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ROLE OF COMPREHENSIVE DIABETES CARE IN KNOWN DIABETES PATIENTS FROM KOLHAPUR AREA OF MAHARASHTRA

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ABSTRACT

Background: The occurrence of Diabetes mellitus (DM) has been creating a havoc since past few decades on a global platform. One published epidemiological study across major districts of Maharashtra state, reported shockingly high prevalence rates of DM in Kolhapur district i.e.18%. Comprehensive Diabetes Care (CDC) is a form of Ayurvedic therapy which combines panchkarma and diet management. **Aims and objectives**: The present study was planned to evaluate the effectiveness of CDC in patients of DM by analysing changes in body mass index (BMI), body weight, OGTT, HbA1c, etc. **Materials and Methods**: The present study was of retrospective design, conducted at Madhavbaug clinics in Kolhapur, Maharashtra. The duration of study was of one year, conducted from November 2018 to November 2019. It included patients diagnosed with type 2 DM i.e. HbA1c>6.5%, who were given CDC therapy. **Results:** In the present study, out of 127 type 2 diabetic patients, 61 were males (52%), while 66 were females (48%), thus male: female ratio was 0.9:1. On analysing the results of HbA1c in patients who had completed 12 weeks of CDC therapy, it was found that controlled DM status was seen in 61 patients (48%), while abnormal HbA1c readings were noted in 36 patients (29%) as compared to 67 patients (53%) at baseline. **Conclusion:** From the findings of the present study, it is clear that CDC is effective in the form of increasing number of euglycemic patients at the end of study period, as well as reduction in all glycaemic and anthropometric parameters, and reducing dependency on conventional medicines.

KEYWORDS: Diabetes mellitus, Comprehensive Diabetes Care, HbA1c.

INTRODUCTION

Diabetes mellitus (DM) is defined as chronic metabolic disease characterized by persistently elevated blood glucose levels and deranged metabolism of proteins, carbohydrates, and fats. These changes are manifestations of underlying defects of derangement in insulin secretion, action or both. Consequently, the glucose utilization by the tissues is hampered which leads to increased blood glucose levels. The knowledge of DM dates back to 2500 BC, where the disease has been termed as Madhumeha.[1]

Almost 80 million population is affected by DM with a prevalence rate of 9%, out of which 69 million live in India. It is estimated that number of diabetic patients in India will be above 120 million in the next 2 decades, which means that almost 12% of the population will be diabetic. DM is associated with plethora of complications like myocardial infarction, angina pectoris, renal failure, neuropathy, retinopathy, blindness, amputation, frailty, fractures, depression, decrease in cognitive function, etc. Cardiovascular and renal complications are the commonest causes of mortality in diabetic patients. As per Indian data, a little above 1 million people die annually due to diabetic

complications.[1] One published epidemiological study across major districts of Maharashtra state, reported shockingly high prevalence rates of DM in Kolhapur district i.e.18%.[2]

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.[3]

Traditionally, DM is diagnosed by oral glucose tolerance tests which consists of measuring fasting and post meal blood sugar levels. Fasting blood sugar more than or equal to 126 mg/dl and post meal level of more than or equal to 140 mg/dl are considered to be diagnostic of DM. Currently, measurement of HbA1c is gaining popularity as preferred diagnostic test for DM. This is due to the fact that it not only helps to diagnose DM, but also helps to get fair idea about kinetics of blood glucose control over past 2-3 months.[4]

Oral antidiabetic drugs (OADs) are used for the treatment of type 2 DM, and insulin is used in management of type 1 DM. Although these drugs act to reduce the blood sugar levels, there are plentiful of adverse effects associated their use. These range from fainting episode to overt pancreatitis. Added to this, the increased cost of therapy further complicated the management of DM. The most worrying factor is that, despite lots of research, availability of multiple number of antidiabetic drugs, numerous guidelines in place the prevalence of DM is still rising. This is warning signal that we need to explore for other potential forms of therapy which be efficacious as well devoid of drawbacks of conventional therapy.[5]

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.[6] 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.[7] In order to substantiate the clinical effectiveness of CDC in management of DM, we initiated the present study.

Subjects and Methods

1. Study design: Retrospective record based study.
2. Study site: Madhavbaug clinics across Kolhapur area of Maharashtra.
3. Study period: October 2018 to December 2019.
4. Study participants: Patients of either sex and any age, suffering from type 2 DM (HbA1c>6.5%),[4] who attended Madhavbaug clinics in Kolhapur area of Maharashtra were included in the study.
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, 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.[7]
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.

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 $\leq$ 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% *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 90th day after treatment. Histogram were used to represent the graphs.

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

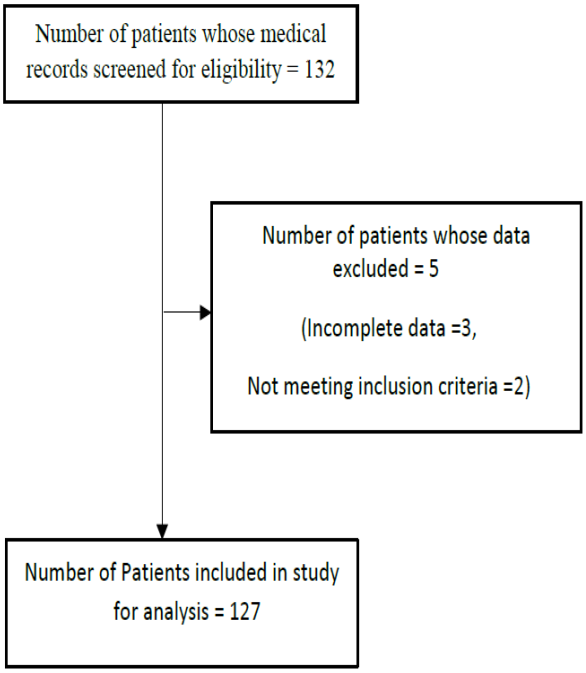

Figure 1: Patient record selection for the present study.

RESULTS

In the present study, out of 127 type 2 diabetic patients, 61 were males (52%), while 66 were females (48%), thus male: female ratio was 0.9:1 [figure 1].

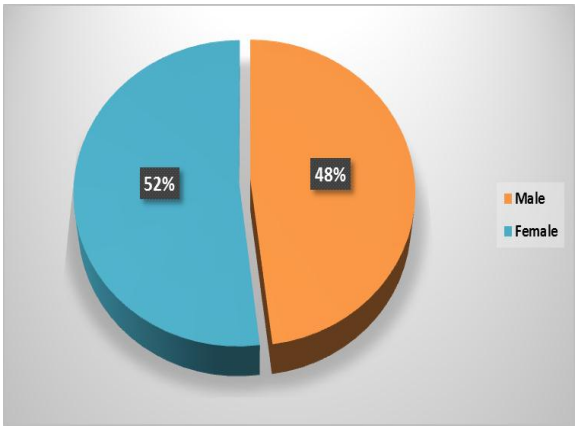

Figure 1: Sex distribution in patients of the present study.

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].

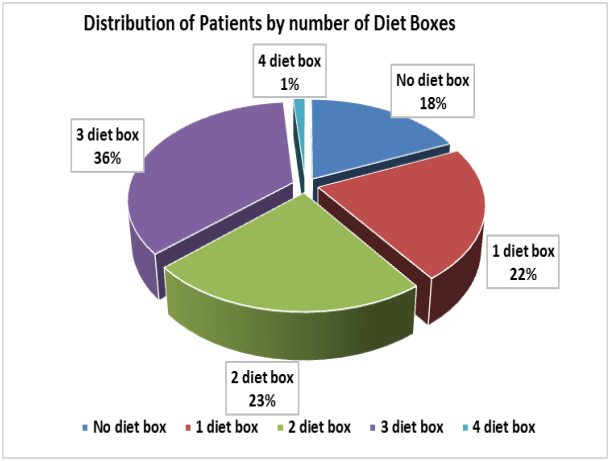

Figure 2: number of diet boxes used by patients of present study.

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 101.28 ± 6.1 at baseline to 94.53 ± 5.8 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	68.90±4.2	64.88±5.2	0.05
		BMI	26.71 ± 1.08	25.19 ± 1.12	0.05
		ABG	96.60 ± 4.6	91.24 ± 3.1	0.04
2	Cardio-pulmonary	SBP	130.04 ± 6.2	120.31 ± 5.9	0.02
		DBP	79.82 ± 3.6	75.39 ± 3.3	0.06
		VO2 peak	15.74 ± 1.01	22.41 ± 1.1	0.00
3	Lipid profile	Cholesterol	192.56±7.1	107.56±6.3	0.001
		HDL	39.33±1.4	41.30±2.1	0.01
		LDL	91.28±5.2	69.25±5.8	0.001
		TG	204.5±4.6	141.25±6.27	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 HbA1c in patients who have completed 12 weeks of CDC therapy, it was found that normal HbA1c was seen in 61 patients (48%), borderline HbA1c was seen in 30 patients (23%) as compared to 60 patients (47%) at baseline, while deranged HbA1c readings were noted in 36 patients (29%) as compared to 67 patients (53%) at baseline [Figure 3].

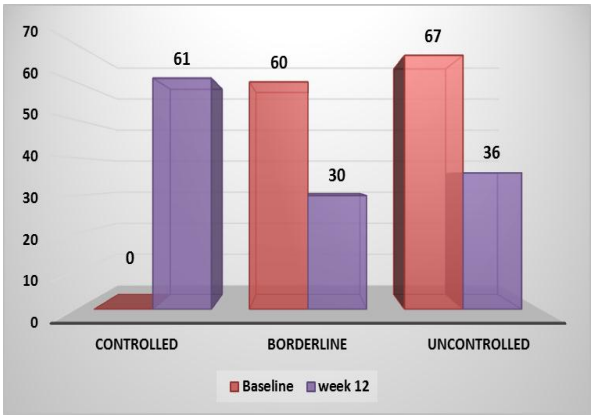

Figure 3: Results of HbA1c in patients who had completed 12 weeks of CDC therapy.

Glycosylated hemoglobin (HbA1c) reduced from 8.61 at baseline to 7.2 at week 12 of completion of CDC therapy, and the difference was statistically significant [figure 4].

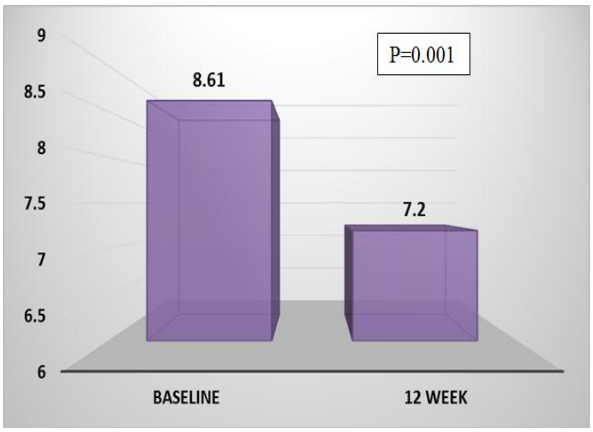

Figure 4: Glycosylated haemoglobin (HbA1c) in patients of present study at baseline and at 12 weeks of taking CDC therapy.

Medication history was available in 127 patients, out of which majority of the patients were taking biguanides and sulfonylureas (SU). The number of tablets/patient ratio reduced from 2.03 at baseline to 1.01 at week 12 of CDC therapy, thus there was 50% 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	21	16	0.03
2	ARB	28	24	0.61
3	CCB	16	14	0.59
4	Diuretic	17	11	0.08
5	SU	48	33	0.001
6	Biguanide	61	12	0.001
7	Antiplatelet	19	12	0.05
8	DPP4 inhibitor	16	2	0.001
9	Statins	33	5	0.001
10	Tablet/patient ratio	2.03	1.01	0.04

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	22	1	23
	week 12	12	5	6	23
2-10 yrs	Baseline	0	25	20	45
	week 12	20	14	11	45
> 10 yrs	Baseline	0	13	46	59
	week 12	29	11	19	59

DISCUSSION

Despite availability of armamentarium of antidiabetic drugs and extensive guidelines for the management of DM, the prevalence of disease and morbidity and mortality rates are continually rising to epidemic levels.[1] This calls for search of potential alternative treatment option, which will be effective and safe in the patients of DM. Similar to conventional antidiabetic drugs, a variety of herbal drugs have shown to reduce the blood sugar levels to optimal levels.[8] Thus, Ayurvedic form of Medicine might serve as a potential alternate therapeutic option for management of DM.

CDC is a form of Ayurvedic therapy which is intended to manage DM. Typically, it consists of Panchkarma, administration of herbal drugs and diet therapy to induce and maintain negative calorie. Panchkarma is an internal healing procedure that is proven to possess detoxification actions. It consists of Vamana, Virechana, Nasya, Basti, Snehana, Swedana, etc.[9] Panchkarma techniques used in CDC are Snehana, Swedana and Basti. These techniques helps in attenuating the disease activity in patients of DM by:

- Reducing the internal glucose output by halting production of glucose through gluconeogenesis. This action is thought to be accomplished by limiting the sympathetic stimulation.[10]
- Corrects the dyslipidaemia[11]
- Reduces the vascular shear stress by inducing sodium and water loss via induction of sweating.[12] This might help to reduce the vascular complications in diabetic patients.

Additionally the supporting findings from the present study i.e. significant reductions in HbA1c, BMI, body weight, abdominal girth at the end of 12 weeks of CDC therapy reinforces the vital role of CDC in management of DM.

Reduction in HbA1c levels is the major target in the management of DM. It is now of the independent prognosticator, especially that of cardiovascular morbidity and mortality ion diabetic patients.[13] Apart from providing gist of glycaemic control over preceding 2-3 months, it is also proven that 1% decrease in HbA1c was associated with significant reduction in cardiovascular events like myocardial infarction, heart failure, stroke, and also the complications leading to morbidity and mortality n diabetic patients.[14] Therefore, the reduction in HbA1c in the present study by 1.41 is anticipated to carry a favourable prognosis in diabetic patients treated by CDC.

However, it should be noted that over-enthusiastic reduction in HbA1c levels should not be practiced. This was highlighted in recently concluded landmark multicentric clinical trial- ACCORD. It compared the cardiovascular outcomes in 2 groups:

- Group A- intense HbA1c reduction (<5.7%) with multiple antidiabetic drugs.
- Group B- usual target reduction in HbA1c (7-7.9%) with single antidiabetic drug and lifestyle modifications.

It was found that cardiovascular events were more than thrice times with group A as compared to group B.[3,15,16] Thus, it can be inferred that multiple use of antidiabetic drugs in pursuit of intense reduction of HbA1c actually increases risk of cardiovascular complications, and thus such regime should be avoided. If reduction of HbA1c by another therapeutic option is possible, its use should be encouraged. Thus, CDC might serve as potent therapeutic option for managing DM.

Moreover, increased BMI, body weight, and abdominal girth are known to be associated increased risk of development of DM, as all of them are increased in obesity.[17] In the present study, CDC significantly reduced HbA1c, BMI, abdominal girth, body weight. Thus CDC can play significant role in preventing development of complications in patients of DM, thereby reducing morbidity and mortality.

Biguanides and sulphonylureas are one of the commonly prescribed oral antidiabetic drugs in India.[18] However, their use is associated with increased adverse effects and cost of therapy, both of which reduce the patient compliance towards therapy.[19] The dependency on these

medications was significantly reduced in the present study after 12 week CDC therapy and also HbA1c was reduced by 1.41. All of these findings point out towards favourable actions of CDC.

The present sudsy had certain limitations like its retrospective design, therefore chances of bias cannot be rule out. Secondly, direct comparison with standard therapy was not possible, which would have given better idea about effect of CDC.

CONCLUSION

Given the significant improvements in key therapeutic indicator with CDC therapy, like HbA1c, body weight, abdominal girth, etc. it can be used as potent therapeutic option in management of DM. Moreover, it reduced the dependency on allopathic medications, which will further help to reduce the cost of therapy and adverse effects, thus improving patient compliance.

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Conflicts of interest: None declared by the authors.

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