

Original Research Article

Role of comprehensive diabetes care in known diabetes patients from western Mumbai region: an observational study

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ABSTRACT

Background: The occurrence of Diabetes Mellitus (DM) has been creating a havoc since past few decades on a global platform. As per available literature, prevalence of DM in Mumbai is around 10%. Comprehensive Diabetes Care (CDC) is a form of Ayurvedic therapy which combines panchkarma and diet management. The present study was planned to evaluate the effectiveness of CDC in patients of DM by analysing changes in body mass index (BMI), body weight, OGTT, HbA1c, etc.

Methods: The present study was of retrospective design, conducted at Madhavbaug clinics in western Mumbai. The duration of study was of one year, conducted from October 2018 to September 2019. It included patients diagnosed with type 2 DM i.e. HbA1c > 6.5%, who were given CDC therapy.

Results: In the present study, out of 183 type 2 diabetic patients, 99 were males (52%), while 84 were females (48%), thus male: female ratio was 1.17:1. On analysing the results of HbA1c in patients who had completed 12 weeks of CDC therapy, it was found that controlled DM status was seen in 109 patients (59%), while uncontrolled DM status was noted in 33 patients (19%) as compared to 102 patients (58%) at baseline.

Conclusions: From the findings of the present study, it is clear that CDC is effective in the form of increasing number of euglycemic patients at the end of study period, as well as reduction in all glycaemic and anthropometric parameters, and reducing dependency on conventional medicines.

Keywords: Comprehensive diabetes care, Diabetes mellitus, HbA1c

INTRODUCTION

The occurrence of Diabetes mellitus (DM) has been creating a havoc since past few decades on a global platform.¹ More than 400 million individuals have been suffering from diabetes mellitus all over the world.¹ In Indian scenario, latest published evidence suggests that India has 70 million patients suffering from diabetes

mellitus and the prevalence rates ranges between 5 to 17%.² With these worrying statistics, India ranks 2nd, only beyond China in terms of highest number of cases of diabetes mellitus in the world.³ As per report by World Health Organization (WHO), mortality in diabetes is high i.e. around 30 deaths for every lac of population.¹ More worryingly the prevalence in metro cities like Mumbai is

very high and continually rising. As per published study, prevalence of DM in Mumbai is around 10%.⁴

Oral glucose tolerance test has been conventionally used to diagnose DM. Values of fasting blood sugar levels (FBS) ≥ 126 mg/dl and/ post meal blood sugar levels ≥ 140 mg/dl are cutoff levels for diagnosing DM.⁵ However, OGTT reflects only the blood glucose control over short period. Hence, estimation of glycosylated hemoglobin (HbA1c) has been favored as the diagnostic modality since past few years, as it gives an idea on control of blood glucose levels in previous 2 months.⁶ Serum levels of HbA1c $>6.5\%$ is diagnostic of DM, while concentration $<5.7\%$ is considered as normal. Aim of any antidiabetic therapy is to keep the HbA1c levels to less than 6.5%.⁶ DM is associated with plethora of complications, which are broadly categorized as microvascular complications like kidney diseases, retinopathy, neuropathy and macrovascular complications like stroke, central and peripheral arterial diseases.⁷ As per guidelines, DM should be managed initially by dietary rectifications and regular augmented physical exercise if HbA1c is marginally raised. If the derangement persists despite 6-8 weeks of lifestyle changes, then oral antidiabetic drug (OAD) should be added.⁸ Major challenge with use of OADs is the occurrence of adverse effects like hypoglycemia, increased urinary tract infections, pancreatitis, etc. which hamper the patient's adherence to treatment.⁹ This was corroborated in clinical study on diabetic patients, wherein adherence to OADs was just over 50%. Reasons attributed to such less adherence were increased adverse effects and cost of therapy.¹⁰ Thus, it becomes imperative to explore for alternate potent therapeutic options which will not only possess good efficacy, but it should also circumvent the challenges of low patient adherence

which are frequently seen with conventional OAD therapy.

The major action of OADs is to lower the blood glucose levels, optimize HbA1c levels, and correct deranged OGTT parameters. Multiple herbal drugs have been shown to possess similar properties, which makes them a potent alternate option for management of DM.¹¹⁻¹³

Herbal drugs are typically given in initial phase of disease, while Panchkarma- an internal cleansing process is administered in later stages by the Ayurvedic physicians. One of the commonly used Ayurvedic therapeutic regimen is Comprehensive Diabetes Care (CDC), which is amalgamation of administering Panchakarma in the form of Snehana- centripetal oleation, Basti-administration of herbal drugs through rectal route, and Swedana-passive heat therapy, all of which are known to possess cleansing actions.^{14,15}

There is scarcity of data on effectiveness of CDC in patients of DM. Therefore, the present study was planned to evaluate the effectiveness of CDC in patients of DM by analyzing changes in body mass index (BMI), body weight, OGTT, HbA1c, etc.

METHODS

The present study was of retrospective design, conducted at Madhavbaug clinics in western Mumbai. The duration of study was of one year, conducted from October 2018 to September 2019. It included patients diagnosed with type 2 DM i.e. HbA1c $>6.5\%$.⁶ Out of these, data of patients who were given CDC for minimum 6 sittings within a period of 90 days were finally included in the study for further analysis.

Table 1: Study treatment: comprehensive diabetes care (CDC).

Step of CDC	Type of Therapy	Herbs used for therapy	Duration of Therapy
Snehana	Massage or external oleation (centripetal upper strokes on the body)	100 ml Azadirachta indica (neem) extract processed in sesame oil	20 minutes
Swedana	Passive heat therapy to the body	Dashmoola (group of ten herbal roots) with steam at ≤ 40 degrees Celsius)	15-20 minutes + 3-4 minutes of relaxation after procedure
Basti kadha	Per-rectal drug administration should be in body for ≥ 15 minutes for maximum absorption	Mixture of 40% Gudmaara (Gymnema sylvestre), 20% Daruharidra (Berberis aristata) and 40% Yashtimadhu (Glycyrrhiza glabra)	10 minutes

According to the medical records, CDC was given with specialized Prameha diet kits consisting of low carbohydrates, low fats and moderate amount of proteins. Only those patient records were included which had complete required details at baseline and week 12. These

details included socio-demographic parameters, OGTT parameters, HbA1c, anthropometric parameters like body mass index (BMI), abdominal girth, cardiac parameters like systolic blood pressure (SBP), diastolic blood pressure (DBP), etc. at baseline and week 12.

Based on HbA1c levels after CDC therapy the patients were categorised as:

- Controlled- HbA1c <5.7
- Borderline- HbA1c 5.7-6.5
- Uncontrolled- HbA1c >6.5.

Diet box: Diet box was given to the patients, which was 1 month food packing designed to comply with low carbohydrate and low fat diet with daily calorie intake of 800 calories. 1 diet box was designed for 1 month, therefore number of diet boxes were equivalent to number of months on taking the compliance diet.

As per records, CDC was given to these patients after light breakfast. Details of the procedure are as mentioned in Table 1: ¹⁶.

Statistical analysis

Data were pooled and entered in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyse the data. Categorical data were represented in the numeric form and continuous data were presented as the Mean ± SD. Paired t-test was used to assess the difference between baseline values and 12 weeks after the treatment.

RESULTS

In the present study, out of 183 type 2 diabetic patients, 99 were males (52%), while 84 were females (48%), thus male: female ratio was 1.17:1 (Figure 1).

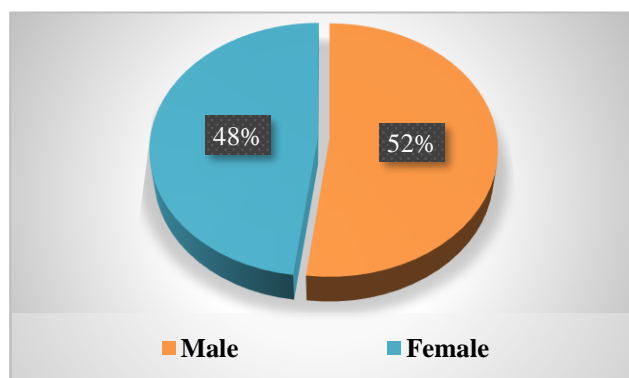


Figure 1: Sex distribution in patients of the present study.

There were 18% of the total patients were not given any diet boxes, while 1 diet box was given to 22%, 2 diet boxes to 23%, 3 diet boxes to 36% and 4 diet boxes were given to 1% of the patients (Figure 2).

On analysing the anthropometric parameters in the patients of present study, it was found that body mass index (BMI) was reduced from 26.95±1.12 kg/m² at baseline to 25.20±1.06 kg/m² at the end of 12 weeks of CDC therapy, and this difference was statistically significant (p=0.05). Similarly abdominal girth was

reduced from 94.62±2.3 at baseline to 90.3±1.9 at 12 weeks of CDC therapy (p=0.05). Similarly cardiopulmonary parameters like systolic blood pressure (SBP), diastolic BP (DBP), VO₂ peak showed improvements in reading at 12 weeks of CDC therapy, as compared to baseline and these differences were highly statistically significant. Lipid parameters showed similar trends which can be seen in Table 2.

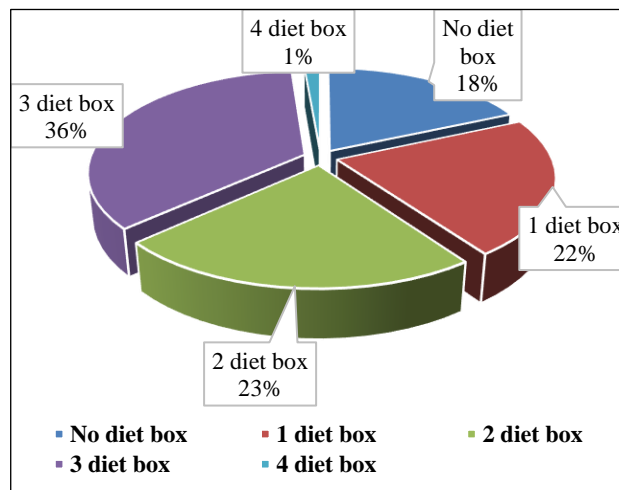


Figure 2: Number of diet boxes used by patients of present study.

Table 2: Anthropometric, cardio-pulmonary and lipid parameters in the patients of present study at baseline and 12 weeks of CDC therapy.

Parameter	Measurement	Baseline	12 week	P-value
Anthropometry	Weight	70.71±5.6	66.37±4.8	0.05
	BMI	26.95±1.12	25.20±1.06	0.05
	ABG	94.62±2.3	90.31±1.9	0.01
Cardio-pulmonary	SBP	130.50±5.6	124.19±5.1	0.001
	DBP	81.52±3.8	77.77±4.1	0.001
	VO ₂ peak	19.04±1.6	26.9±2.5	0.001
Lipid profile	Cholesterol	224.0±6.1	174.67±7.9	0.000
	HDL	42.63±2.1	43.0±2.38	0.12
	LDL	137.21±4.12	112.69±5.12	0.002
	TG	306.0±6.1	183.0±8.33	0.000

On analysing the results of HbA1c in patients who had completed 12 weeks of CDC therapy, it was found that normal HbA1c was seen in 109 patients (59%), borderline HbA1c was seen in 41 patients (22%) as compared to 81 patients (44%) at baseline, while abnormal HbA1c readings were noted in 33 patients (19%) as compared to 102 patients (58%) at baseline (Figure 3). Glycosylated hemoglobin (HbA1c) reduced from 8.99 at baseline to 7.22 at week 12 of completion of

CDC therapy, and the difference was statistically significant (Figure 4).

Medication history was available in 180 patients, out of which majority of the patients were taking biguanide and sulfonylureas (SU).

The number of tablets/patient ratio reduced from 3.47 at baseline to 1.57 at week 12 of CDC therapy, thus there was 55% reduction in number patients taking allopathic medications after 12 weeks of CDC therapy, with major reduction seen in intake of biguanides and SU (Table 3).

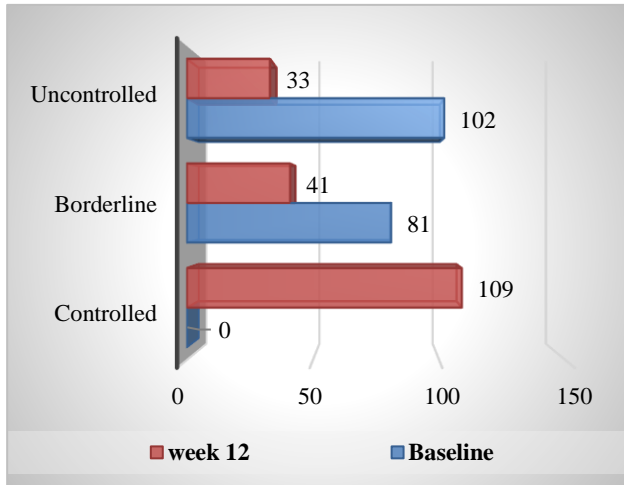


Figure 3: Results of HbA1c in patients who had completed 12 weeks of CDC therapy.

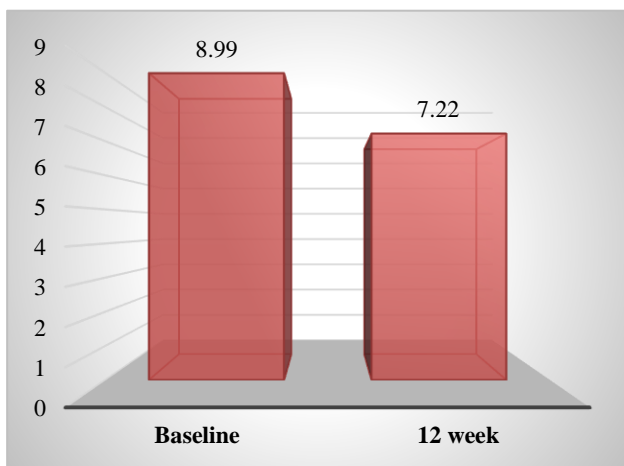


Figure 4: Glycosylated haemoglobin (HbA1c) in patients of present study at baseline and at 12 weeks of taking CDC therapy.

On analyzing HbA1c status at end of week 12 of CDC therapy, it was found that number of patients with controlled DM status increased and that with uncontrolled status reduced at week 12.

The greatest changes were observed in patients with duration of DM > 10 years (Table 4).

Table 3: Consumption of allopathic medications by the patients in the present study at baseline and at 12 weeks of CDC therapy.

No. of patients taking allopathic medicines			
Medication	Baseline	Week 12	p-value
β blocker	36	22	0.001
ARB	78	49	0.001
CCB	49	28	0.001
Diuretic	16	10	0.001
SU	142	91	0.001
Biguanides	193	49	0.001
Antiplatelet	25	15	0.001
DPP4 inhibitor	41	10	0.001
Statins	60	15	0.03
Tablet/patient ratio	3.47	1.57	0.001

Table 4: HbA1c results and duration of DM at week 12.

Duration of DM	Period of CDC therapy	HbA1c status			N
		Controlled	Borderline	Uncontrolled	
<2 yrs	Baseline	0	14	33	47
	week 12	29	12	6	47
2-10 yrs	Baseline	0	32	38	70
	week 12	40	19	11	70
> 10 yrs	Baseline	0	35	31	66
	week 12	40	10	16	66

DISCUSSION

Globally, DM remains one of the commonest contributor to morbidity and mortality, despite the availability of armamentarium of antidiabetic drugs and extensive guidelines in place. This can be an alarming signal for the researchers and physicians to explore for a newer therapeutic alternative which will not only lower the blood glucose levels but also be devoid of adverse effects associated with the use of conventional antidiabetic drugs. Panchkarma and herbal drug administration are proven to have similar therapeutic benefits as that of conventional antidiabetic drugs in the diabetic patients.¹⁷ CDC utilizes combination therapy of Panchkarma-an internal cleansing process and diet kit therapy which consists of low carbohydrates, fats and moderate amount of proteins. Proposed mechanisms of beneficial effects of CDC in DM are:

- Reducing glucose internal glucose output by reduction in sympathetic stimulation-helps to reduce blood glucose level.
- Swedana enables sweating through passive heat therapy, which helps to get rid of excess sodium and water, thus the wear and tear of vascular endothelium is halted and thus the risk of vascular complications might get reduced.¹⁸

In the present study, it was found that there was significant (p<0.05) improvement in HbA1c, weight, BMI, abdominal girth at the end of CDC therapy. Most

importantly, patient's dependency on traditional allopathic medication was also reduced at the end of study period.

HbA1c levels are considered to be major prognosticator in diabetic patients, as it reflects glycaemic control over preceding 2-3 months, as well as it was found in UKPDS study that, patients with controlled HbA1c levels were at lower risk of developing diabetic complications as compared to patients with elevated HbA1c levels.¹⁹

Till date HbA1c reduction was the major target of any antidiabetic therapeutic regime. But a landmark multicentric clinical trial-ACCORD trial showed that intensive HbA1c reduction (<6%) with multiple combination of antidiabetic drugs increased the cardiovascular mortality as compared to usual regime with less number of antidiabetic drugs.²⁰⁻²² Thus, if dependency on antidiabetic drugs is reduced and at the same time therapy is able to reduce the HbA1c gradually to optimal range then such therapy can be expected to carry a better prognosis. Given the findings of the present study, in terms of reduction in HbA1c and reduction in dependency on allopathic medications, it can be anticipated that CDC can be a potent therapeutic option with good prognosis.

In resource poor countries, the cost burden of long term antidiabetic drug therapy is huge. To add to the agony of the patients, these drugs are associated with numerous adverse effects, as well.⁹ In the present study, CDC therapy was able to reduce the patient's dependency on allopathic medication at the end of therapy. Thus, CDC will also help to bring down the cost burden of patient as well as it is devoid of adverse effects encountered with conventional antidiabetic drugs.

The major limitation of the present study was retrospective design, therefore chances of recall bias cannot be ruled out. Moreover, comparison with standard therapy alone was not possible, which have added more value.

CONCLUSION

From the findings of the present study, it is clear that CDC is effective in the form of increasing number of euglycemic patients at the end of study period, as well as reduction in all glycaemic and anthropometric parameters.

It also reduced patients' dependency on allopathic medications, which will help to reduce cost of therapy, and thus improve patient compliance.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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