



ROLE OF COMPREHENSIVE DIABETES CARE IN KNOWN DIABETES PATIENTS FROM PUNE REGION

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ARTICLE INFO

Article History:

Received 13th May, 2020

Received in revised form 11th June, 2020

Accepted 8th July, 2020

Published online 28th August, 2020

Key words:

Diabetes mellitus, Comprehensive Diabetes Care, CDC, panchkarma, HbA1C, BMI

ABSTRACT

Background: Global burden of diabetes mellitus has increased consistently since past few decades. Unfortunately, India has emerged as a major contributor to this global burden of DM. Comprehensive Diabetes Care (CDC) utilizes combination therapy of Panchkarma, administration of herbal drugs and diet therapy.

Aims and objectives: The present study was planned to analyse the effectiveness of CDC therapy along with diet therapy in patients with type 2 DM attending Madhavbaug clinics in Pune region.

Materials and methods: This was a retrospective study conducted between October 2018 and May 2019, wherein we identified the data of obese patients suffering from type 2 DM (HbA1c \geq 6%) of either gender and any age, and who had attended the out-patient departments (OPDs) at multiple Madhavbaug clinics located in Pune region of Maharashtra. The data of patients who had been administered CDC with minimum 6 sittings over a span of 12 weeks were considered for the study.

Results: On analysing the results of HbA1c level in patients who had completed 12 weeks of CDC therapy, it was found that controlled diabetes (HbA1c < 5.7) was seen in 44 patients (48%). Other parameters like body mass index, body weight, cardio-pulmonary parameters showed improvement at the end of 12 week CDC therapy. Dependency on conventional allopathic medications was also reduced.

Conclusion: From the findings of present study, CDC has been found to exert significant euglycemic action, and can serve as potent alternate option for management of DM.

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INTRODUCTION

Global burden of diabetes mellitus has increased consistently since past few decades. Unfortunately, India has emerged as a major contributor to this global burden of DM.¹ DM has become one of the commonest non-communicable disease to contribute to morbidity and mortality.² DM has been identified as key focus non-communicable disease for chalking out contingency planning by the United Nations.³

Diabetes mellitus (DM) adds to significant piece of morbidity, mortality, and human healthcare cost on a worldwide level.

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The predominance of DM is rising alarmingly, around the world. India is just second to China, as far as pervasiveness of DM, with a commonness pace of around 10% i.e. each tenth grown-up in India is experiencing DM. As indicated by WHO report, around 30 individuals kick the bucket per 1 lac populace in India, because of diabetic entanglements.¹

Insulin resistance and hyperglycemia are typical features encountered in patients of type 2 DM. Classically, these patients are diagnosed by measuring blood glucose levels after overnight fasting i.e. fasting blood sugar (FBS) and 2 hours after giving the patients oral glucose solution i.e. post prandial blood sugar levels (PPBS). FBS of 110-126 mg/dl and PPBS of 126-140 mg/dl is labelled as impaired glucose tolerance, while values above these cutoff points is diagnosed as DM.

But, OGTT reflects only acute control of blood glucose levels, whereas it is vital to know the blood glucose levels over past 2-3 months to get a better idea of glucose metabolism and utilization. This need gap in diagnosis is fulfilled by measurement of glycosylated hemoglobin (HbA1c). Normal HbA1c levels should be less than 5.7%, while values falling in between 5.7% to 6.4% are considered as borderline cases of DM, which are at greater risk of developing overt DM. HbA1c >6.5% is diagnostic of DM, and the aim of treatment is to keep the levels of HbA1c below the diabetic cutoff value.⁴

DM is associated with plethora of complications, and worrisome fact is that some of them are significant contributors of fatality. Some of the major complications of DM are myocardial infarction, angina pectoris, renal failure, retinopathy, intermittent claudication, etc. Apart from these, it may also lead to sexual dysfunction in males, gangrene, non-healing ulcers on foot.⁵

Conventionally, DM is managed by oral hypoglycemic drugs (OHDs) which include biguanides like metformin, sulphonylureas like glimepiride, etc. and insulin. Along with these, dietary and lifestyle modifications including regular physical exercise are also advised to the diabetic patients.⁶

However, patient compliance to these conventional OHDs is less. Extensive adverse effect profile and augmented cost of therapy are commonest reasons cited for such low adherence to treatment. Irregular intake of drugs leads to ineffectiveness of the said therapy. Some of commonest adverse effects of OHDs are hypoglycemia, manifesting as fainting, dizziness, and urinary tract infections. Even insulin use is associated with adverse effects like injection site reactions.⁷

Despite the availability of armamentarium of OHDs, the prevalence of DM is rising alarmingly.

Thus, it becomes imperative to search for viable therapeutic option which will not only possess efficacy, but also overcomes problems faced with conventional OHDs.

Major action of conventional OHDs is lowering of blood glucose levels. Similar action is seen with many herbal drugs which has been cited in various published studies.⁸ Ayurveda is ancient medical science which aims to treat the disease from its root cause. Comprehensive Diabetes Care (CDC) utilizes combination therapy of Panchkarma, administration of herbal drugs and diet therapy.

Panchkarma is a holistic internal purification process which is proven to remove toxins from the body.⁹ Panchkarma in CDC utilizes 3 key procedures, namely Basti- administration of herbal drugs through rectal route, Swedana- passive heat therapy, Snehana- oleation therapy.¹⁰

There is shortage of clinical data on effect of these Ayurvedic regimens in patients of type 2 DM. Hence the present study was planned to analyze the effectiveness of CDC therapy along with diet therapy in patients with type 2 DM attending Madhavbaug clinics in Pune region.

SUBJECTS AND METHODS

This was a retrospective study conducted between October 2018, wherein we identified the data of obese patients suffering from type 2 DM (HbA1c \geq 6.5%) of either gender

and any age, and who had attended the out-patient departments (OPDs) at multiple Madhavbaug clinics located in Pune region of Maharashtra. The data of patients who had been administered CDC with minimum 6 sittings over a span of 12 weeks were considered for the study. According to patient medical records, the diet plan consisted of low carbohydrates, moderate proteins, and low fats. Cases were identified, and data was assessed from the records of Madhavbaug clinics in Pune region of Maharashtra. The selection was based upon the availability of complete relevant baseline data (day 1 of CDC) and final day data (12 week of CDC) of the patients i.e. body weight, body mass index (BMI), abdominal girth, laboratory investigations, HbA1c. The information about prescribed concomitant medicines, if any, was also noted down.

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.^[11,12]

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 kadhha	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 aristata</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 91 type 2 diabetic patients, 52 were males (57%), while 39 were females (43%), thus male: female ratio was 1.3:1 [figure 1].

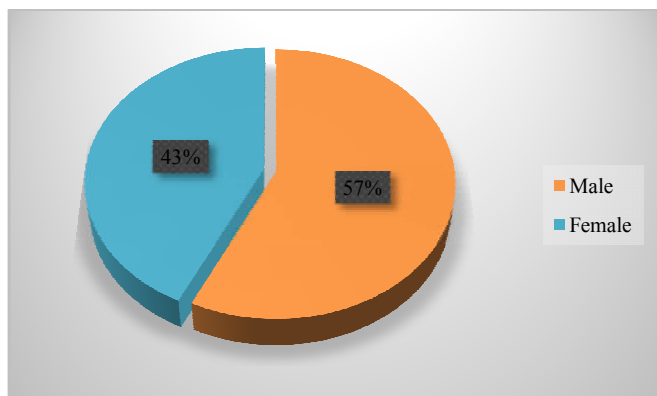


Figure 1 Sex distribution in patients of the present study

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].

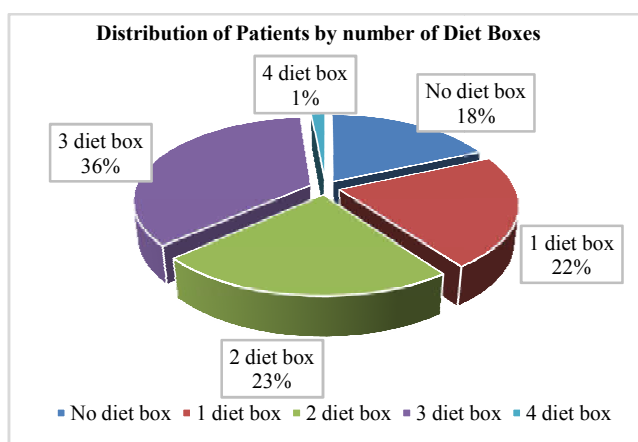


Figure 2 number of diet boxes used by patients of present study

On analysing the anthropometric parameters in the patients of present study, it was found that body mass index (BMI) was reduced from $27.80 \pm 1.28\text{kg/m}^2$ at baseline to $26.22 \pm 1.10\text{kg/m}^2$ at the end of 12 weeks of CDC therapy, and this difference was statistically significant [$p=0.05$]. Similarly abdominal girth was reduced from 99.27 ± 5.2 at baseline to 91.59 ± 4.2 at 12 weeks of CDC therapy [$p=0.01$]. 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	73.80±2.9	68.69±3.4	0.05
		BMI	27.80 ± 1.28	26.22 ± 1.10	0.08
		ABG	99.27 ± 5.2	91.59 ± 4.2	0.01
2	Cardio-pulmonary	SBP	129.95 ± 5.3	122.01 ± 6.12	0.04
		DBP	79.93 ± 4.1	77.69 ± 3.9	0.12
		VO ₂ peak	8.53 ± 1.6	19.20 ± 2.5	0.001
3	Lipid profile	Cholesterol	300.0±4.16	233.0±5.11	0.020
		HDL	28.0±1.9	39.0±2.2	0.001
		LDL	186.0±6.2	157.0±5.39	0.001
		TG	250.0±6.26	185.0±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 analysing the results of HbA1c level in patients who had completed 12 weeks of CDC therapy, it was found that controlled diabetes (HbA1c<5.7) was seen in 44 patients (48%), borderline diabetics was seen in 19 patients (21%) as compared to 37 patients (41%) at baseline, and uncontrolled diabetic readings were noted in 28 patients (31%) as compared to 54 patients (59%) at baseline [Figure 3].

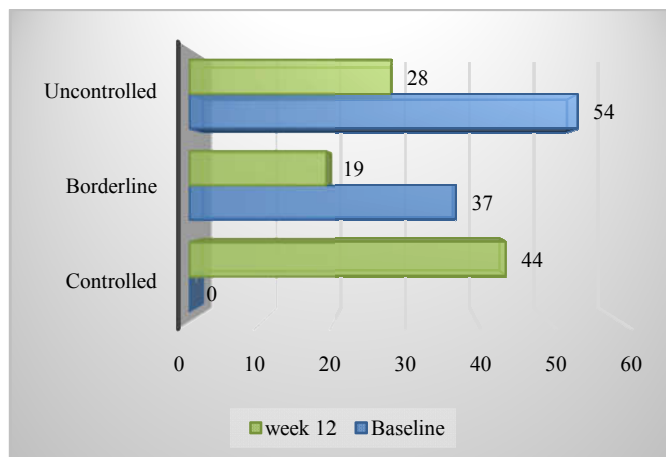


Figure 3 Results of HbA1c in patients who had completed 1 month of CDC therapy

Glycosylated haemoglobin (HbA1c) reduced from 8.56 at baseline to 6.84 at week 12 of completion of CDC therapy, and the difference was statistically significant [figure 4].

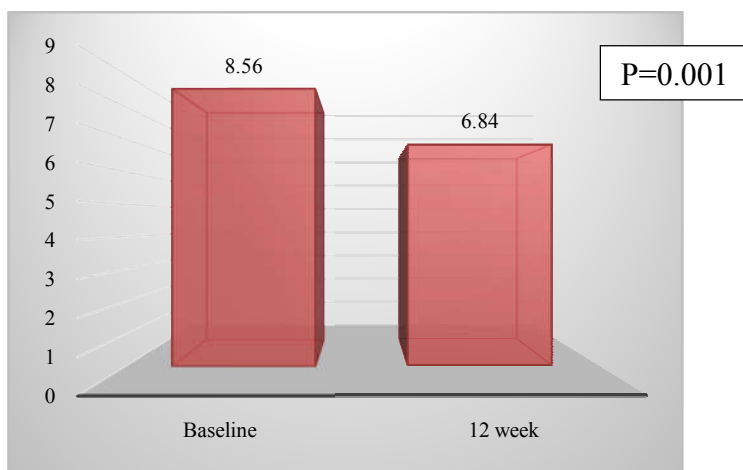


Figure 4 Glycosylated haemoglobin (HbA1c) in patients of present study at baseline and at 12 weeks of taking CDC therapy

Medication history was available in 91 patients, out of which majority of the patients were taking biguanides and sulfonylureas (SU). The number of tablets/patient ratio reduced from 3.73 at baseline to 1.52 at week 12 of CDC therapy, thus there was 59% 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

Sr. No.	Medication	No. of patients taking allopathic medicines		
		Baseline	Week 12	p-value
1	β blocker	22	11	0.001
2	ARB	42	25	0.001
3	CCB	24	9	0.001
4	Diuretic	16	5	0.001
5	SU	67	35	0.001
6	Biguanides	103	34	0.001
7	Antiplatelet	18	8	0.01
8	DPP4 inhibitor	19	5	0.001
9	Statins	29	7	0.001
10	Tablet/patient ratio	3.73	1.52	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 i.e. DM control status and duration of DM.

Duration of DM	Period of CDC therapy	HbA1c status			N
		Controlled	Borderline	Uncontrolled	
<2 yrs	Baseline	0	9	5	14
	week 12	5	3	6	14
2-10 yrs	Baseline	0	11	21	32
	week 12	16	6	10	32
> 10 yrs	Baseline	0	17	28	45
	week 12	23	10	12	45

DISCUSSION

DM is being treated by Ayurvedic physicians since ages with the help of variety of herbal formulations and panchkarma techniques. The postulated antidiabetic actions of these Ayurvedic therapeutic modalities are a virtue of their pancreatic and extra-pancreatic actions which ultimately help to reduce the blood sugar levels. Comprehensive diabetes care (CDC) is a type of Ayurvedic therapeutic regime which utilizes panchkarma, diet kit therapy. Panchkarma in CDC is comprised of 3 key processes- Basti i.e. herbal drug therapy administered per rectum, Swedana i.e. passive heat therapy, and Snehana i.e. internal oleation therapy.¹⁰ In the present study, we analysed the effects of CDC therapy on glycaemic parameters like HbA1c and anthropometric parameters like BMI, body weight, abdominal girth, etc.

These parameters were significantly attenuated at the end of therapy. HbA1c is considered as an indicator of prolonged glycaemic control and is known to reflect the blood glucose control over past 2-3 months.¹³ Thus, significant reduction in HbA1c in the present study indicates effective therapy.

However, ACCORD trial results does not favour intense reduction of HbA1c in management of DM. This multicentric trial was conducted to evaluate the effect of intense HbA1c reduction therapy with the help of multiple antidiabetic drugs as compared to standard regime with less number of antidiabetic drugs on cardiovascular outcomes, with special focus on persistent hyperglycaemia, dyslipidaemia and hypertension. The group with intense reduction in HbA1c

showed increase in cardiovascular events by 3.5 times as compared to standard therapy. Thus, dependency on standard therapy should be least.^{14,15,16} In the present study dependency on standard allopathic drugs reduced significantly at the end of study period, which indicates that this might have a better cardiovascular outcome.

As per published evidences, increased BMI, and abdominal girth are associated with increased likelihood of developing complications in diabetic patients.¹⁷ In the light of these facts, we evaluated the effect of CDC on these parameters and it was seen that both, BMI and abdominal girth were reduced significantly at the end of therapy.

Also, few studies have shown that weight reduction and reduced BMI in diabetic patients are associated with better optimization of HbA1c levels as compared to patients with increased weight and BMI.¹⁷

Snehana is one of the major Panchkarma technique which was used in the present study. It relieves the sympathetic stress of the patient and thus the intrinsic gluconeogenesis, which is under the control of sympathetic nervous system is reduced. It is done with help of Azadirachta indica oil, which has natural anti-infective properties and might help to counteract the dermatological infections in diabetic patients.¹⁸ Swedana exposes the diabetic patients to high temperature of 40-42 degree Celsius through steam. Such passive heat therapy is postulated to sooth the patient and induce sweating, which get rid of excess of sodium and water load in diabetic patients, which maintains the vascular health and thus reducing the chances of vascular complications.¹⁹ Basti is per rectal administration of herbal drugs like 40% *Gudmaar* (*Gymnemasylvestre*), 20% *Daruharidra* (*Berberisaristate*) and 40% *Yashtimadhu* (*Glycyrrhizaglabra*). These drugs are known to stimulate insulin release by stimulating the production of islets of Langerhans and beta cells in the pancreas.¹⁰

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.²⁰

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, CDC has shown promising results in terms of improvement in glycaemic as well as anthropometric parameters like HbA1c, BMI, abdominal girth, body weight, etc. Also, the number of euglycemic patients at the end of study period were high at the end of CDC, indicating its effective antidiabetic action.

Conflict of interest: None declared by the authors,

Source of funding: Not applicable.

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How to cite this article:

Dr. Rohit Sane *et al* (2020) ' Role of Comprehensive Diabetes Care in Known Diabetes Patients from Pune Region', *International Journal of Current Advanced Research*, 09(08), pp. 22937-22941.
DOI: <http://dx.doi.org/10.24327/ijcar.2020.22941.4534>
