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# A Study To Evaluate Efficacy Of Homoeopathic Remedy Gymnema Sylvestre In 6th Centesimal Potency In The Patients Suffering From Type 2 Diabetis Melitus - A Prospective Observational Study

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**ABSTRACT:**

**Background:** World Health Organization report shows that 300 million people may suffer from Diabetes up to 2025 in which 79 million people from India. Diabetes mellitus (DM) states to a group of common metabolic disorders that share the phenotype of hyperglycemia due to reduced insulin secretion, decreased glucose utilization or increased glucose production. Some distinct types of DM are caused by a complex interaction of genetics and environmental factors. Most common is Type 2 Diabetes Mellitus in which body does not make enough insulin or does not properly utilize it. People living with Type-2 DM are more vulnerable to various forms of complications, both short-term and long-term, which often lead to their premature death. Homoeopathy, a common form of alternative medicine is used worldwide and plays a major role in healing of different diseases. Due to minimal side-effects, homoeopathic remedies may serve as potential method of treatment and in the management of diabetes. Gymnema sylvestre, in various homoeopathic preparations, have reported beneficial effect for treating in Type-2 diabetes mellitus. This study proposed to explore the role of an organ remedy Gymnema sylvestre in reducing the blood sugar level and improving the quality of life of such patients suffering from type 2 DM.
**Aim and Objective:** To evaluate the efficacy of Gymnema sylvestre in 6CH potency in Type-2 diabetes mellitus patients to improve the QoL of the patients suffering from Type-2 diabetes mellitus.
**Materials and Method:** This prospective, open label, observational trial, conducted at OPD and IPD of Shaheed Raja Hari Prasad Mall Government Homoeopathic Medical College and Hospital, Barhalganj-Gorakhpur (U.P.) and camps organized by various departments and hospital itself. A total 100 pre-diagnosed cases were enrolled for this study considering all ethical criteria, inclusion and exclusion criteria's as per ICD-10. Data were recorded on standard case proforma, and entered Microsoft® Excel worksheet 2019, and exported into SPSS v29.0 (IBM, USA) for statistical analysis. Each case was followed up for a period of 12 months. The result of post- treatment outcome in each patient was assessed on the basis of collected pre and post FBS, PPBS, HbA1C, DM score and QoL (Part-1) & QoL (Part-2) values was tested by Paired 'T' test.
**Results:** Out of 255 screened patients, 100 patients (68 males and 32 females) with type 2 DM were enrolled in the study. 20 left the study, so total 80 patient's (57 males & 23 females) data analysis was done after a follow-up period of 12 months of treatment. In the 80 Cases of Type 2 DM the pre- mean value of FBS level was 7.51 mmol/l, PPBS level was 11.63 mmol/l and HbA1c % was 8.066 whereas the post- mean values were improved to 6.7 mmol/l, 10.54 mmol/l and 6.656 respectively. The pre- mean DM assessment score was 8.0, QoL (Part- 1) was 3.8 and QoL (Part-2) was 5.7, whereas post-mean value improved to 1.6, 4.7 and 5.9 respectively after the end of the treatment of the study population.
**Conclusion:** Homoeopathic preparations of Gymnema sylvestre in 6CH potency is proved to effective in management of diabetes mellitus is confirmed through the study. The medicine was also helped to improve the quality of life of the patients.

**Keywords:** Clinical trial, homoeopathy, Gymnema sylvestre, nonrandomized, type 2 diabetes mellitus

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**INTRODUCTION:**

Diabetes mellitus is a metabolic disorder of multiple aetiology, characterised by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both.[1]

Diabetes mellitus (DM) is one of the oldest human disorders known to civilization. Elevated blood glucose levels are a symptom of diabetes, a heterogeneous, complicated metabolic condition caused by either resistance to the action of insulin, inadequate insulin secretion, or both.[2]

DM can be classified broadly into Type 1 Diabetes Mellitus (Insulin Dependent or Juvenile type of DM) and type 2 Diabetes Mellitus (Adult Onset or Insulin Non-Dependent DM). Both types are preceded by a phase of abnormal glucose homeostasis as the pathogenic processes progress.[3]

IDDM accounts for 5%–10% of all cases of DM. This type can be further classified into immune-mediated and idiopathic DM. [4], while Type 2 diabetes mellitus is the predominant form of diabetes worldwide, accounting for 90% of cases globally.[5] Type 2 DM is caused due to combination of resistance to insulin action and an inadequate compensatory insulin secretory response.[6]

Lack of insulin affects the metabolism of carbohydrate, protein and fat, and can cause a significant disturbance of water and electrolyte homeostasis. [7,8,9]

Insulin secreted from pancreatic β cells into the portal circulation) being, an anabolic hormone with profound effects on the metabolism of carbohydrate, fat and protein causing a brisk increase in response to a rise in blood glucose. Insulin lowers blood glucose by suppressing hepatic glucose production and stimulating glucose uptake in skeletal muscle and fat. [9,10,11]

Type 2 diabetes is a more complex condition than type 1 diabetes because there is a combination of resistance to the actions of insulin in liver and muscle together with impaired pancreatic β-cell function leading to 'relative' insulin deficiency. [7,8,12]

In patients with type 2 diabetes excessive production of glucose in the liver and under-utilisation of glucose in skeletal muscle result from resistance to the action of insulin. A characteristic feature of type 2 diabetes is that it is often associated with other medical disorders, particularly central (visceral) obesity, hypertension and dyslipidaemia (characterised by elevated levels of small dense LDL cholesterol and triglycerides, and a low level of HDL cholesterol). [8,9]

Epidemiological studies provide evidence that type 2 diabetes is associated with overeating, especially when combined with obesity and underactivity. Obesity probably acts as a diabetogenic factor (through increasing resistance to the action of insulin.

Under ICD 10-CM Classification diagnosis Code of Type II Diabetes Mellitus is E11.9 (Type II Diabetes Mellitus without any Complication.[13]

Though signs and symptoms of diabetes are disregarded by many, because of the chronic progression nature of the disease. Mostly People do not consider this as a serious problem because unlike many other diseases the consequences of hyperglycemia are not manifested immediately.

***Symptoms of Hyperglycaemia:*** [8]

1. Thirst, dry mouth
2. Polyuria
3. Nocturia
4. Tiredness, fatigue
5. Recent change in weight
6. Blurring of vision
7. Pruritus vulvae, balanitis (genital candidiasis)
8. Nausea; headache
9. Hyperphagia; predilection for sweet foods
10. Mood change, irritability, difficulty in concentrating, apathy

Diabetes Mellitus diagnosed by simple blood sugar level (Fasting and Post Prandial Blood sugar level) test easily. Glycated haemoglobin provides an accurate and objective measure of glycaemic control over a period of weeks to months. This can be utilised as an assessment of glycaemic control in a patient with known diabetes. [7,12]

***Diagnosis Criteria for Diabetes Mellitus:*** **[14,15]**

- Fasting plasma glucose - 7.0 mmol/L (126 mg/dL) or
- Two-hour plasma glucose - 11.1 mmol/L (200 mg/dL) during an oral glucose tolerance test or
- A1C ≥6.5% (48mmol/mol) or
- Symptoms of diabetes plus random blood glucose concentration - 11.1 mmol/L (200 mg/dL) or

The top three countries with the highest number of individuals with diabetes are China (140.9 million), India (74.2 million), and USA (31.0 million) in 2019. It is expected this trend to continue in 2030 and 2045, with China (140.5 and

147.2 million) and India (101.0 and 134.2 million) continuing to have the highest burden of diabetes.[16] This is supported by the Global Burden of Disease Study, which reported that population growth and ageing in the world's largest countries, such as China and India, are driving the absolute increase in the number of people with diabetes.
The methods of treatment of diabetes are: dietary/lifestyle modification, oral anti-diabetic agents and insulin by injection. Approximately 50% of new cases of diabetes can be controlled adequately by diet alone, 20-30% will need an oral anti-diabetic medication, and 20-30% will require insulin. The development of a foot ulcer, renal impairment, sensory loss or retinopathy in a patient with long-standing diabetes would be recognised as a long-term complication. [8,12]
Homoeopathy believes in holistic model of health, taking an overview of the patient's mind, body and spirit, life situation, and other circumstances central in evolving a curative approach to chronic disease and complex cases, which helps in selecting a remedy that suits a patient, rather than to just a disease.[17] And, treatment of DM is no exception to this concept. There were evidences that homoeopathic medicines could control blood sugar levels, prevent and control complications such as renal failure, retinopathy, and peripheral vascular disease, and reduce the dosage of allopathic antidiabetic drugs, and insulin.[18]
A few homoeopathic medicines used empirically in DM are Abroma augusta, Cephalandra indica, Gymnema sylvester, Syzygium jambolanum, Thyroidinum and Insulinum.[19]
The proving data of homoeopathic medicine Gymnema sylvestre and its use in DM are documented in homoeopathic literature. But no research has been conducted so far in homoeopathy on potency specific to Gymnema sylvestre to know its hypoglycemic action.

**OBJECTIVES:**

***Primary Objectives:***

1. To determine the feasibility in evaluating the effect of homoeopathy on impaired glucose regulation.
2. To evaluate the mean change in blood glucose level after administration of homoeopathic medicines Gymnema sylvestre in 6$^{th}$ Centesimal Potency along with life style modification (LSM).

***Secondary Objectives:***

To evaluate the effects of Gymnema sylvestre 6CH interventions upon-

1. Fasting blood glucose (FBS), and Post prandial blood glucose (PPBS) levels
2. HbA1c
3. Symptomatic changes

**HYPOTHESIS:**

***$H_0$ (Null Hypothesis):*** The homoeopathic drug Gymnema Sylvestre in 6CH Potency has no hypoglycemic effect in the patients suffering from Type 2 Diabetes mellitus.
***$H_1$ (Alternative Hypothesis):*** The homoeopathic drug Gymnema sylvestre in 6CH Potency has hypoglycemic effect in the patients suffering from Type 2 Diabetes mellitus.

**MATERIALS & METHODS:**

***Study Setting:*** Primary data of the patients were collected from OPD/IPD, diabetic camps at peripheral villages, talukas and remote areas of Shaheed Raja Hari Prasad Mall State Homoeopathic Medical College & Hospital, Barhalganj-Gorakhpur (U.P.) - 273402. and the follow-up were done at the OPD of the hospital.
***Study Design:*** It was a prospective, nonrandomized, noncontrolled, single-blind clinical trial.

***Participants:***

Patients aged 40 years and above, both sexes with type 2 DM without complication, and those presenting symptomatology similar to those of Gymnema sylvestre and who provided voluntary written consents were included in the study. Out of 255 screened cases of type 2 DM, 100 cases were selected based on the inclusion and exclusion criteria, whereas 155 cases were excluded as 42 of them did not agree to give consent, 27 patients did not fulfil the age criteria, and 86 patients did not exhibit symptomatology of Gymnema sylvestre. 20 out of enrolled left out during the study period. So, Data analysis of all 80 cases enrolled in the study was done. The patients were advised to report once a month; during each visit, the changes in their symptomatology as well as laboratory data were recorded. However, patients were free to report at any time if any adverse event or emergency situation arose. In case of any emergency condition, the patient was referred for appropriate medical care as required. The flowchart of the participants is given in Figure-1.

***Intervention:***

The homoeopathic medicine Gymnema sylvestre was used as an intervention in 6CH potency; four globules (no. 30) were administered at a time. The potency, dose, and repetition of the remedy were determined based on the homoeopathic principles.[20] Patients were advised to practice lifestyle modifications, which included a healthy diet (rich

in whole grains and fibres, use of good fats such as polyunsaturated fats found in vegetable oils, nuts, and fish), limiting sugary beverages, red meat, and other sources of saturated fats; regular physical exercise; maintaining normal body weight and relieving stress by relaxation techniques, that is, deep breathing, meditation, rhythmic exercise, yoga, and to avoid smoking and alcohol.

***Study Duration:***

The duration of the study was one and a half years, from January 2021 to June 2022, including 6 months for enrollment and 12 months for follow-up.

***Outcome Assessment:***

Each patient enrolled was assessed by changes in symptoms of DM assessment scoring scale,[21] changes in blood sugar level, that is, fasting blood sugar (FBS), postprandial blood sugar (PPBS), haemoglobin (HbA1C) %, and routine urine test for sugar, and changes in the quality of life (QoL).[22] Parameters adopted for the assessment of response to treatment were as follows:

***Marked Improvement*** - 75% and above improvement in symptom score from baseline score;

**Moderate Improvement** - 50% to less than 75% improvement in symptom score;

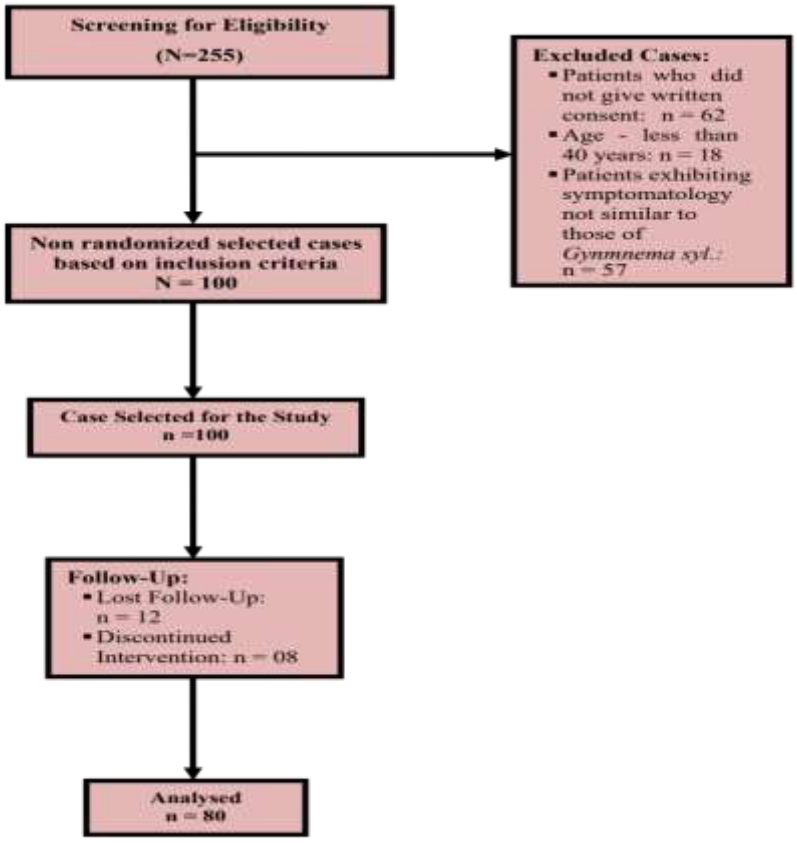
*Mild Improvement* - 25% to less than 50% improvement in symptom score;

No significant improvement - less than 25% improvement in symptom score;

No Improvement - No change in symptom score at the end of treatment from baseline score;

Statistically data analysis was done with the help of SPSS software version 18.[23] Proportions used for presenting descriptive data were as follows:

- Mean and standard deviations were used for quantitative data.
- For statistical analysis, paired t test was used to assess the difference before and after treatment with homoeopathic intervention. The conclusions were made based on P value, that is, P value <0.001 was considered statistically significant.




*Img.39: Study Flow Diagram*

***RESULTS:***

Out of 255 enrolled cases of type 2 DM, 100 cases were enrolled based on the inclusion and exclusion criteria and followed up for 12 months with a frequency of every month. Since, 20 left the study, only 80 patient's data were analysed. The following observations were made: Highest incidence of Type 2 DM was found in the age group of 55-60 years, with 28

cases (35.0%) observed out of 80 cases. This corroborates with the IDF Diabetes Atlas 2021 (10th Edition) [24], whereas the minimum incidence was 5 cases i.e., 6.25% in the age group of 40-45 years. In this study, the sex incidence of Type 2 DM was found to have Male predominance, which correlates with the study of the IDF Diabetes Atlas 2021 (10th Edition) [24]. There were 57 males (71.25%) and 23 females (28.75%) in the study population. The habitat incidence of Type 2 DM was found maximum in urban population, i.e., 48 cases (60.0%), whereas 32 cases (40.0%) belonged to the rural area. This correlates with the study of the IDF Diabetes Atlas 2021 (10th Edition) [24]. The socio-economic status of the study population shows that maximum patients belonged to middle class, i.e., 38 cases (47.5%) and 30 cases (37.5%) belonged to upper class whereas the minimum 12 cases (15.0%) were from lower class. This may be due to the trend of urbanization and lifestyle changes, including a "Western-style" diet [25], which correlate with the present study. The employment status of the study population showed that there was maximum incidence of Type 2 DM in employed group, i.e., 42 cases (52.5%), whereas 12 cases (15.0%) were in un-employed group. This may be due to environmental influences, urban migration, the economic boom, lifestyle changes [26] and stress [27] which correlate with the present study. In this study, the incidence of Type 2 DM was found maximum where there was family history of DM. There were 56 cases with family history of DM, i.e., 70.0%, whereas without family history the number was 24 cases, i.e., 30.0%. This correlate with the study of the IDF Diabetes Atlas 2021 (10th Edition) [24]. In the study population, all the 80 cases of Type 2 DM before treatment, the FBS was ≥ 7mmol/, i.e. 100.0%. But after the treatment, FBS ≥ 7mmol/l was found in 12 cases, i.e., 15.0% whereas FBS was < 7 mmol/l in 68 cases, i.e., 85.0%. By applying paired t - test the result shows highly significant with p value <0.001, i.e., statistically post- treatment FBS level was reduced from pre- treatment FBS level. The mean value of FBS prior to treatment was 7.6mmol/l, whereas after treatment it was reduced to 6.6mmol/l. In the study the PPBS level ≥11.6mmol/l before treatment was observed in all the 80 cases of Type 2 DM, i.e. (100.0%) whereas after treatment, PPBS level ≥10.5mmol/l was reduced in 16 cases, i.e., 20.0% and PPBS level < 11.1mmol/l was seen in 64 cases, i.e., 80.0%. By applying paired t - test the result is highly significant with p value <0.001, i.e., statistically post- treatment PPBS level was reduced from pre- treatment PPBS levels. The mean value of PPBS prior to treatment was 11.63mmol/l whereas after treatment it reduced to 10.54mmol/l. It was also observed that there were changes in HbA1c % in pre- and post- treatment of the study population. The mean value of HbA1c % pre-treatment was 8.066 % whereas at the end of the treatment, it was reduced to 6.656 %. By applying the paired t - test, the result is statistically highly significant with p value <0.001, i.e., statistically, post- treatment HbA1c % was reduced than pre- treatment HbA1c %. Sugar was present in urine, before treatment in 08 cases (10%) and 72 cases (90%) had no sugar in urine whereas after the treatment the presence of sugar in urine was observed in only 1 case (2.5%) and 79 cases (97.5%) had no sugar in urine. It was observed that the mean DM score [21], prior to treatment was 8.0, whereas after treatment it was reduced to 1.6. So, there was marked improvement in 56 cases (70.0%), moderate improvement in 15 cases (18.75%). Statistical analysis done by applying paired t - test shows that p value <0.001 (highly significant), i.e., post- DM score was significantly reduced than pre- score. and mild improvement in 9 cases (11.25%). Quality of Life (QOL) scale [22] was adopted to assess the quality of life of the study population after being treated with Gymnema sylvestre 6CH, who were also and advised for diet regulation, lifestyle management and stress management. It was observed that the mean score QoL (Part-1) before treatment was 3.8 whereas after treatment it was increased to 4.7 and mean score QoL (Part-2) before treatment was 5.7 while after treatment it was increased to 5.9. Statistical analysis of pre- and post- score by applying paired t - test shows that p value <0.001, i.e., statistically highly significant improvement in QOL (Part-1 & Part-2).

**Pre - and post -treatment result of FBS, PPBS, Urine sugar and DM Score of study population with Gymnema sylvetre 6CH**

| | **Base line Status of the study population** | **End status of the study population treatment with Gymnema sylvetre 6CH** |
|---|---|---|
| | **No. of Case (%)** | **No. of Cases (%)** |
| FBS LEVELS | | |
| < 7 mmol/l | 0 (0) | 68 (85) |
| > 7 mmol/l | 80 (100) | 12 (15) |
| PPBS LEVELS | | |
| < 11.1mmol/ | 0 (0) | 64 (80) |
| > 11.1mmol/ | 80 (100) | 16 (20) |
| Urine Sugar | | |
| NO | 72 (90) | 79 (98.75) |
| YES | 08 (10) | 01 (1.25) |
| Improvement in DM score | | |
| No improvement | 0 | 0 |

| | | |
|---|---|---|
| Mild improvement | 0 | 09 (11.25) |
| Moderate improvement | 0 | 15 (18.75) |
| Marked improvement | 0 | 56 (70) |

By applying the paired t - test between post- mean score of DM and post- mean score of QOL (1 & 2) to know the changes, it shows that p value < 0.001 (statistically highly significant).
The effectiveness of homoeopathic organ remedy Gymnema sylvestre in 6CH potency in the treatment of Type 2 Diabetes mellitus in reducing the blood sugar level was confirmed through this study. It was also ascertained that Gymnema sylvestre helps to improve the quality of life of the patients suffering from Type 2 Diabetes mellitus.

**DISCUSSION:**

The present study was conducted to assess the role of homoeopathic drug Gymnema sylvestre 6CH in reducing the blood sugar level in patients suffering from type 2 DM by adopting the DM assessment score[21], and to assess the QoL of such patients by adopting the scale "Quality of life index in Diabetes."[22] Most of the observations in this study correlate with those of the study of the IDF Diabetic Atlas of 2021, which exhibited the following facts: The incidence of DM increased with age, its inclination toward male gender and urban population, and increased incidence in those with a family history of DM compared with those without a family history. Maximum patients belonged to middle class, whereas the least number of patients were from the lower class. This may be due to the trend of urbanization and lifestyle changes, including a "Western-style" [25] diet. Most cases of type 2 DM were from the employed group compared with the unemployed persons. This may be due to environmental influences, urban migration, the economic boom, lifestyle changes [26], and stress [27]. It was also ascertained that Gymnema sylvestre helped to improve the QoL of the patients suffering from type 2 DM.

**CONCLUSION:**

The study was conducted to assess the hypoglycemic effects of homoeopathic remedy Gymnema sylvestre in 6 Centesimal Scale during the treatment of Type 2 Diabetes mellitus which was confirmed through this study. The medicine was also helped to improve the quality of life of the patients. The results of the study showed statistically significant improvement in DMS in the patients with type 2 DM ($P < 0.001$) by adopting the DM assessment scale and statistically significant improvement of QoL of patients ($P < 0.001$) by adopting the scale "Quality of life index in Diabetes."
For better scientific validation, it is suggested to undertake further clinical trials on type 2 DM based on randomized controlled trial study design with a greater sample size. The effects of other potencies of Gymnema sylvestre in type 2 DM should also be studied

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**ETHICAL CLEARANCE:**

The clinical protocol was permitted by the Institutional Ethical Committee (IEC) of Tantia University, Sri Ganganagar prior to conducting the study. No objection certificate was given by Shaheed Raja Hari Prasad Mall Government Homoeopathic Medical College & Hospital, Barhalganj-Gorakhpur (U.P.) – 273402, to conduct the research work at Hospital OPD & IPD.

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**CONFLICTS OF INTEREST:**

There are no conflicts of interest.

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