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Interventions for preventing postpartum constipation (Review)

Turawa EB, Musekiwa A, Rohwer AC

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[Intervention Review]

Interventions for preventing postpartum constipation

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ABSTRACT

Background

Postpartum constipation, with symptoms such as pain or discomfort, straining, and hard stool, is a common condition affecting mothers. Haemorrhoids, pain at the episiotomy site, effects of pregnancy hormones and haematinics used in pregnancy can increase the risk of postpartum constipation. Eating a high-fibre diet and increasing fluid intake is usually encouraged, although laxatives are commonly used in relieving constipation. The effectiveness and safety of available interventions for preventing postpartum constipation needs to be ascertained.

Objectives

To evaluate the effectiveness and safety of interventions for preventing postpartum constipation.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 April 2015), Stellenbosch University database, ProQuest Dissertation and Theses database, World Health Organization International Clinical Trials Registry Platform (ICTRP), ClinicalTrials.gov (30 April 2015) and reference lists of included studies.

Selection criteria

All randomised controlled trials (RCTs) comparing any intervention for preventing postpartum constipation versus another intervention, placebo or no intervention. Interventions could include pharmacological (e.g. laxatives) and non-pharmacological interventions (e.g. acupuncture, educational and behavioural interventions).

We included quasi-randomised trials. Cluster-RCTs were eligible for inclusion but none were identified. Studies using a cross-over design were not eligible for inclusion in this review.

Data collection and analysis

Two review authors independently screened the results of the search to select potentially relevant studies, extracted data and assessed risk of bias. Results were pooled in a meta-analysis only where there was no substantial statistical heterogeneity.

Main results

We included five trials (1208 postpartum mothers); four compared a laxative with placebo and one compared a laxative alone versus the same laxative plus a bulking agent in women who underwent surgical repair of third degree perineal tears. Trials were poorly reported and risk of bias was unclear for most domains. Overall, there was a high risk of selection and attrition bias.

Laxative versus placebo

None of the four trials included in this comparison assessed any of our pre-specified primary outcomes (***pain or straining on defecation, incidence of postpartum constipation*** or ***changes in quality of life)***.

All four trials reported ***time to first bowel movement*** (not pre-specified in our protocol). In one trial, more women in the laxative group had their first bowel movement less than 24 hours after delivery compared to women in the placebo group (risk ratio (RR) 2.90, 95% confidence interval (CI) 2.24 to 3.75, 471 women). Individual trials also reported inconsistent results for days one, two and three after delivery. Pooled results of two trials showed that fewer women in the laxative group were having their first bowel movement at day four compared with controls (average RR 0.36, 95% CI 0.21 to 0.61, 671 women).

Regarding secondary outcomes, no trials reported on ***stool consistency using the Bristol stool form scale*** or***relief of abdominal pain/discomfort*** . One trial reported the number of women having loose or watery stools and there were more women who experienced this in the laxative group compared to the placebo group (RR 26.96, 95% CI 3.81 to 191.03, 106 women). One trial found no clear difference in the ***number of enemas*** between groups (RR 0.63, 95% CI 0.38 to 1.05, 244 women). One trial reported more women having more than two bowel movements per day in the laxative compared to the placebo group (RR 26.02, 95% CI 1.59 to 426.73, 106 women).

Adverse effects were poorly reported; two trials reported the number of women having abdominal cramps, but their results could not be pooled in a meta-analysis due to substantial statistical heterogeneity. In one trial, more women in the laxative group had abdominal cramps compared to the placebo group (RR 4.23, 95% CI 1.75 to 10.19, 471 women), while the other trial showed no difference between groups (RR 0.25, 95% CI 0.03 to 2.20, 200 women). With regards to ***adverse effects of the intervention on the baby*** , one trial found no difference in the incidence of loose stools (RR 0.62, 95% CI 0.16 to 2.41, 281 women) or diarrhoea (RR 2.46, 95% CI 0.23 to 26.82, 281 women) between the two groups.

Laxative versus laxative plus bulking agent

Only one trial was included in this comparison and reported on ***pain or straining on defecation*** in women who underwent surgical repair of third degree perineal tears; there was no reported difference between groups (median (range) data only). No difference was reported in the ***incidence of postpartum constipation*** (data not reported) and the outcome ***changes in quality of life*** was not mentioned.***Time to first bowel movement*** was reported as a median (range) with no difference between the two groups. In terms of ***adverse effects*** , women in the laxative plus stool-bulking group were reported to be at a greater risk of faecal incontinence during the immediate postpartum period (median (range) data only). However the number of women having any episode of faecal incontinence during first 10 days postpartum was reported with no clear difference between the two groups (14/77 (18.2%) versus 23/70 (32.9%), RR 0.55, 95% CI 0.31 to 0.99, 147 women). The trial did not report on adverse effects of the intervention on the babies.

The trial reported none of the following pre-specified secondary outcomes: ***stool consistency using Bristol stool form scale*** , ***use of alternative products*** , ***laxative agents*** **,** ***enemas*** , ***relief of abdominal pain/discomfort*** and ***stool frequency*** .

Authors' conclusions

We did not identify any trials assessing educational or behavioural interventions. We identified four trials that examined laxatives versus placebo and one that examined laxatives versus laxatives plus stool bulking agents. Results from trials were inconsistent and there is insufficient evidence to make general conclusions about the effectiveness and safety of laxatives.

Further rigorous trials are needed to assess the effectiveness and safety of laxatives during the postpartum period for preventing constipation. Trials assessing educational and behavioural interventions and positions that enhance defecation are also needed. Future trials should report on the following important outcomes: pain or straining on defecation; incidence of postpartum constipation, quality of life, time to first bowel movement after delivery, and adverse effects caused by the intervention such as: nausea or vomiting, pain and flatus.

PLAIN LANGUAGE SUMMARY

Interventions for preventing constipation after giving birth

Constipation is a bowel disorder that is characterised by symptoms such as pain or discomfort, straining, hard lumpy stool and a sense of incomplete bowel evacuation. Pain and discomfort during defecation can be a source of concern to the new mother who is recuperating from the stress of delivery, particularly if she has had perineal tears repaired or has developed haemorrhoids. Postpartum constipation can be stressful for women because of undue pressure on the rectal wall, leading to restlessness and painful bowel movements which may affect the quality of life of the mother. The administration of enemas before labour, the ability of women to eat during active labour, and irregular and altered eating habits during the first few days after delivery can each have an influence on bowel movements in the days after giving birth. We aimed to find all the trials assessing interventions that could prevent postpartum constipation. We examined the available evidence up to 30 April 2015. We included five randomised controlled trials (involving a total of 1208 women from the first day of giving birth) in this review. Overall, the trials were poorly conducted and reported.

Four trials compared a laxative with a placebo control. The trials did not look at pain or straining on defecation, incidence of constipation, or changes in the quality of life, but did assess the time to first bowel movement. More women in the laxative group had a bowel movement on the day of delivery in one trial. For days one, two and three after the birth, the findings from the trials were not consistent. Combined results of two trials found that more women in the placebo group had their first bowel movement bowel four days after delivery compared to the laxative group. Adverse effects of the intervention were poorly reported in the trials. Two trials reported on abdominal cramps but we were unable to combine the results of the two trials because they were very different (one study found more women had abdominal cramps compared to the women in the placebo control group whereas the other study found no difference between groups). In terms of adverse effects of the intervention for the baby, one trial found that babies whose mothers received laxative were no more likely to experience loose stool or diarrhoea.

One trial compared a laxative with a laxative plus a stool-bulking agent (Ispaghula husk) for women who underwent surgery to repair a tear of the perineum involving the internal or external anal sphincter muscles (third degree) that occurred during vaginal delivery. The trial reported on pain or straining on defecation but did not find a difference in the pain score between groups. In terms of adverse effects of the intervention, the trial reported that women who were given laxative plus a stool-bulking agent were more likely to experience fecal incontinence during the immediate postpartum period. However the number of women having any episode of faecal incontinence during first 10 days postpartum was reported with no clear difference between the laxative and the laxative plus stool-bulking agent group (14/77 (18.2%) versus 23/70 (32.9%), 147 women). This trial reported no data in relation to any adverse effects that the intervention might have on the baby.

There is not enough evidence from randomised controlled trials on the effectiveness and safety of laxatives during the early postpartum period to make general conclusions about their use to prevent constipation. We did not identify any trials assessing educational or behavioural interventions such as a high-fibre diet and exercise.

We found some evidence that adding a stool-bulking agent to a laxative for women who underwent surgery to repair a third degree perineal tear is not beneficial. Large, high-quality trials are needed on this topic. In addition, trials looking at non-medical interventions, such as advice on diet and physical activity, are needed.

BACKGROUND

Description of the condition

The postpartum period comprises the first six weeks after delivery during which the mother's body returns to the pre-pregnant state (Liu 2009). It is a critical transitional time for the new mother, her newborn baby and her family. Many complications can occur during this period and if unrecognised and not treated promptly, may lead to physical discomfort, psychological distress, low self-esteem and poor quality of life for the mother (Zainur 2006). Therefore, adequate attention, appropriate advice and services need to be available to mothers during this period in order to prevent postnatal health problems as well as detect medical complications at an early stage (World Health Organization 1998).

Constipation can be defined as difficult bowel evacuation characterised by straining, lumpy or hard and dry stools, sensation of incomplete evacuation, anorectal obstruction, or manual ma-

noeuvres (Higgins 2004). It is a functional bowel disorder and a common health problem across all ages and a source of concern during pregnancy, the postpartum period and after surgery (National Institute of Health 2013). The diagnosis of constipation is both subjective and objective, however, according to the Rome diagnostic criteria III (Drossman 2006), a diagnosis of functional constipation needs to include two of the following criteria, which must be fulfilled for the last three months with symptom onset at least six months prior to diagnosis: straining during at least 25 % of defecations, lumpy or hard stools in at least 25% of defecations, sensation of incomplete evacuation for at least 25% of defecations, sensation of anorectal obstruction/blockage for at least 25% of defecations, manual manoeuvres to facilitate at least 25% of defecations (e.g. digital evacuation, support of the pelvic floor), fewer than three defecations per week; and loose stools are rarely present without the use of laxatives (Lee-Robichaud 2010).

Globally, constipation is common to all ages and the prevalence was estimated to lie between 4.1% and 25.6% in studies using the self-report measure of constipation and between 2.6% and 26.9% in those using the Rome criteria (Schmidt 2014); it is higher in the non-white population than in the white population (Gandell 2013; Stewart 1992; Towers 1994). It was reported that constipation is more prevalent in women (37%) than in men (14%), and that low-income and individuals with a low socio-economic status are at higher risk of constipation (Collete 2010). The prevalence of postpartum constipation was reported to be 41.8% by self-report and 24.7% as classified by the Rome criteria (Ponce 2008); and that 25% of women suffer from constipation throughout pregnancy and at three months postpartum (Bradley 2007). Furthermore, an association between defecation symptoms in early pregnancy (12 weeks' gestation) in women with lower body mass index (BMI) and constipation at 12 months after childbirth was reported by Van Brummen 2006. A study reported that having two or fewer bowel movements a week is thought to occur in one third of women in their third trimester of pregnancy (Wald 2003).

Postpartum constipation is characterised by symptoms such as abdominal pain or discomfort, excessive straining, hard stool that is difficult to pass, lumpy stool and a sensation of incomplete evacuation (Cullen 2007). Constipation in the postpartum period is thought to be caused by the high progesterone levels during pregnancy and interruption in dietary intake (Glazener 1995). Haemorrhoids are a frequent anorectal ailment in pregnancy and in the postpartum period. Fear of expected pain from swelling at the anus as a result of haemorrhoids, pain at the episiotomy site, a bruised perineum and lacerations in the vagina may contribute to postpartum constipation. Haematinics (agents used to stimulate blood cell formation or to increase the haemoglobin in the blood) used in pregnancy (Bradley 2007), reduced physical activity following delivery, ignoring the urge to move the bowel and diets low in fibre may increase the risk of developing postpartum constipation (National Institute of Health 2013). During the postpartum period, not only is pain from constipation a discomfort to the new mother, it may also impact on her physical and social health status and may hinder timely response to the needs of the newborn (Cheng 2006).

Description of the intervention and how the intervention might work

A good understanding of the causes of constipation can help in preventing and averting problems that are associated with constipation. Constipation occurs when the stool stays in the colon longer than expected and the colon absorbs too much water from the stool, thus making the stool hard and dry and therefore, difficult to pass (National Institute of Health 2013). The interventions for preventing constipation include pharmacological and non-pharmacological interventions. Lifestyle interventions refer to diet and physical exercise and are advocated during pregnancy and the postpartum period. A diet high in fibre and adequate fluid intake may be all that is required for prevention of postpartum constipation (Zainur 2006). High-fibre foods such as fruits and vegetables can help to relieve symptoms and prevent constipation in the postpartum period (Liu 2009). Fibre is indigestible, adds bulk to the stools and stimulates bowel movements, and it also improves digestion and prevents constipation by softening the stools (Balch 2010). Gradual resumption of physical exercise that is medically safe should be encouraged as soon as the mother becomes fit for exercise. This time-point varies from one individual to another with some women able to resume routine exercise within days of delivery (Koltyn 1997).

For pharmacological interventions, laxatives are the drugs of choice in relieving symptoms of constipation and can be taken orally in either liquid, tablet, powder or granule form. Laxatives are grouped into categories according to their mode of action: bulk forming laxatives, osmotic laxatives, stimulant laxatives, faecal softeners and lubricants (Candy 2011). Bulk forming laxatives, such as bran and methylcellulose, increase the weight and water content and facilitate peristaltic movement of stools (Balch 2010). Osmotic laxatives, such as Milk of Magnesia and lactulose, help retain water in the colon thereby softening the stool and increasing the number of stools (National Institute of Health 2013). Stimulant laxatives, such as bisacodyl and senna, directly stimulate the afferent nerves and irritate the intestinal wall thereby easing bowel movement (Andrew 2011). Stimulant laxatives are useful when constipation is not responsive to osmotic laxatives (Balch 2010).

Alternative interventions for constipation also exist. Studies have reported on the efficacy of acupuncture and Chinese herbal medicine as an intervention in the prevention of postpartum constipation. Chinese herbs reportedly work by correcting the underlying malfunctions through strengthening the intestinal tract, and thereby improving peristalsis. The Yun-chang capsule, a Chinese herb capsule, was found to be effective and safe for the treatment of patients with functional constipation (Jia 2009), while a sys-

tematic review reported an overall significant benefit of traditional Chinese medicine in relieving constipation (Lin 2009).

Why it is important to do this review

The postpartum period is a crucial time for the new mother, newborn baby and the entire family. A number of health problems may occur during this period that may result in physical discomfort and poor quality of life for the mother and the baby. According to Peppas 2008, constipation has a significant negative impact on the quality of life, in terms of morbidity and cost of treatment. A number of systematic reviews on interventions for constipation have been published (e.g. Gordon 2012; Higgins 2004; Lee-Robichaud 2010; Mugie 2011; Peppas 2008). We recently conducted a Cochrane review on interventions for treating postpartum constipation (Turawa 2014). We did not find any trials eligible for inclusion, but some of the excluded trials assessed interventions for the prevention of constipation. To our knowledge, there is no systematic review on preventing postpartum constipation and considering the debilitating effect of constipation on the new mother and her baby, and the financial implications, it is necessary to assess the effectiveness and safety of the available interventions for preventing postpartum constipation.

OBJECTIVES

To assess the safety and effectiveness of interventions for preventing postpartum constipation.

METHODS

Criteria for considering studies for this review

Types of studies

We included all randomised controlled trials comparing any intervention for the prevention of postpartum constipation with another intervention, placebo or no intervention. Quasi-randomised controlled trials were included. Cluster-randomised trials were eligible for inclusion but none were identified. Cross-over trials were not eligible for inclusion because the physiological condition of women during the first month postpartum might not be the same as at six months after childbirth.

Types of participants

We included all postpartum women (up to six months post delivery) with symptoms of postpartum constipation using pre-specified criteria (Rome and Bristol Stool Form Scale) and self-report. Postpartum women with co-morbidities, such as sphincter injuries, were included. The six months criterion was used because constipation is a problem that may last longer than six weeks following delivery, which is the usual postpartum period.

Types of interventions

Intervention

Any intervention for the prevention of postpartum constipation, both pharmacological (e.g. laxatives) and non-pharmacological interventions (e.g. acupuncture, educational and behavioural interventions).

Control

Any other intervention for the prevention of postpartum constipation, placebo or no intervention.

We considered the following comparisons.

1. One intervention versus no intervention
2. One intervention versus placebo
3. Two different interventions compared
4. One intervention versus a combination of interventions
5. Combination of interventions versus no intervention
6. Combination of interventions versus placebo
7. Different combinations of interventions

Types of outcome measures

Primary outcomes

1. Pain or straining on defecation
2. Incidence of postpartum constipation as per self-report and other diagnostic criteria
3. Changes in quality of life as measured in included studies (using e.g. maternal postpartum quality of life (MAPP-QOL) questionnaire)
4. Time to first bowel movement (days) (outcome not pre-specified at the protocol stage - see Differences between protocol and review)

Secondary outcomes

1. Stool consistency using Bristol stool form scale. Appendix 1. The Bristol Stool Form Scale is a formal research tool that is used to categorise stool into seven criteria according to stool

consistency (Lewis 1997). It is also useful for evaluating the effectiveness of intervention for gastrointestinal tract disease and clinical assessment. It helps patients to report on stool consistency.

2. Use of alternative products, laxative agents, enemas.
3. Relief of abdominal pain/discomfort.
4. Stool frequency.
5. Adverse effects caused by the intervention, including:
   i) pain;
   ii) nausea and vomiting;
   iii) diarrhoea, flatus, and faecal incontinence.
6. Any adverse effects of the intervention on the baby.

Search methods for identification of studies

The following methods section of this review is based on a standard template used by the Cochrane Pregnancy and Childbirth Group.

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (30 April 2015).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE (Ovid);
3. weekly searches of Embase (Ovid);
4. monthly searches of CINAHL (EBSCO);
5. handsearches of 30 journals and the proceedings of major conferences;
6. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL, MEDLINE, Embase and CINAHL, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

In addition, we searched the Stellenbosch University database, ProQuest Dissertation and Theses database, and the following sources.

1. The US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov).
2. The World Health Organization International Clinical trials Registry platform (ICTRP).

Searched carried out on 30 April 2015. See: Appendix 2 for search terms used.

Searching other resources

We checked the reference list of retrieved studies for additional studies and contacted authors and experts in the field.

We did not apply any language or date restrictions.

Data collection and analysis

Selection of studies

Two review authors (Eunice Turawa (ET) and Alfred Musekiwa (AM)) independently assessed for inclusion all the potential studies we identified from the searches. We resolved any disagreement through discussion or, if required, we consulted the third review author (Anke Rohwer (AR)).

We developed a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) study flow chart to display the number of records identified, included and excluded from the review (Liberati 2009).

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors (ET and AM) extracted the data using the data extraction form. For each dichotomous outcome, we extracted the number of participants experiencing the event and the number of participants in each treatment group. For each continuous outcome, we planned to extract the arithmetic means and standard deviations (or information to estimate the standard deviations). We resolved discrepancies through discussion or, if required, we consulted the third author (AR). We entered data into Review Manager software (RevMan 2014) and checked for accuracy. When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors (ET and AM) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion or by involving a third review author (AR).

(1) Random sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal allocation to interventions prior to assignment and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.
We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies are at low risk of bias if they were blinded, or if we judge that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.
We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.
We assessed methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses which we undertook.
We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation). Attrition bias of 20% and above were considered as high risk of bias;
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.
We assessed the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we have about other possible sources of bias.
We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

The results were summarised using the 'Risk of bias' summary and the 'Risk of bias' graph in addition to the 'Risk of bias' tables. Where clarity was required or in case of missing data, we contacted the trial authors for clarification. We resolved any disagreement by discussion.

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we planned to use the mean difference if outcomes were measured in the same way between trials. We would have used the standardised mean difference to combine trials that measured the same outcome, but used different methods. In either case, corresponding 95% confidence intervals would have been presented.

Unit of analysis issues

There were no unit of analysis issues as only individually-randomised trials were included.

Cluster-randomised trials

We did not identify any cluster-randomised trials for inclusion in this review. However, in future updates of this review, if we identify any cluster-randomised trials we will include them in the analyses along with individually-randomised trials. We will adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* Section 16.3.4 (Higgins 2011), using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely. We will also acknowledge heterogeneity in the randomisation unit and perform a subgroup analysis to investigate the effects of the randomisation unit.

Other unit of analysis issues

In future studies, if a multi-arm study contributes multiple comparisons to a particular meta-analysis, we will either combine treatment groups or split the 'shared' group as appropriate and precautions will be taken to avoid the inclusion of data from the same participant more than once in the same analysis.

Dealing with missing data

No imputation measures were applied for missing data. Where data from the trial reports were insufficient, unclear or missing, we contacted the trial authors by email for additional information or clarification. For included trials, we took note of the level of attrition.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we included all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised, minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial where an I^2 was greater than 30% and either a T^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

In future updates of this review, if there are 10 or more studies in the meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2014). Where there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or substantial statistical heterogeneity was detected, we did not pool trial results in a meta-analysis. In cases where statistical heterogeneity was not substantial we used random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. Where the average treatment effect was not clinically meaningful, we did not

combine trials. Where we used random-effects analyses, the results were presented as the average treatment effect with 95% confidence intervals, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

We were not able to conduct subgroup analysis in this review since the meta-analyses performed had very few trials. For future updates, we will use subgroup analyses to investigate heterogeneity. We will carry out the following subgroup analyses.

1. Type of laxatives (osmotic laxatives versus stimulant laxatives; bulk forming laxatives versus stimulant laxatives)
2. Study design (individually-randomised versus cluster-randomised trials)
3. Mode of delivery (caesarean section versus spontaneous vaginal delivery)

We will limit these subgroup analyses to the primary outcomes of the review.

We will assess subgroup differences by interaction tests available within RevMan (Higgins 2011). We will report the results of subgroup analyses quoting the X^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

We were not able to conduct sensitivity analysis in this review since the meta-analyses performed had very few trials. For future updates of the review, we will perform sensitivity analysis with respect to:

1. robustness of the methods used regarding allocation concealment;
2. rates of attrition;
3. imputed values of intra-cluster correlations (ICC).

RESULTS

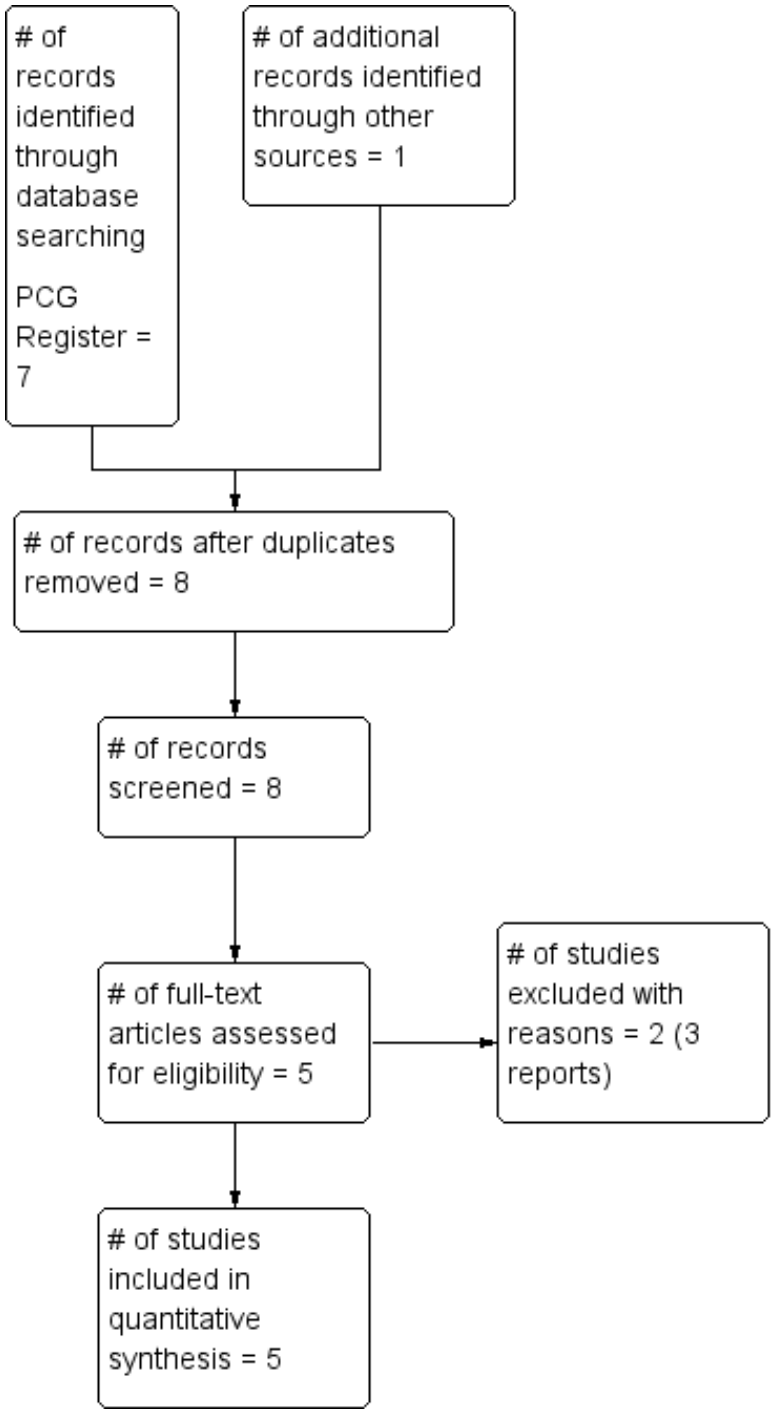
Description of studies

See Characteristics of included studies and Characteristics of excluded studies.

Results of the search

The search of Cochrane Pregnancy and Childbirth Group's Trials Register retrieved seven trial reports. The Stellenbosch University database; ProQuest Dissertation and Theses database search yielded one additional trial making a total of eight reports. We excluded two trials (Liu 2009; Mahony 2004) (published in three reports) with reasons reported in Characteristics of excluded studies. We included five trials in this review (Diamond 1968; Eogan 2007; Mundow 1975; Shelton 1980; Zuspan 1960). See Figure 1.

Figure 1. Study flow diagram.



Included studies

Details of the included studies are provided in the Characteristics of included studies We included five trials with a total of 1208 participants. Of the five included trials, three are randomised controlled trials (Diamond 1968; Eogan 2007; Shelton 1980) and two trial records are quasi-randomised controlled trials (Mundow 1975; Zuspan 1960). Four of the trials were from developed countries (Diamond 1968 ; Eogan 2007; Mundow 1975 and Zuspan 1960), while the fifth trial was from a developing country (Shelton 1980). All trials were conducted in a tertiary institution and the unit of randomisation for all trials was the individual. Trials were published in English language, four of the trials compared a pharmaceutical intervention (laxative) with a placebo, while the fifth trial compared a laxative with a bulking-agent plus the same laxative in the prevention of postpartum constipation. The drugs used in three of the trials (Diamond 1968; Shelton 1980 and Zuspan 1960) were supplied by pharmaceutical companies and the statistical analysis of Shelton 1980 was carried out by the same company that provided the drug. None of the trials discussed conflicts of interest.

Excluded studies

We excluded two trials (Liu 2009, Mahony 2004). The reason for exclusion was that trials did not evaluate interventions to prevent postpartum constipation. See the Characteristics of excluded studies table.

Risk of bias in included studies

We presented judgements regarding the risk of bias in each of the included trials in the Characteristics of included studies. Summary tables of risk of bias in all included trials are also displayed in Figure 2 and Figure 3.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

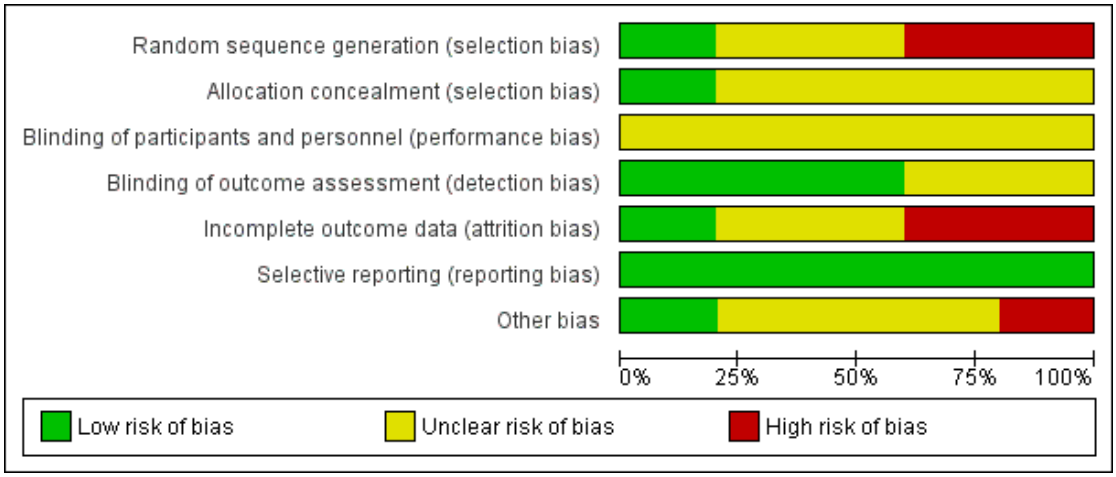
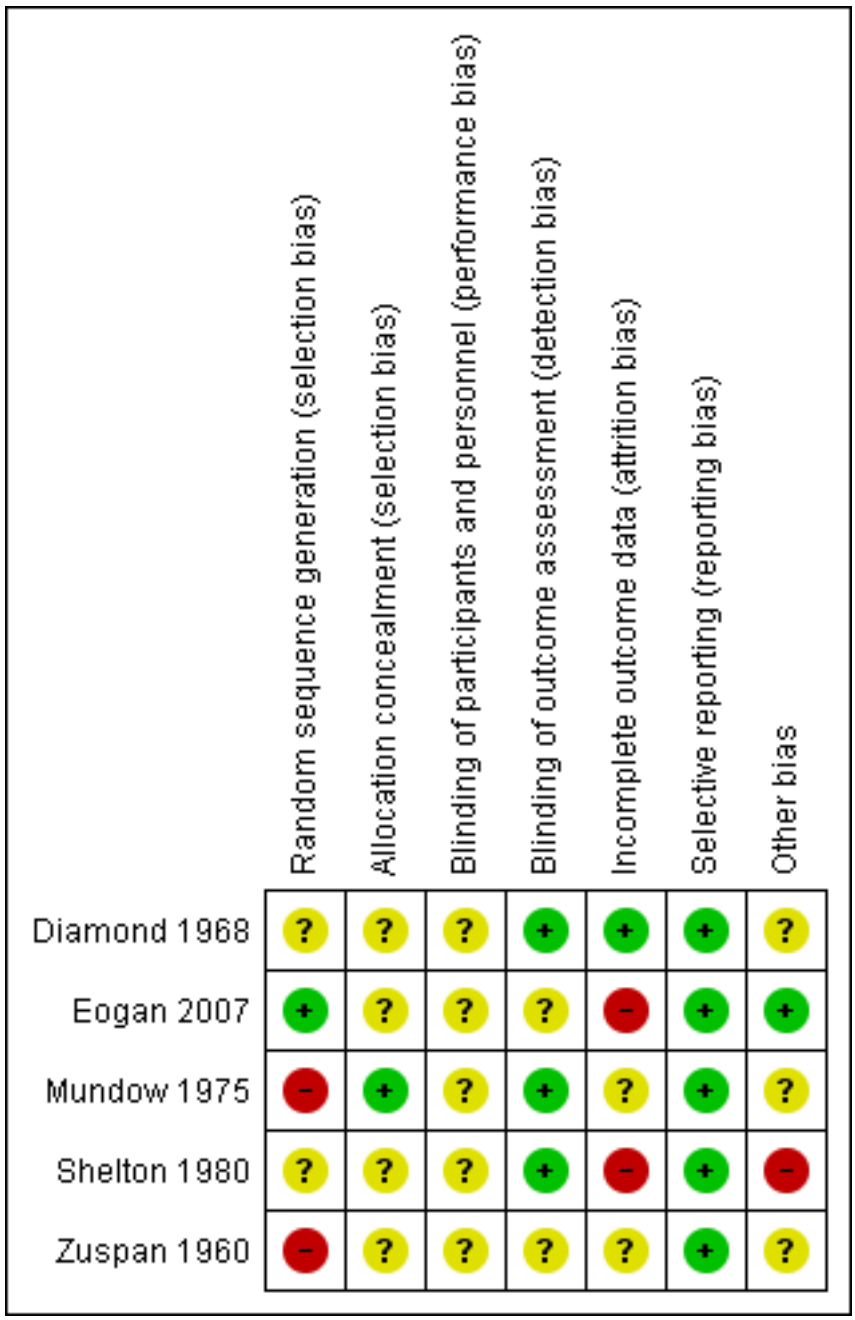


Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

Allocation refers to both the generation of the random allocation sequence and concealment of assignment to prevent selection bias.

Generation of allocation sequence

Allocation sequence generation method was assessed in each of the included trials and judged as either 'Low risk', 'High risk' or 'Unclear'. Eogan 2007 used computer-generated numbers in ratio of 1:1 for generating the allocation sequence, and thus was judged to have low risk of selection bias; two trials (Diamond 1968; Shelton 1980) provided insufficient information to enable us to judge whether there was a low or high risk of selection bias, we therefore judged them as having unclear risk of selection bias. The remaining two trials (Mundow 1975; Zuspan 1960) were quasi-randomised trials, where the method used to generate allocation sequence was not indicated. Therefore both trials were considered as having high risk of selection bias.

Allocation concealment

Four trials (Diamond 1968; Eogan 2007; Shelton 1980 and Zuspan 1960) were judged as having unclear risk of bias since none of them provided sufficient information to enable us to judge whether the trials were of either low or high risk of selection bias. Diamond 1968 used sealed and identical envelopes but the authors did not report whether they were opaque and sequentially numbered. Eogan 2007 employed the sealed opaque envelope technique where all the tablets (active and placebo) used were identical in number and appearance but sequential number arrangement of the envelopes was not explicitly stated. We emailed the corresponding author of Eogan 2007 requesting further information on the method of allocation concealment but no response was received. For Shelton 1980, the tablets (active and placebo) were identical in all respects and women only received drugs from a numbered bottle allocated to them. Zuspan 1960 reported that indistinguishable capsules were given to the women but there was no further explicit information on assignment. The fifth trial, Mundow 1975 reported that yellow identical capsules were taken from a numbered bottle that was assigned to each woman. The code was held by the laboratory and was only sent to the investigators at the end of the trial. Therefore this trial was judged as having low risk of bias for this domain. Contact details of corresponding authors were not provided for the other trials (Diamond 1968, Shelton 1980; Zuspan 1960).

Blinding

All included trials had unclear risk of performance bias (Diamond 1968, Eogan 2007, Mundow 1975;Shelton 1980; Zuspan 1960) because it was unclear whether or not the participants and personnel were adequately blinded to the assignment. There was a lack of sufficient and explicit information on the methods used for blinding. Diamond 1968 reported that participants and investigators were not aware of the content of the identical drugs and envelopes, but did not provide information on identical colour, shape and size of drug to enable explicit judgement. Eogan 2007 did not supply any information on blinding of participants, personnel and the investigators and it was judged as unclear risk of bias for both performance and detection bias. Shelton 1980 reported that the trial was "double-blind" but did not explicitly explain what steps were followed to ensure adequate blinding of the participants and personnel, it was therefore judged as unclear of performance bias. Zuspan 1960 stated that the trial was "double blind" but failed to report on whether capsules were identical in appearance, shape and size, and no information was provided on blinding of investigators and the personnel to the assignment, thus it was judged as unclear of performance and detection bias. Mundow 1975 reported that the active and placebo tablets were indistinguishable to participants and observers, the code was only sent to the investigator at the end of the study but did not provide information on whether the people administering the intervention were also prevented from identifying the interventions; hence it was judged as having low risk of detection bias but unclear risk of performance bias. Diamond 1968 reported that " the knowledge of the random code number and type of drug was not revealed till the completion of the study"; it was therefore judged as having low risk of detection bias. Shelton 1980 stated that "Statistical analyst had no knowledge of which participants received active treatment or placebo" and that the code was only broken at the final stage of analysis and it was therefore also judged as having low risk of detection bias.

Incomplete outcome data

In Diamond 1968, all participants in the trial were adequately reported on and they were included in the final analysis and therefore the trial was considered as having low risk of attrition bias. Two trials (Eogan 2007; Shelton 1980) were assessed as having high risk of attrition bias. Eogan 2007 reported that all participants attended the first follow-up at 10 days postpartum, but 26 participants did not turn up for assessment at three months following delivery, despite the repeated reminder sent to them. Of these, 24 gave a personal reason and two could not be traced and were therefore excluded from the final analysis. The attrition rate was more than 15% in both groups and the study was considered as having high risk of attrition bias. Forty of the participants in Shelton 1980 were excluded from the analysis because the result showed a small difference and the number was small (according

to trial authors); the trial was therefore considered as having high risk of attrition bias. Two trials (Mundow 1975; Zuspan 1960) were judged as having unclear risk of attrition bias. Mundow 1975 did not give an explicit report of the number of participants in each trial group and there was no flow diagram to illustrate the flow of participants. Zuspan 1960 also did not provide adequate information on the flow of participants in the trial.

Selective reporting

All five included trials (Diamond 1968; Eogan 2007; Mundow 1975; Shelton 1980; Zuspan 1960) appeared to be free of selective outcome reporting. The protocols were not available but all the pre-specified outcomes stated in the methods section of each trial were adequately reported. All trials were therefore judged as having low risk of selective reporting bias.

Other potential sources of bias

Diamond 1968 and Zuspan 1960 were supported by drug companies (Wyeth Laboratories and Purdue Fredrick Co, respectively). There was no declaration of interest and the trial authors did not specify whether the companies influenced the results or not. Consequently Diamond 1968; and Zuspan 1960 were judged as having unclear risk of other bias. Mundow 1975 was also judged as having an unclear risk of bias because the trial report did not contain information on conflicts of interest, funding sources, how the sample size was determined or whether ethical approval was obtained.

Shelton 1980 was judged to be at high risk of other bias. The authors reported that the drugs used in the trial and statistical evaluation were provided by Reckitt & Colman, but there was no information on declaration of interest to ascertain whether the company might have influenced the trial results or not. There was also no information relating to ethical approval.

Eogan 2007 appeared to be free of other bias.

Effects of interventions

The five included trials (Diamond 1968; Eogan 2007; Mundow 1975; Shelton 1980; Zuspan 1960) examined two different comparisons given below.

Laxative versus placebo - Comparison 1

Four included trials (Diamond 1968; Mundow 1975; Shelton 1980; Zuspan 1960) examined the effectiveness and safety of a laxative versus a placebo control. The laxatives studied by the four trials were as follows: studied Bisoxatin acetate (Diamond 1968); active senna (Shelton 1980); Dorbanex (Mundow 1975); and Dioctyl-sodium succinate plus senna (Zuspan 1960).

Primary outcomes

Pain or straining on defecation

None of the four trials evaluating this comparison reported on pain or straining during defecation.

Incidence of postpartum constipation as per self-report and other diagnostic criteria

None of the four trials evaluating this comparison reported on the incidence of postpartum constipation.

Changes in quality of life as measured in included studies (using e.g. maternal postpartum quality of life (MAPP-QOL) questionnaire)

None of the four trials evaluating this comparison reported on changes in quality of life.

Time to first bowel movement (days) (outcome not pre-specified in our protocol)

Four trials reported on this outcome (Diamond 1968; Mundow 1975; Shelton 1980; Zuspan 1960). Three trials (Diamond 1968; Mundow 1975; Shelton 1980) reported on the number of women having their first bowel movement on the day of delivery, day one, day two, day three, and day four. Zuspan 1960 reported the mean days to first bowel movement. We analysed data accordingly.

Number of women having their first bowel movement in less than 24 hours

Results from one trial (Shelton 1980) found that more women had their first bowel movement in less than 24 hours in the laxative group compared to the placebo group (142/224 (63%) versus 54/247(21.9%), risk ratio (RR) 2.90, 95% confidence interval (CI) 2.24 to 3.75, 471 women, one trial) (Analysis 1.1).

Number of women having their first bowel movement on day one

Results from random-effects meta-analysis of three trials (Diamond 1968; Mundow 1975; Shelton 1980) showed substantial unexplained heterogeneity between trials ($Tau^2 = 0.14$; $Chi^2 = 5.45$, $P = 0.07$; $I^2 = 63\%$). We therefore did not carry out meta-analysis; in the data and analysis we report subtotals only and set out the results of individual trials. Diamond 1968 found that more women in the laxative group had their first bowel movement on day one when compared to women in the placebo group (23/54 (42.6%) versus 11/52 (21.2%), RR 2.01, 95% CI 1.09 to 3.70,

106 women). Results from Mundow 1975 (7/100 (7%) versus 9/100 (9%), RR 0.78, 95% CI 0.30 to 2.01, 200 women); and Shelton 1980 (69/224 (31%) versus 81/247 (4.0%), RR 0.94, 95% CI 0.72 to 1.22, 471 women) showed no difference between laxative and placebo groups (Analysis 1.2).

Number of women having their first bowel movement on day two

Random-effects meta-analysis of three trials (Diamond 1968; Mundow 1975; Shelton 1980) showed substantial unexplained heterogeneity between trials (Tau² = 2.27; Chi² = 45.00, P < 0.00001, I² = 98%). We therefore report on the results of individual trials. Diamond 1968 and Mundow 1975 both found that more women in the laxative group had their first bowel movement on day two compared to the placebo group (26/54 (48.1%) versus 9/52 (17.3%), RR 2.78, 95% CI 1.44 to 5.36, 106 women, (Diamond 1968), and 49/100 (49%) versus 12/100 (12%), RR 4.08, 95% CI 2.32 to 7.20, 200 women, (Mundow 1975)).Shelton 1980 found that fewer women in the laxative group compared to the placebo group had their first bowel movement on day two (9/224 (4.0%) versus 44/247(17.8%), RR 0.23, 95% CI 0.11 to 0.45, 471 women) (Analysis 1.3).

Number of women having their first bowel movement on day three

Random-effects meta-analysis of two trials (Mundow 1975; Shelton 1980) showed substantial unexplained heterogeneity between trials (Tau² = 3.89; Chi² = 4.65, P = 0.03; I² = 78%). We therefore report on the results of individual trials. One trial (Shelton 1980) found that fewer women had their first bowel movement on day three in the laxative group compared to the placebo group (0/224 (0%) versus 10/247 (4.0%), RR 0.05, 95% CI 0.00 to 0.89, 471 women) whereas the other trial (Mundow 1975) found no clear difference between the two groups (30/100 (30%) versus 33/100 (33%), RR 0.91, 95% CI 0.60 to 1.37, 200 women) (Analysis 1.4).

Number of women having their first bowel movement on day four

Random-effects meta-analysis of two trials (Mundow 1975; Shelton 1980) found a clear difference where, on average, significantly fewer women in the laxative group had their first bowel movements on day four compared to the placebo group (RR 0.36, 95% CI 0.21 to 0.61, 671 women) and there was no substantial statistical heterogeneity detected between the trials (Tau² = 0.00, Chi² = 0.21, P = 0.65, I² = 0%) (Analysis 1.5).

Number of days to first bowel movement

Zuspan 1960 reported the mean number of days before the first bowel movement occurred as 2.48 days versus 2.55 days for the laxative versus placebo groups. However, since there were no standard deviations and P values reported we are unable to analyse these data further.

Secondary outcomes

Stool consistency using Bristol stool form scale

There were no trials reporting on stool consistency using the Bristol stool form scale. However, Diamond 1968 reported the number of women having loose or watery stools and noted that there were more women with this outcome in the laxative group compared to the placebo group (28/54 (51.9%) versus 1/52 (1.9%), RR 26.96, 95% CI 3.81 to 191.03, 106 women, one trial, Analysis 1.6). The wide CI is due to the fact there was only event in the placebo group.

Use of alternative products, laxative agents, enemas

Zuspan 1960 reported the number of postpartum enemas given and there was no difference between the laxative and placebo groups (20/123 (16.3%) versus 31/121 (25.6%), RR 0.63, 95% CI 0.38 to 1.05, 244 women, one trial, Analysis 1.7).
Mundow 1975 reported the number of women receiving suppositories or enemas and there were fewer women receiving these in the laxative group compared to the placebo group (7/100 (7%) versus 24/100 (24%), RR 0.29, 95% CI 0.13 to 0.65, 200 participants, one trial, Analysis 1.8).

Relief of abdominal pain/discomfort

None of the four trials evaluating this comparison reported on relief of abdominal pain/discomfort.

Stool frequency

Diamond 1968 reported the number of women having more than two bowel movements per day. There were more women having more than two bowel movements per day in the laxative group compared to the placebo group (13/54 (24.1%) versus 0/52 (0%), RR 26.02, 95% CI 1.59 to 426.73, 106 women, one trial, Analysis 1.9). The wide confidence interval is due to the fact that there were zero events in the placebo group.
Mundow 1975 reported the number of days (from zero to five days) that women recorded bowled movements (Analysis 1.10). Fewer women had no bowel movement for five days in the laxative group compared to women in the placebo group (0/100 (0%) versus 9/100 (9%), RR 0.05, 95% CI 0.00 to 0.89, 200 women).There

were no differences between the laxative and placebo groups in the number of women having bowel movements on one, three and five days. However, there were fewer women having bowel movements on two days in the laxative compared to the placebo group (25/100 (25%) versus 42/100 (42%), RR 0.60, 95% CI 0.39 to 0.90, 200 women, one trial,). Conversely, more women had bowel movements on four days in the laxative compared to the placebo group (27/100 (27%) versus 10/100(10%), RR 2.70, 95% CI 1.38 to 5.28, 200 women, one trial).

Adverse effects caused by the intervention

Shelton 1980 and Mundow 1975 reported on the number of women having abdominal cramps but their results were not pooled in a meta-analysis due to substantial statistical heterogeneity (Tau^2 = 3.32; Chi^2 = 5.63, P = 0.02; I^2 = 82%, Analysis 1.11). While Shelton 1980 reported that more women were having abdominal cramps in the laxative group compared to the placebo group (23/224 (10.3%) versus 6/247 (2.4%), RR 4.23, 95% CI 1.75 to 10.19, 471 women, one trial), there were no clear difference between the laxative and placebo groups in Mundow 1975 (RR 0.25, 95% CI 0.03 to 2.20, 200 women, one trial).

Any adverse effects of the intervention on the baby

Shelton 1980 reported on adverse effects of the intervention on the baby and there were no clear differences in the incidence of loose stools (RR 0.62, 95% CI 0.16 to 2.41, 281 women, one trial) or diarrhoea (RR 2.46, 95% CI 0.23 to 26.82, 281 women, one trial) between the two groups (Analysis 1.12).

Laxative alone versus laxative plus a bulking agent - Comparison 2

One trial (Eogan 2007) compared a laxative (Lactulose) alone versus the same laxative plus a bulking agent (Lactulose plus a sachet of Ispaghula husk) in women who had sustained sphincter injuries during vaginal delivery and had subsequently undergone surgical repair of the tear.

Primary outcomes

Pain or straining on defecation

Eogan 2007 reported on the level of pain or discomfort with the first postpartum bowel movement using a Likert scale (1 = no pain to 5 = excruciating pain) during the first 10 days postpartum. The median (range) pain score for both study groups was one (one to five) and there were no differences between the two groups (P = 0.11, as reported by trial authors). We were unable to further analyse these data since the data were only reported in terms of medians (range).

Incidence of postpartum constipation as per self report and other diagnostic criteria

Eogan 2007 reported that there was no difference in incidence of postpartum constipation (data not reported).

Changes in quality of life as measured in included studies (using e.g. maternal postpartum quality of life (MAPP-QOL) questionnaire)

Change in quality of life was not reported by the trial evaluating this comparison.

Time to first bowel movement (days)

Eogan 2007 reported that the first postpartum bowel motion occurred at a median (range) of three (one to six) days and three (one to five) days in the two groups and there was no difference between the two groups (P = 0.34).

Secondary outcomes

Stool consistency using Bristol stool form scale

Stool consistency was not reported by the trial assessing this comparison.

Use of alternative products, laxative agents, enemas

Use of alternative products, laxative agents, enemas was not reported by the trial assessing this comparison.

Relief of abdominal pain/discomfort

Relief of abdominal pain/discomfort was not reported by the trial evaluating this comparison.

Stool frequency

Stool frequency was not reported by the trial assessing this comparison.

Adverse effects caused by the intervention

Eogan 2007 reported incontinence using a bowel function questionnaire with score from 0 to 20 (0 = incomplete continence up to 20 = complete incontinence). Scores were assigned according to participants' symptoms including faecal urgency or incontinence as well as flatus incontinence on day three, day 10 and after three months postpartum. The incontinence score on day three in the laxative plus bulking agent group was significantly higher than in the laxative alone group (median (range): one (0 to 10) versus 0

(0 to 12) respectively, P = 0.02 as reported by trial authors). However, there was no difference in the incontinence scores between the two groups at three months postpartum (median (range): 0 (0 to six) versus 0 (0 to 10) respectively, P = 0.57 as reported by trial authors). No further analysis was possible since results were only reported as medians (range).

The trial also reported the number of participants having any episode of faecal incontinence during first 10 postpartum days. There was no clear difference in the number of women having any episode of faecal incontinence during the first 10 postpartum days between the two groups (14/77 (18.2%) versus 23/70 (32.9%), RR 0.55, 95% CI 0.31 to 0.99, 147 women, one trial, Analysis 2.1).

Any adverse effects of the intervention on the baby

The trial evaluating this comparison did not report on adverse effects of the intervention on the baby.

DISCUSSION

Summary of main results

The objective of this review was to assess the effectiveness and safety of different interventions for preventing postpartum constipation. We conducted a comprehensive electronic search of potential trials, without language restrictions. We included five trials (involving a total of 1208 postpartum women) in this review.

All Included trials dealt with the prevention of postpartum constipation by administering laxatives within the first day of the postpartum period. The quality of included trials was poor, with unclear risk of bias for most domains across trials. Although the results of some of the outcomes showed clear differences between groups within single trials, the trials varied in sample size, duration of study, interventions and reported outcomes, which limited the number of meta-analyses that could be done.

Four trials (Diamond 1968; Mundow 1975; Shelton 1980; Zuspan 1960) compared a laxative and a placebo. None of the trials reported on the primary outcomes of the review: pain or straining on defecation; incidence of postpartum constipation; or changes in quality of life. For the outcome 'number of days to first bowel movement', trials reported the number of women having their first bowel movement on day one to day four postpartum. Random-effects meta-analysis, done per day postpartum, showed substantial unexplained heterogeneity for days one to three and results were therefore reported per trial. No heterogeneity was present in the meta-analysis for day four, and a pooled result was reported. On day four, a random effects meta-analysis of two trials showed that on average, more women in the placebo group were having their first bowel movement compared to the laxative group.

This review's secondary outcomes were poorly reported in the included trials. Diamond 1968 reported on stool frequency as an adverse effect of the intervention (Bisoxatin) and the results show a higher stool frequency in the laxative group compared to the placebo group. The same trial reported on stool consistency, with more women in the laxative group compared to the placebo group having experienced loose or watery stools. According to Shelton 1980, loose stools or diarrhoea in both mother and babies could not be attributed to administration of senna given to the mother in the early postpartum period, however there were significantly more women in the laxative group with abdominal cramps ranging from mild to severe. Both trials did not report on the use of additional products or changes in quality of life.

The fifth trial (Eogan 2007) compared a laxative (oral Lactulose) versus the same laxative plus a bulking agent (Ispaghula husk) in women undergoing surgical repair of a third degree perineal tear. The trial found no clear difference in pain scores between the two groups in relation to first postpartum bowel motion. However, fear of pain caused by the repaired perineal tear or episiotomy could cause a postpartum woman to refrain from emptying her bowel when she has the urge to defecate, which in turn could lead to constipation. Considering this, it would be difficult to ascertain whether the pain was due to the repaired perineal tear or due to postpartum constipation. The trialist reported no clear difference between groups regarding time to first bowel movement (data provided as median and range, not analysed further in this review). The trial did not provide data in relation to the incidence of postpartum constipation (but reported no clear difference between groups). Change in quality of life was not reported. Adverse effects were the only secondary outcomes reported. The trial found a higher risk of faecal incontinence at 10 days postpartum in the laxative plus bulking agent group, but the trialist reported that there was no difference after three months (and loss to follow-up at three months was high for this group (Lactulose = 16%, Lactulose plus Ispaghua husk = 20%).

Overall completeness and applicability of evidence

The five trials were conducted in three different countries (United States of America, Ireland and South Africa), all in tertiary hospitals. Three of the trials (Diamond 1968; Mundow 1975; Shelton 1980) examined the time to first bowel movement (days) as one of the their outcomes. All included trials assessed pharmaceutical interventions in preventing postpartum constipation.

None of the trials assessed other interventions such as dietary advice and modification, promotion of healthy physical activities and correct positioning for defecation, which also have a very important place in promoting bowel movement during the postpartum period. Consideration also needs to be given to other factors that might influence postpartum bowel movement, such as the administration of enemas before labour, the ability of women to

eat during active labour, and irregular and altered eating habits during the first few days after delivery. None of these factors were reported on in the included trials. In addition, included trials only assessed bowel movements during the first five days after delivery. Constipation can become a problem at a later stage of the postpartum period, up to six months postpartum (Van Brummen 2006). Factors such as limited physical exercise, irregular and altered dietary pattern, insufficient intake of fluids and emotional concerns of being a new mother may have a negative influence on bowel movements during this period (National Institute of Health 2013).

One trial (Eogan 2007), evaluated two different interventions amongst women who had undergone surgical repair of a third degree perineal tear. This is a very specific group of trial participants and the results can therefore not be extrapolated to the general postpartum woman. The pain experienced with the first bowel movement was most likely attributed to pain due to the perineal tear and surgery and not necessarily due to constipation. Fear of pain can also play a role in this group of women, which might lead to constipation.

Only a few adverse effects were reported in the included trials and there is thus insufficient evidence to make general conclusions on safety and effectiveness of these interventions.

Quality of the evidence

All the five trials included in this review lacked methodological rigour. Two trials are quasi-randomised controlled trials with a high risk of selection bias. Only one trial (Eogan 2007) reported an adequate method for sequence generation. Allocation concealment was unclear in four trials (Diamond 1968; Eogan 2007; Shelton 1980; Zuspan 1960), while Mundow 1975 adequately reported on allocation concealment. Blinding was poorly reported in all included trials. All included trials were judged as having unclear risk of performance bias due to insufficient information. Diamond 1968; Mundow 1975 and Shelton 1980 had low risk of detection bias while Eogan 2007 and Zuspan 1960 were judged as having unclear risk of detection bias. One trial was judged as having low risk of attrition bias (Diamond 1968); Eogan 2007 and Shelton 1980 had a high risk of attrition bias due to incomplete outcome data, and Mundow 1975 and Zuspan 1960 were judged as having unclear risk of attrition bias due to insufficient information provided. The drugs used in three of the trials (Diamond 1968; Shelton 1980; Zuspan 1960) were supplied by a drug company and we cannot rule out the possibility that the company may have influenced the trial results since there was no declaration of interest. Shelton 1980 had high risk of other bias due to statistical analysis provided by the same drug company that supplied the drugs for the trial, while Eogan 2007 had low risk of other bias. All included trials were free of selective outcome reporting bias.

Potential biases in the review process

We attempted to minimise potential bias in this review in a number of ways. A comprehensive trial search was conducted to include published and unpublished trials in all languages. At least two review authors independently scrutinised and selected trials for inclusion in the review using eligibility criteria, assessed risk of bias, and extracted data. We were unable to examine reporting biases using funnel plots, as we had less than 10 included trials in a meta-analysis.The primary outcome 'number of days to first bowel movement' was supposed to be analysed using time-to-event analysis methods, but this could not be done due to insufficient individual patient data on censoring. The separate analyses per day do not take account of the fact that the denominator was decreasing as the number of days after delivery increased due to the fact that once a woman experienced the event, they could not experience the event again thereafter.

Agreements and disagreements with other studies or reviews

There is no other systematic review on interventions for preventing postpartum constipation. Dietary fibre in the form of e.g. wheat and brans offers relief for constipation in non-pregnant mothers and raise no serious concerns about side effects to mother and baby. Other measures such as behavioural and educational interventions, increased exercise and positioning during bowel movement were not discussed in the included trials. Symptomatic rectal haemorrhoids also play a significant role in postpartum constipation and dietary fibre seems to offer effective treatment in relieving haemorrhoids which may contribute to constipation (Alonso-Coello 2005).

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence to make general conclusions about the effectiveness and safety of laxatives during the immediate postpartum period (up to five days postpartum). Trials did not follow participants up through the entire postpartum period and we did not find any evidence on the effectiveness and safety regarding the use of laxatives during the entire postpartum period up to six months. The evidence from one small trial suggests that the use of stool-bulking agent in addition to a laxative to initiate bowel movement in women who sustained anal sphincter injury at vaginal delivery does not improve postnatal pain or straining on defecation.

Implications for research

There are few trials on interventions for preventing postpartum constipation reporting on the following important outcomes: pain or straining on defecation; incidence of postpartum constipation, quality of life, time to first bowel movement after delivery, and adverse effects caused by the intervention such as: nausea or vomiting, pain and flatus. No trials evaluating non-pharmacological interventions (such as acupuncture, educational or behavioural interventions and positioning during bowel movement) are currently available. Further large, rigorous randomised controlled trials are needed to address the safety and effectiveness of laxatives for preventing constipation during the entire postpartum period. Trials assessing educational and behavioural interventions aiming to promote a healthy diet and physical activity in preventing postpartum constipation are also needed.

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As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team), two members of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Diamond 1968

Methods	Study design: randomised controlled trial. Trial duration: 12 weeks (April 11, 1966 to July 13, 1966). Trial location: University of Minnesota Hospitals, Minneapolis, USA
Participants	Number of participants: 106 postpartum women aged 15-41 years Intervention group: 54 women (29 primiparous and 25 multiparous) Control group: 52 women (26 primiparous and 26 multiparous).
Interventions	Intervention: Bisoxatin acetate (3 tablets); 1 tablet was given orally 1st day postpartum and if no bowel action occur that 1st day, the dose was increased to 2 tablets by the 2nd day. If no bowel activity occur by the 3rd day other form of laxative was used Control: lactose placebo (3 tablets).
Outcomes	**Primary outcomes** 1. Number of participants having their first bowel movement by day 1, day 2, and day 3 2. Number of stools per day. 3. Side effects: diarrhoea, loose or watery stool.
Notes	Ethics approval: not stated. Funding: the study was supported by the Wyeth Laboratories, Philadelphia, Pennsylvania, USA Correspondence with authors: no email address available. We would have requested details regarding risk of bias, for instance whether random number tables or a computer were used in random sequence generation

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote "Each patient was assigned a number according to a random code". It is unclear how the random sequence was generated
Allocation concealment (selection bias)	Unclear risk	Quote "Identical envelopes and drugs were used". It was not clear whether adequate precaution were taken to conceal the assignment from the participants and investigators
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote "The patients and investigators were not aware of the content of the identical drugs and envelopes". Insufficient information on identical colour, shape and size of

Diamond 1968 (*Continued*)

		drug to enable explicit judgement
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote "The knowledge of the random code number and type of drug was not revealed till the completion of the study"
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing outcome data. All women enrolled were included in the final analysis
Selective reporting (reporting bias)	Low risk	No published protocol available, but all outcomes that were pre-specified in the methods session were addressed
Other bias	Unclear risk	The study was supported by Wyeth Laboratories but the trial authors do not specify whether the drug company influenced the results

Eogan 2007

Methods	Study design: randomised controlled trial. Trial duration: 12 months (May, 2003 to April, 2004). Trial location: National Maternity Hospital, Holles St Dublin, Ireland
Participants	Participants: 147 postpartum women with sphincter injury at vaginal delivery, undergoing primary repair of a recognised anal sphincter tear Intervention group: 70 postpartum women. Control group: 77 postpartum women. Exclusion criteria: history of colorectal disease, inflammatory bowel disease, diabetes mellitus or colorectal malignancy
Interventions	Intervention: oral lactulose 10 mL thrice daily for the first 3 postpartum days followed by sufficient lactulose to maintain a soft stool for 10 days plus 1 sachet of Ispaghula husk for 10 days Control: oral lactulose 10 mL thrice daily for the first 3 postpartum days followed by sufficient lactulose to maintain a soft stool for 10 days All patients were given routine antibiotic (co-amoxyclavulanic acid), while erythromycin and metronidazole were used in those with penicillin allergy All participants were provided with a diary card to keep record of their bowel habits and motions for 10 days Opiate was avoided in both groups.
Outcomes	**Primary outcomes** 1. Discomfort with 1st postpartum bowel motion (using pain scale from 1 - no pains to 5 - excruciating pains) 2. Incidence of postnatal constipation and incontinence. **Secondary outcomes** 1. Time until first bowel motion.

	2. Duration of postnatal stay. 3. Symptomatic and functional outcomes 3 months postpartum. All participants were provided with a diary card to keep record of their bowel habits and motions for 10 days, opiate was avoided in both groups
Notes	Funding: the study was supported by the Irish Health research board Correspondence: email was sent to the author (colm.oherlihy@ucd.ie) requesting for further information on method used to ensure adequate concealment of the assignment and blinding processes, but there was no response Declaration of interest: no comment provided.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation was carried out using computer-generated allocations
Allocation concealment (selection bias)	Unclear risk	"Sealed opaque envelopes was used to concealed allocation identity". It was not specified whether the envelopes were sequentially numbered to prevent selection bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	There was no explicit information on blinding of the participants, personnel and investigators to the assignment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information to judge whether the assessors were blinded to the assignment or not
Incomplete outcome data (attrition bias) All outcomes	High risk	All participants attended the first 10 days follow-up, 26 did not attend postpartum review at 3 months despite 2 repeated appointments sent, 24 of whom gave a personal reason and 2 could not be traced Attrition rate in intervention group (LG) = 16%. Attrition rate in control group (FG) = 20%.
Selective reporting (reporting bias)	Low risk	All outcomes that were pre-specified in the methods were addressed
Other bias	Low risk	The study appears to be free of other sources of bias.

Mundow 1975

Methods	Study design: quasi-randomised trial. Trial Duration: 6 weeks (May 5th,1974 to June11th, 1974). Trial location: St James' Hospital Dublin. Ireland.
Participants	200 normal postpartum women. Intervention group: 100 primiparous and multiparous women. Control group: 100 primiparous and multiparous women.
Interventions	Intervention: Danthron/Poloxalkol (Dorbanex). Each patient was given 2 yellow capsules at 18:00 hour every evening starting from the 3rd day of delivery for the next 3 days (6 capsules). The capsules were taken from numbered bottles Control: 'Placebo' - author did not give name of placebo; It was said that an identical code was used for both the placebo and experimental intervention
Outcomes	**Outcomes** 1. Number of days to first bowel movement. 2. Visible haemorrhoids. 3. Abdominal pain. **Secondary outcomes** 4. Diarrhoea. 5. Nausea. 6. Urine discolorations.
Notes	There was no information on number of participants in each arm of intervention. Ethical approval not stated and declaration of interest not provided. The funding organisation was not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote "Consecutive patients were enrolled into study, Randomization component not explicitly stated"
Allocation concealment (selection bias)	Low risk	Quote ''The yellow identical capsules were taken from a numbered bottle, each of which contained 6 capsules. There were 200 bottles and one was assign to each participant. The code was held by the laboratories and was only sent to the investigators at the end of the study"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote "The placebo and the active capsules were indistinguishable to the participant". No information on the personnel and method used in blinding the both participant and the personnel

Mundow 1975 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote "The code which identify the active from the placebo was held at Riker Laboratories at Loughborough and was sent to the investigator only at the end of the study, the active and placebo were indistinguishable"
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The number of participants in each group was not stated explicitly and there was no flow diagram to illustrate this
Selective reporting (reporting bias)	Low risk	Study protocol was not available, but all outcomes specified in the method section were addressed
Other bias	Unclear risk	There was no information on conflicts of interest, how sample size was determined and no comment was made on ethical approval. The funding organisation was not reported

Shelton 1980

Methods	Study design: randomised controlled trial. Trial setting: multicentre. Trial location: Department of Obstetrics and Gynaecology,University of Cape Town, Groote Schuur Hospital and Peninsula Maternity Hospitals, Cape Town South Africa
Participants	Participants: 511 normal postpartum women with vaginal delivery White postpartum women: 267 (from GrooteSchuur Hospital). Coloured postpartum women: 204 (Peninsula Maternity Hospital) Black postpartum women: 40. Exclusion criteria: women delivered by caesarean section or complicated by 3rd degree perineal tear
Interventions	Intervention: active senna tablets, 2 tablets were given in the morning and 2 tablets in the evening immediately after delivery, and 2 tablets twice daily until bowel action occurred or end of regimen (16 tablets used up) Control: placebo (powdered corn flakes and dried grass).
Outcomes	**Primary outcomes** 1. Initial spontaneous bowel movement within the first 24 hours of delivery 2. Initial spontaneous bowel movement within 48 hours of delivery 3. First bowel movement on the third day of delivery. 4 .Time of dosage. 5.Time and nature of bowel action. **Infant side effects** 1. Loose stools or diarrhoea. 2. Number, colour and nature of stools for duration of trial

Shelton 1980 (*Continued*)

	3. Proportion of babies with normal stools. 4. Mode of feeding. **Secondary outcomes** 1. Enema during labour and state of perineum following delivery 2. Maternal side effects: e.g. abdominal colic pains. 3. Mode of delivery.
Notes	Sponsor: the drugs were supplied by Reckitt & Colman and statistical evaluation provided by them Ethics approval: not stated. Decaration of interest: not disclosed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Author did not provide sufficient information on how randomisation was done. Quote "Trial preparation was administered according to a strict double - blind random selection procedure"
Allocation concealment (selection bias)	Unclear risk	The authors did not provide sufficient information to enable a clear judgement. Quote "tablets (active and placebo) were identical in all respect and patient only received drugs from a numbered bottle allocated to her"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote "Treatment assignment was masked from all study personnel and participants for the duration of the study". Information on methods used to mask the colour, shape and size was not supplied
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote "Statistical analyst had no knowledge of which patients received active treatment or placebo". The code was only broken at the final stage of analysis
Incomplete outcome data (attrition bias) All outcomes	High risk	The result of 40 participants was not included because the results showed minimal differences
Selective reporting (reporting bias)	Low risk	All the pre-specified outcomes in the method section were addressed adequately

Shelton 1980 (*Continued*)

Other bias	High risk	Sponsor: the drugs used were supplied by Reckitt & Colman and statistical evaluation provided by them Ethics approval: not stated. Declaration of interest: not disclosed.

Zuspan 1960

Methods	Study design: quasi-randomised trial. Trial setting: Department of Obstetrics and Gynaecology, University Hospital Cleveland, Ohio. United States of America Trial location: United States of America.
Participants	244 postpartum women.
Interventions	Intervention: Dioctyl-sodium succinate (50 mg) + senna (225 mg); 1 capsule twice daily. The 1st capsule was given as soon postpartum as practical. No other laxative drugs given except enema saponis at patients' request Control: capsulated inert ingredients (placebo), 1 capsule twice daily. 1st dose given as soon as postpartum is practical. No other laxative administered except enema saponis at patients' request
Outcomes	1. Number of days before 1st spontaneous bowel movement. 2. Number of capsule (laxative) taken before 1st spontaneous bowel movement 3. Number of postpartum enemas given.
Notes	Purdue Fredrick Co. supplied the laxative (Senokap) used for the trial

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	There was no information on random allocation sequence generation method (quasi-RCT)
Allocation concealment (selection bias)	Unclear risk	Insufficient information to enable us make a clear judgement on allocation concealment Quote: "Indistinguishable coded capsules were given to the patients"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Quote "All patients received double blinded capsule as soon as postpartum is practical and they were intentionally not told whether the capsule was a laxative or not". No report on method used blinding the both the participants and personnel

Zuspan 1960 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information was given on knowledge of allocation interventions been prevented during measurement of outcomes
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No information was provided on the flow of participants.
Selective reporting (reporting bias)	Low risk	No published protocol available, but the pre-specified outcomes were addressed adequately Pre-specified outcomes. 1. Number of days before 1st spontaneous bowel movement. 2. Number of capsule (laxative) taken before 1st spontaneous bowel movement 3. Number of postpartum enemas given.
Other bias	Unclear risk	Ethics approval not stated. Purdue Fredrick Co. supplied the laxative (Senokap) used for the trial Conflict of interest was not addressed; we are not sure if there is a conflict of interest

RCT: randomised controlled trial

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Liu 2009	Trial did not study interventions to prevent postpartum constipation
Mahony 2004	Trial did not study interventions to prevent postpartum constipation

DATA AND ANALYSES

Comparison 1. Laxative versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of days to first bowel movement:less than 24 hours	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2 Number of days to first bowel movement: day one	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3 Number of days to first bowel movement: day two	3		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4 Number of days to first bowel movement: day three	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5 Number of days to first bowel movement: day four	2	671	Risk Ratio (M-H, Random, 95% CI)	0.36 [0.21, 0.61]
6 Stool consistency - loose or watery stools	1	106	Risk Ratio (M-H, Fixed, 95% CI)	26.96 [3.81, 191.03]
7 Number of postpartum enemas given	1	244	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.38, 1.05]
8 Number receiving suppositories or enemas	1	200	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.13, 0.65]
9 Number having two or more bowel movements per day	1	106	Risk Ratio (M-H, Fixed, 95% CI)	26.02 [1.59, 426.73]
10 Number of days a movement occurred	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
10.1 Zero days	1	200	Risk Ratio (M-H, Random, 95% CI)	0.05 [0.00, 0.89]
10.2 One day	1	200	Risk Ratio (M-H, Random, 95% CI)	1.13 [0.45, 2.80]
10.3 Two days	1	200	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.39, 0.90]
10.4 Three days	1	200	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.88, 2.06]
10.5 Four days	1	200	Risk Ratio (M-H, Random, 95% CI)	2.7 [1.38, 5.28]
10.6 Five days	1	200	Risk Ratio (M-H, Random, 95% CI)	0.8 [0.22, 2.89]
11 Number having abdominal cramps	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
12 Adverse effects on the baby	1	562	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.26, 2.83]
12.1 Loose stools	1	281	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.16, 2.41]
12.2 Diarrhoea	1	281	Risk Ratio (M-H, Random, 95% CI)	2.46 [0.23, 26.82]

Comparison 2. Laxative alone versus laxative plus bulking agent

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Faecal incontinence during first 10 postpartum days	1	147	Risk Ratio (M-H, Fixed, 95% CI)	0.55 [0.31, 0.99]

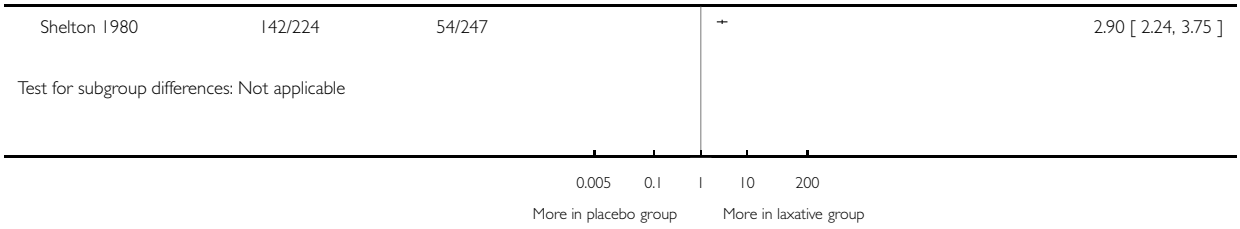
Analysis 1.1. Comparison 1 Laxative versus placebo, Outcome 1 Number of days to first bowel movement:less than 24 hours.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 1 Number of days to first bowel movement:less than 24 hours

Study or subgroup	Laxative n/N	Placebo n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Shelton 1980	142/224	54/247			2.90 [2.24, 3.75]
Test for subgroup differences: Not applicable					

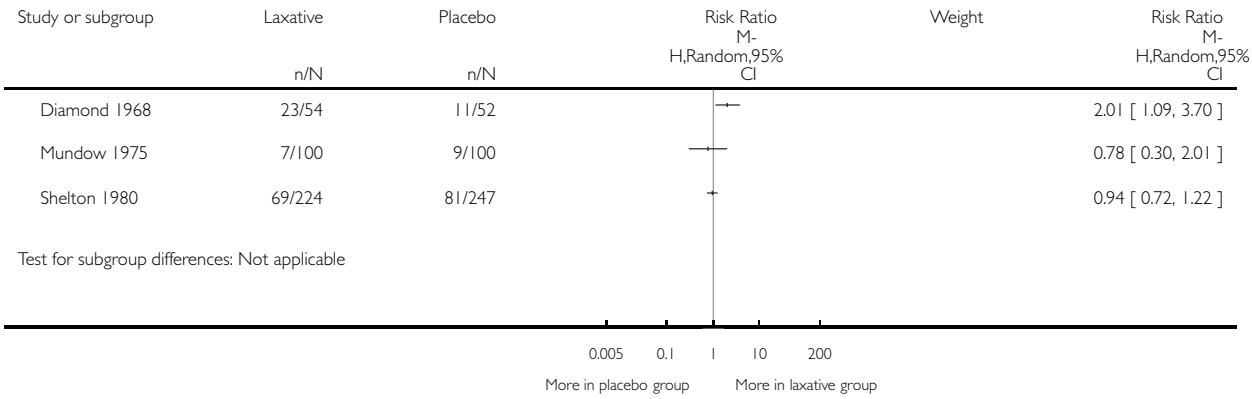


Analysis 1.2. Comparison 1 Laxative versus placebo, Outcome 2 Number of days to first bowel movement: day one.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 2 Number of days to first bowel movement: day one

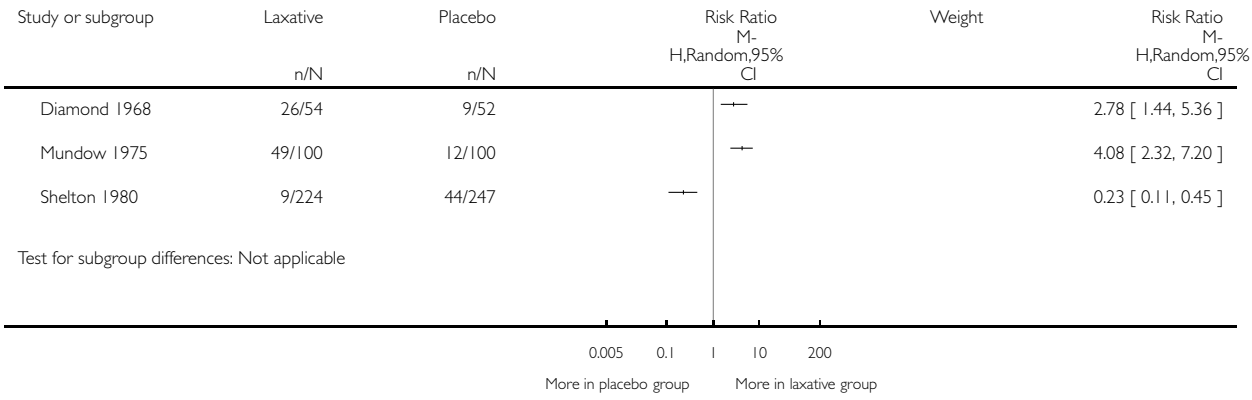


Analysis 1.3. Comparison 1 Laxative versus placebo, Outcome 3 Number of days to first bowel movement: day two.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 3 Number of days to first bowel movement: day two

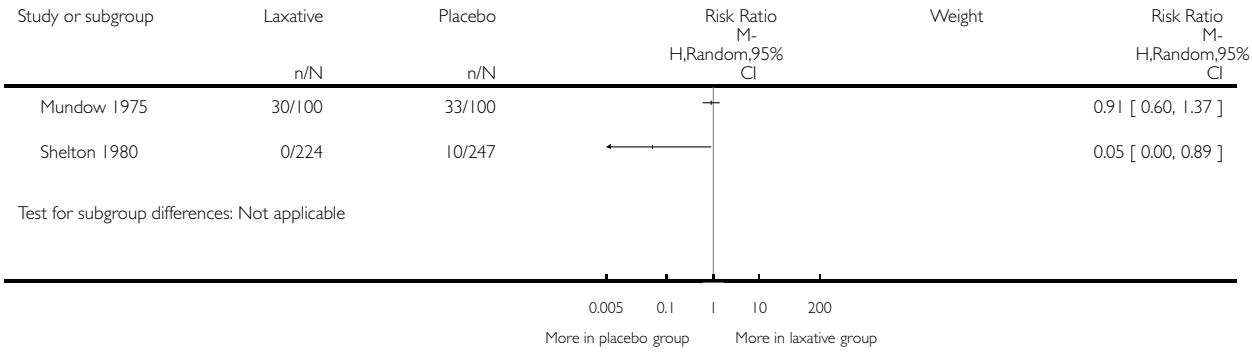


Analysis 1.4. Comparison 1 Laxative versus placebo, Outcome 4 Number of days to first bowel movement: day three.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 4 Number of days to first bowel movement: day three



Analysis 1.5. Comparison 1 Laxative versus placebo, Outcome 5 Number of days to first bowel movement: day four.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 5 Number of days to first bowel movement: day four

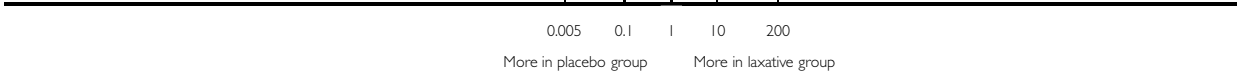
Study or subgroup	Laxative n/N	Placebo n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Mundow 1975	14/100	38/100		93.9 %	0.37 [0.21, 0.64]
Shelton 1980	1/224	5/247		6.1 %	0.22 [0.03, 1.87]
Total (95% CI)	**324**	**347**		**100.0 %**	**0.36 [0.21, 0.61]**

Total events: 15 (Laxative), 43 (Placebo)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.21$, df = 1 (P = 0.65); $I^2 = 0.0\%$

Test for overall effect: Z = 3.81 (P = 0.00014)

Test for subgroup differences: Not applicable



Analysis 1.6. Comparison 1 Laxative versus placebo, Outcome 6 Stool consistency - loose or watery stools.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 6 Stool consistency - loose or watery stools

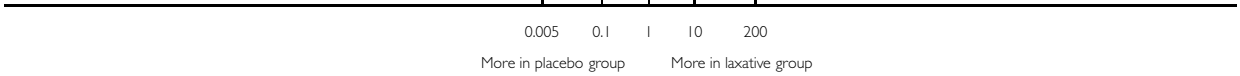
Study or subgroup	Laxative n/N	Placebo n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Diamond 1968	28/54	1/52		100.0 %	26.96 [3.81, 191.03]
Total (95% CI)	**54**	**52**		**100.0 %**	**26.96 [3.81, 191.03]**

Total events: 28 (Laxative), 1 (Placebo)

Heterogeneity: not applicable

Test for overall effect: Z = 3.30 (P = 0.00097)

Test for subgroup differences: Not applicable



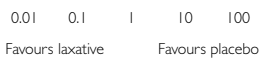
Analysis 1.7. Comparison 1 Laxative versus placebo, Outcome 7 Number of postpartum enemas given.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 7 Number of postpartum enemas given

Study or subgroup	Laxative n/N	Placebo n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Zuspan 1960	20/123	31/121		100.0 %	0.63 [0.38, 1.05]
Total (95% CI)	**123**	**121**		**100.0 %**	**0.63 [0.38, 1.05]**
Total events: 20 (Laxative), 31 (Placebo)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.77 (P = 0.076)					
Test for subgroup differences: Not applicable					



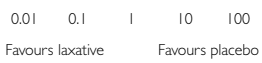
Analysis 1.8. Comparison 1 Laxative versus placebo, Outcome 8 Number receiving suppositories or enemas.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 8 Number receiving suppositories or enemas

Study or subgroup	Laxative n/N	Placebo n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Mundow 1975	7/100	24/100		100.0 %	0.29 [0.13, 0.65]
Total (95% CI)	**100**	**100**		**100.0 %**	**0.29 [0.13, 0.65]**
Total events: 7 (Laxative), 24 (Placebo)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.04 (P = 0.0024)					
Test for subgroup differences: Not applicable					



Analysis 1.9. Comparison 1 Laxative versus placebo, Outcome 9 Number having two or more bowel movements per day.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 9 Number having two or more bowel movements per day

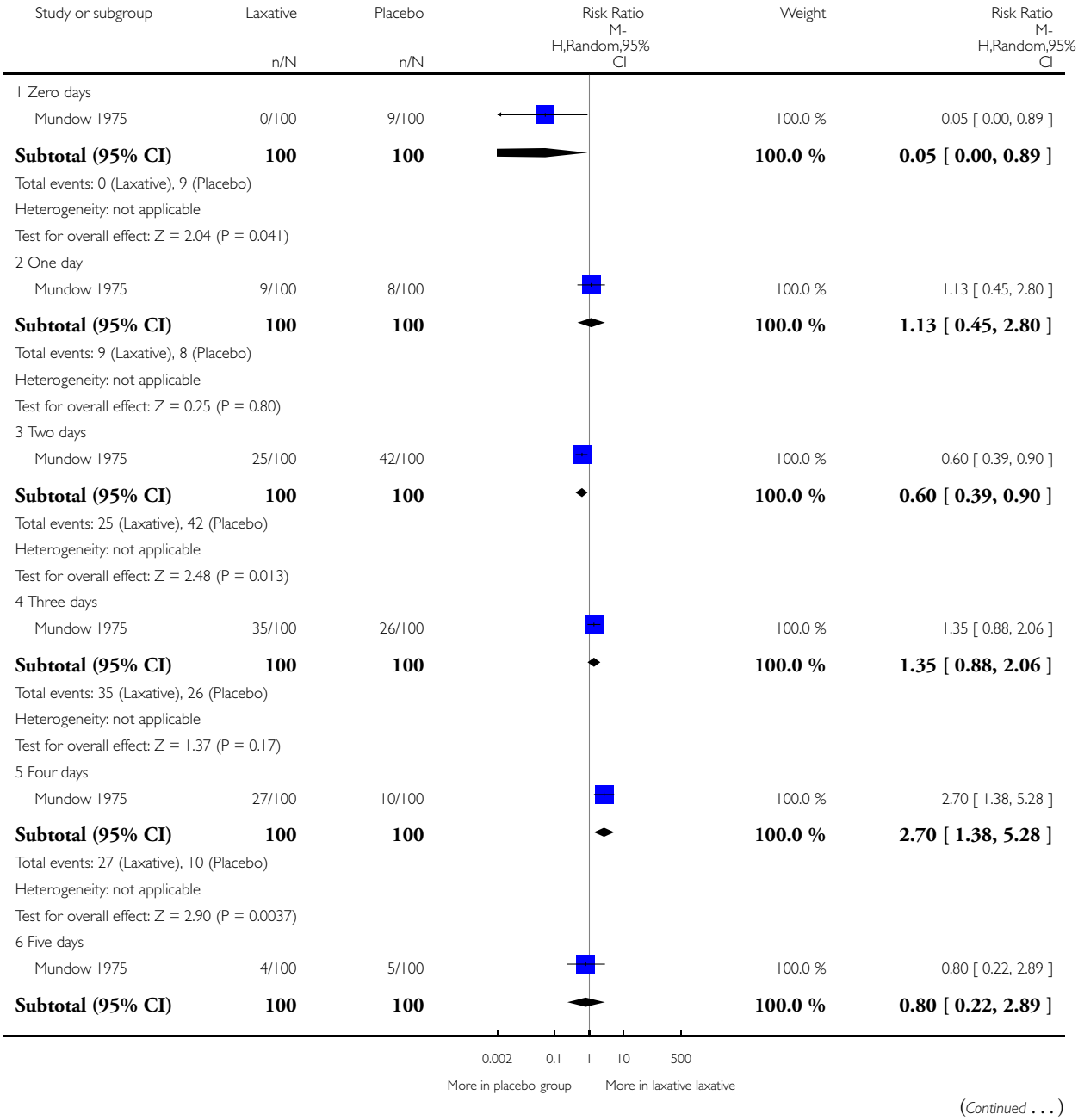
Study or subgroup	Laxative n/N	Placebo n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Diamond 1968	13/54	0/52		100.0 %	26.02 [1.59, 426.73]
Total (95% CI)	**54**	**52**		**100.0 %**	**26.02 [1.59, 426.73]**
Total events: 13 (Laxative), 0 (Placebo)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.28 (P = 0.022)					
Test for subgroup differences: Not applicable					

Analysis 1.10. Comparison 1 Laxative versus placebo, Outcome 10 Number of days a movement occurred.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

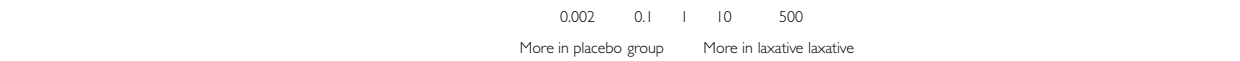
Outcome: 10 Number of days a movement occurred



(*Continued . . .*)

(. . . *Continued*)

Study or subgroup	Laxative n/N	Placebo n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Total events: 4 (Laxative), 5 (Placebo)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.34 (P = 0.73)					
Test for subgroup differences: Chi^2 = 20.75, df = 5 (P = 0.00), I^2 =76%					



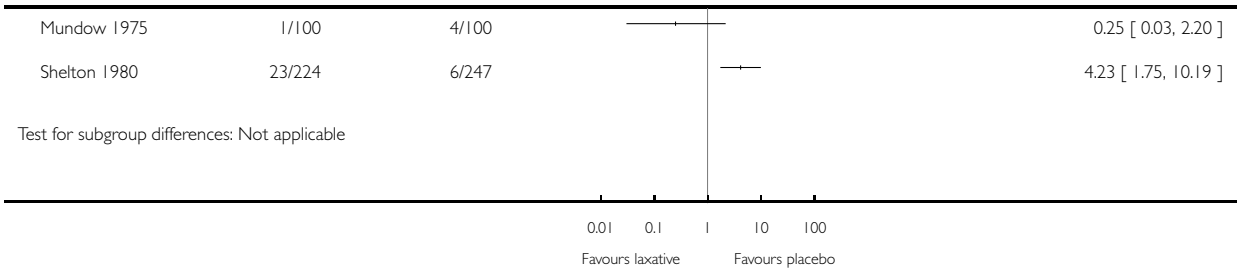
Analysis 1.11. Comparison 1 Laxative versus placebo, Outcome 11 Number having abdominal cramps.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 11 Number having abdominal cramps

Study or subgroup	Laxative n/N	Placebo n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Mundow 1975	1/100	4/100			0.25 [0.03, 2.20]
Shelton 1980	23/224	6/247			4.23 [1.75, 10.19]
Test for subgroup differences: Not applicable					

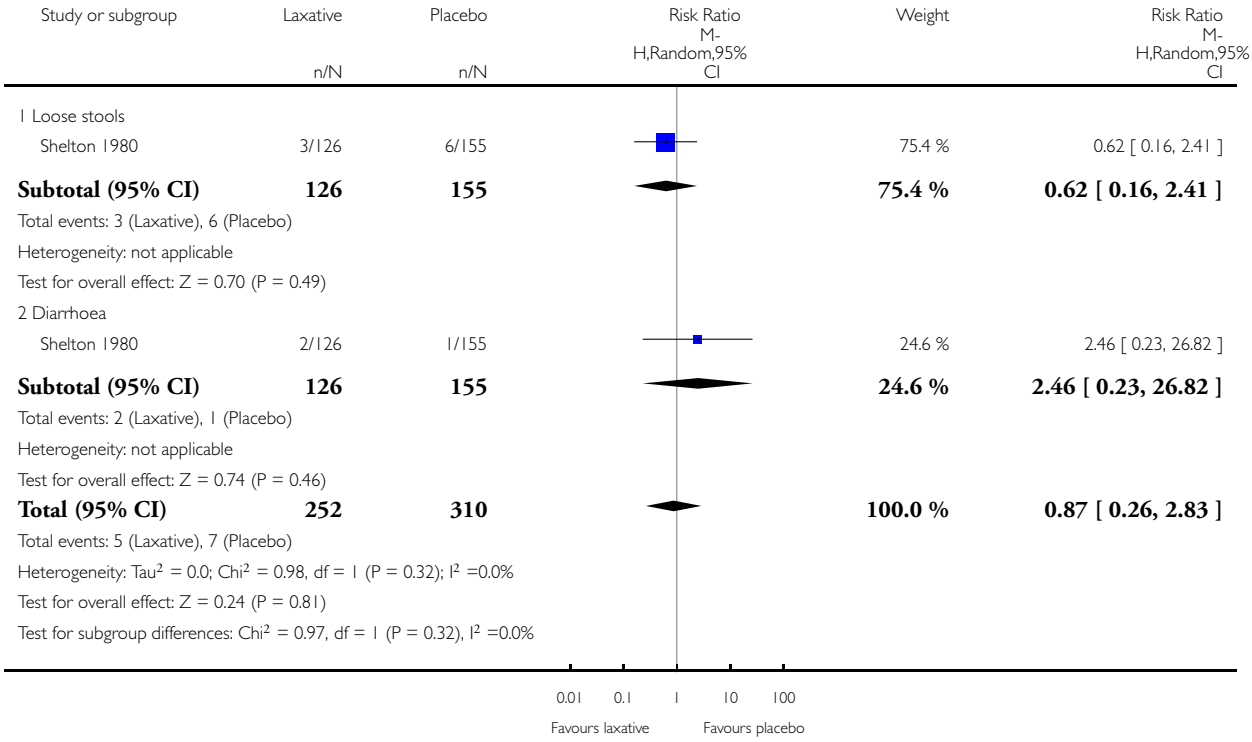


Analysis 1.12. Comparison 1 Laxative versus placebo, Outcome 12 Adverse effects on the baby.

Review: Interventions for preventing postpartum constipation

Comparison: 1 Laxative versus placebo

Outcome: 12 Adverse effects on the baby



Analysis 2.1. Comparison 2 Laxative alone versus laxative plus bulking agent, Outcome 1 Faecal incontinence during first 10 postpartum days.

Review: Interventions for preventing postpartum constipation

Comparison: 2 Laxative alone versus laxative plus bulking agent

Outcome: 1 Faecal incontinence during first 10 postpartum days

Study or subgroup	Laxative alone n/N	Laxative + bulking agent n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Eogan 2007	14/77	23/70		100.0 %	0.55 [0.31, 0.99]
Total (95% CI)	**77**	**70**		**100.0 %**	**0.55 [0.31, 0.99]**
Total events: 14 (Laxative alone), 23 (Laxative + bulking agent)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.00 (P = 0.046)					
Test for subgroup differences: Not applicable					

APPENDICES

Appendix 1. Bristol stool form scale

Type	Description
1	Separate hard lumps like nuts (difficult to pass)
2	Sausage-shaped but lumpy
3	Like a sausage but with cracks on its surface
4	Like a sausage or snake, smooth and soft
5	Soft blobs with clear-cut edges (passed easily)
6	Fluffy pieces with ragged edges, a mushy stool

(*Continued*)

7	Watery, no solid pieces, entirely liquid

Appendix 2. Search terms

The US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov) and the World Health Organization International Clinical Trials Registry platform (ICTRP).
Search terms: constipation AND (postpartum OR postnatal OR "after birth" OR "post delivery") AND (interventions OR prevent* OR avert OR avoid).
For University of Stellenbosch database we will use the following terms: (postnatal OR "post delivery" OR postpartum) AND (constipat* OR hard stool* OR "impacted stool" OR "lumpy stool" OR "rock-like stool") AND (interventions OR prevent* OR avert OR avoid).
Search terms for ProQuest: (post-delivery OR postpartum OR postnatal OR afterbirth) AND (constipat* OR hard stool* OR rock-like stool OR lumpy stool) AND (prevent* OR avoid OR interventions).

CONTRIBUTIONS OF AUTHORS

AR, ET and AM conceptualised the question. ET and AM drafted the review. AR critically engaged with the draft and provided comments. All authors have seen and approved of the final version of the review. ET is guarantor of this review.

DECLARATIONS OF INTEREST

- Eunice Turawa: none known.
- Alfred Musekiwa: none known.
- Anke Rohwer: is supported in part by the Effective Health Care Research Consortium, which is funded by UKaid from the UK Government Department for International Development. This DFID grant is aimed at ensuring the best possible systematic reviews, particularly Cochrane Reviews, are completed on topics relevant to the poor, particularly women, in low- and middle-income countries. DFID does not participate in the selection of topics, in the conduct of the review, or in the interpretation of findings.

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Internal sources

- No sources of support supplied

External sources

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- Department for International Development, UK.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We have added the primary outcome: Time to first bowel movement. This was not one of the pre-specified outcomes in our protocol (Turawa 2015).

INDEX TERMS

Medical Subject Headings (MeSH)

*Postpartum Period; Constipation [*prevention & control]; Dietary Fiber [*therapeutic use]; Laxatives [*therapeutic use]; Perineum [injuries]; Randomized Controlled Trials as Topic

MeSH check words

Adult; Female; Humans