



# Effect of *Abhaya Ghana Vati* along with *Pathya Aahara Vihara* (Diet and Lifestyle Regime) on Patients of Diabetes – A Single Arm Clinical Trial

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## Abstract

**Introduction:** *Ayurveda* beautifully amalgamates herbal drugs and lifestyle modifications in the management of various diseases and lifestyle disorders. Diabetes is one condition representing the two most prevalent chronic non-communicable diseases, i.e., Diabetes and Obesity According to *Ayurveda*, both conditions are referred to as *Prameha* and *Sthoulya*, respectively. Both the conditions are *Santarpanotha Vyadhi* (diseases arising from excessive and improper nutrition), having the common vitiation of *Kapha Dosha*, *Meda Dhatu* and *Ama* and similar lines of treatment. *Haritaki* or *Abhaya* (*Terminalia chebula*) is a herb that has the potential to manage both diabetes and obesity. The present study focuses on the efficacy of *Abhaya Ghana Vati* as a single drug regime coupled with *Pathya Aahara Vihara* (diet and lifestyle regime) in the management of diabetes. **Methods:** *Abhaya Ghana Vati* along with *Pathya Aahara Vihara* (diet and lifestyle regime), was administered in 41 patients for three months, including follow-up. The patients were assessed for the effect of the intervention on the subjective and objective criteria. **Results:** The intervention showed significant improvement in most of the parameters of outcome measures like BMI (27% improvement,  $p < 0.001$ ), Waist Hip Ratio ( $p < 0.002$ ), Abdominal Girth Circumference ( $p < 0.001$ ), Chest Girth circumference ( $p < 0.001$ ), Waist circumference ( $p < 0.001$ ). The Fasting Blood Sugar (FBS) levels declined significantly from the mean (187.4 to 168.9,  $p < 0.048$ ), and PPBS reduced from the mean (260 to 230.4,  $p < 0.011$ ), which was statistically significant. However, HbA1c declined very marginally from the mean of 8.32 to 8.23 ( $p < 0.71$ ). Effect of treatment on subjective parameters like *Apatarpana Lakshana*, *Dhatusamyak Lakshana* and Quality of Life parameters showed significant change. **Conclusions:** Administration of *Abhaya Ghana Vati* and *Pathya Aahara Vihara* are beneficial in patients of diabetes.

**Keywords:** *Abhaya Ghana Vati*, Diabetes, Diabetes, Obesity, *Pathya Aahara Vihaara*, *Sthula Pramehi*, *Sthoulya*, *Prameha*

## 1. Introduction

*Ayurveda Samhita* represents the age-old yet contemporary medical and cultural heritage of not only the Great Land of India but also the entire mankind. *Ayurveda* texts were put forth through the experiential knowledge of seers and require an evidence base to strengthen further study. This research study is an attempt to establish the scientific principles mentioned in *Ayurveda* concerning clinical scenarios in day-to-day

life. *Ayurveda* beautifully amalgamates the use of herbal drugs along with lifestyle advice in the management of various diseases, especially lifestyle disorders. Diabetes is one such condition representative of the two most prevalent chronic non-communicable diseases, i.e., diabetes and obesity<sup>1</sup>. Diabetes is spreading and has the potential to rise as a lifestyle epidemic<sup>2</sup>. The global prevalence of Type 2 diabetes alone is 6.1% depicting the gravity of the combined influence of diabetes and obesity<sup>3</sup>. According to *Ayurveda*, both conditions can

be referred to as *Prameha* and *Sthoulya*, respectively. Both the conditions are *Santarpanottha Vyadhi* (diseases arising from excessive nutrition) having the vitiation of *Kapha Dosha*, *Meda Dhatu* and *Ama*, hence having similar lines of treatment<sup>4</sup>. Many medications and dietary regimes as a part of the treatment regime are mentioned for the management of such conditions. *Haritaki* or *Abhaya* (*Terminalia chebula*) is one such herb that has the potential to manage lifestyle disorders including diabetes<sup>5</sup> and Obesity<sup>6</sup>. No study has yet been done to target both these conditions in the form of diabetes, also considering the basic concepts like *Santarpanottha Vyadhi*. The present study focuses on the efficacy of *Abhaya Ghana Vati* as a single drug regime coupled with *Pathya Aahara Vihara* (diet and lifestyle regime) in the management of diabetes.

## 2. Materials and Methods

- **Type of Study Design:** Single Arm Study (Figure 1).
- **Research Design:** Interventional Pilot study assessing Pre-Post change in parameters
- **Setting:** The OPD and IPD of Hospital of All India Institute of *Ayurveda*, New Delhi.
- **Purpose:** Research and Treatment.
- **Masking:** Open label.
- **Sample size:** As the study was a pilot study, initially, only 30 patients were planned to be enrolled in the study. After screening, 41 patients were enrolled in the study, including 5 dropouts.
- **Grouping-** The study was conducted in one single group with the administration of *Abhaya Ghana Vati* with lukewarm water.
- **Study Population-** Patients with diabetes (meeting the inclusion criteria) attending the OPD and IPD of Hospital, All India Institute of *Ayurveda*, New Delhi.
- **Duration of Trial:** 60 days along with 30 days following equalling 90 days (3 months) in total.

### 2.1 Inclusion Criteria

- Patients of both genders of the age group of 20-60 years with complaints of diabetes and obesity irrespective of caste, religion, and socio-economic status, who agreed to written informed consent.

- Patients having at least 5 of the classical symptoms of *Prameha* and *Sthoulya* like *Prabhuta Mutrata* (excessive urination), *Avila Mutrata* (turbidity of urine), *Chala- Sphika-Udara* (fat deposition over the abdomen, chest region), etc.
- First-time diagnosed or newly diagnosed patients with diabetes.
- Patients following the criteria for diabetes as suggested by WHO<sup>7</sup>.
- FBS- >126 mg/dl to <300mg/dl
- PPBS- >150 mg/dl to <450mg/dl
- RBS- >200 mg/dl
- HbA1c- >6.5% to <11gm%
- Both obese and overweight individuals were chosen as per Merriam-Webster's definition of diabetes<sup>8</sup>. The BMI (Body Mass Index) of more than 25 kg/m<sup>2</sup> was considered a cut-off level as per the guidelines of WHO<sup>9</sup>.
- Overweight - BMI more than 25 kg/m<sup>2</sup>
- Obese - BMI greater than or equal to 30 kg/m<sup>2</sup>

### 2.2 Exclusion Criteria

- Patients who were under conventional therapy for diabetes.
- Patients with Graves' Disease, psychological disorders, and suffering from severe acute illness.

### 2.3 Criteria for Assessment

- Blood sugar levels (Fasting and Post-Prandial) along with BMI of patients were assessed every 15 days (total 8 times, Day 0, Day 15, Day 30, Day 45, Day 60, Day 75, Day 90 and Day 105). The random Blood Sugar (RBS) was assessed using the Morepen Gluco-one Blood Glucose Monitoring System Model- BG-03 and Waist Hip Ratio, Abdominal girth was also assessed every time.
- Lipid profile was checked on day 0 and day 90.
- HbA1c of patients was also assessed at day 0 and day 90. It was assessed after 3 months to detect the cumulative effect of both *Apatarpana Chikitsa* (debilitating treatment) and *Pathya Aahara Vihara* in patients of diabetes. Similarly, the effect of the treatment on the Quality of Life was assessed using the

SF-36 Self Health Assessment tool at day 0 and day 90.

- Detailed medical history, clinical examination, and baseline laboratory investigations, including Complete Blood Count (CBC), and urine analysis were done.
- The symptoms of *Prameha* and *Sthoulya* mentioned in classical texts were the major subjective criteria for assessment. These were assessed on day 0, day 30, day 60 and day 90.
- Other subjective parameters like signs of *Apatarpana* and signs of *Dhatusamyia* indicating the effect of treatment were also assessed.

## 2.4 Criteria for Diagnosis

- Patients diagnosed with diabetes and obesity as per the criteria of the WHO.
- Patients having symptoms of *Prameha* and *Sthoulya* as explained in *Ayurveda* classical texts as per the proforma designed priory were included in the study.

### 2.4.1 Symptoms of *Prameha* according to *Ayurveda* Classical Texts

*Prabhuta Mutrata* (polyuria), *Avila Mutrata* (turbid urine), *Kshudha Adhikya* (polyphagia),

*Pipasa Adhikya* (polydipsia), *Dourbalya* (weakness), *Suptangata* (peripheral numbness),

*Daha* (burning sensation), *Pindikodweshtana* (pain in calf region), *Atiswedana* (excessive perspiration), *Alasya* (lethargy), *Sheetapriyatwa* (excessive liking towards cold products), *Angagandha* (body odour), *Madhurasyata* (sweetness of mouth), *Dantadinam Maladhyatwam* (coating over teeth, tongue), *Mukhashosha* (dryness of mouth), *Vibandha* (constipation), *Mutre Mutra Dosha* (urinary tract infections), *Shoola* (body pain), *Kesheshu Jatilibhava* (oiliness of hair) mentioned as the *Poorvarupa* (prodromal signs) and *Roopa* (presenting signs) of *Prameha* according to *Ayurveda* texts.

**Table 1.** Information regarding the drug administered

Drug content	Botanical name	Family	Part used	Proportion in the formula (daily dose)
Abhaya/ Haritaki	<i>Terminalia chebula</i> Linn.	Combrataceae	Fruit rind/Fruit Carp	2 Tablets –Thrice daily (3 gm per day)

### 2.4.2 *Lakshana of Sthoulya* according to *Ayurveda* Classic Texts

*Bhara Vriddhi* (weight gain), *Chala Sphika Udara Stana* (flabbiness of buttocks, abdomen, breast region), *Angagaurava* (heaviness of body), *Ayatha-Upachaya* (disproportionality of body parts), *Dourgandhya* (excessive body odour), *Atikshudha* (polyphagia), *Atipipasa* (excessive thirst), *Swedadhikya* (excessive perspiration), *Kshudrashwasa* (exertional dyspnoea), *Nidradhikya* (excessive sleepiness), *Angashaithilya* (flabbiness of body parts), *Gatrasaada* (fatigue), *Snighangata* (unctuousness of body), *Alpavyayama* (lack of physical exercise), *Utasahahani* (lack of enthusiasm), *Javoparodha* (discomfort or inability in performing daily activities), *Krucchravyavayata* (loss of libido) mentioned as a part of *Atisthoulya*, *Medo-Roga* (diseases due to vitiation of *Meda Dhatu*) and *Medo-dushti* (Vitiatio of *Meda Dhatu*) were chosen for assessment.

## 3. Intervention

The tablets of *Abhaya Ghana Vati* were procured from Chaitanya Pharmacy, Nashik, Maharashtra, which is a GMP-certified company (Tables 1 and 2).

## 4. Parameters for Assessment of Study Outcomes

### 4.1 Primary Endpoint

- Assessment of the effect of treatment on blood sugar levels, lipid profile, anthropometric parameters and BMI of patients, along with symptoms of *Apatarpana*, were the primary endpoints.
- The effect of treatment on symptoms of *Prameha*, *Sthoulya* as mentioned was also assessed.

### 4.2 Secondary Endpoint

The Secondary endpoint was to assess the improvement in the Quality of life. This was assessed with the help SF 36 Self Health assessment questionnaire.

**Table 2.** Posology

<b>Drug</b>	<i>Abhaya Ghana Vati</i>
<b>Form</b>	Tablet form or <i>Ghana Vati</i> form
<b>Dose</b>	3 gm- 2 tablets (500 mg) thrice daily before breakfast/meals ( <i>Apana Kaala</i> )
<b>Mode of administration</b>	Oral
<b>Anupana</b>	<i>Ushnodaka</i> (Lukewarm water)
<b>Duration</b>	60 Days + 1 month follow-up Follow-up of 1 month included <i>Pathya Aahara Vihaara</i> as prescribed to the patient
<b>Drug Procured from</b>	Chaitanya Pharmacy (GMP-certified pharmacy), Nashik, Maharashtra

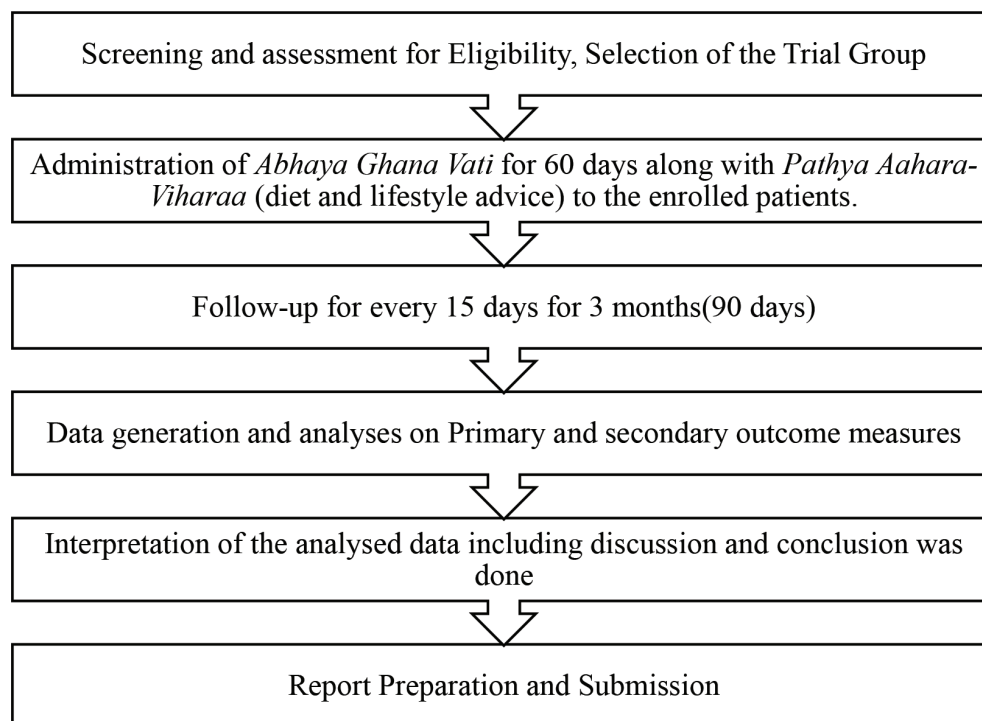
## 5. Statistical Methods

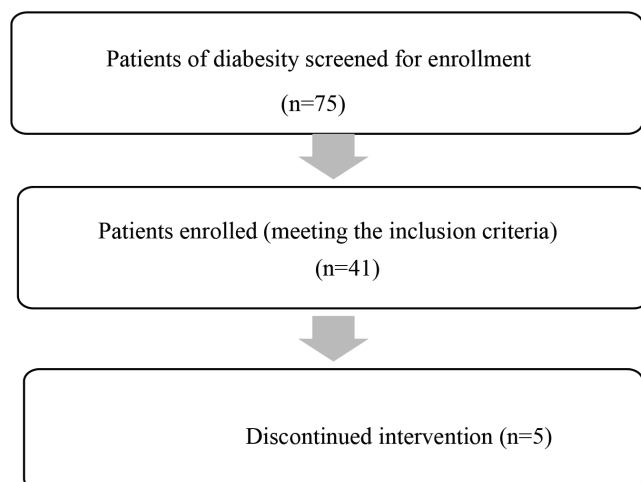
- A paired t-test was used to determine the effect of the intervention on the objective parameters like laboratory investigations and anthropometric measures before and after the completion of the study within the group for the analysis of 36 patients.
- Repeated measure ANOVA is used for analysis where measurements are repeated more than twice, and the Variance ratio test (F test) which is presented for assessing significance in trend was used to assess the subjective criteria like signs and symptoms of *Sthula Pramehi*.

- Descriptive statistics was used to analyze the effect of intervention on the Random Blood Sugar (RBS) levels.
- SPSS version 26 (Statistical Package for Social Sciences software) was used to analyse the data.

## 6. Adverse Effects Observed

No adverse effects were observed during the study. A total of 75 patients with diabetes were screened out of which 41 were enrolled in the present study out of which 36 patients completed the study and there were 5 dropouts due to noncompliance (Figure 2).

**Figure 1.** Study design.



**Figure 2.** Patient enrolment flowchart.

## 7. Results

The fasting blood sugar and postprandial blood sugar levels showed a mean difference of 18.450 and 29.648, which were found to be significant at C. I. of 95% with  $p < 0.01$ , while the differences between the HbA1c, weight, BMI, Waist Hip ratio, Abdominal girth circumference, Chest girth circumference and waist

circumference were found to be highly significant at  $p < 0.001$  (Table 3). Statistically insignificant results were obtained for the changes in mid-arm circumference, HDL, LDL, Total Cholesterol, Serum Triglycerides, Systolic Blood pressure and Diastolic Blood pressure before and after the administration of the treatment.

It was observed that the mean random Blood Sugar of 36 patients at the beginning was 208.06 mg/dl, which gradually reduced to 182.33mg/dl during the 4<sup>th</sup> visit but increased slightly thereafter to 87.72 mg/dl during the 5<sup>th</sup> visit and 193.97 mg/dl during the final 8<sup>th</sup> visit (Table 4).

Statistically insignificant results were found for *Angagandha*, *Dantadinaam*, *Maladhyatwa*, *Mutremutradosha*, *Bharavridhhi*, *Nidra Adhikya*, *Gatrasaada*, *Kricchravyavayata* at  $p < 0.005$  in 36 patients (Table 5).

Statistically highly significant result ( $p < 0.000$ ) was obtained for the effect of intervention in the occurrence of *Apatarapana* in 36 patients (Table 6).

The mean *Dhatusamya* score grading changed from 2.86 before treatment to 3.67 on Day 60, i.e., after treatment and to 3.89 on Day 90, i.e., after follow-up. This difference was found to be statistically significant at  $p < 0.000$  (Table 7).

**Table 3.** Effect of interventions on objective parameters

Parameter	Means		Paired Differences			t	df	p-value
	BT	AT	Mean Diff (BT-AT)	S.D.	S.E.			
Fasting Blood sugar	187.4	168.94	18.45	54.02	9.00	2.04	35	0.048
Post Prandial Blood Sugar	260	230.44	29.64	66.40	11.06	2.68	35	0.011
HbA1c	8.32	8.23	0.09	1.35	0.22	0.38	35	0.706
Weight	71.8	69.42	2.46	10.42	1.71	1.43	35	0.160
BMI	27.1	26.83	0.30	0.42	0.07	4.36	35	0.000
Waist hip ratio	0.96	0.95	0.01	0.03	0.01	2.43	35	0.020
Abdominal girth circumference	100.5	99.86	0.69	1.17	0.19	3.54	35	0.001
Chest girth circumference	93.2	92.89	0.35	0.59	0.1	3.60	35	0.001
Waist circumference	101.5	101.10	0.46	0.75	0.12	3.73	35	0.001
Mid arm circumference	36	36.2	-6.58	41.39	6.89	-0.95	35	0.346
HDL	46.2	46.27	0.02	16.24	2.70	0.00	35	0.994
LDL	125.4	119.47	5.90	38.32	6.38	0.92	35	0.362
Total Cholesterol	200	189.27	10.92	57.65	9.60	1.13	35	0.263
Serum Triglycerides	185	174.03	11.02	84.33	14.05	0.78	35	0.438
Systolic Blood pressure	134	131.25	2.77	12.65	2.10	1.31	35	0.196
Diastolic Blood pressure	79.42	79.33	0.08	8.18	1.36	0.06	35	0.952



**Table 4.** Effect of intervention on Random Blood Sugar levels (N = 36)

RBS and Visit levels	Mean	S.D
Random BSL Day 0	208.06	74.858
Random BSL Day 15	196.14	76.80
Random BSL Day 30	183.06	64.42
Random BSL Day 45	182.33	74.12
Random BSL Day 60	187.72	67.50
Random BSL Day 75	193.19	67.94
Random BSL Day 90	190.25	65.12
Random BSL Day 105	193.97	67.47

**Table 5.** Effect of intervention on subjective parameters (N = 36)

Subjective Parameter	Mean +SD Day 0	Mean+SD Day 30	Mean +SD Day 60	Mean +SD Day 90	F <sub>1</sub>	p-value
<i>Prabhuta Mutrata</i>	0.94+0.41	0.78+ 0.48	0.36+0.54	0.25+0.5	75.0	0.000
<i>Avila Mutrata</i>	0.86 +0.59	0.69+ 0.58	0.47+0.61	0.36+0.59	25.3	0.000
<i>Kshudha Adhikya</i>	1.31+0.71	0.89+0.62	0.61 +0.64	0.56 +0.60	50.0	0.000
<i>Pipasa Adhikya</i>	0.86+0.59	0.47+0.50	0.33+0.47	0.25+ 0.44	33.3	0.000
<i>Suptangata</i>	0.78+0.59	0.64+0.54	0.28 + 0.45	0.25+0.44	31.7	0.000
<i>Daurbalya</i>	0.08 +0.60	0.75 +0.50	0.50 +0.56	0.39 +0.55	53.5	0.000
<i>Daha</i>	0.67 +0.68	0.50 + 0.60	0.36 +0.59	0.33 +0.59	11.1	0.002
<i>Pindikodweshtana</i>	0.69+ 0.58	0.50 + 0.56	0.25 +0.5	0.25 +0.50	23.4	0.000
<i>Atiswedana</i>	0.58 +0.73	0.28+0.51	0.25+0.50	0.25+0.50	17.2	0.000
<i>Alasya</i>	0.83+ 0.56	0.58 + 0.55	0.36+0.54	0.36+0.59	24.8	0.000
<i>Sheetapriyata</i>	0.69 + 0.62	0.42 +0.55	0.28 +0.51	0.22+ 0.42	30.2	0.000
<i>Angagandha</i>	0.56+0.58	0.39 +0.55	0.25 +0.44	0.31 +0.53	6.24	0.017
<i>Madhurasyata</i>	0.67+ 0.63	0.42+ 0.55	0.31+ 0.52	0.28 +0.51	18.1	0.000
<i>Dantadinaam Maladhyatwa</i>	0.58+ 0.73	0.47+ 0.70	0.47+0.70	0.42 +0.69	7.00	0.012
<i>Mukhashosha</i>	0.89 + 0.58	0.69 + 0.52	0.44 +0.56	0.42+ 0.55	30.1	0.000
<i>Vibandha</i>	0.75+ 0.69	0.56+0.60	0.33 +0.48	0.36+0.54	15.7	0.000
<i>Mutremutra Dosha</i>	0.61+0.64	0.53 +0.65	0.36 +0.59	0.39 +0.65	5.87	0.021
<i>Shoola</i>	0.97 +0.73	0.81 +0.67	0.72 +0.66	0.72 +0.66	9.21	0.005
<i>Bharavridhi</i>	0.81+ 0.40	0.81 +0.40	0.75 +0.44	0.96+0.47	4.27	0.046
<i>Chala Angatva</i>	0.94 +0.47	0.83 +0.50	0.75 +0.55	0.69 +0.58	11.3	0.002
<i>Angagaurava</i>	0.81+0.52	0.69 +0.52	0.42+0.55	0.31 +0.47	26.5	0.000
<i>Ayatha Upachaya</i>	0.92 +0.50	0.89 +0.52	0.78 +0.64	0.69 +0.62	7.76	0.009
<i>Kshudra Shwasa</i>	0.92 +0.65	0.75 +0.60	0.47 +0.56	0.39 +0.49	37.5	0.000
<i>Nidra Adhikya</i>	0.36 +0.59	0.39 +0.6	0.28+0.57	0.25 +0.55	3.61	0.066
<i>Anga Shaithilya</i>	0.81 +0.52	0.69 + 0.52	0.53 + 0.50	0.53 +0.50	11.05	0.002
<i>Gatrasada</i>	0.89 +0.40	0.72 +0.45	0.36 +0.49	0.61 +1.84	1.60	0.213
<i>Snigdhangata</i>	0.64 +0.54	0.47 + 0.56	0.36 +0.54	0.36 + 0.54	13.0	0.001
<i>Alpavyayam</i>	0.83+0.44	0.50 + 0.50	0.22 +0.42	0.17 +0.38	65.88	0.000
<i>Utsahahani</i>	0.69 +0.67	0.53 + 0.70	0.28 + 0.57	0.25 +0.55	19.8	0.000
<i>Javoparodha</i>	0.47 +0.61	0.31 +0.52	0.17 + 0.45	0.14 +0.35	16.9	0.000
<i>Kricchravyavayata</i>	0.14+ 0.49	0.14+0.49	0.11+0.49	0.06+0.23	3.11	0.086

**Table 6.** Effect on *Apatarpana* score (N = 36)

<i>Apatarpana</i> Score	Mean	S.D	F value	Significance
<i>Apatarpana</i> Score BT	22.78	8.17	221	0.000
<i>Apatarpana</i> Score AT	14.22	5.53		
<i>Apatarpana</i> Score FU	12.00	5.72		

**Table 7.** Effect of intervention on scores of SF-36 questionnaire (N = 36)

Criteria	Mean values		Paired Differences			T	Sig.(2 tailed)
	BT	AT	Mean Diff	SD	SE		
Physical Health	86.11	89.44	-3.33	5.85	0.97	-3.41	0.002
Limitations due to physical health	42.36	60.41	-18.05	20.36	3.39	-5.32	0.000
Limitations due to mental health	68.51	77.78	-9.26	21.98	3.66	-2.52	0.016
Energy/Fatigue	58.33	63.05	-4.72	9.09	1.51	-3.11	0.004
Emotional wellbeing	69.13	74.34	-5.20	11.00	1.83	-2.84	0.007
Social function	61.41	67.64	-6.22	9.80	1.63	-3.81	0.001
Pain	61.08	69.66	-8.58	10.91	1.81	-4.71	0.000
General Health	52.50	56.88	-4.38	6.04	1.00	-4.35	0.000
Health condition	47.22	51.52	-4.30	11.47	1.91	-2.25	0.031

**Table 8.** Effect on *Dhatusamy Lakshana*

<i>Dhatusamy</i> Score	Mean	S.D	Df	F value	Significance
<i>Dhatusamy</i> Grading BT	2.86	1.26	1	57.9	0.000
<i>Dhatusamy</i> Grading AT	3.67	1.26			
<i>Dhatusamy</i> Grading FU	3.89	1.36			

Statistically significant results were obtained for all the criteria related to quality-of-life assessment using the SF36 questionnaire in 36 patients (Table 8).

- Statistically significant results were obtained for the change in fasting blood sugar, Post prandial blood sugar level, BMI, Waist Hip Ration, Abdominal girth, Chest Circumference, Waist Circumference, effect on subjective parameters (*Apatarpana Lakshana*, *Dhatusamy Lakshana* and effect on quality of life at  $p < 0.001$  in 36 patients.
- Statistically insignificant results were observed for the effect on HbA1c, effect weight, effect on mid-arm circumference, and effect on lipid profile (HDL, LDL, Serum Triglycerides, Serum Cholesterol) at  $p < 0.001$  in 36 patients.

## 8. Discussion

Both diabetes and obesity contribute to insulin resistance and metabolic dysfunction diabetes. These conditions further intensify the risk of cardiovascular diseases, cerebro-vascular accidents and end stage renal diseases<sup>10</sup>. These results act substantially in reducing the quality and expectancy of life in suffering individuals elevating the morbidity and mortality risk<sup>11</sup>. The etiological factors contributing to the “obesogenic niche”, like a sedentary lifestyle, lack of physical activity, unbalanced diet, disturbed sleep and psychological impairments can also worsen diabetes<sup>12</sup>. The recent therapeutic approaches are directed against the principal pathophysiology of diabetes, which includes the innate immune system, incretin system,

inflammatory mediators, oxidative stress, mediators of insulin resistance and the balance between energy intake and expenditure<sup>13</sup>. *Ayurveda* can target all these components due to its multidimensional and holistic approach. Hence, studies on herbs like *Haritaki* can help in the effective management of chronic conditions like diabetes<sup>14</sup>. Behavioural therapy and lifestyle modifications stay at the epicentre of maintenance and preventive therapy where the *Pathya-Aahara Vihara* come into the light<sup>15</sup>. Thus, *Ayurveda* can play a role as a major contributor to the management of such conditions. As the disease condition under consideration is diabetes, the components of obesity were measured in terms of BMI (Body Mass Index), waist hip ratio, abdominal girth circumference, waist girth circumference, mid-arm circumference and lipid profile according to the objectives of the study. The components of diabetes were assessed by blood sugar levels (fasting, random and postprandial blood sugar levels) and HbA1c. Significant results were obtained in most of the parameters assessed during the clinical study except for HbA1c, Lipid profile and Mid-arm circumference. The HbA1c didn't show any significant difference before and after administration of treatment as it indicates long-term hyperglycaemia and may not justify the results for short-term study. *Apatarpana* is the treatment of choice for the patients of *Sthula Prameha*. Hence, this aspect was rightfully chosen for assessment in the present study<sup>16</sup>. *Haritaki* being *Kashaya Rasa Pradhana dominant in Kashaya Rasa* and its *Ushna Veerya* possesses the antagonist properties to the *Meda Dhatu* and *Kapha Dosha*. It also balances *Agni* (digestive fire) and *Vata Dosha* rendering optimum *Apatarpana* in the form of a decrease in blood sugar levels<sup>17</sup>. Hence, it may be stated that the *Apatarpana Chikitsa* consisting of a combination of *Haritaki* and *Pathya Aahara-Vihara* has a significant effect on the *Santarpanjanya* conditions like *Sthula Prameha* which may be correlated with conditions like diabetes. Identical *Pathya Aahara Vihaara* was advised to all the patients details of which are attached in the annexure (see the *Pathya* chart attached herewith).

As the study was carried out on one single group, the independent effect of *Pathya Aahara Vihara* and *Haritaki* could not be determined. Hence, the intervention can be administered in two groups to assess the proper effect. The study was carried out only

for three months hence the long-term effect of the intervention could not be determined. The study can be carried out for a longer duration and with a larger sample size to obtain precise results.

Annexure - *Pathya* (Diet and Lifestyle chart) prescribed to patient

## 9. Conclusion

It can be concluded that interventions given to see changes in diabetes have shown reasonably significant results in most of the parameters of outcome measures, as among the six components of Obesity, five parameters showed significant decline due to intervention. These are BMI ( $p < 0.001$ ), Waist Hip Ratio ( $p < 0.002$ ), Abdominal Girth Circumference ( $p < 0.001$ ), Chest Girth circumference ( $p < 0.001$ ), Waist circumference ( $p < 0.001$ ). Further, the Fasting Blood Sugar also declined significantly from a mean of 187.4 to 168.9 ( $p < 0.048$ ), and Post Prandial Blood Sugar reduced from a mean of 260 to 230.44 ( $p < 0.011$ ), which was found to be statistically significant. However, HbA1c declined very marginally from the mean of 8.32 to 8.23 ( $p < 0.706$ ). Effect of treatment on subjective parameters like *Apatarpana Lakshana*, *Dhatusamya Lakshana* and Quality of Life parameters have shown significant outcomes. Thus, it may be concluded that the *Apatarpana* with *Abhaya Ghana Vati* and *Pathya Aahara Vihara* are beneficial in patients with diabetes.

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## Annexure - Pathya (Diet and Lifestyle chart) prescribed to patient

परहेज का तक्ता (Diet and Lifestyle Chart)	
पथ्य (क्या खाना चाहिये)	अपथ्य (क्या नहीं खाना चाहिये)
जौ का आटा –उससे बनी रोटी ,ज्वार ,बाजरे का आटा	रीफाईड धान्य , पोलीश धान्य
शाली – षष्ठि धान्य से बने चावल	पोलीश चावल
गेहूँ के आटे की रोटी – जौ के आटे में मिलाकर	मैदा ,पुरी ,पराठा (ज्यादा तेलवाला) ,ब्रेड
कुलत्थ , मूंग , तूरी , मसूर , भूने हुए चने की सबजी , मुरमुरा ,लाई सक्तू- उपरोक्त दाल का चूर्ण , धाना , दलिया ,सिंगारे का आटा , मखाना.	उड़द , राजमा , सेम ,छोले, बेसन, मांसाहार , मछली .
करेला , परवल , मेथि , पालक , मूली , बैंगन ,भिंडी , लौकी –सब्जी , फूल गोबी , ककड़ी, सहजन, तोरी , पत्ता गोबी , सिताफल – इन सबकी सबजी	आलू ,बासी सबजी, ज्यादा तेल में बना सबजी , बाहर का खाना, तिखी सबजी , मिर्च , सिमला मिर्च , टमाटर.
लहसून , काली मिर्च , हिंगु ,इलायची , अतसी(भूनी हुई) , मधु , तिल , जीरा , सोंठ , हलदी , अजवायन , धनिया , सरसो , चिरोंजा .	शक्कर , गुड़ , गुड़ से बनी चीझे , गन्ना तथा गन्ने का ज्यूस
शहद का पानी , छाच , दिन में 3-4 बार गरम पानी , गर्मियों में उबालकर थंडा किया हुआ पानी , सोंठ/अजवायन का पानी , करेल/लौकी इत्यादि सबजी का ज्यूस	दूध (विशेषकर भैंस का) , चाय/कोफी (अधिक प्रमाण में), मद्यपान , मीठा शरबत ,दही ,खोया , पनीर ,खीर ,लस्सी ,शीत पेय.
गाय का घी , सरसो का तैल , अतसी का तैल ,मूंगफली का तैल ,तिल का तैल	ज्यादा मात्रा में तेल , ज्यादा मात्रा में घी , सोयाबीन तेल, सनफलोवर का तेल
आमला (विशेषकर हलदी के साथ) , कच्चा केला , जामुन ,अनार ,मुनक्का ,अमरूद ,खजूर , बादाम , काजू ,	आम , अंगूर , सिताफल , चिकू , केला.
चलना 40 मिनट तक – 4-5 किलोमीटर तक , खाने के बाद 100 कदम चलना(10-15 मिनट) , दौड़ लगाना ,योग-ध्यान तथा प्राणायाम करना	एक जगह पर ज्यादा टाइम तक बैठे रहना ,बिलकूल व्यायाम न करना
नियमित स्नान करना , तिल के तैल से अभ्यंग तथा त्रिफला के पावडर से 1 बार उद्घर्तन करना	बिलकूल स्नान न करना तथा देह की स्वच्छता न रखना
रात में 7-8 घंटे तक अच्छी नींद लेना. उचित समय पर सोना- रात में 9 बजे उचित समय पर जगना- सुबह 6 से पहले	दोपहर में सोना ,उचित समय के अतिरिक्त सोना , रात में देर से सोना , सुबह जल्दी न उठना

नित्य करने हेतु कुछ आसन , प्राणायाम – सुबह 6 से 7 बजे के बीच



Dhanurasana/धनुरासन



Pranayama/प्राणायाम



Vrikshasana/वृक्षासन



Vajrasana/वज्रासन



Mandukasana/मंडुकासन



Paschimottasana/पश्चिमोत्तानासन



Trikonasana/त्रिकोणासन



Pawanmuktasana/पवनमुक्तासन



Tadasana/ताडासन



Gomukhasana/गोमुखासन



Bhujangasana/भुजंगासन