Effect Ayurveda-based Comprehensive Diabetic Care Program on Glycemic Control in Type 2 Diabetic Mellitus Patients: An Observational Study

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Original Research Article

ABSTRACT

Background: The prevalence of diabetes mellitus in India is alarmingly high despite availability of several therapeutic agents. Thus, the current study was conducted to understand the role of Ayurveda based Comprehensive Diabetes Care (CDC) program in the management of type 2 diabetes mellitus.

Methods: A retrospective, observational study was conducted from January 2014 to September 2022 at Madhavbaug Clinic, Maharashtra. Patients aged 18 years and above with a diagnosis of

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type 2 diabetes mellitus according to the American Diabetes Association (ADA) with body mass index >25 participated in the CDC program and were included in this study. Follow-up was conducted after 90 days. Baseline data was compared with follow-up data.

Results: A total of 63 patients were assessed. Of the male patients, 29.3%, 43.9%, and 26.8% were found to have impaired, negative and positive glucose tolerance. Among the females, 22.7%, 63.6%, and 13.6% were found to be have impaired, negative and positive glucose tolerance. Weight decreased from 70.70 ± 9.82 kg to 65.15 ± 9.83 kg ($p<0.001$) from day 1 to day 90. Body mass index decreased from 27.00 ± 3.88 to 24.91 ± 3.75 ($p<0.001$) from day 1 to day 90. Glycated haemoglobin (HbA1c) decreased from $7.87 \pm 1.90\%$ to $5.79 \pm 0.51\%$ ($p<0.001$) from day 1 to day 90.

Conclusion: Remission of type 2 diabetes mellitus in obese patients is possible with Ayurvedic principles and diet compliance.

1. INTRODUCTION

Diabetes mellitus is a complex and multifactorial metabolic disorder. It is triggered by reduction in insulin or resistance to the effects of insulin leading to hyperglycaemia [1]. Symptoms include frequent urination, increased fluid uptake, blurred vision, weight loss, lethargy, and fluctuating energy levels. The risk factors of diabetes include overweight/obesity, heredity, sedentary lifestyle, poor diet, smoking, and alcohol consumption. The American Diabetes Association recommends management through exercise, diet, and lifestyle [2]. However, current management strategies focus on reducing hyperglycaemia through targeted molecular drugs which fail to address the chronicity and systemic complications of diabetes – this evokes lifetime dependency on medication. The need of the hour is a paradigm shift in the perspective of diabetes management [1].

Ayurveda is an ancient evidence-based medicinal practice that uses several herbal formulations and therapeutic measures such as *Panchakarma* including meditation and Yogic exercises to avert, alleviate and manage diabetes according to individual patients [3]. There is existing evidence indicative that Ayurveda may augment therapy and management of diabetes mellitus. It can therefore play a role as a robust tool for diabetes mellitus management. The Comprehensive Diabetic Care (CDC) Program combines *Panchakarma* and diet management to manage diabetes mellitus. Thus, the rationale of the current study was to understand the role of Ayurveda based CDC program in the management of type 2 diabetes mellitus.

2. MATERIALS & METHODS

2.1 Study Design and Patient Population

A retrospective, observational study was conducted at Madhavbaug Clinic between January 2014 and September 2022. Patients aged 18 years and above with a diagnosis of type 2 diabetes mellitus according to the American Diabetes Association (ADA) [4] and with body mass index >25 even those with microvascular complications who participated in the CDC program were included in this study. Patients that were underweight or had suffered acute emergencies were excluded from the study. Patients with body mass index 25.1–28.0, 28.1–30.0, 30.1–32.0 were categorized as overweight, obese 1, obese 2, and morbid obese, respectively.

2.2 Comprehensive Diabetes Care Program

The Comprehensive Diabetes Care (CDC) program comprises of 3 steps, each session lasting for 65–75 mins. The procedures commenced after patients had a light breakfast. The first procedure was *Snehana* which is external oleation with Neem oil massaged on the hands, legs, shoulders, thorax, abdomen, and the back in a centripetal manner. The duration of this massage was 15–25 mins as 15–30 strokes were applied on each of the aforementioned body parts. *Swedana* was the next procedure and refers to heat therapy with Dashmoola decoction. The patient's body was positioned in a supine position in a wooden box. The patient's neck was permitted to protrude outside the box. The duration of this therapy was 10–15 mins followed by a relaxation period of 3–4 minutes after the therapy. The third step was *Basti* which

was medicated enema of 100 ml decoction of *Gymnema sylvestre*, *Berberis aristate*, and *Glycyrrhiza glabra*. This was administered through rectum administration with the drug to remain inside the body for >15 mins to allow maximum absorption. The CDC program comprises 6 sessions in total i.e. 4 sessions within the first month, 1 in the second month and the 1 in the third month, an entire duration of 90 days. Patients were restricted to a diet plan comprising 800–1000 calories. The diet comprised low carbohydrates, moderate proteins, and low fats.

2.3 Glucose Tolerance Test

The glucose tolerance test, also known as oral glucose tolerance test, measures the body's response to sugar (glucose). The glucose tolerance test can be used to screen for type 2 diabetes. This test indicates glucose metabolism strength of an individual, 75 gm of oral sugar infusion was given to the patients after collection of fasting samples, and again after 1 hr and 2 hrs of post prandial blood sugar was recorded. Patients were asked to sit in one position for the duration from fasting till 2 hrs after sampling. No orally administered antihyperglycemic agents (OHAs) or insulin was taken before or during the procedure. Normal glucose tolerance was considered as <90 mg/dL after fasting, <180 mg/dL at 1 hr, and <140 mg/dL at 2 hrs. Impaired glucose tolerance was considered as <90 mg/dL after fasting, >180 mg/dL at 1 hr, and <140 mg/dL at 2 hrs. Diabetes was considered as >90 mg/dL at fasting, >180 mg/dL at 1 hr, and >140 mg/dL at 2 hrs.

2.4 Data Collection

Data for patient demographics, anthropometrics, and laboratory findings were collected and analysed 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 glycated haemoglobin (HbA1c) levels were measured.

This was repeated on day 90 of the CDC program. Data of day 1 was compared with data of day 90. Data of only those patients who had completed a total of 6 sessions was collected and analysed.

2.5 Statistical Analysis

Categorical data are shown as number (percentage) and continuous data are shown as mean ± standard deviation. Paired t test was used to calculate the difference between baseline and the 90-day follow-up. P value ≤0.05 was considered as statistically significant.

3. RESULTS

3.1 Baseline Demographic and Anthropometric Measurements

The mean age of the study population was 50.51 ± 10.62 years. Of the 61 patients, 41 (65.1%) patients were male. Weight decreased from 70.70 ± 9.82 kg to 65.15 ± 9.83 kg (p<0.001) from day 1 to day 90. Body mass index decreased from 27.00 ± 3.88 to 24.91 ± 3.75 (p<0.001) from day 1 to day 90. HbA1c decreased from $7.87 \pm 1.90\%$ to $5.79 \pm 0.51\%$ (p<0.001) from day 1 to day 90. The anthropometric measurements at baseline and 90-day follow-up are detailed in Table 1. The demographic and anthropometric measurements according to age, gender, HbA1c, and body mass index at baseline and 90-day follow-up are elaborated in Table 2.

3.2 Glucose Tolerance Testing

Of the male patients, 29.3%, 43.9%, and 26.8% were found to have impaired, negative and positive glucose tolerance. Among the females, 22.7%, 63.6%, and 13.6% were found to be have impaired, negative and positive glucose tolerance. The glucose tolerance testing findings are displayed in Fig. 1.

Table 1. Baseline demographic and anthropometric measurements

Variables	Day 1	Day 90	p value
Age, years	50.51 ± 10.62		
Males	41 (65.1%)		
Weight, kg	70.70 ± 13.19	65.15 ± 9.83	<0.001
Body mass index	27.00 ± 3.88	24.91 ± 3.75	<0.001
HbA1c, %	7.87 ± 1.90	5.79 ± 0.51	<0.001

All data are expressed as number (percentage) or mean ± standard deviation- HbA1c – glycated haemoglobin

Table 2. Demographic and anthropometric measurements according to age, gender, HbA1c, and body mass index

Variables	HbA1c Day 1	HbA1c Day 90	p value	Change %	Weight Day 1	Weight Day 90	p value	Change %	BMI Day 1	BMI Day 90	p value	Change %
Age, years												
25–45	7.94 ± 1.87	6.03 ± 0.50	<0.001	-1.91	75.08 ± 9.47	70.15 ± 9.87	<0.001	-4.92	27.29 ± 4.13	25.50 ± 4.20	<0.001	-1.79
45–65	7.94 ± 2.00	5.62 ± 0.46	<0.001	-2.32	68.42 ± 9.95	62.56 ± 9.53	<0.001	-5.86	26.80 ± 3.98	24.53 ± 3.61	<0.001	-2.27
>65	7.33 ± 1.77	5.86 ± 0.60	<0.001	-1.47	68.01 ± 5.55	62.04 ± 4.25	<0.001	-5.96	27.08 ± 2.85	24.91 ± 3.06	<0.001	-2.17
Gender												
Male	8.00 ± 1.93	5.91 ± 0.50	<0.001	-2.09	72.08 ± 10.15	66.97 ± 9.54	<0.001	-5.10	25.86 ± 3.47	24.06 ± 3.33	<0.001	-1.81
Female	7.62 ± 1.90	5.56 ± 0.47	<0.001	-2.06	68.13 ± 9.07	61.76 ± 9.91	<0.001	-6.37	29.12 ± 3.87	26.50 ± 4.13	<0.001	-2.62
HbA1c, %												
<5.7	5.14 ± 0.38	5.58 ± 0.73	<0.001	0.44	75.80 ± 9.19	76.12 ± 12.33	<0.001	0.32	28.90 ± 4.68	28.98 ± 5.51	<0.001	0.09
5.8–7.0	6.62 ± 0.32	5.65 ± 0.52	<0.001	-0.97	68.83 ± 9.49	63.63 ± 9.18	<0.001	-5.21	25.85 ± 2.87	24.00 ± 3.02	<0.001	-1.85
7.1–10	8.45 ± 0.88	5.85 ± 0.47	<0.001	-2.60	71.38 ± 10.64	64.55 ± 9.63	<0.001	-6.83	27.72 ± 4.44	25.05 ± 3.73	<0.001	-2.67
10.1–15.0	11.87 ± 1.10	6.19 ± 0.25	<0.001	-5.69	70.81 ± 9.07	64.88 ± 8.84	<0.001	-5.94	26.84 ± 4.00	24.59 ± 3.85	<0.001	-2.25
Body mass index												
Normal	7.78 ± 1.95	5.92 ± 0.53	<0.001	-1.85	62.15 ± 7.01	58.40 ± 5.17	<0.001	-3.75	22.61 ± 2.12	21.32 ± 1.45	<0.001	-1.29
Overweight	7.86 ± 1.55	5.76 ± 0.50	<0.001	-2.10	70.68 ± 6.10	65.34 ± 9.03	<0.001	-5.43	26.36 ± 0.97	24.35 ± 2.14	<0.001	-2.01
Obese 1	7.98 ± 2.43	5.52 ± 0.55	<0.001	-2.47	72.50 ± 9.39	64.28 ± 8.83	<0.001	-8.22	28.84 ± 0.52	25.66 ± 1.10	<0.001	-3.18
Obese 2	8.33 ± 1.26	6.05 ± 0.54	<0.001	-2.28	80.98 ± 12.24	72.68 ± 7.76	<0.001	-8.30	30.89 ± 0.40	27.89 ± 1.74	<0.001	-3.00
Morbid obesity	87.69 ± 2.63	5.89 ± 0.35	<0.001	-1.80	82.54 ± 7.76	78.11 ± 10.36	<0.001	-4.42	34.40 ± 2.33	32.50 ± 3.12	<0.001	-1.90

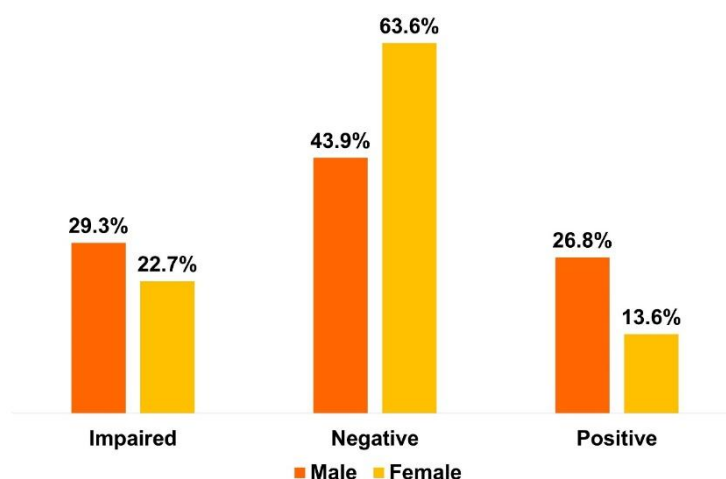*All data are expressed as mean ± standard deviation*

Fig. 1. Glucose tolerance testing

4. DISCUSSION

Overweight and obesity are significant risk factors for the development of non-communicable diseases, particularly type 2 diabetes – majority of the individuals with type 2 diabetes mellitus are overweight or obese. According to the World Health Organization, obesity and overweight account for 44% diabetes cases and predict the prevalence of obesity-related diabetes to double by 2025 [5]. The main causative factors of overweight and obesity are high-calorie or high-fat foods, inadequate physical activity, and a sedentary lifestyle. European guidelines recommend at least 150 min/week of moderate aerobic activity along with 3 weekly sessions of resistance training to increase muscle strength [6-9]. Physical activity reduces intra-abdominal fat, increase in lean mass, and causes improvement in glucose tolerance, insulin sensitivity, and physical fitness. Moreover, current evidence suggests even more favourable results of weight loss when combined with an energy-restricted diet. This refers to a low-fat and low-carbohydrate diet [5]. The Finnish Diabetes Prevention Study [10] revealed that intensive dietary and exercise regimen decreased overall risk of diabetes by 58%. The Diabetes Prevention Program [11] revealed moderate weight loss and lifestyle intervention in an obese population with impaired glucose tolerance can reduce incidence of diabetes by 58% while metformin alone reduced it by only 31%. The Look AHEAD [12] study evidenced that 5–10% body weight reduction can improve overall fitness, reduce HbA1c levels, improve cardiovascular disease risk factors, and decrease the use of anti-hyperglycaemic levels, anti-hypertensive, and lipid-lowering medications after 1 year. In the current study, weight decreased from 70.70 ± 9.82 kg to 65.15 ± 9.83 kg after 90 days. Body mass index has a strong correlation with diabetes and insulin resistance and is still used to classify obesity and overweight. Body mass index decreased from 27.00 ± 1.90 to 5.79 ± 0.51 after 90 days in our study.

Ayurveda is emerging as a complementary and alternative treatment strategy for chronic illness. The current study aimed to understand the role of Ayurveda based CDC program in the management of type 2 diabetes mellitus. The main goal of the management of diabetes mellitus is to reduce blood glucose levels within a therapeutic range through medication, diet, and lifestyle modification. HbA1c is a widely used diagnostic marker, reflective of average HbA1c levels over a 3-month period [13]. A reduction in HbA1c of at least 0.3% or 0.4% is considered to be clinically meaningful, [14]. The current study revealed changes of 0.44%, -0.97%, -2.60%, and -5.69% for HbA1c ranges >5.7, 5.8–7.0, 7.1–10.0, and 10.1–15.0, respectively. These findings are in line with other similar studies [15-17].

Yoga has found acceptance and has been practiced by individuals with all social strata. Yoga regulates eating pattern and leads to adherence of medication. A 3-arm controlled trial aimed to validate if Yoga can improve blood glucose and HbA1c in individual with pre-diabetes. Study findings revealed significant decrease in fasting blood sugar (FBS) (-21.13 ± 21.16 mg/dl) and postprandial blood sugar (PPBS) (-15.0 ± 14.89 mg/dl) in group 1

(*Rasahara* and Yoga) and FBS (20.62 ± 32,68 mg/dl) in group 2 (Yoga), while the increases in group 3 (no intervention) was only significant for the PPBS level (9.62 ± 21.83 mg/dl) [18].

5. CONCLUSION

Restoration of euglycemia in type 2 diabetes mellitus can be achieved with Ayurveda-based diet and CDC program, further long-term relapse study with the larger sample size is needed to conclude complete remission of type 2 diabetes mellitus.

CONSENT

As per international standard or university standard, Participants' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

It is not applicable.

ACKNOWLEDGEMENTS

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
https://www.sdiarticle5.com/review-history/99565