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Role of Ayurveda Based Comprehensive Diabetic Care Program in Restoration of Euglycemia in Known Type 2 Diabetic Mellitus

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Abstract: Remission of diabetes mellitus could be an ideal solution to prevent impact of the pandemic of non-communicable disease in India. This study sought to understand the extent to which Ayurveda can impact remission of diabetes mellitus and achieve good glycaemic control in patients with diabetes mellitus. A retrospective, observational, single-centre study was conducted between 2018 and 2022 in Maharashtra, India. Patients aged 18 years and older with a diagnosis of diabetes mellitus, regardless of underlying comorbidities participated in the CDC program and were therefore included in this study. Follow-up was conducted at 30, 60, and 90 days. Day 1 and day 90 data were compared. A total of 63 patients were assessed. Of the 63 patients, 77.0% demonstrated post prandial normoglycemia, 50.8% demonstrated remission of diabetes mellitus, and 22.2% remained positive for diabetes mellitus. Variables such as weight (day 1: 70.70 ± 9.82 kg and day 90: 65.15 ± 9.93 kg; $p < 0.001$), body mass index (day 1: 27.00 ± 3.88 and day 90: 24.91 ± 3.75; $p < 0.001$), abdomen girth (day 1: 98.13 ± 10.08 cm and day 90: 89.24 ± 8.40 cm; $p < 0.001$), and glycated haemoglobin A1c (HbA1c) levels (day 1: 7.87 ± 1.90% and day 90: 5.79 ± 0.51; $p < 0.001$) decreased significantly. The improvement in HbA1c levels and other risk factors through implementation to improve glucose metabolism can help restore euglycemic status in 12 weeks of time with adherence to the CDC program. Remission of diabetes mellitus may be dependent on patients' compliance to a low carbohydrate diet provided during the treatment period.

Keywords: Ayurveda, Cardiovascular Diseases, Body Mass Index, Diabetes Mellitus, Dietary Management, Obesity, Remission of Type 2 Diabetes Mellitus, Restoration of Euglycemia

1. Introduction

Diabetes mellitus has gradually increased throughout the decades and is now epidemic in several low and middle-income countries. The prevalence of diabetes mellitus has sharply increased from 2.4% and 3.3% in 1972 to 15.0% and 19.0% in 2019 in urban and rural India, respectively. According to consensus data, 107 million adults in India have diabetes mellitus [1]. The spectrum of associated complications includes macrovascular complications such as ischemic heart disease, peripheral vascular disease, and cerebrovascular disease and microvascular complications such as retinopathy, nephropathy, and neuropathy which progress to affect several organs of the body [2]. The prescribed antidiabetic medication includes biguanides, dipeptidyl peptidase-4 (DPP-4) inhibitors, sodium-glucose cotransporter (SGLT2) inhibitors, insulin, glucagon-like peptide-1 (GLP-1) agonists, sulfonylureas, and thiazolidinediones — however, these are associated with a plethora of adverse effects [3]. The cost of these antidiabetic medications is yet another hindrance to compliance of medication.

Ayurveda is an ancient medicinal practice that has originated in India and dates back to 1000 BC. Its Sanskrit translation means 'science of life'. Ayurvedic practices focus on the use of herbal supplements, although exercise, weight management, and various supplemental therapies

also play a pivotal role. The goal of Ayurvedic practices in the treatment of diabetes mellitus focuses on reducing haemoglobin A1c (HbA1c) levels within a therapeutic range. Since the cause as well as treatment of diabetes mellitus lie within diet and lifestyle modifications, Ayurveda which is based on diet and lifestyle, is a logical approach to treat diabetes mellitus [4]. There are anecdotal reports [5–8] as well as larger studies [9, 10] and systemic review and meta-analysis [11] evidencing the use of Ayurveda to improve outcomes in patients with diabetes mellitus. The Comprehensive Diabetic Care (CDC) Program combines *Panchakarma* and diet management to reverse diabetes. Against this background, the present study sought to understand the extent to which Ayurveda can impact remission of diabetes mellitus and achieve good glycaemic control in patients with diabetes mellitus.

2. Materials & Methods

2.1. Study Design and Patient Population

This was a retrospective, observational study conducted at Madhavbaug Clinic, Mumbai, Maharashtra between 2018 to 2022. Patients aged 27 to 73 years with a diagnosis of diabetes mellitus as outlined by the American Diabetes Association (ADA) [12], regardless of co-morbidities such as coronary artery disease, hypertension, hypothyroidism, obesity, and percutaneous transluminal coronary angioplasty were included in this study. Lean diabetic patients and patients with type 1 diabetes were excluded from the study.

2.2. Comprehensive Diabetes Control Program

The CDC program is a 3-step procedure and each session lasts for approximately 65–75 mins. This procedure was performed on the patients after a light breakfast. The first procedure, Snehana was external oleation with Neem oil massaged on hands, legs, shoulders, thorax, abdomen and the back in a centripetal manner. The duration of this massage was 15–25 minutes as 15–30 strokes were applied on each aforementioned body part. The second procedure, Swedana was passive heat therapy with Dashmoola decoction with the patient in supine position in a wooden box. The patient's neck was allowed to protrude outside the box. The duration of this therapy was 10–15 minutes followed by a relaxation period of 3–4 minutes after the therapy. The third procedure, Basti was medicated enema of 100 ml Gymnema sylvestre, Berberis aristate, and Glycyrrhiza glabra. Administration was rectal with the drug to remain inside the body for >15 minutes to enable maximum absorption. The CDC program encompassed a total of 6 sessions (4 within the first month, one in the second month, and one in the third month) extending over the duration of 90 days. Patients were restricted to a diet plan of 800–1000 calories intake daily. The diet plan comprised of low carbohydrates, moderate proteins, and low fats. The CDC program is illustrated in Figure 1.

Figure 1. *Graphical representation of the components of the Comprehensive Diabetes Care Program.*

2.3. Data Collection

Data for patient demographics, anthropometrics, laboratory findings, and medications were collected and analysed from the patients' medical records. On day 1 of the CDC program, a detailed patient history was taken, anthropometric measurements were recorded and the fasting serum HbA1c levels were measured. Details of concomitant standard antidiabetic medication were also recorded. This activity was repeated on day 90 of the CDC program. Data of day 1 was compared with data of day 90. Data of only those patients who had completed a total of 6 sessions was collected and analysed.

2.4. Statistical Analysis

Categorical data are expressed as number (percentage) and continuous data are expressed as mean ± standard deviation. Paired t test was used to determine the difference between baseline and follow-up at 90 days. P value ≤ 0.05 was considered as statistically significant. R Version 3.4.1 software was used to analyse the data.

3. Results

3.1. Glucose Tolerance Test

A total of 82 patients were screened, however due to non-compliance 19 patients were excluded. Of the 63 patients, 49 (77.0%) patients (negative + impaired) demonstrated post prandial normoglycemia, 32 (50.8%) patients (negative) demonstrated remission of diabetes mellitus, and 14 (22.2%) patients (positive) remained positive for diabetes mellitus. The findings of the glucose tolerance test are displayed in Figure 2.

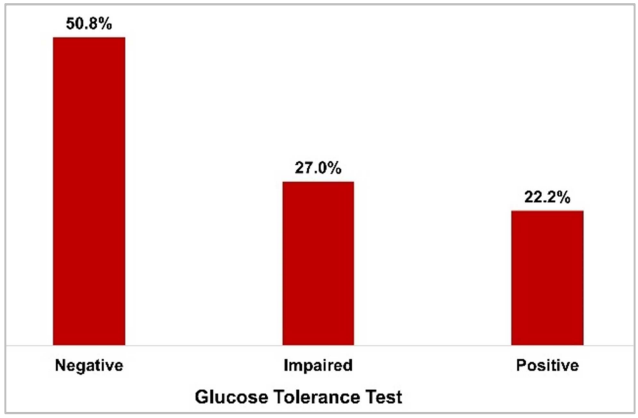

Figure 2. *The Glucose tolerance test findings.*

3.2. Anthropometric Measurements and Laboratory Investigations

Of the 63 patients, 41 (65.1%) patients were male. The mean age of the study patients was 50.5 ± 10.6 years. A significant decrease in weight (day 1: 70.70 ± 9.82 kg; day 30: 67.82 ± 9.42 kg; day 60: 65.54 ± 9.24 kg; day 90: 65.15 ± 9.93 kg; $p<0.001$), body mass index (day 1: 27.00 ± 3.88; day 30: 25.93 ± 3.75; day 60: 25.07 ± 3.70; day 90: 24.91 ± 3.75 $p<0.001$), and abdomen girth (day 1: 98.13 ± 10.08 cm; day 30: 93.79 ± 9.26 cm; day 60: 91.08 ± 89.24 cm; day 90: 89.24 ± 8.40 cm; $p<0.001$) was observed throughout the follow-up duration. Furthermore, a significant improvement in HbA1c levels was also observed (day 1: 7.87 ± 1.90%; day 30: 6.85 ± 1.41%; day 60: 6.25 ± 0.85%; day 90: 5.79 ± 0.51; $p<0.001$). The anthropometric measurements and laboratory investigations assessed are outlined in Table 1.

3.3. Antidiabetic Medication

At baseline i.e., day 1, 28, 23, and 9 patients adhered to biguanide, sulfonylurea and DPP-4 inhibitor, respectively. After treatment this reduced to 8, 4, and 1 patient adhering to these respective antidiabetic medications. The adherence to the antidiabetic medication is shown in Figure 3.

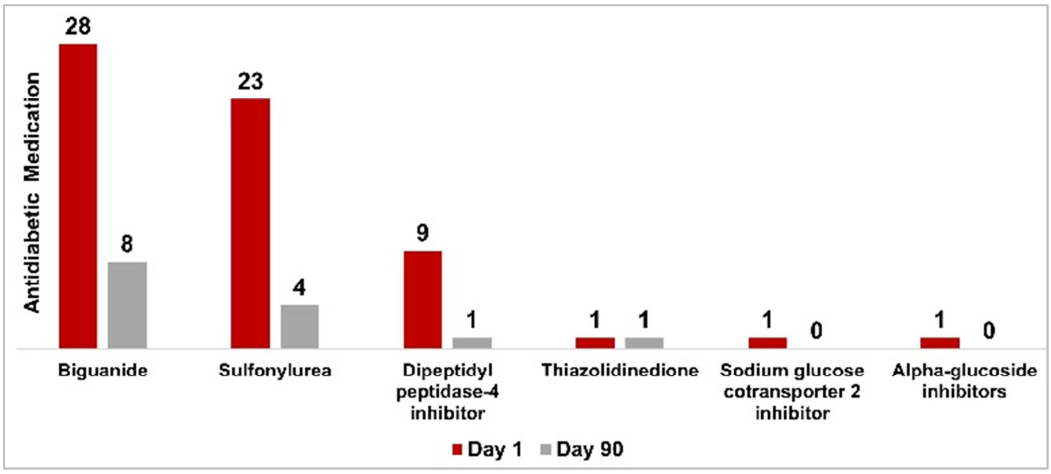

Figure 3. *Patient adherence to antidiabetic medication.*

4. Discussion

Obesity is one of the risk factors of diabetes mellitus and it evokes insulin substance to some extent. However, those patients that do not satisfy the criteria for obesity are likely to have increased percentage of body fat predominantly at the abdominal region [12]. Body mass index is another risk factor of diabetes mellitus in healthy individuals, it is also positively associated with hypertension, cardiovascular and other chronic diseases [3]. The aforementioned reasonings justify assessment of weight, body mass index, and abdominal girth in the evaluation of treatments for diabetes mellitus. Hence, the current study sought to understand the extent to which Ayurveda can impact remission of diabetes mellitus and achieve good glycaemic control in patients with diabetes mellitus. Weight significantly reduced from 70.70 ± 9.82 kg to 65.15 ± 9.93 kg at the 90-day follow-up. Similarly, other studies assessing the CDC program documented significant weight reduction to 77.11 ± 12.27 kg [13] and 69.46 ± 10.39 kg [14] at the 90-day follow-up. Body mass index significantly reduced from 70.70 ± 9.82 to 24.91 ± 3.75 at the 90-day follow-up. Earlier similar studies documented significant body mass index reduction to 31.13 ± 3.91 [13], 25.39 ± 1.53 [15] and 25.91 ± 3.29 [14]. These studies further fortify our study findings.

Diabetes mellitus is induced by a combination of resistance to insulin action and inadequate insulin secretory response. In the latter scenario, the extent of hyperglycaemia may not be sufficient to prompt pathologic and functional changes in the various target tissues, but may asymptomatically persist for an extended duration of time before a diagnosis of diabetes can be confirmed. During this asymptomatic window period, it is possible to detect an abnormality in carbohydrate metabolism by measuring plasma glucose in the fasting state. Therefore, the American Diabetes Association recommend fasting plasma glucose (FBG) ≥ 126mg/dl (>7 mmol/L) as a criterion for the diagnosis of diabetes mellitus (12). The shortcoming of this diagnostic test, is that at times patients fail to disclose food

ingestion prior to testing thereby decreasing the credibility of the FBG test. This shortcoming shifts preference towards glycated HbA1c values as a diagnostic biomarker [16]. HbA1c is a widely used diagnostic marker, reflective of average glycated haemoglobin levels spread over a 2–3-month duration. This diagnostic biomarker plays a critical role in the treatment of diabetic patients as it correlates well with microvascular complications and to a lesser extent macrovascular complications. A few of the advantages it holds over FBG is convenience as it does not necessitate the patient to fast which is indicative of greater preanalytical stability, and less day-to-day perturbations during periods of stress and illness. Treatment strategies aim to achieve HbA1c levels below 6.5% [12]. In the current study, HbA1c levels significantly decreased from 7.87 ± 1.90% to 5.79 ± 0.51%.

Table 1. *Anthropometric measurements and laboratory investigations.*

Variables	Day 1 (n=63)	Day 30 (n=63)	Day 60 (n=63)	Day 90 (n=63)	p value
Weight, kg	70.70 ± 9.82	67.82 ± 9.42	65.54 ± 9.24	65.15 ± 9.93	<0.001
Body-mass index	27.00 ± 3.88	25.93 ± 3.75	25.07 ± 3.70	24.91 ± 3.75	<0.001
Abdomen girth, cm	98.13 ± 10.08	93.79 ± 9.26	91.08 ± 89.24	89.24 ± 8.40	<0.001
Systolic blood pressure, mmHg	130.19 ± 17.32	121.51 ± 11.55	119.56 ± 11.38	122.60 ± 11.51	<0.001
Diastolic blood pressure, mmHg	81.29 ± 9.32	81.67 ± 9.47	77.87 ± 8.52	77.95 ± 6.82	0.01
HbA1c, %	7.87 ± 1.90	6.85 ± 1.41	6.25 ± 0.85	5.79 ± 0.51	<0.001

[*] All data are expressed as number (percentage) or mean ± standard deviation

The prevalence of diabetes mellitus in India has rapidly increased. There are a few reasonings for this modern-day transition. First, modern day lifestyle has triggered this steep increase in diabetes mellitus prevalence. Dietary preferences have evolved throughout the decades resulting in dietary choices skewed towards less consumption of whole grains and increased consumption of highly processed foods. Higher availability of processed foods and greater purchasing power have further fueled this dietary shift. According to the Indian National Sample Survey Organization (NSSO) data, the years 1993 to 2005 witnessed a decline of intake of cereals. This data substantiates the correlation of higher income with a dietary shift away from cereal-based foods towards high fat, highly processed, high-energy dense, unhealthy foods, devoid or lacking nutrients [17, 18]. Second, rural-to-urban migration has prompted a more sedentary lifestyle among these migrants. Higher levels of physical inactivity among urban residents have been demonstrated [19, 20]. Third, ethnicity also plays a role in prevalence of diabetes mellitus. Individuals of South Asian ethnicity are at increased risk of developing diabetes as compared to individuals of other ethnicities. Moreover, manifestation of the disease is more aggressive and is associate with a higher degree of complications [21].

5. Conclusion

The improvement in HbA1c levels and other risk factors through implementation to improve glucose metabolism can help restore euglycemic status in 12 weeks of time with adherence to the CDC program. Remission of diabetes mellitus may be dependent on patients' compliance to a low carbohydrate diet provided during the treatment period.

6. Limitations

There are a few limitations of the current study that deserve mention. The first is the small sample size. The second was the retrospective, single-arm study design due to which the study findings may not be generalised. Thirdly, the short follow-up duration limits insights regarding long-term outcomes. A prospective, comparative study of larger sample size and longer follow-up duration may provide further insights towards the long-term outcomes of the CDC program in the management of diabetes mellitus.

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