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Effect of two doses of Fenugreek Flakes (FenuLean ™) on appetite, body-weight and blood glucose homeostasis: A randomized, double-blind, multicenter, three-arm, long-term, control study in 100 healthy subjects

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Abstract
Introduction: Dietary fiber, more importantly soluble fiber finds its way into nutrition to be combined with functional foods[1]. The active study products for this study contained FenuLean™ - Fenugreek Flakes (FF) 5g and 10g. Both FF study products are proprietary products of Bio-gen Extracts Pvt. Ltd., Bangalore, India. The study products are de-fatted and de-bitterized having a high fiber content of ≥ 50% of which 20% are soluble fibers and 30% are insoluble fibers. In addition, they also have a protein content of ≥ 20%[2]. The method of extraction and formulation of the product are intended to maximize the health benefits that Fenugreek Flakes (FF) can bring to the consumer at large. Here, the study products were assessed for their effects on appetite scores, secondary changes to blood glucose, change in body weight, BMI and serum insulin levels[3].
Methods: A double-blind, randomized, three-arm, parallel study to evaluate the efficacy and safety of FenuLean™ - Fenugreek Flakes (FF), n=100. The study had two active arms with dosages of 5g and 10g of Fenugreek Flakes (FF) versus the third control arm. The study sample population included 100 subjects, 45 subjects in each of the two active arms and 10 subjects in the control arm where no intervention was given. The primary assessment of appetite scores, secondary changes to blood glucose, body weight, BMI and serum insulin levels were measured at baseline and at each of the visits through the duration of study.
Results: This study established positive effect of the two doses of FenuLean™ - Fenugreek Flakes (FF) on subjective assessment of appetite scores using Visual Analogue Scale (VAS) scale, changes in body weight, BMI and measurements of glucose homeostasis in subjects falling within the body mass index (BMI) ≥18 to ≤29.9 kg/m.[2] The study was also able to show a significant reduction in fasting glucose and post prandial glucose for the duration of treatment period specifically in both the FF groups that was not observed in the control group across the study visits. There were no significant changes noted in serum insulin parameters in the study.
Conclusions: This study established the fact that supplementation with FF under normal dietary conditions (without any restrictions) decreased energy intake through reduction in hunger, feeling of fullness and feeling of satiety at the end of forty-five days of supplementation or treatment. Consumption of Fenugreek Flakes (5g and 10g) over the duration of study treatments were able to demonstrate a linear relationship of dose dependency effect of FF on appetite scores and reduction in body weight and BMI.

Keywords: Fenugreek Flakes, Soluble Fiber, Insoluble Fiber, Appetite Scores, Fasting Blood Glucose, Post Prandial Blood Glucose, Weight Change, Serum Insulin.

Introduction
Much of the hypoglycemic effect of fenugreek in clinical studies has been attributed to its galactomannan fraction [4], which inhibits glucose absorption and slows gastric emptying [5]. Studies using fenugreek seeds have also found reductions in postprandial blood glucose concentrations [6]. Fenugreek Flakes (FF) with a varied mixture of soluble and insoluble fibers have shown some significant effect in blood glucose. This is an area where significant amount of work needs to be established on the efficacy of fiber, especially the soluble part of fenugreek dietary fiber on blood glucose and insulin production [7]. There is growing evidence in literature that fenugreek fibers can improve glucose homeostasis by delaying carbohydrate digestion, absorption and enhancing insulin action [8]. Fenugreek has long been used to control appetite as well.
In the proof of concept study conducted on eighteen healthy subjects, the administration of FenuLean™ - Fenugreek Flakes (FF) demonstrated a significant increase in satiety, reduction in appetite and increase in the feeling of fullness [12]. FF 10g resulted in significantly lower (P=0.0001) desire for consumption of food compared to FF 5g. Satiety scores were

found to be significantly high (P=0.0146) in FF 10g compared to FF 5g. The prospective consumption in FF 10g resulted in significantly lower scores (P<0.008) compared to FF 5g. Hunger scores were significantly reduced (P=0.0006) with FF 10g compared to FF 5g. Fullness scores were significantly greater (P=0.01) with FF 10g compared to FF 5g. This study was a single daily administration study and the appetite scores were measured post meal to get both pre and post prandial measurements as well indicators that influenced future meals for one day [9].

The current pivotal study was conducted to reassess and reconfirm appetite scores when measured periodically at intervals of 15 days, three times over a period of forty-five days from the start day of treatment with FF 5g or FF 10g. The assumption was based on the hypothesis that large fiber(s) found in FF can lodge in the stomach to produce viscosity and reduced absorption of glucose, which may impact gastric emptying time. Delayed gastric emptying time may change appetite scores through the visual analogue scale associated with post prandial measures of appetite scores 10. FF may act as physiological obstacle to energy intake through at least three mechanisms: 1. FF may displace available calories and nutrients from the diet (reduced hunger, feeling of fullness and satiety) or 2. FF may help one to increase chewing (mastication), which limits intake by promoting the secretion of saliva and gastric juice, resulting in an expansion of the stomach (fullness) and increased satiety (desire to consume of food and prospective food consumption) or 3. FF may reduce the absorption of food and efficiency of the small intestine (satiation and satiety). In previous studies on obese patients, fenugreek seeds have shown significant efficacy on appetite control. Most of the studies carried out with fiber have been short-term interventions with fenugreek fiber including the study conducted on FenuLean ™ ranging from one day to seven days interval interventions. The study design across majority of clinical studies with other fibers similar to FF, have been quite similar.

No other studies have established the ability of FF in modulating appetite scores and to have compared appetite scores over a period of time with a control. This study was unique wherein the study was conducted to align the ability of the FF as one of the key fibers in modulating or sensitizing the appetite scores (as an outcome measure of a double-blind study). This study investigated whether supplementation with FF under normal conditions without any food intervention had observed any changes in energy intake and/or hunger, feeling of fullness and satiety feelings at the end of forty-five days.

Methodology

This study was conducted as a randomized, prospective, three-arm, parallel group, multi-center double-blind long-term clinical study in adult subjects with BMI ≥18 to ≤29.9 kg/m^2. The study involved one hundred subjects and was conducted in five visits over a period of forty-five days at two sites in Bangalore, India. Out of 100 subjects, 10 subjects were designated into the control arm, 45 subjects were in active arm one and 45 subjects were in active arm two. Subjects who consented to written informed consent forms were enrolled for screening procedures at visit 1. Subjects were assigned subject screening number (SSN) and underwent eligibility criteria assessment. After clearing the eligibility criteria, subjects were randomized into control arm and two active arms to receive FenuLean™ - Fenugreek Flakes (FF) either 5g or 10g in a ratio of 1:1 at visit 2. The subjects underwent various physical and biochemical tests (that included complete blood count, glycosylated haemoglobin, fasting blood sugar, postprandial blood sugar, serum insulin and urine routine analysis).

Subject (s) in the active and control arms were assessed on various parameters mentioned in the primary and secondary endpoints over visits 2, 3, 4 and 5 respectively. In order to assess subjective appetite sensations (that included hunger, fullness, satiety, desire to consume food and prospective need of food), visual analogue scales (VAS) were used. VAS scores were composed of lines (of varying length) with words anchored at each end, describing the extremes (that is, 'I have never been more-hungry'/'I am not hungry at all'). Subjects were asked to make a mark across the line corresponding to their feelings. Quantification of the scores was done by measuring the distance from the left end of the line to the mark [10]. These measures were important to evaluate the ability to subjectively assess the right measure to treatments and to objectively assess the outcomes to the study.

Investigational Product

FenuLean™ - Fenugreek Flakes is a proprietary ingredient of Bio-gen Extracts Pvt. Ltd., Bangalore, INDIA. The ingredient is derived from fenugreek seeds and is de-fatted and de-bitterized. Fenugreek Flakes (5g/10g) were consumed with water along with a regular breakfast. In this study we didn't mimic any standard breakfast as this was to simulate a normal daily routine. The composition of FenuLean™ remains the same as mentioned in the published pilot study [12].

Statistics

Data analyses were performed using the following software: SAS® for Windows 95/NT (Version 9.1 or higher, SAS Institute, Cary, North Carolina, USA). Area under the curve (AUC) was calculated using trapezoidal rule using WinNonlin® software (Version 5.3). ANCOVA (Analysis of covariance) was performed for the primary variables using baseline as covariates else paired or independent t-test were performed between the treatments. AUC of the VAS satiety scores was calculated using trapezoidal rule. The baseline characteristics were compared among treatment groups. The baseline characteristics which were found to be significant between study groups were accounted in primary analysis model. For continuous variables (age etc.), data was summarized using number of subjects (N), mean, standard deviation (SD), median, minimum and maximum. For categorical variables, data was presented with the number of exposed subjects, number with percentage in various categories of the endpoint, where percentage was based on the exposed subjects. The descriptive variables (gender etc.) were evaluated using Cochran-Mantel-Haenszel test stratified by study center at 0.05 level of significance.

Primary efficacy analysis

Changes from baseline for all the primary endpoints such as satiety, fullness, hunger, desire to consume food and prospective food consumption VAS scores were evaluated to

assess the functional benefits of fenugreek flakes (FF). Descriptive statistics were performed. Sub group analysis was performed for 2 groups by treatment and the data is presented in appropriate charts. ANCOVA (Analysis of covariance) was performed for the primary variables using baseline as covariates else paired or independent t-test were performed between the treatments.

Satiety, fullness, hunger, desire to consume food and prospective food consumption Rating assessment VAS ratings were converted to a numerical score (0 to 100) from the far-left anchor of the scale. Peak scores (mm) as well as area under curve (AUC, mm*h) were calculated. The cut-off for AUC was 3.5 hrs. AUC was calculated using the trapezoidal rule.

For satiety, ratings of 0 on the scales = I am completely empty. Ratings of 100 = I cannot eat another bite. For hunger, ratings of 0 = I am not hungry at all. Ratings of 100 = I have never been more-hungry. For fullness, ratings of 0 on the scales = I am not at all full. Ratings of 100 = I am totally full. For desire to consume food, ratings of 0 on the scales = I do have desire to eat. Ratings of 100 = I do not have desire to eat food. For prospective consumption of food, ratings of 0 on the scales = I do like to eat. Ratings of 100 = I do not like to eat

Secondary efficacy analysis

Post consumption of the IP the effect of fenugreek fiber flakes on the BMI, body weight, blood glucose and serum insulin and organoleptic properties including visual, taste, smell and palatability of test products at each visit was compared by paired t-tests.

Results

Figure 1, subjects treated with FF 10g significantly had lesser desire to consume food over the period of time. This was observed to be almost similar in all visits of the study as 15, 30 and 45 days. Lodged fibers (FF 10g) in the stomach may have delayed the absorption of glucose and thereby delayed the gastric emptying time. Delayed gastric emptying indirectly reduces desire to consume food and this was significantly higher in the FF 10g group. FF at 5g had a similar profile like FF 10g (up to 60 mins), after which there was shift of appetite score to match the control arm throughout the observed time (upto 210 mins). There was no significant change observed in terms of desire to consume the next meal (post 60 mins) in FF 5g compared to 10g. However, there was a significant difference in subjects' desire to consume food amongst FF 10g group in comparison to that of FF 5 g and control groups.

At visits 3, 4 and 5, the profile of FF 5g matched with that of FF 10g (for the first 60 minutes) and then matched with the control arm in their response to prospective consumption of food. The mechanism of action of FF (irrespective of the dose) was similar, which was lodging of fibers in the stomach. At the onset of consumption of FF (both strengths), there was a lodging of material in the stomach and delayed absorption of glucose (period of 60 mins) which was quite different from the control arm. A fiber quantity (FF 5g) may not be sufficient to sustain (up to 210 mins) to produce similar duration of action as FF 10g. FF 10g had shown to produce significant reduction in desire to consume food or prospective consumption (though could be due to higher proportion insoluble fibers to soluble fibers) (Please explain this sentence. The relative proportion of soluble & insoluble fibers is the same 20% & 30%). Ratio of higher insoluble fibers to soluble fibers may be required to produce pronounced reduced desire to consume food or prospective consumption of food at Visit 02.

Subjects treated with FF 10g significantly reduced prospective need for food (Figure 3). When measured over 210 mins (3.5 hrs); amount of food lodged in the stomach had not emptied in 3.5 hrs (post consumption) with FF 10g. This was observed on subjects treated throughout the study and when measured specifically on day 15, 30 and 45. This was quite different from that seen on subjects with FF 5g and control groups. Subjects on FF 5g showed prospective food consumption similar to FF 10 g (for the first 60 mins), while for the rest of the time until 210 mins, it had almost matched that of the control.

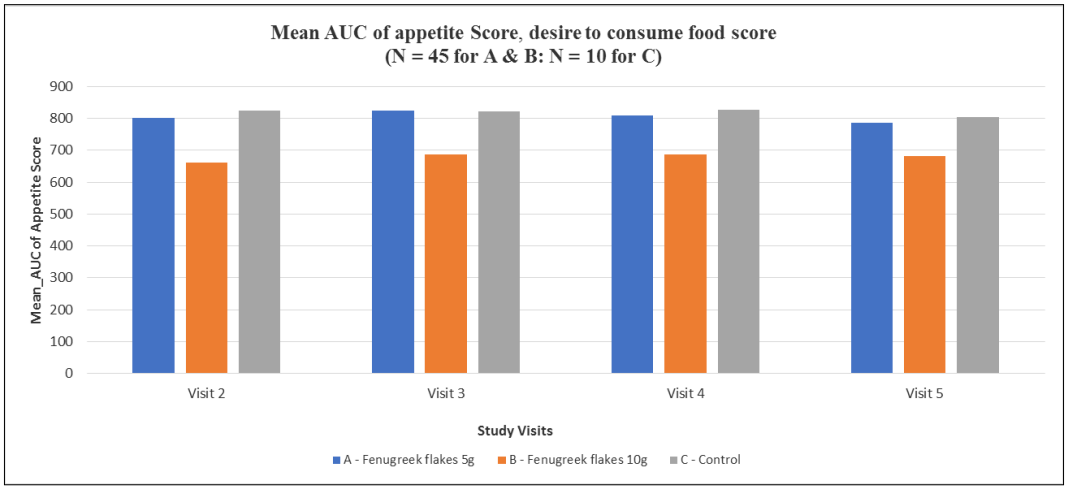


Fig 1: Mean AUC of desire to consume food score across visits

Figure 1. In this graph, lower the AUC score better the efficacy and it clearly shows that FF 10g is better than both FF 5g & control. This is more or less the same across all the visits.

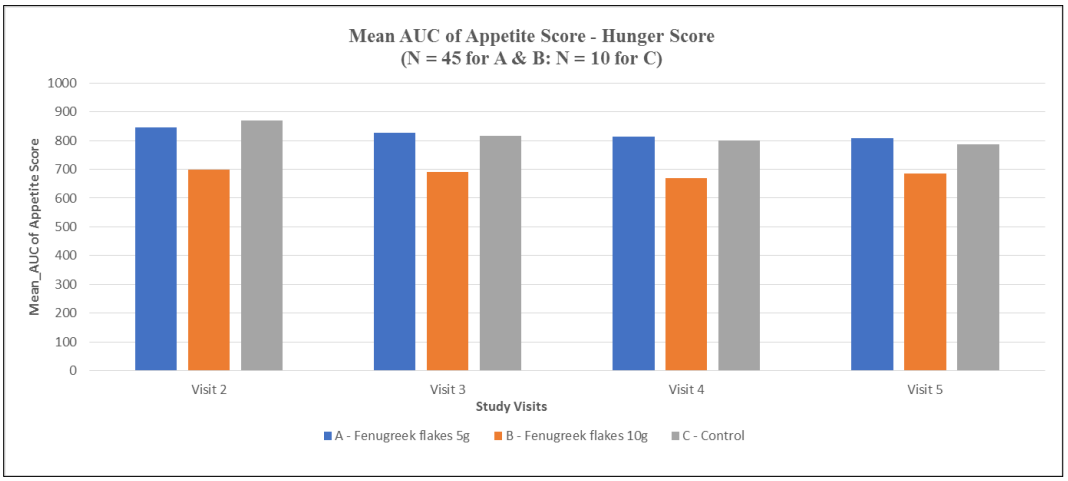


Fig 2: Mean AUC of hunger score across visits

Figure 2. In this graph, lower the AUC score better the efficacy and it clearly shows that FF 10g is better than both FF 5g & control. This is more or less the same across all the visits. Hunger scores have no bearing on the visits and it remained unchanged.

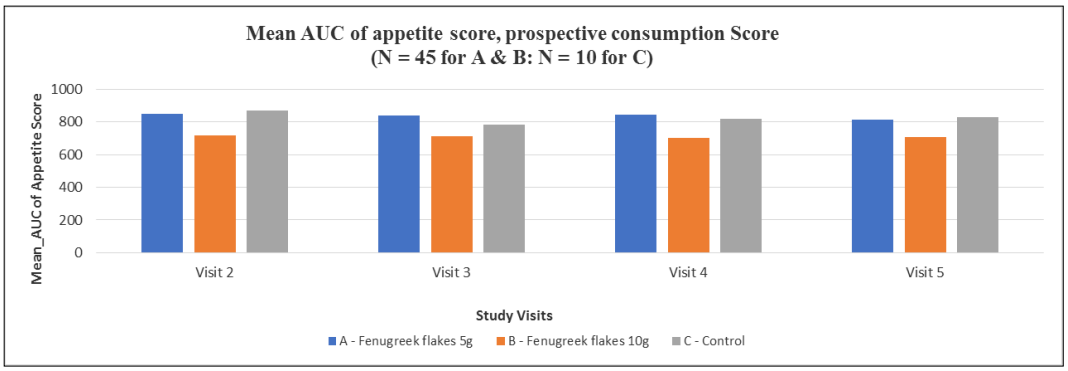


Fig 3: Mean AUC of prospective consumption score across visits

Figure 3. In this graph, lower the AUC score better the efficacy and it clearly shows that FF 10g is better than both FF 5g & control. This is more or less the same across all the visits. Prospective need to consume food has not much changed across the visits However, it is interesting to note that FF 5g is almost similar to control.

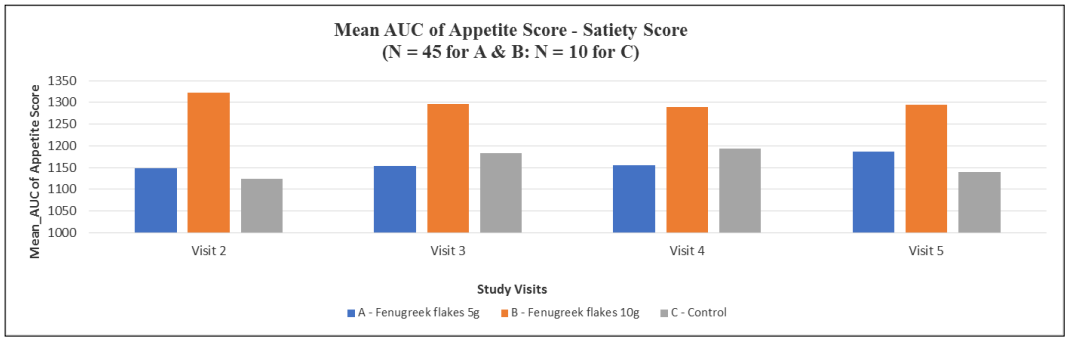


Fig 4: Mean AUC of satiety score

Figure 4. In this graph, higher the AUC score better the efficacy and it clearly shows that FF 10g is better than both FF 5g & control. Satiety scores are higher amongst subjects who has consumed FF 10g and it is seen across the visits. However, there are not many changes that can be observed amongst subjects who has consumed 5g when compared to

control in the different visits

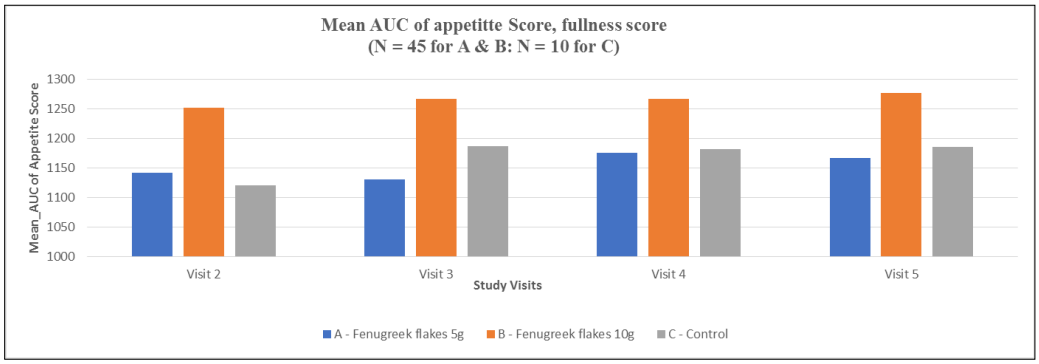
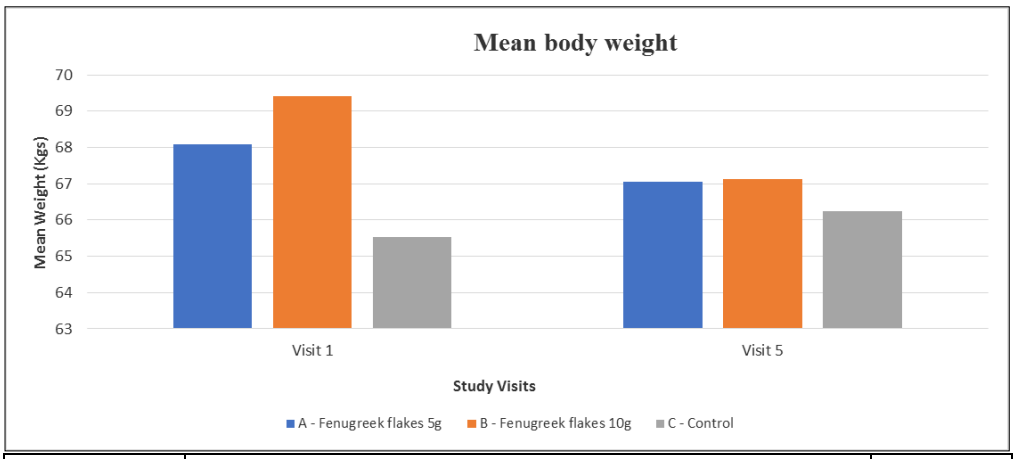


Fig 5: Mean AUC of fullness score across visits

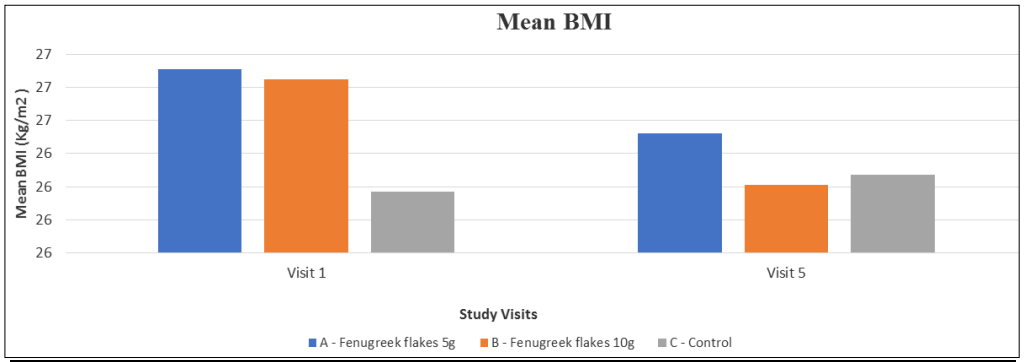
Figure 5. In this graph, higher the AUC score better the efficacy and it clearly shows that FF 10g is better than both FF 5g & control. This is more or less the same across all the visits. Feeling of fullness is not significantly observed in control or FF 5g dose.



*p Value	Test A (Fenugreek 5g) vs Control	<0001
	Test B (Fenugreek 10g) vs Control	<.0001

Fig 6: Mean weight reduction in the treatment groups and control over a period of 45 days

In the above graph when compared to control in Visit 1 (FF 5g & 10g), at Visit 5 (FF 5g & 10g) body weight is significantly reduced (P<0.001) over a period of 45 days. There is a significant increase in body weight amongst control which clearly demonstrates effect of FF 5g and 10g on body weight and how appetite scores have some significant effect on the changes in body weight and metabolic parameters.



*p Value	Test A (Fenugreek 5g) vs Control	0.0009
	Test B (Fenugreek 10g) vs Control	<.0001

* ANCOVA Analysis

Fig 7: Change of BMI in the treatment groups and control over a period of 45 days.

In the above graph when compared to control in Visit 1 (FF 5g & 10g), at Visit 5 (FF 5g & 10g) BMI is significantly reduced (P=0.0009 & P<0.0001) over a period of 45 days. There is a significant increase in BMI amongst control which clearly demonstrates effect of FF 5g and 10g on BMI and how appetite scores have some significant effect on the changes in body metabolic processes.

Body weight and body mass index (BMI) in Fenugreek 5g, 10g and the control arms were summarized by visit and treatment. Mean changes in body weight and BMI from baseline to end of treatment (EOT) were summarized and compared between treatments using independent t-test with 5% level of significance. Data suggested that if the study was exposed to a longer treatment period, even further significant changes may be observed in body weight and BMI. In the control group, there was a significant increase in body weight. This clearly demonstrates the effect of FF 5g and 10g on BMI, especially acting through reduced appetite scores that could play a large part causing changes in the metabolic processes of the body. These indicators provided potential insight to look at this effect in long term consumption of FF.

Table 1: Fasting Blood Sugar (FBS) & Post Prandial Blood Sugar (PPBS) in the treatment groups and control over visits (1 vs 5)

Treatment-A (Fenugreek 5g)	**Baseline**	**Baseline**	**Visit 5**	**Visit 5**
	FBS (mg/dL)	**PPBS (mg/dL)**	**FBS (mg/dL)**	**PPBS (mg/dL)**
N	45	45	45	45
Mean	90.36	111.867	82.82	103.311
SD	10.11	13.534	7.29	16.789
*p Value (Baseline vs V5)			0.0001	0.0092
Treatment-B (Fenugreek 10g)	Baseline	Baseline	Visit 5	Visit 5
	FBS (mg/dL)	PPBS (mg/dL)	FBS (mg/dL)	PPBS (mg/dL)
N	45	45	45	45
Mean	92.82	114.156	81.56	99.489
SD	10.83	18.211	6.77	15.250
*p Value (Baseline vs V5)			<.0001	<.0001
Treatment-C (Control)	Baseline	Baseline	Visit 5	Visit 5
	FBS (mg/dL)	PPBS (mg/dL)	FBS (mg/dL)	PPBS (mg/dL)
N	10	10	10	10
Mean	94.40	111.600	87.40	107.700
SD	9.78	15.672	10.20	20.407
*p Value (Baseline vs V5)			0.1346	0.6375

* ANOVA Analysis

Table 1. shows the effect of FF in comparison to control groups on the blood levels of glucose both at baseline and in Visit 5. Fasting blood glucose (FBS) is reduced significantly in FF 5g (P=0.0001) and FF 10 g (P<0.0001) between the two visits on Visit 1 and Visit 5. This difference is not observed in the control group when the measures of FBS were done on Visit 1 and Visit 5. The effect of FF on FBS is profoundly observed in higher doses compared to lower doses, which also establishes the theory of dose dependency in controlling glucose levels. FF (5g/10g) is able to show reduction in fasting glucose and some inherent effects on glucose metabolism which is reported in literature.

Post prandial blood glucose (PPBS) is reduced significantly in FF 5g (P=0.0092) and FF 10 g (P<0.0001) between the two visits on Visit 1 and Visit 5. This difference is not observed in the control group when the measures of PPBS were done on Visit 1 and Visit 5. PPBS is an important indicator to assess surge of glucose levels (changes post consumption of a meal) and its effect on serum insulin levels10. Effect of FF on PPBS (like FBS) is dose dependent and at higher strength (FF 10g) produced significant reduction in PPBS levels. All the subjects in the study had impaired glycosylated haemoglobin who may have had higher BMI (>25) with no other metabolic aberrations. This also establishes the fact that these actions are beneficial and shows how the reduction in glucose reabsorption and appetite scores is correlated. Effect on PPBS is absent in the control arm of the study across the visits.

Table 2. shows effect of treatment and control arm on serum insulin at baseline (both at 1 and 120 mins) at Visit 1 and Visit 5. There are no significant differences observed in serum insulin from visit 1 and 5. Serum insulin is not impacted by treatment or by time (pre and post consumption of FF). Insulin changes and its impact on glucose levels are important today in dietary modifications especially in non-diabetes subjects with a BMI of over 25.

Table 2: Serum insulin & Post meal (at 120 min) serum insulin in the treatment groups and control over visits.

Treatment-B (Fenugreek 10g)	Baseline	Baseline	Visit 5	Visit 5
	Serum insulin (µU/ml)	Post meal (at 120 min) serum insulin (µU/ml)	Serum insulin (µU/ml)	Post meal (at 120 min) serum insulin (µU/ml)
N	45	45	45	45
Mean	16.29	30.447	21.42	32.362
SD	10.73	18.931	13.25	27.195
*p Value (Baseline vs V5)			0.0465	0.6991

Treatment-A (Fenugreek 5g)	Baseline	Baseline	Visit 5	Visit 5
	Serum insulin (µU/ml)	Post meal (at 120 min) serum insulin (µU/ml)	Serum insulin (µU/ml)	Post meal (at 120 min) serum insulin (µU/ml)
N	45	45	45	45
Mean	19.71	29.640	20.76	33.749
SD	17.75	19.705	18.06	29.769
*p Value (Baseline vs V5)			0.7822	0.4421

Treatment-C (Control)	Baseline	Baseline	Visit 5	Visit 5
	Serum insulin (µU/ml)	Post meal (at 120 min) serum insulin (µU/ml)	Serum insulin (µU/ml)	Post meal (at 120 min) serum insulin (µU/ml)
N	10	10	10	10
Mean	14.24	45.940	15.36	53.550
SD	10.74	28.848	10.34	41.225
*p Value (Baseline vs V5)			0.8149	0.6382

Discussion

Most of the studies carried out with fibers have been short-term interventions of only one day and not more than one week, like in some other similar fiber(s) such guar gum or psyllium seeds [11-13]. There were some changes in the outward explicit actions of FF 5g and FF 10g when compared to control. Reactions observed initially were the same for both treatment groups for the initial sixty minutes, however eventually the load bearing effects was exhibited by the lodging of polysaccharides in the stomach. Polysaccharides are primary material in FF (in form of soluble or insoluble fibers) and they have different actions post sixty minutes, where they start to disintegrate and take the further course of action through the alimentary canal. FF 10g may produce additional viscous fibers in comparison to FF 5g that may be useful as they prolong the intestinal phase of nutrient digestion and absorption [13]. This suggested that there is a longer time over which the macronutrients can interact with the pre-absorptive mechanisms of satiation and satiety, as well as prolong the time course of post-absorptive signals, impacting both desire to consume food and prospective need to consume food which together makes the appetite score. It is thought to impact satiation - the satisfaction of appetite during feeding that marks the end of eating (fullness) and satiety (inhibition of hunger as a result of having eaten) because of their properties of adding bulk (satiation) and producing viscosity (satiety).

FF 10g may be associated with increased effort and/or time of mastication because of higher insoluble fibers, which leads to increased satiety through a reduction in rate of ingestion. This would lead to fullness as shown in various visits across the study over a period of forty-five days. Lodged fibers mixed with saliva and gastric juice in the stomach may have delayed glucose absorption and reduced gastric emptying time, bringing down the future intake or delay in preparing for the next meal [12]. It is the time taken by the fiber to produce the necessary bulking and viscosity enhancing properties important to produce changes measured through appetite scores [14].

The study clearly demonstrated that body weight significantly reduced ($P<0.001$) in the active arms over a period of forty-five days in comparison with the control arm. There was an increase in body weight noted amongst the control group of subjects, clearly demonstrating the effect of FF 5g and 10g on body weight and also that appetite scores had significant effects on the changes in body weight and metabolic parameters. BMI ($P<0.001$) was significantly reduced over a period of forty-five days in comparison to that in the control arm. Fasting blood glucose (FBS) was reduced significantly in FF 5g ($P=0.0001$) and FF 10 g ($P<0.0001$) between the two visits (Visit 1 and Visit 5). However, this difference in FBS was not observed in the control group at Visit 1 to Visit 5.

The effect of FF on FBS was more profoundly observed in higher doses compared to lower doses which also established the theory of dose response relationship on controlling glucose levels. It also establishes the fact that FF of both strengths was able to show reductions in fasting glucose. FF may also reduce gastric emptying and/or slows energy and nutrient absorption, leading to lower postprandial glucose and maintaining possible insulin levels. It was interesting to note the change in serum glucose levels both before and after meals had no impact on insulin levels which is important, further establishing the fact that FF does not cause secretion of insulin either that could influence the glucose metabolism. FF is

devoid of its impact on insulin changes and these are important factors today in planning dietary program that surfaces when consuming dietary fibers.

Conclusion

No other studies have been established to assess the ability of FF to modulate appetite scores and compare appetite scores over a period of time with control in a large sample size (~ 100 subjects). Clinical investigators evaluated the ability of the FF (as key fibers) in modulating or impacting the appetite scores as primary outcome measures in a randomized, multi-center, parallel group, long term, prospective double-blind clinical study. This study established the fact that supplementation with FF under normal dietary conditions (without any restrictions) decreased energy intake through reduction in hunger, feeling of fullness and feeling of satiety at the end of forty-five days of supplementation or treatment. These parameters were part of the quantifiable postprandial appetite scores which were essential to assess the quality and impact of quantity of FF in the study.

This also e0stablished the fact these actions were beneficial and exhibited how glucose reabsorption, reduction and appetite scores correlated to the carbohydrate metabolism. One of the important factors to assess the effect of insulin with respect to food enriched with FF and its action on glucose metabolism. Significant changes were observed in about forty-five days with FF finding some beneficial effect on the dietary and nutritional value as established in previous studies. There was a clear linear relationship established of dose dependent effect of FF on fasting blood sugar, post prandial glucose, appetite score, weight loss and BMI.

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