ABPRO-10™

Tablets

Probiotics 10 billion CFU

***Probiotics***

*Scientific Name(s): Bifidobacterium bifidum, Bifidobacterium breve, Bifidobacterium infantis, Bifidobacterium longum, Enterococcus faecium, Lactobacillus acidophilus, Lactobacillus bulgaricus, Lactobacillus casei, Lactobacillus helveticus, Lactobacillus plantarum, Lactobacillus rhamnosus, Saccharomyces boulardii, Streptococcus salivarius, Streptococcus thermophilus*
*Common Name(s): Indian yogurt, Probiotics, Sour milk, VSL-3, Yogurt*

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*Clinical Overview*

***Use***

*Sufficient clinical trials have been conducted to enable meta-analyses for several clinical conditions. For specific probiotic strains in defined conditions, clear evidence has not yet been established.*

*There is evidence to support probiotic use in bacterial vaginosis, pediatric candidemia and candiduria, diarrhea (eg, acute infectious, antibiotic-associated, persistent), GI*

*surgery, irritable bowel syndrome, necrotizing enterocolitis in neonates, upper respiratory tract infections (URTIs), blood pressure, and ventilator-associated pneumonia. Meta-analyses have shown no effect in asthma prevention, Crohn disease, eczema treatment, or ulcerative colitis with the use of probiotics, but there is equivocal evidence to support their use in the prevention of eczema, diabetes, and dyslipidemia, and in patients in intensive care.*

*Dosing*

*Daily intake of oral probiotic preparations is commonly recommended, but some trials have used twice-weekly dosing. Preparation strength is usually measured as million/billion colony-forming units (CFUs) per capsule.*

*Contraindications*

*Use of probiotics in severe acute pancreatitis is contraindicated. Use is also not advised in patients at risk of opportunistic infections and in those with badly damaged GI tracts.*

*Pregnancy/Lactation*

*Information regarding safety and efficacy in pregnancy and lactation is lacking. Trials investigating probiotic use in pregnant women have not resulted in adverse reactions.*

*Interactions*

*None well documented.*

*Adverse Reactions*

*Probiotics are considered to be relatively safe. Studies using probiotics have reported abdominal cramping, nausea, fever, soft stools, flatulence, and taste disturbances. Isolated case reports link probiotics to adverse reactions such as bacteremia, endocarditis, septicemia, pneumonia, and deep abdominal abscesses.*

*Toxicology*

*Information is lacking.*

*History*

*The use of probiotic preparations has been discerned throughout history. Abraham's longevity, as described in a Persian version of the Old Testament, was the result of drinking sour milk. The Roman historian Plinius in 76 BC described fermented milk as a remedy for gastroenteritis. In 1916, experiments were conducted to implant Escherichia coli as a means of fighting pathogenic intestinal flora.[1]*

*In 1965, the term probiotic was first used when describing "substances secreted by one microorganism which stimulates the growth of another," in other words, the opposite of an antibiotic.[1] Revised definitions have appeared in literature to accommodate*

*mechanisms of action and stimulation of systems other than bacteria, and an all-encompassing version has been proposed by one group: "A preparation of or a product containing viable, defined microorganisms in sufficient numbers, which alter the microflora (by implantation or colonization) in a compartment of the host and by that exert beneficial health effects in this host."[1] Related concepts of prebiotics and synbiotics have also been elaborated.[1, 2] The study of microbes inhabiting the human GI tract and their effect on disease is an important part of the ongoing Human Microbiome Project of the US National Institutes of Health.[3]*

*Uses and Pharmacology*

*The potential mechanisms by which probiotics exert their action may include production of pathogen-inhibitory substances, inhibition of pathogen attachment, inhibition of the action of microbial toxins, stimulation of immunoglobulin A, and trophic effects on intestinal mucosa.*

*Each agent or preparation may have unique actions, with some bacterial strains more or less effective than others. Trials included in meta-analyses are generally heterogeneous, especially with respect to the strain of probiotic used. For specific strains in defined conditions, clear evidence has not yet been established.([4, 5, 6])*

*Animal data*

*Widespread use of probiotics, together with a largely safe adverse event profile, makes data from animal experimentation mostly irrelevant to human health. There have been a sufficient number of clinical trials to enable meta-analyses for certain clinical conditions. A published review argues that a meta-analysis of data from animal experiments (rat and dog) could not have predicted the unexpected increased mortality observed in the probiotics group in the Probiotics in Pancreatitis Trial (PROPATRIA) multicenter trial.([7])*

*CNS/Psychological conditions*

*Systematic reviews and meta-analyses have been conducted on the effects of probiotics on depression([136]) and subclinical psychological symptoms([137]) mostly in healthy adults. Overall, meta-analysis showed a significant improvement in depression scores for probiotics compared to controls (P=0.005). Of the 5 randomized controlled trials, randomized clinical trial (N=365), one study enrolled patients with major depression (n=40) whereas the remainder were conducted in healthy volunteers. Subgroup analyses revealed that improvement in depression scores remained significant for patients as well as volunteers with mean differences of −0.73 and −0.25, respectively, (P=0.03 for each) and for adults no greater than 60 years of age (MD= −0.43; P=0.005). Risk of bias among the studies was low.([136]) The impact of probiotics on subclinical psychological symptoms of anxiety, depression, and perceived stress*

*was assessed in 7 randomized clinical trials (N=570). All studies enrolled healthy individuals. The meta-analysis showed an overall significant reduction in the preclinical symptom scores (P=0.01) in the probiotic group compared to placebo. Heterogeneity was substantial (67%).(137) Limited data exist in patients.*

*Diabetes*

*Limited studies have been conducted in patients with type 2 diabetes. One study found L. acidophilus effective in maintaining insulin sensitivity versus placebo.(8) A clinical trial using probiotic yogurt over 6 weeks resulted in decreased fasting blood sugar and hemoglobin $A_{1c}$, as well as improved antioxidant status, but no effect on insulin,(9) while a similar study over 30 days resulted in improvements in fasting blood glucose but no effect on dyslipidemia.(10) Protocols for 2 subsequent clinical trials (N = 120 and N = 540 patients to be enrolled, respectively) have been published, with results pending.(11, 12)*

*Diarrhea*

*Acute infectious diarrhea*

*Trials conducted through 2010 that evaluated the effect of probiotics on acute infectious diarrhea were included in a Cochrane meta-analysis. Probiotics were found to be safe and to shorten both the mean duration of diarrhea (mean difference, 24.76 hours; 95% confidence interval [CI], 15.9 to 33.6 hours) and the likelihood of ongoing diarrhea after 4 days (relative risk [RR], 0.41; 95% CI, 0.32 to 0.53).(13) Trials were generally heterogeneous, with further studies possibly providing more information about the efficacy of specific strains and appropriate regimens.(13)*

*There are several guidelines discussing probiotics and the relationship with Clostridium difficile infection. The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommends probiotics for the treatment of acute diarrhea in adults based on level 2 and 3 evidence reported for specific probiotic strains. In children, use of probiotics for treatment of acute gastroenteritis, prevention of nosocomial diarrhea, and for infections in those attending daycare centers is based on level 1, 2, and 3 evidence.(145) Infection in adults (2010) note that the administration of currently available probiotics is not recommended to prevent primary C. difficile infection, based on limited supportive data and a potential risk of bloodstream infection. This is a lower level recommendation (C) based on poor evidence from opinions of respected authorities, clinical experience, descriptive studies, or reports of expert committees.(15)*

*Antibiotic-associated diarrhea*

*Because antibiotic-associated diarrhea is generally self-limiting, probiotic use should be reserved for patients in whom diarrhea would be a clinically important adverse effect of antibiotic use; adequate dosage should be used.(17, 18)*

*A meta-analysis of 16 clinical trials in children conducted up to May 2010 found a reduction in the incidence of diarrhea when probiotics were used, compared with placebo (RR, 0.52; 95% CI, 0.38 to 0.72).(19) A high loss to follow-up was found in these studies, and using intention-to-treat analysis, reduction in the incidence of diarrhea was not significant with probiotics.(19)*

*For higher-dose probiotics, an a priori subgroup analysis found that the number needed to treat (NNT) to prevent 1 incidence of diarrhea was 7 (95% CI, 6 to 10) for doses of at least 5 billion CFU/day.(19)*

*Similarly, a meta-analysis including 16 studies to February 2012 found a reduction in antibiotic-associated diarrhea in children (RR, 0.55; 95% CI, 0.38 to 0.8; P = 0.008; NNT = 11) but not in elderly patients (older than 65 years; 3 trials) (RR, 0.81; 95% CI, 0.4 to 1.63; P = 0.55).(20) The RR for antibiotic-associated diarrhea for all age groups combined (63 trials) was 0.58 (95% CI, 0.5 to 0.68; P < 0.001; NNT = 13). Significant heterogeneity existed in the included trials.(20) Evidence for efficacy of individual strains remains equivocal.(17, 18, 19, 21)*

*Trials conducted since a meta-analysis in elderly hospital patients (older than 65 years) found no effect of 21 days of therapy with a multistrain preparation of Lactobacilli and Bifidobacteria on occurrence of antibiotic-associated diarrhea within 8 weeks (RR, 1.04; 95% CI, 0.84 to 1.28; P = 0.71).(22) Two smaller trials also found a nonsignificant effect on occurrence of diarrhea among hospital inpatients.(23, 24) The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for antibiotic-associated diarrhea in adults based on level 1, 2, and 3 evidence reported for specific probiotic strains.(145)*

*Clostridium difficile–associated diarrhea*

*Results of a meta-analysis of more than 20 trials have been published, and reductions of more than 60% in the incidence of C. difficile–associated diarrhea have been reported.(25, 26) A meta-analysis including 23 clinical trials to February 2013 found a pooled RR of 0.36 (95% CI, 0.26 to 0.51) favoring probiotics in the prevention of C. difficile–associated diarrhea.(26) Subgroup analysis found no difference between adult and pediatric populations, in different probiotic strains or in studies with lower or higher bias. Evidence based guidelines (2013) recognize that there is limited evidence for the use of adjunct probiotics to decrease recurrences in patients with recurrent C. difficile infection (CDI) (moderate recommendation, moderate-quality evidence).*

*The American College of Gastroenterology has incorporated the new genus name (Clostridioides) into its updated clinical guidelines for the prevention, diagnosis, and treatment of Clostridoides difficile (2021) and recommends against the use of probiotics for prevention of C. difficile infections in patients undergoing primary prevention with antibiotics in most patients (conditional, moderate) or for the secondary prevention of recurrence (strong, very low).(100) The Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) updated guidelines for C. difficile infection in adults and children (2017) states that data are currently insufficient to recommend use of probiotics for primary prevention of C. difficile infections outside of clinical trials.(126) The European Society of Clinical Microbiology and Infectious Diseases updated treatment guidance document for C. difficile infection (2014) and their update for C. difficile infection in adults (2021) continues to cite insufficient evidence to support administration of probiotics. In adults on antibiotics, routine probiotic use is not recommended to prevent C. difficile infection (strong, low). Some data suggest that probiotics may actually delay microbiome reconstitution after antibiotic treatment, and increased mortality was observed in a pancreatitis trial.(16, 143) The World Gastroenterology Organization updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for the prevention of C. difficile-associated diarrhea and its recurrence in adults based on level 2 and 3 evidence reported for specific probiotic strains.(145)*

*Persistent diarrhea*

*Persistent diarrhea (lasting more than 14 days) is an important issue in undernourished children or other children at risk. A 2012 Cochrane meta-analysis of 4 trials (N = 464) found a decrease in the duration of diarrhea (mean difference, 4.02 days; 95% CI, 4.61 to 3.43) and a decrease in stool frequency. The reviewers noted the limited availability of quality trials for analysis.(27)*

*Radiation-associated diarrhea*

*A 2013 meta-analysis of 6 trials (N = 452) found a pooled odds ratio (OR) of 0.44 (95% CI, 0.21 to 0.92) favoring probiotics for the prevention of radiation-induced diarrhea.(28) Another randomized clinical study (N = 40) found a significant decrease in rectal volume with regard to the positioning of the prostate among patients given L. acidophilus 10 million CFU twice daily.(29)*

*The World Gastroenterology Organization updated global guidelines on probiotics and prebiotics (2017) made no recommendation on the use of probiotics for prevention of radiation-induced diarrhea but noted evidence from a 2013 meta-analysis concluding probiotics may be beneficial in prevention and possibly in treatment of radiation-induced diarrhea.(145)*

*Dyslipidemia*

*It has been suggested that appropriately selected probiotics may be useful adjuncts in controlling hypercholesterolemia because of the bacteria's ability to assimilate cholesterol in the GI tract and assist with enzymatic degradation of bile acids, as well as in the conversion of cholesterol to coprostanol.(30, 31)*

*Findings from a meta-analysis of 13 clinical studies (N = 485) conducted up to October 2010 found a significant reduction in total cholesterol (−6.40 mg/dL; 95% CI, −9.93 to −2.87) and low-density lipoprotein (−4.9 mg/dL; 95% CI, −7.91 to −1.9) but not high-density lipoprotein or triglycerides.(32) Another study (N = 70) found significant differences from baseline measurements for probiotic yogurt, but changes in the lipid profile were insignificant compared to that found with conventional yogurt.(30) In combination with Step 1 diet therapy, 12 weeks of supplementation with probiotic capsules containing 1 × $10^9$ CFU each of 3 bifidobacterium strains significantly reduced total cholesterol by 3.4% and low-density lipoprotein cholesterol by 3.8% compared with diet plus placebo (P = 0.02 and P = 0.001, respectively) in 38 children 8 to 13 years of age with primary dyslipidemia.(130)*

*Eczema/Allergy*

*Numerous clinical trials have been conducted among pregnant and lactating women to evaluate the efficacy of probiotics in preventing eczema in pediatric patients, and meta-analyses have been published. However, the efficacy of using probiotics for the prevention of eczema or atopic dermatitis remains unclear, and strain-specific effects, as well as timing of the intervention, still require elucidation. Overall, good evidence suggests safe and effective preventative use.(139)*

*One meta-analysis of 7 clinical trials (to 2009) in infants (N = 2,843) found a positive effect for monotherapy with Lactobacillus-containing probiotics (4 trials, P = 0.045) but not for mixed-culture or other single-strain probiotics (3 trials, P = 0.204).(33) Another meta-analysis of 25 trials, including studies administering probiotics to infants both pre- and postnatal (N = 4,031, published up to 2012), found a significant reduction in total serum immunoglobulin E (IgE) and risk of atopic sensitization as measured by skin prick test or specific IgE testing. However, subgroup analysis of 10 clinical trials associated L. acidophilus with an increased risk of atopic sensitization (P = 0.002), and no effect on the risk of asthma or wheezing was found.(34) Long-term follow-up of trial participants revealed conflicting results. Follow-up at 5 years in 1 publication(35) and at 8 to 9 years of age in another(36) revealed no effect on wheezing, asthma, or sensitization with the use of postnatal-administered probiotics; however, a 2012 meta-analysis of 14 clinical trials found that probiotics reduced the incidence of atopic dermatitis and IgE-associated eczema in infants (RR, 0.79; 95% CI, 0.71 to 0.83).(37) These findings were corroborated by a 2015 systematic review and meta-analysis of 17 studies (N = 4,755) that evaluated probiotics supplemented during pregnancy and early infancy for preventing atopic diseases. A significant reduction in the risk of eczema was*

*demonstrated in infants treated with probiotics (P = 0.0003) compared to controls, but no significant effect was seen for the prevention of asthma or rhinoconjunctivitis. A mixture of probiotic supplementation of both Lactobacilli and Bifidobacteria was suggested most effective (P = 0.00001) for the prevention of eczema.(132)*

*The efficacy of probiotics in the treatment of eczema or atopic dermatitis remains unclear.(38, 39) A Cochrane review of clinical trials conducted in children with eczema found no effect on symptom severity or participant/parent preference for treatment option with the use of probiotics. Important heterogeneity exists among the 12 included trials, with the exception of 3 trials that used the same probiotic strain (L. rhamnosus GG) and were consistently negative. Subgroup analysis did not reveal any populations that might benefit from probiotic use.(38, 40) The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) made no recommendations regarding the use of probiotics to prevent eczema in children. However, they note that the World Allergy Organization recommends probiotic use during pregnancy, breastfeeding, and weaning in families at high risk of allergic disease based on evidence that shows a net benefit of probiotics during perinatal period in preventing allergic disease.(145)*

*GI uses*

*Crohn disease*

*A multicenter, randomized, double-blind, placebo-controlled trial (N = 119) evaluated the use of VSL#3, a mixture of 8 different bacterial probiotic species including Lactobacillus, Bifidobacterium, and Streptococcus, for the prevention of Crohn disease recurrence after surgery. Endoscopic recurrence rates at day 90 in patients who received VSL#3 was not different from those who received placebo (9.3% vs 15.7%, P = 0.19).(131) Meta-analyses have consistently revealed no effect on clinical response in Crohn disease with the use of probiotics, or any significant impact on maintaining remission or on recurrent episodes.(39, 41, 42, 43, 44)*

*The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) made no recommendations for use of probiotics for maintenance of remission of Crohn disease based on a lack of evidence to support benefit.(145)*

*Irritable bowel syndrome*

*Meta-analyses of clinical trials published throughout 2007(45) to May 2008(46) found that probiotics performed better than placebo in reducing symptoms of irritable bowel syndrome (IBS) (RR, 0.71; 95% CI, 0.57 to 0.88). A reduction in overall symptoms, including abdominal pain and flatulence, was demonstrated,(45, 46) and the NNT to prevent 1 occurrence of overall symptoms with at least 1 week of probiotics use was 4.(46) Among children, 3 studies included in a meta-analysis reported a higher rate of*

*responders (reduction in pain) (RR, 1.7; 95% CI, 1.27 to 2.27; NNT = 4), favoring the use of L. rhamnosus.(47)*

*The British Society of Gastroenterology's updated guidelines on the management of IBS (2021) make a weak recommendation on the use of probiotics as an effective treatment for global symptoms and abdominal pain in IBS. They suggest that patients who want to try probiotics should take them for up to 12 weeks and discontinue if no symptom improvement is observed (very low).(144) Likewise, The American College of Gastroenterology monograph on the management of IBS and chronic idiopathic constipation (CIC) (2014) states that overall, probiotics improve global symptoms, bloating, and flatulence in IBS with constipation. However, data are insufficient or equivocal regarding effectiveness of specific species (weak, low evidence). Insufficient evidence is available to recommend probiotics for management of CIC (weak, very low evidence).(125) The American College of Gastroenterology (ACG) clinical guideline for the management of irritable bowel syndrome (2021) suggests against the use of probiotics for the treatment of global IBS symptoms (conditional; very low).(141) The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for irritable bowel syndrome, functional constipation, uncomplicated symptomatic diverticular disease, and small bowel injury from NSAIDs in adults based on level 2 and 3 evidence reported for specific probiotic strains. In children, probiotic use for abdominal pain-related functional GI disorders is based on level 1 and 3 evidence reported for Latobacillus reuteri DAM 17938 and a mixture probiotic strains, respectively.(145)*

*GI surgery*

*L. acidophilus reduced the length of hospital stay and the need for surgery in patients with partial adhesive small-bowel obstruction(49); a meta-analysis of 13 clinical trials found a lower risk of postoperative sepsis with probiotic administration (OR, 0.42; 95% CI, 0.23 to 0.75).(50) A decrease in the duration of postoperative antibiotic therapy was also noted for synbiotics (weighted mean difference, −1.71; 95% CI, −3.2 to −0.21).*

*The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for irritable bowel syndrome, functional constipation, uncomplicated symptomatic diverticular disease, and small bowel injury from NSAIDs in adults based on level 2 and 3 evidence reported for specific probiotic strains. In children, probiotic use for abdominal pain-related functional GI disorders is based on level 1 and 3 evidence reported for Latobacillus reuteri DAM 17938 and a mixture probiotic strains, respectively.(145)*

*Ulcerative colitis*

*A meta-analysis of 13 clinical trials conducted through August 2009 found no additional benefit for probiotics in inducing remission, but a more favorable profile than with*

*placebo was suggested in maintaining remission.(51) The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for induction and maintenance of clinical remission of ulcerative colitis in adults based on level 2 and 3 evidence reported for specific probiotic strains. Additionally, probiotics for the treatment of active pouchitis and maintenance of clinical remission in adults is based on level 1 and 2 evidence. In children, use of probiotics for induction of remission in ulcerative colitis is based on level 2 evidence reported for specific probiotic strains.(145) In prevention of pouchitis, evidence from meta-analyses suggests a potential role for probiotics in preventing relapse following anastomosis in chronic ulcerative colitis (OR, 0.039; 95% CI, 0.011 to 0.142).(52, 53) Based on limited clinical data, VSL#3 may be more effective than single-strain Lactobacillus.(53)*

*Other GI uses*

*Infantile colic*

*Limited studies suggest more rapid gastric emptying times and decreased symptoms of colic with probiotic use in infants. No difference in weight gain, stool frequency, incidence of constipation, or regurgitation was found.(54, 55)*

*The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for prevention and management of infantile colic based on level 1 evidence reported for specific probiotic strains.(145)*

*Dysbiosis*

*Atypical intestinal microbiota (dysbiosis) is commonly associated with congenital heart disease (CHD), and both are primary risk factors for necrotizing enterocolitis. A double-blind, placebo-controlled pilot study evaluated the effect of B. longum ssp infantis administration (4.2 x 109 colony-forming unit twice daily) on fecal microbiota and plasma cytokines in 16 neonates with CHD scheduled for cardiac surgery. After 8 weeks of therapy, no significant effect was observed in fecal microbiota with probiotic administration versus placebo. Cytokine plasma levels were significantly different between groups at various time points for interferon-gamma (P = 0.007) and interleukin 1-beta (P = 0.04).(123)*

*Nutrition/Lactose intolerance*

*The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for reducing symptoms associated with lactose maldigestion in adults based on level 1 evidence reported for specific probiotic strains.(145) Milk and yogurt containing L. acidophilus have been studied in patients with lactose intolerance, but controversy regarding L. acidophilus' efficacy in aiding lactose digestion remains.(56, 57) The need for adequate, live bacteria, which may*

*account for the variation of results in other studies, has been demonstrated in lactose-intolerant adults.(58)*

*Other*

*Probiotics increased fecal Bifidobacterium counts, reduced fecal blood and pH (Bifidobacterium, L. acidophilus, and Enterococcus), and decreased the incidence of fecal Clostridium (Bacillus subtilis and E. faecium) in patients with liver cirrhosis.(59) Postprandial gas-related intestinal symptoms were reduced with probiotic use in a clinical trial.(60)*

*The efficacy of a multistrain probiotic as treatment for constipation in patients with Parkinson disease was explored in a double-blind, randomized, placebo-controlled trial in 72 adults 40 years and older. The probiotic contained 10 billion CFU of 8 bacterial strains (L. acidophilus, L. gasseri, L. reuteri, L. rhamnosus, B. bifidum, B. longum, Enterococcus faecalis, E. faecium) and was taken once daily for 4 weeks. An increase in spontaneous bowel movements was observed in the probiotic group compared to placebo when adjusted for baseline differences (mean difference, 1.1 per week [95% CI, 0.6 to 1.5; P<0.001). Secondary outcomes were also significantly improved in the probiotic group that included stool consistency, constipation severity, and quality of life. Overall, 65.6% vs 21.6% in the treatment and placebo groups, respectively, reported satisfaction with the intervention (P<0.001) and 5.9% vs 26.3% experienced deterioration. One patient discontinued probiotics 1 week after starting therapy due to lethargy.(140)*

*The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for in healthy adults to reduce the incidence of hard, lumpy stools based on level 3 evidence reported for specific probiotic strains.(145)*

*Hepatic encephalopathy*

*The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for hepatic encephalopathy in adults based on level 2 evidence reported for mixtures of specific probiotic strains.(145) A meta-analysis of 7 clinical trials (N = 550) found no effect on all-cause mortality, recovery, adverse events, or quality of life with the use of probiotics; however, there was significant heterogeneity in these trials. Probiotics were associated with a decreased plasma ammonia concentration, but no effect on clinical outcomes was found.(61)*

*Infection*

*Bacterial vaginosis*

*A meta-analysis of clinical trials conducted through December 2007 found evidence of effect for short-course therapy (5 days) of Lactobacillus versus metronidazole in the*

*treatment of bacterial vaginosis.(62) Long-term administration (6 months of once-weekly vaginal applications) of L. rhamnosus has been compared with a single course of metronidazole (7 days) and an impact on the restoration of normal vaginal flora was found even at 12 months.(63)*

*Candida infections*

*Long-term trials investigating the effect of oral hydrogen peroxide–producing L. acidophilus in preventing candidiasis have shown mixed results following long-term use (6 months) but were limited because of the high loss to follow-up of trial participants.(2, 64) A large, randomized, placebo-controlled, double-blind trial of oral or vaginal L. rhamnosus and B. longum over 10 days showed no effect in treating postantibiotic candidiasis compared with placebo.(65) In another placebo-controlled, double-blind trial, daily oral intake of L. rhamnosus and Lactobacillus fermentum modified vaginal flora and decreased the amount of yeast and coliforms.(66) A systematic review of probiotics in the prevention of vulvovaginal candidiasis in HIV-positive women found only 1 quality clinical trial in which no significant effect with the use of probiotics was reported.(67)*

*In critically ill children, a probiotic mix twice a day for 7 days significantly reduced candidemia and candiduria in children 3 months to 12 years of age who received broad-spectrum antibiotics.(119) This restrospective study compared prevalence of candidemia and candiduria before and after the introduction of routine use of probiotics in the pediatric intensive care unit. The probiotic mix contained L. acidophilus, L. rhamnosum, B. longum, S. boulardii, and S. thermophilus.(119)*

*Helicobacter pylori infection*

*The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics as adjuvant therapy for the eradication of H. pylori in adults based on level 1, 2, and 3 evidence reported for specific probiotic strains as well as for H. pylori eradication in children based on level 2 evidence.(145) A meta-analysis of 10 clinical trials in adults (N = 1,469) evaluating mixed-strain supplements with Lactobacillus strains and Bifidobacterium only found an eradication OR of 2.066 in favor of probiotics (95% CI, 1.398 to 2.321) and a decreased incidence of side effects.(68) A clinical trial published subsequently to the meta-analysis (N = 107) found no effect with the use of a mixed-strain probiotic preparation over 30 days.(69)*

*A meta-analysis of randomized clinical trials conducted in children evaluated efficacy of probiotic supplementation in triple therapy on H. pylori eradication rates and therapy-related side effects.(101) Pooled odds ratios of 7 studies (n = 508) indicated improved eradication rates in children with low heterogeneity. Additionally, total side effects in the probiotics group were significantly decreased, and when each side effect (ie, diarrhea, constipation, nausea or vomiting) was analyzed individually, probiotic supplementation*

*was shown to significantly reduce the incidence of diarrhea. Specific probiotic search terms for the meta-analysis included S. salivarius, Enterococcus, Lactobacillus, and Lactococcus.(101)*

*Neonatal necrotizing enterocolitis*

*The role of probiotics in preventing necrotizing enterocolitis is now well established. The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for prevention of necrotizing enterocolitis in preterm infants based on level 2 evidence reported for Lactobacillus reuteri DSM 17938. However, Saccharamyces boulardii CNCM I-745 and Bifidobacterium breve BBG-001, Bb12 have been shown to be ineffective so it is unclear which specific probiotic strains should be recommended.(145)*

*Several meta-analyses have been conducted, with overlap of most trials included.(70, 71, 72, 73)*

*All meta-analyses report a decreased incidence of severe necrotizing enterocolitis (NEC) and all-cause mortality, but only 1(71) found a decrease in the incidence of nosocomial sepsis. No adverse effects of probiotic use were found, including no systemic infection from the probiotic.(73) Suggested mechanisms of action include colonization of the gut by beneficial organisms and prevention of colonization by pathogens, improved maturity of the mucosal barrier, and modulation of relevant enzyme systems.(70) Additional clinical trials are needed to establish efficacy of different strains and dosage regimens, but placebo-controlled trials are unnecessary.(39, 70, 73) Significant decreases in NEC and the combined outcome of NEC or death were reported in 294 infants less than 32 weeks' gestational age who received 2 billion CFUs once daily of FloraBABY, a combination of B. breve, B. bifidum, B. infantis, B. longum, and L. rhamnosus GG. Probiotic administration was continued until 34 weeks' of age.(124)*

*Otitis media infection*

*A meta-analysis of 4 clinical trials (N = 1,805) based in Finland and Croatia found a decreased risk of acute otitis media (RR, 0.76; 95% CI, 0.64 to 0.91; NNT = 17) with probiotic use in pediatric populations.(74)*

*Ventilator-associated pneumonia*

*A meta-analysis of trials conducted through April 2009 found a lower incidence of ventilator-associated pneumonia (OR, 0.61; 95% CI, 0.41 to 0.91) and a lower incidence of colonization with Pseudomonas aeruginosa (OR, 0.35; 95% CI, 0.13 to 0.93) with probiotics. No effect on all-cause mortality was found.(75) Another meta-analysis of patients in intensive care found a significant reduction in intensive care unit–acquired pneumonia (OR, 0.58; 95% CI, 0.42 to 0.79) but no effect on other outcomes.(76)*

*Upper respiratory tract infection*

*Meta-analysis including 10 trials (N = 3,451) up to May 2011 evaluated the effect of probiotics for at least 7 days on the prevention of acute URTIs.(77) A significant reduction in the rate ratio of acute URTI (events per person-year) was found (RR, 0.88; 95% CI, 0.81 to 0.96), as was a reduction in the use of antibiotics (OR, 0.67; 95% CI, 0.45 to 0.98). No effect on the duration of episodes and no difference in significant adverse events was found.(77) A further meta-analysis of 4 clinical trials (N = 1,805) found a decreased risk of URTI (NNT = 4) with the use of probiotics, specifically in pediatric populations, but there was no decrease in respiratory tract infections overall in this subpopulation.(74)*

*The analysis did not include missed work or school days, which were reduced in several clinical trials.(78, 79, 80, 81, 82)*

*Urinary tract infection*

*Few quality trials on the effect of probiotics in preventing recurrent or chronic urinary tract infections (UTIs) exist. A phase 1 study of Lactobacillus crispatus vaginal suppositories found positive results for the prevention of UTIs in women compared to results with placebo,(83) whereas other trials have produced equivocal results.(2, 84)*

*The American Urological Association/Canadian Urological Association/Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction's updated guideline on recurrent uncomplicated UTI infections in women (2022) noted insufficient evidence was available to support the prophylactic use of Lactobacillus probiotics for recurrent UTIs as a nonantibiotic option due to a lack of data indicating benefit.(14) The Scottish Intercollegiate Guidelines Network's updated guideline on the management of suspected bacterial lower urinary tract infection (2020), which is now specific for adult women, indicated that based on high-quality data no significant effect on the prevention of recurrent UTIs has been demonstrated overall with the use of cranberry products. However, sensitivity analyses that excluded ineffective Lactobacillus strains as well as delivery methods used to establish vaginal colonization reported Lactobacillus was associated with a significant risk reduction in recurrent UTIs.(142) The Society of Obstetricians and Gynaecologists of Canada's updated guidelines on recurrent urinary tract infection (2017) state that probiotics cannot be offered as proven therapy for recurrent UTI (level II-2C).(85) The Infectious Diseases Society of America's updated clinical practice guideline for the management of asymptomatic bacteriuria (2019) recommends against screening for or treating asymptomatic bacteriuria in healthy premenopausal, nonpregnant, or healthy postmenopausal women (strong, moderate). Additionally, they cite a recent study that demonstrated no benefit for the prophylactic use of Lactobacillus probiotics in subsequent symptomatic UTI.(135)*

*Other infection uses*

*Six months of Lactobacillus supplementation (6 billion units daily) in 1 crossover study reduced pulmonary exacerbations and hospital admissions in children with cystic fibrosis.(86)*

*Trials have evaluated the effect of probiotics as an alternative to antibiotic therapy in infectious mastitis. Greater reductions in bacterial count and pain score have been found for L. fermentum, Lactobacillus salivarius, and Lactobacillus gasseri in 1 large (N = 352) and 1 smaller study (N = 20).(87, 88)*

*Studies in some populations have reported decreases in yeast counts and incidence of hyposalivation, suggesting a potential role for probiotics in the prevention of oral candidiasis among elderly patients.(89, 90) In orthodontic patients, probiotics decreased the count of salivary Streptococcus mutans,(91) while a review found a generally positive effect for probiotics on oral health, especially with regard to cariogenic and periodontal pathogens.(90)*

*A clinical trial evaluating a probiotic preparation with fermentable dietary fiber (synbiotic) found no effect on bacterial translocation as a measure of restoration of GI tract integrity or immune activation.(92)*

*The World Gastroenterology Organisation's guidelines (2011) state that data are insufficient to support the use of probiotics and synbiotics in critically ill adults in intensive care units.(145)*

*Intensive care/trauma, adults*

*Meta-analyses evaluating the effect of probiotics added to enteral feeds in critically ill patients have been published. No change in length of intensive care unit stay, incidence of nosocomial infections or pneumonia, or mortality was found in 1 meta-analysis.(93) Another analysis found a significant reduction in intensive care unit–acquired pneumonia (OR, 0.58; 95% CI, 0.42 to 0.79) but no effect on other outcomes.(76)*

*Another meta-analysis of 5 randomized, controlled trials in trauma patients (N = 281) and found significant heterogeneity but reported decreases in nosocomial infections (RR, 0.65; 95% CI, 0.45 to 0.94), ventilator-associated pneumonia (RR, 0.59; 95% CI, 0.42 to 0.81), and length of stay (standardized mean difference, −0.71; 95% CI, −1.09 to −0.34). No change in mortality was found.(94)*

*Pancreatitis*

*Meta-analyses of clinical studies conducted through March 2010 on the effect of probiotics in acute pancreatitis found no reduction of clinical outcomes, including complications from infections, multiple organ failure, length of antibiotic therapy, surgical interventions, or mortality.(95, 96, 97) Results from the PROPATRIA multicenter clinical trial evaluating the role of probiotics in the prophylaxis of predicted severe acute pancreatitis found no effect in reducing the risk of infections, as well as an increased*

*risk of mortality. Consequently, probiotic use in severe acute pancreatitis is contraindicated.(98)*

*Other uses*

*Allergy*

*A World Allergy Organization Position Paper (2012) on the use of probiotics in the management of pediatric allergies concluded that probiotics do not have an established role in the prevention or treatment of allergy based on a systematic review of the published literature. Based on this evidence, supplementation with probiotics remains empirical in allergy management. This position paper also recognizes that no probiotic supplement(s) efficiently affect allergic symptoms or long-term disease. Further research is needed to determine whether probiotic supplements will be useful in preventing allergy.(99)*

*Asthma*

*The British Guideline on the Management of Asthma (revised 2019) states that there is insufficient evidence to indicate that the use of dietary probiotics in pregnancy reduces the incidence of childhood asthma. In addition, without evidence of benefit, probiotics cannot be recommended for the management of asthma.(138) These data were corroborated by a 2013 systematic review and meta-analysis of probiotic supplementation during pregnancy or infancy that found no evidence to support a protective effect on childhood asthma or wheeze (N = 3,257).(121)*

*Cancer*

*Despite positive in vitro studies showing decreased carcinogenic aflatoxins and beta-glucuronidase, efficacy studies in humans are lacking.(101, 102) The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) made no recommendation on the use of probiotics for prevention of colorectal cancer. Although biomarkers associated with colorectal cancer have been improved with probiotics and prebiotics, data are limited in humans that demonstrate any benefit.(145)*

*Cardiovascular*

*A meta-analysis of clinical trials evaluating the effect of probiotics on blood pressure reported a significant decrease in systolic blood pressure (3.1 mm HG; 95% CI, −4.64 to −1.56) and diastolic blood pressure (1.09 mm HG; 95% CI, −2.11 to −0.06). Subgroup analysis found greater decreases in Japanese trials over European studies and in hypertensive populations over normotensive populations.(103) Another meta-analysis of 9 randomized controlled trials (N = 543) through January 2014 conducted in adults with or without hypertension assessed the effects of live-bacteria probiotic products on blood pressure in patients with a variety of conditions (ie, hypercholesterolemia,*

*metabolic syndrome, obesity). Results of the meta-analyses on data for systolic and diastolic blood pressure revealed a statistically significant reduction by 3.56 mm Hg and 2.38 mm Hg, respectively, compared to controls; studies exhibited a high level of heterogeneity and evidence of publication bias. Subgroup analysis indicated a greater effect with baseline blood pressure (130/85 mm Hg or higher) when multiple species of probiotics in doses at least $10^{11}$ colony-forming units were given daily for at least 8 weeks. Stomach gas and flatulence were reported in 2 studies.(134)*

*Immunity*

*Dietary consumption of probiotics (eg, Bifidobacterium lactis, L. rhamnosus) has enhanced some aspects of cellular immunity in elderly and stressed patients.(104, 105, 106, 107, 108, 109) The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) made no recommendation on the use of probiotics for improving the immune response but noted evidence from various studies that suggests an enhanced immune response.(145)*

*Late-onset sepsis*

*Very preterm infants (N = 1,099) were administered a daily probiotic combination of B. infantis, B. lactis, and S. thermophilus containing 1 x $10^9$ total organisms in a prospective multicenter, double-blind, placebo-controlled, randomized clinical trial. No significant difference was detected in late-onset sepsis or all-cause mortality with probiotics; however, necrotizing enterocolitis Bell stage 2 or higher was significantly reduced.(122)*

*Liver disease*

*The World Gastroenterology Organization's updated global guidelines on probiotics and prebiotics (2017) recommend probiotics for non-alcoholic fatty liver disease and non-alcoholic steatohepatitis in adults based on level 2 and 3 evidence reported for specific probiotic strains.(145)*

*Osteoporosis*

*Clinical data*

*The North American Menopause Society's updated position statement on the management of osteoporosis in postmenopausal women (2021) indicated that preliminary human studies suggest that probiotics could have a role in preventing bone loss.(127)*

*Reproductive hormones*

*Studies have investigated the effect of L. acidophilus and B. longum on plasma phytoestrogens, but no association has been found in pre- or postmenopausal women.(110, 111, 112)*

*Rheumatoid arthritis*

*A small trial found improvements in patient pain-assessment scores and pain scales for Bacillus coagulans versus placebo.(113)*

*Dosing*

*Daily intake of oral probiotic preparations is commonly recommended, but some trials have used twice-weekly dosing. Preparation strength is usually measured as million/billion CFUs per capsule.*

*Neonates necrotizing enterocolitis*

*Dosages used in clinical trials for necrotizing enterocolitis in neonates include B. breve 0.5 billion to 1.6 billion CFUs daily and L. casei GG and L. acidophilus 6 billion CFUs daily; however, specific trials are required for definite recommendations.70 FloraBABY (2 billion CFUs/day of 4 Bifidobacteria and Lactobacillus rhamnosus GG) mixed with 1 mL water and given once daily just before a milk feed and continued until 34 weeks of age has been used successfully in almost 300 infants less than 32-weeks' gestational age.124*

*Irritable bowel syndrome*

*Up to 5 billion units daily taken for 4 to 6 weeks has been used in clinical trials.45*

*Pregnancy / Lactation*

*Information is lacking regarding the safety and efficacy of the different strains of probiotics in pregnancy and lactation, despite studies conducted in pregnant women for the prevention of atopic eczema in children and for the treatment of bacterial vaginosis. An uncontrolled study evaluating the effect of probiotics in pregnancy-associated constipation has been reported.114*

*A meta-analysis regarding the safety of Lactobacillus and Bifidobacterium species in pregnancy115 included 11 trials conducted through September 2007 and found no evidence of miscarriage or malformations. In addition, no effect on the incidence of cesarean delivery, birth weight, or gestational age was found.115*

*Interactions*

*None well documented. One study evaluated the effect of 2 weeks' consumption of probiotics on vitamin B levels in healthy women. Vitamin $B_1$ (thiamine) and $B_2$ (riboflavin) levels were enhanced; however, no effect was observed on vitamin $B_6$.116*

*Adverse Reactions*

*Probiotics are considered to be relatively safe, even with low-birth-weight infants and neonates. Studies using probiotics have reported abdominal cramping, nausea, fever, soft stools, flatulence, and taste disturbances.26*

*Results from a multicenter clinical trial evaluating the role of probiotics in the prophylaxis of predicted severe acute pancreatitis found an increased risk of mortality. Consequently, probiotic use in severe acute pancreatitis is contraindicated.98 Isolated case reports link probiotics to adverse reactions, including bacteremia, endocarditis, septicemia, pneumonia, and deep abdominal abscesses.19 B. longum bacteremia was reported in 3 preterm, very low birth-weight infants on probiotic therapy with Infloran that contained viable B. longum; the bacteremia was transient in 2 infants and did not require antibiotic therapy, but the third infant developed necrotizing enterocolitis that necessitated explorative laparotomy and antibiotics.133 Probiotics should be used cautiously in patients at risk of opportunistic infections and in those with badly damaged GI tracts.2, 117 A case of fatal gastrointestinal mucormycosis was reported in a premature infant who, as part of an in-hospital regimen, was administered a contaminated probiotic supplement containing B. lactis ($420 \times 10^6$), S. thermophilus ($420 \times 10^6$), and L. rhamnosus ($160 \times 10^6$); the contaminant was a Rhizopus species mold.128, 129*

*The FDA has issued a warning that advises practitioners of the potential risks of using dietary supplements containing live bacteria or yeast in immunocompromised patients (ie, prematurely born infants).128*