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Chronic Diseases and Translational Medicine 2 (2016) 34−41

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Meta Analysis

Comparison of maintenance effect of probiotics and aminosalicylates on ulcerative colitis: A meta-analysis of randomized controlled trials

Yong Jiang [a], Zhi-Guang Zhang [a], Feng-Xiang Qi [a], Ying Zhang [a], Tao Han [b,*]

[a] *Department of Gastroenterology, The Second Hospital of Tianjin Medical University, Ping Jiang Road No 23, He Xi District, Tianjin 300170, China*

[b] *Department of Hepatology and Gastroenterology, Tianjin Third Central Hospital of Tianjin Medical University, Jin Tang Road No 83, He Dong District, Tianjin 300170, China*

Received 21 April 2016

Available online 9 August 2016

Abstract

Objective: To evaluate the maintenance effect of probiotics versus that of aminosalicylates on ulcerative colitis.

Methods: MEDLINE, EMBASE, the Cochrane Controlled Trials Register, and the Chinese Biomedical Database were searched in English or Chinese. Data extracted were selected with strict criteria.

Results: In six randomized controlled trials (RCTs), a total of 721 participants were enrolled and the maintenance effect of probiotics ($n = 364$) versus that of aminosalicylates ($n = 357$) on ulcerative colitis was investigated. No significant difference was observed between probiotics and aminosalicylate groups (relative risk (*RR*) = 1.08; 95% confidence interval (*CI*): 0.91−1.28; $P = 0.40$). Three RCTs compared the incidence of adverse events with probiotics versus those with aminosalicylates. No significant difference was observed in the incidence of adverse events between the two groups (*RR* = 1.20; 95% *CI*: 0.92−1.56; $P = 0.17$).

Conclusions: Probiotics and aminosalicylates both showed a maintenance effect on ulcerative colitis. However, more well-designed RCTs are required.

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Keywords: Maintenance effect; Probiotics; Aminosalicylates; Ulcerative colitis; Meta-analysis

Introduction

Ulcerative colitis (UC) is a relapsing, chronic, immune-mediated intestinal disease that mainly affects the large bowel, and whose causes and etiology remain unknown. Its main symptoms are watery or bloody stools, abdominal pain, urinary urgency and (or) tenesmus.[1] Consequently, UC severely affects patients' quality of life.

* Corresponding author.
E-mail address: hantaomd@126.com (T. Han).

Peer review under responsibility of Chinese Medical Association.

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http://dx.doi.org/10.1016/j.cdtm.2016.07.002

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Aminosalicylates are recommended for maintenance treatment in patients with UC.[2] However, many patients are intolerant to either classic aminosalicylate sulfasalazine or sulfur-free compounds. In addition, the potential side effects, costs, and a poor compliance to long-time therapy, have led researchers to look for novel therapeutic approaches.[3]

Probiotics are live microbial feed supplements, which beneficially affect the host by altering the enteric flora. Increasing evidence indicates the role of intestinal micro flora in the pathogenesis of UC.[4–6] Although several observations have suggested that some probiotics and aminosalicylates have comparable effects in the maintenance of remission in UC,[3,7–17] the evidence is based on a relatively few number of studies, which are not sufficient to determine whether they are definitely helpful or harmful. Therefore, the present meta-analysis systematically identifies and analyzes randomized controlled trials (RCTs) in order to evaluate the maintenance effect of probiotics versus that of aminosalicylates on UC.

Materials and methods

Search strategy

We searched for RCTs from the following databases: MEDLINE (1966 to August 2015), EMBASE (1980 to August 2015), the Cochrane Controlled Trials Register (1995 to August 2015), and the Chinese Biomedical Database (1981 to March 2015). The keywords used were probiotic, *Lactobacillus*, *Bifidobacterium*, *Saccharomyces*, *Escherichia coli*, yeasts, probiotic mixture VSL#3, mesalazine, osalazine, 5-aminosalicylic acid (5-ASA), balsalazide, and ulcerative colitis, maintenance of remission, or relapse. The studies were limited to those published in English or Chinese. Moreover, manual searching of reference lists, authors, and associated meeting reports or abstracts was also performed. Two participators (Yong Jiang and Ying Zhang) searched the results.

Selection criteria and quality assessment

The selection criteria were as follows: (a) They were RCTs; (b) Both adult and children studies were included; (c) Meeting reports or abstracts were included; (d) The studies compared the maintenance effect of probiotics to aminosalicylates with standard therapy for UC; (e) Patients who had UC used definite diagnostic standards; (f) Reviews and case reports were excluded.

Two participants selected the articles after careful searching. We evaluated the quality of each selected article and verified the details. When discrepancies occurred, a third author (Feng-Xiang Qi) resolved them. The quality of the selected RCTs was assessed by the Cochrane Reviewer Handbook 5.0, RCTs' quality assessment standard, using the following criteria: sequence generation, allocation sequence concealment, blinding method, incomplete outcome data, and selective outcome reporting.[18] The Jadad score was used to evaluate the quality of every RCT. High-quality RCTs, which scored three points or more, were included in this meta-analysis.[19]

Statistical analysis

The statistical analysis was performed using Cochrane Collaboration's Revman 5.3 software. Relative risks (*RR*) with 95% confidence interval (*CI*) were calculated based on the studies. A statistical heterogeneity test was performed by using the Chi-square test and I^2 statistics, and an I^2 value of more than 50% was considered to have substantial heterogeneity. A random-effects model was selected when the heterogeneity test showed an I^2 value of more than 50%; otherwise, a fixed-effects model was used.[18] Subgroup analyses were used depending on species of probiotic. A funnel plot was used as an indicator of publication bias when the number of studies was 5 or more.

Results

We identified 4984 relevant studies from the literature searched. Nineteen potentially eligible studies[3,7–17,20–26] were initially identified; however, two studies[7,13] were excluded as they studied the maintenance effect of probiotics without aminosalicylates, four studies[14–17] were excluded as they were meta-analyses, and seven studies[20–26] were excluded as they only observed the induction of remission of UC (Table 1). Eventually, six RCTs[3,8–12] (four in English and two in Chinese) that satisfied the inclusion criteria were identified and included in the analyses (Fig. 1, Table 2).

Study characteristics

Six RCTs with a total of 721 participants were published during 1999–2009. The length of follow-up of these trials ranged from 3 to 12 months. Five studies[3,8–10,12] were conducted on adults, and one study[11] on children. Each of the five adult studies scored 4 points and the one pediatric study scored 3 points, respectively, based on the quality assessment criteria (Table 3).

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