5.0 Introduction

Diabetes Mellitus is a metabolic-cum-vascular syndrome of multiple etiologies characterized by chronic hyperglycemia with disturbances of carbohydrates, fat and protein metabolism resulting from defects in insulin secretion, insulin action or both. This disorder is frequently associated with long term damage, which can lead to failure of organs like eyes, kidneys, nerves heart and blood vessels.

Type2 diabetes or non-insulin dependent diabetes (NIDDM), accounts for most cases of diabetes mellitus worldwide. It is estimated that in 2000 there were approximately 150 million individuals with the disease and that this number is likely to double by 2025. Type2 diabetes is the fourth or fifth leading cause of death in most developed countries and there is growing evidence that it has reached epidemic proportions in many developing and newly industrialized countries. The lowest rates of type 2 diabetes are found in rural communities where people retain traditional lifestyles, and consume traditional and herbal indigenous ingredients in their routine/daily meal.

Type 2 diabetes is treated with medicines and regulated diet. Alternative treatments for diabetes have become increasingly popular in the last several years, including medicinal herbs, nutritional supplementation, acupuncture, and hot tub therapy. Since ancient times, plants and plant extracts were used to combat diabetes. Many traditional medicines are derived from medicinal plants, minerals and organic matter. The World Health Organization (WHO) has listed 21,000 plants, which are used for medicinal purpose around the world. Among these, out of which 150 species are used commercially on a fairly large scale (Zohary et.al., 2000).

Numerous studies related to diabetes have been conducted in past. So it was considered worthwhile to observe effect of indigenous food ingredients MKK (Methidana, Kali jiri, Kale til) on blood glucose level of NIDDM patients.
5.1 Objectives

1. To compare the effect of MKK & MKK+Hypoglycemic drugs on blood glucose levels of NIDDM patient.
2. To compare the change in weight of NIDDM patient taking MKK & MKK+Hypoglycemic drugs.
3. To study the Dietary pattern of NIDDM patient taking MKK & MKK+Hypoglycemic drugs.
4. To study the Nutrient intake of NIDDM patient taking MKK & MKK+Hypoglycemic drugs.

5.2 Materials and Methods

Hypothesis

1. There shall be no significant difference in mean of fasting and postprandial blood glucose level of NIDDM patient taking MKK and MKK + Oral Hypoglycemic drugs.
2. There shall be no significant difference in change in mean body weight of NIDDM patient taking MKK and MKK + Oral hypoglycemic drugs.
3. There shall be no significant difference in dietary patterns of NIDDM patient taking MKK and MKK + Oral hypoglycemic drugs.
4. There shall be no significant difference in mean nutrient intake of NIDDM patient taking MKK and MKK + Oral hypoglycemic drugs.

5.3 Sample and Sampling Technique

a. The Sample

When a small group is taken as the representative of the whole, the study is called sampling study. “Sample is a miniature picture of the universe”.

b. The Purpose of Sampling

It is more or less impossible to study every single person in a target population so researcher selects a sample or sub-group of the population that is likely to be representative of the target population.
c. Criterion for the Study

Criterion for the Study was as follows

- NIDDM patients; age 40 to 50 years, were selected belonging to any socioeconomic status, cast, religion and sex. This was because type 2 Diabetes usually develops after the age of 40 and diabetes is not affected by above particulars.
- NIDDM patients who were willing to take indigenous foods (MKK) ingredient for the experiment (Group I - sample size 50).
- NIDDM patients who were on oral hypoglycemic drugs and willing to take indigenous food (MKK) ingredients with regular medication (Group II-sample size 50).

d. Sampling unit and Sourcing of Samples

Samples were collected from local clinic, social clubs, diagnostic centers and personal contacts from Indore. Here sampling unit is NIDDM diabetic patients aged between 40 to 50 years, staying at Indore city, Madhya Pradesh, India.

e. Sampling Technique

Sampling is the process of selecting a sufficient number of elements from the population. There are various types of sampling method. In the present study random sampling method was used. Non- insulin dependent diabetic patients were selected randomly. It is the simplest possible design and its procedure of analysis is also easier.

5.4 Tools and Techniques

For data collection following tools were implemented:

- Interview schedule
- Observation

1. Interview Schedule: According to Floyd J. Fowler Jr. An interview schedule is the guide an interviewer uses when conducting a structured interview. It has two components: a set of questions designed to be asked exactly as worded, and
instructions to the interviewer about how to proceed through the questions. The questions appear in the order in which they are to be asked. The questions are designed so they can be administered verbatim, exactly as they are written. The questions need to communicate what information is being asked of respondents.

**Following data was collected through this Interview schedule:**

**a. General Information:** General information like age, education, occupation, family history of diabetic patients was collected by using interview schedule.

**b. Food Habits and Consumption of food groups of samples:** 24 hours Dietary recall method was used to collect information related to food habits and consumption of food group. Daily food intake of each sample was analyzed on the basis of food groups like cereals, pulses and legumes, fats and oils, sugar, milk and milk product, fruits and vegetables.

**c. Nutrient Intake:** To calculate nutrient intake, the daily menu was fragmented into their ingredients. The nutritive values of these foods in terms of energy, carbohydrates, proteins, fats were calculated with the help of Food consumption table given in “Nutritive value of Indian food” by Gopalan et al. 2004.

**2. Observation:** Observation is a way of gathering data by watching behavior, events, or noting physical characteristics in their natural setting. Observations can be overt or direct (everyone knows they are being observed) or covert or indirect (no one knows they are being observed and the observer is concealed). The benefit of covert observation is that people are more likely to behave naturally if they do not know they are being observed. In this the information was collected by observation without interviewing the respondents in the following heads:

**a. Anthropometric Measurement:**

**(i) Height:** Standard height measuring instrument (company: Prestige, India) was used for height measurement and was measured in cms.
(ii) **Weight:** Weight machine (Crown Victoria DX,) manufactured by Ramon Surgical, Delhi was used for weight measurement. Body weight was measured in kgs for each sample before schedule started and after schedule was over.

**b. Blood Sugar Level:** Biochemical Analysis: In the development of any disease biochemical changes can be expected to occur prior to clinical manifestations (Mehtab, S. Bamji. 1996). Biochemical tests related to fasting and postprandial blood glucose was taken into account before and after one month. The laboratory procedures applied for the analysis of fasting and postprandial blood glucose was GOD-POD method.

**GOD-POD Method**
Glucose is the reducing monosaccharide that serves as the principal source of cellular energy in the body. It enters into the cell under the influence of insulin and undergoes a series of chemical reactions to produce energy. Lack of insulin or resistance to its action at the cellular level causes diabetes. Therefore, in diabetes mellitus the blood glucose level are very high.

**Principle**
Glucose is oxidized by glucose oxidase (GOD) to produce gluconate and hydrogen peroxide. The hydrogen peroxide is then oxidatively coupled with 4 amino-antipyrine (4-AAP) and phenol in the presence of peroxidase(POD) to yield a red quinoeimine dye that is measured at 505nm. The absorbance at 505 nm is proportional to concentration of glucose in the sample.

\[
\text{Glucose} + 2\text{H}_2\text{O} + \text{O}_2 \rightarrow \text{Gluconate} + \text{H}_2\text{O}_2
\]

\[
2\text{H}_2\text{O}_2 + 4\text{-AAP} + \text{Phenol} \rightarrow \text{Quinoeimine Dye}
\]

Absorbance of the colored solution is directly proportional to the glucose concentration, when measured at 505nm.
Experimental Schedule

100 samples of NIDDM patients were selected and were divided into two groups of 50 samples each.

- Group I NIDDM patients willing to take MKK powder and not taking any other medicine.
- Group II NIDDM patients who are already on hypoglycemic drugs but willing to take MKK.

5.5 Preparation of MKK Powder (Indigenous food)

As per the guidance and suggestions of Ayurvedic doctor equal proportion of MKK can be beneficial for the treatment of NIDDM patients. Thus 100 gm Methidana, 100 gm Kaletil, 100 gm Kaliziri were taken, cleaned, mixed and grinded in the form of fine powder. The feeding program was conducted on the selected samples by giving MKK powder.

- Amount of feed - 10 grams at a time (twice a day)
- Timing - 15 min. before the meal
- Duration - one month

5.6 Data Analysis

For the data analysis consultations were made with statisticians and then statistical package of social science SPSS 17 was used for whole data analysis process. The collected data was analyzed for statistical significance by applying t test and Chi Square test using SPSS 17.

5.7 Ethical Issue

Before starting the experiment, information and relevant documents on all ingredients of indigenous food were collected. The methidana seeds are available all over India and are used as one of the major constituent of Indian spices. It has long been used as a spice and herbal remedy in India. People harvest and roast dried seeds of the plants.
for food flavoring and medicinal purpose. Similarly kale tils have been a source of food and oil in Indian diet. Kaliziri is widely used in the Ayurvedic system of medicine preparation and distributed widely in India. The reviews showed, that there was no risk on mental health and physical injury, disability and death by using these ingredients. Voluntary concern of the study samples was considered as a must before selecting them.

5.8 Results

From this study following results were obtained

5.8.1 Result related to $H_0$ No.1 are summarized below

(a) Fasting Blood glucose level (before starting experiment)

For the interpretation of data collected an independent student t test was applied to compare fasting blood glucose level of two groups before experiment. It was found that the mean score value of the samples was 141.8 mg/dl and 129.5 mg/dl for group I and group II respectively. The t value was significant i.e. Before starting the experiment there was a significant difference on initial fasting blood glucose level of Group I and Group II. This is justified as Group I was not taking any hypoglycemic drugs while Group II was already taking hypoglycemic drugs (which makes difference in initial Fasting blood glucose level).

(b) Fasting blood glucose level (After experiment)

At the end of the experiment, again an independent student t test was applied to see the effect of MKK powder on the blood glucose level of two groups. The mean value of the Fasting blood glucose level after experiment was 121mg/dl and 114 mg/dl for Group I and Group II respectively. The result showed that there was a significant difference in fasting glucose level of Group I and Group II.

In group I initial mean score of fasting blood glucose level was found to be 141.8mg/dl and after experiment this level was reduced to 121mg/dl, thus there was a reduction of 20 mg/dl in their fasting blood glucose level. Similarly in group II initial
mean fasting blood glucose value was 129mg/dl and after treatment this value was reduced to 114 mg/dl thus there was reduction of 15 mg/dl in their fasting blood glucose level. It signifies that MKK has significant effect on reducing fasting blood glucose level of both the groups.

(c) Postprandial blood glucose level (before experiment)

For the interpretation of data collected an independent student t test was applied to compare postprandial blood glucose level of both the groups before experiment. It was found that the mean score value of PPBG level of samples was 204.8 mg/dl and 195.3 mg/ dl for group I and group II respectively. The t value was significant i.e. before starting the treatment there was a significant difference on initial postprandial blood glucose level of Group I and Group II. This is justified as Group I was not taking any hypoglycemic drugs (which makes difference in postprandial blood glucose level) while Group II was already taking hypoglycemic drugs.

(d) Postprandial blood glucose level (After experiment)

At the end of the experiment, again an independent student t test was applied to see the effect of MKK powder on postprandial blood glucose level of both the groups. The mean value of the postprandial blood glucose level after experiment was found to be 175.3mg/dl and 175.9mg/dl for Group I and Group II respectively .The result showed that there was no significant difference in postprandial blood glucose level of Group I and Group II.

Recorded data related to postprandial blood glucose level showed that “there is no significant difference in postprandial blood glucose level of both the groups”. “In group I mean value of initial postprandial blood glucose was found to be 204mg/dl and after experiment this value was reduced to 175mg/dl. Thus there was a reduction of 29 mg/dl in their postprandial blood glucose level, similarly in group II mean value of initial postprandial blood glucose level was 195mg/dl which reduced to 175mg/dl after experiment, thus there was a reduction of 20mg/dl in their postprandial blood glucose level. It signifies that MKK has a very significant effect on reducing postprandial blood glucose level of both the groups.
From the above results it can be interpreted that our hypothesis $H_0$ No.1 is partially rejected as there was a significant difference in final fasting blood glucose level of group I and group II while there was no significant difference in postprandial blood glucose level of both the groups.

Here it should be highlighted that although there was no significant difference in postprandial blood glucose level of two groups, but there was a significant reduction of postprandial blood glucose level by 14% and 10% in group I and group II due to consumption of MKK powder.

### 5.8.2 Result related to $H_0$ No.2 are summarized below

**(a) Initial weight of Samples (before experimentation)**

For the interpretation of data collected an independent student t test was applied to compare initial mean weight of two groups before experiment started. It was found that the mean value of weight of the samples were 65.7 Kg and 65.9 Kg for group I and group II respectively. The t value was not significant i.e. Before starting the experiment there was no significant difference on initial weight of samples of Group I and Group II.

**(b) Final weight of Samples (after experimentation)**

At the end of the experiment, again an independent student t test was applied to see the effect of MKK powder on mean weight of two groups. The mean value of the samples after experiment was 63.8 Kg. and 65.0 Kg. for Group I and Group II respectively. The result showed that there was no significant difference in final weight of Group I and Group II.

From the above results it can be interpreted that our hypothesis $H_0$ No.2 is accepted as there was no significant difference in final weight of group I and group II. Here it should be highlighted that although there was no significant difference in final mean weights of two groups, but there was a reduction of mean weights of approximately 2Kg and 1 Kg for group I and group II respectively due to consumption of MKK powder.
5.8.3 Result related to H0 No.3 are summarized below

For the interpretation of data collected, an independent student t test was applied to compare dietary patterns of both the groups. Results of the t test are shown below:

(a) Cereals- For the interpretation of data collected an independent student t test was applied to compare amount of cereal consumption of two groups. It was found that the mean value of the consumption of the cereal of samples were 347.5 gm and 357.7gm for group I and group II respectively. The t value was not significant i.e. there was no significant difference on amount of cereal consumption in Group I and Group II.

(b) Pulses- For the interpretation of data collected, an independent student t test was applied to compare amount of pulses and legumes consumption of both the groups. It was found that the mean value of consumption of pulses of samples were 81.6gm and 67.3 gm for group I and group II respectively. The t value was not found to be significant i.e. there was no significant difference on amount of pulses and legumes consumption Group I and Group II.

(c) Milk and Milk Product - For the interpretation of data collected an independent student t test was applied amount of Milk and Milk Product consumption of two groups. It was found that the mean value of the consumption of milk of samples were 318.5ml and 324.5ml for group I and group II respectively. The t value was not found to be significant i.e. there was no significant difference on amount of Milk and Milk Product consumption Group I and Group II.

(d) Fruits- For the interpretation of data collected an independent student t test was applied to compare amount of fruits consumption of two groups. It was found that the mean values of the consumption of fruits of samples were 294gm and 331 gm for group I and group II respectively. The t value was not found to be significant i.e. there was no significant difference on amount of fruits consumption in Group I and Group II.

(e) Vegetable - For the interpretation of data collected, an independent student t test was applied to compare amount of vegetable consumption (of different types) of both
the groups. It was found that the mean values of the vegetable consumption of samples were 141gm and 122 gm for Roots and tubers of group I and group II respectively. The t value was not found to be significant i.e. there was no significant difference on amount of Roots and tubers consumption Group I and Group II. It was found that the mean value of consumption were 230.5gm and 238gm for green leafy vegetable of group I and group II respectively. The t value was not significant i.e. there was no significant difference on amount of green leafy vegetable consumption Group I and Group II. It was found that the mean value of the samples were 145.5gm 1nd 122 gm for other vegetables of group I and group II respectively. The t value was not found to be significant) i.e. there was no significant difference on amount of other vegetables consumption in Group I and GroupII.

(f) Fats and Oils -. For the interpretation of data collected, an independent student t test was applied to compare amount of Fats and Oils consumption of two groups. It was found that the mean value of the consumption were 51.3 gm and 47.9 gm for group I and group II respectively. The t value was not found to be significant i.e. there was significant difference on amount of Fats and Oils consumption in Group I and Group II.

(g) Sugar- For the interpretation of data collected an independent student t test was applied to compare amount of sugar consumption of two groups. It was found that the mean values of the consumption were 30.9gm and 31.2 gm for group I and group II respectively. The t value was not found to be significant i.e. there was no significant difference on amount of sugar consumption in Group I and Group II.

For the interpretation of data collected on food habits chi square test was applied.

The Chi-Square value for the association between group I and group II for Vegetarian/ non- Vegetarian food habits was obtained as .25 for 1 degrees of freedom is not significant ( Significance Probability less than 6.635). Thus, there is no significant difference in habits of Vegetarian/ non- Vegetarian from group I and group II in our sample.
The Chi-Square value for the association between group I and group II for alcoholic/Non alcoholic habit was obtained as .36 for 1 degrees of freedom is not significant (Significance Probability less than 6.635). Thus, there is no significant difference in alcoholic/Non alcoholic in group I and group II in our sample.

“The Chi-Square value for the association between group I and group II for Use of artificial sweetener was obtained as .25 for 1 degrees of freedom is not significant (Significance Probability less than 6.635). Thus, there is no significant difference in Use of artificial sweetener in group I and group II in our sample.

The Chi-Square value for the association between group I and group II for smoker/non smoker was obtained as .25 for 1 degrees of freedom is not significant (Significance Probability less than 6.635). Thus, there is no significant difference in smoker/non smoker habit in group I and group II in our sample.

There is no significant difference in consumption of food groups and other habits in both the groups, hence $H_0$ No.3 is accepted that “there is no difference in dietary pattern of NIDDM patients of both group”. Since NIDDM patients are more attentive towards their health and therefore the intake and food pattern of their meal are almost similar in both the groups. The choice of food preference, likes and dislikes are same in both groups. These patients are very particular and conscious what they take, therefore the consumption of Cereals, Pulses, Milk & Milk product, fruits, vegetables, fats, oil and sugar are similar.

**5.8.4 Result related to $H_0$ No.4 are summarized below**

For the interpretation of data collected, an independent student t test was applied to compare calories and nutrients like carbohydrates, protein and fats of NIDDM patients of both groups. Results of the t test are shown below:

(a) **Calories** - To compare the intake of calories and nutrients of the two groups’ was studied. For the interpretation of data collected an independent student t test was conducted to compare amount of calories consumption of two groups. It was found that the mean value of the consumption of samples were 2401cal and 2427 cal for
group I and group II respectively. The t value was not found to be significant i.e. there was no significant difference on amount of calories consumption in Group I and Group II.

(b) Carbohydrates - To compare the intake of Carbohydrates of the two groups’ was studied. For the interpretation of data collected an independent student t test was conducted to compare amount of Carbohydrates intake of both the groups. It was found that the mean value of the consumption of samples were 373.6gm and 377.7 gm for group I and group II respectively. The t value was not found to be significant at i.e. there was no significant difference on amount of Carbohydrates intake in Group I and Group II.

(C) Protein - To compare the intake of Protein of the two groups was studied. For the interpretation of data collected an independent student t test was conducted to compare amount of intake of Protein of two groups. It was found that the mean value of the consumption of samples were 69.4gm and 71.5gm for group I and group II respectively. The t value was not found to be significant i.e. there was no significant difference on amount of Protein intake in Group I and Group II.

(d) Fats: To compare the intake of total fats of the two groups was studied. For the interpretation of data collected an independent student t test was conducted to compare amount of fats intake of two groups. It was found that the mean value of the consumption of samples were 70gm and 69.9gm for group I and group II respectively. The t value was not found to be significant i.e. there was no significant difference on amount of total fats intake in Group I and Group II.

There is no significant difference in consumption of calorie and nutrients of Group I and Group II; hence H$_0$ No. 4 is accepted that “there is no difference in calorie and nutrients intake of NIDDM patients of both groups”.

5.9 Conclusion

Normally Type 2 diabetes is treated with oral hypoglycemic drugs. But these have long term side effects, thus alternative therapies with anti-hyperglycemic effects are
increasingly sought by patients, society and medical practitioners. Among these herbal medications is the most important alternative therapy for blood glucose control. Since ancient times indigenous foods (ingredients) have been used in Ayurveda and traditional medication and do not have any side effects. For this reason this subject is selected for the experimentation so that a baseline in Herbal medications can be provided to the society. From this study following conclusions were drawn:

1. MKK powder reduces fasting and postprandial blood glucose level in both the groups.
2. The efficiency of MKK powder was similar to oral hypoglycemic drugs.
3. MKK powder had weight reducing effect in NIDDM patients.
4. There is no adverse effect found in any patients with diabetes, who were taking MKK powder.
5. MKK powder is economic and these ingredients are easily available in the market. So no extra efforts are required to arrange these herbs for treatment of diabetes.

In conclusion, MKK powder helps in controlling Fasting and postprandial blood glucose level and reduces weight of diabetic patients. Hence, MKK powder can be used as a substitute to control blood glucose level and regulate weight of type 2 diabetic patients. Here it is noted that to control the blood glucose level of NIDDM patients MKK powder is more beneficial as compared to taking it with hypoglycemic drug.

5.10 Limitations

1. It was very difficult to get volunteers for such type of studies as the indigenous food ingredients are not certified by medical council as a source of treatment. Therefore people were reluctant to offer themselves as a sample case.
2. Type1 diabetic patients were not considered as they were on insulin and considered as a sensitive case. Close monitoring is required which was not possible in the present study.
3. In present study controlled group could not be formed due to risk factor.
5.11 Suggestions

1. The pharmacological actions of these ingredients (MKK) need to be evaluated in studies involving these ingredients on human to justify the use of these herbs or their active principles for the treatment of diabetes. It is also important to establish the active components from these plant extracts.

2. It would also be useful to investigate the efficacy of single herb therapies versus the relative combination of herbs used. It is not clear from the currently available literature if the use of combination of herbs provide any additional benefit over the use of a single herb.

3. There is a need for conducting clinical research in herbal drugs, developing simple bioassays for biological standardization, pharmacological and toxicological evaluation and developing various animal models for toxicity and safety evaluation.