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Research Article

Effects of *Momordica charantia* (Bittergourd) and *Trigonella foenum-graecum* (Fenugreek) Supplements in Type-2 Diabetics Taking Allopathic Drugs

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ABSTRACT

Background: Bittergourd fruit and Fenugreek seeds are the herbal supplements well known with glucose and lipid-lowering properties.**Objective:** To assess the effects of Bittergourd and Fenugreek supplements in Type-2 diabetics taking allopathic drugs on blood sugar and lipid profile.**Methods:** Open-label, 4-parallel-group, prospective interventional clinical trial was conducted on 48 Type-2 diabetics. They were divided into four groups of 12 each. Group I received allopathic drugs alone, Group II, III and IV received supplementation of Bittergourd juice, Fenugreek seeds and Bittergourd juice+Fenugreek seeds together respectively. Fasting blood sugar (FBS), postprandial blood sugar (PPBS) and fasting lipid profile were measured on day 0, 7, 15, 30 and 90. P-value was set at 0.05 level of significance. One-way ANOVA and post-hoc multiple comparison by Tukey was applied using SPSS version 21.**Results:** Forty two participants completed the study with no adverse events. Supplementation with Bittergourd juice + Fenugreek on day 90 significantly (p-value=0.021) lowered FBS by 19% (p-value=0.021) and PPBS by 35% (p-value=0.001). Supplementation with Fenugreek and Bittergourd juice+Fenugreek both on day 90 significantly (p-value=0.000) lowered serum cholesterol by 16% and 14%, Serum triglyceride by 16% and 21% and LDL-cholesterol by 18% and 17%; however, only Fenugreek supplementation was significantly (p-value=0.015) able to increase HDL-cholesterol by 10%.**Conclusion:** Effects of different herbal supplements in Type-2 diabetics for 90 days was observed. Bittergourd juice+Fenugreek seeds combination can lower FBS and PPBS. Fenugreek seeds and Bittergourd juice+Fenugreek seeds combination could lower serum cholesterol, Triglyceride and LDL-cholesterol. However, only Fenugreek seeds were capable of increasing serum HDL-cholesterol.**Keywords:** Bittergourd; Fenugreek; Herbal-supplement; Type 2 diabetes mellitus

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INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a growing problem worldwide entailing enormous financial burden and medical care policy issues.¹ According to International Diabetes Federation, the number of individuals with diabetes in 2011 crossed 366 million, with an estimated 4.6 million deaths each year.² The Indian subcontinent has emerged as the capital of this diabetes epidemic. The reported prevalence of

diabetes in adults between the ages of 20 and 79 is as follows: India 8.31%, Bangladesh 9.85%, Nepal 3.03%, Sri Lanka 7.77%, and Pakistan 6.72%. T2DM is treated with synthetic oral hypoglycemic agents like sulphonylureas and biguanides.^{3,4} Recent estimates show that over 80% of people living in developing countries still depend on complementary and alternative medicine for treatment health conditions.⁵ Herbal drugs are considered free from side effects than

synthetic one. They are less toxic, relatively cheap and popular.⁶

Momordica charantia (MC) is known as bitter melon or bitter melon or Karela. It is a perennial climber of cucurbitaceae family and is characterized by warty-fruit like gourds or cucumbers. It contains a mixture of steroidal saponins, phenols, flavonoids, isoflavones, terpenes, anthroquinones and glucosinolates.⁷ Results of animal and human studies show that the fruits, leaves and seed extracts of this plant possesses hypoglycaemic effects. The active compound of MC is believed to be charantin, vicine and polypeptide. Studies have demonstrated the ability of MC extract to increase cellular glucose uptake by enhancing cellular insulin signaling pathways through the up regulation of GLUT4 and PI3K, as well as upregulating PPAR gamma.⁸ In a study conducted on Taiwanese adults, a significant reduction in waist circumference, improvement in diabetes and symptoms of metabolic syndrome has been observed.⁹

Trigonella foenum-graecum (fenugreek) is a plant belonging to the family leguminosae. Its seed is often used as a spice as well as a medicine around the world. The leaves, chemical extracts and shoots of the plant have shown anti-oxidant, anti-diabetic and hypocholesterolaemic properties.¹⁰ It stimulates the tyrosine phosphorylation of the insulin receptor and enhances glucose uptake into cells.¹¹ In rodents, it has been shown to inhibit the intestinal disaccharidases as well as normalize the deranged levels of Pyruvate Kinase and phosphoenol pyruvate carboxykinase enzymes.¹² The blood glucose-lowering activity of karela has been reported in several animal models.¹³ The results of other clinical studies regarding efficacy of MC in T2DM failed to show a significant improvement in the measured parameters.¹⁴⁻¹⁷ There is not sufficient human studies on supplementary effect of *Momordica charantia* and *Trigonella foenum-graecum* in T2DM taking allopathic drugs. Therefore the current study aimed to assess the effects of *Momordica charantia* and *Trigonella foenum-graecum* supplements in type 2 diabetics taking allopathic drugs on fasting blood sugar, postprandial blood sugar and fasting lipid profile.

MATERIALS AND METHODS

Type of study: Open label, 4-parallel-group, prospective interventional clinical trial

Study setting: Outpatient department of Internal Medicine, BPKIHS

Study duration: 1 year (July 2015 to June 2016)

Baseline variables: age, weight, height

Outcome variables: Fasting blood sugar, postprandial blood sugar, fasting lipid profile

Study population: Clinically diagnosed type 2 diabetic patients as per ADA guidelines 2015 were enrolled in the study.¹⁸

Sample size: In a clinical trial conducted by Prasanna et al, the minimum difference of lipid profile (LDL) was reported as 27mg/dL(145mg/dL versus 118mg/dL) between the groups (group 2 and group 3) with standard deviation of 17.6.¹⁹ Using power and sample size program, we enrolled 10 subjects in each group, to be able to reject null hypothesis that the means of two different groups are equal with probability of power 95% and at 5% level of significance. Adding 20% to maintain loss to follow up, total number of subjects was 48 (12 in each group).

Sampling technique: Random sampling

Inclusion Criteria:

- I. Type 2 diabetic patients having fasting blood glucose (FBG) ≥ 126 mg/dL or Two hour Postprandial blood glucose (PPG) ≥ 200 mg/dL or symptoms of hyperglycemia or hyperglycemic crisis + random plasma glucose ≥ 200 mg/dL or HBA1C ≥ 6.5
- II. The patients well oriented to time, place and person
- III. Age of the patients above 30 years
- IV. Patients who agreed to take only physician advised medicine
- V. Patients agreed to take the herbal supplements
- VI. Patients who strictly followed diet advice
- VII. Ambulatory patients
- VIII. Patients who gave inform consent

Exclusion criteria:

- I. Type 1 diabetic patients, secondary diabetes and gestational diabetes.
- II. Age of the patients below 30 years.
- III. Patients with history of hypoglycemia.
- IV. Patients suffering from serious or recurrent infection.
- V. Pregnancy or breastfeeding women, immunodeficiency or HIV patients.
- VI. Patients with findings of any physical or mental abnormality, which would interfere with or be affected by the study procedure.
- VII. Patients who did not will to give informed consent.

Informed consent: Before recruitment and enrollment into the study, each candidate was given a full explanation of the study and the informed written consent was taken.

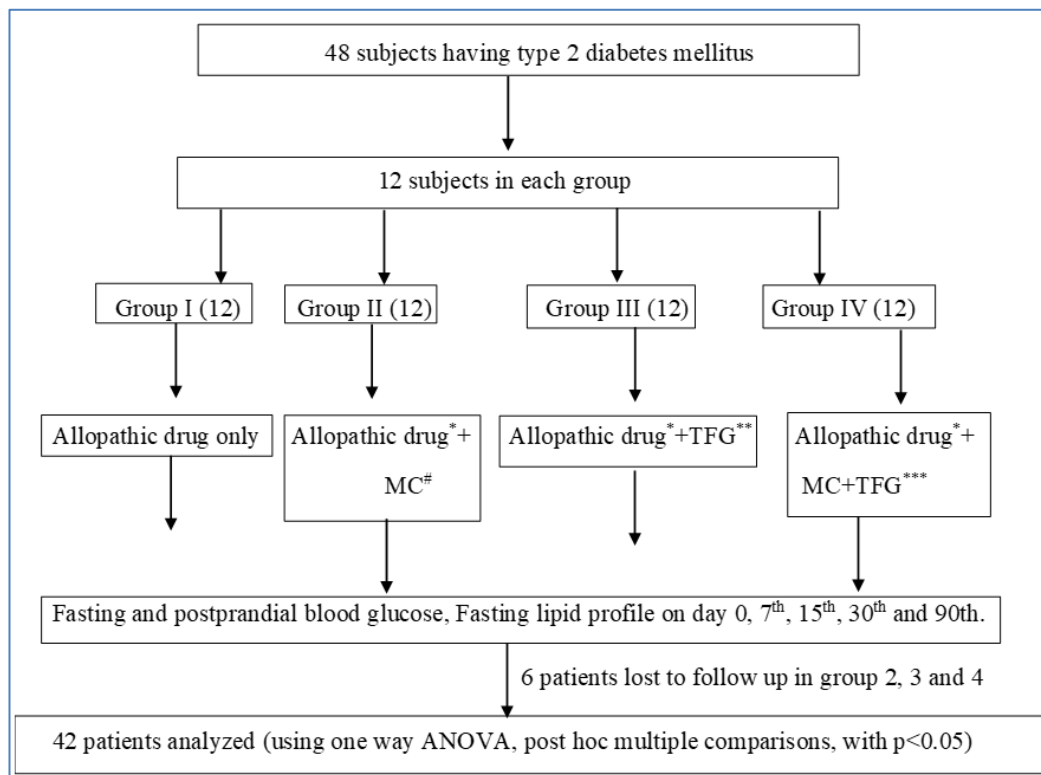


Figure 1: Study flowchart

*Allopathic drug: drug dose adjusted.

#MC: 200ml/day juice of *Momordica charantia* in the morning in empty stomach.

**TFG: 6-7gm/day (1 teaspoonful) *Trigonella foenum-graecum* seeds in empty stomach with mastication and swallowing.

***MC+TFG: 200ml/day juice of *Momordica charantia* and 6-7gm/day (1 teaspoonful) *Trigonella foenum-graecum* seeds taken in a gap of half an hour in empty stomach.

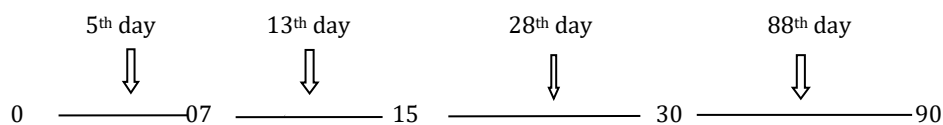
Preparation of *Momordica charantia* juice:

1. One medium sized *momordica charantia* fruit crushed in mixer grinder with water.
2. The resultant passed through tea filter and 200 ml juice to be taken.

Preparation of *Trigonella foenum-graecum* seeds:

1. 6-7 grams of fenugreek (one teaspoonful) was soaked whole night in water.
2. The following morning swallowed with mastication.

Follow up schedule: Patients were informed and reminded of the next visit as following.



Ethical considerations: Ethical clearance was obtained from the Institutional Review Committee, BPKIHS.

Data analysis: Mean, Standard Deviation was calculated for fasting and postprandial blood glucose and lipid profile. Statistical differences between the treatment and control groups were analysed by one way ANOVA followed by Tukey HSD post hoc test for multiple comparisons using SPSS

version 19. P-value of more than 0.05 was considered statistically significance.

RESULTS

A total of 42 Type 2 diabetic patients completed the study among which 18 (42.9%) were male and 24 (57.1%) were female. The mean (\pm SD) age of the patients was 56.6 \pm 1.5 years and mean BMI (\pm SD) was 25.7 \pm 0.5 Kg/m².

Table 1: Baseline characteristics of the patients (n=42)

Variables	Group I (Allopathic drugs only) (n=12)	Group II (Allopathic drugs + Bittergourd juice) (n=10)	Group III (Allopathic drugs + Fenugreek seeds) (n=10)	Group IV (Allopathic drugs + Bittergourd juice + Fenugreek seeds) (n=10)
Age in years	61.9±3.1	57.7±2.9	47.6±2.5	58.5±2.1
Weight in kg	63.5±3.6	58.7±2.3	61.9±2.6	68.0±3.9
Height in meter	1.5±0.02	1.60±0.02	1.57±0.02	1.63±0.02
BMI	25.61±0.90	22.75±0.73	24.91±0.82	25.48±1.25
Fasting blood sugar (mg/dL)	177.08±19.9	156.9±5.4	136.2±8.3	188.7±21.1
Postprandial blood sugar (mg/dL)	236.2±24.9	227.5±33.3	240.7±27.7	372.4±38.7
Total serum cholesterol (mg/dL)	201.08±4.7	197.6±9.3	216.6±10.5	209.7±17.9
Serum Triglycerides (mg/dL)	159.0±10.04	212.7±22.5	194.8±8.4	248.7±45.8
Serum LDL- cholesterol (mg/dL)	114.6±7.09	101.10±12.4	115.7±3.5	125.2±11.4
Serum HDL- Cholesterol (mg/dL)	40.1±2.6	41.1±2.8	40.2±1.9	43.0±2.8

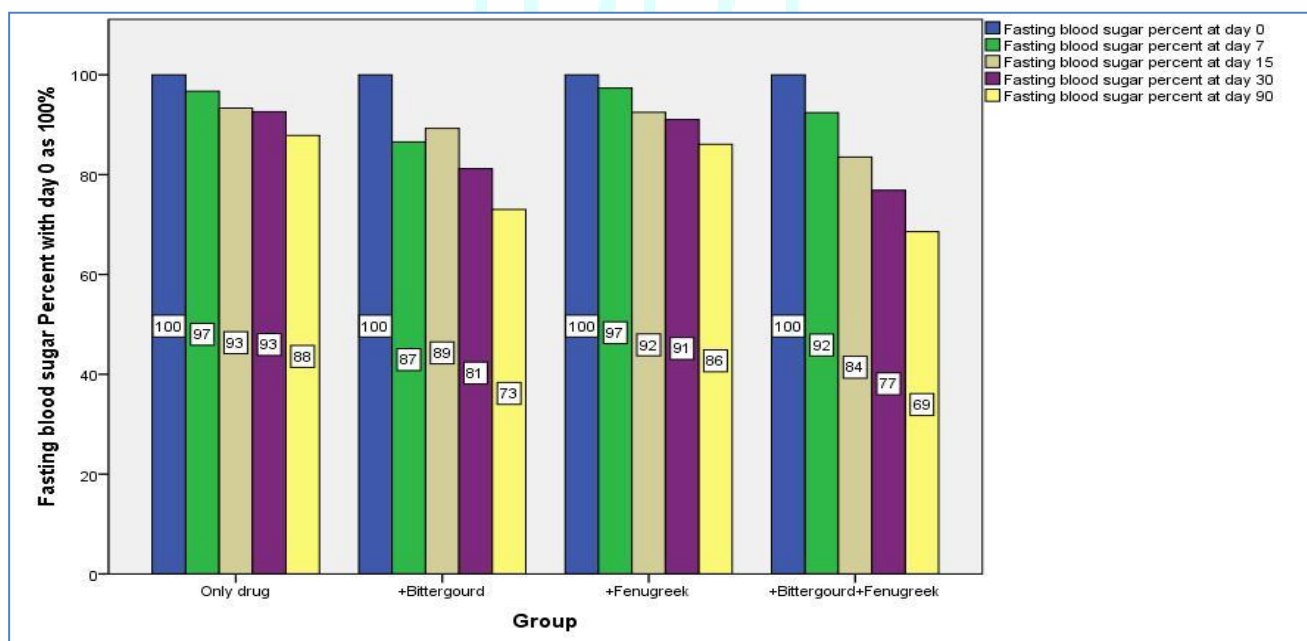
Fasting Blood Sugar

Fasting blood sugar (FBS) had decreased in all four treatment groups. Magnitude of decrease was directly proportional to the duration of treatment (Table2).

Table2: Mean fasting blood sugar (FBS) of 4 treatment groups at day 0, 7, 15, 30 and 90.

Treatment groups of the patients	FBS at day 0	FBS at day 7	FBS at day 15	FBS at day 30	FBS at day 90	P-value
Only drug	177.1	169.0	159.7	157.4	147.5	0.126
Drug+Bittergourd juice	156.9	134.7	137.0	124.8	108.7	0.106
Drug +Fenugreek seeds	136.2	132.3	125.9	122.6	115.4	0.992
Drug +Bittergourd juice +Fenugreek seeds	188.7	173.4	152.2	139.8	122.2	0.021*

*P-value (<0.05) was statistically significant (One-Way ANOVA test and Tukey HSD post hoc test).

**Figure 2: FBS percentage with day 0 as the baseline in four treatment groups**

To make FBS comparable among the groups, we expressed FBS in percentage taking FBS at day 0 as 100% (Figure 2). FBS decreased with duration in each treatment group and was least at day 90 in each group. In between-group comparison of FBS percent on 90th day by One-way ANOVA test was significant (p=0.009). Multiple comparison by post-hoc analysis of FBS on day 90 revealed that group IV receiving bittergourdjuice + fenugreek seeds

supplementation had significantly (p=0.021) lower FBS compared to those taking equivalent allopathic drug alone.

Postprandial Blood Sugar

Postprandial blood sugar (PPBS) had decreased in all four treatment groups. Magnitude of decrease was directly proportional to the duration of treatment (Table 3).

Table3: Mean Postprandial Blood Sugar (PPBS) of 4 treatment groups at day 0, 7, 15, 30 and 90.

Treatment groups of the patients	PPBSat day 0	PPBS at day 7	PPBSat day 15	PPBSat day 30	PPBSat day 90	P-value
Only drug	236.3	224.5	216.9	205.9	197.7	0.712
Drug +Bittergourd juice	227.5	208.1	205.2	184.0	154.5	0.608
Drug +Fenugreek seeds	240.7	230.4	211.2	200.7	184.3	0.830
Drug+Bittergourd juice+Fenugreek seeds	372.4	296.6	249.6	216.0	176.3	0.001*

*P-value (<0.05) was statistically significant (One-Way ANOVA test and Tukey HSD post hoc test).

To make PPBS comparable among the groups, we expressed PPBS in percentage taking PPBS at day 0 as 100% (Figure 3). PPBS decreased with duration in each treatment group and was least at day 90 in each group. In between-group comparison of PPBS percent on 90th day by One-way ANOVA

test was significant (p=0.002). Multiple comparison by post-hoc analysis of PPBS on day 90 (Table3) revealed that group IV receiving bittergourd juice+fenugreek seeds supplementation had significantly (p=0.001) lower PPBS compared to those taking equivalent allopathic drug alone.

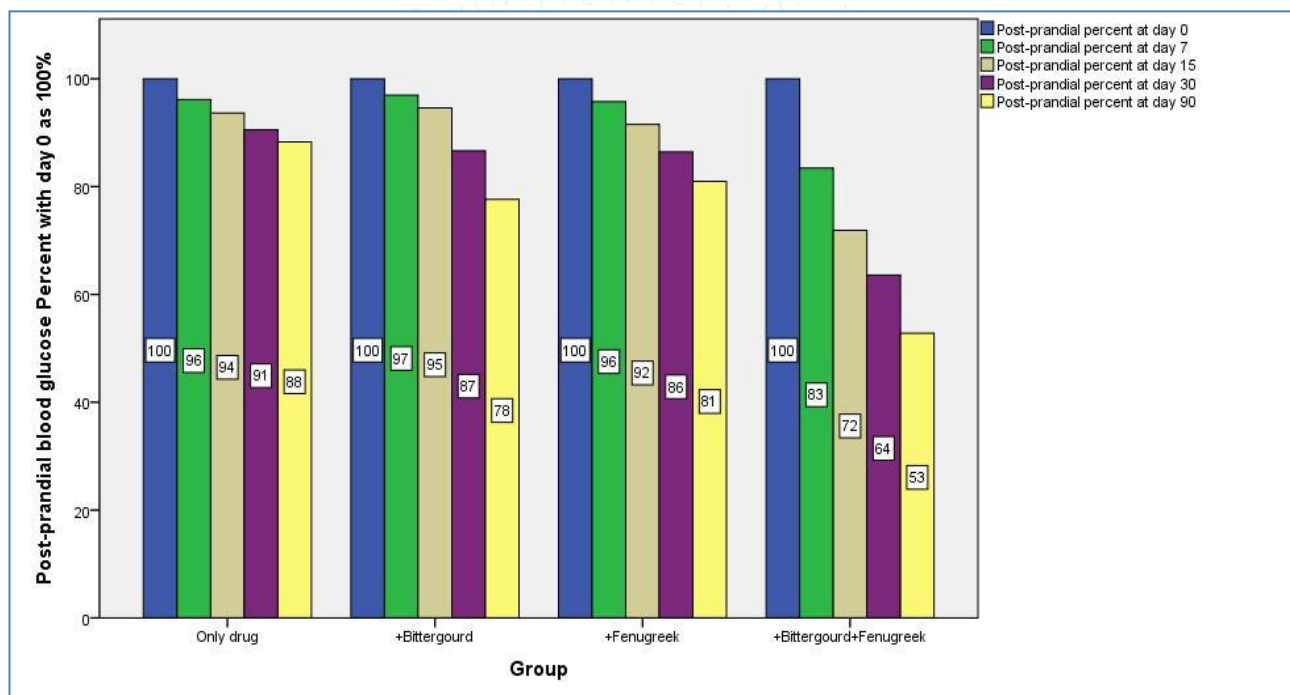


Figure 3: PPBS percentage with day 0 as the baseline in four treatment groups

Total Serum Cholesterol

Total serum cholesterol had decreased in all four treatment groups. Magnitude of decrease was directly

proportional to the duration of treatment (Table 4) except in the group taking allopathic drug alone.

Table 4: Mean Total Serum Cholesterol (Chol) of 4 treatment groups at day 0, 7, 15, 30 and 90.

Group	Cholat day 0	Cholat day 7	Cholat day 15	Cholat day 30	Cholat day 90	P-value
Only drug	201.1	200.0	200.9	200.0	197.9	0.924
Drug +Bittergourd juice	197.6	196.3	193.1	188.5	184.5	0.322
Drug +Fenugreek seeds	216.6	210.3	201.1	191.6	176.5	0.000*
Drug+Bittergourdjuice+Fenugreek seeds	209.7	206.1	200.8	192.7	172.4	0.000*

*P-value (<0.05) was statistically significant (One-Way ANOVA test and Tukey HSD post hoc test).

To make total serum cholesterol comparable among the groups, we expressed serum cholesterol in percentage taking cholesterol at day 0 as 100% (Figure 4). Serum cholesterol decreased with duration in each treatment group and was least at day 90 in each group. In between-group comparison of total serum cholesterol percent on 90th day by One-way ANOVA test was significant ($p=0.000$). Multiple

comparison by post-hoc analysis of total serum cholesterol on day 90 (Table 4) revealed that group III receiving fenugreek seeds supplementation and group IV receiving bittergourd juice+ fenugreek seeds supplementation had significantly ($p=0.000$ and $p=0.000$ respectively) lower total serum cholesterol compared to those taking equivalent allopathic drug alone.

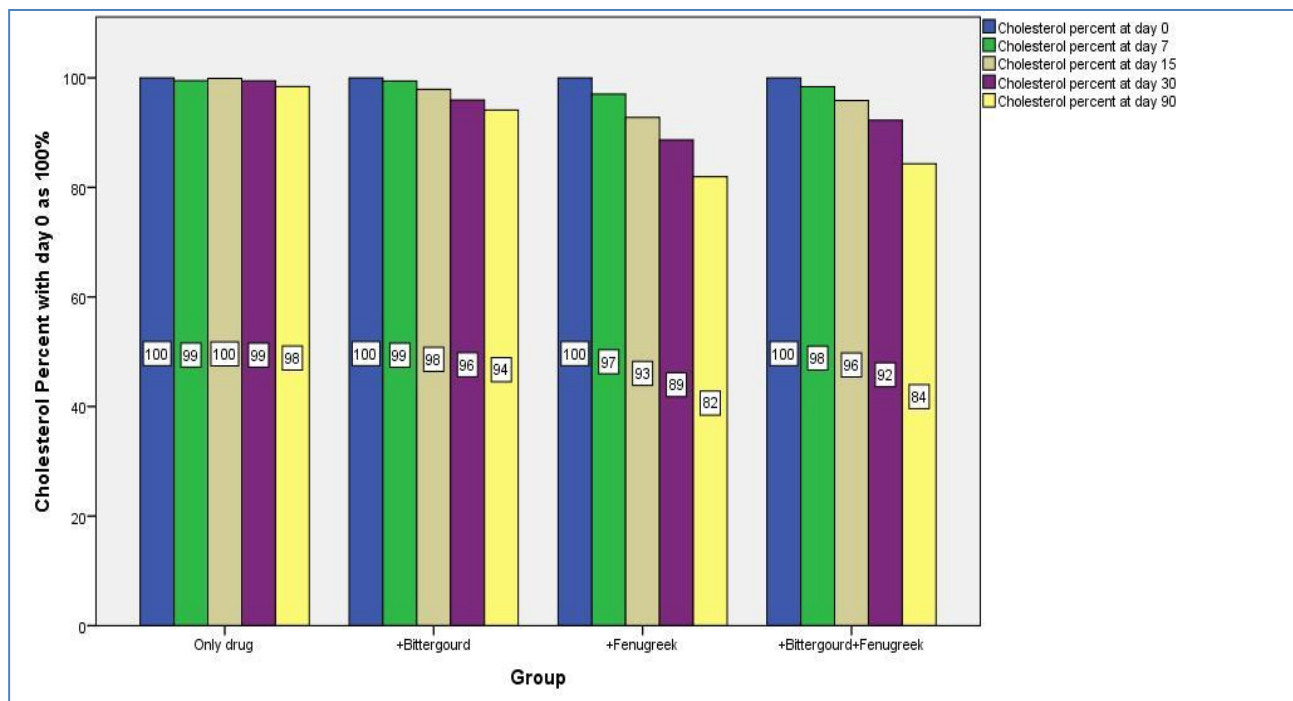


Figure 4: Serum total cholesterol percentage with day 0 as the baseline in four treatment groups

Serum Triglyceride

Serum triglyceride had decreased in all four treatment groups. Magnitude of decrease was directly proportional to

the duration of treatment (Table 5) except in the Group I taking allopathic drugs alone.

Table 5: Mean serum triglyceride (TG) of 4 treatment groups at day 0, 7, 15, 30 and 90.

Group	TG at day 0	TG at day 7	TG at day 15	TG at day 30	TG at day 90	P-value
Only drug	159.0	159.3	158.2	157.2	157.8	0.906
Drug +Bittergourd juice	212.7	210.9	208.9	202.7	198.9	0.520
Drug +Fenugreek seeds	194.8	191.0	187.4	178.3	162.4	0.000*
Drug+Bittergourdjuice+Fenugreek seeds	248.7	245.5	228.9	220.8	176.0	0.000*

*P-value (<0.05) was statistically significant (One-Way ANOVA test and Tukey HSD post hoc test).

To make serum triglyceride comparable among the groups, we expressed it in percentage taking serum triglyceride at day 0 as 100% (Figure 5). Serum triglyceride decreased with duration in each treatment group and was least at day 90 in each group. In between-group comparison of serum triglyceride percent on 90th day by One-way ANOVA test was significant ($p=0.000$). Multiple comparison by post-hoc

analysis of serum triglyceride on day 90 (Table 5) revealed that group III receiving fenugreek seeds supplementation and group IV receiving bittergourd juice+ fenugreek seeds supplementation had significantly ($p=0.000$ and $p=0.000$ respectively) lower serum triglyceride compared to those taking equivalent allopathic drug alone.

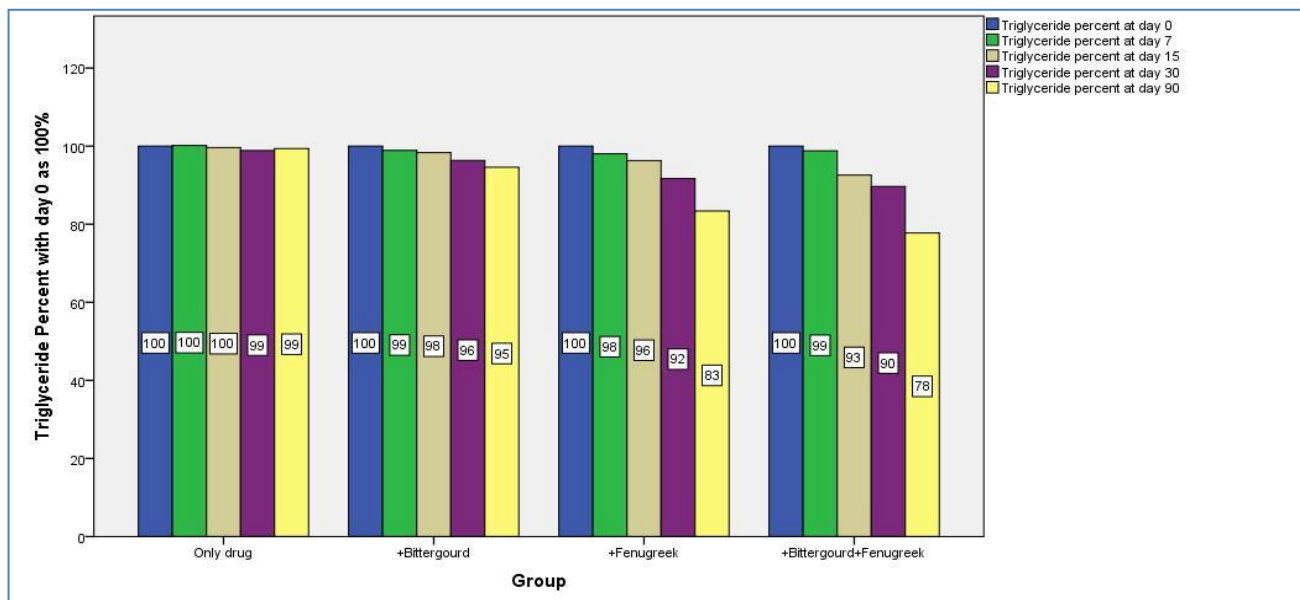


Figure 5: Serum triglyceride percentage with day 0 as the baseline in four treatment groups

Serum LDL- Cholesterol

Serum LDL-Cholesterol had decreased in all four treatment groups. Magnitude of decrease was directly proportional to the duration of treatment (Table 6).

Table 6: Mean serum LDLCholesterol of 4 treatment groups at day 0, 7, 15, 30 and 90.

Group	LDL at day 0	LDL at day 7	LDL at day 15	LDL at day 30	LDL at day 90	P-value
Only drug	114.7	114.0	114.8	116.5	114.3	-
Drug +Bittergourd juice	101.1	99.5	97.4	96.4	93.5	0.113
Drug +Fenugreek seeds	115.7	112.0	108.7	104.6	94.5	0.000*
Drug+Bittergourdjuice+Fenugreek seeds	125.2	121.8	118.5	115.0	101.6	0.000*

*P-value (<0.05) was statistically significant (One-Way ANOVA test and Tukey HSD post hoc test).

To make serum LDL-cholesterol comparable among the groups, we expressed it in percentage taking serum LDL-cholesterol at day 0 as 100% (Figure 6). Serum LDL-cholesterol decreased with duration in three treatment groups (supplementation with bittergourd juice, fenugreek seeds and bittergourd juice+fenugreek seeds) and was least on day 90 in groups II, III and IV except the group I taking allopathic drugs alone. In between-group comparison of

serum LDL-Cholesterol percent on 90th day by One-way ANOVA test was significant (p=0.000). Multiple comparison by post-hoc analysis on day 90 (Table 6) revealed that group III receiving fenugreek seeds supplementation and group IV receiving bittergourd juice+fenugreek seeds supplementation had significantly (p=0.000 and p=0.000 respectively) lower LDL-Cholesterol compared to those taking equivalent allopathic drug alone.

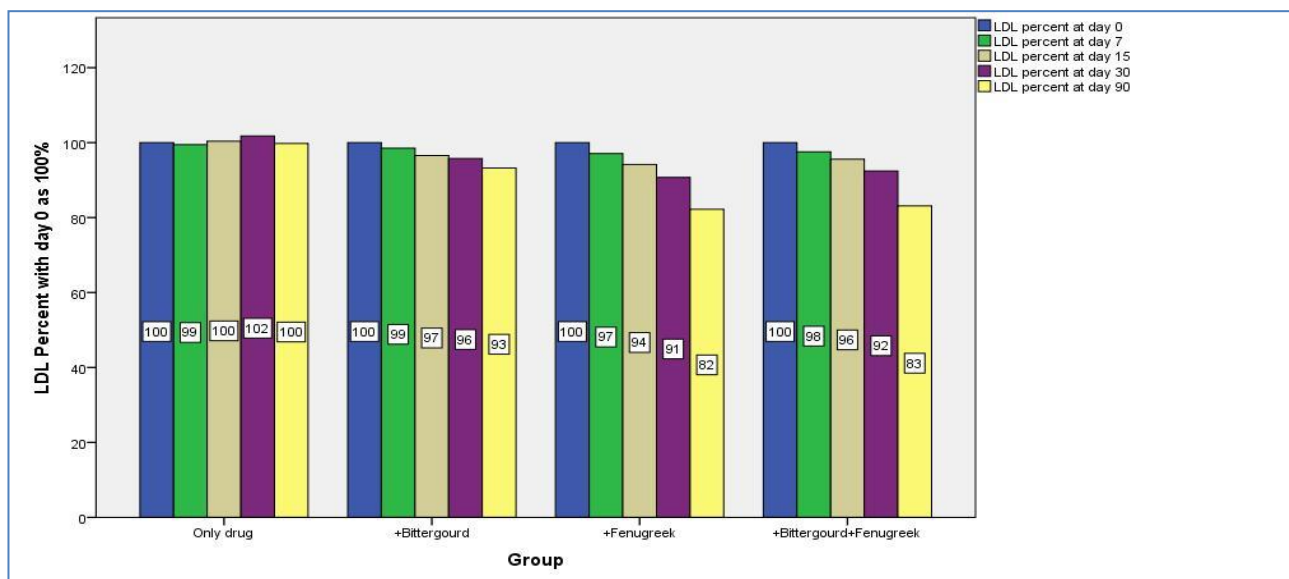


Figure 6: Serum LDL-Cholesterol percentage with day 0 as the baseline in four treatment groups

Serum HDL-Cholesterol

Serum HDL-Cholesterol had increased in all four treatment groups. Magnitude of increase was directly proportional to the duration of treatment (Table 7).

Table 7: Mean Serum HDL-Cholesterol of 4 treatment groups at day 0, 7, 15, 30 and 90

Group	HDL at day 0	HDL at day 7	HDL at day 15	HDL at day 30	HDL at day 90	P-value
Only drug	40.2	40.3	41.1	40.6	40.9	0.978
Drug +Bittergourd juice	41.1	41.1	41.0	41.8	41.8	1.000
Drug +Fenugreek seeds	40.2	40.5	42.8	43.3	44.4	0.015*
Drug+Bittergourdjuice+Fenugreek seeds	43.0	43.1	43.9	44.5	45.6	0.367

*P-value (<0.05) was statistically significant (One-Way ANOVA test and Tukey HSD post hoc test).

To make Serum HDL-Cholesterol comparable among the groups, we expressed it in percentage taking HDL-Cholesterol at day 0 as 100% (Figure 7). Serum HDL-cholesterol increased with duration in each treatment group and was highest at day 90 in each group. In between-group comparison of serum HDL-Cholesterol percent on 90th day

by One-way ANOVA test was significant ($p=0.009$). Multiple comparison by post-hoc analysis of Serum HDL-Cholesterol on Day 90 (Table 7) revealed that group III receiving fenugreek seeds supplementation had significantly ($p=0.015$) increased HDL-Cholesterol compared to those taking equivalent allopathic drug.

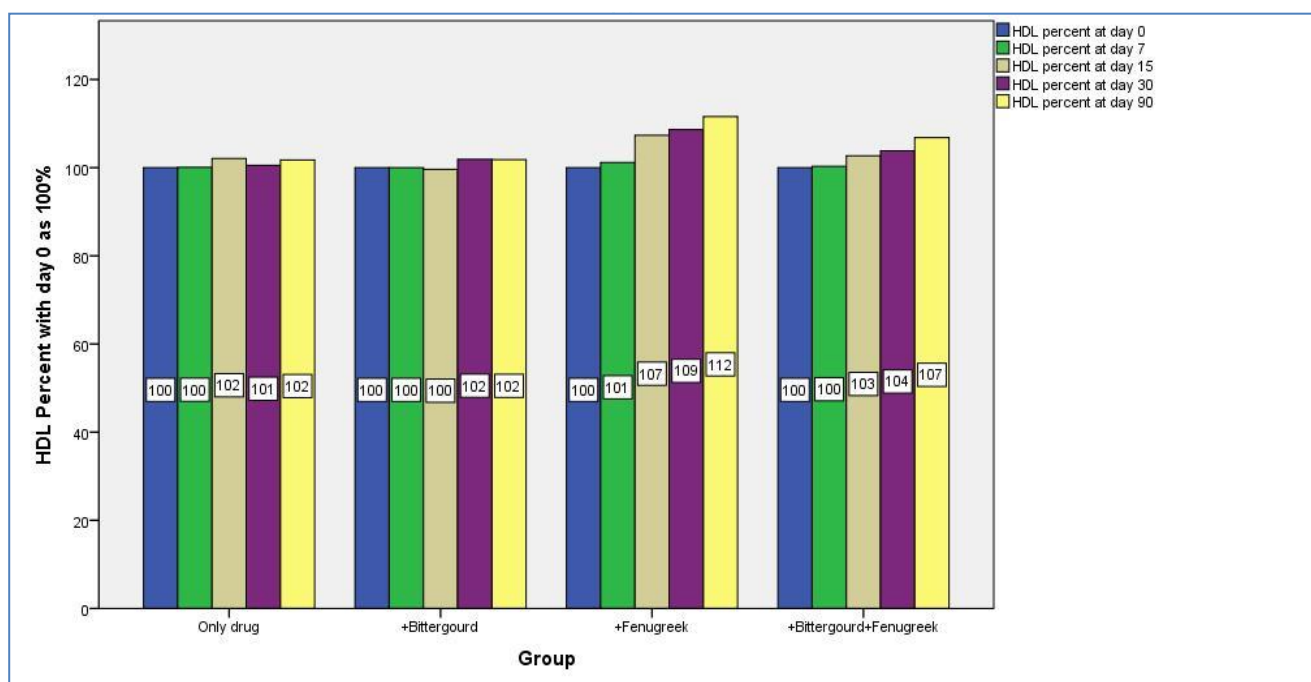


Figure 7: Serum HDL-Cholesterol percentage with day 0 as the baseline in four treatment groups

DISCUSSION

The present study has been undertaken to demonstrate the supplementary effect of *Momordica charantia* (bittergourd) juice and *Trigonella foenum-graecum* (fenugreek) seeds on FBS, PPBS and lipid profile in type 2 diabetics taking allopathic drugs.

Our study has shown that those taking allopathic drugs along with added bittergourd juice and fenugreek seeds have comparatively lower FBS and PPBS than those taking allopathic drugs alone by day 90. It was also seen that bittergourd juice and fenugreek seeds supplementation when either was used alone, decreased sugar (both FBS and PPBS) but not significantly and this finding was similar to a preclinical study by Tripathi et al. Alloxan-induced diabetic rats demonstrated glucose lowering effect of

Momordica charantia and *Trigonella foenum-graecum* extracts.¹⁷ The findings of the study was also supported by John et al and Mathern et al in which experimental studies with bittergourd and fenugreek respectively were not capable of reducing blood sugar profile alone by themselves.^{14,20} Potential hypoglycemic components in bittergourd have been identified as glycosides, saponins, alkaloids, triterpenes, polysaccharides, proteins, and steroids.⁸ The glucose lowering effect of fenugreek has been hypothesized to be due to the amino acid 4-hydroxyisoleucine which acts by the enhancement of insulin sensitivity and glucose uptake in peripheral tissues.²¹ The steroids present in fenugreek seeds also have been reported to reduce blood glucose level when supplemented to diabetic rats.²²

Previous studies by Madar et al. and Robert et al had demonstrated significant antidiabetic effect of fenugreek when used even in isolation.^{23,24} Similarly studies by Ahmed et al and Suthar et al proved that bittergourd is capable of reducing sugar significantly even when used alone.^{25,26} However, the present study showed that bittergourd juice and fenugreek seeds supplementation when either was used alone, decreased sugar but not significantly. It may be due to small sample size of the patients.

In present study, fenugreek alone and with bittergourd supplementation had shown significant beneficial effects on lipid profile (reduced total serum cholesterol, serum triglyceride, LDL-cholesterol) by day 90. However, only fenugreek supplementation showed significant increase in HDL-cholesterol by day 90. The better lipid profile may be due to fenugreek seeds' components like saponins, diosgenin, steroid saponins and 4-hydroxy isoleucine.^{27,28} Plant phenols in the bitter gourd has hypolipidemic properties with ability to inhibit lipid peroxidation.^{29,30} The strong antihyperlipidemic effect of bittergourd fruit juice could also be through its control of hyperglycemia as this is a major determinant of total and very low density lipoprotein and triglyceride concentration.³¹ Previous animal studies also had exhibited that streptozocin-induced rats taking bittergourd had lipid lowering salutary effect in lipid profile like our finding.^{32,33} Findings of the present study on lipid profile was also supported by the studies by Gupta et al and Xue et al in which fenugreek seeds had better effects in lipid profile (significant reduction in total serum cholesterol, serum triglycerides, LDL-cholesterol) along with significant rise in HDL-cholesterol.³⁴⁻³⁷ However, another study by Moosa et al was not capable of showing significant changes in HDL-cholesterol level.³⁸

Limitations of the study

The present study had some limitations. Duration of the study was short. It had also small sample size. Compliance and intake of supplements by the patients as prescribed couldn't be guaranteed. Glycosylated haemoglobin should have been measured at the end of 90 days which would have omitted the bias regarding temporary food effect in PPBS and FBS.

CONCLUSION

Our study revealed the short-term beneficial effect of Fenugreek seeds and Bittergourd juice oral supplementation in addition to the regular allopathic drug in sugar and lipid profile. Bittergourd or Fenugreek supplementation lowered sugar profile (both fasting and postprandial) nonsignificantly whereas Fenugreek and Bittergourd combined supplementation significantly lowered sugar profile (both fasting and postprandial). Bittergourd lowered total serum cholesterol, triglycerides and LDL-Cholesterol nonsignificantly whereas Fenugreek or Bittergourd+Fenugreek combined supplementation significantly lowered total serum cholesterol, triglycerides and LDL-Cholesterol. Only Fenugreek supplementation was capable of significantly increasing the serum HDL cholesterol. A longterm study in larger population should be conducted to validate and generalize the study findings.

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