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ROLE OF COMPREHENSIVE DIABETES CARE (CDC) IN KNOWN DIABETES PATIENTS FROM MARATHWADA REGION

Dr. Rohit Sane[1], Dr. Rahul Mandole[2]*, Dr. Gurudatta Anand Amin[3], Dr. Pravin Ghadigaokar[4], Dr. Sneha Paranjape[5], Dr. Prakash Jondhale[6], Dr. Swati Kumthekar[7], Dr. Archana Kelhe[8] and Dr. Sonali Gaikwad[9]

[1]Managing Director, MD, Madhavbaug Cardiac Hospitals and Clinics, India.
[2]Head of Department of Research & Development, Madhavbaug Cardiac Clinic and Hospital, Thane, Maharashtra, India.
[3]Chief Medical Officer, Madhavbaug Cardiac Clinic and Hospital, Thane, Maharashtra, India.
[4]Head Medical Operations, Madhavbaug Cardiac Clinic and Hospital, Thane, Maharashtra, India.
[5]Chief Dietitian, Madhavbaug Cardiac Clinic and Hospital, Mumbai, Maharashtra, India.
[6]Regional Medical Head, Marathwada Region, Madhavbaug Cardiac Clinic and Hospital, Mumbai, Maharashtra, India.
[7]Clinic Head and FO at Savedi Road, Ahmednagar, Madhavbaug Cardiac Clinic and Hospital, Marathwada, Maharashtra, India.
[8]Clinic Head and FO at Madhavbaug CIDCO Clinic, Nashik, Madhavbaug Cardiac Clinic and Hospital, Marathwada, Maharashtra, India.
[9]Clinic Head at Garkheda Clinic, Marathwada, Madhavbaug Cardiac Clinic and Hospital, Marathwada, Maharashtra, India.

***Corresponding Author: Dr. Rahul Mandole**
Head of Department of Research & Development, Madhavbaug Cardiac Clinic and Hospital, Thane, Maharashtra, India.

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ABSTRACT

Background: Diabetes Mellitus (DM) stays as one of the audacious worldwide plagues of the twenty-first century. CDC therapy is Panchkarma based Ayurvedic therapy for the management of DM. **Aims and objectives:** The aim of the present study was to analyze the effectiveness of CDC in patients of DM attending Madhavbaug clinics in Marathwada region of Maharashtra on glycemic parameters like HbA1c, FBS, PPBS, and anthropometric parameters like body weight, body mass index, etc. **Materials and methods:** This was a retrospective study conducted at Madhavbaug clinics located in Marathwada region of Maharashtra, wherein we identified the data of obese patients suffering from type 2 DM (HbA1c $\geq$ 6.5%) of either gender and any age. Out of these, data of patients who had been administered CDC with minimum 6 sittings over a span of 12 weeks were considered for the study. **Results:** Out of 188 type 2 diabetic patients, 101 were males (54%) while 87 were females (46%). Number of patients with controlled DM status increased and that with uncontrolled status reduced at week 12, and the mean HbA1c reduced from 8.84 at baseline to 6.85 at week 12 of CDC therapy. Other anthropometric, cardiorespiratory parameters showed statistically significant improvement after 12 week of CDC therapy as compared to baseline, and the consumption of allopathic medications was also significantly reduced. **Conclusion:** From the findings of the present study, it can be concluded that CDC can serve as effective therapy for management of type 2 DM.

KEYWORDS: Diabetes mellitus, comprehensive diabetes care, Ayurveda, Panchkarma.

INTRODUCTION

Diabetes Mellitus (DM) stays as one of the audacious worldwide plagues of the twenty-first century. Diabetes mellitus is conceivably arriving at epidemic extents in India. There are enormous dissimilarities in diabetes predominance between states in India. As expressed by an ongoing methodical survey dependent on the measurements from ICMR-INDIAB, the general commonness of diabetes in 15 cities of India was 7.3%. The etiology of diabetes in India is unpredictable and incorporates hereditary elements combined with ecological effect, for example, weight related with rising standard of solace, steady urban relocation, and way of life changes.[1]

There is metabolic derangement of glucose, proteins and fats in patients of DM. It leads to persistent hyperglycemia and specifically insulin resistance in case

of type 2 DM. It is diagnosed mainly laboratory investigations, of which oral glucose tolerance test i.e. OGTT and glycosylated hemoglobin i.e. HbA1c are most commonly used. Traditionally, OGTT is used on wide scale for diagnosing DM, and it includes 2 components- fasting bloods sugar (FBS) and post prandial blood sugar (PPBS) levels. FBS ≥ 126 mg/dl and PPBS ≥ 140 mg/dl are diagnostic of DM. Recently, glycosylated hemoglobin i.e. HbA1c measurements are being used on a large scale for the same purpose. The major advantage ofHbA1c over the conventional OGTT is that it reflects blood glucose homeostasis over past 2 months. HbA1c level ≥ 6.5% is accepted as diagnostic of DM.[2]

DM leads to various complications which contribute to morbidity and mortality in these patients. Major adverse effects include microvascular complications which arises due to affection of small blood vessels and macrovascular complications that occur due to affection of medium to large sized blood vessels. Microvascular complications include nephropathy, neuropathy, and retinopathy, while macrovascular complications include stroke, coronary artery disease, intermittent claudication, gangrene, etc.[3]

Being a chronic disorder, DM usually requires lifelong treatment with oral antidiabetic drugs (OADs) which cannot cure the disease, but helps to reduce the symptoms and minimize the risk of developing complications. OADs include variety of drugs like metformin, glimepiride, acarbose, remogliflozin, canagliflozin, etc. Major action of these drugs is optimization of blood sugar levels, which is executed via multiple mechanisms like reduction in intrinsic glucose production in the body, increased glycolysis, augmented tissue uptake of glucose, etc.[4]

However, patient's adherence to these OAD therapy is very low, as was found in one clinical study. In this study the treatment adherence was found to be <60%.[5] Contributory factors for this low adherence rates are adverse effect profile and increased cost of treatment. Common adverse effect s of these OADs include hypoglycemic symptoms like fainting, dizziness, and other adverse effects like pancreatitis, normocytic normochromic anemia, etc.[6]

Although variety of OADs are available in the market, the prevalence of DM as well as the associated morbidity and mortality is continually rising.[1] This finding enables a researcher as well as clinician to look out for newer therapeutic option which will be effective as well as overcome the drawbacks associated with the use of OADs. Ayurveda is an ancient medicinal science, which is practiced in India, since many ages. It has been proven to effective and devoid of adverse effects.[7] It can serve as viable alternate therapeutic option for the management of DM. Comprehensive Diabetes Care (CDC) is a form of Ayurvedic therapy, which comprises of administration of herbal drugs, Panchkarma along with dietary modifications.

Panchkarma is defined as internal purification process which gets rid of toxins from the body. Usually, it consists of Vamana, Virechana, Rakta Moksha, Nasya and Basti. CDC utilizes 3 key procedures of Panchkarma i.e. Basti- herbal drug therapy administered rectally, Swedana- steam therapy, Snehana- oleation therapy.[8] The clinical data regarding the efficacy of such therapy is very limited. Thus, the present study was planned to evaluate the effectiveness of CDC in patients of DM attending Madhavbaug clinics in Marathwada region of Maharashtra on glycemic parameters like HbA1c, FBS, PPBS, and anthropometric parameters like body weight, body mass index, etc.

SUBJECTS AND METHODS

1. Study design: Observational, record based, retrospective study.
2. Study site: Madhavbaug clinics across Marathwada region of Maharashtra state of India.
3. Study period: December 2018 to December 2019.
4. Study participants: Patients of either sex and any age suffering from type 2 DM (HbA1c>6.5%),[2] who attended Madhavbaug clinics in Marathwada region of Maharashtra.
5. 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. According to patient medical records, the diet plan consisted 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. Following information was retrieved and entered into predesigned Microsoft Excel spreadsheet.
   - Socio-demographic details.
   - Anthropometric parameters like body weight, BMI, abdominal girth.
   - Glycemic parameters like HbA1c, FBS, PPBS.
   - Laboratory measurements.
6. 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.
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 boxes were equivalent to number of months on taking the compliance diet.

The details of CDC therapy are described in table 1.[9]

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 *Azadirechta 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% *Gudmaar* (*Gymnema sylvestre*), 20% *Daruharidra (Berberis aristate)* and 40% *Yashtimadhu (Glycyrrhiza glabra)*	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 ± SD. Paired t-test was used to assess the difference between baseline values and 12th week of treatment. Histogram were used to represent the graphs.

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

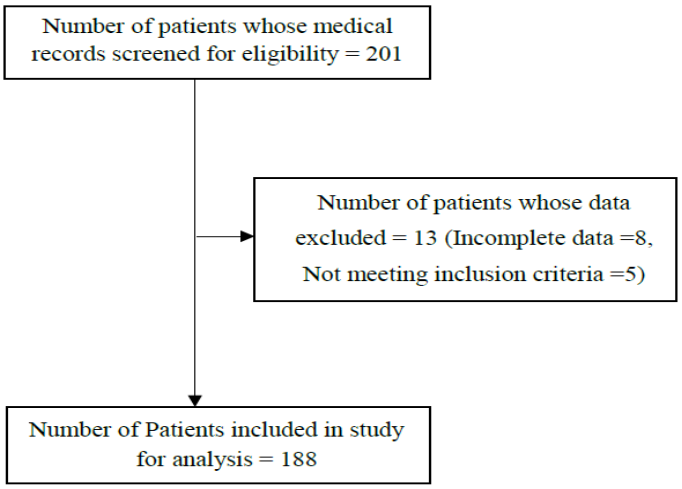

Figure 1: Patient record selection for the present study.

RESULTS

In the present study, out of 188 type 2 diabetic patients, 101 were males (54%) while 87 were females (46%), thus male: female ratio was 1.16:1 [figure 1].

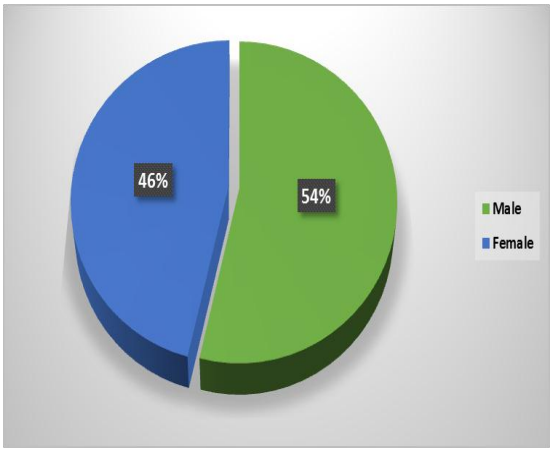

Figure 1: Sex distribution in patients of the present study.

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].

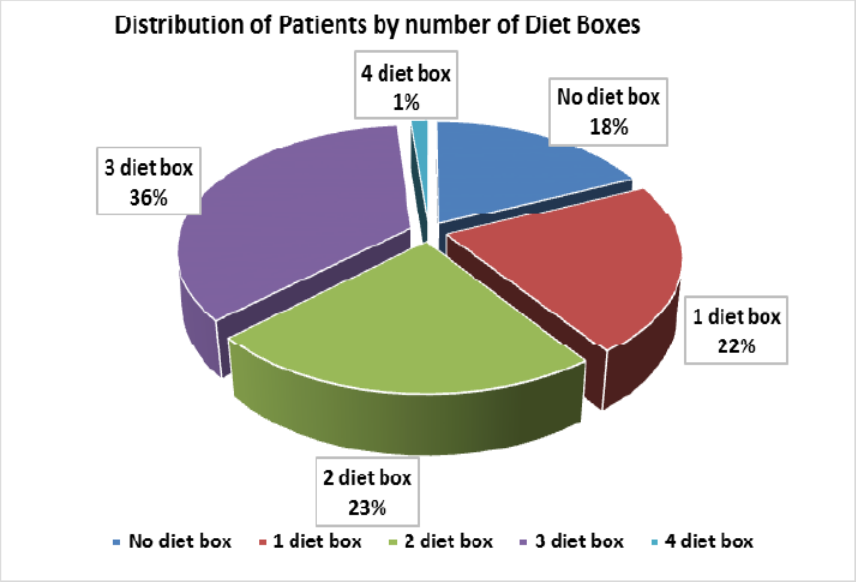

Figure 2: number of diet boxes used by patients of present study.

On analysing the anthropometric parameters in the patients of present study, it was found that body mass index (BMI) was reduced from 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 84.01 ± 4.9 at baseline to 78.41 ± 3.2 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	69.58±4.6	64.85±5.2	0.05
		BMI	26.71 ± 1.08	25.19 ± 1.12	0.05
		ABG	84.01 ± 4.9	78.41 ± 3.2	0.05
2	Cardio-pulmonary	SBP	130.30 ± 4.1	122.43 ± 5.12	0.04
		DBP	81.19 ± 2.9	77.14 ± 4.1	0.05
		VO2 peak	17.22 ± 0.93	24.25 ± 1.2	0.001
3	Lipid profile	Cholesterol	153.0±4.26	116.33±5.01	0.001
		HDL	28.0±1.1	31.0±2.1	0.01
		LDL	90.33±3.5	70.33±5.2	0.001
		TG	223.33±4.96	101.33±6.27	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 analysing the results of HbA1c results in patients who have completed 12 weeks of CDC therapy, it was found that normal HbA1c was seen in 108 patients (57%), borderline HbA1c was seen in 30 patients (16%) as compared to 79 patients (42%) at baseline, while abnormal HbA1c readings were noted in 50 patients (27%) as compared to 109 patients (58%) at baseline [Figure 3].

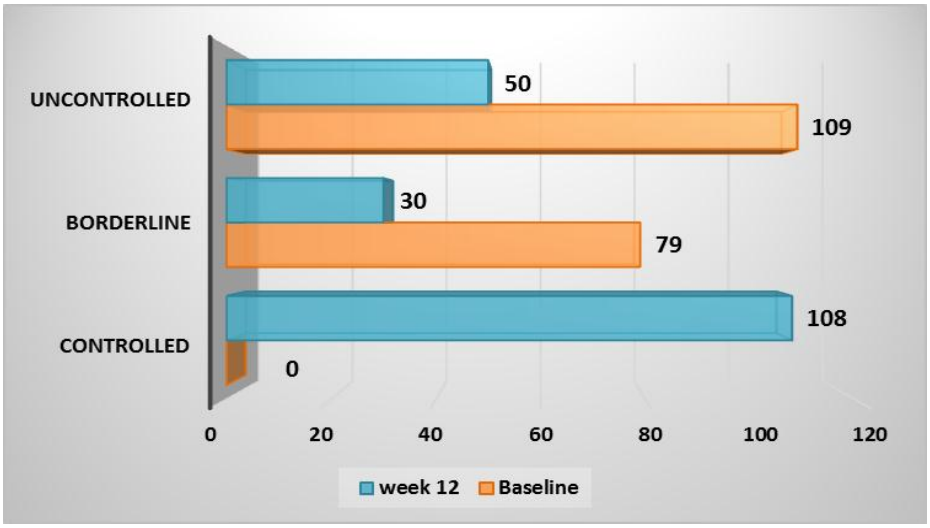

Figure 3: Results of HbA1c in patients who had completed 12 weeks of CDC therapy.

Glycosylated hemoglobin (HbA1c) reduced from 8.84 at baseline to 6.85 at week 12 of completion of CDC therapy, and the difference was statistically significant [figure 4].

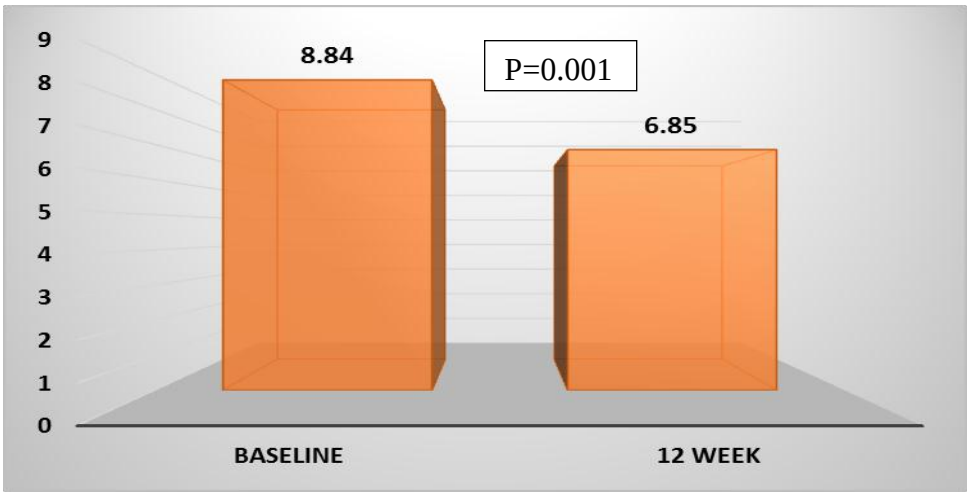

Figure 4: Glycosylated haemoglobin (HbA1c) in patients of present study at baseline and at 12 weeks of taking CDC therapy.

Medication history was available in 188 patients, out of which majority of the patients were taking metformin and sulfonylureas (SU). The number of tablets/patient ratio reduced from 2.01 at baseline to 0.78 at week 12 of CDC therapy, thus there was 61% 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	24	11	0.001
2	ARB	48	22	0.001
3	CCB	28	13	0.001
4	Diuretic	12	5	0.02
5	SU	76	47	0.001
6	Biguanide	109	23	0.001
7	Antiplatelet	25	8	0.001
8	DPP4 inhibitor	24	9	0.001
9	Statins	32	9	0.001
10	Tablet/patient ratio	2.01	0.78	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 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	18	25	43
	week 12	27	4	12	43
2-10 yrs	Baseline	0	29	27	56
	week 12	30	10	16	56
> 10 yrs	Baseline	0	32	57	89
	week 12	51	16	22	89

DISCUSSION

Despite availability of plethora of therapeutic options for treatment of type 2 DM, its prevalence and contribution to global morbidity and mortality remains significantly high and is increasing continuously. Therefore, alternate therapeutic option to curb the menace of DM is urgent necessity of current time. Conventionally used allopathic medicines in the treatment of type 2 DM act by reducing blood sugar levels. Ayurvedic medicines serves as potential alternate therapeutic option for management of type 2 DM, since many herbal drugs have been found to significantly lower blood glucose levels in clinical studies. Ayurvedic physicians administer panchkarma to the patients of DM.[9] Panchkarma along with diet therapy consisting of low carbohydrates and fats with moderate amount of proteins is administered in CDC. Probable mechanism, by which CDC might benefit patients with type 2 DM are.

1. Reducing glucose production in liver by hampering sympathetic stimulation on gluconeogenesis,
2. Reducing the shear stress of vascular endothelium by promoting water loss via sweating. This may help in reducing vascular complications significantly.[9]

In the present study, CDC was found to significantly reduce ($p<0.001$) HbA1c, BMI, body weight, abdominal girth, at the end of study period i.e. 90th day. Another crucial finding of our study was that there was significant reduction in patient's dependency on conventional allopathic antidiabetic medications at the end of study period.

HbA1c value is one of the most crucial parameter in diabetic patients as it echoes blood sugar level control over preceding 2-3 months. Another important feature of HbA1c is its prognosticator value in type 2 DM, since it has been found that morbidity and mortality is directly related to sustained increased HbA1c.[10] Thus it can be anticipated form the findings of our study that CDC carries good prognosis in diabetic patients as it significantly reduces HbA1c.

In a landmark clinical trial –ACCORD, the effect of intensified glycemic control therapeutic regimen (targeting HbA1c <6%) was compared to usual glycemic control regimen (targeting HbA1c 7-7.9%) in terms of cardiovascular mortality outcomes.[11,12] They found that intense glycemic control regimen actually increased cardiovascular mortality by 3.5 times as compared to the usual regimen.[13] This means that aim of HbA1c reduction should not be brisk, which is usually happens with conventional OADs. Thus, any alternate therapy which is able to reduce HbA1c gradually within optimal range and same time reduce the dependency on conventional OADs might actually help to improve outcomes in terms of cardiovascular after effects.

Obesity and sedentary lifestyle contribute to development of DM, which is indicated by increased BMI.[14] Apart from DM, high BMI has epidemiological linkage with many chronic diseases like HTN and other CVDs.[14] Sustained control of blood sugar levels is the utmost important factor in diabetic patients, since it has been established that poor blood sugar level control is associated with increased incidence of complications.[15] CDC can help in reducing complications of DM since it showed sustained reduction in all parameters like HbA1c, BMI, body weight, etc.

Another major issue with the use of conventional drugs is increased cost of therapy along with increased incidence of adverse effects associated use of these drugs.[16] Hence, we assessed the effect of CDC on dependency on conventional medications. In our present study we found that there was overall reduction in dependency of patients on conventional medications at the end of study period. Also, the number of patients who went off the conventional drugs increased at the end of 90th day.

In order to generalize the findings of our study to larger population, we recommend conduction of similar studies with dual arms, to allow direct comparison with conventional therapy, prospective design, and long follow up period with larger sample size.

CONCLUSION

Findings of our study- significant reduction in HbA1c, BMI, body weight, abdominal girth coupled with reduction in patient's dependency on conventional allopathic medications suggest that CDC not only promotes favourable prognosis, but also helps in increasing patient adherence to treatment. Hence, it can be concluded that CDC can serve as effective therapy for management of type 2 DM.

Conflict of interest: None declared by the authors.

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