Food Research 7 (6) : 135 - 144 (December 2023)
Journal homepage: https://www.myfoodresearch.com

FOOD RESEARCH

RESEARCH PAPER

Effect of fenugreek seed supplementation on fasting and postprandial blood glucose level in type 2 diabetic subjects

[1,*]Khatun, A.A., [1,2]Saifullah, S.B., [1]Ove, T.A., [1]Noor, F., [3]Akhter, M.J., [1]Tahosin, A. and [1]Nila, H.I.

[1]*Department of Food Science and Nutrition, Hajee Mohammad Danesh Science and Technology University, Dinajpur, Bangladesh*
[2]*Department of Public Health, North South University, Dhaka, Bangladesh*
[3]*Department of Food Processing and Preservation, Hajee Mohammad Danesh Science and Technology University, Dinajpur, Bangladesh*

Article history:
Received: 1 May 2022
Received in revised form: 7 June 2022
Accepted: 30 July 2023
Available Online: 13 December 2023

Keywords:
Trigonella foenum-graecum,
Methi,
Fasting,
Postprandial,
Glycemic control

DOI:
https://doi.org/10.26656/fr.2017.7(6).035

Abstract

Diabetes mellitus has a high prevalence, morbidity and mortality globally. Management of type 2 diabetes is difficult with synthetic drugs as they cause many side effects and have some limitations. Thus, as an alternative and immense interest in medicinal plants with indigenous, inexpensive fenugreek (*Trigonella foenum-graecum* L.) is considered to be a potent food-based treatment for managing type 2 diabetes. This study was undertaken to evaluate the blood glucose levels and diabetes status with the consumption of fenugreek seed powder in type 2 diabetic patients. In a clinical trial study, 49 type 2 diabetic patients were pooled using randomization and divided into two groups (controlled and exposed group). The exposed group was placed on 10 g/day of powdered fenugreek seeds soaked in water for 60 days, while the control group was not placed on any test diet. Demographic, clinical characteristics, fasting blood glucose (FBG) and postprandial blood glucose (PBG) were measured before and after the study. No adverse reaction was found after the treatment resumed and all participants finished the trial. Findings showed that 20.83% of the patients who took the supplementation had reached the non-diabetic state where zero success rates were observed in the control group. Multivariable linear regression demonstrated that patients' blood glucose level was significantly associated with fenugreek supplementation ($p < 0.001$) and the type of therapy ($p < 0.05$) while adjusted with their demographic variables, physical and medical conditions. When adjusted for covariates, fasting and postprandial blood glucose in the exposed group was estimated to be 2.38 mmol/L (95% CI: -3.45, -1.32, $p < 0.001$) and 4.18 mmol/L (95% CI: -5.41, -2.95, $p < 0.001$), which was significantly lower than the control group, respectively. The lowering of blood glucose level in the exposed group was gradually distributed over time while significant changes were observed starting from 30 days of supplementation. It is therefore concluded that fenugreek seed supplementation could be generalized to mitigate the complications of type 2 DM.

1. Introduction

Diabetes mellitus (DM) is a metabolic disorder diagnosed as elevated blood glucose levels. With an improved economy and quality of living DM is emerging worldwide. American Diabetes Association has scaled DM as having fasting and postprandial blood glucose of 7.0 mmol/L and 11.1 mmol/L or higher, respectively (ADA, 2012). This abnormality prevails owing to insufficient pancreatic insulin or its duff reception by the peripheral tissues (Geberemeskel *et al*., 2019). More than 537 million of the world's population are suffering from DM. This prevalence is forecasted to reach 783 million by 2045 (International Diabetes Federation (IDF), 2021). Evidence shows that DM is the third most challenging human health-threatening disease after cancer and cardiovascular disease (Grintsova *et al*., 2014). An estimated 6.7 million adult deaths in 2021 were accountable due to diabetes and its complications (IDF, 2021).

Diverse management strategies are available against DM aiming to maintain blood glucose levels as close to

*Corresponding author.
Email: *anwarakhatun@gmail.com*

eISSN: 2550-2166
Published by Rynnye Lyan Resources

normal while avoiding hypoglycemia (Kaul *et al*., 2013). Common approaches in DM management mostly depend on injectable insulin and anti-diabetic drugs (ADA, 2012; Geberemeskel *et al*., 2019). Evidence shows that these drugs may have toxic effects that can cause nausea, vomiting, hematological and dermatological reactions, jaundice, and weight gain (Spiller and Sawyer, 2006; Geberemeskel *et al*., 2019). A new trend is on the rise in developing herbal and other alternative medicines. Researchers believe that medicinal plants can be the alternative solution to their synthetic counterparts with lower toxicity and higher bioavailability (Campbell-Tofte, 2012; Hong *et al*., 2015).

Diet and dietary knowledge were treated as the mainstays of DM management until the growth of cardiovascular diseases and glycemic disorders (Grant and Kirkman, 2015). A study enlisted more than 800 plants with possible hypoglycemic activity (Patel *et al*., 2012). Fenugreek (*Trigonella foenum-graecum* L.) is a part of ancient Ayurveda, used widely in Asia and Middle Eastern countries (Neelakantan *et al*., 2014). It is also known as methi, Greek hayseed, and bird's foot having a pleasantly bitter and slightly sweet taste (Naidu, 2011). Worldwide, fenugreek seeds are used as a spice and condiment whereas the leaves are used as green leafy vegetables (Zia *et al*., 2001; Geberemeskel *et al*., 2019). The dried ripe seeds of fenugreek are loaded with dietary fibers, amino acids, phenolic acids, alkaloids, saponins, and salicylate (Naidu, 2011; Neelakantan *et al*., 2014; Aamir Jalal, 2021). They are said to have multipurpose medicinal effects such as aphrodisiac, carminative, tonic, antiulcer, hypocholesterolemic, and hypoglycaemic activity (Zia *et al*., 2001; Baset *et al*., 2020).

Several animal-centered and patient-centered studies have shown the crude hypoglycemic activity of fenugreek seeds. Fenugreek (*Trigonella foenum-graecum*) seeds have been reported to have hypoglycemic and cholesterol lowering effects in type-1 and type 2 diabetes mellitus patients and in experimental diabetic animals. Many of the beneficial effects of fenugreek in diabetes have been attributed to four bioactive components including diosgenin, 4-hydroxyisoleucine, furostanolie saponins, and the fiber in fenugreek (Aamir Jalal, 2021). A significant decrease in blood glucose level of type 2 diabetic patients were seen after 30 and 60 days of treatment with 20 gm/day supplementation of fenugreek seeds powder (Rehman *et al.,* 2021). Alluri *et al.* (2020) reported a prolonged action in the reduction of blood glucose by *Trigonella foenum-graecum* and the mode of action of the active compounds fenugreek is probably mediated through enhanced secretion of insulin from the β cells of Langerhans or through extra pancreatic mechanism. Marine *et al.* (2020), revealed that fenugreek showed significant improvement in blood glucose, renal and liver functions in an animal trial. Ahmad *et al.* (2022) found that cinnamon and fenugreek seeds are effective on blood glucose, HbA1C, serum cholesterol and triglyceride in newly diagnosed type 2 diabetic subjects. Radhika *et al.* (2021) reported a significant reduction in fasting blood sugar levels among type 2 diabetic subjects with supplementation of fenugreek seeds water and ladies finger water. Singh *et al.* (2022), reported that 4 Hydroxyisoleucine (4 HIL), a non-proteinogenic amino acid isolated from the fenugreek seeds has potential antihyperglycemic activity without any toxic effects in type 2 diabetic rats. Geberemeskel *et al.* (2019), studied the antidiabetic effect of fenugreek seed powder solution on hyperlipidemia in diabetic patients they found that fenugreek seed powder had a distinct effect in improving lipid metabolism in type 2 diabetic patients with no adverse effects, thereby providing new alternatives for the clinical management of type 2 diabetes. However, the patient's lifestyle and the socio-demographic effects are often neglected. In low-income countries, individuals with diabetes often do not have access to appropriate medications due to a lack of financial resources (Neelakantan *et al*., 2014). It was hypothesized that fenugreek seed supplementation is a feasible choice in diabetes management for its efficacy and cost-effectiveness. In this study, the association between the consumption of fenugreek seed powder with blood glucose levels and diabetes status among the selected type 2 DM patients were examined using a randomized controlled study.

2. Materials and methods

2.1 Study design

The study was conducted using a randomized controlled design, involving an experimental group, which was given fenugreek juice daily for two months, and a control group, which was maintained without administering any intervention. A single-centered, single-blinded, 60-day long randomized case-control trial (RCT), approved by the institutional review board and ethical committee of Hajee Mohammad Danesh and Science and Technology University, Dinajpur, Bangladesh was performed maintaining international ethical standards guaranteed by the Declaration of Helsinki and its successive amendments. Written informed consent was obtained from all participants.

2.2 Location of the study

The study was conducted in Bogura district, located 210 km north-west of the capital city of Bangladesh

https://doi.org/10.26656/fr.2017.7(6).035

between July 2018 and December 2018. Bogura metropolitan area has a population of about 0.7 million which is covered by 5 government and 4 private hospitals. Bogura Diabetic Hospital (V9M4+FW Bogura) is the only specialized hospital for diabetes; hence, it was selected as the study center.

2.3 Sample size calculation

Based on the desired power, effect size, and level of confidence, researchers suggest that a pilot study should have 20 to 150 samples (Whitehead, 2016). Using Cochran's formula with 95% confidence intervals, 50% probability, 10% margin of error, 0.5 design effects, and 5% chance of loss to follow-up, which generated a target of 51 subjects required to have a significant difference between the controlled and exposed group (Cochran, 1977). The population frame was randomized using Research Randomizer with 26 each in both controlled and exposed arms (Urbaniak and Plous, 2018).

2.4 Selection of subjects

Type 2 diabetic men and women receiving regular care from Bogura Diabetic Hospital for at least 6 months were invited to participate in the study. Geriatric patients, pregnant or lactating mothers, and patients with chronic disease or systemic disease were excluded from the study. Initially, 116 patients were briefed on the nature and purpose of the study following which written consent was obtained from those willing to participate (n = 51). The consenting subjects were exposed to scrutiny using the following criteria. The eligible diabetic patients were included those having diagnosed with type 2 DM, obesity and/or metabolic syndrome, aged between 30–60 years, Patients on insulin or any oral hypoglycemic therapy, HbA1C of more than 8%. Furthermore, patients with severe diseases, Pregnant women, below the age of 20 years or above 70 years and those who were not willing to participate in the study and unable to give information were excluded from the study.

2.5 Study tools

A structured questionnaire was developed to collect information from the study subjects, with the guidance of experts. Which was divided into two sections as per the objectives. Part, one consists of selected demographic variables such as age, gender, marital status, religion, educational status, occupation, following diabetic diet, regular exercise, duration of illness and family history (Stringhini *et al*., 2012). The height and weight were taken as anthropometric data to calculate the Body mass index (BMI). Part two contained clinical variables such as assessment of fasting blood glucose and 2 hrs after breakfast. Standardized glucometer (Accu-Chek® Active, Roche, India) and the strip were used to determine blood glucose level.

2.6 Preparation of fenugreek seed powder and consumption

Fenugreek (*Trigonella foenum-gracium*) seeds were collected from the local market Bahadur Bazar of (JJGM+H7 Dinajpur), Bangladesh. Seeds were first sorted and then rinsed with tap water. Afterwards, a cabinet dryer (CO-150, Human Lab Inc, Suwon-Si, Korea) was operated at 40±2^{o}C for 8 hrs to lower the moisture below 10%, wet-basis (Naidu, 2012). A mechanical grinder (Jaipan Mate 850W, Jaipan Industries Ltd, India) was utilized to make fine particles of the seeds and pass through meshes (0.5 mm) to maintain the quality of the powder. Small sachets were used for packaging 10 grams of fenugreek seed powder and stored for distribution. Two hundred gm (20 sachets) of fenugreek seed powder was supplied to each selected subject for 15 days' consumption. The participants were advised to soak 10 gm of fenugreek seed powder in one glass (200 ml) of water overnight (12 hrs) and consume it the next morning on an empty stomach. After every 15 days while measuring the blood glucose level they were again supplied with the fenugreek seed powder for the next 15 days. Likewise, the participants consumed fenugreek seed powder for a period of two months (Kassaian, 2009; Ranade and Mudgalkar, 2017).

2.7 Determination of blood glucose level

Fasting and post-prandial blood glucose levels were measured by the glucometer after an overnight fast and 2 hours following breakfast, respectively. Each set of glucometer readings was read by the trained personnel. A small drop of blood was collected from the fingertip and placed on a strip containing chemicals and electrodes. A chemical reaction between the glucose in the blood and the chemical on the strip gives rise to an electrical current and color change which was then read by the meter. Before starting consumption of fenugreek seed powder fasting and 2 hrs after breakfast blood glucose level (PBG) was measured by glucometer from both the control as well as experimental group and recorded. Fasting and 2 hrs PBG blood glucose level was measured after 15, 30, 45 and 60 days' consumption of fenugreek seed powder.

2.8 Statistical analysis

Analyses were performed by a blinded analyst using statistical software Stata version 16.0 (Stata Corp LLC, Texas, USA). Continuous data were summarized by the mean±SE (Standard Error), and categorical data by number and percentages. Independent two-sample T-test (for continuous variables), and Proportion and Chi-square test (for categorical variables) were used to

https://doi.org/10.26656/fr.2017.7(6).035

compare the differences between the controlled and exposed group. Multivariable linear regression analysis was used to scrutinize the association of both fasting and postprandial blood glucose levels with the intake of the fenugreek diet separately. All prevalence, absolute differences, and crude and adjusted β-coefficients were reported with 95% confidence intervals (CIs).

3. Results

3.1 Baseline characteristics of the study population

The baseline characteristics of the study population by their allocation group are shown in Table 1. The study population consisted of 49 (26 male and 23 female) type 2 diabetes patients. At the baseline, all of the demographic, anthropometric, and metabolic variables were homogenous ($p > 0.05$) between the control and exposed groups. The mean fasting and postprandial blood glucose level was found to be 9.63 mmol/L and 13.92 mmol/L, respectively. No significant differences were observed in fasting and postprandial blood glucose levels among the control and exposed groups. Body Mass Index (BMI) was 24.95, 25.06, and 24.84 concerning mean, control, and exposed groups. However, a few clinical variables e.g. types of treatment, physical activity levels, and diet therapy varied significantly ($p < 0.05$). The majority of the participants (72%) were under drug and diet therapy, whereas 28% followed only diet therapy. The participants were classified into three groups according to their physical activity level and it was observed that 80% of participants in the control group were engaged in moderate activity compared to 45.83% who were engaged in sedentary and moderate activity.

3.2 Association of fasting blood glucose and fenugreek supplementation

Figure 1 represents the day-wise distribution of fasting blood glucose (FBG) levels among the control and exposed groups, on an interval of 15 days up to two months. It is observed that the FBG level of the control group was consistent throughout the study but for the exposed group, the level declined with the progress of the study. A significant reduction in blood glucose level

Table 1. Baseline characteristics of the study population randomized to the intervention of Fenugreek supplementation and analyzed in this study.

Characteristics	Total (n = 49)	Control (n = 25)	Exposed (n = 24)	p-value
Age				
30-39	22 (44.9)	9 (36.0)	13 (54.17)	0.431
40-49	14 (28.57)	8 (32.0)	6 (25.0)	
50-59	13 (26.53)	8 (32.0)	5 (20.83)	
Sex				
Male	26 (53.06)	11 (44.0)	15 (62.5)	0.195
Female	23 (46.94)	14 (56.0)	9 (37.5)	
Highest level of education				
Primary	1 (2.04)	0 (0)	1 (4.17)	0.726
Secondary	11 (22.45)	5 (20.0)	6 (25.0)	
Higher Secondary	24 (58.98)	13 (52.0)	11 (45.83)	
Graduation	13 (26.53)	7 (28.0)	6 (25.0)	
Socioeconomic status				
Lower Class	21 (42.86)	10 (40.0)	11 (45.83)	0.518
Middle Class	18 (36.73)	11 (44.0)	7 (29.17)	
Higher Class	10 (20.41)	4 (16.0)	6 (25.0)	
Body Mass Index				
Overall	24.95±0.26	25.06±0.40	24.84±0.33	0.667
Blood glucose levels				
Fasting blood glucose	9.63±0.29	9.48±0.41	9.78±0.40	0.598
Postprandial blood glucose	13.92±0.32	13.44±0.47	14.43±0.43	0.129
Type of therapy				
Only diet therapy	22 (44.90)	7 (28.0)	15 (62.50)	0.015*
Drug and diet therapy	27 (55.10)	18 (72.0)	9 (37.50)	
Physical activity level				
Sedentary	15 (30.61)	4 (16.0)	11 (45.83)	0.045*
Moderate	31 (63.27)	20 (80.0)	11 (45.83)	
Heavy	3 (6.12)	1 (4.0)	2 (8.33)	

Age, sex, the highest level of education, socioeconomic status, type of therapy, and physical activity level were expressed as frequency (%). Body Mass Index and Blood Glucose levels were expressed as mean±SE. *Significant difference at $p \leq 0.05$.

https://doi.org/10.26656/fr.2017.7(6).035

of the exposed group is observed over the control group. The reduction starts from 15 days and a strong reduction was observed (highly significant) at the end of 60 days.

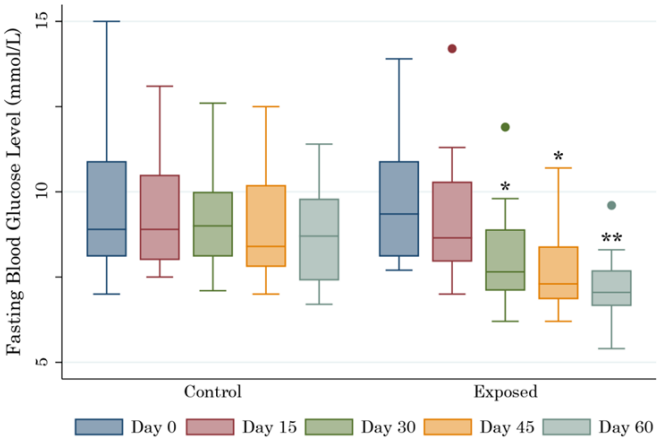

Figure 1. Boxplots of Fasting Blood Glucose Level distribution among the control and exposed groups randomized to the intervention of Fenugreek supplementation, arranged in the order of observation days. *Significant difference at $p \leq 0.05$, **Significant difference at $p < 0.001$.

Table 2 represents the relative impacts of age, gender, level of education, diet, physical activity, and BMI on fasting and postprandial blood glucose levels upon supplementation with fenugreek seed powder. This indicates that fenugreek supplementation had a significant association with FBG level for both adjusted and unadjusted linear regression models. The exposed group had 1.83 mmol/L significantly lower FBG than the control group (95% CI: -2.65, -1.01; $p < 0.001$). The difference increased to 2.38 mmol/L (95% CI: -3.45, -1.32; $p<0.001$) when adjusted for covariates i.e. age, sex, education, socioeconomic status (SES), BMI, diabetes history and duration, type of therapy, and patient's physical activity level. SES of the participants also showed a significant difference ($p < 0.05$) between lower, middle and higher income groups during the univariable assessment but was found to be homogenous when all other covariates were adjusted.

Table 2. Linear regression analysis of the effect of Fenugreek seed supplementation on fasting blood glucose level.

Characteristics	Univariable analysis		Multivariable analysis	
	β-coefficient [b] [95% CI]	p-value	β-coefficient [a] [95% CI]	p-value
Fasting blood glucose (vs. Control Group)				
Exposed Group	-1.83 [-2.65, -1.01]	<0.001**	-2.38 [-3.45, -1.32]	<0.001**
Age (vs. 40-49)				
30-39	-0.16 [-1.33, 1.01]	0.783	-0.29 [-1.38, 0.81]	0.601
50-59	-0.75 [-2.07, 0.56]	0.255	-0.49 [-2.06, 1.07]	0.528
Sex (vs. Male)				
Female	0.20 [-0.78, 1.18]	0.685	0.18 [-1.00, 1.36]	0.758
Highest level of Education (vs. Primary school)				
Secondary School	2.12 [-1.47, 5.72]	0.240	2.01 [-2.48, 6.50]	0.369
Higher Secondary School	2.27 [-1.25, 5.78]	0.201	1.51 [-3.07, 6.10]	0.506
Graduate School	2.38 [-1.19, 5.96]	0.186	1.70 [-3.10, 6.50]	0.475
Socioeconomic Status (vs. Middle Class)				
Lower Class	-1.13 [-2.16, -0.11]	0.031*	-0.28 [-1.59, 1.03]	0.670
Higher Class	-1.63 [-2.89, -0.37]	0.013*	-0.76 [-2.20, 0.69]	0.297
Body Mass Index (vs. Control Group)				
Overall	-0.14 [0.42, 0.13]	0.295	-0.09 [-0.38, 0.19]	0.505
Family history of diabetes (vs. No)				
Yes	0.29 [-0.73, 1.32]	0.570	-0.29 [-1.25, 0.67]	0.544
Duration of diabetes (vs. 1-5 years)				
Less than 1 year	-0.79 [-1.86, 0.29]	0.148	0.27 [-0.86, 1.41]	0.624
More than 5 years	-1.30 [-2.69, 0.09]	0.066	-0.55 [-2.27, 1.16]	0.515
Type of therapy (vs. Only diet therapy)				
Drug and diet therapy	-0.55 [-1.52, 0.42]	0.263	-0.94 [-1.97, 0.10]	0.074
Physical activity level (vs. Moderate)				
Sedentary	-0.43 [-1.51, 0.64]	0.422	0.91 [-0.34, 2.16]	0.147
Heavy	-1.08 [-3.15, 0.98]	0.296	0.21 [-2.37, 2.79]	0.870

[a] β-coefficient were adjusted

[b] Crude

*Significant difference at $p \leq 0.05$, **Significant difference at $p < 0.001$.

https://doi.org/10.26656/fr.2017.7(6).035

3.3 Association of postprandial blood glucose and fenugreek supplementation

Figure 2 denotes the day-wise distribution of postprandial blood glucose (PBG) levels among the control and exposed groups, with an interval of every 15 days of fenugreek supplementations. Visual inspection suggested that the PBG level of the control group was inconsistent with ups and downs throughout the study but for the exposed group, the level declined with the progress of the study. It is clearly understood that postprandial blood glucose levels were reduced in the experimental group than in the control group. The reduction of PBG starts after 15 days of supplementation and gradually it started reducing significantly, which was highest at the end of 60 days.

Fenugreek supplementation had a significant association with PBG level for both adjusted and unadjusted linear regression models (Table 3). The exposed group had 3.65 mmol/L significantly lower PBG than the control group (95% CI: -4.65, -2.64; p < 0.001). The difference increased to 4.18 mmol/L (95% CI: -5.41, -2.92; p<0.001) when adjusted for covariates i.e. age, sex, education, SES, BMI, diabetes history and duration, type of therapy, and patient's physical activity level.

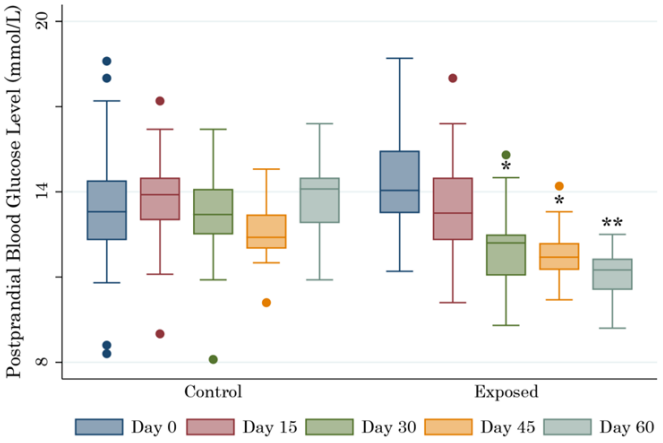

Figure 2. Boxplots of Postprandial Blood Glucose Level distribution among the control and exposed group randomized to the intervention of Fenugreek supplementation, arranged in the order of observation days. *Significant difference at p ≤ 0.05, **Significant difference at p < 0.001.

Table 3. Linear regression analysis of the effect of Fenugreek seed supplementation on postprandial blood glucose level.

Characteristics	Univariable analysis		Multivariable analysis	
	β-coefficient [b] [95% CI]	p-value	β-coefficient [a] [95% CI]	p-value
Postprandial blood glucose (vs. Control Group)				
Exposed Group	-3.65 [-4.65, -2.64]	< 0.001**	-4.18 [-5.41, -2.95]	< 0.001**
Age (vs. 40-49)				
30-39	-0.62 [-2.38, 1.14]	0.484	-0.64 [-1.92, 0.63]	0.311
50-59	-0.82 [-2.80, 1.17]	0.411	-0.19 [-2.01, 1.63]	0.837
Sex (vs. Male)				
Female	1.35 [-0.07, 2.76]	0.062	0.86 [-0.50, 2.23]	0.206
Highest level of Education (vs. Primary school)				
Secondary School	1.04 [-4.42, 6.49]	0.704	-0.65 [-5.86, 4.56]	0.801
Higher Secondary School	1.31 [-4.02, 6.64]	0.624	-1.32 [-6.64, 3.99]	0.615
Graduate School	1.52 [-3.90, 6.95]	0.574	-0.68 [-6.25, 4.88]	0.804
Socioeconomic Status (vs. Middle Class)				
Lower Class	-1.51 [-3.09, 0.07]	0.061	-0.78 [-2.30, 0.74]	0.303
Higher Class	-1.87 [-3.81, 0.08]	0.059	-1.11 [-2.78, 0.57]	0.187
Body Mass Index (vs. Control Group)				
Overall	-0.23 [-0.64, 0.18]	0.266	-0.18 [-0.52, 0.15]	0.264
Family history of diabetes (vs. No)				
Yes	0.88 [-0.64, 2.39]	0.252	-0.02 [-1.14, 1.10]	0.972
Duration of diabetes (vs. 1-5 years)				
Less than 1 year	-0.56 [-2.22, 1.09]	0.497	-0.65 [-1.96, 0.66]	0.321
More than 5 years	-0.96 [-3.11, 1.18]	0.369	-0.65 [-2.63, 1.34]	0.511
Type of therapy (vs. Only diet therapy)				
Drug and diet therapy	-0.40 [-1.87, 1.07]	0.583	-1.72 [-2.92, -0.52]	0.006*
Physical activity level (vs. Moderate)				
Sedentary	-1.42 [-2.99, 0.14]	0.074	0.60 [-0.85, 2.05]	0.404
Heavy	-1.51 [-4.52, 1.51]	0.320	-0.49 [-3.48, 2.50]	0.741

[a] β-coefficient were adjusted
[b] Crude
*Significant difference at p ≤ 0.05, **Significant difference at p < 0.001.

https://doi.org/10.26656/fr.2017.7(6).035

Table 4. Diabetes status of the patients after the completion (60 days) of the Fenugreek supplementation study.

Characteristics	Overall n = 49 (%)	Allocation		p-value
		Control Group n = 25 (%)	Exposed Group n = 24 (%)	
Diabetic state	44 (89.80)	25 (100)	19 (79.17)	0.024*
Non-diabetic state	5 (10.20)	0(0)	5 (20.83)	

*Significant difference at $p \leq 0.05$

Although the type of therapy was found homogenous ($p = 0.583$) during the univariable assessment, adjustment of all other covariates showed that those who took medications with diet had 1.72 mmol/L significantly lower PBG (95% CI: -2.92, -0.52; $p = 0.006$).

3.4 Efficacy of fenugreek supplementation

The diabetic status of the patients after the completion (60 days) of fenugreek supplementation is revealed in Table 4. Data are tabulated based on the ascertainment of the disease. Fenugreek supplementation had a significant ($p < 0.05$) impact on the patient's diabetic status. At the end of the study, all of the patients from the controlled group retained their diabetic state, while 5 patients from the exposed group were declared as non-diabetic. Fenugreek supplementation accounted for 20.83% relative risk reduction among type 2 DM patients.

4. Discussion

The rate of progression to diabetes during the intervention in controls and fenugreek group is determined in the present study. No major harmful side effects of fenugreek were reported in all included studies.

4.1 Baseline characteristics of the study population

Corresponding to the current investigation (Table 1), the exposed group (62.50%) followed only diet therapy, compared to the control group (28%) by a considerable margin ($p < 0.05$). However, dietary prescriptions must be customized regarding the patient's eating habits and give a good distribution of macronutrients according to the metabolic balance and the nutritional needs of the patient. Physical exercise must also be adapted to each patient's abilities and precisely coordinated with nutritional recommendations (Gbakayoro *et al*., 2018). Physical activity differed considerably between the control and exposed groups, according to the findings. Despite the relevance and positive impact of expedient food therapy follow-up and regular physical activity on diabetes balance, this study found that 63.27% (Table 1) of diabetes network patients reported engaging in moderate physical activity. In both the control and exposed groups, it was also observed that most diabetic patients prefer sedentary and moderate physical exercise to vigorous activity. However, over the last decade, the benefits of regular physical activity have been proven, both in type 2 diabetes prevention (a 50% reduction in the incidence of type 2 diabetes in people with high metabolic risk) and type 2 diabetes management for improved glycemic control (Duclos *et al*., 2013). All existing recommendations point out that an appropriate diet and regular physical activity are the "keystone" of the therapeutic management of diabetes.

4.2 Association of fasting blood glucose and fenugreek supplementation

The mean initial fasting blood glucose level of the control and fenugreek exposed group was above the normal level (> 8 mmol/L, Table 1). There was a gradual reduction in the fasting as well as postprandial blood glucose level observed among the exposed group than the control group at the end of the 60-day intervention (Figure 1). A significant difference in the fasting blood glucose level was observed in the exposed group, while no significant difference was observed among the control group. Several authors have found significant improvement in diabetes management as measured by fasting blood sugar levels while assessing the impact of fenugreek seeds on blood glucose control (Ranade and Mudgalkar, 2017). However, the dose of fenugreek seeds supplementation also affects blood sugar levels, and a higher dose shows more hypoglycemic effects, the dose ranges from 2 to 25 g/day (Ranade and Mudgalkar, 2017; Ahmad *et al*., 2020).

4.3 Association of postprandial blood glucose and fenugreek supplementation

Hyperglycemic effects during the study period FPG ($p < 0.05$) and PPBG ($p < 0.01$) reduced significantly at the end of 60 days (Figure 2) in the exposed group. The hypoglycemic effect of fenugreek seed powder discussed in this study is well supported by a few studies (Gaddam *et al*., 2015). Previous animal investigations have pointed out that fenugreek seeds have broad therapeutic efficacy, implying that fenugreek may likewise include a component that stimulates insulin production or sensitization, besides lowering postprandial glucose levels (Verma *et al*., 2016; Alluri *et al*., 2020). Various studies depicted a significant reduction ($p < 0.001$) in the postprandial blood glucose levels in diabetic rats on treatment with fenugreek formulation (Kumar and Sinha

https://doi.org/10.26656/fr.2017.7(6).035

2012; Singh *et al*., 2022). Whole fenugreek raw seeds, extracted seed powder, cooked seeds (25 g) and gum isolate of seeds (5 g) decreased postprandial glucose levels, whereas degummed seeds (25 g) showed little effect (Neelakantan *et al*., 2014). In addition, a few clinical trials have discussed using either 15 g of fenugreek seed powder with meals reported a reduced rise in blood glucose after the meal or taking 2.5 g of fenugreek seed twice a day for 3 months reduced blood glucose levels in people with mild type 2 diabetes (Verma *et al*., 2016). But overdosing can have negative health consequences, resulting in a few side effects, such as flatulence, diarrhea, and dizziness when taken at the prescribed dose (Syed *et al*., 2020). Hence, the current study used 10 g of seed powder to eliminate the aforementioned issues while still adhering to the prior findings.

4.4 Progression to diabetes

Although a random sampling approach was employed and the fact that a small number of volunteers have been recruited in this investigation, data were collected precisely. Besides, the information via survey might be biased as patients mostly have awareness regarding health, which may differ in results from a person without awareness. In addition, risk factors such as dietary, alcohol and tobacco consumption were excluded in this study. Accordingly, these studies on fenugreek seed powder showed a significant ($p \leq 0.05$) fall in blood glucose levels after the completion of 60 days when compared to controls (Table 4). In a similar study with 3 years follow-up, it was found that glucose levels normalized in fenugreek subjects than the controls (Gaddam *et al*., 2015). Thus, the present findings reveal that the worsening of diabetes can be controlled by the consumption of fenugreek seed powder as it helps in managing glycemic control in diabetic patients.

5. Conclusion

Diabetes mellitus has a high prevalence, morbidity, and mortality globally. Management of type 2 diabetes is difficult with synthetic drugs as they cause many side effects and have some limitations. This study provides evidence that a simple complementary addition of fenugreek seed powder has a synergistic effect on fasting and postprandial blood glucose levels within 60 days of treatment. Therefore, fenugreek can be used effectively as a sugar-lowering agent specifically for patients with Type 2 diabetes. However, this investigation paves the way to do further randomized control trials in this regard with a large sample size to increase the strength.

Conflict of interest

The authors declare that they have no financial or non-financial conflict of interest in the subject matter or materials discussed in this article.

Acknowledgments

The authors are grateful to the authority of Bogura Diabetic Hospital for permitting them to conduct the study. The authors also thank all the participants and experienced personnel for taking part in this study.

References

Aamir Jalal, A.M. (2021). Review Article: The use of fenugreek supplementation in diabetes. *Recent Research in Endocrinology and Metabolic Disorder*, 3(1), 31-36. http://dx.doi.org/10.33702/rriemd.2021.3.1.5

Ahmad, A., Amir, R.M., Ameer, K., Ali, S.W., Siddique, F., Hayat, I., Ahmad, Z. and Faiz, F. (2020). Ameliorative effects of fenugreek (*Trigonella foenum-graecum*) seed on type 2 diabetes. *Food Science and Technology*, 41(2), 349-354. https://doi.org/10.1590/fst.03520

Ahmad, H., Kashif, S., Afreen, A., Safdae, M. and Ahmed, Z. (2022). Comparative effect of Fenugreek and Cinnamon on management of newly diagnosed cases of Type 2 Diabetes Mellitus. *Food Science Technology (Campinas)*, 42, 1-7. https://doi.org/10.1590/fst.47720

Alluri, R., Ghelani, H., Devi, S.A., Inampudi, V. and Nammi, S. (2020). Preclinical investigation of the acute effects of *Trigonella foenum-graecum* seed powder on blood glucose in normal and alloxan-induced diabetic rabbits. *Obm Integrative and Complementary Medicine*, 5(3), 036. https://doi.org/10.21926/obm.icm.2003036

American Diabetes Association (ADA). (2012). Standards of medical care in diabetes--2012. Diabetes care, 35, S11–S63. https://doi.org/10.2337/dc12-s011

Baset, M.E., Ali, T.I., Elshamy, H., El Sadek, A.M., Sami, D.G., Badawy, M.T., Abou-Zekry, S.S., Heiba, H.H., Saadeldin, M.K. and Abdellatif, A. (2020). Anti-diabetic effects of fenugreek (*Trigonella foenum-graecum*): A comparison between oral and intraperitoneal administration - an animal study. *International Journal of Functional Nutrition*, 1(1), 1-9. https://doi.org/10.3892/ijfn.2020.2

Campbell-Tofte, J.I., Mølgaard, P. and Winther, K. (2012). Harnessing the potential clinical use of medicinal plants as anti-diabetic agents. *Botanics:*

Targets and Therapy, 2, 7-19. http://dx.doi.org/10.2147/BTAT.S17302

Cochran, W.G. (1977). Sampling techniques. 3rd ed. New York: John Wiley and Sons.

Duclos, M., Oppert, J.M., Verges, B., Coliche, V., Gautier, J.F., Guezennec, Y. and Strauch, G. (2013). Physical activity and type 2 diabetes. Recommendations of the SFD (Francophone Diabetes Society) diabetes and physical activity working group. *Diabetes and Metabolism*, 39(3), 205-216. http://dx.doi.org/10.1016/j.diabet.2013.03.005

Gaddam, A., Galla, C., Thummisetti, S., Marikanty, R.K., Palanisamy, U.D. and Rao, P.V. (2015). Role of Fenugreek in the prevention of type 2 diabetes mellitus in prediabetes. *Journal of Diabetes and Metabolic Disorders*, 14(1), 1-10. http://doi.org/10.1186/s40200-015-0208-4

Gbakayoro, J.B., Irié, A.B.Z.B., Anvoh, Y.B., Abodo, J.R. and Brou, K. (2018). Assessment of Dietary Management in AODCI-WDF Diabetes Network in Provinces of Côte d'Ivoire. *International Journal of Clinical Nutrition and Dietetics*, 4(2), 137-142. https://doi.org/10.15344/2456-8171/2018/137

Geberemeskel, G.A., Debebe, Y.G. and Nguse, N.A. (2019). Antidiabetic effect of fenugreek seed powder solution (*Trigonella foenum-graecum* L.) on hyperlipidemia in diabetic patients. *Journal of Diabetes Research*, 2019, 8507453. http://doi.org/10.1155/2019/8507453

Grant, R.W. and Kirkman, M.S. (2015). Trends in the evidence level for the American Diabetes Association's "Standards of Medical Care in Diabetes" from 2005 to 2014. *Diabetes Care*, 38(1), 6-8. https://doi.org/10.2337/dc14-2142

Grintsova, O., Maier, W. and Mielck, A. (2014). Inequalities in health care among patients with type 2 diabetes by individual socio-economic status (SES) and regional deprivation: a systematic literature review. *International Journal for Equity in Health*, 13(1), 1-14. https://doi.org/10.1186/1475-9276-13-43

Hong, L., Guo, Z., Huang, K., Wei, S., Liu, B., Meng, S. and Long, C. (2015). Ethnobotanical study on medicinal plants used by Maonan people in China. *Journal of Ethnobiology and Ethnomedicine*, 11(1), 1-35.

International Diabetes Federation (IDF). (2021). IDF Diabetes Atlas. 10th ed. Brussels: International Diabetes Federation. Retrieved on July 7, 2021 from IDF Website:https://diabetesatlas.org/idfawp/resource-files/2021/07/IDF_Atlas_10th_Edition_2021.pdf

Kassaian, N., Azadbakht, L., Forghani, B. and Amini, M. (2009). Effect of fenugreek seeds on blood glucose and lipid profiles in type 2 diabetic patients. *International Journal for Vitamin and Nutrition Research*, 79(1), 34-39. https://doi.org/10.1024/0300-9831.79.1.34

Kaul, K., Tarr, J.M., Ahmad, S.I., Kohner, E.M and Chibber, R. (2013). Introduction to Diabetes Mellitus. In Ahmad, S.I. (Eds). Diabetes. Advances in Experimental Medicine and Biology, p. 1-11. New York, NY: Springer. https://doi.org/10.1007/978-1-4614-5441-0_1

Kumar, R.V. and Sinha, V.R. (2012). A novel synergistic galactomannan-based unit dosage form for sustained release of acarbose. *Aaps Pharmscitech*, 13(1), 262-275. https://doi.org/10.1208/s12249-011-9724-9

Marine, E.B., Tasneem, I.A., Hanan, E., Ahmed, M. El Sadek., Diana, G.S., Marwa, T.B., Sara, S.A.-Z., Hana, H.H., Mona, K.S. and Ahmed, A. (2020). A comparison between oral and intraperitoneal administration - an animal study. *International Journal of Functional Nutrition*, 1, 2.

Naidu, M.M., Shyamala, B.N., Naik, J.P., Sulochanamma, G. and Srinivas, P. (2011). Chemical composition and antioxidant activity of the husk and endosperm of fenugreek seeds. *LWT-Food Science and Technology*, 44(2), 451-456. https://doi.org/10.1016/j.lwt.2010.08.013

Naidu, M.M., Khanum, H., Sulochanamma, G., Sowbhagya, H.B., Hebbar, U.H., Prakash, M. and Srinivas, P. (2012). Effect of drying methods on the quality characteristics of fenugreek (*Trigonella foenum-graecum*) greens. *Drying Technology*, 30(8), 808-816. https://doi.org/10.1080/07373937.2012.666607

Neelakantan, N., Narayanan, M., De Souza, R.J. and Van Dam, R.M. (2014). Effect of fenugreek (*Trigonella foenum-graecum* L.) intake on glycemia: a meta-analysis of clinical trials. *Nutrition Journal*, 13(1), 1-11. https://doi.org/10.1186/1475-2891-13-7

Patel, D.K., Kumar, R., Laloo, D. and Hemalatha, S. (2012). Diabetes mellitus: an overview on its pharmacological aspects and reported medicinal plants having antidiabetic activity. *Asian Pacific Journal of Tropical Biomedicine*, 2(5), 411-420. https://doi.org/10.1016/S2221-1691(12)60067-7

Radhika, R., Navaneetha, M., Ravichandran, K. and Hemavathi, P. (2021). Comparing the effect of ladies' finger water with fenugreek seeds water on the blood glucose level among subjects with type 2 diabetes mellitus-a randomized controlled trial. *International Journal of Clinical Trials*, 8(1), 10-16. http://www.ijclinicaltrials.com pISSN 2349-3240 |

eISSN 2349-3259

Ranade, M. and Mudgalkar, N. (2017). A simple dietary addition of fenugreek seed leads to the reduction in blood glucose levels: A parallel group, randomized single-blind trial. *AYU (An International Quarterly Journal of Research in Ayurveda)*, 38(1), 24–27. https://doi.org/10.4103/ayu.AYU_209_15

Rehman, M.H.U., Ahmad, A., Amir, R.M., Ameer, K., Ali, S.W., Siddique, F., Hayat, I., Ahmad, Z. and Faiz, F. (2021). Ameliorative effects of fenugreek (*Trigonella foenum-graecum*) seed on type 2 diabetes. *Food Science and Technology*, 41(2), 349-354.

Singh, P., Ishteyaque, S., Prajapati, R., Yadav, K.S., Singh, R., Kumar, A., Sharma, S., Narender, T. and Mugale, M.N. (2022). Assessment of antidiabetic effect of 4-HIL in type 2 diabetic and healthy Sprague Dawley rats. *Human and Experimental Toxicology,* 41, 1-11. https://doi.org/10.1177/09603271211061873

Spiller, H.A. and Sawyer, T.S. (2006). Toxicology of oral antidiabetic medications. *American Journal of Health-System Pharmacy*, 63(10), 929-938. https://doi.org/10.2146/ajhp050500

Stringhini, S., Berkman, L., Dugravot, A., Ferrie, J.E., Marmot, M., Kivimaki, M. and Singh-Manoux, A. (2012). Socioeconomic status, structural and functional measures of social support, and mortality: The British Whitehall II Cohort Study, 1985–2009. *American Journal of Epidemiology*, 175(12), 1275-1283. https://doi.org/ 10.1093/aje/kwr461

Syed, Q.A., Rashid, Z., Ahmad, M.H., Shukat, R., Ishaq, A., Muhammad, N. and Rahman, H.U.U. (2020). Nutritional and therapeutic properties of fenugreek (*Trigonella foenum-graecum*): a review. *International Journal of Food Properties*, 23(1), 1777-1791. https://doi.org/10.1080/10942912.2020.1825482

Urbaniak, G.C. and Plous, S. (2018). Research Randomizer (Version 4.0). Retrieved on September 30, 2018 from Randomizer Website: www.randomizer.org Software

Verma, N., Usman, K., Patel, N., Jain, A., Dhakre, S., Swaroop, A. and Bagchi, D. (2016). A multicenter clinical study to determine the efficacy of a novel fenugreek seed (*Trigonella foenum-graecum*) extract (Fenfuro™) in patients with type 2 diabetes. *Food and Nutrition Research*, 60(1), 32382. https://doi.org/10.3402/fnr.v60.32382

Whitehead, A.L., Julious, S.A., Cooper, C.L. and Campbell, M.J. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, 25(3), 1057-1073. https://doi.org/10.1177/0962280215588241

Zia, T., Hasnain, S.N. and Hasan, S.K. (2001). Evaluation of the oral hypoglycaemic effect of *Trigonella foenum-graecum* L. (methi) in normal mice. *Journal of Ethnopharmacology*, 75(2-3), 191-195. https://doi.org/10.1016/s0378-8741(01)00186-6

