

## Hypoglycemic Effect of Herbs on Type 2 Diabetic Patients: An Intervention Study

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**ABSTRACT** The present study was conducted to analyse the effect of five herbs (*Momordica charantia*, *Azadirachta indica*, *Gymnema sylvestre*, *Citrullus colocynthis* and *Berberis aristata*) on blood glucose levels in Type 2 Diabetes Mellitus patients. The method used for the study was a subjective evaluation. Subjects selected were taking an oral hypoglycemic drug and were willing to participate in the intervention study. Information regarding the name, age, religion, lifestyle pattern, was collected with the help of an interview schedule. Anthropometric parameters were collected prior to intervention to assess the nutritional status. Blood glucose levels were assessed before and after intervention period. Every day one gram of herbal powder was used as the intervention by the subjects in two the divided doses a period of three months. Total 56 subjects were enrolled, mean age  $51 \pm 7.5$  years. Age range was 35-65 years, out of which 39.3 percent (22) were male and 60.7 percent (34) were female. Fasting blood glucose level before and after the intervention was  $161 \pm 47$  mg/dl and  $120 \pm 29$  mg/dl respectively (p-value < 0.001). Postprandial blood glucose level before and after the intervention was  $231 \pm 81$  mg/dl and  $162 \pm 32$  mg/dl respectively (p-value < 0.001). Hb1Ac level of before and after the intervention was  $9.2 \pm 2.1$  percent and  $7.5 \pm 1.2$  percent respectively (p-value < 0.001). Herbs had positive and encouraging effects over blood glucose levels. No adverse effect was observed on the health status of the subjects. These herbs were effective in lowering the fasting as well as postprandial blood glucose and HbA1c levels. These herbs can be used as an adjunct for treatment of Type 2 Diabetes Mellitus patients.

### INTRODUCTION

Diabetes Mellitus is a chronic ailment which occurs due to malfunction of the pancreas. Usually it occurs when body does not use insulin present in the body properly or generate less insulin. It is featured by metabolic malfunction primarily carbohydrates metabolism, protein and fat in the body. Body cells do not utilize glucose, resulting in an increased level of glucose in the blood (Hyperglycemia) (Rizvi and Mishra 2013).

There are mainly two types of diabetes Type 1 and Type 2. Diabetes mellitus is a major health problem in India as well as in other developing countries. In developing countries like India, diabetes occurs in younger age affecting the most

productive years of their life. The higher prevalence of diabetes is related to obesity, family history of diabetes, impaired glucose tolerance and reduced physical inactivity.

There is an international search for alternative oral hypoglycemic which are effective but have less toxicity, especially for Type 2 diabetes mellitus cases. As in the cases from all over the world, in this country also the insulin dependent diabetes mellitus (IDDM) or Type 1 constitute only two percent of the total diabetic population leaving approximately ninety-eight percent cases of Type 2 diabetes mellitus.

There are 387 million people living with diabetes worldwide so its prevalence is about 8.3 percent, among them 46.3 percent people are undiagnosed. One in two people with diabetes does not know that they have it. There are 4.9 million deaths per year with this disease and fifty percent of deaths are under 60 years of age. At every 7<sup>th</sup> second one person dies from diabetes. By 2035, almost 600 million of us may be living with diabetes. Seventy-seven percent of

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diabetic patients live in low and middle-income countries (DSCF 2015).

There are many allopathic medicines existing in the market like oral hypoglycemic medicine and insulin. But similarly, there are many trials on alternative therapy going on throughout the world. Herbal medicines are gaining worldwide hegemony due to their specific advantages. Developing countries such as India have started discovering the ethnopharmacological perspective of new drug research.

There are many herbal formulations available in the market for their hypoglycemic properties. These trials are continuing process which are going on throughout the world. The present study also attempts to intervene new combination of various herbs which are not available in the market to treat diabetes. A lot of work has been already carried out for the natural therapy to treat diabetes using different herbs (Yeh et al. 2003; Ghorbani 2013; Parasuraman et al. 2014), but the use of *Momordica charantia*, *Azadirachta indica*, *Gymnema sylvestre*, *Citrullus colocynthis* and *Berberis aristata* herbs in combination is still unexplored for the treatment of diabetes (Baskaran et al. 1990; Shanmugasundaram et al. 1990; Yin et al. 2008; Paliwal et al. 2009; Efirid et al. 2014; Yin et al. 2014). Therefore, to fulfill this research gap, present study was done.

All the five herbs have been mentioned in classical Ayurvedic literature as potent anti-diabetic drugs. There has been a number of clinical and experimental studies on the efficacy of each individual or combination (different) of these herbs as potent oral hypoglycemic anti-diabetic drugs. The medicinal effect of these herbs may be due to the presence of active compounds such as: 1). *Gymnema sylvestre* has active compound Gymnemic acid. It prevents the absorption of excess glucose. It is steroids; 2). *Momordica charantia* have two components. Charantin components have insulin properties. It is a steroidal saponin agent. Momordicin an alkaloid possess hypoglycemic properties; 3). *Azadirachta indica* has active compounds Azadirachtin, Quercetin, and Nimbodin; 4). *Citrullus colocynthis* have active compounds Myristic and Palmitic; 5). *Berberis aristata* has active compound Berberine. It is alkaloids.

### Objective

The main objective of this intervention research study was to assess the impact of herbal

powder on blood glucose levels in Type 2 diabetes mellitus patients. Another objective of the study was the prevention of complication of diabetes and disappearance of diabetic symptoms.

### MATERIAL AND METHODS

This intervention research study was carried out in the Department of Endocrinology, OPDs, Postgraduate Institute of Medical Education and Research, PGIMER Chandigarh. A total of seventy Type 2 diabetic patients were enrolled for this intervention research.

#### Inclusion Criteria

1. The persons willing to participate in the study and provide informed consent.
2. Provisionally diagnosed diabetes mellitus cases (Type 2).
3. Age between >18 and <65 years.
4. Both male and female.
5. Known diabetes cases of less than 1 year duration.

#### Exclusion Criteria

The cases having the following sign and symptoms were excluded from the trail.

1. Age <18 years and >65 years.
2. On clinical examination with presenting symptoms of neuropathy retinopathy and nephropathy.
3. Infection of the skin, lungs or urinary tract.
4. Insulin-dependent ketonuria.
5. Patients not willing to participate in the study.

The patients were referred from endocrinology OPD. On adopting the rigid criteria of inclusion and exclusion, 70 patients of both genders were included in the trial. On baseline first visit, detailed clinical history and medical examination of each patient was carefully recorded. The routine clinical examinations, pathological and biochemical investigations were carried out. Anthropometric parameters like height and weight were also noted and BMI was calculated. This study was single-blind study. The clinical examination of the pathological and biochemical investigation was repeated at intervals of 12 weeks. The HbA1c test was done by HPLC Ion exchange high-performance liquid chromatography. Fasting blood glucose levels and postpran-

dial blood glucose levels were assessed before (at baseline) and after (12 weeks) period by GOD-POD procedure by ROCH analyzer. All patients were asked to revisit at every 4<sup>th</sup> week interval that is, first visits at 4<sup>th</sup> week, the second visit at 8<sup>th</sup> week and last or third visit at 12<sup>th</sup> week. There were 56 cases left for final analysis.

The herbs mixture consist of the following five plants: 1. *Gymnema sylvestre*; 2. *Momordica charantia*; 3. *Azadirachta indica*; 4. *Citrus colocyntis*; 5. *Berberis aristata*.

These five herbs were mixed in a proportion of 1: 0.5: 1: 1: 1 respectively. All herbs were shade dried, cleaned well to make them dust and grit free. These herbs were then pounded, churned into a powder and then sieved with 100 no mesh (sieve), then weighed and packets (pudia) were made each of 1 gram.

#### Herbal Powder Intervention

Subjects recruited from the Endocrinology OPDs according to enrollment inclusion criteria. They were briefed about this intervention research study and participant's informed consent was taken. They were also briefed about the details regarding the composition of this herbal powder, uses and benefits. Selected subjects were asked to take the prescribed dose (BD) (about 1gm) half an hour before breakfast and before dinner with water and were asked to follow their normal routine diet (diabetic diet) and activity pattern throughout the period of investigation. The intervention was done for a period of three months. Each day 1 gm of powder two times a day was given. The fasting, postprandial blood glucose level, and HbA1c lev-

el were assessed before the intervention (at baseline/ 0 week) and after (12 weeks) the intervention period.

#### Ethical Aspect

Ethical permission was granted by Institutional Ethical Committee of PGIMER, Chandigarh (Ref No. NK/313/res/500 dated: 15/11/2012).

#### Statistical Criteria

The mean difference of fasting blood glucose level, post prandial blood glucose level, and HbA1c level before and after treatment was calculated and statistically analyzed using student t-test and level of significance  $p < 0.05$ . Statistical analysis was carried out using SPSS 20 software.

### RESULTS

Table 1 data shows that the majority of the respondents were female that is, 34 (60.7%) while rest 22 (39.3%) respondents were male. The maximum Type 2 diabetic patients that is, 39.3 percent belonged to the age group of 46-55 years while 35.7 percent respondents were in the age group of 56-65 years and twenty-five percent were in the age group of 35-45 years.

Mean height of the respondents was  $165 \pm 5.7$  cm, mean height of males was  $168.6 \pm 3.49$  cm and females was  $162 \pm 5.42$  cm. Mean weight was  $67 \pm 9.2$  kilogram, mean weight for males was  $71.8 \pm 6.27$  kg and for females was  $64 \pm 9.80$  kg. Mean Body Mass Index was  $24.9 \pm 3.2$  kg/m<sup>2</sup>, for

**Table 1: Baseline characteristics of Type 2 diabetic patients**

	Male	Female	Total	p value
Number (n=56)	22 (39.3%)	34 (60.7%)	56	
Age group(35-45 years)	6 (42.85%)	8 (57.15%)	14	(p <0.05)*
Age group(46-55 years)	9 (40.90%)	13 (59.10%)	22	(p <0.05)*
Age group(56-65 years)	7 (35%)	13 (65%)	20	(p <0.05)*
Age (mean $\pm$ SD) in years	50.86 $\pm$ 7.5	51.47 $\pm$ 7.5	51.23 $\pm$ 7.5	(p <0.001)**
Body weight (mean $\pm$ SD) Kg	71.8 $\pm$ 6.27	64 $\pm$ 9.80	67 $\pm$ 9.2	(p >0.001)**
Height (mean $\pm$ SD) Cm	168.6 $\pm$ 3.49	162 $\pm$ 5.42	165 $\pm$ 5.7	(p >0.001)**
BMI (mean $\pm$ SD) kg/m <sup>2</sup>	25 $\pm$ 2.80	24.75 $\pm$ 3.47	24.9 $\pm$ 3.2	(p <0.001)**
Fasting Blood Glucose (mean $\pm$ SD)mg/dl	151 $\pm$ 50	167 $\pm$ 45	161 $\pm$ 47	(p <0.001)**
Postprandial Blood Glucose (mean $\pm$ SD) mg/dl	223 $\pm$ 67	235 $\pm$ 90	231 $\pm$ 81	(p <0.001)**
HbA1c (mean $\pm$ SD) %	7.5 $\pm$ 0.8	9.3 $\pm$ 2.1	8.6 $\pm$ 1.9	(p <0.001)**
Age onset of diabetes (years)	46.77 $\pm$ 6.7	46.71 $\pm$ 8.3	46.73 $\pm$ 7.7	(p >0.001)**

Note: Result are expressed as mean  $\pm$  SD; Data was analyzed using ANOVA test; Significance was considered at  $p < 0.05^*$ ,  $p < 0.001^{**}$

males mean BMI was  $25 \pm 2.80$  kg/m<sup>2</sup> and for females it was  $24.75 \pm 3.47$  kg/m<sup>2</sup>. The age of onset of diabetes in both the gender was 46 years (Table 1). Weight, height and HbA1c level in both the groups were statically significant while age, BMI, FBG, PPG and age onset of diabetes were non-significant.

Table 2 data shows that the (n=56) mean fasting blood glucose (FBG) level of the subject before starting the intervention (at baseline) was  $161 \pm 47$  mg/dl and was  $120 \pm 29$  mg/dl after twelve weeks. Mean FBG level for the male was  $151 \pm 50$  mg/dl before the intervention and  $111 \pm 22$  mg/dl after the intervention. The mean FBG level for the female was  $167 \pm 45$  mg/dl before the intervention and  $127 \pm 32$  mg/dl after the intervention. The mean postprandial blood glucose (PPBG) level before the intervention (at baseline) was  $231 \pm 81$  mg/dl and after intervention (12 weeks), it was reduced to  $162 \pm 32$  mg/dl. The mean PPBG level for the male before the intervention was  $223 \pm 67$  mg/dl and after the intervention, it was reduced to  $160 \pm 23$  mg/dl. The mean PPBG level for the female before the intervention was  $235 \pm 90$  mg/dl and after the intervention, it was reduced to  $163 \pm 37$  mg/dl. The HbA1c level before the intervention was  $9.2 \pm 2.1$  percent and after the intervention, it was reduced to  $7.5 \pm 1.2$  percent. The HbA1c level for the male before the intervention was  $7.8 \pm 0.4$  percent and after the intervention, it was reduced to  $6.8 \pm 0.8$  percent. The HbA1c level for the female before the intervention was  $10.1 \pm 2.2$  percent and after the intervention, it was reduced to  $8.0 \pm 1.3$  percent.

The reduction in blood glucose in both fasting and post prandial between the initial and final levels (before and after treatment respectively) in both genders is statistically significant ( $p < 0.001$ ) by student t test.

## DISCUSSION

The researchers' subjects showed a poor diabetic control despite being on OHA or Insulin. The overall awareness, care, treatment and adequacy of control of diabetes in researchers' sample was low.

The study done by Mohan and Pradeepa (2009) states that Type 2 diabetes has become more prevalent even in younger age group people, which could have long lasting effects on health or people and health of nation and economy of the nation. In the present study also prevalence was recorded among younger age group.

Elevated blood glucose at a high level is the commonest problem in Type 2 diabetic patients. The researchers' study accords with the study done by Madaan et al. (2014) that the mean fasting blood glucose level in male diabetic was  $149 \pm 19.51$  mg/dl and females  $147 \pm 18$  mg/dl. Mean post prandial blood glucose level was  $259.94 \pm 5136$  mg/dl and  $259.65 \pm 51.39$  mg/dl in male and female diabetic patients respectively.

The researchers' study results are comparable to a study by Kautzky Willer et al. (2015) in which fasting, post prandial and HbA1c level were less in males when compared to females.

**Table 2: Effect of herbal powder intervention on blood glucose levels in type 2 diabetic patients**

	Group	Time period		
		Baseline (0 week) before intervention	12 week after intervention	P value
Fasting Blood Glucose Level (Mean)mg/dl	Male (n=22)	151± 50	111± 22	(p <0.001)*
	Female (n=34)	167± 45	127± 32	
	Total (n=56)	161± 47	120± 29	
Post Prandial Blood Glucose Level (Mean)mg/dl	Male (n=22)	223± 67	160± 23	(p <0.001)*
	Female (n=34)	235± 90	163± 37	
	Total (n=56)	231± 81	162± 32	
HbA1c (Mean) %	Male (n=22)	7.8± 0.4	6.8± 0.8	(p < 0.001)*
	Female (n=34)	10.1± 2.2	8.0± 1.3	
	Total (n=56)	9.2± 2.1	7.5± 1.2	

Note: Result are expressed as mean± SD; Student paired t test was used for before and after intervention results; Significance was considered at  $p < 0.001$ \*

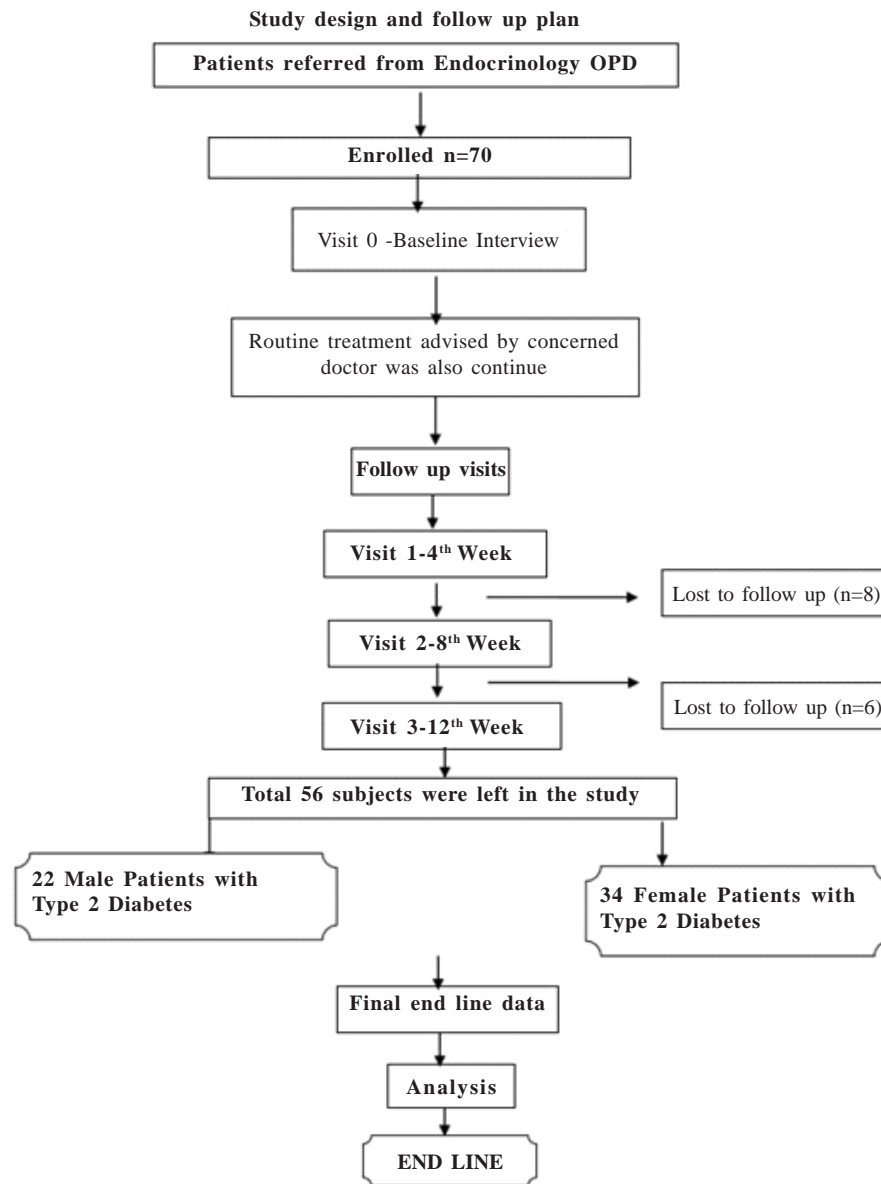


Fig. 1. Study design and follow-up plan for intervention study in Type 2 diabetic patients

In this study, the combination of five herbs powder depicted a percent reduction of 25.47 percent fasting blood glucose level (FBG), 29.87 percent in post prandial blood glucose level (PPBG) and 18.83 percent HbA1c after an intervention period of three months. In other similar studies (Joffe and Freed 2001) only one herb,

*Gymnema sylvestre* extract (400mg) was given twice a day to diabetic patients for three months'. FBG and PPBG level decreased by eleven and thirteen percent respectively. A 0.6 to 0.8 percent decrease was observed in HbA1c. It shows the combination of herbs has a better effect on FBG, PPBG and HbA1c levels as compared to a single herb.

The researchers' study results are comparable to some studies (Shanmugasundaram et al. 1990; Anuradha and Vidhya 2001; Paliwal et al. 2009) as well where administration of spirulina, Gurmar extract and Gurmar leaf powder was done in diabetic patients for 60 days along with diet counseling. Significant reduction in the blood glucose levels (fasting, postprandial and random) in the experimental group was noticed.

#### Adverse Event and Side Effect

There was not any adverse event or any side effect noted of these herbal interventions. This herbal powder was well tolerated during the study period.

#### CONCLUSION

In this study, clinical trial on 56 cases of Type 2 diabetes mellitus patients, a herbal formulation brings down a highly significant reduction in fasting, post-prandial blood glucose and HbA1c levels in both genders. Thus these herbal supplements may be used as an adjunct for treatment of Type 2 Diabetes Mellitus.

#### RECOMMENDATIONS

Based on the results of the study the following recommendations were given:

1. As results show there can be a big scope and great potential for its utilization of this herbal powder supplement to use as an adjunct for treatment of diabetic mellitus patients.
2. The similar study can be done on diabetic children (Type 1).
3. Duration of the study intervention may be increased to six months for better results.
4. The effect of herbs on other parameters such as C-peptide and body insulin level can be checked.

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