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Probiotics Effective in Combating Antibiotic-Associated Diarrhea; "Good Bugs" Look Promising as Anti-Inflammatory Agent for Patients with Ulcerative Colitis, Psoriasis, Chronic Fatigue Syndrome

Washington, DC (October 31, 2011) – In four different studies presented at the American College of Gastroenterology's (ACG) 76th Annual Scientific meeting in Washington, DC, researchers explored the effectiveness of probiotics for antibiotic-associated diarrhea; as an anti-inflammatory agent for patients with ulcerative colitis, psoriasis and chronic fatigue syndrome; and for people with abdominal discomfort and bloating who have not been diagnosed with a functional bowel disorder, such as irritable bowel syndrome (IBS).

These four studies will be featured during an ACG press briefing on Tuesday, November 1, 2011 entitled: "***Good, Bad and Ugly Bugs: Mother Nature as a Treatment for Better Health in the GI Tract,"*** which will highlight new clinical science that explores the role of the "gut microbiota" – the bacterial composition of the GI tract – and the efficacy of probiotics and fecal microbiota transplantation in treating various GI conditions.

Probiotics are considered "good bacteria" that help maintain the natural balance of microflora in the digestive tract where trillions of bacteria live. While most of the more than 400 different species in the gut are healthy bacteria, others, "bad bugs" have the potential to cause damage to the digestive system. At times, an imbalance between the good and bad bacteria can lead to uncomfortable symptoms or illnesses. Probiotics are bacteria, or even sometimes yeast, which may alleviate common GI symptoms and are found in many commercial products including yogurt, juices, soy products, fermented milk, tempeh and other dietary supplements. They also come in capsule, tablet or powder formulations.

Probiotic Therapy Reduce the Incidence of Antibiotic Associated Diarrhea

Antibiotic-associated diarrhea (AAD) and *Clostridium difficile*-associated diarrhea (CDAD) are complications of long-term antibiotic use and are associated with significant cost and morbidity.

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While the role of probiotics in treating AAD and CDAD has been investigated in several trials with conflicting results, this review, ***"Probiotic Prophylaxis Significantly Reduces the Incidence of Antibiotic Associated Diarrhea: A Meta-Analysis,"*** by researchers from the Maimonides Medical Center in Brooklyn, New York, is the first meta-analysis examining the role of probiotics in treating these conditions.

Twenty-two studies were identified and a total of 3096 patients were included, 63 percent of whom were adults and all treated with various species of probiotics. Four studies (35 percent of the population of the study) used *S. boulardii* as the probiotic of choice. The average treatment period with probiotics was 1.5 weeks, with the shortest period being five days and the longest period being three weeks, according to Steven Shamah, MD, who presented the findings.

"Overall in twenty-two studies, probiotic prophylaxis significantly reduced the odds ratio of developing AAD by approximately 60 percent. This analysis clearly demonstrates that probiotics offer protective benefit in the prevention of these diseases," said principal investigator Rabin Rahmani, MD.

"These findings suggest that all patients who are at high-risk for these infections demonstrated by recent antibiotic useage, old age, recent hospitalization, low albumin, and immunosuppression should be considered for probiotic therapy," said Dr. Shamah. He added that further prospective studies are warranted to examine the most efficacious duration, dose and specific species of probiotics in prevention of AAD and CDAD in high risk patients.

Another related meta-analysis, ***"Probiotics in Antibiotic-Associated Diarrhea: An Updated Meta-Analysis of Randomized Controlled Trials,"*** confirmed earlier results suggesting the preventative effects of probiotics in AAD. Researchers from Beth Israel Deaconess Medical Center, Harvard Medical School, aimed to estimate the reduction in risk of developing AAD with probiotic therapy in randomized controlled trials (RCT), and identify factors associated with such reduction. The analysis included 28 randomized controlled trials with 3,338 total patients receiving single or combination antibiotics for various indications.

"The preventive effect of probiotic use remained significant regardless of species used, adult versus child populations, study quality score and antibiotic administered," said researcher Elizabeth Videlock, MD, who presented the findings. "The preventive effect of probiotics is also apparent during combined antibiotic treatment for *H.pylori* eradication."

B. infantis 35624 Investigated in Non-Patient Population

In the largest study on probiotics done in the United States in a non-patient population, researchers from the University of North Carolina at Chapel Hill assessed the efficacy of *B. infantis* 35624--a probiotic that has been effective in relieving symptoms in IBS patients—for the relief of abdominal discomfort and bloating in a non-patient population.

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The double-blind, randomized, placebo controlled, parallel study with a two-week placebo run-in phase followed by a four-week intervention phase was conducted at ten clinical centers in the US. The study included 302 non-patients who experienced abdominal discomfort and bloating more than twice weekly on average for at least three months but had not seen a physician or received prescribed medication for their symptoms in the past 12 months. They called in daily to report symptom severity on a six point Likert scale during the run-in and treatment phase.

Although mean severity scores for both, abdominal discomfort and bloating improved during the intervention period, there were no significant differences between the placebo and probiotic group, according to Yehuda Ringel, MD, who presented the findings.

"Unlike previous clinical studies in IBS patients, we were not able to demonstrate a statistically significant improvement in mean severity of abdominal discomfort and bloating with *B. infantis* 35624 in a non-patient population," said Dr. Ringel. He attributed this in part to the high placebo response and the possible "floor effect" which means the severity of symptoms is too low to measure any improvement. "This doesn't mean that *B. infantis* 35624 cannot help ease abdominal discomfort and bloating in non-patients—we just couldn't demonstrate it because the room for improvement is low compared to IBS patients, where symptom severity is much higher. Our secondary finding of significantly more bloating-free days in the *B. infantis 35624* group needs further studies, particularly in the non-patient, healthy population."

Probiotic *B. infantis* 35624 Promising as Anti-Inflammatory Agent for Patients with Ulcerative Colitis, Psoriasis, Chronic Fatigue Syndrome

Microbial imbalance has been proposed as one possible explanation for the increased incidence of a wide range of inflammatory disorders, including ulcerative colitis, suggesting that altering the balance between good and bad bacteria in the gut may promote an immune regulatory response that could reduce inflammation, according to researchers at the Alimentary Pharmabiotic Centre at University College Cork and Alimentary Health Ltd in Cork, Ireland, who aimed to determine if B. infantis could influence systemic pro-inflammatory biomarkers in patients with inflammatory disease.

The double-blind, placebo controlled study, **"*Oral Administration of the Probiotic* Bifidobacterium Infantis *35624 to Humans Induces Immunoregulatory Responses in Vivo,"*** included healthy volunteers, and patients with psoriasis, ulcerative colitis and chronic fatigue syndrome. According to the results, plasma levels of the anti-inflammatory cytokine, IL-10, were significantly increased in healthy volunteers and psoriasis patients, but not placebo for eight weeks; while plasma levels of the pro-inflammatory cytokines TNF-alpha and IL-6 were significantly reduced in all patient groups that received *B. infantis*. In addition, C-reactive protein (CRP) levels were also significantly reduced in psoriasis, ulcerative colitis and chronic fatigue patients at the end of treatment with *B. infantis* compared to placebo treated patients.

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"The human immunological response to *B. infantis* further supports the hypothesis that manipulation of the microbiota with specific therapeutic microbes can have a significant effect on host inflammatory processes," said Eamonn M.M. Quigley, MD, FACG, who presented the findings. "This anti-inflammatory effect is not restricted to a specific disease state, suggesting that *B.infantis* induces a critical cellular response, which may include the induction of regulatory cell subsets."

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About the American College of Gastroenterology
Founded in 1932, the American College of Gastroenterology (ACG) is an organization with an international membership of more than 12,000 individuals from 80 countries. The College is committed to serving the clinically oriented digestive disease specialist through its emphasis on scholarly practice, teaching and research. The mission of the College is to serve the evolving needs of physicians in the delivery of high quality, scientifically sound, humanistic, ethical, and cost-effective health care to gastroenterology patients. www.acg.gi.org View releases on other research breaking at the ACG meeting at www.acg.gi.org/media/press.asp Follow ACG on Twitter