

Role of Comprehensive Diabetes Care in Known Diabetes Patients from Vidarbha Region

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Abstract: Introduction: Number of patients with Diabetes Mellitus (DM) have been doubled in past few decades. India is particularly facing impending massive rise in number of diabetic cases, and therefore India is termed as Diabetes capital of the world by most of the clinicians. Worryingly, prevalence in Vidarbha region in India is rising and its figure as per published literature is >5%. Comprehensive diabetes care (CDC) is form of Ayurvedic therapy which combines panchkarma techniques and herbal drugs. Aims and objectives: The present study was initiated to evaluate the effectiveness of CDC in patients of DM in terms of glycosylated haemoglobin (HbA1c), body mass index (BMI), oral glucose tolerance test (OGTT), body weight, abdominal girth, etc. in Vidarbha region of India. Materials and methods: The present observational study was conducted across various Madhavbaug clinics in Vidarbha region of India. Data of the patients who were diagnosed with DM i.e. HbA1c>6.5% and received CDC therapy of 6 settings over 12 weeks was analysed. Results: In the present study, out of 293 type 2 diabetic patients, 179 were males (61%), while 114 were females (39%), thus male: female ratio was 1.57:1. At the end of 12 weeks of CDC therapy, number of patients with controlled DM (154) was significantly increased as compared to baseline (0), while the HbA1c also reduced from 6.89 at week 12 as compared to 8.45 at baseline, which was statistically significant. Other parameters like BMI, abdominal girth, etc. were significantly improved after 12 weeks of CDC therapy. Conclusion: Given the findings of present study, CDC therapy can be used as efficacious alternative form of therapy in the management of DM.

Keywords: Diabetes Mellitus, Comprehensive Diabetes Care, Ayurveda, Panchkarma

1. Introduction

Past few decades have witnessed a massive rise in prevalence of non-communicable diseases and hence their contribution to diseased states and fatality. Diabetes mellitus is one of the commonest non-communicable disease falling

in this category. It has been cited that number of patients with DM have been doubled in past few decades [1]. Globally, there are nearly 450 million patients of DM, of which major chunk of patients are found in China and India. India is particularly facing impending massive rise in number of diabetic cases, and therefore India is termed as Diabetes capital of the world by most of the clinicians [1]. Worryingly,

prevalence in Vidarbha region is rising and its figure as per published literature is >5% [2].

Clinically, DM is characterized by clinical triad of polydipsia, polyuria and polyphagia. However, DM is diagnosed definitively by laboratory diagnosis. In this regard, oral glucose tolerance test (OGTT) still remains the commonly employed test to diagnose DM, as it is comparatively cheaper, easily available, fair amount of sensitivity and specificity etc. It consists of fasting blood glucose (FBG) and post meal glucose levels (PMG) Since, DM is disorder of glucose metabolism, it is vital to know about the glucose control homeostasis over preceding 2-3 months period. This cannot be detected by the conventional OGTT, but can be detected by serum measurement of glycosylated hemoglobin i.e. HbA1c. The diagnostic cutoff levels for diagnosis of DM in FBS, PMG, and HbA1c are ≥ 126 mg/dl, 140 mg/dl and 6.5%, respectively [3].

The persistent hyperglycemia in DM alters the cardiovascular dynamics in the body and it leads to variety of complications like nephropathy, coronary heart disease, vaso-occlusive episodes, etc. The major cause of mortality in diabetic patients are renal and cardiac complications. Apart from these, non-fatal complications like diabetic foot ulcer, retinopathy, etc. significantly hamper the quality of life of patients and it may also results in disability [4].

Since, DM is chronic disease it cannot be cured completely but it can be managed to keep the derangements to minimum possible limits. It is usually treated by allopathic class of drugs known as oral hypoglycemic drugs (OHDs) along with advice on dietary and lifestyle modifications [5]. These drugs act by reducing the blood glucose levels, and the aim of therapy is to reduce the insulin resistance and hyperglycemia. They act by various mechanisms which vary from form increase glucose uptake by tissues, reducing gluconeogenesis, promoting lipolysis thus reducing the insulin resistance [6].

Major drawback of these drugs is increased cost burden of treatment, and more importantly adverse effects which further hamper the quality of life which is already deranged due to the disease. It is due to these factors that patient's compliance to this therapy is less. This has been to be as low as 97% in one of the clinical study by Alawdi et al. who reported moderate to poor patient adherence to OHDs in these patients [7]. Some of these adverse effects are hypoglycemia, dizziness, fainting, headache, urinary tract infections, anemia of chronic disease, megaloblastic anemia [6].

Despite availability of numerous OHDs and extensive guidelines for management of DM, the prevalence of disease is continually rising raises an alarm to explore for a newer therapeutic alternate for the management of DM. One such potent option is Ayurvedic therapy, which is ancient Indian medical science aiming to treat the disease from its root cause. Ayurvedic physicians administer various herbal drugs, panchakarma, diet therapy depending on the type of disease [8]. Comprehensive Diabetes Care (CDC) is one such therapy which combines Panchakarma, herbal drugs usage and diet therapy.

Panchakarma is an internal detoxification process, which involves 3 key procedures under the umbrella of CDC therapy- Snehana i.e. centripetal oleation, Swedana i.e. passive heat therapy, Basti i.e. per rectal herbal drug administration [9]. However, clinical data on effectiveness of CDC in patients of DM in Vidarbha region is scarce. Therefore, we planned the present study to evaluate the effectiveness of CDC in patients of DM in terms of HbA1c, BMI, OGTT, body weight, abdominal girth, etc.

2. Subjects and Methods

2.1. Study Design

Retrospective record based study.

2.2. Study Site

Madhavbaug clinics across Vidarbha region of Maharashtra state.

2.3. Study Period

July 2017 to January 2018.

2.4. Study Participants

Patients suffering from type 2 DM (HbA1c > 6.5%) [5], of either sex who attended Madhavbaug clinics across Vidarbha region of Maharashtra.

2.5. Methodology

The data of patients who had been administered CDC with minimum 6 sittings over a span of 12 weeks were considered for the study, out of which 4 sittings were done in 1st month, and 1 sitting per month for next 2 months. These patients were maintained on diet plan of 800-1000 calories intake per day, according to patient medical records. The diet plan consisted of low carbohydrates, moderate proteins, and low fats. Cases were identified, and data was assessed from the records of Madhavbaug clinics in Maharashtra. The selection was based upon the availability of complete relevant baseline data (day 1 of CDC) and final day data (day 90 of CDC) of the patients. The information about prescribed concomitant medicines, if any, was also noted down. The CDC is a 3-step procedure which was performed on the patients of type 2 DM after a light breakfast. One sitting of the procedure took 65-75 minutes, as described in table 1 [10].

2.6. Patient Categorization Post CDC Therapy

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

2.7. 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 compliance diet.
boxes were equivalent to number of months on taking the

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 <i>Azadirachta indica</i> (neem) extract processed in sesame oil	20 minutes
Swedana	Passive heat therapy to the body	<i>Dashmoola</i> (group of ten herbal roots) with steam at < 40 degrees Celsius)	15-20 minutes + 3-4 minutes of relaxation after procedure
Basti kadhā	Per-rectal drug administration should be in body for > 15 minutes for maximum absorption	Mixture of 40% <i>Gudmaar</i> (<i>Gymnema sylvestre</i>), 20% <i>Daruharidra</i> (<i>Berberis aristate</i>) and 40% <i>Yashtimadhu</i> (<i>Glycyrrhiza glabra</i>)	10 minutes

2.8. Statistical Analysis

Data were pooled and coded in 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. Paired t-test was used to assess the difference between baseline values and 90th day after treatment. Histogram were used to represent the graphs.

Patient record data selection for the present study is depicted in figure 1.

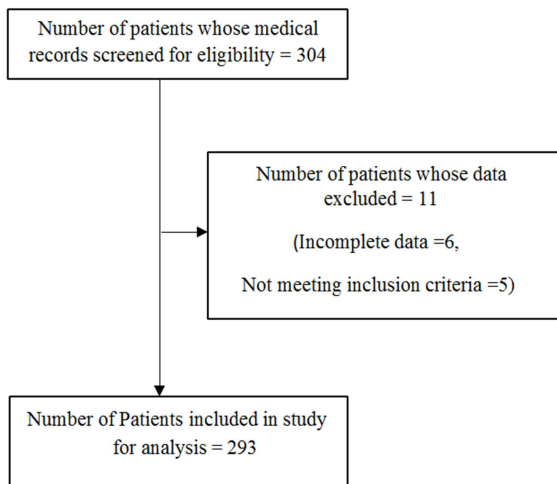


Figure 1. Patient record selection for the present study.

3. Results

In the present study, out of 293 type 2 diabetic patients, 179 were males (61%), while 114 were females (39%), thus male: female ratio was 1.57:1 [figure 1].

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

Sr. No.	Parameter	Measurement	Baseline	12 week	p-value
1	Anthropometry	Weight	71.48 \pm 3.1	67.12 \pm 3.3	0.05
		BMI	27.88 \pm 0.98	26.10 \pm 1.1	0.05
		ABG	97.47 \pm 4.6	92.81 \pm 3.8	0.05
2	Cardio-pulmonary	SBP	131.07 \pm 4.7	124.25 \pm 6.22	0.02
		DBP	80.39 \pm 2.9	76.42 \pm 3.4	0.07
		VO2 peak	16.68 \pm 1.1	26.15 \pm 2.2	0.001
3	Lipid profile	Cholesterol	128.5 \pm 3.96	90.83 \pm 5.01	0.020
		HDL	32.09 \pm 1.4	39.0 \pm 2.34	0.01
		LDL	79.1 \pm 4.1	52.09 \pm 5.1	0.001
		TG	120.91 \pm 5.16	78.22 \pm 6.13	0.001

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].

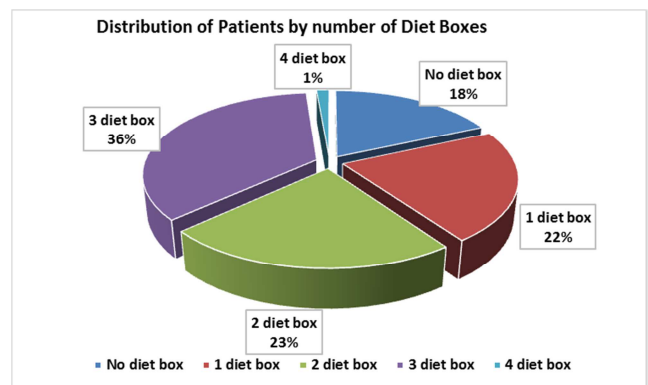


Figure 2. Number of diet boxes used by patients of present study.

On analysing the anthropometric parameters in the patients of present study, it was found that body mass index (BMI) was reduced from 27.88 \pm 0.98 kg/m² at baseline to 26.10 \pm 1.1 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 97.47 \pm 4.6 at baseline to 92.81 \pm 3.8 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.

BMI- Body Mass Index, ABG-abdominal girth, SBP-systolic blood pressure, DBP-diastolic blood pressure, HDL-High Density Lipoprotein, LDL- Low Density Lipoprotein, TG-Triglycerides.

On analysing the results of HbA1c values in patients who have completed 12 weeks of CDC therapy, it was found that normal HbA1c was seen in 154 patients (52%), borderline HbA1c was seen in 61 patients (18%) as compared to 131 patients (48%) at baseline, while abnormal HbA1c readings were noted in 78 patients (30%) as compared to 162 patients (55%) at baseline [figure 3].

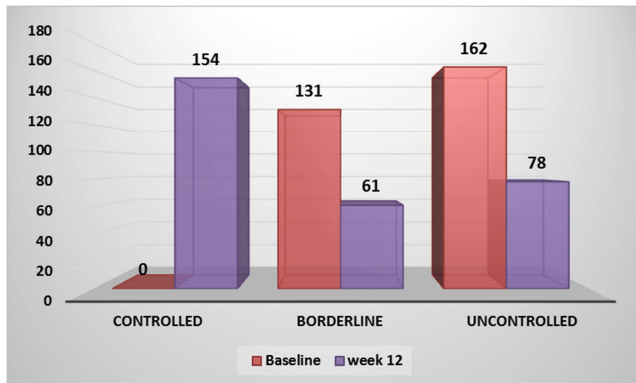


Figure 3. Results of HbA1c in patients who had completed 12 weeks of CDC therapy.

Glycosylated hemoglobin (HbA1c) reduced from 8.45 at baseline to 6.89 at week 12 of completion of CDC therapy, and the difference was statistically significant [figure 4].

Medication history was available in 293 patients, out of which majority of the patients were taking biguanide and sulfonylureas (SU). The number of tablets/patient ratio reduced from 1.04 at baseline to 0.39 at week 12 of CDC therapy, thus there was 62% 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].

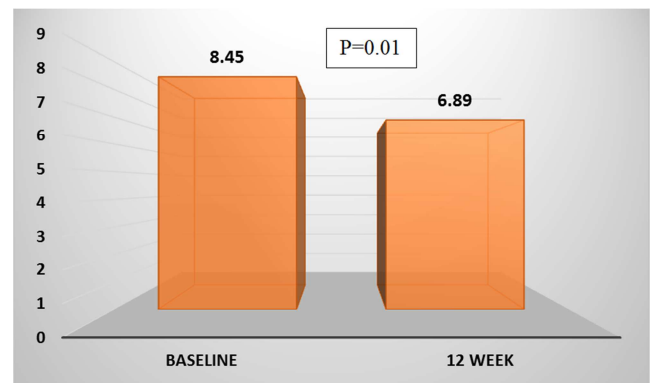


Figure 4. Glycosylated haemoglobin (HbA1c) in patients of present study at baseline and at 12 weeks of taking CDC therapy.

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				
Sr. No.	Medication	Baseline	Week 12	p-value
1	β blocker	22	12	0.001
2	ARB	42	25	0.001
3	CCB	34	15	0.001
4	Diuretic	8	3	0.05
5	SU	70	37	0.001
6	Biguanide	81	17	0.001
7	Antiplatelet	12	3	0.001
8	DPP4 inhibitor	18	2	0.001
9	Statins	18	1	0.001
10	Tablet/patient ratio	1.04	0.39	0.001

ARB-angiotensin receptor blocker, CCB-calcium channel blocker, SU-sulfonylurea, DPP4- dipeptidyl peptidase.

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 4. HbA1c results and duration of DM.

Duration of DM	Period of CDC therapy	HbA1c status			N
		Controlled	Borderline	Uncontrolled	
<2 yrs	Baseline	0	24	28	52
	week 12	27	12	13	52
2-10 yrs	Baseline	0	39	52	91
	week 12	44	21	26	91
> 10 yrs	Baseline	0	68	82	150
	week 12	83	28	39	150

4. Discussion

Ayurvedic physicians have been treating DM since ages using Panchkarma procedures and administration of herbal drugs, along with dietary modifications. The anti-hyperglycaemic effects of these therapeutic modality might help to optimize the blood sugar levels in these patients.

Comprehensive diabetes care (CDC) is a type of Ayurvedic therapy intended to manage DM, and it involves use of Panchkarma, herbal drugs administration. Panchkarma is a detoxification process, whose cleansing properties have been proven in literature [9]. There are 3 Panchkarma techniques that are used in CDC- Oleation therapy i.e. Snehana, steam therapy i.e. Swedana, and rectally administered herbal drug therapy i.e. Basti. All these procedures acts by reducing

glucose production in the liver by inhibit the process of gluconeogenesis, reduction in wear and tear of vascular endothelium, optimization of deranged lipid levels, etc [10].

In the present study, CDC significantly reduced all the important parameters like HbA1c, BMI, etc. Most important of all these parameters is HbA1c, as it is the only diagnostic parameter amongst the available tests to indicate long term glycaemic control over 2-3 months. It is also an independent prognostic indicator in patient of DM. Persistently elevated HbA1c levels is associated with increased complications and thus the elevated morbidity and mortality rates [11]. From the findings of the present study, CDC can be expected to improve the prognosis, given the significant reduction in HbA1c at the end of therapy.

However, ACCORD trial results does not favour intense reduction of HbA1c in management of DM. This multicentric trial was conducted to evaluate the effect of intense HbA1c reduction therapy with the help of multiple antidiabetic drugs as compared to standard regime with less number of antidiabetic drugs on cardiovascular outcomes, with special focus on persistent hyperglycaemia, dyslipidaemia and hypertension. The group with intense reduction in HbA1c showed increase in cardiovascular events by 3.5 times as compared to standard therapy. Thus, dependency on standard therapy should be least [12-14]. In the present study dependency on standard allopathic drugs reduced significantly at the end of study period, which indicates that this might have a better cardiovascular outcome.

It is well known fact that central obesity, as indicated by increased BMI, abdominal girth, body weight is associated with increased risk of complications in patients with DM [15]. Thus, reduction in these parameters are one of the targets for any antidiabetic regimen. It can inferred from the findings of the present study that CDC will help to reduce the risk of complications in patients of DM, as BMI, abdominal girth, body weight were reduced significantly at the end of CDC therapy.

Snehana is one of the major Panchkarma technique which was used in the present study. It relieves the sympathetic stress of the patient and thus the intrinsic gluconeogenesis, which is under the control of sympathetic nervous system is reduced. It is done with help of Azadirachta indica oil, which has natural anti-infective properties and might help to counteract the dermatological infections in diabetic patients [16]. Swedana exposes the diabetic patients to high temperature of 40-42 degree Celsius through steam. Such passive heat therapy is postulated to soothe the patient and induce sweating, which get rid of excess of sodium and water load in diabetic patients, which maintains the vascular health and thus reducing the chances of vascular complications [10]. Basti is per rectal administration of herbal drugs like 40% *Gudmaar* (*Gymnema sylvestre*), 20% *Daruharidra* (*Berberis aristate*) and 40% *Yashtimadhu* (*Glycyrrhiza glabra*). These drugs are known to stimulate insulin release by stimulating the production of islets of Langerhans and beta cells in the pancreas [10].

Insulin resistance is one of the major pathogenic factor in

type 2 DM. Sedentary lifestyle and faulty dietary habits have been cited as the major causes for these insulin resistance. Especially canned foods, junk foods have high amount of calories which are deleterious to already compromised glucose handling mechanism in diabetic patients. Therefore, while explaining the management to the diabetic patients, diet with low carbohydrates and fats with moderate amount of protein is advised to induce and maintain negative calories balance, which is known to improve glucose handling mechanics of the body, and thus reduce the insulin resistance [17].

Dependency on allopathic medications was also reduced in the present study at the end of study period. This will help to reduce the cost burden of the patients, as well reduction in adverse effects associated with the use of allopathic drugs.

5. Conclusion

From the findings of the present study, antidiabetic actions of CDC in the form of reduction in HbA1c, BMI, abdominal girth, etc. have shown effective readings. This was corroborated by more number of patients with controlled diabetic status at the end of therapy. Given the current scenario of rise in number for diabetic patients and their poor compliance to long term use of conventional antidiabetic drugs, CDC can serve as a potent therapeutic alternative in management of DM which will help to overcome these issues.

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Not applicable.

Conflicts of Interest

The authors declare that they have no competing interests.

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