



Effect of administration of fenugreek seeds on HbA1C levels in uncontrolled diabetes mellitus – a randomized controlled trial

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Abstract: Background: India is the diabetic capital of the world. With ever increasing demand for a better control of diabetes, introduction of food with medicinal values become essential. In this background, we decided to study the effect of fenugreek seeds on control of diabetes mellitus.

Methods: Sixty patients of uncontrolled diabetes mellitus (HbA1C of more than 7.5) reporting to our institute were included in the study. They were randomized to receive either 30 gm of fenugreek seeds thrice a day for 8 weeks (group F) or nil intervention (Group C). The pre and the post HbA1c levels were recorded. Any side effects were noted.

Results: All sixty patients completed the study. The demographic variables, the pre HbA1C levels were similar between the groups ($p > 0.05$). Patients of both control and fenugreek group showed reduction of HbA1c. The difference in reduction is significant in group F. i.e there was more reduction of HbA1c in patients treated with fenugreek seeds ($p < 0.05$). There were no significant side effects in either group.

Conclusion: Daily administration of 30 gm of fenugreek seeds in divided doses decreased HbA1C levels in uncontrolled diabetes mellitus without significant side effects.

Key words: diabetes mellitus, HbA1c, fenugreek seeds.

Introduction

The prevalence of diabetes mellitus is increasing globally everyday with approximately half of all diabetic persons are living in Asia. India is currently the diabetic capital with largest number of cases¹. A wide range of natural food products claiming to lower blood glucose levels or prevent complications of diabetes are marketed in the public. One of the most promising amongst them is *Trigonella foenum-graecum* commonly known as fenugreek². In humans, short term ingestion of fenugreek seeds reduced postprandial (PP) glucose and insulin levels. In addition, several clinical trials showed reductions in fasting, PP glucose levels and glycated haemoglobin (HbA1c)³⁻⁵. Hence in this study we hypothesized that 8 weeks of fenugreek seeds intake may decrease HbA1c levels significantly.

Methods:

Sixty patients of uncontrolled diabetes mellitus (HbA1C of more than 7.5) reporting to our institute were included in the study. The research work was registered with Protocol Exchange with a number ISSN 2043-0116. All patients either with controlled diabetes mellitus or the presence of severe co morbid conditions will be excluded. They were randomized to two different groups of thirty each by a sealed envelope technique. All patients were informed about the study. As it was a natural food intake intervention, it does not invoke

ethical concerns. As the seed consumption is well known in this geographical area, it was assumed that less than 1 % will go as noncompliant. With the expected reduction of more than 0.5 % in HbA1C after the treatment and earlier studies the sample size was decided with a power of 80 % and the level of significance as 0.05. HbA1C was measured and noted along with the other demographic variables. Age, sex and the duration of diabetes were noted. All patients were taking oral hypoglycemic agents. The sixty patients were randomized to two groups using a sealed envelope technique, group F which received fenugreek seeds and Group C which did not receive any intervention. The study group (group F) was administered 10 gms of fenugreek seeds half an hour before three main food intake in a day for 8 weeks. As this study deals with an intake of food as compared to controls, the blinding issue does not erupt. After an 8 week interval, the patients are reviewed with similar tests along with the compliance. Any intervening admissions, sickness, change of drugs will be taken as negatives and they will not be part of the study. Statistics: All demographic variables like, age, sex, years of diabetes were described as mean \pm SD and will spread in an excel sheet to compare with student t test in SPSS software 16.0. Testing within group was done with paired and between groups testing was done with unpaired T test. Chi square test was used for ratio. Any side effects and uneventful events will be noted.

Results:

All the sixty patients completed the study. There were no drop outs. There were neither admissions nor critical illness during the study. The results are tabled in table 1.

Table 1 showing the results:

	Group F	Group C	Statistics (p value)
Age in years	50.37 \pm 14.7	50.1 \pm 11.2	0.46
Male/ female	19/11	18/12	0.9
Duration of diabetes (years)	7.63 \pm 2.85	6.63 \pm 2.61	0.08
HbA1C (pre)	7.906 \pm 0.62	7.89 \pm 0.62	0.4
HbA1C (post)	7.71 \pm 3.91	7.80 \pm 0.57	0.28
Reduction	0.19 \pm 0.15	0.09 \pm 0.11	0.0017 ω

Results given in Mean \pm SD.

ω = p value < 0.05

The mean age, sex difference and the duration of the disease were similar in both the groups. The initial HbA1C was comparable between both groups. There was a reduction of HbA1C in both the groups, but it was more in group F. Statistically significant reduction of HbA1C was found in group F. even though the difference is just 0.1. To be precise, in Group F, HbA1C reduced from 7.9 to 7.71 while in control group it was from 7.89 to 7.8. This means that the reduction is 0.19 in group F while it is 0.09 in group C with a difference of 0.1 as stated above. There were no side effects like nausea, gut problems in any of the patients.

Discussion:

Trigonella foenum graecum is a herb belonging to family Leguminosae extensively cultivated in many parts in India. Two distinct types of plants are recognized, the dwarf type grown for culinary purposes and the tall type is usually grown for medicinal purposes. The seeds of this plant contain an alkaloid trigonelline and choline. These chemicals are shown to possess hypoglycemic and antitussive effect. Standardized hydroalcoholic extract of *Trigonella foenum-graecum* seeds demonstrated reversal of symptoms and glycemic control in progressive model of type 2 DM (n-STZ) in rats by improving glucose homeostasis probably by insulinotropic properties⁶. Several long term clinical trials showed reductions in fasting and post-prandial glucose levels and glycated haemoglobin (HbA1c) after administration of fenugreek seeds but some trials did not show benefit. There was a significant reduction in 24h urinary glucose excretion, and HbA1c after eight weeks of fenugreek intake⁷⁻⁹. A meta-analysis of the effect of herbs on glucose balance in type 2 diabetes patients, by Boaz and colleagues¹⁰, stated that HbA1c was significantly reduced when fenugreek was used as a food supplement. There was a significant reduction of HbA1c after eight weeks of fenugreek administration in our study. There are a lot of studies which focus on antilipidemic effect of fenugreek. We did not attempt to find out the same¹¹. A reduction of HbA1C of 0.1 decreased the incidence of microvascular and macrovascular complications¹². In our study, the actual reduction in HbA1C levels in group F was 0.2 while there was a difference of 0.1 from the control group which still means there is a significant contribution of fenugreek

towards reduction of complications. It may seem clinically insignificant yet there are reports of decrease in complications even with 0.1 % decrease in HbA1c. Gupta et. al¹³. reported an incidence of abdominal dyspepsia in their study of intake of fenugreek seeds We did not encounter any bloating sensation as a side effect, . In our study, the average intake was 30 grams / day while many studies report the results with 10 and 20 grams only¹⁴. We also insisted on our patients that the dosage should be divided before each meal to enable the maximal efficiency of the seeds. Even though there are variable results with powdered, soaked seeds, we opted for fresh seeds to increase patient compliance¹⁵. Hence in our study there were no drop outs. The limitations of our study include small sample size, single analysis at 8 weeks instead of repeating again at 12 and 24 weeks to ascertain any better long term benefits and ignoring lipid profiles. We also admit that this is not a comparative study between different types of formulation of fenugreek in diabetic control.

Conclusion:

Short term ingestion of fenugreek seeds as 30 grams /day in divided doses for 8 weeks, significantly decreased HbA1C levels in patients with uncontrolled diabetes mellitus than in patients without seed intake. There were no significant side effects.

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