years	53.78 ± 11.08					
Male	34 (68%)					
Weight, kg	72.43 ± 12.38	70.45 ± 12.33	69.41 ± 12.15	69.15 ± 12.34	70.38 ± 12.26	0.00
Body mass index	27.51 ± 3.68	26.76 ± 3.83	26.43 ± 3.78	26.31 ± 3.90	26.78 ± 3.94	0.00
Abdominal girth, cm	96.54 ± 8.74	93.80 ± 8.98	92.14 ± 8.56	91.72 ± 8.59	92.84 ± 8.61	0.00
Systolic blood pressure, mmHg	132.98 ± 17.97	125.30 ± 12.35	126.32 ± 13.17	128.90 ± 12.70	128.52 ± 13.29	0.09
Diastolic blood pressure, mmHg	81.96 ± 8.07	76.78 ± 8.20	78.88 ± 8.70	81.02 ± 7.28	81.18 ± 10.71	0.66
Heart rate, bpm	83.06 ± 12.89	80.80 ± 10.76	78.62 ± 11.86	80.64 ± 13.84	81.52 ± 12.11	0.40
HbA1c, %	8.28 ± 2.10	7.22 ± 1.45	6.83 ± 1.02	6.55 ± 0.84	6.74 ± 0.81	0.00

Bpm - beats per minute, All data are expressed as mean ± standard deviation.

Adherence to medication

The adherence to medication such as sodium glucose co-transporter-2, sulfonylurea, dipeptidyl peptidase-4 inhibitor, thiazolidinedione, biguanide, and alpha-glucosidase inhibitor decreased at the follow-ups as shown in Table 3.

Table 3: Medication adherence

Medication	Day 1 (n=34)	Day 90 (n=34)	Latest
Sodium glucose co-transporter-2	8	2	1
Sulfonylurea	19	4	9
Dipeptidyl Peptidase-4 inhibitor	12	3	4
Thiazolidinedione	2	0	2
Biguanide	34	11	12
Alpha-glucosidase inhibitor	4	0	0

HbA1c levels according to age, gender, and HbA1c category

The mean HbA1c levels according to the 30–55 yrs age group (day 1: 8.04 ± 1.87%, day 30: 6.94 ± 1.49%, day 60: 6.60 ± 0.87%, day 90: 6.41 ± 0.78%, and after 1 year: 6.70 ± 0.69) and 56–80 yrs age group (day 1: 8.56 ± 2.30%, day 30: 7.53 ± 1.33%, day 60: 7.11 ± 1.10%, day 90: 6.70 ± 0.88%, and after 1 year: 6.79 ± 0.92%) improved significantly. Similarly, mean HbA1c levels according to male gender (day 1: 8.10 ± 1.87%,

Day 30: 6.92 ± 1.07%, day 60: 6.62 ± 0.89%, day 90: 6.40 ± 0.73%, and after 1 year: 6.71 ± 0.75%), and female gender (day 1: 8.65 ± 2.47%, day 30: 7.85 ± 1.89%, day 60: 7.28 ± 1.12%, day 90: 6.87 ± 0.96%, and after 1 year: 6.80 ± 0.91%) improved significantly. Similarly mean HbA1c levels according to HbA1c levels 5.8–7.0% (day 1: 6.43 ± 0.37%, day 30: 6.28 ± 0.50%, day 90: 6.21 ± 0.50%, and after 1 year: 6.36 ± 0.54%), HbA1c levels 7.1–10% (day 1: 8.23 ± 0.68%, day 30: 7.02 ± 0.70%, day 60: 6.70 ± 0.56%, day 90: 6.53 ± 0.68%, and after 1 year: 6.77 ± 0.77%), and HbA1c levels 10.1–15 (day 1: 12.08 ± 1.31%, day 30: 9.59 ± 1.56%, day 60: 8.40 ± 1.09%, day 90: 7.60 ± 0.94%, and after 1 year: 7.43 ± 0.86%) also improved significantly. HbA1c levels according to age, gender, and HbA1c category are elaborated in Table 4.

Table 4: HbA1c levels according to age, gender, and HbA1c category

	Day 1	Day 30	Day 60	Day 90	After 1 Year
Age (30–55 yrs)	8.04 ± 1.87	6.94 ± 1.49	6.60 ± 0.87	6.41 ± 0.78	6.70 ± 0.69
Age (56–80 yrs)	8.56 ± 2.30	7.53 ± 1.33	7.11 ± 1.10	6.70 ± 0.88	6.79 ± 0.92
Male	8.10 ± 1.87	6.92 ± 1.07	6.62 ± 0.89	6.40 ± 0.73	6.71 ± 0.75
Female	8.65 ± 2.47	7.85 ± 1.89	7.28 ± 1.12	6.87 ± 0.96	6.80 ± 0.91
HbA1c, (5.8–7.0%)	6.43 ± 0.37	6.28 ± 0.50	6.21 ± 0.50	6.04 ± 0.34	6.36 ± 0.54
HbA1c, (7.1–10%)	8.23 ± 0.68	7.02 ± 0.70	6.70 ± 0.56	6.53 ± 0.68	6.77 ± 0.77
HbA1c, (10.1–15%)	12.08 ± 1.31	9.59 ± 1.56	8.40 ± 1.09	7.60 ± 0.94	7.43 ± 0.86

Data are expressed as %.

HbA1c levels according to glucose tolerance testing

The HbA1c levels according to glucose tolerance testing are detailed in Table 5.

Table 5: HbA1c levels according to glucose tolerance testing

GTT Status	HbA1c Day 1	Change% (Day 1-30)	HbA1c Day 30	Change% (Day 30-60)	HbA1c Day 60	Change% (Day 60-90)	HbA1c Day 90	Change% (Day 90-After 1 year)	HbA1c After 1 year	Change% (Day 1-After 1 Year)
Negative (n=22)	7.79	-13.01	6.78	-6.64	6.33	-4.17	6.06	3.45	6.27	-19.49
Impaired (n=7)	6.97	-7.17	6.47	-1.32	6.39	-2.01	6.26	2.74	6.43	-7.79
Positive (n=3)	8.20	-15.04	6.97	-9.09	6.33	-4.74	6.03	11.05	6.70	-18.29
Not tested (n=7)	10.63	-15.99	8.93	-9.28	8.10	-5.64	7.64	1.68	7.77	-26.88

Discussion

The risk for diabetes mellitus is greatly affected by genetic predisposition and family history, as well as factors such as ethnic background, age, obesity, sedentary lifestyle, poor diet, and behavioral patterns.[4] In the Indian population type 2 diabetes mellitus onset is seen at a younger age and occurs at lower body mass index levels.**[3]** Individuals of Indian origin have a specific phenotype characterised by elevated levels of intra-abdominal fat and insulin resistance despite low BMI which predisposes them to type 2 diabetes mellitus.**[4]** Thus, body mass index was considered a variable in this study. The body mass index decreased (day 1: 27.51 ± 3.68, day 30: 26.76 ± 3.83, day 60: 26.43 ± 3.78, day 90: 26.31 ± 3.90, and 1 year: 26.78 ± 3.94, p=0.00) significantly at the 1-year follow-up. This finding is in line with earlier similar studies.

An earlier study in elderly male patients reported decrease in body mass index from 27.65 ± 3.20 to 25.91 ± 3.29.**[6]** Another earlier study of diabetic obese patients documented decrease in body mass index from 33.79 ± 3.80 to 31.13 ± 3.91.**[7]** Similarly in another study of pre-obese patients the body mass index decreased from 25.39 ± 1.53 vs 27.24 ± 1.33.**[8]**

Reducing patient dependency on allopathic medications has become an increasing concern, particularly in low-income countries where the high cost of these drugs poses a significant barrier. Additionally, the potential for adverse effects further complicates reliance on allopathic treatments. In the present study, CDC therapy effectively reduced patients' dependency on allopathic medications by the end of the treatment. This finding aligns with several other studies that have reported similar outcomes.**[9-11]**

By decreasing reliance on allopathic medicines, the CDC program not only helps lower treatment costs for patients but also minimizes the risk of adverse effects associated with these medications.

Study limitations

This study has a few limitations. Firstly, the limited number of participants. Furthermore, the retrospective and non-comparative nature of the study design restricts the applicability of the results to broader populations. Future investigations employing a prospective, controlled methodology with a larger cohort are needed to gain deeper insights into efficacy of the CDC program in managing type 2 diabetes mellitus.

Conclusion

Integrated Ayurvedic management of type 2 diabetes mellitus over a 90-day period has proven highly effective in maintaining long-term glycemic control, even after one year of follow-up, while also significantly reducing dependence on allopathic medications.

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