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The Effect of Probiotic Supplementation on Gastrointestinal Quality of Life

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Purpose. The purpose of this research study was to investigate the effect of Puritan's Pride probiotic on gastrointestinal quality of life of working adults at the Loma Linda Support Services Building aged 18 to 65 years.
Methods. Working adults, 18 to 65 years of age, from the Loma Linda Support Services Building were eligible to participate in the study. Subjects were excluded if they were taking antibiotics or had taken antibiotics within the previous six months. Subjects who consented were given an initial Gastrointestinal Quality of Life Index (GIQLI)[12] test and a probiotic supplement for 60 days. Subjects' body composition was also tested during the initial visit. After the 60 days of supplementation, subjects returned to retake the GIQLI and to retest their body composition.
Results. Eleven subjects, 1 male and 10 females, reported for post intervention GIQLI and body composition testing. A mean increase of 10.7 (SD= 11.1) in GIQLI scores was found after probiotic supplementation ($p = .009$). No significant differences were found in pre and postintervention measurements for BMI, body fat, and weight. The best predictor of postintervention GIQLI scores was preintervention GIQLI scores.
Conclusion. There was an improvement in the related gastrointestinal quality of life in our subjects as shown through a significant increase in GIQLI scores and subjects' commentary. The best predictor of posttest GIQLI scores was pretest GIQLI scores.

Key words: Probiotic, Supplement, Supplementation, Bacteria, Microbiome, Quality of life, Gastrointestinal, GIQLI, Gut, Digestion

In the United States, immune-mediated and gut-related health issues are progressively increasing.[1] According to the National Institute of Health, digestive diseases including, but not limited to, irritable bowel diseases and chronic constipation affect approximately 70 million Americans annually.[2] Because inflammatory and immunologic activation predominantly occurs in the gut, achieving and maintaining optimal gut bacteria is advantageous in counteracting these inflammatory effects.[1] Probiotic supplementation may aid in achieving the optimal balance of gut bacteria. These positive effects of probiotic supplementation have garnered the interest of many, as reflected in recent statistics provided by the National Center for Complementary and Integrative Health. "In 2012, the use of probiotics or prebiotics by adults in the United States was four times higher than in 2007."[3]

According to the Food and Agriculture Organization of the United Nations World Health Organization, probiotics are defined as "live microorganisms which when administered in adequate amounts confer a health benefit on the host."[4] A myriad of bacteria strains exist, but in order for a strain to be classified as a probiotic, it must be scientifically shown to have beneficial physiological effects, be safe for human consumption, derived from human origin, stable in both acid and bile, and adhere to intestinal mucosa.[1] Lactobacillus sp. and Bifidobacterium sp. are the two most predominant strains studied in the literature because they have shown promising results in improving gastrointestinal quality of life.

Researchers have shown that probiotic use is positively correlated with gastrointestinal function regulation and gastrointestinal quality of life improvement.[5] More specifically, probiotics "promote gut-barrier functions, give maturational signals for the gut-associated lymphoid tissues, and balance the generation of pro- and anti-inflammatory cytokines."[1] Furthermore, researchers have found that probiotic supplementation decreases gastrointestinal

transit time, increases stool frequency, and improves stool consistency with no adverse events.[6] Lastly, in some patients with irritable bowel syndrome, probiotic supplementation has decreased symptoms in diarrhea-predominant irritable bowel syndrome, reduced bloating, and improved bowel movement consistency, all of which led to improved quality of life.[7]

In today's society, advancements in technology have led to more sedentary jobs and a demand for higher output in the workplace. This demand can often cause chronic stress in employees. Sedentary occupations and occupations performed indoors are associated with a higher risk of inflammatory bowel disease. This association may be caused by a lack of physical activity and the stress created by the demand for a higher output.[8] Job stress has been shown to play a role in the development of gastric issues, contribute to negative health behaviors, and inhibit workers' abilities to make positive changes to lifestyle behaviors.[9, 10] Additionally, chronic stress associated with the workplace is a major risk factor in the pathogenesis of different diseases of the gastrointestinal tract including gastroesophageal reflux disease (GERD), peptic ulcer, functional dyspepsia, inflammatory bowel disease (IBD), and irritable bowel syndrome (IBS).[11]

Probiotics, available on the market, contain a variety of strains and differing dosages. Despite the number of probiotic choices, we chose to select and analyze one specific probiotic supplement brand in order to determine its effectiveness. Therefore, the purpose of this graduate student research study was to investigate the effect of Puritan's Pride probiotic on gastrointestinal quality of life in working adults aged 18 to 65 years.

Methods

Subjects

Subjects were recruited through flyers posted within the Loma Linda Support Services Building (LLUAHSC 101), as well as through email. Authorized investigators were present on site to answer questions and check eligibility on specified dates. Subjects included a total of 11 employees from LLUAHSC 101 in the city of Loma Linda, California who had never taken a probiotic supplement in their lifetime and were between the ages of 18 to 65 years. Subjects were excluded if they had taken antibiotics within the last six months. Only subjects from LLUAHSC 101 were included to limit variability in workplace behavior and activity level.

Potential subjects who responded to posters and emails were given an informed consent form during the initial meeting with employees and prior to the first administration of the Gastrointestinal Quality of Life Index (GIQLI) (Appendix A). The investigators were present to answer any questions. Subjects had 15 minutes to consider participating in the study. Subjects were chosen on a first come, first serve basis, as long as they fulfilled both inclusion and exclusion criteria. A total of 17 subjects were recruited, but only 11 subjects completed the study.

Supplementation

The probiotic supplement used was Puritan's Pride Probiotic 10. The capsules contained 20 billion live probiotic cultures from 10 probiotic strains. These 10 strains were Lactobacillus plantarum, Bifidobacterium bifidum, Lactobacillus rhamnosus, Lactobacillus bulgaricus, Lactobacillus salivarius, Lactobacillus brevis, Lactobacillus acidophilus, Bifidobacterium lactis, Lactobacillus paracasei, and Lactobacillus casei. The remaining ingredients were gelatin,

dicalcium phosphate, silica, vegetable magnesium stearate, and some milk ingredients. Puritan's Pride manufactured the probiotic supplement used and the supplement was purchased online through their website (www.puritan.com).

Gastrointestinal Quality of Life Index

Quality of life was measured using the Gastrointestinal Quality of Life Index (GIQLI) before and after a two-month intervention. The GIQLI is a valid and well-known tool for assessing quality of life of patients with gastrointestinal complaints, and was developed by a team of four surgeons and three methodologists.[12] The GIQLI consists of 36 questions which fall into the following five main categories: core symptoms, psychological, physical, social, and disease-specific. Core symptom questions include abdominal pain, epigastric fullness, bloating, flatus, belching, abdominal noises, bowel frequency, enjoyed or restricted eating, and fatigue. An example question is "How often during the past 2 weeks have you been troubled by uncontrollable stools?" Psychological questions encompass coping with stress, sadness, nervousness, happiness, and frustration. Physical items include feeling unwell or unfit, trouble sleeping, changes in appearance, and loss in physical strength or endurance. Social questions inquire about completion of normal daily activities and recreational activities, as well as worsened personal relationships and impairment of sexual life. Lastly, disease-specific questions regarding frequency of issues regarding regurgitation, dysphagia, eating speed, nausea, diarrhea, bowel urgency, constipation, and blood in the stool are included. Each symptom is rated from 0 to 4 (0 being the worst and 4 being the best) with a maximum score of 144 points.

Procedures

The experiment was a repeated-measures study in which 11 subjects were given a pretest prior to the intervention and a posttest following the intervention. Once consented, subjects were asked to fill out a questionnaire regarding current gastrointestinal quality of life. Subject were then provided with a 60-day supply (120 capsules) of Puritan's Pride probiotic supplement, consisting of a dosage of 40 billion live cultures. Subjects were instructed to take two capsules daily in the morning until posttesting.

Intervention

During the two months of the study, subjects:

- Took two capsules of the Puritan's Pride probiotic supplement every morning.
- Received weekly email or phone reminders by subject's preference.
- Filled in a weekly diary regarding compliance with taking probiotic supplement and core symptoms while taking the probiotic supplement (Appendix B).
- Continued supplementation on the following day for any days missed, and logged it in the diary.
- Returned the diary at the final visit to the investigators.
- Filled out the same GIQLI at the end of the two month duration.

Data Analysis

All collected data was analyzed using SPSS ver. 24.0 (SPSS Inc., Chicago, IL, USA) and a p-value $< .05$ indicated statistical significance. Paired t-tests were used to determine significant changes between pre and post anthropometric measurements and GIQLI scores. Stepwise regression tests were used to find the best predictor of the post intervention GIQLI score.

Results

Eleven of the 17 subjects (64.7%) completed the study. Six subjects were lost to follow up. The characteristics of the study group are summarized in Table 1. A female predominance (91%) was noted among the 11 subjects, with only 1 male subject (9%). The age of subjects ranged from 24 to 62 years, with a mean of 45.4 years. Based on the subjects' height and weight, a BMI status was able to be determined. The BMI of our subjects ranged from normal to obese, with the mean BMI being overweight. Overall, our typical subject was overweight, middle-aged, and 5'5" in height.

We examined the difference between pretest and posttest Gastrointestinal Quality of Life Index scores using a paired t-test. We found a mean increase in GIQLI scores of 10.7 (SD = 11.1) which was significant ($p = .009$). Even with the one male subject removed, statistical analysis still confirmed a significant increase in GIQLI scores, with a mean increase of 9.4 (SD = 10.7, $p = .02$). Initially, we had planned on comparing the effect of probiotic supplementation for those with high initial GIQLI scores to those with low initial GIQLI scores; however, because of low participation and high variability, this comparison was not done.

We examined the differences between pre and postintervention measurements for BMI, body fat, and weight. The mean differences were as follows: change in BMI .10 kg/m^2 (SD = .34), change in body fat -1.26% (SD = 4.49), change in weight .63 pounds (SD = 1.98). There was no significant difference in changes in BMI ($p = .36$), body fat ($p = .36$), or weight ($p = .31$).

From our stepwise regression tests, we found that the best predictor of posttest GIQLI scores was pretest GIQLI scores ($p = .001$). BMI ($p = .85$), body fat ($p = .67$), and weight ($p = .47$) were not significant predictors of post-test GIQLI scores.

Discussion

The findings from this study are consistent with current literature that probiotic supplementation is related to gastrointestinal function regulation and gastrointestinal quality of life improvement.[5] We observed a significant improvement in GIQLI scores after a two-month intervention of two probiotic capsules daily. These results are consistent with a previous study's findings that probiotic supplementation decreases gastrointestinal transit time, increases stool frequency, and improves stool consistency with no adverse effects.[6]

Although the media suggests that probiotics may promote weight loss, the present study did not find significant changes in BMI, body fat, or weight. This suggests that probiotic supplementation may not play a significant role in weight management in this population; however, although both occurred between the hours of 12:00PM and 2:00PM, anthropometric measurements of body fat mass may have been affected by subjects' hydration status per the instruction manual for the InBody scale.

The primary strength of our study is that our results add to the growing body of knowledge and research about probiotic supplementation. Our pilot study shows feasibility, cost effectiveness, and timeliness. Even with a small sample size, our findings revealed that probiotic supplementation can improve gastrointestinal quality of life. Future studies can use this evidence to justify the use of resources and support further investigation of probiotics on gastrointestinal quality of life. Another strength of our study is subject compliance when taking the probiotic supplements. Of those who successfully completed the study, compliance was high, mean of 92.8% compliant. Our study also supports literature findings that the use of probiotic supplementation seems to be safe and well tolerated by healthy adults.[1]

This study has a few limitations. First, due to the small sample size and drop out rate, findings may not have been fully representative of the population. Another limitation of this study is that the subjects may be affected by subject bias. In recent years, consuming probiotics has gained popularity in the media as a weight loss method. Knowing this, subjects may have consciously or subconsciously followed healthier dietary habits while taking the probiotic supplement which may have affected the results.

In addition to the study's limitations, there are several confounding factors that may have influenced the results of this study. Two possible confounders for this study were physical exercise and daily caloric intake. These variables were not tracked or accounted for during the course of the study. The time of year during which this study took place could have also impacted results, as the study began in October and ended in mid-December. The Thanksgiving holiday and the holiday season in general could be confounding factors due to the commonly increased food intake during this time of year; however, no documentation of calorie intake was collected.

We suggest a randomized controlled study design with a larger sample and the use of a placebo in order to eliminate subject bias which will give a more complete explanation of the potential benefits of probiotic supplementation and the mechanisms behind them. Future designs may also want to consider providing standardization for any qualitative data collected to account for subjects' perceived physiological improvements. Lastly, accounting for or standardizing physical activity and caloric intake may provide more representative results in relation the changes in anthropometric measures of BMI, body fat, and weight.

Conclusion

Our research study found significant differences between pretest and posttest GIQLI scores in employees from LLUAHSC 101. There was a significant improvement in the quality of life in our subjects after probiotic supplementation, with patients reporting improved regularity of bowel movements, and better sense of overall well-being. There were no significant differences in anthropometrics in our subjects after intervention. We found that the best predictor for our posttest GIQLI scores were pretest GIQLI scores. Overall, our research study adds to the body of knowledge and research surrounding probiotic supplementation for improved gastrointestinal quality of life.

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Table 1.
Summary of Data from 11 Subjects who Completed the Probiotic Supplementation Study

	N	Minimum	Maximum	Mean	Standard Deviation
Age (years)	11	24	62	45.4	13.0
BMI	11	23.0	38.3	29.78	5.13
Body Fat (%)	11	30.80	53.00	41.25	8.07
Height(in)	11	60	71	65.0	3.5
Weight(lb)	11	119.7	246.5	181.1	44.58
GIQLI pretest	11	71	136	102.4	19.4
GIQLI posttest	11	83	140	113.1	20.8
Change in GIQLI scores	11	-5	32	10.7	11.1
Percent Compliance with supplement	10	75	100	92.8	9.4

Table 2.
Stepwise Regression Test for Variables predicting GIQLI Posttest Scores

Variable	p-value*
GIQLI pretest	.001
Weight	.47
BMI	.85
Body Fat	.67

**Stepwise regression test, significance at $p \leq .05$*