

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

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ABSTRACT

Introduction: Globally, multiple million of the population is suffering from diabetes mellitus (DM), which follows chronic course. The prevalence of DM in Karnataka has been reported to be as high as 12%. Comprehensive diabetes care program (CDC) is an Ayurvedic form of therapy which consists of management of T2DM by Panchkarma, diet therapy.

Aims and objectives: The present study was planned to analyze the effectiveness of CDC on blood glucose, physical and cardiorespiratory parameters in patient of T2DM.

Materials and methods: This observational study was conducted from November 2018 to October 2019, wherein the data of type 2 DM patients (HbA1c >6.6%) who attended out-patient departments (OPDs) at Madhavbaug clinics across Karnataka were identified. Data of patients who were administered CDC over 12 weeks were considered. All the glycemetic parameters were compared at baseline and week 12.

Results: In the present study, out of 35 patients the number of patients with controlled DM status rose from zero at baseline to 17 (48%) at week 12 of CDC therapy. Mean HbA1c levels were reduced from 9.01 at baseline to 7.36 at week 12 ($p=0.001$). All the anthropometric parameters, lipid parameters, etc., showed statistically significant improvement, and reduction in dependency on allopathic medications at week 12 of CDC therapy.

Conclusion: From the findings of the present study, it was clear that CDC improved two most critical parameters- reduction in HbA1c and patient's dependency on conventional medicines, which helps to reduce cost of therapy and thus improve patient compliance.

Keywords: DM, Comprehensive Diabetes Care, CDC, panchkarma, glycosylated HB, HbA1C.

INTRODUCTION

Globally, diabetes mellitus has created a havoc, whose majority share is by developing, resource poor countries. As per the World Health Organization report, numbers of diabetic patients by 2014 were above 420 million, which is estimated to cross 360 million by next decade. In Indian context, more than 60 million people are

diagnosed with DM. Reasons cited for such high prevalence of the disease are increased in number of middle aged population, faulty dietary habits, reduced physical activity, etc. all of which contribute to increase in disease load of the country.¹ The prevalence of DM in Karnataka has been reported to be as high as 12%, which call for active screening and intervention.²

DM is dreaded due to its morbidity and mortality. DM is associated with range of complications like pancreatitis, anaemia of chronic disease, renal failure, cardiovascular complications, blindness, sexual dysfunction in males, etc. Cardiovascular complications and renal complications are a major cause of mortality in diabetic patients.³ DM is usually diagnosed by measurement of serum sugar levels, in fasting state and after administering 75 mg glucose oral solution to the patient. However, glycosylated haemoglobin i.e. HbA1c has been utilized for diagnosed of DM, as well as marker of long term blood glucose control in the management of diabetic patients. HbA1c is formed due to non-enzymatic reaction during metabolism of glucose, and it roughly reflects the transient homeostasis of blood glucose in past 3 months.⁴ HbA1c > 6.5% is diagnostic of DM, and the aim of any antidiabetic therapy is to keep it <6.5%.

In a clinical study it was found that the likelihood of developing these complications increased manifold in patients with persistent hyperglycemia, as measure by levels of glycosylated hemoglobin (HbA1c). Roughly, an increase in HbA1c by 1% leads to 18% increase in cardiovascular complications, 12% increase in premature deaths, and almost 40% increased risk of retinopathy changes.⁵

DM is usually treated with variety of antidiabetic drugs (ADD) which are either used as monotherapy or in combination with different class. Some of these ADDs are metformin, acarbose, canagliflozin, gliclazide, etc. These drugs act by reducing blood glucose levels by multiple mechanism like increased tissue uptake of glucose, increase glucose transporter 4 protein, decreased gluconeogenesis, increased glycolysis, etc.⁶

However, there lots of adverse effects associated with the use of these ADDs, which include fainting, dizziness, gastric upset, dyspepsia, diabetic ketoacidosis, etc. The quality of life is

already hampered in diabetic patients due to distressing symptoms. These adverse effects further reduce the quality of life of these patients. This is the major reason for poor patient compliance to conventional antidiabetic therapy.⁶ Thus, it is need of the hour to search for effective alternate therapy which will be devoid of shortcomings of conventional therapy.

Ayurveda is ancient form of Indian medicine which is practices since centuries. Its efficacy has been proven in many diseases, as well as it is devoid of adverse effects.⁷ Comprehensive diabetes care (CDC) is a form of Ayurvedic therapy which utilizes a combination of Panchkarma-a detoxification process, giving herbal drugs to the patients, and diet therapy. These herbal drugs are known to act by reducing blood sugar level i.e. similar to OADs, but without the adverse effects that are seen with OADs.^{8,9} Since there is very less data regarding the effectiveness of CDC in patients of DM, we carried out the present study to evaluate the same by analyzing effect of CDC on HbA1c, fasting and post meal blood sugar levels and other anthropometric parameters which are linked to insulin resistance.

SUBJECTS AND METHODS

Study design: Retrospective record based study.

Study site: Madhavbaug clinics across Karnataka state.

Study period: September 2018 to November 2019.

Study participants: Patients of either sex or any age, suffering from type 2 DM, who attended Madhavbaug clinics in Karnataka state.

Methodology: The data of patients who had been administered CDC with minimum 6 sittings over a span of 90 days (\pm 15 days) were considered for the study, out of which 4 sittings were done in 1st month, and 1 sitting per month for next 2 months. According to patient medical records, these patients were given diet kits consisting of low carbohydrates, moderate proteins, and

low fats. 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.^[19,20]

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.

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 katha	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

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. Histograms were used to represent the graphs.

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

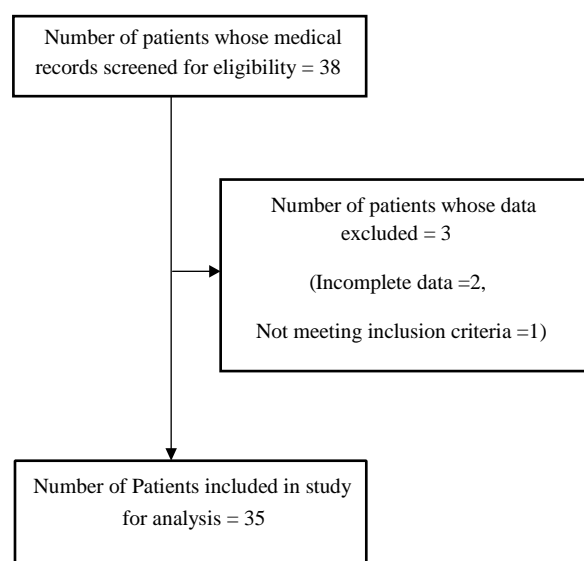


Figure 1: Patient record selection for the present study.

RESULTS

In the present study, out of 35 type 2 diabetic patients, 19 were males (46%), while 16 were females (54%), thus male: female ratio was 1.18:1 [figure 2].

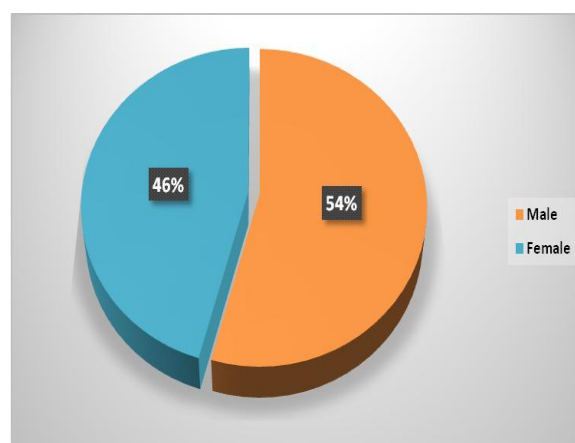


Figure 2: Sex distribution in patients of the present study.

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 3].

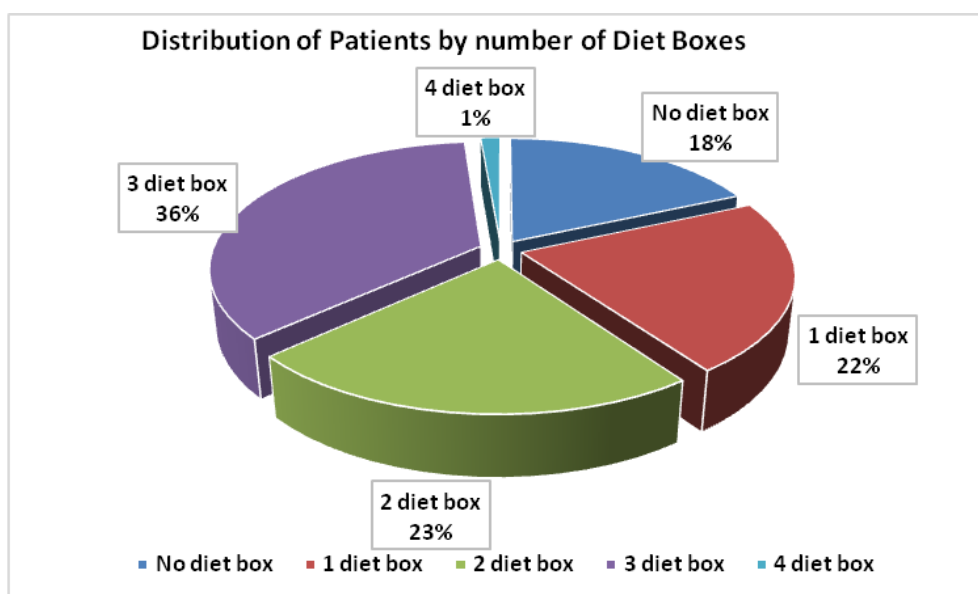


Figure 3: number of diet boxes used by patients of present study.

On analysing the anthropometric parameters in the patients of present study, it was found that body mass index (BMI) was reduced from 26.71 ± 1.08 kg/m² at baseline to 25.19 ± 1.12 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 93.39 ± 5.3 at baseline to 88.32 ± 4.3 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.

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	65.39±5.1	62.18±4.4	0.05
		BMI	26.71 ± 1.08	25.19 ± 1.12	0.05
		ABG	93.39 ± 5.3	88.32 ± 4.3	0.05
2	Cardio-pulmonary	SBP	133.37 ± 5.9	122.23 ± 6.3	0.01
		DBP	78.77 ± 4.1	73.49 ± 3.6	0.05
		VO ₂ peak	17.76 ± 1.01	23.13 ± 0.99	0.001
3	Lipid profile	Cholesterol	188.6±8.3	108.6±6.1	0.000
		HDL	40±1.1	43.12±2.1	0.01
		LDL	94.12±4.1	65.5±5.2	0.001
		TG	199.5±7.6	144.25±5.16	0.010

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 HbA_{1c} levels in patients who have completed 12 weeks of CDC therapy, it was found that normal HbA_{1c} was seen in 17 patients (48%), borderline HbA_{1c} was seen in 6 patients (17%) as compared to 14 patients (40%) at baseline, while deranged readings were noted in 12 patients (34%) as compared to 21 patients (60%) at baseline [Figure 4].

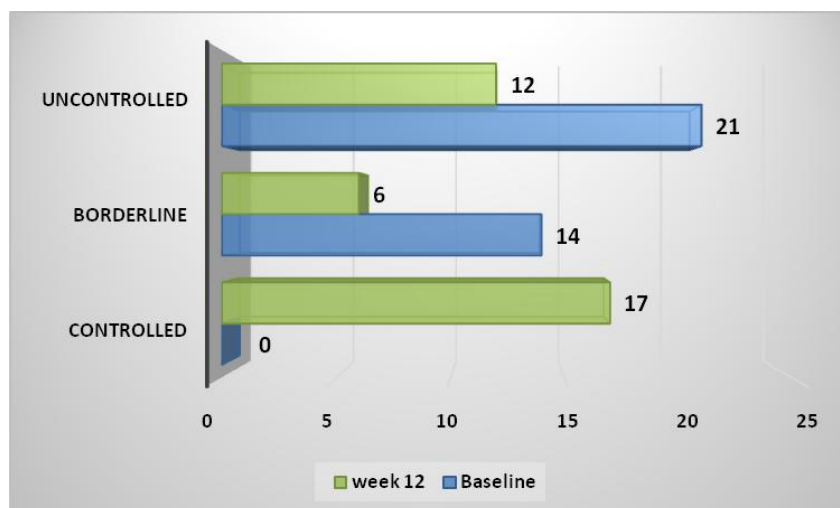


Figure 4: Results of OGGT in patients who had completed 12 weeks of CDC therapy.

Glycosylated hemoglobin (HbA1c) reduced from 9.01 at baseline to 7.36 at week 12 of completion of CDC therapy, and the difference was statistically significant [figure 5].

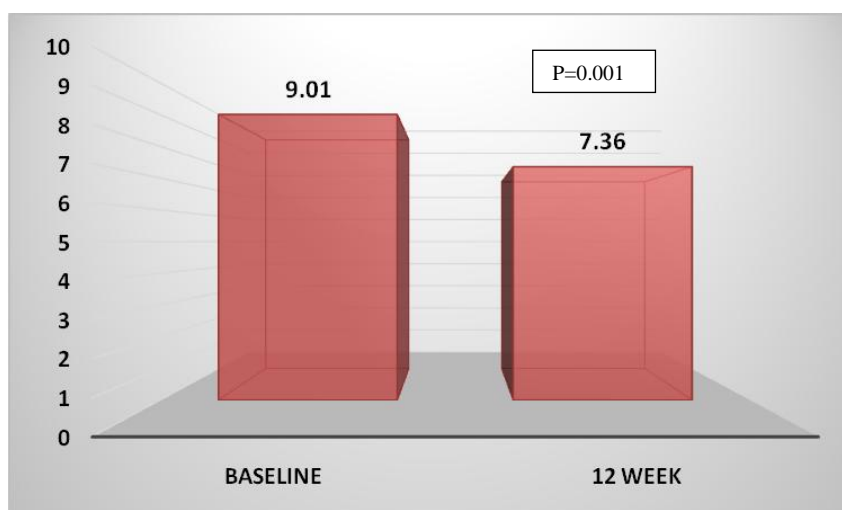


Figure 5: Glycosylated haemoglobin (HbA1c) in patients of present study at baseline and at 12 weeks of taking CDC therapy.

Medication history was available in 35 patients, out of which majority of the patients were taking biguanide and sulfonylureas (SU). The number of tablets/patient ratio reduced from 1.23 at baseline to 0.48 at week 12 of CDC therapy, thus there was 72% 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].

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				
Sr. No.	Medication	Baseline	Week 12	p-value
1	β blocker	4	3	0.08
2	ARB	8	8	0.001
3	CCB	1	1	0.25
4	Diuretic	4	3	0.56
5	SU	14	6	0.001
6	Biguanide	21	6	0.001
7	Antiplatelet	3	2	0.06
8	DPP4 inhibitor	1	0	0.001
9	Statins	4	0	0.001
10	Tablets/patient ratio	1.23	0.48	0.001

ARB-angiotensin receptor blocker, CCB-calcium channel blocker, SU-sulfonylurea, DPP4- dipeptidyl peptidase 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	4	5	9
	week 12	4	2	3	9
2-10 yrs	Baseline	0	5	3	8
	week 12	4	1	3	8
> 10 yrs	Baseline	0	5	13	18
	week 12	9	3	6	18

DISCUSSION

The prevalence of type 2 diabetes mellitus is increasing continuously throughout the world and has emerged as one of the commonest culprit of morbidity and mortality. This becomes more worrisome when we already have huge armamentarium of conventional drugs therapy available to control disease. Thus, it becomes imperative to search and validate other viable treatment alternatives which will aid in curtailing the havoc caused by type 2 diabetes mellitus. Major action of traditional oral hypoglycemic drugs is to reduce the elevated blood glucose levels towards optimal range. Variety of herbal drugs have been found to have similar actions on blood sugar levels, and thus Ayurvedic form of medicine can serve as most potent alternative in management of type 2 diabetes mellitus. Panchkarma is the commonest Ayurvedic therapy given to the patient so type 2 diabetes mellitus.⁸ CDC combines Panchkarma diet regimen consisting of low levels of carbohydrates and fats and modest amount of proteins.

Swedana i.e. sudation therapy was used in the present study, which acts by increasing the core body temperature by 2-3 degree Celsius. This stimulates the temperature regulatory centre in the hypothalamus, which in turn activates the vasodilation of cutaneous blood vessels, which play a major role in thermoregulation. Vasodilation coupled with increased permeability induced by Swedana helps to get rid of sodium and thus soothes the vascular endothelium and therefore less chances of developing vascular complications.¹⁰ Snehana act by reducing the elevated lipids i.e. it reduces the dyslipidaemia.¹¹ Basti helps to improve

the function of nephrons and thus helps to relieve nephropathy.¹²

HbA1c is important titration factor in any antidiabetic therapy for dual reasons. Firstly, it reflects blood glucose control over preceding 2 months and secondly, it acts as independent prognosticator in diabetic patients. Persistently elevated levels of hbA1c is associated with increased complications and thus the resulting morbidity and mortality.¹³ Thus, target of any antidiabetic therapy is to keep the HbA1c levels within optimal range. Since CDC therapy was able to reduce the HbA1c towards optimal levels, it can be anticipated that it will improve the prognosis in diabetic patients.

However, intense HbA1c reduction should not be targeted enthusiastically while treating diabetic patients. This was proven in ACCORD trial, which evaluated the effect of intense HbA1c reduction by multiple antidiabetic drug administration for long duration on cardiovascular outcomes. It was found that this intense therapy increased cardiovascular mortality by 3.5 times.¹⁴ This means that increased exposure to multiple antidiabetic drugs will actually worsen the prognosis. Thus, it can be inferred that reduction in dependency on allopathic medications by CDC in the present study is a welcome sign.

Biggest challenge of chronic therapy in developing country like India is the increase cost of therapy, which most of the patients cannot afford. Furthermore, the extensive adverse effects encountered with antidiabetic drugs worsen the scenario.¹⁵ Thus, patient compliance is very less in such type of diseases. In this regards, CDC can prove to be advantageous since it reduced the allopathic drug dependency, thus reducing both cost and adverse effects

which will help to improve patient compliance.

CONCLUSION

CDC therapy enabled more number of patients in controlled diabetic group, reduced glycosylated haemoglobin, body mass index, abdominal girth and also the patient's dependency on conventional medications. Thus, it can be concluded that CDC will not only serve as effective option to manage type 2 DM, but it will also improve the prognosis, as well as patient compliance.

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Conflicts of interest: None declared by the authors.

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