

A Naturalistic, Controlled, Crossover Trial of Plum Juice versus Psyllium versus Control for Improving Bowel Function

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Citation

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Abstract

Prunes and prune juice have long been used to improve bowel regularity. Because of its high fiber content, plum juice may also improve bowel function, as well as have the potential to reduce appetite and excess body weight via an effect on satiety. This controlled study evaluated the effects of consuming a daily portion of plum juice (PlumSmart) prior to a meal for 14 days in 36 adults reporting chronic constipation symptoms, compared with a non-fruit source of fiber, psyllium (Metamucil) and equicaloric, fiber-free clear apple juice (placebo control). The main findings were 1) that softer stools were associated with plum juice compared to apple juice alone and apple juice with Metamucil 2) plum juice was as likely as psyllium to provide immediate relief (within 24 hours of first use) of constipation symptoms, and both performed better than the placebo (apple juice alone), and 3) the taste of plum juice was equal to apple juice alone, and was preferred over apple juice with psyllium. This study provides preliminary evidence to support the daily use of natural product, plum juice, as an accepted and effective treatment for stool softening and immediate relief of constipation symptoms.

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INTRODUCTION

Constipation is the most common digestive complaint, periodically or continually affecting nearly a quarter of the US adult population, and accounting for upwards of \$400 million in health care costs, 2.5 million physician visits annually, as well as lost work productivity and impairment of health-related quality of life [1]. Between 2 and 27% of the population suffer from such symptoms as infrequent bowel movements or abdominal bloating [3]. Indeed, there is evidence that constipation has plagued humanity even before recorded history, with every conceivable type of laxative and purgative being prescribed by early practitioners. While a number of over-the-counter and prescription pharmacologic treatments currently exist, they are limited by cost, side effects, and variable effectiveness [4,5] [6]. Causes of this high level of impairment of gastrointestinal function due to constipation include irritable bowel syndrome [7,8], diverticular disease [9], idiopathic constipation, and the low-fiber diet that is commonly consumed in the US [10,11].

Hippocrates is reported to have been among the first to say,

“Let food be your medicine.” Prunes, likely owing to their high fiber content, sorbitol, xylitol, and phenolic compounds, have been shown to improve gastrointestinal (GI) transit times and often provide relief from constipation without resorting to potent stimulant laxatives [12,13,14,15,16,17]. Also, surveys have shown that there is a high level of public belief that prunes are useful in improving stool consistency [18].

Sunsweet has recently developed a new product line called PlumSmart that is designed to improve bowel function comparably to the effect of prunes and prune juice, with comparable or better taste and ease of use than fiber supplements commonly used to improve bowel habits.

In addition to its hypothesized effect on bowel function, there is reason to believe that plum juice, via an effect on satiety, may be of benefit to those seeking to control appetite and excess body weight. Satiety, or ease of attaining fullness, can be manipulated through altering the energy density of the diet, especially via increasing fiber content ([19,20,21,22,23], as well as by altering portion size [24] and palatability [25]. In addition to its potential role in facilitating bowel function in constipated individuals, because of its

high fiber content, plum juice may also serve to reduce appetite.

Previous studies of satiety tested primarily young, normal-weight adults in a laboratory setting. The previous studies of the effect of prunes on constipation were performed almost exclusively among older adults, often nursing home residents. The existing data suggest the need for further, carefully designed studies in a broader range of age and weight categories to confirm the efficacy of prunes, and specifically plum juice in promoting bowel regularity, as well as exploring the possibility that it may prove beneficial in appetite and weight control.

The present study sought to investigate whether consuming a daily portion of plum juice prior to a meal, over the course of 2 weeks, would improve bowel function among constipated adults, as well as decrease hunger compared with a non-fruit source of fiber (Metamucil) and equicaloric, fiber-free clear apple juice (placebo control). We wished to examine the effect of the treatments in both men and women and in normal weight, overweight and obese individuals; therefore, the study was stratified for both gender and BMI cut-offs (described below). We hypothesized that the plum juice supplementation diet would induce significant improvements in bowel frequency, and consistency, and possibly decrease appetite compared to baseline as well as placebo and psyllium treatments. Secondary aims included evaluating immediate relief of constipation (within 24 hours of supplementation) and taste.

METHODS

Potential participants were recruited from the Baltimore-Washington metropolitan area by newspaper advertisement and flyers placed around the Johns Hopkins University medical campus. Initially, when potential participants enquired about the study, the study was described via telephone, and initial eligibility determined. If interested, potentially eligible participants were invited to the clinic for further screening and consent.

Participants were considered eligible if they self-reported being generally healthy but had symptoms of constipation. Specifically, participants were required to meet the standard (Rome II Consensus Conference) criteria for chronic, functional constipation, i.e., 2 or reporting more of the following for at least 12 weeks during the past 12 months:

- Straining in more than ¼ of defecations

- Lumpy/hard stool in more than ¼ of defecations
- Sensation of incomplete evacuation in more than ¼ of defecations
- Sensation of anorectal obstruction/blockage in more than ¼ of defecations
- Manual maneuvers needed to facilitate more than ¼ of defecations
- Fewer than 3 defecations per week
- Absence of loose stools/diarrhea

Potential participants were excluded if they had a history of partial or total colectomy, colorectal cancer or inflammatory bowel disease; if they were unwilling to consume plum juice, psyllium fiber, or apple juice on a daily basis for the duration of the study. Women who self-reported pregnancy or nursing were also excluded.

Eligible participants were weighed on a balance-beam scale and had their height measured with a stadiometer (both in ordinary street clothes, but with shoes off). They also had their waist circumference measured by measuring tape. Participants filled out questionnaires regarding known medical and surgical conditions, medications, and current and historical basic GI symptoms. In addition, basic dietary information was obtained and a food-frequency questionnaire completed. The study was stratified for both gender and 2 BMI stratas (BMI <25 and BMI between 25 and 35). Participants were randomized to 1 of the 6 possible sequences of the 3, 2-week intervention periods:

- plum juice, control (apple juice alone), apple juice with psyllium fiber
- plum juice, apple juice with psyllium fiber, control (apple juice alone)
- Apple juice with psyllium fiber, plum juice, control (apple juice alone)
- Apple juice with psyllium fiber, control (apple juice alone), plum juice
- Control (apple juice alone), plum juice, apple juice with psyllium fiber
- Control (apple juice alone), apple juice with psyllium fiber, plum juice

Following randomization, each participant was given their first treatment and a measuring cup. They were instructed to take it based on their randomization assignment (15-30 minutes prior to their main meal of the day, in a single serving (of 8 ounces of plum juice as PlumSmart each day, or 3g psyllium as sugar-free Metamucil (Proctor & Gamble, Cincinnati, OH) in 9 oz apple juice, or 9 oz apple juice alone)). The slight difference in volumes prescribed was to ensure that the beverages were equicaloric. Participants were given a 2-week supply of their first treatment product and instructed to take the treatment daily while eating as they normally do under all 3 conditions. Participants were also instructed in how to complete the take home diaries (questionnaires assessing stool frequency, consistency, compliance, hunger and satiety in real-time). The PI and staff controlled and dispensed all intervention products.

Participants returned to the clinic on a bi-weekly basis. During these bi-weekly visits, weight measurements were taken, take home diaries were returned, and a food frequency questionnaire was completed for the previous two-week period. Participants were then given the next treatment, and new take home diaries (with daily questionnaires, described above). Participants were compensated \$40 after completion of each of the first two, 2-week intervention periods and \$100 after completion of the final 2-week intervention period.

DATA ANALYSIS

Exploratory data analyses were performed. Friedman's anova (for non-normal dependent data) were used to examine bivariate relationships between treatment and outcome measures (i.e., constipation symptoms, taste, appetite, etc.). The test statistic, Kendall's coefficient of concordance, W , holds the null hypothesis that all treatments have identical effects. If the null is rejected (i.e., $p < 0.05$), at least one treatment has larger values than at least one other treatment. Pairwise comparisons were then employed using Wilcoxon's matched pair tests.

Random effects logistic regression models were employed to examine multivariate associations between treatment and dichotomous outcome variables (e.g., relief, yes or no). Random effects linear regression was used to examine the relationship between treatment and continuous outcome variables (e.g., constipation symptoms). Also, random

effects Poisson count regression models were used to examine the incident rate ratio for one of the outcomes, number of bowel movements per treatment. Data analysis was designed to allow maximum data retention, even from participants who have missing data or have dropped out prior to the end of the study, although this was minimal in the current study. The following potential confounding variables were explored for their effect on all outcomes: randomization sequence, gender, income, education, and race. These variables were only left in final regression models if they were found to be statistically significant.

Due to small samples sizes, data from participants with Hispanic ethnicity ($n=2$ in total) were dropped from any regression models in which race was a covariate because of limited power to make group comparisons. If study completers were missing 3 or less appetite assessments of the 14 repeated appetite ratings per treatment (i.e., $< 25\%$), the average of the remaining appetite assessments was imputed using the individual-level mean for that treatment. Results with and without the substitution were compared and when similar, mean substituted data are presented. Significance was defined as a p -value ≤ 0.05 . Statistical trends were defined as a p -value ≤ 0.10 . Exploratory and bivariate analyses were conducted using SPSS 11.0 statistical software (SPSS Inc., Chicago, Illinois). Regression analyses were conducted using Stata (Version 10.0, Stata Corporation, College Station, TX).

RESULTS

Forty-two adults were screened for the study and 3 were found ineligible. Thirty nine were enrolled and 36 (92.3%) completed the 6 week study: 18 females (50%), 18 males (50%). Participants were 51.3 ± 12.9 (range 18-88 years) years old. Forty-three percent identified themselves as Caucasian, 51% as African American, and 6% as Hispanic. Over half of the participants (53%) had no a high school diploma or less, 11% had some college, while 36% had obtained a college or advanced degree. Almost 64% of participants reported an annual income of less than \$25,000, 22% between \$25 – 49,999, and 14% more than \$50,000. Participants had an average body mass index (BMI; weight in kg/height in m^2) of 26.7 ± 4.7 , with 39% categorized as normal weight (BMI < 25.0), 39% overweight (BMI ≥ 25 and < 30) and 22% as obese (BMI ≥ 30). (Table 1)

Figure 1

Table 1: Socio-Demographic Characteristics among Completers

	(n=36) 100 %
Gender	
Male	50 (n=18)
Female	50 (n=18)
Age (years), mean	51.3 ± 12.9
Education, %	
HS diploma or less	52.8 (n=19)
Some college	11.1 (n=4)
College Graduate	13.9 (n=5)
Advanced Degree	22.3 (n=8)
Annual Income, %	
Less than \$25,000	63.9 (n=23)
\$25,000 to 49,999	22.2 (n=8)
\$50,000 to 74,999	8.3 (n=3)
Greater than \$75,000	5.6 (n=2)
Race/Ethnicity, %	
Caucasian	42.9 (n=15)
African American	51.4 (n=18)
Hispanic	5.7 (n=2)
Asian	0
Body Mass Index	26.7 ± 4.7
Normal weight	38.9 (n=14)
Overweight	38.9 (n=14)
Obese	22.2 (n=8)

FIGURING OF BOWEL MOVEMENTS

Upon entry into the study, all participants reported symptoms of constipation, including a mean figuring of bowel movements per week (less than 1 per day). During the interventions, participants were queried about bowel movements using two methods. First, participants were asked, retrospectively, how many bowel movements they had per week following each treatment. This method of reporting was consistent with their baseline retrospective assessment of bowel movement frequency. Following treatment, participants reported 11.9 ± 15.0 bowel movements per week with apple juice alone, 9.5 ± 5.9 with apple juice and psyllium, and 10.0 ± 9.7 per week with plum juice. With this method, significant improvements in the number of movements were seen with all three treatments (including the placebo treatment, apple juice alone) compared to baseline.

Second, participants were asked to keep a daily diary of the number of bowel movements during each intervention treatment. Participants reported 1.2 ± 0.8, 1.2 ± 0.7, and 1.3 ± 0.7 bowel movements per day for apple juice alone, apple juice with psyllium, and plum juice, respectively. There were no significant differences between these treatments when bivariate or regression analyses were performed.

CONSISTENCY OF DAILY BOWEL MOVEMENTS

For each of the three treatments, participants were asked to record the consistency of daily bowel movements. Participants recorded this information daily in a diary by rating consistency of bowel movements as 0=soft, 1=firm, 2=hard or 3=very hard. The average of the daily ratings was estimated for each individual and each treatment. Twenty-one participants had complete data on bowel movement consistency. On average, these participants reported mean consistency ratings of 0.85 ± 0.38 for apple juice alone, 0.88 ± 0.50 for apple juice with psyllium and 0.74 ± 0.41 with plum juice. When examined using bivariate analyses (Friedman’s Anova), there was a statistical trend (p=0.1) indicating that plum juice was associated with softer bowel movements on average, compared to apple juice alone or apple juice with psyllium. When examined using random-effects regression (to control for missing data and other potential confounders), there were no significant differences in stool consistency between apple juice and apple juice with psyllium (p=0.88). However, bowel movements were reported as significantly softer while using plum juice than while using either apple juice (p=0.02) or apple juice with

psyllium (p=0.01). While using plum juice participants reported a 0.19 and 0.20 oz (?) average decrease in bowel movement firmness compared to apple juice alone and apple juice with psyllium, respectively.

COMBINED ASSESSMENT OF GI SYMPTOMS (TABLE 2A)

Figure 2

Table 2a: Summary GI Symptoms (weekly) by Treatment among Completers (compared with baseline)

mean ± SD	Baseline	Apple Juice	Apple Juice plus Metamucil	Plum Juice	Statistics
†Summary GI score	47.27 ± 18.79 N=32	22.81 ± 23.09 N=35	20.29 ± 20.29 N=35	18.43 ± 18.58 N=36	Kendall’s W=0.3642 [†] 32.72 Df=3 P=0.0001

†Summary GI score = Average percent of bowel movements that are : a) hard/lumpy, b) accompanied by straining, c) a sensation of incomplete evacuation, d) a sensation of blockage, or e) the need to manually facilitate

At baseline, participants reported almost 50% of bowel movements being (47.3±18.8%) as associated with one or more of the following symptoms: hard/lumpy, accompanied by straining, a sensation of incomplete evacuation, a sensation of blockage, or the needed to be manually facilitated. During treatment periods, participants reported an average of 22.8 ± 23.1, 20.3± 20.3 and 18.4 ± 18.6% of bowel movements being associated with one or more of the above-mentioned symptoms for apple juice alone, apple juice with psyllium, and plum juice, respectively. While bivariate statistics (Friedman’s anova) did not reveal significant differences, when examined using random effects regression, there was a statistical trend indicating that plum juice reduced the percent of bowel movements associated with at least one these symptoms compared to apple juice alone (p=0.08). The magnitude of the decrease was ~18%. There was no statistical effect for apple juice with psyllium compared to apple juice alone, nor was there one when comparing apple juice with psyllium and plum juice.

INDIVIDUAL ASSESSMENT OF EACH GI SYMPTOM (TABLE 2B)

Figure 3

Table 2b: Weekly GI Symptoms (presented separately) by Treatment among Completers

mean ± SD	Apple Juice	Apple Juice plus psyllium	Plum Juice	Statistics
Number of Bowel Movements per week	11.86 ± 15.03 N=36	9.51 ± 5.87 N=35	10.03 ± 9.67 N=35	Kendall's W=0.028 X ² = 1.91 Df=2 P=0.384
Percent of very hard or lumpy bowel movements per week.	34.06 ± 33.62 N=35	31.58 ± 35.38 N=36	30.03 ± 33.25 N=36	Kendall's W=0.014 X ² = 0.980 Df=2 P=0.613
Percent of bowel movements accompanied by straining.	32.06 ± 36.69 N=36	29.8 ± 37.29 N=35	26.94 ± 35.35 N=36	Kendall's W=0.087 X ² = 6.062 Df=2 P=0.048
Percent of bowel movements accompanied by a sensation of incomplete evacuation	24.83 ± 30.75 N=36	22.97 ± 33.39 N=36	18.56 ± 25.06 N=36	Kendall's W=0.006 X ² = 0.463 Df=2 P=0.793
Percent accompanied by a sensation of anorectal obstruction/blockage	8.25 ± 18.11 N=36	8.31 ± 18.01 N=36	7.11 ± 14.71 N=36	Kendall's W=0.01 X ² = 0.453 Df=2 P=0.797
Percent of bowel movements that require manual/digital maneuvers to facilitate	13.47 ± 25.48 N=36	7.47 ± 14.91 N=36	9.50 ± 18.05 N=36	Kendall's W=0.05 X ² = 3.234 Df=2 P=0.198
Did you have loose stools/diarrhea more than rarely				
No	86.1 (n=31)	94.4 (n=34)	91.7 (n=33)	
Yes	13.9 (n=5)	5.6 (n=2)	8.3 (n=3)	

In these analyses, each of the following symptoms were analyzed separately: 1) percent hard/lumpy stools, 2) percent of stools accompanied by straining, 3) percent of stools associated with a sensation of incomplete evacuation, 4) percent of stools associated with a sensation of blockage, and 5) percent of stools which needed to be manually facilitated. When comparing these baseline constipation symptoms with those following the three interventions (i.e., apple juice, apple juice with psyllium, and plum juice), significant improvements in all symptoms (again, analyzed separately) were reported following all three interventions. However, when directly comparing the three interventions, the percent of bowel movements accompanied by straining showed a significant difference between treatments (p=0.05). When direct pairwise comparisons were made, there was a statistical trend (defined as p<0.1) indicating that bowel movements while on plum juice were less likely to be accompanied by straining than those while on apple juice alone (Z=-1.59, p=0.1). There were no pairwise differences between apple juice and apple juice with Metamucil (Z=-1.37, p=0.2). Plum juice performed as well as apple juice with Metamucil on the reduction of straining (Z=-0.03, p=0.10).

IMMEDIATE RELIEF OF CONSTIPATION (WITHIN 24 HOURS)

Participants were asked, after each of the three interventions, if they received immediate relief (within 24 hours of using the product) and were asked to categorize their response as “yes” or “no”. Only 25% of participants (n=9) reported immediate relief following apple juice alone, compared to 50% (n=18) after apple juice with Metamucil and 58% (n=21) after using plum juice. Compared to apple juice alone, both apple juice with Metamucil and plum juice significantly increased the odds of reporting immediate relief. After receiving the apple juice with Metamucil treatment, participants were 3.1 times more likely to report relief within 24-hours of first use compared to apple juice alone (p=0.05) and 4.7 times more like after receiving plum juice compared to apple juice alone (p=0.01). When compared directly, there was no significant difference in immediate relief between apple juice with Metamucil and plum juice. In summary, plum juice and apple juice with Metamucil worked equally well and both better than apple juice alone (placebo treatment).

APPETITE AND TASTE

Pre-meal appetite was assessed following a pre-load of either apple juice, apple juice with psyllium or plum juice. Participants were asked to drink each treatment beverage approximately 15-20 minutes before their main mealtime, then just prior to eating, to assess their pre-meal hunger using a 100mm Visual Analog Scale (VAS) in which they marked where on the continuum they rated their hunger (with 0 indicating no hunger, and 100 indicating extreme hunger). There were no significant differences in pre-meal hunger between the three treatments. Changes in appetite were also assessed by subtracting 1-hr post-meal hunger from pre-meal hunger. The changes in appetite rating (from pre-meal hunger to post meal hunger) were -39.5 ± 27.2, -39.1 ± 30.9, and -41.5 ± 25.5 for apple juice, apple juice with psyllium, and plum juice, respectively. Taste ratings for the three intervention beverages (i.e., apple juice, apple juice with Metamucil, and plum juice) were assessed. Participants were asked to rate each using a 10-point Likert scale (1= Did not like the taste at all, to 10 = Loved the taste). On average, participants rated the apple juice with psyllium the lowest (least tasty), with an average rating of 6.0 ± 2.6; however apple juice alone was rated highly (8.1 ± 2.4), as was the plum juice (8.2 ± 2.1). When comparing all three treatments, at least one of the treatments was significantly different from the others (p<0.0001), therefore direct pairwise comparisons

were employed. These indicated that both apple juice alone and plum juice were preferred over apple juice with psyllium ($Z=-4.13$, $p<0.0001$, and $Z=-3.12$, $p=0.002$, respectively). There was no significant difference in the taste rating of apple juice and plum juice ($Z=-0.49$, $p=0.624$). These results were confirmed by regression analysis. Of note, gender was found to be significantly associated with taste ratings in women assigned all beverages significantly lower ratings than did men ($p=0.004$), however the addition of this confounder to the final model did not modify the magnitude or the statistical significance of the differences found between intervention beverages.

DISCUSSION

Plums are dehydrated to make prunes, a well-known laxative agent. This effect is probably due to the sorbitol (14.7g/100g in prunes and 6.1g/100g in prune juice) and fiber content, though there are a number of other compounds present that may have healthful effects, such as polyphenols, which have cardio-protective and anti-inflammatory effects [26]. The substantial amount of polyphenols (184mg/100g) in prunes may also contribute to the laxative action. Prunes also contain diphenylisatin [27], which is a diphenol similar to oxyphenisatine- a known laxative.

Though phenolic content of prunes depends on the temperature at which plums are dried and is lesser at higher drying temperatures, much of the available literature suggests that the drying process leads to some significant degradation of phenolic content in plums, which is a possible explanation for the decreased amounts of active substances in prunes as compared to plums and plum juice, and, potentially, a somewhat lesser laxative potency[28]. This study evaluated the effects of consuming a daily portion of plum juice (PlumSmart) prior to a meal (for 14 days) on gastrointestinal symptoms and appetite, compared with a non-fruit source of psyllium fiber as Metamucil and equicaloric, fiber-free clear apple juice (placebo control) in individuals who self-reported constipation.

When examining the frequency of bowel movements, two different assessments were performed. The retrospective weekly assessment was employed in order to have comparability to baseline assessment (i.e., improvement from baseline could be assessed quantitatively). These data, overall, suggest that all 3 treatments (i.e., apple juice alone, apple juice with psyllium and plum juice) significantly increased bowel movement frequency compared to that reported prior to the study. However, caution should be

taken when interpreting this result. With these retrospective data, the standard deviations are high, indicating high variation in response to these treatments between people, but also likely, reflect the problem of reliability when using retrospective recall, as noted in many research studies. Indirect support of this interpretation of this comparison is found in the retrospective data with daily diaries (for the same intervention period). Daily diaries rely less on memory, as the information is specified to be recorded at, or soon following, the time of the event. In this study, bowel movement frequency data from daily diaries had less variability between individuals and bowel movement frequencies were in the anticipated range.

Bowel movement consistency was also rated each day using take-home diaries. Improved statistical power, using regression analysis, confirmed what bivariate analyses suggested (via statistical trend): that, on average, plum juice was associated with reports of softer bowel movements compared to the other two treatments. While the magnitude was relatively modest (an average decrease of 0.19-0.20 units in firmness rating), it was highly significant.

In addition to daily records of the number of bowel movements and consistency rating, other weekly retrospective data were collected regarding constipation-related symptoms. Specifically, participants were asked to report the percent of bowel movements associated with each of the Rome II Consensus Conference criteria for chronic constipation (as described in Methods). Five of the 7 criteria were combined into a sum score with the intent to assess overall constipation severity/relief (Table 2a). The two factors excluded were 1) fewer than 3 defecations per week and 2) absence of loose stools/diarrhea. These were excluded because the data were not collected in percentages and did not fit logically into a combined score. Interestingly, participants reported significant improvement in this summary score following all three treatments, including the placebo control compared to baseline. Multiple reasons may exist for this.

First, there is a possibility of respondent bias when participants tell researchers what they think the researchers want them to report. Second, it is possible that a few outliers (i.e., extreme responders) dramatically affected these mean scores. The standard deviations for these scores, again, are extremely high relative to the mean, indicating highly variable response to all treatments. Third, summarizing data in percentages over a period of one to two weeks may be

conceptually and practically difficult for people; this could influence both the means and the standard deviations. However, even taking these limitations and potential biases into account, one would expect these above-mentioned influences, and thus the variability caused by them, to remain consistent across treatments, allowing for some comparability.

While bivariate analyses only revealed significant changes from baseline, random effects regression demonstrated a statistical trend, suggesting that plum juice reduced the percent of bowel movements associated with at least one of these symptoms compared to apple juice alone ($p=0.08$). Given the limited sample size and high variability in the data, this trend may represent a robust, clinically significant effect on constipation symptoms compared to the placebo control. Future studies, perhaps to validate this trend, should collect all of these variables in real-time in order to prevent the bias resulting from summarized retrospective data.

Each constipation criterion was examined separately as well (Table 2b). Reflecting the results from the combined score, all constipation criteria were individually improved by all 3 treatments, compared to baseline (data not shown). Interestingly, many of these criteria (e.g., percent hard/lumpy, accompanied by straining, a sensation of incomplete evacuation, a sensation of blockage) also exhibited non-significant improvements following plum juice treatment, especially when compared with apple juice alone. However, the appreciable variability in the data is likely the prohibiting factor in finding statistical difference between the 3 treatments. Only one criterion was found to have a statistical difference between treatments: the percent of bowel movements associated with straining. When compared directly with other treatments using bivariate pairwise comparisons, there was a trend showing that bowel movements following plum juice were less likely to be reported as being accompanied by straining than those while on apple juice alone ($Z=-1.59$, $p=0.1$). This result is theoretically consistent with the finding that there is improved bowel consistency (i.e., reduced hardness).

An important goal of this study was to examine the effect of these 3 treatments on immediate relief of bowel symptoms. We asked participants to report whether they received relief in their overall constipation symptoms within 24-hours of each of the 3 products. Plum juice, and apple juice with Metamucil, the two fiber-based treatments, worked equally well, and were both more likely than apple juice alone to be

associated with immediate relief. It is both statistically and clinically significant that participants were 3.1 times more likely to report relief within 24-hours of first use of apple juice with Metamucil compared to apple juice alone, and 4.7 times more likely after receiving plum juice.

Another specific aim was to compare the effect of these three treatments, one placebo control versus two different fiber sources, on appetite ratings. Fiber is well documented to have satiety-related effects [24] and therefore we hypothesized that pre-meal intake of fiber-containing beverages would alter appetite. Interestingly, there were no significant differences between the treatments in either the pre-meal appetite rating or the change in appetite (from pre to post-meal hunger ratings). One factor that confounds this analysis is the lack of real time food intake information. While dietary intake was assessed at baseline and following each treatment using a food frequency questionnaire, dietary intake was not recorded on a daily basis. Nonetheless, this study did not support the effectiveness of fiber-containing beverages to control or curb pre-meal appetite.

Finally, a taste rating was performed on all three intervention beverages. Apple juice alone and plum juice were rated equally high and both were preferred over apple juice with Metamucil. This is an important clinical finding as both psyllium and plum juice are potential long-term over-the-counter preventative or maintenance treatments for chronic constipation; if participants dislike the taste they may be less likely to be compliant with a daily regimen.

While there are several limitations to the study, including the relatively small sample size and the nature of some of the retrospective data, there are several strengths. The study included both men and women, in a broad range of BMIs, thus making the results generalizable across these demographic groups. Second, while there was some missing data on the individual-level, it was minimal, as was the study drop-out rate, which allows for less complicated interpretation of the results. Third, the cross-over study design and the related appropriate statistics allow each person to serve as their own control; this is optimal when treatment order is assigned randomly and order effects are examined, as was done in the current study.

SUMMARY

The goal of this study was to examine the effect of three treatments on chronic constipation symptoms and appetite. The main findings from this research are 1) that softer stool

was associated with plum juice compared to apple juice alone and apple juice with psyllium, 2) plum juice was as likely as psyllium to provide immediate relief (within 24 hours of first use) of constipation symptoms, and both performed better than apple juice alone, and 3) the taste of plum juice was equal to apple juice alone, and was preferred over apple juice with psyllium. This study provides preliminary evidence to support the daily use of plum juice as an acceptable and effective treatment for stool softening and immediate relief of symptoms of constipation.

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