

Microbial Preparations (Probiotics) for the Prevention of Clostridium difficile Infection in Adults and Children: An Individual Patient Data Meta-analysis of 6,851 Participants

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Abstract

OBJECTIVE. To determine whether probiotic prophylaxes reduce the odds of Clostridium difficile infection (CDI) in adults and children.

DESIGN. Individual participant data (IPD) meta-analysis of randomized controlled trials (RCTs), adjusting for risk factors.

METHODS. We searched 6 databases and 11 grey literature sources from inception to April 2016. We identified 32 RCTs (n=8,713); among them, 18 RCTs provided IPD (n=6,851 participants) comparing probiotic prophylaxis to placebo or no treatment (standard care). One reviewer prepared the IPD, and 2 reviewers extracted data, rated study quality, and graded evidence quality.

RESULTS. Probiotics reduced CDI odds in the unadjusted model (n=6,645; odds ratio [OR] 0.37; 95% confidence interval [CI], 0.25-0.55) and the adjusted model (n=5,074; OR, 0.35; 95% CI, 0.23-0.55). Using 2 or more antibiotics increased the odds of CDI (OR, 2.20; 95% CI, 1.11-4.37), whereas age, sex, hospitalization status, and high-risk antibiotic exposure did not. Adjusted subgroup analyses suggested that, compared to no probiotics, multispecies probiotics were more beneficial than single-species probiotics, as was using probiotics in clinical settings where the CDI risk is 5%. Of 18 studies, 14 reported adverse events. In 11 of these 14 studies, the adverse events were retained in the adjusted model. Odds for serious adverse events were similar for both groups in the unadjusted analyses (n=4,990; OR, 1.06; 95% CI, 0.89-1.26) and

adjusted analyses (n=4,718; OR, 1.06; 95% CI, 0.89-1.28). Missing outcome data for CDI ranged from 0% to 25.8%. Our analyses were robust to a sensitivity analysis for missingness.

CONCLUSIONS. Moderate quality (ie, certainty) evidence suggests that probiotic prophylaxis may be a useful and safe CDI prevention strategy, particularly among participants taking 2 or more antibiotics and in hospital settings where the risk of CDI is $\geq 5\%$.

Palabras clave

KeyWords Plus: [ANTIBIOTIC-ASSOCIATED DIARRHEA](#); [PLACEBO-CONTROLLED TRIAL](#); [DOUBLE-BLIND](#); [SACCHAROMYCES-BOULARDII](#); [CLINICAL-TRIAL](#); [EFFICACY](#); [EPIDEMIOLOGY](#); [APPROPRIATE](#); [GUIDELINES](#); [DIAGNOSIS](#)

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