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## Osmotic and stimulant laxatives for the management of childhood constipation.

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### Abstract

**BACKGROUND:** Constipation within childhood is an extremely common problem. Despite the widespread use of osmotic and stimulant laxatives by health professionals to manage constipation in children, there has been a long standing paucity of high quality evidence to support this practice.

**OBJECTIVES:** We set out to evaluate the efficacy and safety of osmotic and stimulant laxatives used to treat functional childhood constipation.

**SEARCH METHODS:** We searched MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials, and the Cochrane IBD Group Specialized Trials Register from inception to 10 March 2016. There were no language restrictions. We also searched the references of all included studies, personal contacts and drug companies to identify studies.

**SELECTION CRITERIA:** Randomised controlled trials (RCTs) which compared osmotic or stimulant laxatives to placebo or another intervention, with participants aged 0 to 18 years old were considered for inclusion. The primary outcome was frequency of defecation. Secondary endpoints included faecal incontinence, disimpaction, need for additional therapies and adverse events.

**DATA COLLECTION AND ANALYSIS:** Relevant papers were identified and two authors independently assessed the eligibility of trials, extracted data and assessed methodological quality using the Cochrane risk of bias tool. The primary outcome was frequency of defecation. Secondary endpoints included faecal incontinence, disimpaction, need for additional therapies and adverse events. For continuous outcomes we calculated the mean difference (MD) and 95% confidence interval (CI) using a fixed-effect model. For dichotomous outcomes we calculated the risk ratio (RR) and 95% CI using a fixed-effect model. The Chi(2) and I(2) statistics were used to assess statistical heterogeneity. A random-effects model was used in situations of unexplained heterogeneity. We assessed the overall quality of the evidence supporting the primary and secondary outcomes using the GRADE criteria.

**MAIN RESULTS:** Twenty-five RCTs (2310 participants) were included in the review. Fourteen studies were judged to be at high risk of bias due to lack of blinding, incomplete outcome data and selective reporting. Meta-analysis of two studies (101 patients) comparing polyethylene glycol (PEG) with placebo showed a significantly increased number of stools per week with PEG (MD 2.61 stools per week, 95% CI 1.15 to 4.08). Common adverse events in the placebo-controlled studies included

flatulence, abdominal pain, nausea, diarrhoea and headache. Participants receiving high dose PEG (0.7 g/kg) had significantly more stools per week than low dose PEG (0.3 g/kg) participants (1 study, 90 participants, MD 1.30, 95% 0.76 to 1.84). Meta-analysis of 6 studies with 465 participants comparing PEG with lactulose showed a significantly greater number of stools per week with PEG (MD 0.70, 95% CI 0.10 to 1.31), although follow-up was short. Patients who received PEG were significantly less likely to require additional laxative therapies. Eighteen per cent (27/154) of PEG patients required additional therapies compared to 31% (47/150) of lactulose patients (RR 0.55, 95% CI 0.36 to 0.83). No serious adverse events were reported with either agent. Common adverse events in these studies included diarrhoea, abdominal pain, nausea, vomiting and pruritis ani. Meta-analysis of 3 studies with 211 participants comparing PEG with milk of magnesia showed that the stools per week were significantly greater with PEG (MD 0.69, 95% CI 0.48 to 0.89). However, the magnitude of this difference was quite small and may not be clinically significant. One child was noted to be allergic to PEG, but there were no other serious adverse events reported. One study found a significant difference in stools per week favouring milk of magnesia over lactulose (MD -1.51, 95% CI -2.63 to -0.39, 50 patients), Meta-analysis of 2 studies with 287 patients comparing liquid paraffin (mineral oil) with lactulose revealed a relatively large statistically significant difference in the number of stools per week favouring liquid paraffin (MD 4.94, 95% CI 4.28 to 5.61). No serious adverse events were reported. Adverse events included abdominal pain, distention and watery stools. No statistically significant differences in the number of stools per week were found between PEG and enemas (1 study, 90 patients, MD 1.00, 95% CI -1.58 to 3.58), dietary fibre mix and lactulose (1 study, 125 patients,  $P = 0.481$ ), senna and lactulose (1 study, 21 patients,  $P > 0.05$ ), lactitol and lactulose (1 study, 51 patients, MD -0.80, 95% CI -2.63 to 1.03), hydrolyzed guar gum and lactulose (1 study, 61 patients, MD 1.00, 95% CI -1.80 to 3.80), PEG and flaxseed (1 study, 109 patients, MD 0.00, 95% CI -0.33 to 0.33), PEG and dietary fibre (1 study, 83 patients, MD 0.20, 95% CI -0.64 to 1.04), and PEG and liquid paraffin (2 studies, 261 patients, MD 0.35, 95% CI -0.24 to 0.95).

**AUTHORS' CONCLUSIONS:** The pooled analyses suggest that PEG preparations may be superior to placebo, lactulose and milk of magnesia for childhood constipation. GRADE analyses indicated that the overall quality of the evidence for the primary outcome (number of stools per week) was low or very low due to sparse data, inconsistency (heterogeneity), and high risk of bias in the studies in the pooled analyses. Thus, the results of the pooled analyses should be interpreted with caution because of quality and methodological concerns, as well as clinical heterogeneity, and short follow-up. There is also evidence suggesting the efficacy of liquid paraffin (mineral oil). There is no evidence to demonstrate the superiority of lactulose when compared to the other agents studied, although there is a lack of placebo controlled studies. Further research is needed to investigate the long term use of PEG for childhood constipation, as well as the role of liquid paraffin. The optimal dose of PEG also warrants further investigation.

## Update of

Osmotic and stimulant laxatives for the management of childhood constipation. [Cochrane Database Syst Rev. 2012]

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