



ROLE OF COMPREHENSIVE DIABETES CARE IN KNOWN DIABETES PATIENTS FROM MADHYA PRADESH REGION

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ABSTRACT

Background: Prevalence of Diabetes mellitus (DM) is increasing dramatically in India and worldwide. As per one epidemiological study done in Madhya Pradesh, the prevalence of DM was found to be 8%, which is quite high. Comprehensive Diabetes Care (CDC) is a form of Ayurvedic therapy which combines panchkarma and diet management. **Aims and objectives:** The present study was done to analyze the effectiveness of CDC in the management of DM. **Materials and methods:** This observational study identified and analysed data of type 2 DM patients (HbA1c >6.5%) who attended out-patient departments (OPDs) at Madhavbaug clinics across Madhya Pradesh, who were administered CDC (60-75 minutes) with minimum 6 sittings over 12 weeks. All the glycemic parameters were compared at baseline and week 12. **Results:** Out of 155 patients, CDC showed significant improvement in HbA1c 1.73% (from 8.56 at baseline to 6.83 at 12 weeks). At the end of week 12 controlled DM status was seen in 78 patients (50%). Dependency on concomitant medicines was significantly reduced. **Conclusion:** From the findings of present study, CDC has been found to be effective owing to its dual action i.e. reduction in HbA1c and dependency on conventional antidiabetic drugs. **Keywords:** Comprehensive Diabetes Care, CDC, panchkarma, glycosylated HB, HbA1C, BMI, DM, alternative medicine.

INTRODUCTION

Globally, number of cases of diabetes mellitus (DM) are increasing alarmingly and they have reached epidemic levels. As per the report of International Diabetes Federation the number of patients with DM are expected to cross the 550 million mark by the year 2030. More than 3/4th of these patients are living in resource poor and developing countries. In the next 2 decades India is anticipated to harbor 20% of the diabetic population of the world.^[1] As per one epidemiological study done in Madhya Pradesh, the prevalence of DM was found to be 8%, which is quite high.^[2]

Clinically, symptoms of DM are vague and non-specific, but they raise the suspicion and should be confirmed with laboratory investigations. Clinical triad of increased thirst, increased food intake, increased urination are seen

in diabetic patients. The diagnosis is confirmed by serum measurements of fasting blood sugar, post prandial blood sugar levels, and more recently glycosylated hemoglobin i.e. HbA1c. HbA1c is more preferred by the physicians over the conventional blood sugar estimation tests to diagnose DM.^[3]

Type 2 DM (T2DM) comprises of >90% of all the diabetic cases. Persistent hyperglycemia and insulin resistance are hallmark features of T2DM. These lead to chronic exposure of tissues and vascular endothelium to elevated level of glucose. There is formation of advance glycosylated end products due to this persistent hyperglycemia. The end products lead to variety of complications like retinopathy, nephropathy, cardiovascular complications, etc. all of which contribute to morbidity and mortality.^[4]

There is an armamentarium of antidiabetic drugs which are used to manage DM. Since DM is a chronic disease it requires long term treatment. But, Chronic therapy means increased cost of therapy, which burdens the patients of developing countries like India. Moreover, persistent use of these antidiabetic drugs is associated with development of various adverse effects like hypoglycemic episodes owing to missed dose or overdose, which is a common scenario, normocytic and normochromic anemia, pancreatitis, etc. This reduces the patient compliance to therapy.^[5]

It is high time that clinicians are exploring for newer alternate therapies for the management of DM. Since it has been proven in many studies that herbal drugs possess properties similar to antidiabetic drugs i.e. lowering of blood glucose levels and that devoid of adverse effects, Ayurveda can serve a potential therapeutic alternative in management of diabetic patients. Ayurveda is an ancient form of Indian medicine, which aims to correct the root cause of the disease and not just the symptomatic management.^[6] It combines administration of herbal drugs along with diet therapy and Panchkarma.

Comprehensive Diabetes Care (CDC) is a form of Ayurvedic therapy, wherein Ayurvedic physicians administer Panchkarma- an internal detoxification process consisting of Basti-herbal drug therapy administered per rectum, Swedana- steam therapy, and Snehana-oleation therapy, along with herbal drug administration and dietary therapy in the form of diet kits.^[7]

However, there is paucity of clinical efficacy data of such forms of treatment, which are proving to be efficacious in clinical practice. Thus, the present study was started in order to obtain evidence regarding effectiveness of CDC in patients of DM attending Madhavbaug clinics in Madhya Pradesh region, in terms

of improvement of anthropometric parameters like FBS, PPBS and HbA1c.

SUBJECTS AND METHODS

The present retrospective study was conducted between August 2018 to September 2019, wherein we identified the data of patients suffering from type 2 DM (HbA1c \geq 6.5%)^[8] of either gender and any age, and who had attended the out-patient departments (OPDs) at multiple Madhavbaug clinics located in Madhya Pradesh region. 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. Inclusion criteria for the present study was as follows:

- Patients diagnosed with T2DM
- Complete data at baseline and week 12 was available
- Patients who had undergone CDC therapy for 12 weeks
- Patients who were given diet kit therapy.

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.

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.^[8]

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 \leq 40 degrees Celsius)	15-20 minutes + 3-4 minutes of relaxation after procedure
Basti kadha	Per-rectal drug administration should be in body for \geq 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 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 \pm SD. Paired t-test was used

to assess the difference between baseline values and 90th day after the treatment.

RESULTS

In the present study, out of 155 type 2 diabetic patients, 88 were males (57%), while 67 were females (43%), thus male: female ratio was 1.3:1 [figure 1].

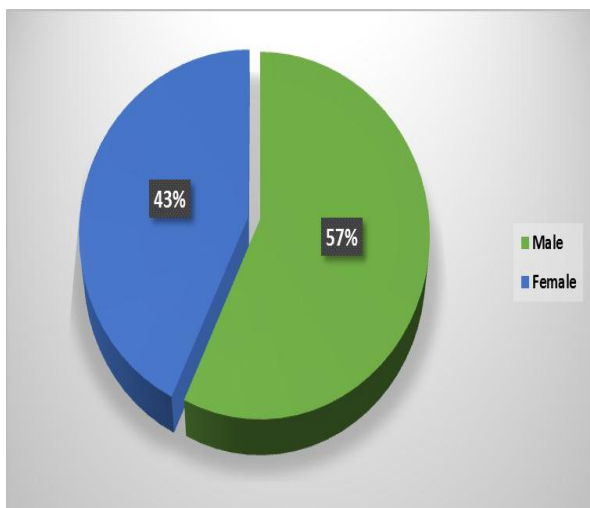


Figure 1: Sex distribution in patients of the present study.

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 2].

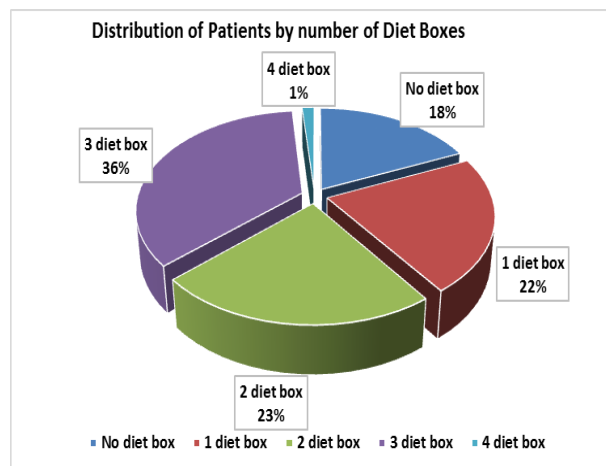


Figure 2: number of diet boxes used by patients of present study.

On analysing the anthropometric parameters in the patients of present study, it was found that body mass index (BMI) was reduced from 27.71 ± 1.08 kg/m² at baseline to 25.76 ± 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 96.93 ± 5.3 at baseline to 92.1 ± 2.1 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 1.

Table 1: 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	72.81±6.7	67.62±5.9	0.05
		BMI	27.71 ± 1.08	25.76 ± 1.12	0.05
		ABG	96.93 ± 5.3	92.1 ± 2.1	0.05
2	Cardio-pulmonary	SBP	132.80 ± 4.1	122.93 ± 3.2	0.01
		DBP	81.21 ± 2.9	76.71 ± 3.3	0.04
		VO ₂ peak	15.39 ± 0.77	22.67 ± 1.1	0.00
3	Lipid profile	Cholesterol	187.44±8.2	152.5±6.1	0.001
		HDL	35.49±1.9	43.1±2.1	0.001
		LDL	121.26±7.2	102.78±5.8	0.001
		TG	222.06±5.1	84.87±6.27	0.000

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} in patients who have completed 12 weeks of CDC therapy, it was found that normal HbA_{1c} was seen in 78 patients (50%), borderline HbA_{1c} was seen in 30 patients (30%) as compared to 61 patients (39%) at baseline, while deranged HbA_{1c} readings were noted in 47 patients (30%) as compared to 94 patients (61%) at baseline [Figure 3].

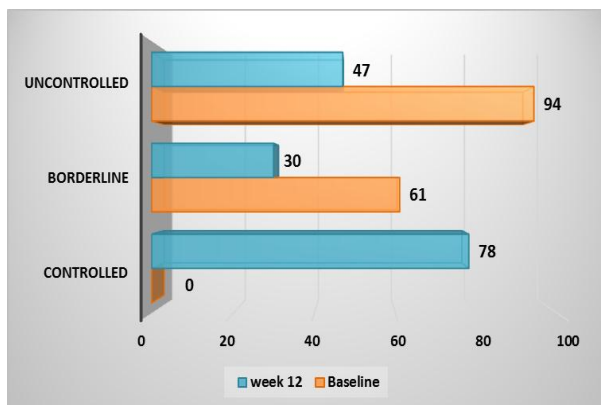


Figure 3: Results of HbA1c in patients who had completed 12 weeks of CDC therapy.

Glycosylated hemoglobin (HbA1c) reduced from 8.56 at baseline to 6.83 at week 12 of completion of CDC therapy, and the difference was statistically significant [figure 4].

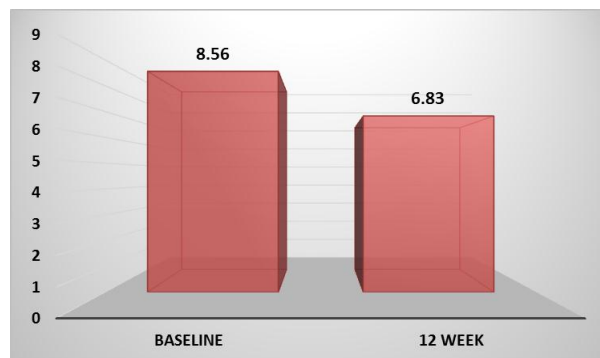


Figure 4: Glycosylated haemoglobin (HbA1c) in patients of present study at baseline and at 12 weeks of taking CDC therapy.

Medication history was available in 155 patients, out of which majority of the patients were taking biguanide and sulfonylureas (SU). The number of tablets/patient ratio reduced from 1.84 at baseline to 0.78 at week 12 of CDC therapy, thus there was 58% reduction in number patients taking allopathic medications after 12 weeks of CDC therapy, with major reduction seen in intake of biguanides and SU [table 2].

Table 2: 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	10	6	0.23
2	ARB	34	22	0.001
3	CCB	25	14	0.001
4	Diuretic	15	9	0.06
5	SU	63	30	0.001
6	Biguanide	93	31	0.001
7	Antiplatelet	6	1	0.13
8	DPP4 inhibitor	21	5	0.001
9	Statins	19	3	0.001
10	Tablet/patient ratio	1.84	0.78	0.02

ARB-angiotensin receptor blocker, CCB-calcium channel blocker, SU-sulfonylurea, DPP4- dipeptidyl peptidase, n 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 3].

Table 3: HbA1c results and duration of DM.

Duration of DM	Period of CDC therapy	HbA1c status			N
		Controlled	Borderline	Uncontrolled	
<2 yrs	Baseline	0	29	11	40
	week 12	25	5	11	40
2-10 yrs	Baseline	0	22	24	46
	week 12	21	14	12	46
> 10 yrs	Baseline	0	10	59	69
	week 12	32	11	26	69

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.^[9] CDC combines Panchkarma diet regimen consist of low levels of carbohydrates and fats and modest 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.^[7]

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.^[10]

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.^[11,12,13] 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.

In a resource limited country like India, where per capita income of majority of the population is still very low, and the long term intake of allopathic medicines increases the cost of therapy to distressing limits. Numerous adverse effects of these drugs complicates the scenario.^[14] There was significant reduction in dependency on allopathic drugs, at the end of study period.

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.

CONCLUSION

From the findings of the present study, it is clearly evident that CDC effectively optimizes the key deranged parameters in DM, which are responsible for morbidity and mortality. Thus, CDC can be anticipated to carry a better prognosis, with added advantage of increased chances of improved patient compliance by reducing cost of therapy and adverse effects.

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REFERENCES

1. Wangnoo S, Maji D, Das A, et al. Barriers and solutions to diabetes management: An Indian perspective. *Indian J Endocrinol Metab*, 2013; 17(4): 594-601.
2. Kumar G, Neeraj K, Khare S. A Study of Diabetes Prevalence and its Risk Factors in the Medical College Faculty of Bhopal, Madhya Pradesh. *Austin J Endocrinol Diabetes*, 2014; 1(2): 3.
3. Olokoba A, Obateru O, Olokoba L. Type 2 Diabetes Mellitus: A Review of Current Trends. *Oman Medical Journal*, 2012; 27(4): 269-273.
4. Jellinger P. Metabolic Consequences of Hyperglycemia and Insulin Resistance. *Clin Cornerstone*, 2007; 8: S30-S42.
5. Chaudhury A, Duvoor C, Reddy V, et al. Clinical Review of Antidiabetic Drugs: Implications for Type 2 Diabetes Mellitus Management. *Front. Endocrinol*, 2017; 8(6): 1-12.
6. Srinivas P, Prameela Devi K, Shailaja B. Diabetes mellitus (madhumeha)-an ayurvedic review. *Int J Pharm Pharm Sci.*, 2013; 6(1): 107-110.
7. Sane R, Ghadigaonkar P, Chaur R, Jain S, Wahane S, Nadapude A, et al. Efficacy of Comprehensive Diabetes Care (CDC) Management Program in Elderly Male Patients of Type II Diabetes Mellitus: A Retrospective Study. *International Journal of Diabetes and Endocrinology*, 2018; 3(2): 29-34.
8. Madhu S, Srivastava S. Diabetes Mellitus: Diagnosis and Management Guidelines. *JIMSA*, 2015; 28(1): 47-50.
9. Nair D. Understanding the Role of Ayurveda Panchakarma Therapy W.S.R. to Vasthi (Enema) in the Management of Type II Diabetes Mellitus- A Case Review. *Int J Complement Alt Med.*, 2017; 8(6): 00276.
10. King P, Peacock I, Donnelly R. The UK prospective diabetes study (UKPDS): clinical and therapeutic implications for type 2 diabetes. *Br J Clin Pharmacol*, 1999; 48(5): 643-8.

11. Buse J, Bigger J, Byington R, et al. Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial: design and methods. *Am J Cardiol*, 2007; 99(12A): 21i-33i.
12. Gerstein H, Riddle M, Kendall D, et al. Glycemia treatment strategies in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial. *Am J Cardiol*, 2007; 99(12A): 34i-43i.
13. Gerstein H, Miller M, Byington R, et al. Effects of intensive glucose lowering in type 2 diabetes. *N Engl J Med.*, 2008; 358(24): 2545-59.
14. Egede L, Axon R, Gebregziabher M, et al. Medication Nonadherence in Diabetes. *Diabetes Care.*, 2012; 35: 2533–2539.