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The synergistic effect of Herbal medicine with probiotics on functional constipation in children : A systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Without financial support.

Review Stage at time of this submission - Piloting of the study selection process.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 July 2023 and was last updated on 26 July 2023.

INTRODUCTION

Review question / Objective This review aims to synergistic the effects of Herbal Medicine(HM) and probiotics for functional constipation in children.

Rationale Three systematic reviews(Paknejad, 2019; Cheng, 2009) including one meta-analysis studies(Lyu, 2022) have been published to evaluate the effect of herbal medicine on functional constipation. However, there is no study on the comparison of the effects of herbal medicine and probiotics limited to Children.

Condition being studied Functional constipation(FC) is a common chronic gastrointestinal disease in all age groups which greatly affects the quality of life in patients(QOL).
When it occurs in children not only children but also parents QOL would significantly decrease. There are some similarities in children and adults but regarding pathophysiology, diagnostic workup, symptomatology and therapeutic management important difference exist.
Since 47% of the patients were not satisfied with conventional treatment due to efficacy, safety, adverse reaction and cost. Complementary therapies are often used as an alternative. Especially herbal medicine and probiotics are used as the most representative treatment in FC.
Therefore, we performed a meta-analysis to research synergistic effect of Herbal medicine with probiotics in functional constipation.

METHODS

Search strategy We will search electronically on English databases, Chinese databases and Korean databases. English databases would be searched with the following English terms. 'Functional constipation' AND ('Pediatrics' OR 'Infant' OR 'Child' OR 'Adolescent') AND ('Herbal medicine' OR 'Korean medicine' OR 'Chinese medicine' OR 'Kampo medicine' OR 'traditional medicine' OR 'Herb' OR 'Herbal drug' OR 'Formula' OR

'Remedy' OR 'Plant' OR 'Decoction' OR 'Solution' OR 'Liquid' OR 'Extract' OR 'Capsule' OR 'Sticking' OR 'Powder')
Chinse databases would be searched with both Chinese and English terms above.
Korean databases would be searched with following terms translated in Korean. 'Functional constipation' AND 'Children' AND 'Korean medicine'.

Participant or population [Inclusion Criteria]1) Patients must meet the diagnostic criteria(according to Rome III, Rome IV diagnostic criteria or other published criteria or guidelines) for functional constipation(FC)2) Age : Under 18 years old[Exclusion Criteria]1) Patients with functional constipation caused by other reasons (ex. drugs, surgery, other intestinal organic diseases, etc)2) Patients must not have major organ problems.(ex. Heart, liver, lung, etc)3) Patients must not be allergic to drugs and probiotics.

Intervention The interventions of the experimental group will include HM with probiotics. 1) Only oral HM will be allowed, with no limitation on the number of herbs, formations(e.g., powder, pill, granules, capsule, decoction, oral solution, and so on), dosages and duration. 2) All probiotic strains, doses, and formations(e.g., capsule, powder, tablet, granules, vitamin-containing compound) will be included.And conventional treatment(e.g., Lactulose, Glycerol Enema, multivitamins, and so on) or basic treatment(e.g. adjusting diet, training defecation habits, and so on) will be considered if the same treatment is provided in the control group.

Comparator The control group should accept the same probiotic as the experimental group. And if conventional treatment or basic treatment were performed in the experimental group, the same treatment should be performed in the control group.

Study designs to be included All the randomized controlled trials(RCTs) were included.

Eligibility criteria All randomized controlled trials (RCTs) study using herbal medicine and probiotics in functional constipation were included.Non-RCTs, RCT protocol, animal studies, case reports, survey and reviews were excluded.

Information sources We will electronically search 11 following databases. Three English databases(MEDLINE via PubMed, EMBASE, the Cochrane Central Register of Controlled Trials), three Chinese databases(China National Knowledge Infrastructure, Wanfang data, and VIP), and five Korean databases (such as Oriental Medicine Advanced Searching Integrated System, Korean studies Information Service System, Korea Citation Index, Research Information Sharing Service, and Korean Medical database) without any language restrictions.

Main outcome(s) Total effective rate, symptom score(Total symptom score, Bristol fecal score, Defecation frequency(per week), Defecation time).

Additional outcome(s) Serum indicator(Substance P (SP), Motilin(MTL) , Gastrin(GAS), Somatostatin (SS), Nitrous oxide(NO), and so on), Intestinal flora (Bifidobacterium, Lactobacillus, Enterococcus, Staphylococcus), Anorectal dynamics parameters, Adverse events, Recurrence rate.

Quality assessment / Risk of bias analysis Quality assessment will be performed using Risk of bias(Rob 2) from the Cochrane Handbook for Systematic reviews of interventions, which include bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, bias in the selection of reported results. The reviewers will summarize the assessments, and categorize the included studies into three levels of bias(low, some concerns and high risk of bias).

Strategy of data synthesis Two authors will independently synthesis the data by Review Manager 5.4 software. For the dichotomous outcomes, data will be summarized using Risk Ratio(RR) with 95% Confidence Intervals(CI). For continuous outcomes, a standard mean difference (SMD) with 95% CI will be used. Heterogeneity was assessed using the Higgins I2 index. I2≥ 50%was considered to be indicative of potential heterogeneity, and I2 ≥ 75% was indicative of considerable heterogeneity.

Subgroup analysis Subgroups analysis would be performed if meta-analysis shows significant heterogeneity.

Sensitivity analysis We will test the robustness of the results through sensitivity analysis by excluding low quality trials, small sample trials and high bias risks. Potential publication bias will be estimated using a funnel plot if more than 10 trials were included.

Language restriction No language restriction.

Country(ies) involved South Korea.

Keywords Children; Function Constipation(FC); Herbal medicine; Probiotics; Systematic review; Meta-anaylsis.

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