Original Research Article

Role of comprehensive diabetes care in known diabetes patients from Gujarat state

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ABSTRACT

Background: Diabetes mellitus (DM) stays as one of the audacious worldwide plagues of the twenty-first century. As per an epidemiological study done in Gujarat, prevalence rate of DM was found to be >8%. CDC therapy is Panchkarma based Ayurvedic therapy for the management of DM. The aim of the present study was to analyze the effectiveness of CDC in patients of DM.
Methods: This was a retrospective study conducted at Madhavbaug clinics located in Gujarat, wherein we identified the data of obese patients suffering from type 2 DM (HbA1c ≥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 98 patients, number of patients with controlled DM status increased and that with uncontrolled status reduced at week 12, and the mean HbA1c reduced from 8.55 at baseline to 7.15 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.
Conclusions: 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: Ayurveda, Comprehensive diabetes care, Diabetes mellitus, Panchkarma

INTRODUCTION

Globally, diabetes mellitus has created a havoc, whose majority share is by developing, resource poor countries. As per the World Health Organization report, number of diabetic patients by 2014 were above 360 million, which is estimated to cross 420 million by next decade. In Indian context, more than 60 million people are diagnosed with DM. Reasons cited for such high prevalence of the disease are increased in number of middle aged population, faulty dietary habits, reduced physical activity, etc. all of which contribute to increase in disease load of the country.[1] As per an epidemiological study done in Gujarat, prevalence rate of DM was found to be >8%.[2]

DM is dreaded due to its morbidity and mortality. DM is associated with range of complications like pancreatitis, anaemia of chronic disease, renal failure, cardiovascular complications, blindness, sexual dysfunction in males,

etc. Cardiovascular complications and renal complications are a major cause of mortality in diabetic patients.[3] DM is usually diagnosed by measurement of serum sugar levels, in fasting state and after administering 75 mg glucose oral solution to the patient. However, glycosylated haemoglobin i.e. HbA1c has been utilized for diagnosed of DM, as well as marker of long term blood glucose control in the management of diabetic patients. HbA1c is formed due to non-enzymatic reaction during metabolism of glucose, and it roughly reflects the transient homeostasis of blood glucose in past 3 months.[4]

HbA1c> 6.5% is diagnostic of DM, and the aim of any antidiabetic therapy is to keep it <6.5%. 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.[5]

DM is usually treated with variety of antidiabetic drugs (ADD) which are either used as monotherapy or in combination with different class. Some of these ADDs are metformin, acarbose, canagliflozin, glimepiride, etc. These drugs act by reducing blood glucose levels by multiple mechanism like increased tissue uptake of glucose, increase glucose transporter 4 protein, decreased gluconeogenesis, increased glycolysis ,etc.[6]

However, there a lot of adverse effects associated with the use of these ADDs, which include fainting, dizziness, gastric upset, dyspepsia, diabetic ketoacidosis, etc. The quality of life is already hampered in diabetic patients due to distressing symptoms. These adverse effects further reduce the quality of life of these patients. This is the major reason for poor patient compliance to conventional antidiabetic therapy. Thus, it is need of the hour to search for effective alternate therapy which will be devoid of shortcomings of conventional therapy.[7]

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.[8] 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 ADDs, but without the adverse effects that are seen with ADDs.[8] Since, there is very less data regarding the effectiveness of CDC in patients of DM, we carried out the present study to evaluate the same by analyzing effect of CDC on HbA1c, fasting and post meal blood sugar levels and other anthropometric parameters which are linked to insulin resistance.

METHODS

Study design: Retrospective record based study.

Study site: Madhavbaug clinics across Gujarat state.

Study period: July 2018 to December 2019.

Study participants: Patients of either sex and any age, suffering from type 2 DM, who attended Madhavbaug clinics in Gujarat state.

Methodology

The data of patients who had been administered CDC with minimum 6 sittings over a span of 12 weeks 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 steps procedure which was performed on the patients of type 2 DM after a light breakfast. One sitting of the procedure took 45-50 minutes, as described in table 1. 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.

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).

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 with 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
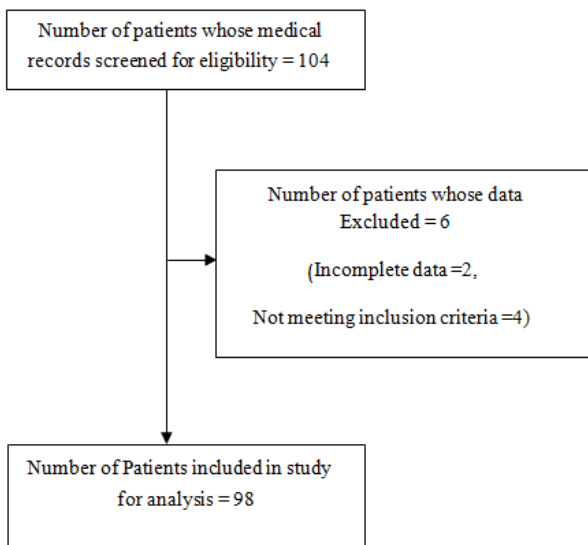
Figure 1: Patient record selection for the present study.

statistically significant. Lipid parameters showed similar trends which can be seen in Table 2.
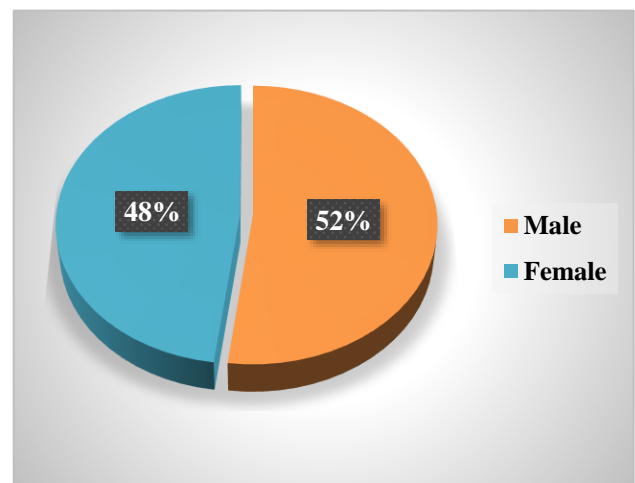

Figure 2: Sex distribution in patients of the present study.

RESULTS

In the present study, out of 98 type 2 diabetic patients, 51 were males (52%), while 47 were females (48%), thus male: female ratio was 1.08:1 (Figure 2).

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 3).

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
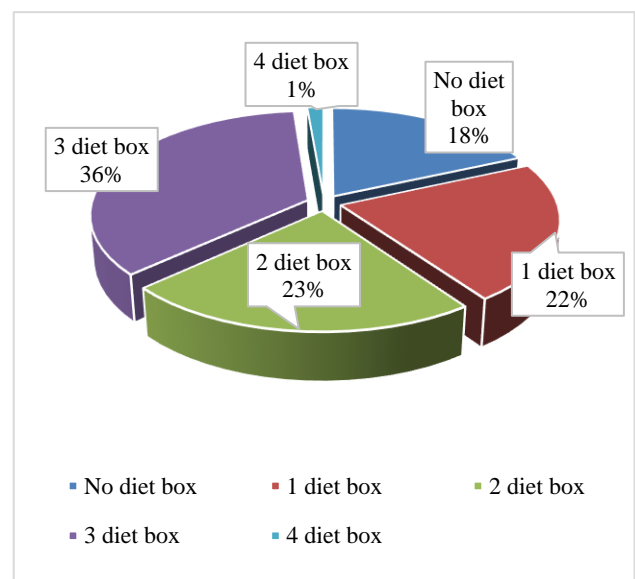

Figure 3: Number of diet boxes used by patients of present study.

Table 2: anthropometric, cardio-pulmonary and lipid parameters in the patients of present study at baseline and 12 weeks of CDC therapy.

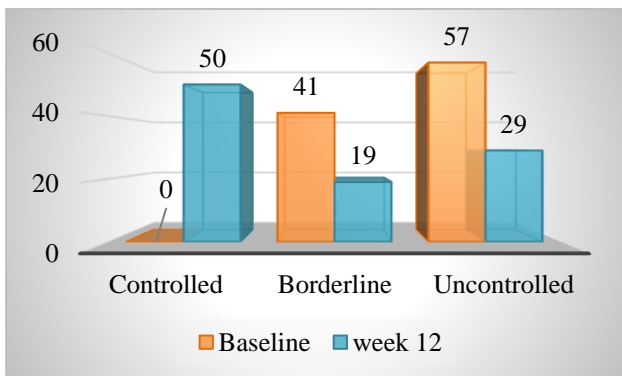| Parameter	Measurement	Baseline	12 week	P value
Anthropo-metry	Weight	74.24 ±5.1	69.64 ±3.8	0.05
	BMI	26.71 ±1.08	25.19 ±1.12	0.05
	ABG	101.28 ±6.1	94.53 ±5.8	0.05
Cardio-pulmonary	SBP	133.13 ±6.1	126.1 ±5.1	0.04
	DBP	82.77 ±3.9	78.84 ±3.6	0.05
	VO2 peak	17.83 ±0.94	18.55 ±1.19	0.01
Lipid profile	Cholesterol	240.25 ±9.1	181.75 ±7.9	0.000
	HDL	41.25 ±1.1	44.25 ±2.1	0.01
	LDL	155.0 ±6.9	112.25 ±5.3	0.00
	TG	204.5 ±6.6	142.75 ±5.16	0.001

Figure 4: Results of HbA1c in patients who had completed 12 weeks of CDC therapy.
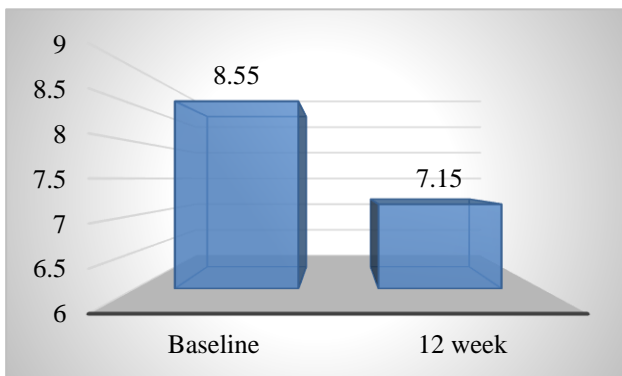

Figure 5: Glycosylated haemoglobin (HbA1c) in patients of present study at baseline and at 12 weeks of taking CDC therapy.

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 50 patients (51%), borderline HbA1c was seen in 19 patients (19%) as compared to 41 patients (42%) at baseline, while deranged readings were noted in 29 patients (30%) as compared to 57 patients (58%) at baseline (Figure 4).

Glycosylated hemoglobin (HbA1c) reduced from 8.55 at baseline to 7.15 at week 12 of completion of CDC therapy, and the difference was statistically significant (Figure 5).

Table 3: 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			
Medication	**Baseline**	**Week 12**	**P value**
β blocker	12	7	0.01
ARB	26	15	0.01
CCB	9	6	0.25
Diuretic	3	1	0.52
SU	38	12	0.001
Biguanide	48	8	0.001
Antiplatelet	11	6	0.06
DPP4 inhibitor	10	2	0.001
Statins	21	5	0.001
Tablet/patient ratio	1.81	0.63	0.001

Table 4: OGTT results and duration of DM.

Duration of DM	Period of CDC therapy	HbA1c status			N
		Controlled	Borderline	Uncontrolled	
<2 yrs	Baseline	0	9	8	17
	week 12	8	5	4	17
2-10 yrs	Baseline	0	13	17	30
	week 12	19	4	7	30
> 10 yrs	Baseline	0	19	32	51
	week 12	23	10	18	51

Medication history was available in 96 patients, out of which majority of the patients were taking biguanide and sulfonylureas (SU). The number of tablets/patient ratio reduced from 1.81 at baseline to 0.63 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 3).

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 4).

DISCUSSION

DM is regarded as one of the commonest non-communicable chronic disorder in the world. It is known to cause end organ damage in uncontrolled cases, which affects the organs like heart, kidneys, vasculature and thus the mortality is more.[9] Consequently, a variety of other diseases are co-associated with DM, which commonly include hypertension, which is virtually seen in almost more than half of long standing diabetic cases, myocardial infarction, angina pectoris, etc.[9] Formation of atherosclerotic plaques are commonly seen in long standing diabetic cases, which also contributes to cardiovascular complications in diabetic patients.[10]

Due to alarming rise in prevalence of DM and its fatal complications despite availability of numerous antidiabetic drugs and treatment guidelines, the search for alternate therapeutic options have gained more value in recent years. Ayurvedic physicians administer panchkarma to the DM patients and most times panchkarma is given along with diet therapy (consisting of low carbohydrates and fats with moderate amount of proteins) in the form of CDC.

Panchkarma is an internal detoxification process, whose effectiveness is established in clinical study.[11] The key actions of procedures used in CDC are Swedana induce sweat by steam therapy, which excretes excess sodium and water, and thus reduces shear stress on vascular endothelium.[12] Basti liquefies amyloid deposition and sensitizes insulin action, remove toxins from gastrointestinal tract.[13] Snehana helps in reduction of lipid production in the body, thus correcting dyslipidaemia.[14]

HbA1c is most critical parameter in type 2 diabetics as it reflects blood glucose control over preceding 2 months.[4] Apart from this, its role as prognostic indicator of morbidity and mortality is well established in literature and is universally accepted, as sustained increased levels are associated with bad prognosis.[4] Keeping these published evidences in mind, it can be deducted from findings of the present study that CDC is anticipated to improve the prognosis in patients of type 2 DM as it significantly reduced HbA1c levels at week 12.

The notion that HbA1c reduction will attenuate the risk of complications and thus improve the prognosis in terms of reduction in mortality and morbidity, was challenged by the results of landmark clinical trial in DM i.e. ACCORD trial has enabled the physicians to readdress the importance of HbA1c as the major target for treatment. In this multicentric trial the effect of intensified HbA1c control regimen was compared with usual HbA1c control regimen on cardiovascular outcomes, which are a major cause of mortality in diabetic patients. The clinical trial found out that intensified HbA1c reduction actually increased the risk of cardiovascular complications by 3.5 times as compared to usual regimen. Intensified regimen utilized use of multiple antidiabetic drugs, while usual regime used least possible antidiabetic drugs along with lifestyle modifications.[5,15,16]

In a resource limited country like India, where per capita income of majority of the population is still very low, and the long term intake of allopathic medicines increases the cost of therapy to distressing limits. Numerous adverse effects of these drugs complicate the scenario.[17] There was significant reduction in dependency on allopathic drugs, at the end of study period.

There are some limitations for this study. The study design was non-comparative and retrospective with a limited sample size. 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

Judging from the findings of the present study, it can be inferred that CDC can serve as effective alternate therapy in management of DM, especially where cost of therapy and safety profile of drugs are more important.

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