Does Beano Prevent Gas? A Double-blind Crossover Study of Oral α-Galactosidase to Treat Dietary Oligosaccharide Intolerance

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Background. Beano, an over-the-counter oral solution of α-galactosidase, is used to prevent flatus and other gastrointestinal symptoms resulting from a high-fiber diet. The efficacy of this product, however, has not yet been adequately evaluated.

Methods. Nineteen subjects were randomized into two groups and fed test meals of meatless chili. At the first test meal, group 1 received eight drops of α-galactosidase solution and group 2 received eight drops of placebo. After the meal, subjects were asked to keep a careful record of gastrointestinal symptoms, including occurrences of intestinal gas passage, for the next 6 hours. One week later, an identical test meal was served to each study subject and the solutions were reversed. Again subjects recorded their symptoms for the next 6 hours. Data were analyzed by means of paired *t* tests.

Results. The number of flatulence events per hour was significantly less in the group treated with α-galactosidase than placebo over the 6-hour follow-up period ($F=2.87$, $P=.016$). When the two groups were compared at each follow-up interval, this difference was statistically significant only for the 5th hour after ingesting the test meal ($t=2.19$, $P=.04$). No differences between the two groups were found in the extent of bloating or pain following the meal.

Conclusions. Oral α-galactosidase solution is efficacious, at least in some patients, for the prophylaxis of gastrointestinal intolerance of oligosaccharides.

Key words. Oligosaccharides; α-galactosidase; legumes; flatulence; intestinal gas; quality of life; community health care. (*J Fam Pract 1994; 39:441-445*)

It is universally well known, that in digesting our common food, there is created or produced in the bowels of human creatures, a great quantity of wind.

—Benjamin Franklin[1]

A high-fiber diet consisting of beans, grains, and other vegetables is recommended for its health benefits, which include a reduction in the incidence of coronary artery disease, some cancers, and a variety of bowel problems. Unfortunately, this type of diet contains large quantities of oligosaccharides, and possibly other compounds as yet not characterized,[2] that are metabolized by colonic bacteria with the resultant production of carbon dioxide, hydrogen, and in some persons, methane.[3] Flatus production is diet-dependent, with larger volumes of flatus produced shortly after the ingestion of meals.[3] Although the production of flatus varies greatly among individuals, the seminal work of Levitt et al[4] suggests that the human average is about 14 passages of flatus daily.

For many individuals, the cramping, bloating and flatulence associated with a high-fiber diet are unacceptable. For others, however, the production of high volumes of resonant, pungent intestinal gas is a source of personal pride and fulfillment and can be used as a greeting or other form of communication (personal communication, M Bowersox, San Diego, California, April

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1992). One person, Joseph Pujol, known throughout turn-of-the-century Paris by the stage name Le Petomane, actually made a career of performing various remarkable feats (melodies, extinguishing flames) by the forceful expulsion of flatus.[5]

Recently, Beano (Akpharma, Pleasantville, NJ), a solution of the enzyme α-galactosidase, has been released for use as a nonprescription antigas agent. This solution is derived from *Aspergillus niger* and contains 650 galactosidase units of enzymatic activity per gram. The solution, marketed as a prophylactic treatment of gastrointestinal symptoms caused by the consumption of oligosaccharides, presumably works by breaking down oligosaccharides before they can be metabolized by colonic bacteria.

To date, the only evidence on the efficacy of α-galactosidase is set forth in three abstracts. One reports that in 20 healthy volunteers who were given 230-g meals of refried black beans, successively higher doses of α-galactosidase solution (5, 10, and 70 drops) were associated with respectively lower levels of breath hydrogen.[6] An additional finding of this study was that the total number of gastrointestinal symptoms decreased as the doses of α-galactosidase were increased.

A second abstract from the same group[7] reported results from a randomized, double-blind study of 20 healthy volunteers who were fed a 230-g meal of black beans. This study reported that 0.5 mL of α-galactosidase solution completely abolished flatulence and diarrhea in 9 (45%) subjects.

A third abstract[8] reported results of a randomized, single-blind study of 20 normal subjects. The study participants were fed a 3-oz meal of refried beans with 5 drops of α-galactosidase solution added to the test meal, and at least 3 days later were given a meal that was identical except for the additive. Breath measurements of hydrogen and methane were taken at baseline and hourly for 8 hours after each meal. The subjects kept a diary of symptoms (flatulence, bloating, and heartburn). A comparison of the gastrointestinal aftermath of the two meals revealed no statistically significant differences in breath hydrogen, methane concentrations, or symptoms.

To further evaluate the efficacy of oral α-galactosidase solution for the prophylaxis of flatulence and other gastrointestinal symptoms, we conducted a prospective, randomized, double-blind, placebo-controlled, crossover study.

Methods

Volunteers were recruited through the use of a humorous flyer distributed at the University of California at San Diego (UCSD) Medical Center and by word of mouth. Subjects were randomized into two groups using a set of computer-generated random numbers. The bottles of α-galactosidase solution (Beano) were purchased from two different pharmacies in the San Diego area and labeled "black." The placebo solution was made from Worcestershire sauce diluted with water to appear and taste like the α-galactosidase solution and placed in identical bottles labeled "white."

The test meal, prepared by one of the authors, consisted of meatless chili (made with navy, pinto, and kidney beans, cabbage, broccoli, cauliflower, and onions), corn bread, and water. Each meal was made using the same recipe and identical food products, including the same brand of food. The beans were not soaked before cooking. The meal was lactose-free and did not include carbonated beverages.

At noon on day 1, the test meal was served to the study subjects. The amounts of all foods served to each person were measured and recorded. Subjects were allowed to eat as much as desired, but were informed that they would be requested to eat an identical amount of each food the following week. Group 1 was given 8 drops of α-galactosidase solution (consistent with the manufacturer's suggested dose) with the first bite of cooled food and with each subsequent one-cup portion of chili. Group 2 was given 8 drops of placebo with the first bite of food and with each subsequent one-cup portion of chili.

After the meal, each subject was asked to ingest nothing except water and to keep a careful record of gastrointestinal symptoms (including occurrences of intestinal gas passage, abdominal pain, and bloating) for the next 6 hours. The 6-hour period was based on personal experience: we expected that there would be a flatulence response to the meal within 6 hours, and we felt that we were unlikely to adequately control the subjects' dietary intake at dinner. Data were recorded by all subjects on a standardized data collection form that included a flatulogram[4] and symptom assessment. Gas volume was assessed on a subjective scale of 1 to 3, and symptoms were measured on a visual analog scale.

At noon on day 8, an identical test meal was served to the subjects. Each subject received the exact amount and type of food eaten on day 1. Group 1 was given 8 drops of placebo solution with the first bite and with each subsequent one-cup portion of chili. Group 2 was given 8 drops of α-galactosidase solution with the first bite and with each subsequent one-cup portion of chili. Again, each subject was asked to carefully record gastrointestinal symptoms for the next 6 hours using the flatulogram and symptom assessment and to ingest nothing except water for that period.

Except for the researcher who prepared the α-galactosidase and placebo solutions, all study participants, re-

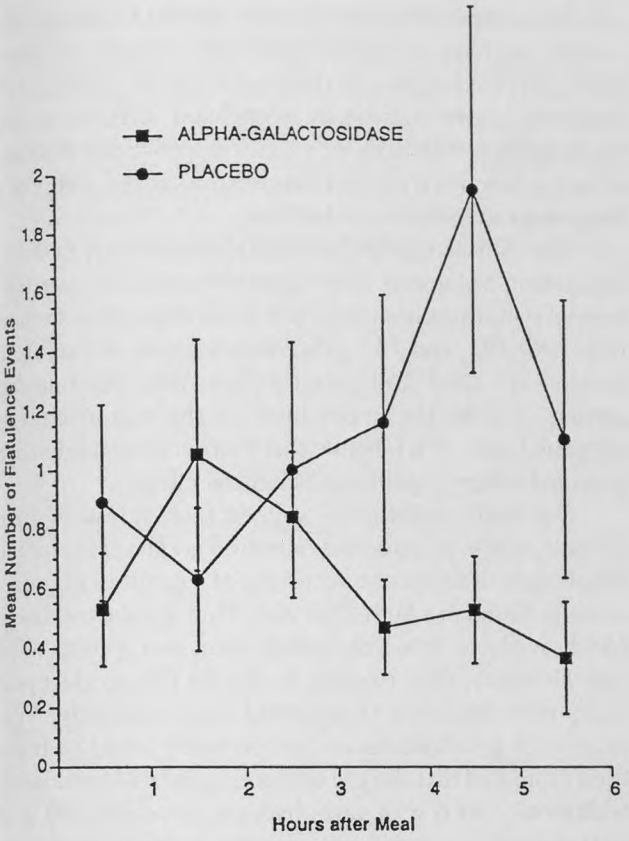

Figure. Comparison of mean (±standard error) number of flatulence events per hour among subjects following the ingestion of a test meal rich in oligosaccharides that had been treated with α-galactosidase (Beano) and an identical meal treated with placebo solution.

searchers, and data analysts were blinded as to the identity of the treatment and placebo solutions. Outcome data (number of flatulence events, symptoms of bloating, and pain) were treated as continuous variables. Comparisons between the drug and placebo administrations were conducted using paired *t* tests and repeated measures analysis of variance. These analyses were further stratified on the basis of age, sex, and history of flatulence associated with eating beans.

This study was approved by the Committee on Investigations Involving Human Subjects of the UCSD School of Medicine.

Results

Thirty healthy volunteers were recruited for the study; however, 5 subjects failed to appear for the first meal and 6 additional subjects were not present at the second meal. Of the 19 subjects who completed the study protocol, 10 (53%) were male, and the mean age was 35 years (standard deviation, 8 years). One volunteer was a family medicine resident, three were family medicine faculty, and the rest were department or medical center employees.

Of the 19 study subjects, only one person had ever used α-galactosidase, and 4 persons had seen the product before the study. Approximately one half (47%) of the subjects expressed the belief that abdominal gas is something natural, 4 (21%) reported that they do not like it but that it is not bad, and 6 (32%) reported that it is very embarrassing. Nine subjects (47%) reported having a problem with gas, and 10 subjects (53%) reported having a particular problem with gas after eating beans. Six subjects (32%) reported experiencing lactose intolerance, and one reported a history of chronic gastrointestinal disease (irritable bowel syndrome).

A comparison of the effect of α-galactosidase and placebo on reported flatulence events per hour after consumption of the meal is presented in the Figure. With the exception of the second hour after the meal (between 1 PM and 2 PM), the number of flatulence events per hour in the α-galactosidase group was less than that in the placebo group. When the two groups were compared with one another over the 6 hours of follow-up, the number of flatulence events per hour in the α-galactosidase group was significantly less than that in the placebo group ($F=2.87$; $df=5, 180$; $P=.016$). However, when the two groups were compared with one another at each time interval of follow-up, this difference was statistically significant only between 4 PM and 5 PM ($t=2.19$; $df=21$; $P=.04$). The power to detect a difference for the other time intervals was: 12 PM to 1 PM = 78%; 1 PM to 2 PM = 77%; 2 PM to 3 PM = 61%; 3 PM to 4 PM = 90%; 5 PM to 6 PM = 91%. No differences between the two groups were found in the extent of bloating or pain following the meal (power = 55% [bloating] and 73% [pain]).

Comparisons between the α-galactosidase and placebo groups were further stratified by sex to determine whether men and women differed with respect to response to the solution. No significant differences in number of flatulence events or symptoms of abdominal pain or bloating were found between the α-galactosidase and placebo groups for either men or women during the 6-hour follow-up period. Among the 10 subjects who described themselves as having problems with gas after eating beans, there were no statistically significant differences in mean flatus episodes per hour, abdominal pain, or bloating between meals with α-galactosidase and meals with placebo.

Discussion

The medical literature on flatus is relatively sparse; a MEDLINE search of the literature for the key words "intestinal gas," "flatulence," and "flatus" yielded only 39 arti-

cles from 1966 through 1992. Nonetheless, flatus remains an important problem for those who suffer from it and even more so for those around them. It is an occupational problem of considerable proportion among submariners, miners, astronauts, and elevator operators. Also, because cow flatus is considered a contributor to the greenhouse effect and global warming,[9] one observer has suggested that "federal helicopters should spray massive quantities of Beano on the nation's dairy farms to reduce the cow methane output."[10] (This suggestion is not farfetched, since a similar product for dogs, CurTail, is commercially available [Akpharma]).

Our study found that a commercially available α-galactosidase solution was effective in reducing intestinal gas formation after ingestion of a highly flatulogenic meal; the effect seems strongest the 5th hour after ingestion. We suggest several possible explanations for this finding. It should not be surprising that there was less effect seen during the 1st, 2nd, and 3rd hours following the meal, since flatus production occurs in the large intestine, and a delay might be expected depending on gastrointestinal transit time. In addition, it may be that the beneficial effect of α-galactosidase peaks after the 5th hour, and that our observation time should have been extended.

There may be a social explanation for our findings as well. Most of our subjects participated in the study over the lunch hour, returning to the workplace after eating the highly flatulogenic meal. It is conceivable that subjects repressed their need to expel flatus until leaving the workplace, which for many employees at our institution is at 4:30 PM. (Following the study, one subject admitted to doing this.) We believe that an additional, somewhat unexpected finding of our study is the suggestion that mannerliness and a concern for the olfactory well-being of others are alive and well in the American workplace. Still another possible explanation of our results is that only a subset of subjects benefited from α-galactosidase. This is in keeping with anecdotal evidence of persons reporting either no benefit or great benefit from α-galactosidase solution.

Although the study population was self-selected, it seems likely that the results of this pilot are generalizable to a primary care practice. The subjects reported a reasonable rate of both lactose intolerance and flatulogenic response to bean consumption.

Self-reporting of flatus passage is a potential limitation of our study. The embarrassment associated with this phenomenon may have inhibited accurate recording. All participants, however, were well educated as to the requirements of the study before participation, and confidentiality was assured. Moreover, the crossover design of our study should have controlled for this potential source of bias.

It is also possible that the expectation of a therapeutic benefit may have diminished flatulence in both the treatment and placebo groups, thus reducing the likelihood of observing more statistically significant differences between groups. Although we cannot disprove this possibility, we are aware of no data demonstrating the ability of a placebo to alter flatus production.

The clinical response to α-galactosidase may be dose-dependent. Solomons et al[6] demonstrated that gastrointestinal symptoms improved in a dose-dependent fashion with 196, 391, and 737 galactosidase units of enzymatic activity. We used 260 galactosidase units per one-cup serving of chili, the upper limit of the manufacturer's suggested dose. It is possible that a larger dose might have provided a more significant beneficial effect.

Our study and others[6,7] suggest that, at least in some patients, oral α-galactosidase solution is efficacious for the prophylaxis of flatulence occurring as a result of oligosaccharides found in a high-fiber diet. Oral α-galactosidase is widely available, relatively inexpensive, and appears to be safe. However, since treating food with this product produces more galactose than would occur naturally,[11] patients with galactosemia should probably avoid it. It has been estimated that the use of this enzyme will produce an additional 2 to 6 g of carbohydrate for every 100 g of treated food,[11] a significant amount, particularly for patients with diabetes mellitus. Rare allergic responses to α-galactosidase may occur, especially in persons allergic to molds.[11]

Conclusions

A commercially available solution of α-galactosidase appears to be somewhat beneficial in the prevention of flatus from dietary oligosaccharides. The optimal dose remains unknown.

Acknowledgments

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