ABSTRACT

Diabetes is a long-term illness that occurs due to the high levels of blood glucose (hyperglycemia). Because our modern lifestyle goes a long way, that more and more people develop type 2 diabetes. So control the blood sugar levels is essential part of healthy life and prevent long-term complications. Thottalvadi Chooranam (*Mimosa pudica*) is one among the unique Siddha anti-diabetic herbal preparation. So the present open clinical study was conducted and analysed the therapeutic potential of Thottalvadi Chooranam among 50 diabetic patients for the period of six months. Diabetes mellitus can be diagnosed only if the presence of any classical symptoms of diabetes and with FBGL ≥ 140 mg/dl, PPBGL ≥ 250 mg/dl and HbA1C ≥ 6.5.

The trial drug was given to all the patients at the dose level of 4gm twice a day with milk for the period of 3 months. At the end of the study period all the above clinical and laboratory parameters along with HbA1C were performed and statistically analyzed. From the result it was observed that the classical clinical signs were improved well. FBGL, PPBGL were significantly reduced from initial readings. It was also observed that 44 patients (88%) had significant reduction in HbA1C when compared with initial reading. The result confirms the therapeutic potential of Siddha herbal drug Thottalvadi Chooranam on type II diabetes mellitus.
Key Words: Diabetes mellitus, Thottalvadi Chooranam, blood glucose level, anti-diabetic activity, HbA1c, Siddha.

INTRODUCTION

Diabetes mellitus is one of the most common chronic metabolic diseases, which determine a dramatic progression of the disease over the past decades. Diabetes meaning ‘run through’ characterized by excretion of large amount of urine (polyuria) and mellitus and its meaning ‘sweet taste’ because glucose is excreted in the urine. In India, the term ‘Madhumeham’ is used with etymological sense of the word ‘passing sweet urine’.

Diabetes is a long-term illness that occurs either because the pancreas does not produce enough insulin or because the body cannot effectively use the insulin it produces, or both. This causes high levels of blood glucose (hyperglycemia). Because our modern lifestyle goes a long way, that more and more people develop type 2 diabetes.

Unusual tiredness, increased thirst, weight loss, frequent urination and headaches, food cravings, itching and blurred vision - that it can be for people in the middle years of evidence that the metabolism of sugar out of rhythm, and a type 2 diabetes develops.

Untreated diabetes will increase the risk of mortality and also with the risk of serious macro and micro vascular complications from the amputation, heart attack, stroke, peripheral vascular disease, blindness to kidney damage. The incidence of type 2 diabetes is growing at an alarming rate of about 347 million people worldwide affected.

It is estimated that this number will increase in 2030 to 100 million. More than 80% of diabetes deaths occur in low- and middle-income countries. WHO projects that diabetes deaths will increase by two thirds between 2008 and 2030. Ten list of countries with the highest diabetes figures led by India with 40.9 million diabetics, followed by China with 39.8 million. Highprevalence is located especially in the fast developing industrial countries expected - such as India and China.

So control the blood sugar levels is essential part of healthy life and prevent long-term complications. Many new therapeutic approaches available in the market, but adverse effects occurred simultaneously. So research of safe and effective drug still continues. Siddha treatment for diabetes has become increasingly popular over the last several years because of its safe and effective therapeutic potential. To date, over 400 traditional plant treatments for
diabetes have been reported. Although only a small numbers of these have received scientific and medical evaluation to assess their efficacy.

Thottalvadi Chooranam (Mimosa pudica) is one among the unique Siddha herbal preparation has been studied extensively in recent years for its various therapeutic potentials especially as anti – oxidant and anti-diabetic in animal models. The anti-oxidant and hypoglycemic effect of Mimosa pudica has been confirmed in animal models of alloxan induced diabetes in rats. So the present open clinical study was conducted and analysed the therapeutic potential of Mimosa pudica among diabetes in general practice.

MATERIALS AND METHODS

Collection, Identification and Preparation of Thottalvadi Chooranam

The Plant Thottalvadi (Mimosa pudica) was collected from in and around Chennai, Tamilnadu, authenticated to identity by Botanist and Gunapadam experts of Government Siddha Medical College, Arumbakkam, Chennai and the specimen sample has been preserved at the department for future reference. After identification, leaves and root were cleaned well and dried for one week in a shady area. Then the dried plant material of Mimosa pudica made into fine powder form (Chooranam) and sieved by a white cloth and further purified as per the procedure given in the Siddha classical literature. The recommended dosage of Thottalvadi Chooranam according to Siddha text was 4 gm twice a day to be taken orally with milk for 30 days.

Study design

A prospective, single-center open clinical study was designed to confirm the anti-diabetic activity of Thottalvadi Chooranam (TVC) in patients with diabetes from Outpatient department of Government Siddha Medical College Hospital, Arumbakkam, Chennai from March 2007 to July 2007. The present research work was approved by the Institutional Ethical Committee and conducted according to the ethical principles of the Declaration of Helsinki and WHO guide for ethics committees of investigations.

Total number of 55 patients of either sex in the age group of 40 to 70 years was selected for the present study. Diabetes mellitus can be diagnosed only if the presence of any classical symptoms of diabetes (polyuria, polydipsia and polyphagia) and patients with FBG ≥ 140 mg/dl, PPBGL ≥ 250 mg/dl and HbA1C ≥ 6.5. Before enrolling the clinical study, all the patients were validated properly by pre-clinical screening which includes signs and
symptoms of diabetes mellitus and laboratory investigation for diabetic screening and any complications of diabetes or other involvements such as cardiovascular, renal diseases. After enrolling the present study, the nature of the present clinical trial, method of study, properties of *Mimosa pudica* and its therapeutic effect, period of study were informed to all the patients. After obtaining the informed consent, the patients were included in the study.

Patients older than 70 years and under 20 years and diagnosis of hypertension or other cardiovascular risk factors, Type I DM, gestational diabetes, dyslipidemia, concomitant infections, pregnancy and lactation, use of other medications, alcohol abuse, participation in any other clinical trial within the three months prior to the baseline screening and any other abnormal findings were excluded from the study.

**Withdrawal criteria**

All the patients had the right to withdraw from the study at any time and for any reason. Each investigator was entitled to withdraw any patient prematurely if this was deemed to be in the patient's best interest (in the case of adverse events, intercurrent illness etc.), deterioration of symptoms or lack of improvement.

**Treatment Period**

The trial drug TVC was given to all the patients at the dose level of 4gm twice a day with milk for the period of 3 months. All the patients were advised not to take any diabetic treatment at least seven days, then followed a run-in period of five-day to wash out the remaining effect of any previous anti diabetic drugs. The drug was given to all the patients in weekly duration. Each weekly visit, clinical improvement, FBGL and PPBGL, adverse effect if any were performed and recorded. At the end of the study period all the above clinical and laboratory parameters along with HbA1C were performed and statistically analyzed.

**Diet and advice**

Healthy diet, regular physical activity along with diabetic medication is often the key components in the management of patients with diabetes. All the patients were advised to follow specific diabetic diet plan depending on their gender, age, occupation and other activities. In general patients were advised to avoid direct sugar, honey and other high sugar foods especially food contains more fat, sugar and salt. They were advised to take grilled, steamed, baked and boiled vegetables, fruits, whole grains and dairy products. They were advised to take more fiber foods. Regular exercise brings many benefits for diabetic patients.
So all the patients were encouraged to do the moderate intensity aerobic exercise depends on their age.

STATISTICAL ANALYSIS
Statistical analysis was done according to intention-to-treat principles. Baseline and outcome data were compared using Student paired ‘t’ test. All data were expressed as mean with standard deviation (Mean ± SD). P value ≤ 0.05 was considered statistically significant.

RESULTS AND DISCUSSION
On three months treatment period, 50 patients were completed the study. 5 patients were withdrawn from the study: 2 patients were withdrawn because of intercurrent illness which requires other medical management, 2 patients shifted their residence to another area and one patient was withdrawn from the study due to personal reason. All the 5 patients were withdrawn from the study within two weeks of the study period and they were not included in the final analysis.

Table 1 highlights the distribution of the diabetic population by age, sex and family history of DM Type II. More men than women participated in the study. According to this data, 54% were male and 46% were female. The age group of the Patients was within the range of 35 to 70 with average of 54.82 ± 9.15 (mean ± SD). 35 patients had family history of DM Type II.

Table No.1 Showing Age, Sex and History of DM

<table>
<thead>
<tr>
<th>Category</th>
<th>35 – 44 years</th>
<th>45-54 years</th>
<th>55-64 years</th>
<th>65-70 years</th>
<th>Total (N=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.of Patients</td>
<td>Male: 04</td>
<td>Male: 10</td>
<td>Male: 10</td>
<td>Male: 03</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>Female: 03</td>
<td>Female: 06</td>
<td>Female: 11</td>
<td>Female: 03</td>
<td></td>
</tr>
<tr>
<td>Family History of DM</td>
<td>Male: 02</td>
<td>Male: 08</td>
<td>Male: 09</td>
<td>Male: 02</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Female: 03</td>
<td>Female: 04</td>
<td>Female: 06</td>
<td>Female: 01</td>
<td></td>
</tr>
</tbody>
</table>

Table 2 highlights the baseline characteristics and socio economic status of the patients who completed the present study. In the study population, 41 patients are married, 3 patients are single and 6 female patients are widow. Duration of diabetes ranged from 0 to 7 years and 15 patients were suffering from DM for more than 4 years. Most study participants with type 2 diabetes mellitus was in underweight. In the study population, 25 (50%) are self-employed, 11 are government/private sector employees and 14 were unemployed and retired, so that about 36 patients are in working life.
Table 2. Showing the socioeconomic status of study participants

<table>
<thead>
<tr>
<th>Status</th>
<th>Male</th>
<th>Female</th>
<th>Status</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
<td><strong>Monthly Income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>02</td>
<td>01</td>
<td>2000-10000</td>
<td>13</td>
<td>09</td>
</tr>
<tr>
<td>Married</td>
<td>25</td>
<td>16</td>
<td>10000-20000</td>
<td>11</td>
<td>03</td>
</tr>
<tr>
<td>Widow/Divorced</td>
<td>00</td>
<td>06</td>
<td>&gt;20000</td>
<td>03</td>
<td>00</td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
<td><strong>Physical activity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self employed</td>
<td>16</td>
<td>09</td>
<td>Sedentary</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Govt/Private sector</td>
<td>08</td>
<td>03</td>
<td>Mild</td>
<td>03</td>
<td>06</td>
</tr>
<tr>
<td>Unemployed</td>
<td>03</td>
<td>11</td>
<td>Moderate</td>
<td>09</td>
<td>06</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td><strong>Other Information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Illiterate</td>
<td>07</td>
<td>09</td>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>School level</td>
<td>08</td>
<td>08</td>
<td>Smoking/Tobacco</td>
<td>13</td>
<td>04</td>
</tr>
<tr>
<td>College level</td>
<td>08</td>
<td>06</td>
<td>Alcohol</td>
<td>17</td>
<td>02</td>
</tr>
<tr>
<td>Higher degree</td>
<td>04</td>
<td>00</td>
<td>Duration of diabetes (in years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Body weight</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Under weight</td>
<td>13</td>
<td>11</td>
<td>1-2 years</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Normal</td>
<td>09</td>
<td>06</td>
<td>2-3 years</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Over weight</td>
<td>04</td>
<td>06</td>
<td>3-4 years</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Obese</td>
<td>01</td>
<td>00</td>
<td>&lt; 4 years</td>
<td>10</td>
<td>7</td>
</tr>
</tbody>
</table>

Table No.3 and Fig No.1 showed the classical signs and symptoms of diabetes mellitus and compares the improvement in clinical features between initial and at the end of the study by percentage of improvement. The classical clinical signs of diabetes include osmotic polyuria that develops due to hyperglycemia, polyphagia and polydipsia were improved well. All the patients showed improvement in other signs and symptoms and the general feeling of wellbeing. Furthermore, the weight gain was observed in 18 out of 24 (75%).

Table No.3 Showing the signs and symptoms of Type 2 DM patients and showing the clinical improvement at the end of the study

<table>
<thead>
<tr>
<th>Clinical features</th>
<th>Before treatment</th>
<th>After treatment</th>
<th>% of improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyuria</td>
<td>46</td>
<td>04</td>
<td>91</td>
</tr>
<tr>
<td>Polydipsia</td>
<td>42</td>
<td>02</td>
<td>95</td>
</tr>
<tr>
<td>Polyphagia</td>
<td>14</td>
<td>01</td>
<td>93</td>
</tr>
<tr>
<td>General weakness</td>
<td>46</td>
<td>03</td>
<td>93</td>
</tr>
<tr>
<td>Itching</td>
<td>08</td>
<td>01</td>
<td>88</td>
</tr>
<tr>
<td>Loss of weight</td>
<td>24</td>
<td>06</td>
<td>75</td>
</tr>
<tr>
<td>Body pain</td>
<td>04</td>
<td>00</td>
<td>100</td>
</tr>
</tbody>
</table>
Fig.1. Showing Clinical improvement of patients at end of the study period

Table 4 showed the efficacy of TVC on biochemical parameters which include FBGL, PPBGL and HbA1C in treated patients. All reported outcomes were measured at the end of treatment. The initial mean FBGL was 155.38 ± 8.56 and PPBGL was 274.68 ± 15.96. After completion of the trial the mean FBGL and PPBGL were 97.44 ± 11.82** and 153.78 ± 7.91** respectively. The initial and final reading of HbA1C was compared statistically. From the result it was observed that 44 patients (88%) had significant reduction in HbA1C when compared with initial reading. The initial level of glycated hemoglobin was 7.012 ± 0.29, and after three months of treatment it was significantly reduced to the level of 5.714 ± 0.36 (p <0.001).

Table No. 4 : Showing the efficacy of Thottalvadi Chooranam on FBGL, PPBGL and HbA1C in treated patients

<table>
<thead>
<tr>
<th>Group</th>
<th>FBGL (mg/dl) (Mean ± SD)</th>
<th>PPBGL (mg/dl) (Mean ± SD)</th>
<th>HbA1C (mg%) (Mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT**</td>
<td>BT</td>
</tr>
<tr>
<td>D.M Type II</td>
<td>155.38 ± 8.56</td>
<td>97.44 ± 11.82</td>
<td>274.68 ± 15.96</td>
</tr>
</tbody>
</table>

Values are expressed in Mean ± SD (n= 50) Student's t test for paired values. Where *P< 0.05, **P< 0.01 and ***P< 0.001.
The type 2 diabetes occurs because the pancreas does not produce enough insulin or because the body does not use it properly, or both resulting in hyperglycemia. In a nutshell the problem increases insulin resistance, insulin release from the pancreas may also be missing, causing increased blood glucose.

This hyperglycemia has several adverse consequences for the organism. It increases blood viscosity and promotes the formation of atherosclerotic plaque. Thus, three out of five diabetics die due to cardiovascular complications. Hyperglycemia can also cause many disturbances of kidney function, Deterioration of retinal capillaries cause retinopathy. Therefore, the key strategy in the treatment of patients with type 2 diabetes is the maintenance of normoglycemia.

Monitoring of blood sugar, especially fasting samples (FBGL) and two hours after a meal (postprandial- PPBGL) sampling is generally necessary until the levels of blood sugar is under control. Glucose may also establish covalent bonds with blood proteins, and thereby alter their function. Diabetics are thus characterized by a higher proportion of glycosylated hemoglobin (HbA1c) than healthy individuals. So the HbA1c is the best indicator for monitoring diabetes mellitus and also to assess the effectiveness of anti-diabetic drug treatment.

*Mimosa pudica* has been widely used as medicinal agents throughout human history for the management of diabetes mellitus. *Mimosa pudica* contains phytosterol, amino acids, alkaloids, flavonoids, tannins, glycosides and fatty acids\(^\text{15}\). Ascorbic acid, crocetin, D-glucoronic acid, linoleic acid, linoleic acid, palmitic and stearic acids, mimosine, D-xylose
and b-sitosterols were found in phytochemical analysis of *M. pudica* root. Ethanol and petroleum ether extracts of *Mimosa pudica* leaves showed antidiabetic effect. Preliminary research suggests that *Mimosa pudica* lowers the blood sugar level in alloxan induced diabetic rats.

*Mimosa pudica* has antioxidant capabilities which enhance the absorption of glucose and the body's sensitivity to insulin which is the root cause of type II diabetes mellitus. It also strengthens the liver function, kidney and boosts the endocrine system. There were no side effects or untoward effects observed during the entire study period.

**CONCLUSION**

The result of present clinical study demonstrates the beneficial effects and the therapeutic potential of Siddha herbal drug Thottalvadi Chooranam on type II diabetes mellitus. The formulation was well tolerated and appeared to be safe in the dosage used. At the conclusion of the study found that administration of Thottalvadi Chooranam reduced the blood sugar level and provide new hope on the potential benefits and also minimize the risk of diabetic complications. Based on the main limitations of the study, multicenter clinical trial is recommended to evaluate the long-term effect of Thottavadi Chooranam.

**ACKNOWLEDGEMENT**

We thank the Principal and HOD, Government Siddha Medical College, Chennai for their enthusiasm and support in fulfilling this clinical study objective.

**CONFLICT OF INTEREST**

The authors declare no conflict of interest.

**REFERENCE**


Antidiabetic efficacy of *Mimosa pudica* (lajwanti) root in albino rabbits. *Int. J. Agric. Biol.*  
2013; 15: 782–786