



ROLE OF COMPREHENSIVE DIABETES CARE IN KNOWN DIABETES PATIENTS FROM CENTRAL MUMBAI REGION.

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ABSTRACT

Background: Globally, multiple million of the population is suffering from diabetes mellitus (DM), which follows chronic course. As the report published by World Health Organization (WHO), number of cases of DM have risen massively by 4 times in 2014, as compared to 3 decades prior period. 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 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%) who attended out-patient departments (OPDs) at Madhavbaug clinics across central Mumbai were identified. Data of patients who were administered CDC (60-75 minutes) with minimum 6 sittings over 12 weeks were considered. All the glycemic parameters were compared at baseline and week 12. **Results:** In the present study, out of 424 type 2 diabetic patients and borderline cases, 225 were males (52%), while 199 were females (48%), thus male: female ratio was 1.13:1. The number of patients with controlled DM status rose from zero at baseline to 215 (51%) at week 12 of CDC therapy. 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: Diabetes, Comprehensive Diabetes Care, CDC, panchkarma, glycosylated HB, HbA1C.

INTRODUCTION

Globally, multiple million of the population is suffering from diabetes mellitus (DM), which follows chronic course. As the report published by World Health Organization (WHO), number of cases of DM have risen massively by 4 times in 2014, as compared to 3 decades prior period. The number of diabetic patients in 2014 were around 422 million.^[1] Worrisome finding in these prevalence rates is the presence of majority of cases in developing countries like India, and due to these high prevalence rates, many researchers have labelled India as 'diabetes capital' of the world. 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%.^[2] Being one of the commonest contributor of global morbidity and deaths, DM also increases the cost burden of therapy in the affected patients. DM is associated with numerous complications like coronary artery disease, stroke, peripheral arterial disease, renal failure, etc.^[3]

Insulin resistance is the hallmark of type 2 DM (T2DM), which leads to hyperglycemia despite normal levels of insulin. Traditionally, T2DM is diagnosed by oral glucose tolerance tests (OGTT), which has 2 components- fasting blood sugar (FBS) and post meal blood sugar (PMBS) levels. Diagnostic cut-off for T2DM is FBS ≥ 126 mg/dl and/ PMBS ≥ 140 mg/dl. Since past few years, glycosylated hemoglobin (HbA1c) is being routinely used for diagnosing T2DM, as it reflects control of blood sugar levels during past 2-3 months. Cut-off value of HbA1c for diagnosis of T2DM is taken as 6.5%. Aim of antidiabetic therapy is to reduce the HbA1c levels to <6.5%.^[4]

The knowledge of DM (Prameha) can be found in ancient Ayurvedic literature, which indicates that Ayurvedic physicians were aware of the disease.^[5] In Ayurvedic form of treatment, there is amalgamation of various regimens comprising of Panchkarma- a multi-step internal cleansing process, diet rectification, and administration of various herbal drugs.^[6] Comprehensive

diabetes care program (CDC) is an Ayurvedic form of therapy which consists of management of T2DM by Panchkarma, diet therapy.

Panchkarma utilizes 3 key procedures under the aegis of CDC therapy. These are Basti i.e. per rectal administration of herbal drugs, Snehana i.e. oleation, and Swedana i.e. thermal vasodilation. These procedures are known to detoxify the body internally.⁶ However, there is a scarcity of data on clinical effectiveness of CDC in patients of T2DM, which can help to establish this form of therapy as potent alternative to conventional treatment regimens. Thus, the present study was planned to analyze the effectiveness of CDC on blood glucose parameters in patient of T2DM.

MATERIALS AND METHODS

1. Study design: Retrospective record based study.
2. Study site: Madhavbaug clinics across central Mumbai and Navi Mumbai, India.
3. Study period: November 2018 to October 2019.
4. Study participants: Patients diagnosed with type 2 DM (HbA1c>6.5%) and borderline cases (HbA1c 5.7 to 6.5%),⁴ who attended Madhavbaug clinics in central Mumbai region of Maharashtra.
5. Sample size: 424 patients suffering from type 2 diabetes mellitus and borderline cases were included in the present study.
6. Methodology: The data of patients who had been administered CDC with minimum 6 sittings over a

span of 90 days (± 15 days) were considered for the study. These patients were maintained on diet plan with low carbohydrates, low fats and moderate amount of proteins. Only those patients medical records were included in the study whose complete data was available at specified time points i.e. baseline and week 12. Co-administered allopathic drugs were also noted for analysis. Following details were noted at baseline and at week 12:

- Anthropometric parameters- body weight, BMI, abdominal girth
 - Cardiopulmonary parameters- SBP, DBP, VO2 max
 - OGTT, HbA1c.
7. 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.
 8. 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 [Table 1].^[6]

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 kadha	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 aristata</i>) and 40% <i>Yashtimadhu</i> (<i>Glycyrrhiza glabra</i>)	10 minutes

Statistical analysis: All the relevant data was filled into predesigned Microsoft Excel sheet. The pooled data was calculated in the form of mean and standard deviation. Difference between baseline and week 12 values was analyzed by paired t-test.

RESULTS

In the present study, out of 424 type 2 diabetic patients and borderline cases, 225 were males (52%), while 199 were females (48%), thus male: female ratio was 1.13:1 [figure 1].

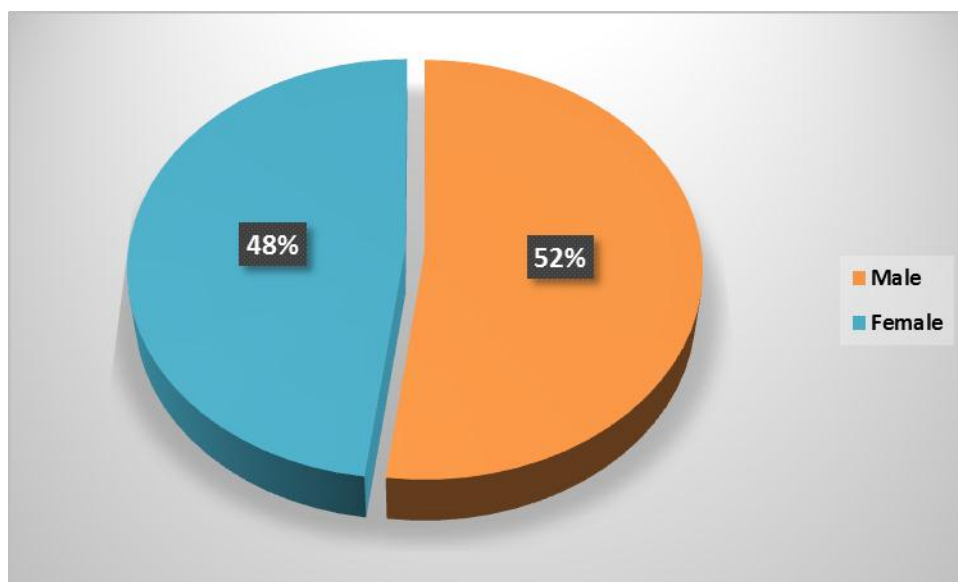


Figure 1: Sex distribution in patients of the present study.

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].

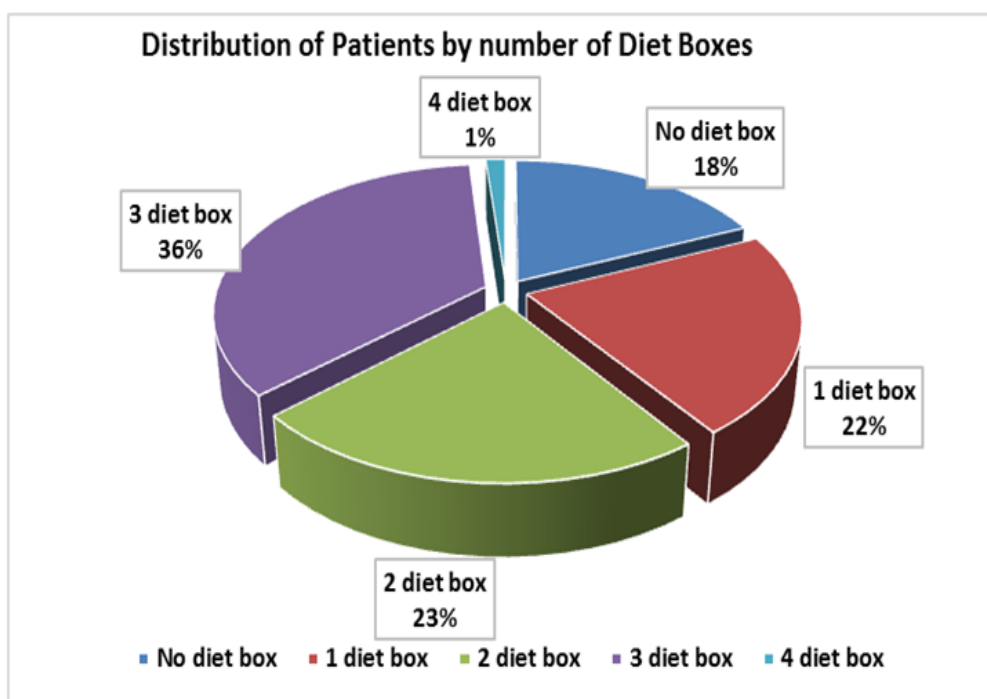


Figure 2: number of diet boxes used by patients of present study.

On analysing the anthropometric parameters in the patients of present study, it was found that body mass index (BMI) was reduced from 27.41 ± 1.08 kg/m² at baseline to 25.67 ± 1.22 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 96.58 ± 2.1 at baseline to 91.18 ± 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 1.

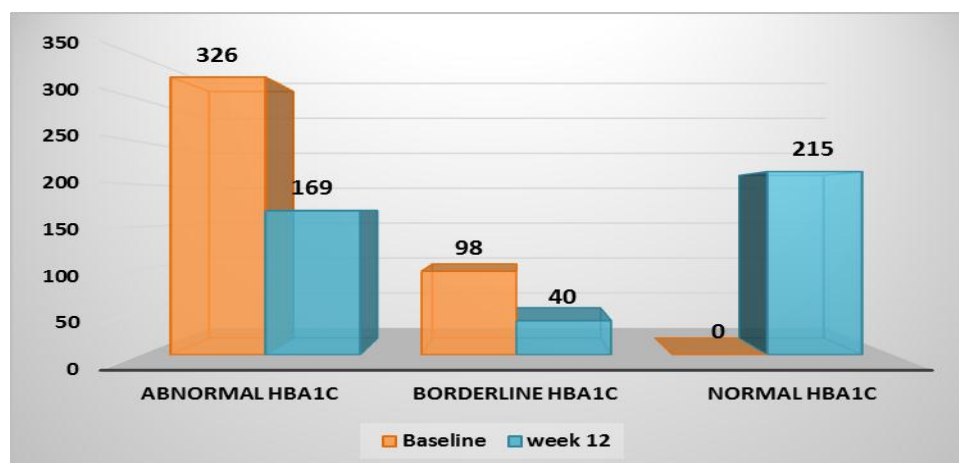
Table 1: anthropometric, cardio-pulmonary and lipid parameters in the patients of present study at baseline and 12 weeks of CDC therapy.

Sr. No.	Parameter	Measurement	Baseline	12 week	p-value
1	Anthropometry	Weight	70.08±4.1	65.95±4.8	0.04
		BMI	27.41 ± 1.08	25.67 ± 1.22	0.05
		ABG	96.58 ± 2.1	91.18 ± 1.9	0.01
2	Cardio-pulmonary	SBP	132.01 ± 4.8	123.44 ± 5.12	0.001
		DBP	80.21 ± 3.1	76.40 ± 3.9	0.01
		VO ₂ peak	24.21 ± 1.6	27.31 ± 2.5	0.01
3	Lipid profile	Cholesterol	121.3±4.86	112.05±5.91	0.020
		HDL	32.0±1.8	34.50±2.12	0.12
		LDL	107.50±4.1	99.0±5.09	0.02
		TG	204.0±5.96	139.25±7.33	0.001

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.

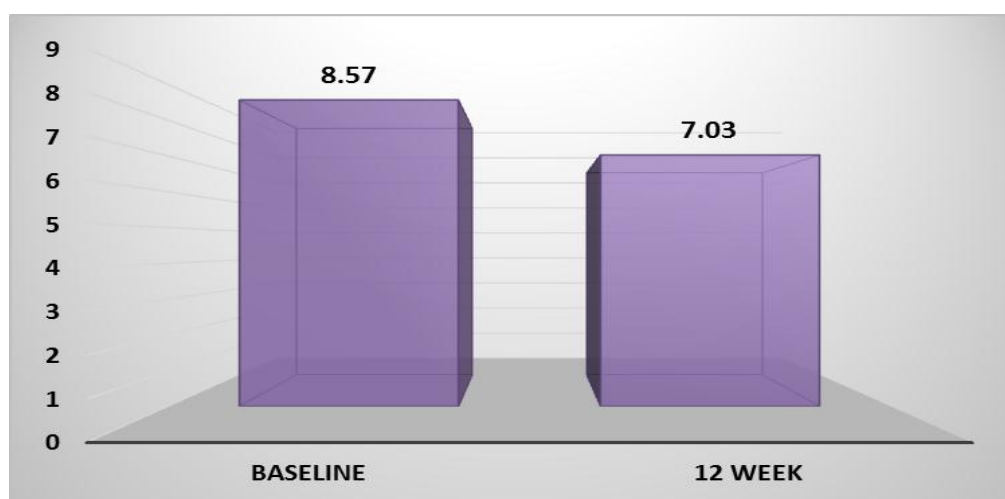
On analyzing the results of HbA1c in patients who have completed 12 weeks of CDC therapy, it was found that

number of patients with abnormal HbA1c was reduced from 326 (77%) at baseline to 169 patients (40%) after 12 weeks of CDC therapy. The number of patients with borderline HbA1c levels were reduced from 98 (23%) at baseline to 40 patients (9%). Finally, the number of patients with normal HbA1c rose from none at baseline to 215 (51%) at week 12 of CDC therapy [Figure 3].

**Figure 3: Results of HbA1c in patients who had completed 1 month of CDC therapy.**

Glycosylated hemoglobin (HbA1c) reduced from 8.57 at baseline to 7.03 at week 12 of completion of CDC

therapy, and the difference was statistically significant [figure 4].

**Figure 4: Mean glycosylated hemoglobin (HbA1c) in patients of present study at baseline and at 12 weeks of taking CDC therapy.**

Medication history was available in 424 patients, out of which majority of the patients were taking biguanides and sulfonylureas (SU). Average number of tablet per patient at baseline was 1.45, which was reduced to 0.76

at week 12 of CDC therapy, thus there was 54% 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	66	47	0.001
2	ARB	102	68	0.001
3	CCB	65	41	0.001
4	Diuretic	38	24	0.001
5	SU	201	125	0.001
6	Biguanides	248	51	0.001
7	Antiplatelet	32	19	0.01
8	DPP4 inhibitor	66	15	0.001
9	Statins	68	20	0.001
Tablet/patient ratio		2.08	0.96	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 controlled DM was achieved in all patients, irrespective of duration of DM [table 3].

Table 3: 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	15	61	76
	week 12	51	9	16	76
2-10 yrs	Baseline	0	36	121	157
	week 12	79	15	63	157
> 10 yrs	Baseline	0	47	144	191
	week 12	85	16	90	191

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.^[6] CDC combines Panchkarma diet regimen consisting of low levels of carbohydrates and fats and modest amount of proteins.

Plethora of herbal drugs are found to possess same action as that of conventional antidiabetic drugs i.e. lowering of blood glucose levels. Thus, Ayurvedic therapy serves as potential form of therapy which can help to control the

elevated HbA1c levels as well as reduce the adverse effects encountered with the use of antidiabetic drugs. CDC utilizes combination of Panchkarma and diet kit therapy in diabetic patients.

CDC is postulated to act via reduction in intrinsic production of glucose through the process of gluconeogenesis, increased glycolysis, and reduction in wear and tear of vascular endothelium.^[6]

BMI, body weight, abdominal girth were significantly reduced in the present study at the end of 12 weeks. Similarly, most critical parameter in type 2 diabetes i.e. glycosylated haemoglobin was also significantly reduced after CDC therapy. Also, the number of patients allopathic medications reduced drastically at the end of 12 weeks, which means that dependency on conventional medications was significantly reduced after CDC therapy.

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.^[7,8,9] 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.

However, it is worthy to mention that diet kit therapy was also given in the present study. It is known that faulty dietary habits in the form of consumption of canned foods, junk foods which are high in calories, bad quality fat are a major cause of insulin resistance. Thus, in diabetic patients diet with low calories, low fat and moderate amount of protein should be ideally given to the patients. This will help to establish the negative calorie balance in diabetic patients which is shown to reduce the effects of insulin resistance.^[10]

However, we recommend that such studies should be carried out prospectively at multiple centers all over India, which aid in comparison and validation of current study findings.

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.

Conflict of interest: None declared by the authors.

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REFERENCES

1. Saeedi P, Petersohn I, Salpea P, Malanda B, Karuranga S, Unwin N, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition. *Diabetes Res Clin Pract*, 2019 Nov; 157: 107843.
2. Mohan V, Pradeepa R. Epidemiology of diabetes in different regions of India. *Health Administrator*, 2009; XXII (1, 2): 1- 18.
3. Forbes JM, Cooper ME. Mechanisms of Diabetic Complications. *Physiol Rev*, 2013; 93:137–188.
4. Verma M, Paneri S, Badi P, et al. Effect of increasing duration of diabetes mellitus type 2 on glycated hemoglobin and insulin sensitivity. *Indian Journal of Clinical Biochemistry*, 2006; 21(1): 142-146.
5. Srikanth N, Haripriya N, Singh R, Manjula, Tewari D. Diabetes mellitus (madhumeha) and ayurvedic management: an evidence based approach. *World Journal of Pharmacy and Pharmaceutical Sciences*, 2015; 4(8): 881-892.
6. Sane R, Ghadigaonkar P, Chaure 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.
7. 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.
8. 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.
9. 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.
10. Taylor R. Calorie restriction and reversal of type 2 diabetes. *Expert Rev Endocrinol Metab*, 2016 Nov; 11(6): 521-528.