



Research Article

TO STUDY EFFICACY OF COMPREHENSIVE DIABETES CARE (CDC) MANAGEMENT PROGRAM IN TYPE II DIABETIC OBESE PATIENTS: AN OBSERVATIONAL STUDY

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ABSTRACT

Context: Diabetes mellitus (DM) contributes to a major chunk of morbidity, mortality, and healthcare cost on a global level. The prevalence of DM is rising alarmingly, worldwide and India. Comprehensive Diabetes Care (CDC) is a combination of *Panchakarma* and diet management.

Aims: This study was conducted to evaluate the effect of CDC on Glycosylated hemoglobin (HbA1c), body mass index (BMI), body weight, abdominal girth and dependency on conventional therapy in DM Patients.

Setting and Design: This observational study was conducted in July 2017, wherein the data of obese Type II DM patients (HbA1c >6.5%) who attended out-patient departments (OPDs) at *Madhavbaug* clinics in Maharashtra, India were identified.

Materials and Methods: Data of patients who were administered CDC (60-75 minutes) with minimum 6 sittings over 90 days (± 15 days) were considered. Variables were compared between day 1 and day 90 of CDC.

Results: Out of 27 patients, 22 were included for analysis, out of which 10 were males while 12 females. CDC showed significant improvement in HbA1c 1.1% (from 8.80 ± 0.93 to 6.98 ± 1.73 ; $p < 0.001$), BMI by 2.66 (from 33.79 ± 3.80 to 31.13 ± 3.91 , $p < 0.001$), weight by 6.56 kg (from 83.67 ± 11.28 to 77.11 ± 12.27 , $p < 0.001$). Abdominal girth (from 104.34 ± 9.74 to 96.97 ± 11.93 ; $p < 0.001$), also showed significant reduction. Dependency on concomitant medicines was reduced, with the number of patients on no concomitant medicines increasing from 27% to 41%.

Conclusion: Comprehensive Diabetes Care Management Program found to be efficacious; by reducing HbA1c, as well as reducing dependency on allopathic medications.

KEYWORDS: Comprehensive Diabetes Care, CDC, *Panchakarma*, Glycosylated HB, HbA1C, BMI, DM, Alternative Medicine.

INTRODUCTION

Diabetes mellitus (DM) contributes to a major chunk of morbidity, mortality, and health care cost on a global level. The prevalence of DM is rising alarmingly, worldwide.^[1] India is only 2nd to China, in terms of prevalence of DM, with a prevalence rate of around 10%, i.e. every 10th adult in India is suffering from DM.^[2] According to WHO report, about 30 people die per 1Lakh population in India, due to diabetic complications.^[3]

Conventionally DM is diagnosed based on blood glucose/sugar levels (BSL), fasting levels more than or equal to 126 mg/dl and post prandial levels more than or equal to 140 mg/dl is considered as a DM. In recent decade diagnosis is also done by measuring glycosylated hemoglobin (HbA1c), since it reflects blood sugar control over the past 2-3 months.

HbA1c levels more than 6.5% is considered as DM, 5.7% to 6.4% as a borderline case/ prediabetes, and less than 5.7% as normal. Target HbA1c for treatment strategies are taken as below 6.5%.^[4]

DM is dreaded due to its complications, which are short term and long term, macrovascular and microvascular. Macrovascular complications include myocardial infarction, coronary artery disease, stroke, cerebrovascular disease, peripheral vascular disease, etc. Microvascular complications include retinopathy, neuropathy, and nephropathy. Out of these, cardiovascular complications are leading cause of morbidity and mortality in diabetic patients.^[5] Diabetic neuropathy may manifest as foot ulcers, sexual dysfunction in young males, amputation, etc.^[6,7] Amongst microvascular complications,

nephropathy is leading cause of morbidity and mortality in diabetic patients.^[8] The prevalence of retinopathy in diabetics is also increasing these days.^[9] It has been postulated from findings of various epidemiological studies that certain cancers are more common in diabetics like, cancers of breast, kidney, colo-rectal, bladder, etc.^[10,11]

The current management plan includes lifestyle modification, including dietary modifications and physical exercise on a daily basis plus pharmacological management (oral antidiabetic drugs).

Antidiabetic drugs/oral hypoglycemic agents (OHA) should be initiated only if a lifestyle modification fails to reduce HbA1c below 6.5% after 2 months. Major class of OHAs includes Biguanides (Metformin), Thiazolidinediones (Pioglitazone), Sulphonylureas (Glimepiride), Dipeptidyl peptidase-4 (DPP-4) inhibitors like Tenelegiptin, Sodium glucose cotransporter-2 inhibitors (canagliflozin). All these drugs act either, by reducing blood glucose via increasing tissue uptake, decreasing endogenous glucose production, preventing breakdown of incretins, etc. Guidelines suggest that, if baseline HbA1c is > 9% or it remains >7.5% despite 1 OHA, then combination of 2 OHAs should be given.^[12]

But, these drugs are associated with a wide variety of adverse effects like hypoglycemia (almost all classes), megaloblastic anemia (biguanides), pancreatitis, upper respiratory tract infections (gliptins), ketoacidosis, bone fractures (SGLT2 inhibitors), lipodystrophy at injection site (insulin), C cell tumour of thyroid (GLP1 agonist), etc.^[13] In a multicentric study on diabetic patients, it was found that adherence of patients to antidiabetic drugs was only 58%. The investigators of the study attributed this low adherence to cost of therapy, adverse effects of medications. Also, despite numerous guidelines for DM, its prevalence is rising continuously.^[14] Thus, it is the need of the hour to explore alternate forms of antidiabetic therapy, which can ameliorate the factors associated with low adherence to allopathic antidiabetic drugs.

The therapeutic benefit of allopathic antidiabetic drugs in diabetes is due to their blood glucose lowering action. Several studies have shown similar effects, with significant reduction in Glycosylated Hemoglobin (HbA1c), Fasting and Post Prandial Blood Glucose (FBG, PPBG) levels and lipids, by using herbal drugs, which serve as interesting potential targets for newer therapeutic options for treatment of DM.^[15,16,17]

Panchakarma is multi-step internal purification process. *Panchkarma* therapy in Ayurveda practice is administered in chronic phase

of the disease, while herbal drugs are preferred in acute phase. Comprehensive Diabetes Care (CDC) combines *Panchakarma* and diet management. Under this management program, *Panchakarma* is advocated through three techniques-

Snehana i.e. oleation, *Swedana* i.e. passive heat therapy and *Basti* i.e. per rectal drug administration. *Panchakarma* techniques are already well established in literature, as detoxifying procedures.^[18,19] DM is found to be linked with depression, reduction in quality of life, etc.^[20] Hence, we planned an Observational study to investigate the efficacy of the CDC, as add-on therapy to standard anti-diabetic therapy in patients with DM. We evaluated the effect of CDC on HbA1c, weight, body mass index (BMI), abdominal girth, and dependency of these diabetic patients on standard conventional oral antidiabetic medications.

Since, numerous factors play a role in causation, progression of DM, its management should be multi-pronged. Given the fact that Ayurveda may serve as potent alternative therapy, its efficacy in DM should be tested.^[15,17,21] Hence, we planned this observational study to investigate the effect of the CDC, as add on therapy to standard anti-diabetic therapy in obese patients with type II diabetes mellitus. We evaluated the effect of CDC on HbA1c, body mass index (BMI), body weight, dependency on oral hypoglycemic drugs/ agents, and abdominal girth.

MATERIALS AND METHODS

This was an Observational study conducted between July 2017, wherein we identified the data of obese patients suffering from type II DM (HbA1c \geq 6.5%, BMI \geq 30) ^[4,5] of either gender and any age, and who had attended the out-patient departments (OPDs) at multiple *Madhavbaug* clinics located in various cities of Maharashtra, India. 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 the 1st month, and 1 sitting per month for next 2 months. These patients were maintained on a 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 were 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 II DM after a light

breakfast. One sitting of the procedure took 65-75 minutes, as described in table 1. [19, 22]

Table 1: Study Treatment: Comprehensive Diabetes Care (CDC)

Step of CDC	Type of Therapy	Herbs used for therapy	Duration of Therapy
<i>Snehana</i>	Massage or external oleation (centripetal upper strokes on the body)	100 ml <i>Azadirachta indica</i> (neem) extract processed in sesame oil	20 minutes
<i>Swedana</i>	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
<i>Basti kadha</i>	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

On day 1 of CDC, the patients have undergone HbA1c, weight, BMI, abdominal girth measurements as per guidelines.[4] This reading was considered as baseline reading. This process was repeated on day 90 of CDC to calculate the change from baseline reading. The BMI for day 1 and day 90 of the patients was calculated by checking the weight and the height from the medical data sheets of patients and using the formula: weight in kilograms/(height in meters)². The dependency on standard medication was calculated both on day 1 and day 90 of CDC as the percentage of patients out of the total enrolled ones who required a conventional allopathic therapeutic agent during the study period of 90 days.

Statistical analysis

Data were pooled and entered in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyze the data. Categorical data were represented in the numeric form and continuous data were presented as the Mean \pm SD. The Paired t-test was used to assess the difference between baseline values and 90th day after the treatment. Box plot, histograms and scatter plot were used to represent the graphs.

RESULTS

Study population

A total of 27 patients' data was screened for inclusion in the study. However, based on the availability of data (Day 1 and Day 90) and the inclusion criteria, 22 patients were selected, and their data were considered for analysis.

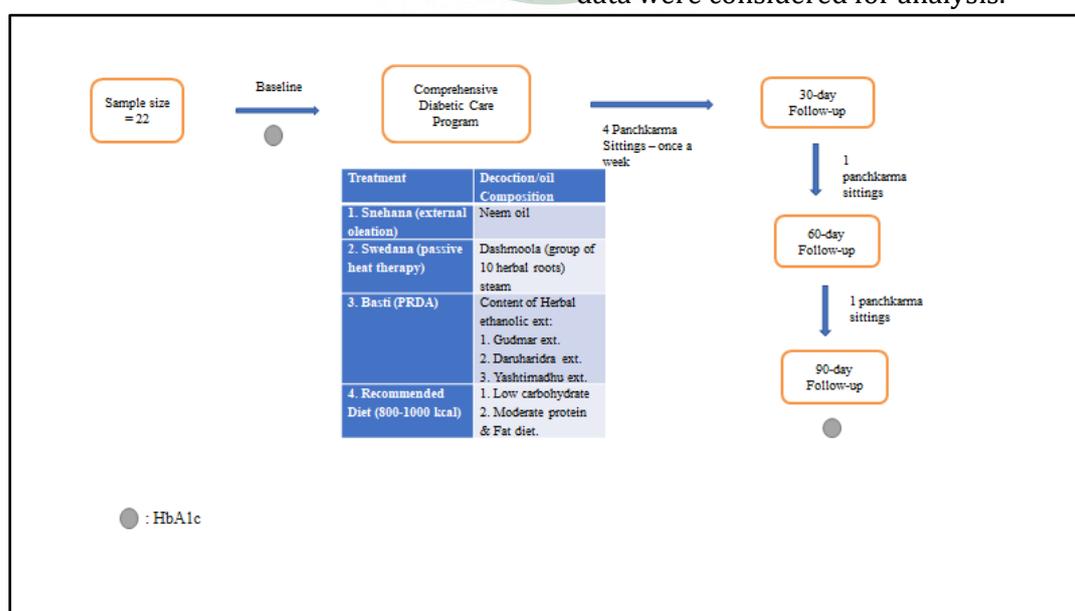


Figure 1: Treatment Plan of Comprehensive Diabetes Care Management

The study comprised of 22 type II diabetic obese patients, among them 10 (45.45%) were men and 12 (54.55%) were female. The mean age of the study patients was 48 ± 12.13 years. A significant improvement in weight, (77.11 ± 12.27 vs. 83.67 ± 11.28 ; $P < 0.001$), BMI (31.13 ± 3.91 vs. 33.79 ± 3.80 ; $P < 0.001$), HbA1c (6.98 ± 1.73 vs. 8.80 ± 0.93 ; $P = 0.0002$) and abdomen girth (96.97 ± 11.93 vs. 104.34 ± 9.74 ; $P < 0.001$) were

Sane Rohit M *et al.* Comprehensive Diabetes Care (CDC) Management Program in Type II Diabetic Obese Patients observed in diabetic obese patients after the treatment (90 days) than before treatment (baseline) (Table 2; Figure 2).

Table 2: Comparison of clinical parameters between baseline values and 90th day of the treatment

Variable	Baseline (Day 1)	After 90 days	Difference	P value
Weight	83.67 ± 11.28	77.11 ± 12.27	6.56	<0.001
BMI	33.79 ± 3.80	31.13 ± 3.91	2.66	<0.001
HbA1c	8.80 ± 0.93	6.98 ± 1.73	1.1	0.0002
Abdomen Girth (n=19)	104.34 ± 9.74	96.97 ± 11.93	7.37	<0.001

BMI, Body Mass Index; HbA1c, Glycosylated hemoglobin

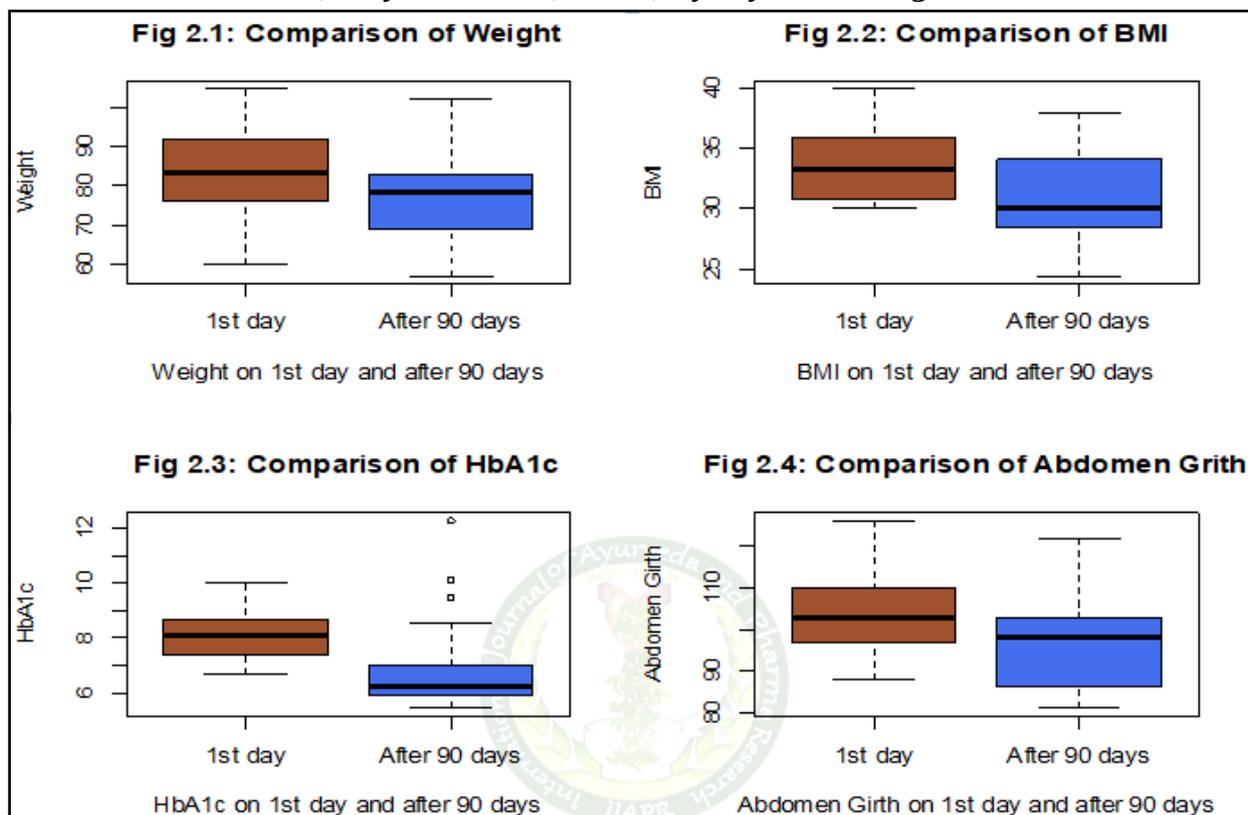


Figure 2: Comparison of clinical parameters between baseline values and 90th day (N = 22)

Most of the type II diabetic obese patients were treated with beta blockers (13.64%), nonsteroidal anti-inflammatory drugs (13.64%), biguanides (54.55%) and sulfonylureas (36.36%). While, the patients depending only on biguanides (36.36%) showed marked decrease after the treatment i.e., 90 days. The patients with the absence of medication history (40.91%) were also improved after treatment (Table 3; Figure 3).

Table 3: Consumption of allopathic medicines on days 1 and 90

Medicine	Baseline	After 90 days
Alpha-glucosidases inhibitors	1 (4.55)	1 (4.55)
DPP-4 inhibitor	3 (13.64)	1 (4.55)
Thiazolidinedione	1 (4.55)	1 (4.55)
Biguanide	12 (54.55)	8 (36.36)
Sulfonylurea	8 (36.36)	8 (36.36)
Antiplatelet	1 (4.55)	1 (4.55)
CCB	1 (4.55)	1 (4.55)
Beta blocker	3 (13.64)	3 (13.64)
ARB	2 (9.09)	1 (4.55)
Statin	1 (4.55)	1 (4.55)
NSAID	3 (13.64)	3 (13.64)
No medicine	6 (27.27)	9 (40.91)

NSAID, Nonsteroidal anti-inflammatory drugs; ARB, Angiotensin II receptor blockers; CCB, Calcium channel blockers; DPP-4 inhibitor, Dipeptidyl peptidase-4

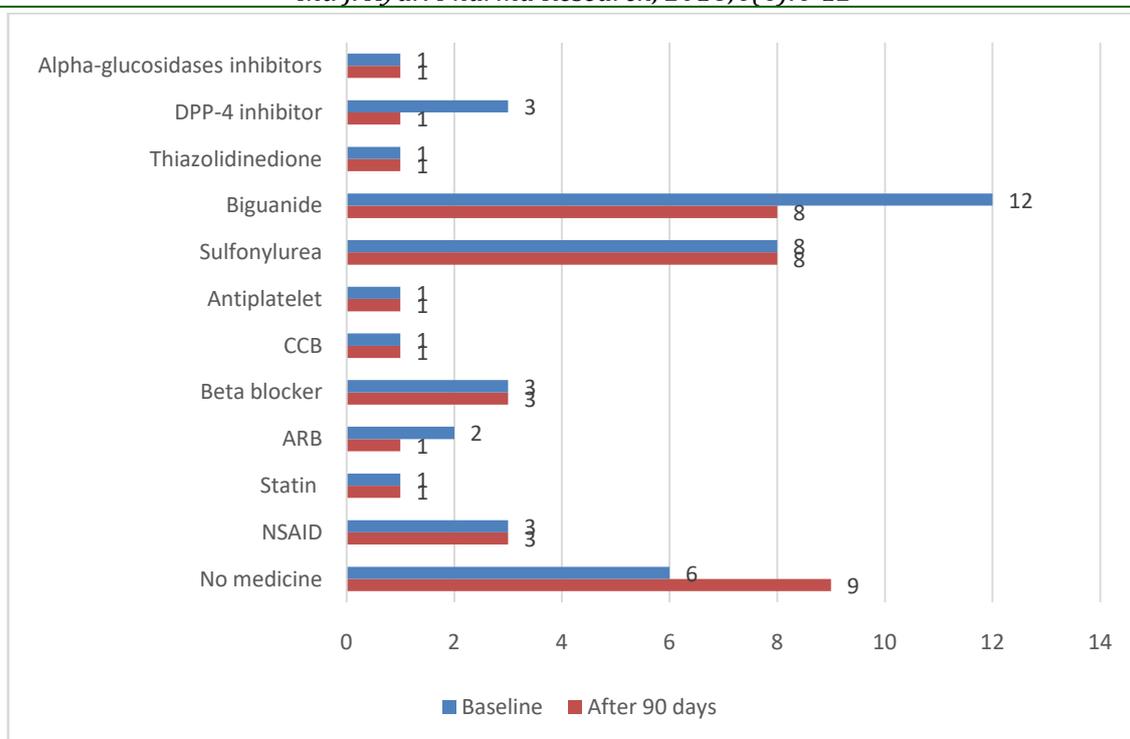


Figure 3: Consumption of allopathy medicines at days 1 and 90 days (N = 22)

NSAID, Nonsteroidal anti-inflammatory drugs; ARB, Angiotensin II receptor blockers; CCB, Calcium channel blockers; DPP-4 inhibitor, Dipeptidyl peptidase-4

The levels of HbA1c were significantly correlated with the BMI after 90 days of treatment ($r = 0.504$; $P = 0.016$) when compared with baseline values ($r = 0.39$; $P = 0.071$). (Table 4; Figure 4).

Table 4: Correlation of BMI and abdominal girth with HbA1c at 1st day and after 90 days of treatment

Correlation between	Baseline		After 90 days	
	r	P value	r	P value
HbA1c & BMI	0.39	0.071	0.504	0.016

BMI, Body Mass Index; HbA1c, Glycosylated haemoglobin

Fig 4.1: BMI & HbA1c at 1st day

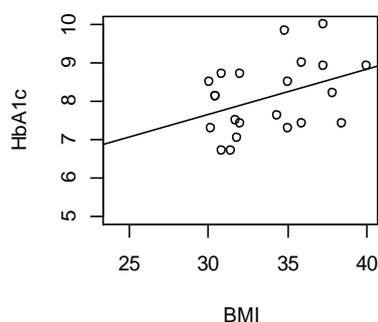
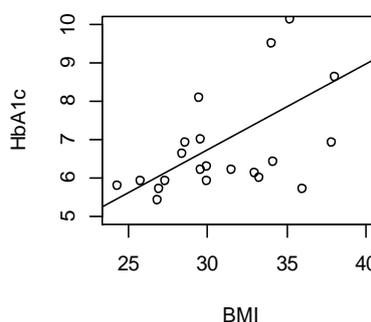


Fig 4.2: BMI & HbA1c at 90th day



BMI, Body Mass Index; HbA1c, Glycosylated hemoglobin

Figure 4: Correlation of BMI and abdominal girth with HbA1c at 1st day and after 90 days of treatment

DISCUSSION

Although there are numerous treatment choices available for treatment of type II DM management, it is still one of the commonest culprits of morbidity and mortality globally. Thus, it is the need of the hour to explore novel therapeutic alternatives for the management of type II DM. Traditional class of antidiabetic drugs has therapeutic benefit in DM of lowering blood sugar

levels. Similar property has been found in various herbal drugs, thus making Ayurveda a potent and viable alternative to standard therapy in the management of type II DM. *Panchakarma* is administered as add on therapy for DM management, by Ayurveda physicians.^[23] CDC combines *Panchakarma* with Low carb moderate protein and low fat diet. CDC acts by reducing sympathetic stress;

reduced sympathetic action lowers hepatic glucose production, which can be helpful to reduce blood sugar levels. *Swedana* helps by inducing sweating and reduces excess of sodium and water, and this comprehensively helps to improve vascular health of DM patients to keep them away from probable vascular complications.^[24] In pursuit of analyzing the efficacy of CDC in type II DM, we found that it showed significant (very high statistical significance) improvement in HbA1c, weight, BMI, abdominal girth at the 90th day of the whole procedure. Most importantly, we found that CDC noticeably reduced patient's dependency on standard allopathic medication at the end of 90 days, may be of therapy.

The HbA1c levels are more important in diabetic patients since it reflects the average blood sugar control over the past 1-2 months.^[25] Importance of HbA1c lies in the fact that, it is an independent predictor of mortality and morbidity in patients with type II DM. This has been corroborated in a prospective study done on diabetic patients, that cardiovascular complication like stroke was significantly lower in patients with an optimal reduction in HbA1c. It was found in large study-UKPDS study on diabetic patients, that reduction in HbA1c by 1% led to reduction of heart failure, heart attack, stroke, amputation and overall morbidity and mortality in diabetic patients.^[25] Hence, significant reduction in HbA1c after CDC in our study indicates favorable prognosis in DM related morbidity.

High BMI is considered to be one of the major risk factor for development of DM in normal subjects. It signifies sedentary lifestyle and obesity.^[26] Also, it has been found that BMI is positively associated with type II diabetes mellitus, hypertension, cardiovascular diseases and other chronic diseases.^[27] Uncontrolled DM frequently leads to the development of complications, hence various management plans across the globe have targeted sustained blood sugar control in patients with DM, to prevent the occurrence of such complications.^[4] In the present study, CDC significantly reduced HbA1c, BMI, abdominal girth, body weight. Thus CDC can play significant role in preventing the development of complications in patients with DM, thereby reducing morbidity and mortality.

In developing economy like India, the dependency of diabetic patients on allopathic medicines escalates the cost of healthcare to troublesome levels. Plethora of adverse effects of these drugs complicates the scenario, furthermore.^[28] Keeping this in mind, we analyzed changes in patient's dependency on allopathic medication by CDC. There was significant reduction in dependency on almost all the class of antidiabetic drugs (oral

hypoglycemic agents), at the end of 90 days, with an increase in the number of patients who went off the allopathic drugs.

One limitation of the study was that, it had only one arm, thus we were not able to compare CDC findings with that of standard therapy alone. The findings of the present study can be generalized only after a comparison with the findings of other such studies with probably prospective design, larger sample size, and more follow up period. This will help in identifying long term outcomes of CDC in the management of type II DM.

CONCLUSION

There was significant improvement in HbA1c after CDC. Also, there was significant reduction in patient's dependency on allopathic medications. Significant reduction in HbA1c, coupled with reduction in BMI, body weight, abdominal girth after CDC indicates a better prognosis in patients with type II DM. Hence, CDC may serve as a potent and viable alternative to standard allopathic treatment of type II DM.

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