‘COMPARING THE METABOLIC EFFECTS OF DIETARY MODIFICATION ALONE AND DIETARY MODIFICATION ALONG WITH FENUGREEK IN PREDIABETICS OF KANPUR’

Abstract

Diabetes mellitus is a metabolic disorder defined by chronic hyperglycemia with deranged fat, carbohydrate and protein metabolism that results from improper secretion or action of insulin. The age standardized prevalence of diabetes has become 8.5% in the adult population. WHO estimates that diabetes will become the seventh most common cause of mortality, worldwide, in the year 2030.

There are two main types of diabetes mellitus (DM): Type 1 DM results from the inability of the pancreas to produce enough insulin, its cause is unknown, Type 2 DM occurs due to insulin resistance, in which the peripheral cells fail to respond to insulin properly. As the disease progresses, failure to produce insulin may also occur. The most common risk factor of type 2 DM is excessive body weight and sedentary lifestyle. Type 2 DM accounts for more than 90% of the diabetes cases worldwide.

Recent studies have revealed that around half of the diabetics in the world are undiagnosed. American Diabetic Association has introduced a new category of blood glucose levels, preceding the onset of diabetes, known as prediabetes. Individuals with prediabetes, have a higher risk of development of diabetes in the future. American Diabetic Association has defined prediabetes as impaired Fasting Glucose, when fasting plasma glucose level ranges from 100 to 125 mg/dl and Impaired Glucose Tolerance, when plasma glucose level 2-h after an oral glucose tolerance test ranges from 140 to 199 mg/dl. The A1C test measures your average blood glucose for the past 2 to 3 months. The advantages of being diagnosed this
way are that you don't have to fast or drink anything. Diabetes is diagnosed at an 
A1C of greater than or equal to 6.5%. The OGTT is a two-hour test that checks your 
blood glucose levels before and 2 hours after you drink a special sweet drink. It 
tells the doctor how your body processes glucose. Diabetes is diagnosed at 2 hour 
blood glucose of greater than or equal to 200 mg/dl 

Criteria for Testing for Diabetes or Prediabetes in Asymptomatic Adults. Some 
the testing criteria for diabetes as follows: Testing should be considered in adults 
who are overweight (BMI ≥25 kg/m² or ≥23 kg/m² in Asian Americans) and have 
additional risk factors, Physical inactivity, First-degree relative with diabetes. High-
risk race/ethnicity (e.g., African American, Latino, Native American, Asian 
American, Pacific Islander), Women who delivered a baby weighing >9 lb or were 
diagnosed with GDM, Hypertension (≥140/90 mmHg or on therapy for hypertension), HDL cholesterol level <35 mg/dL (0.90 mmol/L) and/or a 
triglyceride level >250 mg/dL (2.82 mmol/L), Women with polycystic ovary 
syndrome, A1C ≥5.7%, IGT or IFG on previous testing, Other clinical conditions 
associated with insulin resistance (e.g., severe obesity, acanthosis nigricans), 
History of CVD.

Screening for prediabetes can lead to early diagnosis and treatment and 
prevention of complications. Fenugreek is a plant that grows in parts of Europe 
and western Asia. The leaves are edible, but the small brown seeds are famous for 
their use in medicine. Fenugreek seeds may be helpful to people with diabetes. The 
seeds contain fiber and other chemicals that slow digestion and the body’s 
absorption of carbohydrates and sugar. The seeds may also help improve how the 
body uses sugar and increases the amount of insulin released. Few studies support 
fenugreek as an effective treatment for certain conditions. Many of these studies 
focus on the seed’s ability to lower blood sugar in people with diabetes.
According to one study, a bread incorporating fenugreek using a proprietary process was tested for its taste acceptability and its effect on carbohydrate metabolism. They developed a fenugreek bread formula that was produced in a commercial bakery by incorporating fenugreek flour into a standard wheat bread formula. Eight diet-controlled diabetic subjects were served two slices (56 g) and 5% fenugreek. Blood glucose and insulin were tested periodically over a 4-hour period after consumption. The tests were run on two occasions 1 week apart, once with the fenugreek bread and once with regular bread. The study was double-blind, and the order was randomized and balanced. Fenugreek and whole wheat bread samples were evaluated for sensory attributes and nutrient composition. There was no statistically significant difference in proximate composition, color, firmness, texture, and flavor intensity between the fenugreek and wheat bread (P > .05). The area under the curve for glucose and insulin was lower in the fenugreek condition, but only reached significance with insulin (P < .05). The fenugreek-containing bread was indistinguishable from the whole wheat bread control. Normally, fenugreek flour impacts bread quality negatively. The bread maintained fenugreek's functional property of reducing insulin resistance. Acceptable baked products can be prepared with added fenugreek, which will reduce insulin resistance and treat type 2 diabetes.

According to another study, the results of 18 patients (11 consumed fenugreek in hot water and 7 in yoghurt) were studied. Findings showed that FBS, TG and VLDL-C decreased significantly (25 %, 30 % and 30.6 % respectively) after taking fenugreek seed soaked in hot water whereas there were no significantly changes in lab parameters in cases consumed it mixed with yoghurt. BMI, Energy, Carbohydrate, Protein and fat intake remained unchanged during study. This study showed that fenugreek seeds can be used as an
adjuvant in the control of type 2 diabetes mellitus in the form of soaked in hot water.

Another study stated as High vs. low consumption of (total) meat: RR = 1.17 for type 2 diabetes (95%CI: 0.92 to 1.48), High vs. low consumption of red meat: RR = 1.21 for type 2 diabetes (95%CI: 1.07 to 1.38), High vs. low consumption of processed meat: RR = 1.41 for diabetes (95%CI: 1.25 to 1.60). this study concluded In conclusion we found that high intakes of red meat and processed meat are risk factors for type 2 diabetes. We cannot completely rule out the possibility of residual confounding or a temporal bias, but if the association is real, meat could be added to the list of behavioural factors which can be modified to decrease type 2 diabetes risk.

One more study said that Diet reduced diabetes risk in subjects with impaired glucose tolerance (Hazard Ratio: 0.63; 95%CI: 0.49 to 0.92). 21 trials met the inclusion criteria, of which 17, with 8084 participants with impaired glucose tolerance, reported results in enough detail for inclusion in the meta-analyses. From the meta-analyses the pooled hazard ratios were 0.51 (95% confidence interval 0.44 to 0.60) for lifestyle interventions v standard advice, 0.70 (0.62 to 0.79) for oral diabetes drugs v control, 0.44 (0.28 to 0.69) for orlistat v control, and 0.32 (0.03 to 3.07) for the herbal remedy jiangtangbushen recipe v standard diabetes advice. These correspond to numbers needed to treat for benefit (NNTB) and harm (NNTH) of 6.4 for lifestyle (95% credible interval, NNTB 5.0 to NNTB 8.4), 10.8 for oral diabetes drugs (NNTB 8.1 to NNTB 15.0), 5.4 for orlistat (NNTB 4.1 to NNTB 7.6), and 4.0 for jiangtangbushen (NNTH 16.9 to NNTB 24.8).
Another study found that a daily dose of 10 grams of fenugreek seeds soaked in hot water may help control type 2 diabetes. Another study suggests that eating baked goods, such as bread, made with fenugreek flour may reduce insulin resistance in people with type 2 diabetes. An additional study showed that taking high doses of fenugreek every day for several weeks causes noticeable improvements in plasma glucose levels. The amounts of fenugreek used in cooking are generally considered safe. When taken in large doses, side effects can include gas and bloating. Fenugreek seeds have a bitter, nutty taste. They’re often used in spice blends. Indian recipes use them in curries, pickles, and other sauces. You can also drink fenugreek tea or sprinkle powdered fenugreek over yogurt. Dietitian will help us for adding of fenugreek into our current diabetes meal.

There have not been any serious or life-threatening side effects or complications connected with fenugreek. Keeping blood sugar at normal levels is essential to maintaining a high quality of life with a diagnosis of prediabetes. We can help our body maintain healthy blood glucose levels by making lifestyle changes, including: Sticking to a diet, being active at least half an hour a day, at least five days a week.

Traditional treatments for diabetes is along with fenugreek, we have other options for treating diabetes. Keeping blood sugar at normal levels is essential to maintaining a high quality of life with a diagnosis of prediabetes. We can help our body maintain healthy blood glucose levels by making lifestyle changes, including: Sticking to a diet of foods with little processed foods and high amounts of fiber, such as whole grains, vegetables, and fruits. Choosing lean protein sources and healthy fats, and avoiding excessive processed meat, boxed and processed
foods, and sweetened beverages. Being active at least half an hour a day, at least five days a week.

This is a cross-sectional study carried out in Kanpur. An institutional review board (IRB) approval will be obtained for this study. Informed consent will be given/taken to/from all the subjects before carrying out this study. All participants sign on informed consent (model attached at end) to enter into the study. It is a prospective observational study for about 1 year. For this study patients will be recruited after calculating the sample size by sample size calculator and divided them into two groups. One group as dietary modification alone in prediabetics. And another group as dietary modification along with fenugreek (5gm BD) in prediabetics.

The following materials and methods will be used in our study. The use of Fenugreek has been limited by its bitter taste and pungent odor. Isolation of biologically active components or production of a debitterized extract, which would allow greater use of the plant, has been investigated. Debitterized, defatted and deodorized Fenugreek fiber with vitamins, minerals and amino acids will get supplied (single batch) by pharmaceutical companies from Kanpur. The compound is in the form of a fine powder usually. Fenugreek powder (debitterized and processed) 5 g twice a day, will be given to the subjects along with 200 ml of water half an hour before meals and they were asked to follow the same dosage regime up to the end of study. The number of Fenugreek packs supplied to and returned by the subjects at the follow-up visit will be noted to calculate the compliance.

To the first group I will instruct the diet schedule as dietary modification and to the second group I will give fenugreek along with dietary modification for
control the slight elevated blood sugar levels i.e prediabetes and to prevent the subjects from development/conversion into diabetes. This study is an interventional parallel randomized study. Sample size is $n \geq 126$ each group, rounding our desired sample size is 140 in each group i.e 280 is the total sample size.

All diabetics, Those who were taking drugs that could alter glucose tolerance, Persons with abnormal lipid profile, those who had a history of cancer or any major illness of the liver, kidney and nervous system, pregnant women, breast feeding or planning a pregnancy during the course of the study were excluded from the study, Those who were having habit of smoking, chewing tobacco and alcohol, familial histories such as congestive heart failure, renal failure, jaundice and genetic abnormalities, patients who are not willing to give written informed consent to participate in the study will be excluded.

The proposed study is carried out in the RAMA MEDICAL COLLEGE, RAMA University Kanpur U.P. our aim to study the metabolic effects of dietary modification alone and dietary modification along with fenugreek in prediabetics. Combination therapy might effectively help in preventing the development of prediabetics to diabetics.

With the following hypothesis I will do the study: Combination of fenugreek with dietary modification will be more beneficial than dietary modification alone in prediabetics. Combination therapy might effectively help in preventing the development of prediabetics to diabetics. Combination therapy might effectively help in decreasing the abnormal lipid profile.

Key words: Prediabetes, HbA1C, fenugreek, GTT.