Anti-Heartburn Effects of a Fenugreek Fiber product

By Roberto A. DiSilvestro, Columbus Nutraceuticals Consulting Inc. Dublin, OH, USA, July 2010.

Overview

Heartburn, commonly referred to as stomach acid reflux or acid indigestion, is a frequently occurring inconvenience among populations worldwide. As many as 10% of Americans have episodes of heartburn every day, and 44% report heartburn symptoms at least once a month. People who experience heartburn twice a week or more may have Gastroesophageal Reflux Disease (GERD). European research shows that 1 out of every 10 adults suffers from GERD. The incidence of heartburn is spread across the whole population, but seems to increase dramatically above the age of 40. More than 50% of men and women with GERD are in the age-bracket of 45 to 64 years.

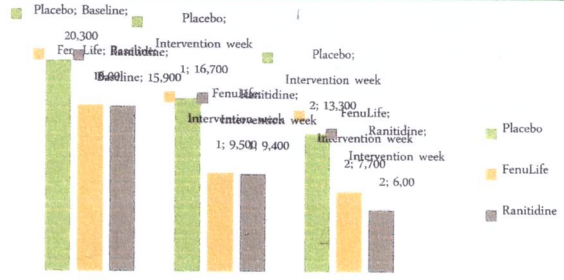
Study Design

In this two-week placebo-controlled, randomized clinical trial, 45 subjects suffering from heartburn, on average of 3-8 times per week, were divided in 3 groups of 15 subjects.
Subjects had a 1 week baseline period which was used for the pre-treatment characterization of heartburn symptoms. Subjects were then randomly assigned to one of three treatments to be followed for 2 weeks post baseline. Treatments were: FenuLife (500mg per capsule, four capsules taken twice/day, 4 g total daily dose), Ranitidine (75 mg per pill, one pill taken twice/day, 150 mg total daily dose) and placebo (starch capsules, four capsules taken twice/day).
The placebo and FenuLife group were blinded to their assignment. The ranitidine group, which served as a positive control, was unblinded. All subjects were instructed to take the assigned product 30 min before their two biggest meals of the day with the other meal to be a bland meal. For that meal, subjects were given written guidelines and list of examples.

Results & Discussion

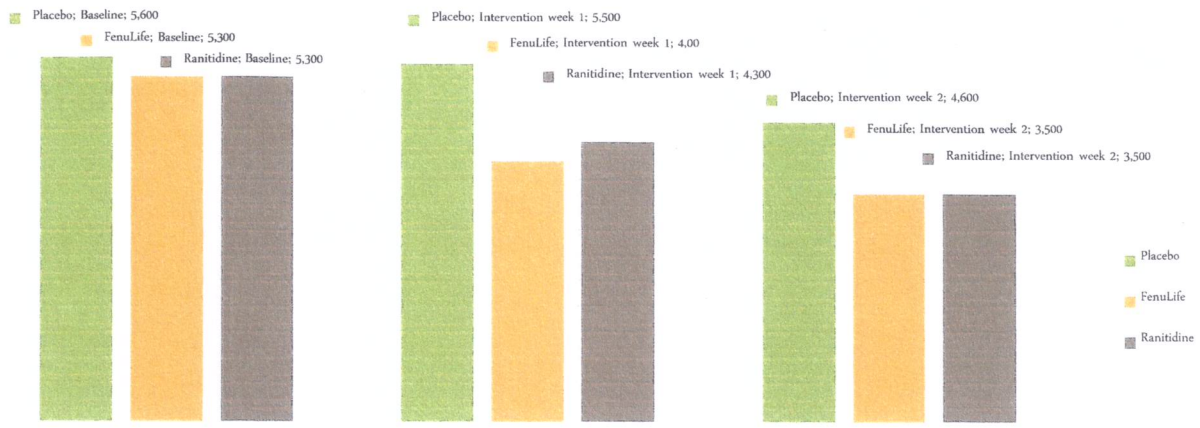
Heartburn severity and the number of days with at least one heartburn incidence were significantly affected by treatment with either FenuLife or the positive control (Ranitidine).
Although placebo treatment led to a statistically significant improvement on the severity score in the second intervention week, the effect was not as great as the effect with treatment by either FenuLife or positive control.

1. Heartburn severity scores per treatment during the trial



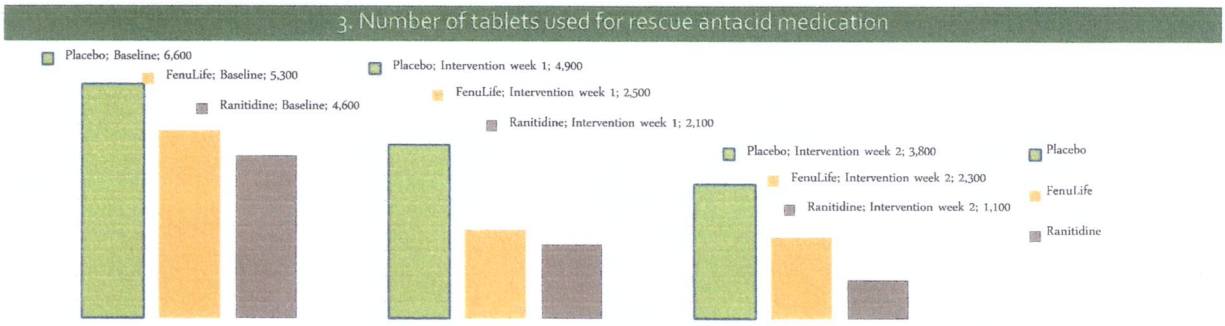
In addition, the frequency of heartburn significantly decreased in both FenuLife and Ranitidine groups.

2. Frequency of heartburn per treatment during the trial



Furthermore, subjects in the FenuLife group showed an average of 1.9 symptom-free days at the end of the second intervention week. This was significantly more compared to placebo (0.7 symptom-free days).

Placebo	0,73 ± 0,33
Fenugreek extract	1,87 ± 0,52
Ranitidine	2,21 ± 1,09



Regarding the use of rescue medication, all three interventions produced statistically significant reductions in both intervention weeks. However, the number of tablets used as rescue medication in both FenuLife and Ranitidine groups was significantly lower compared to placebo
(Figure 3).

Conclusion

The water soluble fiber fraction of FenuLife was more effective than placebo, and similarly effective as the positive control (Ranitidine). This shows that FenuLife may provide a natural alternative for the treatment of heartburn or GERD with an efficacy similar to that of OTC drugs like ranitidine.
A recommended dosage is 2 g FenuLife in capsule or tablet together with a glass of water, 20 to 30 min prior to two meals per day.

Published as:
Disilvestro *et al.* (2010). "Anti-heartburn effects of a fenugreek fiber product." Phytotherapy Research 25(1): 88-91.

Effect of fenugreek fiber on satiety, blood glucose and insulin response and energy intake in obese subjects

Mathem, JR, Raatz SK, Thomas W, Slavin JL 1, Department of Food Science and Nutrition, University of Minnesota, St. Paul, MN USA., 2008.

Overview

Many areas of the world are increasingly faced with an obesity epidemic, with obesity defined as having a Body Mass Index (BMI) over 30. While total energy and fat intake play key roles in the development and treatment of obesity, observational studies have shown that dietary fiber intake is inversely associated with BMI, that obese individuals consume significantly less fiber than lean individuals and that they are more responsive to fiber interventions. Fiber promotes satiety and thereby reduces energy intake. The following randomized crossover study shows that consuming fiber from FenuLife increases satiety and promotes reduced energy intake in obese individuals.

Study Design

18 obese (BMI 36±5), but otherwise healthy men and women (age 32 ± 11) consumed a beverage with either 0 grams (control), 4 grams or 8 grams of FenuLife, followed by a standardized low fiber breakfast consisting of cereal, white bread, butter and jelly (355 Kcal, 12 g protein, 5 g fat and 66 g). carbohydrate). The meals were identical, with as only variable the amount of fiber provided by FenuLife, which is 90% total fiber by weight and >75% soluble fiber. Ratings of satiety, hunger, fullness and prospective food consumption were assessed using visual analog scales (VAS) at 30 minute intervals from the start of breakfast for 3.5 hours. Blood was collected at 15 minute (first hour) and then 30 minute intervals for 3 hours to measure glucose and insulin levels. 3.5 hours after breakfast, participants consumed an *ad libitum* lunch buffet, where energy intake was measured. Participants recorded food consumed for the remainder of the day.

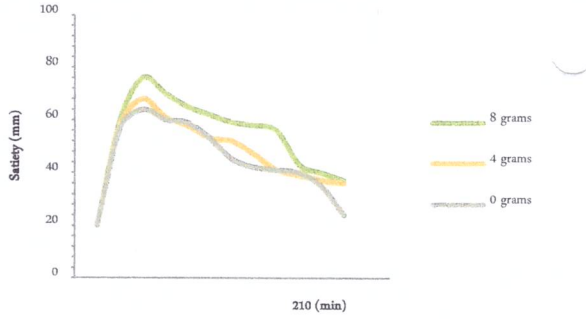
Results / Discussion

For measurements of satiety, hunger, fullness and prospective food consumption, the 8 g dosage of FenuLife was significantly different than the other treatment options. Satiety and fullness measurements, both peak and area-under-the-curve (AUC) were higher, and hunger and prospective food consumption measurements lower. There was no statistical difference between the 4 g dosage and the control (Figure 1). The presence of the viscous fiber from fenugreek may have played a role in promoting satiety ' slowing the rates of gastric emptying.

Energy intake at a lunch buffet tended (p=0.11) to be approximately 100 Kcal less for the 8 g group, while there was no significant difference between 0 and 4 g, and there was no difference in energy consumption for the rest of the day between the treatments (Table 1). This indicates that the satiety effects of FenuLife are short-term.

Postprandial glucose and insulin responses were not statistically different except for the insulin response of the 8 g dosage of FenuLife. The increase in satiety in this study was not related to reduced glucose absorption.

Incremental rating of satiety(mm):



Conclusion

This clinical trial demonstrates that an 8 g dosage of FenuLife added to breakfast significantly increases reported satiety in obese patients. Individuals experienced higher levels of satiety and fullness and reduced hunger and prospective food consumption. This study did not provide evidence of beneficial effects on carbohydrate metabolism. This could be due to the small meal size at breakfast, as a previous study found that 8 g FenuLife significantly reduced glucose AUC response to a glucose drink. The effects on appetite suppression and food intake suggest that FenuLife can be an effective ingredient in weight management and slimming formulations.

Ernergy intake in response to different treatments

	Treatments			F-Test
Measurement	0 gr	4 gr	8gr	P value
Calories eat ad libitum lunch (Kcal)	1285 ± 98ab	1352 ± 98 a	1157 ± 98 b	0.05
Calories eaten rest of study day (Kcal)	1057 ± 150	1266 ± 142	1171 ± 142	0.48

Published as:
Mathern *et al.* (2009). "Effect of fenugreek fiber on satiety, blood glucose and insulin response and energy intake in obese subjects." Phytotherapy Research 23(11): 1543-1548.

Effect of FenuLife on Blood Glucose in type-II Diabetes

By Dr. Hiroyuki Abe, Associate Professor of Kyourin University, Japan, July 2002.

FenuLife EXTRA contains a minimum of 85% of galactomannans, which are indicated to balance sugar absorption in the small intestine, thereby decreasing spikes in blood sugar following a meal. A study was designed to investigate if FenuLife EXTRA influences serum glucose in type-II diabetic patients.

Study design

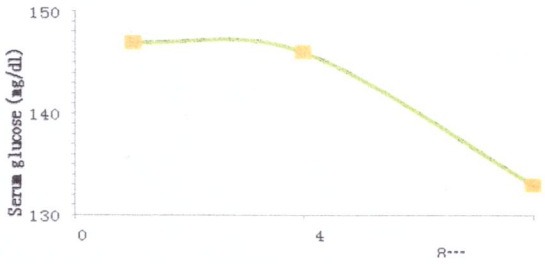
17 Japanese type-II diabetic patients (16 male & 1 female) were divided into 2 groups according to their blood sugar levels. Group A (n=12) had fasting serum glucose levels of 120-200 mg/dl; group B (n=5) was characterized by blood sugar levels > 200 mg/dl. Group A was additionally randomly subdivided into 2 groups of 6 persons (A1 and A2) to receive a different treatment. During the test period of 8 weeks and 2 weeks before, group A could not take diabetic drugs, but group B could. FenuLife EXTRA and placebo (lactose) were provided in hard-gelatin capsules, which were taken 30 minutes before each meal with 200 ml water.

Treatment per group	First 4 weeks	Sec. 4 weeks
A1 Light / moderate diabetis	4 gr placebo / day	4 gr FenuLife / day
A2 Light / moderate diabetis	4 gr FenuLife / day	2 gr FenuLife / day
B Moderate / severe diabetis	4 gr FenuLife / day	2 gr FenuLife / day

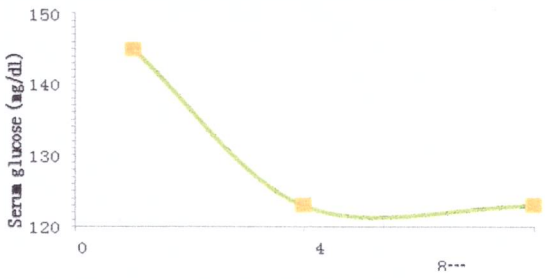
In conclusion

Fasting blood sugar levels were measured at starting point, and at 4 and 8 weeks (see graphs). In all groups FenuLife reduced serum glucose levels. Upon reaching a desired blood sugar level, a reduced intake of FenuLife showed to maintain the serum glucose level. Additionally, FenuLife created a complementary effect on reduction of blood sugar levels along with use of conventional diabetic drugs.

A1: light / moderate diabetes



A2: light / moderate diabetes



B: Moderate / severe diabetes