

Efficacy of Comprehensive Diabetes Care (CDC) Therapy in Patients of Type II Diabetes Mellitus: Relapse of the Disease

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Abstract: Diabetes mellitus (DM) prevalence is rising worldwide at an alarming rate, with India leading the pack with the highest percentage of people with diabetes. The typical diabetic treatment solutions that are currently accessible have some drawbacks, so some alternate treatments are needed. The traditional medicine of India, Ayurveda, contains many treatments for diabetes and its consequences. This study was conducted to study the CDC's effectiveness in treating T2DM relapse in patients with restored glycemia. A total of 25 patients with restored Euglycemia of either sex and aged between 30-70 years suffering from T2DM and completed 1-year follow-up were included in the study. The Comprehensive Diabetes Care (CDC) therapy, a three-step detoxification procedure- *Snehana*, i.e. oleation, *Swedana*, i.e. passive heat therapy, and *Basti*, i.e. per rectal drug administration and food therapy was administered to the patients. The data of their clinical parameters were evaluated. The weight, BMI, ABG, SBP, and DBP values were seen to be reduced after 90 days of the treatment but slightly increased after 1-year post-treatment of CDC therapy. Also, HbA1c was found to be reduced after 90 days, and after one year of follow-up, a slight increase in HbA1c value was seen. The overall change was -21.11% (p-value=0.00). The reduction in allopathic medicines was observed after 90 days and also after 1 year of follow-up. Even though 8% of the patients experienced a Type 2 DM relapse, the other 92% were still non-diabetic after one year.

Keywords: Comprehensive Diabetes Care, Type II Diabetes Mellitus, Restored Euglycemia

1. Introduction

Millions worldwide are at an increased risk of acquiring diabetes, yet many are unaware of this danger. Diabetes is a non-communicable disease that is becoming a significant healthcare issue. Comprehensive type 2 diabetes mellitus (DM2) care aims to lower patient morbidity and death. Identifying people at risk and implementing preventative measures are the most efficient ways to lessen the burden of diabetes [1, 2]. Lifestyle changes have been demonstrated to stop the progression of diabetes in randomised studies [3]. As

a result, new guidelines for managing diabetes mellitus have been implemented, emphasising the importance of early intervention as the most economical method of preventing diabetes and its problems.

Along with proper diagnosis and treatment of the disease's complications, including both the traditional microvascular complications as well as other significant complications like non-alcoholic fatty liver disease, heart failure, or sleep apnea-hypopnea syndrome, comprehensive control of cardiovascular (CV) risk factors is also necessary [4]. DM is typically identified by measuring the patient's serum sugar levels when fasting and after giving them a 75 mg oral

glucose solution. HbA1c, or glycosylated haemoglobin, has been used as a marker of long-term blood glucose control in the care of diabetic patients and has been used to diagnose DM. HbA1c is a product of a non-enzymatic reaction that occurs during glucose metabolism and roughly represents the ephemeral homeostasis of blood sugar over the previous three months [5].

DM is often treated with various anti-diabetic medicines (ADD) alone or with medications from other classes. These medications work to lower blood sugar levels by multiple mechanisms, including enhanced tissue glucose uptake, an increase in glucose transporter four protein, a decrease in gluconeogenesis, an increase in glycolysis, etc. [6].

The standard management of diabetes mellitus is still unsatisfactory and has many adverse associated effects, which is the cause of the problem. Most diabetic patients are overweight or obese and will not be able to achieve or maintain near-normal glycaemia with modern anti-diabetic agents; a sizable percentage of patients will eventually need alternative therapy to maintain long-term glycemic control, either as a single herb/formulation or in conjunction with modern oral anti-diabetic therapy [7]. Ayurveda is the first treatment option for people with diabetes for 21.5% of the general population. For 73% of diabetic patients, whether as dietary supplements or medications, effective Ayurveda medicine is preferred [8]. As a result, the highly developed Ayurvedic therapeutics in the area of managing and preventing diabetes seem to explore the potential for creating a line of dietary guidelines and Panchakarma therapy that Ayurveda inspires for the treatment and the avoidance of Type-2 Diabetes mellitus for use in modern times. Such a treatment using an Ayurvedic approach not only slows the progression of diabetes but also adds a fresh perspective to managing prediabetics to a certain extent. In the Comprehensive Diabetes Care (CDC) Management Program, a three-step detoxification procedure- *Snehana*, i.e. oleation, *Swedana* i.e. passive heat therapy and *Basti*, i.e. per rectal drug administration and food therapy are combined.

The present study is carried out to study the effectiveness of the CDC in treating T2DM relapse in patients with restored glycemia and its effect on various parameters like HbA1c, BMI, body weight, abdominal girth, and reduction in dependency on allopathic drugs after completion of CDC.

2. Subjects and Methods

It is a retrospective study conducted between April 2017 to December 2022 at Madhavbaug Clinics. A total of 307 patients were enrolled in CDC. Out of which 43 patients attempted GTT which, 37 patients were negative and six were GTT impaired. And out of 37, 25 patients completed 1-year follow-up. Twenty-five patients with restored Euglycemia of either sex and aged between 30-70 years suffering from T2DM were included in the study. Patients who are positive oral glucose tolerance tests (OGTT) and have failed to follow up during the study duration were

excluded from the study. The data of patients who had been administered CDC with a minimum of 18 sittings over 1 year were considered for the study. According to patient medical records, these individuals were kept on a diet that called for 800-1000 caloric intake each day. Low carbohydrates, moderate protein, and low fat were the main components of the diet. The patients were chosen based on the availability of their complete and pertinent baseline data (day 1 of CDC) and final day data (after one year of CDC). It was also recorded if any information concerning prescribed concurrent medications was provided. The patients underwent HbA1c, weight, BMI, ABG, heart rate, SBP, and DBP assessments by the recommended procedures on day 1 of the CDC [9]. This procedure was repeated for the CDC on days 30, 60, and 90 to determine the difference from the baseline reading. The proportion of patients out of the total enrollees who needed conventional allopathic medicines over the study period of one year was used to compute the dependency on standard medication on day one, day 90, and after one year of CDC. Following a light breakfast, patients with T2DM underwent the CDC, a three-step technique. According to the following data, one process sitting lasted between 65 and 75 minutes [10].

Snehana is a 25-30-minute *massage* or external oleation (centripetal upper strokes on the body) therapy done using 100 ml Azadirachtin indica (neem) extract processed in sesame oil.

Swedana- It is a 15–20-minute passive heat therapy done using *Dashmoola* (group of ten herbal roots) with steam at <40 degrees Celsius.

Basti- It is a 10-minute per-rectal drug administration therapy done using a mixture of 40% *Gudmaar* (*Gymnema sylvestre*), 20% *Daruharidra* (*Berberis aristata*), and 40% *Yashtimadhu*.

(*Glycyrrhiza glabra*).

Following CDC therapy, the patients were categorised based on their HbA1c values as follows: Controlled- HbA1c <5.7

Borderline- HbA1c 5.8-6.9

Uncontrolled- HbA1c >7

Statistical analysis: Data were pooled and coded in a Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyse the data. Categorical data were represented in the frequency form, and continuous data were presented as the Mean \pm SD.

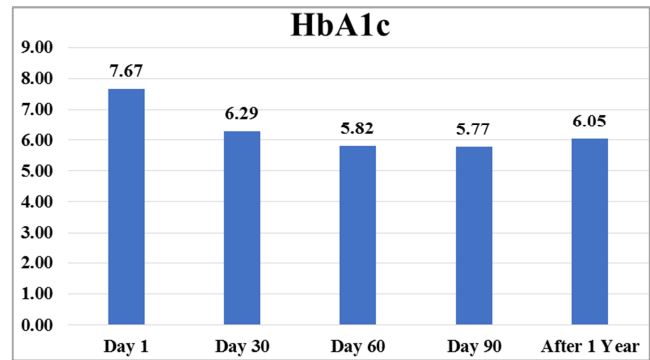
3. Results

Based on the inclusion criteria, 25 patients were selected, and their data were considered for analysis. Out of 25 type 2 diabetic patients, 16 were males (64%), while 9 were females (36%). The mean of their ages is 52.64 \pm 8.94 years. 23 patients were given a *prameha* diet kit, 1 patient was given a *swastyam* kit and 1 patient did not require any diet kit. 64% of the patients were given non-veg diet kits while 36% of patients were given veg diet kits.

Table 1. Comparison of clinical parameters between their initial values and 90 days later.

Parameter	Baseline	Day 90	P value
Weight (kg)	77.82±15.59	70.61±13.73	0.10
BMI (kg/m ²)	29.52±4.23	26.82±3.48	0.02
ABG	101.36±11.47	91.96±11.29	0.01
SBP	126.52±13.56	117.08±8.58	0.00
DBP	80.96±8.89	76.36±7.77	0.05
ABG- Abdominal girth, BMI- Body mass index, DBP- Diastolic blood pressure, SBP- Systolic blood pressure			

Table 1 presents the data of clinical parameters for comparison of the baseline values and the values after 90 days of treatment. After the CDC treatment, weight, BMI, ABG, SBP, and DBP values were seen to be reduced after 90 days of the treatment but slightly increased after 1-year post-treatment. Graph 1 shows the HbA1c values in patients at baseline, after 30 days, after 60 days, after 90 days, and after 1 year of CDC therapy. After 90 days of treatment, HbA1c was found to be reduced. After 1 year of follow-up, a slight increase in HbA1c value was seen. The overall change was -21.11% (p-value=0.00).

**Figure 1.** HbA1c in patients of the present study after CDC therapy.

After the CDC therapy, it was observed that the change in weight in female patients was -8.98% while that in male patients was -9.37% and the change in BMI in female patients was -8.83% and in male patients was -9.68%. change in HbA1c in female patients was -24.90% and in male patients was -18.86% after 1 year of the treatment.

Glucose tolerance test

Table 2. Change in weight and BMI according to the HbA1c classification.

HbA1c Classification	N	Average Weight Day 1	Average Weight Day 90	Change%	Average of BMI Day 1	Average of BMI Day 90	Change%
Less Than 5.7	6	72.68	67.40	-7.27	26.67	24.93	-6.52
5.8 to 6.9	18	79.56	71.78	-9.78	30.79	27.66	-10.15
Greater Than 7	1	77.30	69.00	-10.74	23.83	23.00	-3.48
Grand Total	25	76.51	69.39	-9.31	27.09	25.20	-7.00

GTT was conducted to understand glucose metabolism in 43 Patients who completed an entire 12 weeks of diet and 18 Panchkarma treatments. It was observed that 37 patients out of 43 were showing Euglycemic response to the glucose

tolerance test rest 6 were showing impaired glucose metabolism. Remission of Type 2 DM was observed in 86.05%. Table 2 shows the change in weight and BMI according to the HbA1c classification.

Table 3. Change in HbA1c and GTT results according to the HbA1c classification.

HbA1c Classification	N	Average GTT Fasting	Average GTT 1hr	Average GTT 2hr	Average HbA1c Day 1	Average HbA1c Day 30	Average HbA1c Day 60	Average HbA1c Day 90	Average HbA1c Latest	Change% (Day 1-90)	Change% (Day 1-Latest)
Less Than 5.7	6	95.51	160.70	116.64	7.35	6.25	5.17	5.28	5.23	-28.12	-28.80
5.8 to 6.9	18	108.76	167.20	122.39	7.86	6.33	6.03	5.93	6.22	-24.63	-20.88
Greater Than 7	1	88.42	97.34	79.31	6.00	5.70	5.90	5.90	7.80	-1.67	30.00
Grand Total	25	97.56	141.75	106.11	7.07	6.09	5.70	5.70	6.42	-19.34	-9.23

Also, it was observed that after the CDC therapy diabetic allopathy medicines stopped after 90 days of treatment and also after 1 year of treatment. Table 4 shows a reduction in allopathic medicines after the treatment.

Table 4. Reduction of allopathic medicines.

Medicine Name	Day 1	Day 90	After 1 Year	Day 1%	Day 90 %	After 1 Year %	Change%
Alpha-glucosidase inhibitors	1	0	0	4.00	0.00	0.00	-100
Biguanides	10	0	0	40.00	0.00	0.00	-100
Dipeptidyl peptidase-4 (DPP-4) inhibitors	3	0	0	12.00	0.00	0.00	-100
Sodium-glucose transporter (SGLT) 2 inhibitors	1	0	0	4.00	0.00	0.00	-100
Sulfonylureas	5	0	0	20.00	0.00	0.00	-100.00

4. Discussion

Ayurvedic disease care involves prescribing a customized diet, and way of living, mostly herbal medications, and

systemic purging therapy. Traditionally prescribed allopathic medications for type II diabetes mellitus work by lowering blood sugar levels. Since numerous herbal medications have been demonstrated to considerably lower blood glucose levels in clinical investigations, ayurvedic medicines serve as

a potential alternative therapeutic option for the management of type II DM. Patients of DM are treated with Panchakarma by Ayurvedic doctors [11]. In the CDC, panchakarma is used in conjunction with food therapy that includes low-carbohydrate, low-fat, and moderate-protein diets. The following are potential mechanisms by which CDC might help people with type II diabetes:

- 1) By preventing sympathetic stimulation of gluconeogenesis, one can decrease the generation of glucose in the liver.
- 2) Encouraging water loss through sweating to lower the shear load on the vascular endothelium. This could significantly reduce vascular problems [11].

In the present study, 37 patients based on the signs and symptoms of diabetes with restored Euglycemia underwent CDC therapy, and their data were considered for analysis. Results showed that the values of weight, BMI, ABG, SBP, DBP, and HbA1c were improved after three months of the treatment. This indicates that Euglycemia in Type-2 DM can be achieved successfully in the first 12 weeks of CDC therapy. The same results were obtained after 90 days of the treatment. Now, the question arises whether these results are sustainable or not. So, we took the follow-up of patients after one year of treatment. Out of 37, 25 patients were available for the follow-up. Out of 25 patients who completed one year of follow-up, two patients' glycemic control was seen to be deranged, while the rest 23 are still showing good glycemic control. So, relapse of Type 2 DM was observed in 8% of the patients. The remaining 92% are still Non-diabetic.

One of the most important parameters for diabetes patients is the HbA1c result since it reflects blood sugar control over the previous two to three months [12]. Another crucial aspect of HbA1c is its ability to predict type 2 diabetes outcomes because prolonged high HbA1c levels have been proven to be closely correlated with morbidity and death [13]. Therefore, it follows from the results of our study that CDC has a favourable prognosis in diabetes patients because it dramatically lowers HbA1c. In diabetic patients, maintaining blood sugar level management is crucial since it has been shown that poor blood sugar level control is linked to an increased risk of complications [14]. Since the CDC has shown a consistent decrease in all metrics, including HbA1c, BMI, body weight, ABG, SBP, and DBP, it can aid in lowering the consequences of diabetes with prolonged follow-up.

One of the important results of our study was the reduction in dependency on modern allopathic medications, as allopathic medicines contain numerous health hazards.

However, to compare and validate the results of the current study, we advise that such studies be conducted prospectively at numerous facilities across India with a bigger sample size.

5. Conclusion

After an extended follow-up, the CDC successfully improved patient compliance by reducing dependence on traditional medications and effectively improving weight, BMI, SBP, DBP, ABG, and HbA1c in type 2 DM patients.

Even though Type 2 DM relapse was seen in 8% of the patients, 92% remained free of diabetes.

Conflicts of Interest/Competing Interests

All the authors do not have any possible conflicts of interest.

Authors' Contributions

All authors contributed as per ICMJE guidelines for authorship.

Consent to Participate

Informed consent from each participant was registered.

Consent for Publication

Non-disclosure of personal information was agreed upon, and consent for research publication was obtained.

Ethics Approval

Institutional review board approval and in compliance with the ethical standards of the responsible institution on human subjects as well as with the Helsinki Declaration.

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