

World Congress on ADVANCED NUTRACEUTICALS AND FUNCTIONAL FOODS

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Pilot and pivotal clinical outcome study to determine satiation and satiety through FenuLean (Fenugreek flakes) administered on healthy volunteers with > 30 BMI. Possible mechanism of action?

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FenuLean (Fenugreek flakes) is a proprietary product of Bio-gen Extracts Ltd. was de-fatted and de-bitterized fibres with a high fibre content of $\geq 50\%$ of which 20-25% are soluble fibres and 30-35% are insoluble fibres. The bulking and viscosity properties of dietary fibre in the stomach are predominantly responsible for influencing satiation and satiety which in turn are the key indicators in the weight management program. In the pilot and pivotal study conducted FenuLean, taken thirty minutes prior to meal, effectively suppress the appetite by initiating the sense of satiety, reduction of hunger, feeling of fullness, desire to consume food and prospective need to consume food. Fibre rich foods usually are accompanied by increased efforts and/or time of mastication, which leads to increased satiety through a reduction in rate of ingestion. It makes a good replacement for conventional products in number of bakery items.

Interestingly soluble fibre derived from FenuLean has been identified chemically as galactomannans just like other fibre of guar seeds or psyllium husk. Interestingly the ratio of mannose to galactose in the FenuLean is 1:1 making it superior in terms of its gel-forming characteristic over other galactomannans. Interestingly we found changes in the post prandial glucose response and this could be attributed to the increasing the viscosity of digested food in the gut, these fibres, especially of fenugreek origin, delay the absorption of carbohydrates. Considering the significant amounts of galactomannans in fenugreek seeds, it is of utmost importance that the effects of these in the control of postprandial glycemia and its response to weight management. Our studies using FenuLean showed growing evidence in the literature that fenugreek fibres can improve glucose homeostasis by delaying carbohydrate digestion and absorption and enhancing insulin action.

Primary aim of our study was to examine the effects of FenuLean from fenugreek at 10g and 5g on satiety and fullness, and on reduced ratings of hunger, desire and prospective food consumption. Secondary objective was to determine FenuLean at the same doses from fenugreek would reduce glycemic and insulin response apart from the palatability. The Investigational Product (IP) contained FenuLean 5g and 10g. FenuLean 5g / 10g was consumed orally with water along with a standard meal (breakfast).

FenuLean 5g & 10g consumption lead to improvement in

- Overall satiety of the healthy subjects
- Increased satisfied satiety and higher fullness was observed
- Reduced hunger, desire to consume food and prospective food consumption
- Satiety satisfaction and fullness scores increased from thirty minutes post consumption
- Positive trend of reduction in serum insulin after consumption
- Overall, palatability of the FenuLean 5g and 10g was found to be comparable.

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Viscous and gel-forming property of soluble dietary fibre inhibit macronutrient absorption, reduce postprandial glucose response and may benefit some changes in the body metabolism. However, in our study the increase in satiety was not related to reduced absorption of glucose as our study did not find any effects of FenuLean on postprandial blood glucose concentrations. Healthy volunteers do not show changes in post prandial glucose concentration(s) even post consumption of fibre which is a good sign of maintenance of glucose homeostasis. Currently we are investigating whether FenuLean in over 100 subjects would have significant effects on postprandial blood glucose response to a larger meal or high energy meal or subjects with high BMI. The effects on appetite suppression and food intake suggest that FenuLean (fenugreek flakes) may have a role in the control of food intake in normal individuals.

Biography

Bopanna is a thought leader in the field of clinical and drug development that include being past president of Indian Society of Clinical Research (ISCR), Advisory council member of DIA, Past member of National committee in health and family welfare, Govt of India, Board of management JSS Medical University, Mysore etc. Over twenty-three years of experience in large global pharma company, Information technology company and in contract research organisation as a 'C' level executive for over 13 years. Some of the leading companies he has worked includes AstraZeneca, Tata Consultancy Services, Manipal Acunova (Manipal healthcare and medical group), Next Bio research labs and Semler group of companies. Currently serving as a director in the board of a health, nutraceutical, sports and medical device(s) companies.

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