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Effect of Comprehensive Diabetes Care on Glycaemic Control with Reduction in Dependency of Oral Hypoglycaemic Medicines in Pre-obese Diabetic Patients: A Retrospective Study

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Abstract

Although multiple new drugs are coming out in the market, India has the 2nd highest number of diabetics in the world.The aim of this study was to evaluate effects of Comprehensive Diabetes Care (CDC) on Glycosylated haemoglobin (HbA1c) and metabolic parameters in pre-obese diabetic patients. In this retrospective study, data of pre-obese DM patients who had received 6 CDC sittings over 90 days in the out-patient departments (OPDs) at *Madhavbaug* clinics was collected between May 2013 to April 2018. Demographic and co-morbidity details were noted. HbA1c, body mass index (BMI), abdominal girth, systolic and diastolic blood pressure (SBP, DBP), dependency on medications were assessed on days 1 and 90 of CDC. The patients followed a specific low-calorie diet plan during the study. 89 participants, (52 males, 37 females) were enrolled. Mean HbA1c measured at day 90 was significantly lower than that on day 1 (6.86 ± 1.24 vs 9.02 ± 1.79, $p<0.001$). Mean BMI was significantly reduced on day 90 when compared to baseline (25.39 ± 1.53 vs 27.24 ± 1.33, $p<0.001$). Abdominal girth was significantly decreased on day 90 compared to baseline (91.64 ± 6.26 vs 97.12 ± 7.03, $p<0.001$). SBP (122.83 ± 13.56 vs 131.60 ± 16.10, $p<0.001$) and DBP (77.02 ± 6.81 vs 81.75 ± 9.43, $p<0.001$) were also significantly decreased after 90 days. Dependency on concomitant medicines was reduced. Glycaemic control and metabolic parameters significantly improved after 90-day CDC treatment. Reduction in blood pressure and intake of concomitant medications were also noted.

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Keywords

Comprehensive diabetes care, CDC, Panchakarma, Diabetes mellitus, HbA1c, Body mass index, Ayurveda, Alternative medicine

Introduction

Diabetes mellitus (DM) is a known global health-hazard, affecting millions of people worldwide. According to World Health Organization (WHO), the number of diabetic patients has increased from 108 million in 1980 to a staggering 422 million in 2014. (WHO, 2018) The International Diabetes Federation (IDF) has mentioned that about 1 in 11 adults belonging to the age group of 20 years to 79 years are suffering from DM worldwide. (International Diabetes Federation, 2018) It is interesting to note that 3/4th of the patients suffering from DM worldwide belong to the low-income and middle-income countries, and India is one of them. (Tripathy *et al.*, 2017) It is estimated that in 2015, India had more than 69 million DM patients, which is considered to be the

second highest number in the world, next to only China. (International Diabetes Federation, 2018) The DM prevalence is expected to double after 20 years, because of the elevating age-expectancy, increasing obesity as well as the increased exposure of population to various risk factors. The patients suffering from DM also are at a risk of developing various dangerous complications like retinopathy, neuropathy and various microvascular and macrovascular diseases. Current management of DM aims to render a good glycaemic control and prevent the development or progression of complications. There are multiple treatment modalities for the management of DM which include parenteral insulin preparations and oral hypoglycaemic agents like metformin, sulfonylureas, sodium glucose transport inhibitors, thiazolidinediones. Despite the presence of these multiple classes of drugs, the prevalence of DM is on an upswing. Literature reveals glycated haemoglobin (HbA1c), the main indicator of long term diabetes control, is in the normal range in only 50% of the DM patients. (Del Cañizo-Gómez and Moreira-Andrés, 2004) The various drugs used for the management of DM are also associated with multiple adverse effects. (Goodman *et al.,* 2011) Hence, there is a need for new or alternative therapeutic modalities for the treatment of DM.

Ayurveda is a commonly practiced ancient art of alternative medicine in India, which simply means 'Science of Life'. The main purpose of *Ayurveda* is to keep an equilibrium between the physiological and structural entities, which indicates good health. (AYUSH, 2007) The description of DM (*Madhumeha*) is present in the ancient Ayurvedic literature, indicating that the knowledge of the disease was present with the Ayurvedic physicians. (Upadhyay and Kamla, 1984) The Ayurvedic physicians are using a multi-faceted management approach to treat DM in India, which include the usage of *Panchakarma*, herbal preparations, yoga and breathing exercises along with diet modifications. Comprehensive diabetes care program (CDC) is one such alternative treatment modality, which includes a combination of herbal treatment with *Panchakarma* and allied therapies. The techniques used in *panchakarma* are *Snehana* (Centripetal oleation), *Swedana* (Thermal vasodilation) and *Basti* (per rectal drug administration), which are known to remove toxins from the body. (Mishra, 2003; Uebaba *et al.,* 2008) However, there is a paucity of literature which indicates that this alternative treatment modality is efficient in controlling DM.

Hence, a retrospective study was planned to assess the effect of CDC in the treatment of patients with DM. HbA1C, the main indicator of DM control, was the primary outcome measure in this study. The body mass index (BMI) appears to have a direct relationship with the relative risk of several chronic conditions, including DM, hypertension, coronary heart disease, and cholelithiasis. (Willett *et al.,* 1999) Therefore, those DM patients who had a pre-obese BMI range were enrolled to assess the effect of CDC on various metabolic parameters like BMI, weight and abdominal girth along with the effect on HbA1c.

Subjects and Methods

This was a retrospective study conducted between May 2013 to April 2018, wherein we identified the data of patients who had attended the out-patient departments (OPDs) at multiple *Madhavbaug* clinics located in various cities of Maharashtra in India and were suffering from DM. The data of patients having an HbA1c level above 7% were included in the study. The other main inclusion criterion was that the included patients must have a baseline BMI between 25 kg/m^2 to 29.9 kg/m^2, as the study intended to include pre-obese patients with DM. The patients were administered CDC once a week in the 1st month, followed by once a month in the next two months. Data of only those patients were included who had received the scheduled 6 sitting in a span of 90 days. 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 allopathic medicines was also noted down. The CDC is a 3-step procedure which lasts for about an hour per sitting. The details of the regimen have been mentioned in table 1. Various procedures of the CDC regimen were carried out on a single day for one single patient.

On day 1 of CDC, the fasting serum HbA1C of the patients was assessed along with the assessment the weight, height and the abdominal girth. The details of the concomitant anti-hyperglycaemic treatment were also noted down on day 1. These details were again noted down on day 90 of CDC, for comparison with the baseline (day 1) findings. 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}. Diabetic diet plan, based on the principle of low-calorie and low-carbohydrate diet, was followed by the patients throughout the 90 days study period.

Data were pooled and coded in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyze the data. Categorical data were expressed in the form of frequency (%) and continuous data were expressed in the form of Mean ± SD. The paired t-test was used to assess the statistical difference between baseline and 90th day values. The correlation between abdominal girth and HbA1c as well as between abdominal girth and BMI was calculated using Pearson correlation coefficient. Scatter plot and bar graphs were used to represent the results.

Results and Discussion

The study comprised of 89 participants with striking male predominance (58.43%). Baseline characteristics of the study participants were as given in Table 2. Nearly three-fourth of the study participants had past-history of diabetes mellitus, while the second highest morbidity history reported was hypertension (43.82%). The major baseline characteristics are mentioned in table 2.

The comparison of clinical parameters between baseline values and those noted at 90th day are given in Table 3. The BMI was significantly reduced ($P < 0.001$) along with the measured abdominal girth ($P < 0.001$). HbA1c ($P < 0.001$), systolic blood pressure ($P < 0.001$) and diastolic blood pressure ($P < 0.001$) were also found to be significantly reduced after 90 days of treatment as compared to the respective mean baseline values. Figures 2 to 5 represent the graphical representation of the comparison between baseline and 90th day mean parameters. The correlation between abdominal girth and HbA1c, abdominal girth and BMI as well as between HbA1c and BMI was calculated using Pearson correlation coefficient (table 4). There was a weak positive correlation between abdominal girth and HbA1c (r=0.018) on the 1st day of the treatment and it was not statistically significant (p=0.87), the same is shown in figure 5.1. After 90 days of treatment we found stronger positive relationship between abdominal girth and HbA1c which was approaching to statistical significance (r=0.18, p=0.084) as showed in figure 5.2.

There was a positive correlation between abdominal girth and BMI (r=0.28) on the 1st day of the treatment and it was statistically significant (p=0.007), the same is shown in figure 5.3. After 90 days of treatment we found a highly significant positive relationship between abdominal girth and BMI (r=0.48, p<0.001) same is shown in figure 5.4.

The study participants were on various concomitant medications for DM as well as other co-morbidities. We compared the consumption of the allopathy medications by the participants, on day 90 and day 1, to check whether there was any reduction in the dependency on these standard medications by CDC. Table 5/Figure 6 gives the comparison between the consumption of allopathic medicines at day 1 and day 90.

Ayurvedic practitioners have been treating DM using various preparations like *Chandraprabhavati* since a long time. It is hypothesized that Ayurvedic medicines may be acting via various potential pancreatic and extra-pancreatic effects. Comprehensive diabetes care (CDC) is one such Ayurvedic intervention which consists of 3 main components; *Snehana* (Centripetal oleation), *Swedana* (Thermal vasodilatation) and *Basti* (per rectal drug administration).

We assessed the effects of this treatment technique on HbA1c, weight, BMI and abdominal girth. All these parameters were significantly reduced in the patients on CDC management, at the end of 90 days. HbA1c is a significant indicator of long-term glycaemic control in DM patients, with the capability to reflect the cumulative glycaemic control in the previous two to three months. (Sherwani *et al.*, 2016) Therefore, HbA1c was our primary parameter and the reduction in HbA1c by CDC gives a good evidence. Literature search revealed that even a mildly increased BMI can increase the chances of developing complications in DM. (Gray *et al.*, 2015) the positive effect of CDC in decreasing BMI can help prevent the potential complications too. Research articles have mentioned that abdominal girth is the best parameter to assess adiposity and predict the outcome of DM. (Ghosh and Bandyopadhyay, 2012) Hence, we measured the effect of CDC over abdominal girth, which revealed positive outcome. We also found a strong positive correlation between BMI and HbA1c at the end of CDC treatment. This goes in sync with a research by Gummesson *et al.*, which mentioned that weight loss in the overweight population is consistently associated with HbA1c, in a dose dependent manner. (Gummesson *et al.*, 2017) We also found a reduction in the patients who were on these allopathic drugs. This indicates that CDC may be one of the factors associated with the decrease in load of medications in DM patients, and also helps them in avoiding the potential adverse effects of the allopathic medications.

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

Step of CDC	Type of Therapy	Herbs used for therapy	Durationof Therapy
Snehana	Massage or external oleation (centripetal upper strokes on the body)	100 ml *Azadirachta 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

Table.2 Baseline characteristics of the study participants

Variable	N=89
Age (Years)	56.19 ± 10.98
Gender n (%)	
Male	52 (58.4)
Female	37 (41.6)
Co morbidities n (%)	
Hypertension	39 (43.82)
Obesity	15 (16.85)
Dyslipidemia	10 (11.24)
Ischemic heart disease	8 (8.99)
Coronary artery disease	5 (5.62)
Chronic heart failure	3 (3.37)
Hypothyroidism	3 (3.37)
Chronic kidney disease	1 (1.12)
H/O Coronary angioplasty	1 (1.12)

Age is expressed in mean ± SD and N (%)

Table.3 Comparison of various body parameters at the 1st day and after 90 days of the treatment

Variable	Baseline	After 90 days	t-statistic	p-value
HbA1c	9.02 ± 1.79	6.86 ± 1.24	12.78	<0.001***
BMI (Kg/m^2)	27.24 ± 1.33	25.39 ± 1.53	15.242	<0.001***
Abdominal girth	97.12 ± 7.03	91.64 ± 6.26	10.68	<0.001***
SBP (mmHg)	131.60 ± 16.10	122.83 ± 13.56	5.65	<0.001***
DBP (mmHg)	81.75 ± 9.43	77.02 ± 6.81	5.23	<0.001***

****Highly significant*; *BMI, Body Mass Index; HbA1c, Haemoglobin A1c; SBP, Systolic blood pressure, DBP; Diastolic blood pressure*

Table.4 Correlation between Abdominal Girth, HbA1c & Abdominal Girth, BMI

Correlation between	Baseline		After 90 days	
	r	p-value	r	p-value
Abdominal girth and HbA1c	0.018	0.87	0.183	0.084
Abdomen girth and BMI	0.28	0.007	0.48	<0.001
HbA1c and BMI	-0.008	0.94	0.12	0.26

Table.5 Consumption of medicines at baseline and after 90 days

Medicine	Day 1	After 90 days
Sulfonylurea	39 (43.82)	22 (24.72)
Biguanide	54 (60.67)	33 (37.08)
Alpha-glucosidase inhibitor	13 (14.61)	7 (7.87)
DPP -4 inhibitor	17 (19.1)	2 (2.25)
Thiazolidinedione	2 (2.25)	9 (10.11)
Insulin	7 (7.87)	1 (1.12)
Beta blocker	11 (12.36)	6 (6.74)
ACE inhibitor	2 (2.25)	0 (0)
ARB	20 (22.47)	14 (15.73)
CCB	14 (15.73)	7 (7.87)
Diuretic	9 (10.11)	4 (4.49)
Statin	26 (29.21)	10 (11.24)
NSAID	14 (15.73)	8 (8.99)
No medicine	13 (14.61)	40 (44.94)

Fig.1 Comparison of HbA1c of the patients at baseline and after 90 days

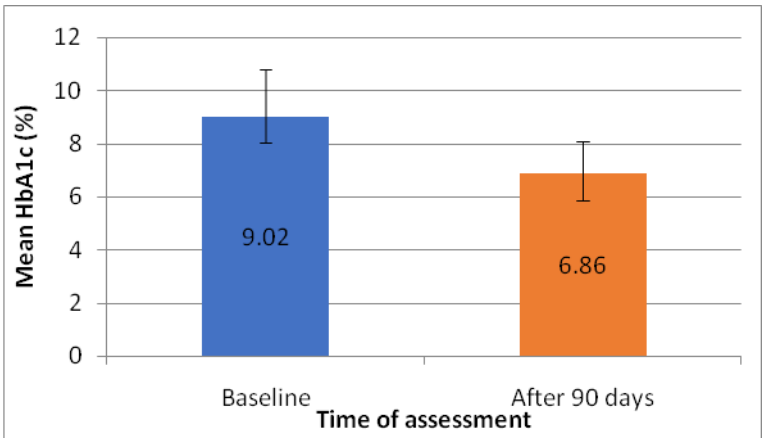


Fig.2 Comparison of BMI of the patients at baseline and after 90 days

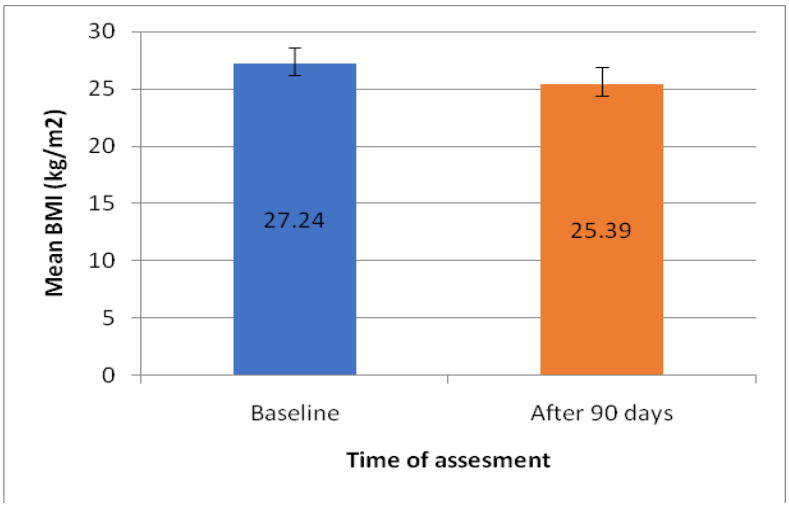


Fig.3 Comparison of abdominal girth of the patients at baseline and after 90 days

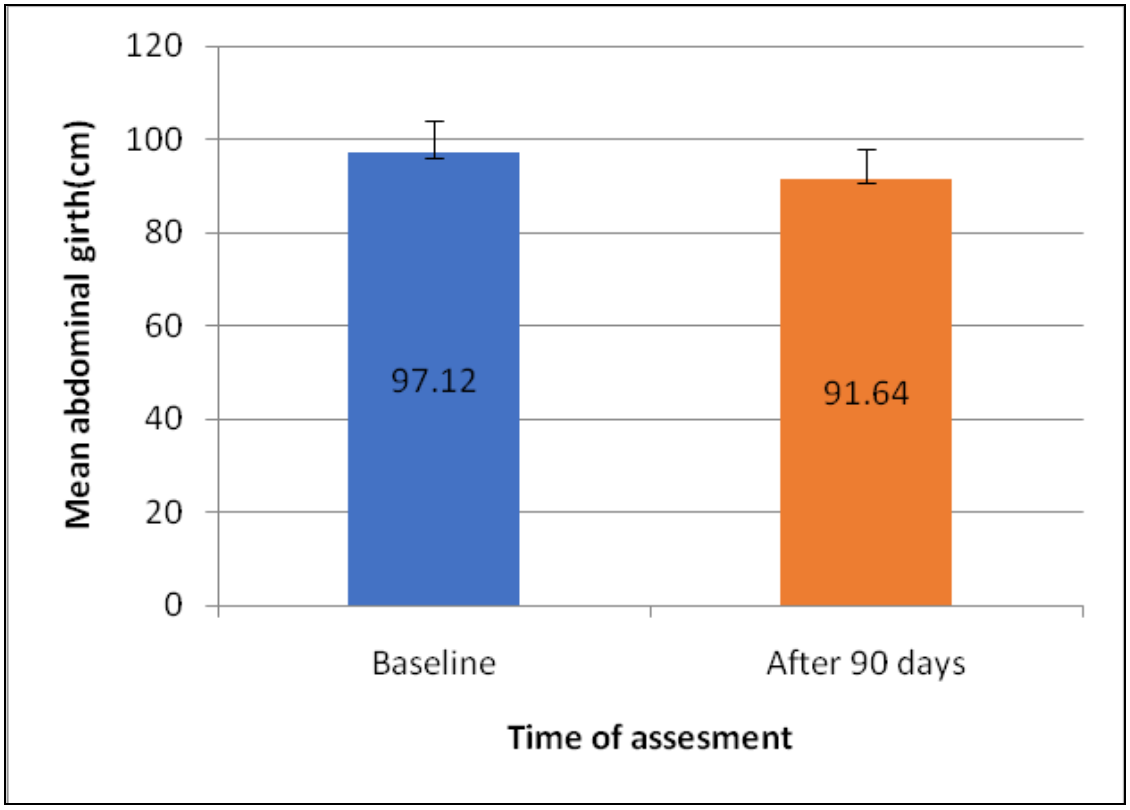


Fig.4 Comparison of SBP and DBP of the patients at baseline and after 90 days

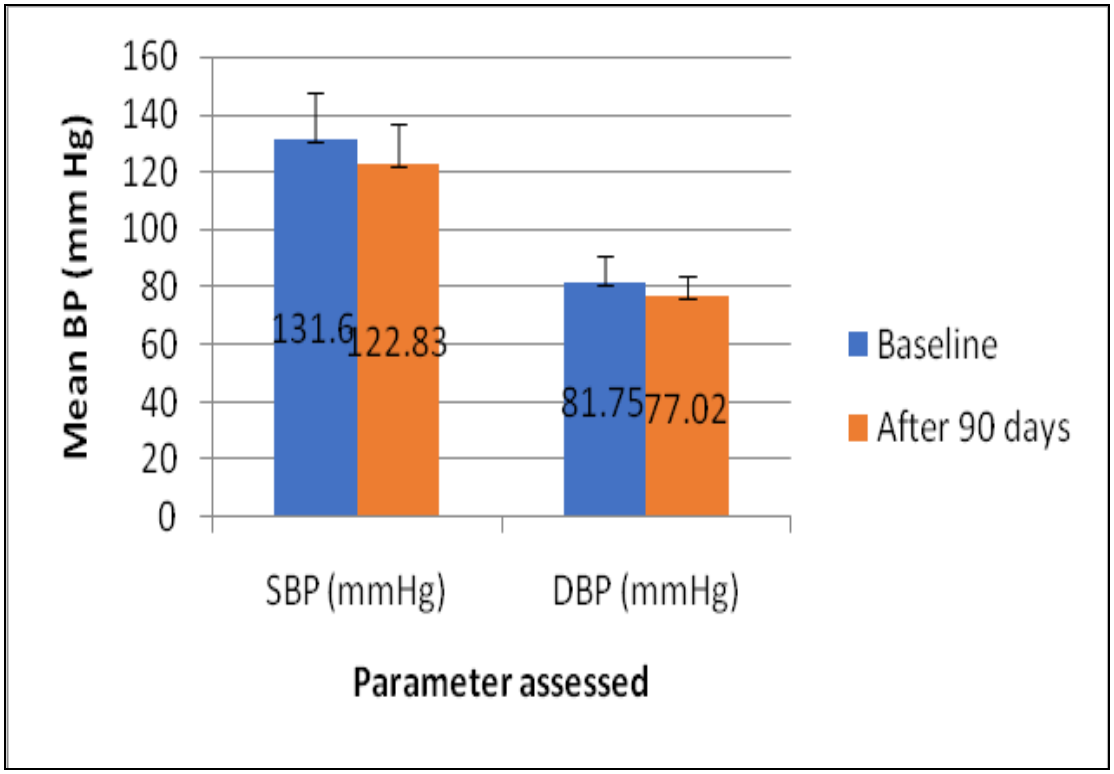


Fig.5 Correlation between Abdominal Girth, HbA1c & Abdominal Girth, BMI

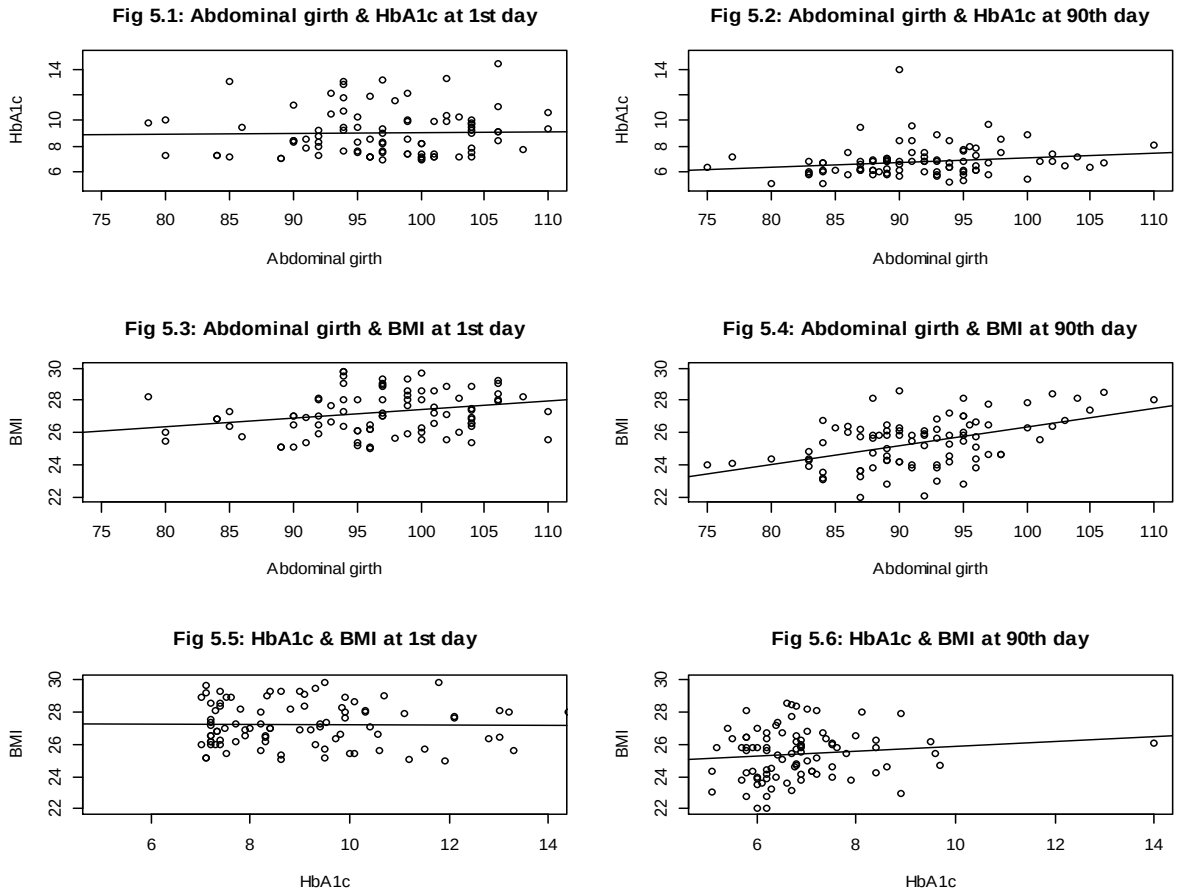
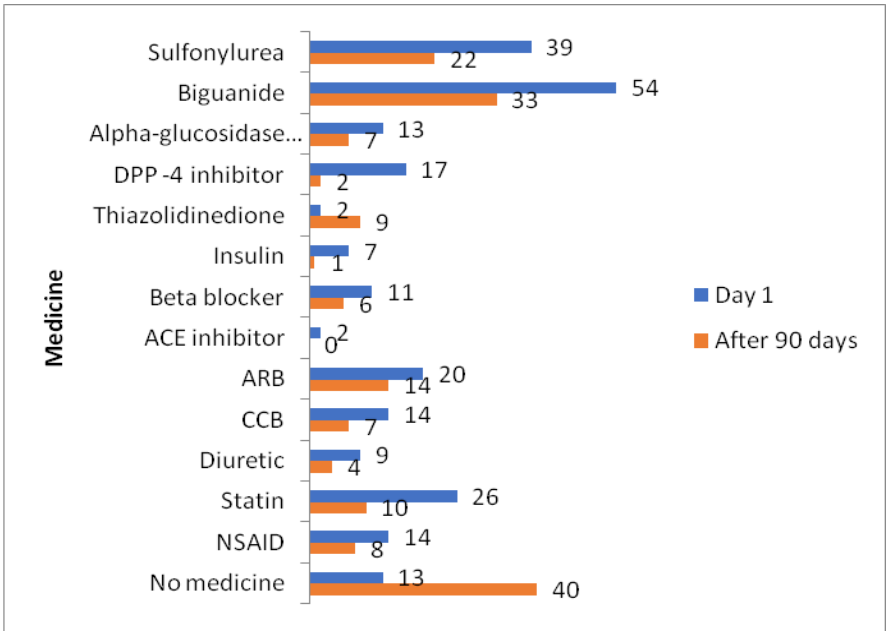


Fig.6 Consumption of medicines at baseline and after 90 days



Snehana is provided using *Neem* (*Azadiracta indica*) oil all over the body. Oleation is an anxiolytic procedure which decreases the sympathetic stress. The reduced sympathetic action decreases the hepatic glucose production, which can be helpful to reduce blood sugar levels. *Azadiracta indica* has antibacterial and antifungal action that can also help to reduce skin infections in DM patients. (Subapriya and Nagini, 2005) *Swedana* is a process wherein diabetic patients get sleep inside a wooden box full of steam with head and neck outside the box, temperature being maintained around 40-45-degree Celsius. After 15-20 min patient is asked to come outside the box. It is hypothesized that hot fomentation, which is a relaxing process, induces sweating and decreases the excess of sodium and water which comprehensively helps to improve vascular health of DM patient to keep them away from probable vascular complications. *Basti* involves per rectal administration of ayurvedic herbal extracts like *Gudmar* (*Gymnema sylvestre*), *Daruharidra* (*Berberis aristate*) and *Yashtimadhu* (*Glycyrrhiza glabra*). *Gymnema sylvestre* has been found to stimulate insulin release, which may be responsible for its possible anti-hyperglycaemic action. (Persaud, 1999) The insulin release may be due to the possible regeneration of islet of Langerhans, as mentioned in a study conducted on streptozotocin-diabetic rats. (Shanmugasundaram *et al.*, 1990) An animal study assessed the anti-hyperglycaemic action of *Berberis aristate* and found strong potential in regulating homeostasis. (Singh and Kakkar, 2009) A clinical study conducted in type 2 DM patients found that *Berberis aristate* can reduce HbA1c efficiently. (Di Pierro *et al.*, 2013) In a pre-clinical study, *Glycyrrhiza glabra* has been found to prevent the deleterious effects of DM on learning and memory. (Hasanein, 2011) It is, however, important to note that low carbohydrate diet of 800 calories/day was advised to these patients throughout the 90 days period that could have add on benefit to this intervention.

Diabetes is known to be associated with poor dietary choices. Dietary choices is a key driver for insulin resistance, especially in an aging and sedentary population. Increased consumption of calorie-dense foods like fast food, meats and other animal fats, highly refined grains, and sugar-sweetened beverages, are thought to play a critical role in the rising rates of type 2 diabetes worldwide. Dietary changes like intake of low calories & high consumption of complex carbohydrates like high intake of fruits and vegetables, legumes, nuts, good quality fat can help in reducing insulin resistance. As per one of the studies, beta cell failure & insulin resistance can be alleviated by acute negative energy balance. Fasting blood glucose and hepatic insulin sensitivity reduced to normal & intrahepatic lipid decreased by 30% over 8 weeks and beta cell function elevated towards normality. (Lim, 2011; Yancy, 2005; Sami, 2017; McMacken and Shah, 2017)

For weight loss one should reduce to around 1000kcal/day which will help reduce 1 kg of body weight per week & 4kg per month. Low calorie and low carbohydrate diet helps in utilization of intra organ fat and reduces insulin resistance which will help in the reversal of diabetes. Diet plan recommended to the patients was based on this principle of low-calorie and low-carbohydrate diet, which is to be followed for 12 weeks. It is based on pulse protein, complex carbohydrates, consumption of fruits and vegetables as well as good quality fats. As the diet plan is low in calories, it can lead to normalise insulin secretion and control diabetes.

This study had a few limitations. It was a single-arm, retrospective study due to which the results were not compared with the standard care. However, this study was a proof-of-concept research, and future cohort studies with larger sample size and longer duration follow-up may be conducted, to generate a stronger evidence.

Treatment with CDC showed a significant decrease in the HbA1c levels of diabetic patients. CDC also showed significant reduction in the metabolic parameters of weight, BMI and abdominal girth of the diabetic patients. Moreover, CDC also decreased the dependency of the diabetic patients on the standard allopathic medications.

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