ClinicalEvidence

Constipation, haemorrhoids, and heartburn in pregnancy

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ABSTRACT

INTRODUCTION: Constipation, heartburn, and haemorrhoids are common gastrointestinal complaints during pregnancy. Constipation occurs in 11–38% of pregnant women. Although the exact prevalence of haemorrhoids during pregnancy is unknown, the condition is common, and the prevalence of symptomatic haemorrhoids in pregnant women is higher than in non-pregnant women. The incidence of heartburn in pregnancy is reported to be 17–45%. METHODS AND OUTCOMES: We conducted a systematic review and aimed to answer the following clinical questions: What are the effects of interventions to prevent or treat constipation in pregnancy? What are the effects of interventions to prevent or treat haemorrhoids in pregnancy? What are the effects of interventions to prevent or treat heartburn in pregnancy? We searched: Medline, Embase, The Cochrane Library and other important databases up to July 2007 (BMJ Clinical Evidence reviews are updated periodically, please check our website for the most up-to-date version of this review). We included harms alerts from relevant organisations such as the US Food and Drug Administration (FDA) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). RESULTS: We found five systematic reviews, RCTs or observational studies that met our inclusion criteria. We performed a GRADE evaluation of the quality of evidence for interventions. CONCLUSIONS: In this systematic review we present information relating to the effectiveness and safety of the following interventions: Acid-suppressing drugs, anaesthetic agents (topical), antacids with or without alginates, bulk-forming laxatives, compound corticosteroid and anaesthetic agents (topical), corticosteroid agents (topical), increased fibre intake, increased fluid intake, osmotic laxatives, raising the head of the bed, reducing caffeine intake, intake of fatty foods, and the size and frequency of meals, rutosides, sitz baths, and stimulant laxatives.

QUESTIONS

INTERVENTIONS

PREVENTING OR TREATING CONSTIPATION IN PREGNANCY

Unknown effectiveness

PREVENTING OR TREATING HAEMORRHOIDS IN PREGNANCY

Likely to be beneficial

Unknown effectiveness

PREVENTING OR TREATING HEARTBURN IN PREGNANCY

Likely to be beneficial

Unknown effectiveness

Covered elsewhere in Clinical Evidence

Constipation in adults

Haemorrhoids

Key points

- Constipation, heartburn, and haemorrhoids are common gastrointestinal complaints during pregnancy.
- Constipation occurs in 11–38% of pregnant women.
- Stimulant laxatives may be more effective than bulk laxatives in improving constipation in pregnancy, although adverse effects, such as abdominal pain and diarrhoea, could limit their use.

  Dietary fibre may improve constipation in pregnant women compared with placebo.

  We don't know whether increasing fluid intake improves constipation in pregnancy. However, because of other health benefits, increased fluid intake may be recommended as one of the first measures to relieve constipation.

  We don't have good evidence to show that bulk-forming or osmotic laxatives are of benefit for constipation in pregnancy.
- Although the exact prevalence of haemorrhoids during pregnancy is unknown, the condition is common, and the prevalence of symptomatic haemorrhoids in pregnant women is higher than in non-pregnant women.
- Rutosides improve the symptoms of haemorrhoids compared with placebo. However, further studies are needed to assess their potential adverse effects.

  We don't know whether increased fibre and fluid intake are effective in relieving the symptoms of haemorrhoids in pregnancy, although it seems reasonable to encourage pregnant women to consume a fluid- and fibre-rich diet as a preventive measure.

  We don't know whether stimulant laxatives, bulk-forming laxatives, or osmotic laxatives are effective in relieving symptomatic haemorrhoids in pregnancy, although, if constipation is associated with haemorrhoids, treating constipation with stimulant laxatives may relieve straining, and thereby provide some symptomatic relief.

  We found no good evidence assessing the effects of topical anaesthetics, topical corticosteroids, or compound topical corticosteroids plus anaesthetics to treat symptomatic haemorrhoids in pregnancy. However, despite this, women who have painful complicated haemorrhoids may be offered topical anaesthetic agents unless contraindicated.
- The incidence of heartburn in pregnancy is reported to be 17–45%.
- Antacids may provide effective heartburn relief in pregnancy.

  We don't know whether dietary and lifestyle modifications are of benefit to prevent or treat heartburn in pregnancy. However, there is consensus that lifestyle and dietary modifications, including avoiding fatty foods and caffeine, should remain first-line treatment for heartburn in pregnant women.

  We also don't know whether acid-suppressing drugs such as ranitidine are of benefit to treat heartburn in pregnancy.

DEFINITION

Constipation: Some women will have experienced chronic constipation prior to becoming pregnant, and in others constipation develops for the first time during pregnancy. [1] For a full definition of constipation, see review on constipation in adults. The diagnosis of constipation is mainly clinical, based on a history of decreased frequency of defecation, as well as on the characteristics of the faeces. An extensive evaluation is usually unnecessary for women who present with chronic constipation, or if constipation develops for the first time during pregnancy. [2] **Heartburn:** Heartburn is defined as a sensation of "burning" in the upper part of the digestive tract, including the throat. [3] [4] It can be associated with oesophagitis. [1] One study reported the results of endoscopy on 73 pregnant women with heartburn, and found endoscopic and histological evidence of oesophagitis in most women. [5] As complications associated with heartburn during pregnancy are rare (e.g. erosive oesophagitis), upper endoscopy and other diagnostic tests are infrequently needed. [4] [6] Therefore, the diagnosis of heartburn is mainly clinical, based on the history. **Haemorrhoids:** Haemorrhoids (piles) are swollen veins at or near the anus, which are usually asymptomatic. [7] [8] Haemorrhoids can become symptomatic if they prolapse (the forward or downward displacement of a part of the rectal mucosae through the anus) or because of other complications such as thrombosis. Associated anal fissures (a break or slit in the anal mucosa) can also lead to symptoms. [9] Haemorrhoids can be classified by severity: [10] first-degree haemorrhoids bleed but do not prolapse; second-degree haemorrhoids prolapse on straining and reduce spontaneously; third-degree haemorrhoids prolapse on straining and require manual reduction; and fourth-degree haemorrhoids are prolapsed and incarcerated. Diagnosis of haemorrhoids is based on history and examination. Symptoms include bleeding, mucosal or faecal soiling, itching, and occasionally pain. [7] [10] Fourth-degree haemorrhoids may become "strangulated" and present with acute severe pain. Progressive venous engorgement and incarceration of the acutely inflamed haemorrhoid leads to thrombosis and infarction. The diagnosis of haemorrhoids is confirmed by rectal examination, and inspection of the perianal area for skin tags, fissures, fistulae, polyps, or tumours. Prolapsing haemorrhoids may appear at the anal verge on straining. It is important to exclude more serious causes of rectal bleeding. Assessment should include anoscopy to view the haemorrhoidal cushions. [11] Haemorrhoidal size, and severity of inflammation and bleeding should be assessed. [10]

INCIDENCE/ PREVALENCE

Constipation: Constipation is common in pregnant women, and can develop during pregnancy or increase in severity during pregnancy. [12] The prevalence of constipation in pregnancy is reported to be 11–38%. [13] Parity or previous caesarean section have been associated with constipation. [14] [15] [16] **Heartburn:** Heartburn is one of the most common gastrointestinal symptoms in pregnant women, with an incidence in pregnancy of 17–45%. [17] [18] [19] In some studies, the prevalence of heartburn has been found to increase from 22% in the first trimester to 39% in the second trimester to 60–72% in the third trimester. [1] [20] However, one prospective cohort study found that, in most pregnant women, heartburn, acid regurgitation, or both began in the first trimester and disappeared during the second trimester; [18] and another cohort study also found that gastrointestinal symptoms, such as heartburn and nausea, were more common in the first trimester. [17] The study also found that primigravidae reported more gastrointestinal symptoms than multiparae. [17] **Haemorrhoids:** Although the exact prevalence of haemorrhoids during pregnancy is unknown, the condition is common in pregnancy, and the prevalence of symptomatic haemorrhoids is higher in pregnant than in non-pregnant women. [21] In a population of pregnant women in Serbia and Montenegro, haemorrhoids were present in 85% of women during the second and third pregnancy. [22] Haemorrhoids are also a frequent complaint among women who have recently given birth, [16] [23] and they become more common with increased age and parity. [24] [25]

AETIOLOGY/ RISK FACTORS

Constipation: Constipation in pregnancy is probably caused by rising progesterone levels. [26] [27] [28] Low fluid and fibre intake may also be contributing factors. There is some evidence that pregnant women consume less fibre than is currently recommended for the non-pregnant population. [29] [30] Low fluid intake has been linked to constipation in pregnancy, particularly in the third trimester. [30] Some medications taken during pregnancy, such as iron salts and magnesium sulphate, have been also been linked to constipation. [31] [32] [33] Hypothyroidism may also be a rare cause of constipation during pregnancy. [27] [34] **Heartburn:** The cause of heartburn during pregnancy is multifactorial. [19] Increased amounts of progesterone or its metabolites cause relaxation of smooth muscle, which results in a reduction in gastric tone and motility, and a decrease in lower oesophageal sphincter pressure. [20] [35] [36] It has also been found that, during pregnancy, the lower oesophageal sphincter is displaced into the thoracic cavity (an area of negative pressure), [35] which allows food and gastric acid to pass from the stomach into the oesophagus, leading to oesophageal inflammation and a sensation of "burning". Pressure of the growing uterus on gastric contents as the pregnancy progresses may worsen heartburn, [3] [37] although some authors believe that mechanical factors have a smaller role. [4] [6] [19] [38] Heartburn may also be caused by medications taken during pregnancy, such as antiemetics. [39] **Haemorrhoids:** Haemorrhoids result from impaired venous return in prolapsed anal cushions, [10] with dilation of the venous plexus and venous stasis. Inflammation occurs with erosion of the anal cushion's epithelium, resulting in bleeding. Constipation with prolonged straining at stool, or raised intra-abdominal pressure as occurs in pregnancy, may result in symptomatic haemorrhoids. [11] During pregnancy, delivery, and the puerperium, sphincteral muscles and pelvic floor structures could be modified in tone and position, leading to an alteration of the normal functioning of the haemorrhoidal cushion, which may predispose to symptoms. [7] [40]

PROGNOSIS

Constipation: Constipation, if mild, is often self-treated with home remedies or non-prescription preparations. Primary-care providers usually are confident managing constipation in pregnancy, unless severe, refractory to conventional management, or if additional diagnostic studies are required. Therefore referral to a gastroenterologist is seldom necessary. [41] **Heartburn:** Most cases of heartburn improve with lifestyle modifications and dietary changes, [4] [19] but in some cases severity may increase throughout the course of pregnancy. [5] [20] **Haemorrhoids:** In women with haemorrhoids, symptoms are usually mild and transient and include pain and intermittent bleeding from the anus. Depending on the degree of pain, quality of life can be affected, varying from mild discomfort to difficulty in dealing with the activities of everyday life. Treatment during pregnancy is mainly directed to the relief of symptoms, especially pain control. For many women, symptoms will resolve spontaneously soon after birth. [7]

AIMS OF INTERVENTION

To prevent constipation, haemorrhoids, and heartburn in pregnancy; to relieve or reduce the severity of symptoms; to minimise and avoid adverse effects of treatment on the mother and fetus (including teratogenicity).

OUTCOMES

Constipation: Prevalence of constipation; frequency of bowel movements; straining at defecation; hard, lumpy stools; sensation of incomplete evacuation/tenesmus; quality of life (visual analogue scales, linear analogue scales, pain expectation scores [PES], numeric rating scales); adverse effects of treatment on mother; adverse effects of treatment on fetus (including teratogenicity). **Heartburn:** Prevalence of heartburn, symptom diaries, number of antacids used, adverse effects of treatment on mother, adverse effects of treatment on fetus (including teratogenicity). **Haemorrhoids:** Prevalence of haemorrhoids, bleeding, prolapse, pain, thrombosis, soilage, and pruritus; quality

of life (visual analogue scales, linear analogue scales, PES, numeric rating scales); adverse effects of treatment on mother; adverse effects of treatment on fetus (including teratogenicity).

METHODS

BMJ Clinical Evidence search and appraisal July 2007. The following databases were used to identify studies for this review: Medline 1966 to July 2007, Embase 1980 to July 2007, and The Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Clinical Trials 2007, Issue 2. Additional searches were carried out using these websites: NHS Centre for Reviews and Dissemination (CRD) — for Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment (HTA), Turning Research into Practice (TRIP), and NICE. Abstracts of the studies retrieved from the initial search were assessed by an information specialist. Selected studies were then sent to the author for additional assessment, using predetermined criteria to identify relevant studies. Study-design criteria for inclusion in this review were: published systematic reviews and RCTs in any language, at least single blinded, and containing more than 20 individuals of whom more than 80% were followed up. There was no minimum length of follow-up required to include studies. We excluded all RCTs described as 'open', 'open label', or not blinded unless blinding was impossible. We also searched for prospective cohort studies on: increased fibre intake and increased fluid intake for preventing or treating constipation in pregnancy; increased fibre intake and increased fluid intake for preventing or treating haemorrhoids in pregnancy; and raising the head of the bed, reducing caffeine intake, and reducing the size and frequency of meals and fatty food intake for the prevention and treatment of heartburn in pregnancy. We also searched for systematic reviews, RCTs, and cohort and case-control studies assessing adverse effects of rutosides in pregnancy. In addition, we use a regular surveillance protocol to capture harms alerts from organisations such as the FDA and the UK Medicines and Healthcare products Regulatory Agency (MHRA), which are added to the review as required. We have performed a GRADE evaluation of the quality of evidence for interventions included in this review (see table, p 15).

QUESTION What are the effects of interventions to prevent or treat constipation in pregnancy?

OPTION BULK-FORMING LAXATIVES FOR CONSTIPATION IN PREGNANT WOMEN New

Symptom relief

Compared with stimulant laxatives Bulk-forming laxatives may be less effective at decreasing the number of women with unresolved constipation (low-quality evidence).

Note

We found no direct information about whether bulk-forming laxatives are better than no active treatment. Although both stimulant and bulk-forming laxatives have been associated with high absolute rates of unacceptable adverse effects, stimulant laxatives cause more adverse effects, such as abdominal pain and diarrhoea, compared with bulk-forming laxatives.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits:

Bulk-forming laxatives versus placebo:

We found one systematic review (search date 2001), which identified no RCTs comparing bulk-forming laxatives versus placebo for the treatment of constipation in pregnancy. [13] We found no subsequent RCTs.

Bulk-forming laxatives versus stimulant laxatives:

See benefits of stimulant laxatives, p 6 .

Harms:

Bulk-forming laxatives versus placebo:

We found no RCTs.

Bulk-forming laxatives versus stimulant laxatives:

See harms of stimulant laxatives, p 6 .

Comment:

Clinical guide:

There is limited evidence of benefit for stimulant laxatives compared with bulk-forming laxatives, and high absolute rates of unacceptable adverse effects with both stimulant and bulk-forming laxatives. However, stimulant laxatives cause more adverse effects, such as abdominal pain and diarrhoea. Therefore, it may be preferable to use bulk-forming laxatives in pregnant women who do not tolerate stimulant laxatives.

OPTION INCREASED FIBRE INTAKE FOR CONSTIPATION IN PREGNANT WOMEN New

Symptom relief
Compared with no treatment Additional dietary fibre in the form of corn-based biscuits or wheat bran may be more effective at increasing bowel frequency at 2 weeks in pregnant women who are constipated (moderate-quality evidence).

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits:

Increased fibre intake versus placebo:
We found one systematic review (search date 2001), which identified no RCTs of sufficient quality. [13] We found no subsequent RCTs or cohort studies.

Increased fibre intake versus no treatment:
We found one systematic review (search date 2001, 1 RCT), which compared additional dietary fibre versus no additional fibre for 2 weeks in pregnant women with self-reported constipation (using any definition). [13] The RCT identified by the review (40 women in the third trimester of pregnancy) found that adding fibre supplements (in the form of corn-based biscuits or wheat bran) significantly increased bowel movement frequency over 2 weeks compared with no fibre supplements (proportion of women with no increased frequency of defecation: 9/27 [33%] with additional dietary fibre *v* 10/13 [77%] with no additional fibre; OR 0.15, 95% CI 0.03 to 0.68; P = 0.01). [13] The RCT identified by the review had two intervention arms and one control arm. Women in the intervention arms were given either 10 g dietary fibre supplement in biscuit form or 10 g dietary fibre supplement as wheat bran. The control group was not given placebo supplementation. In the review, results from both intervention arms were combined and compared with the control group. We found no subsequent RCTs or cohort studies.

Harms:

Increased fibre intake versus placebo:
We found no RCTs or cohort studies.

Increased fibre intake versus no treatment:
The review gave no information on the adverse effects of increased fibre intake. [13] We found no additional RCTs or cohort studies.

Comment:

Clinical guide:
It seems reasonable to recommend an increase in the intake of fibre during pregnancy to women with known dietary fibre deficiency. [42] Fibre should be given in the form of foods such as wheat, vegetables, and brown bread. However, caution should be exercised about the amount of dietary fibre intake, because some studies have shown that high intakes of non-starch polysaccharide may result in calcium, iron, or zinc deficiencies during pregnancy — although these results have been controversial. [42]

OPTION INCREASED FLUID INTAKE FOR CONSTIPATION IN PREGNANT WOMEN New

We found no direct information about increased fluid intake for the treatment of constipation in pregnancy. Increasing fluid intake should be recommended as one of the first measures to relieve constipation in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits:
We found one systematic review (search date 2001), which identified no RCTs of increased fluid intake for the treatment of constipation in pregnancy. [13] We found no subsequent RCTs or cohort studies.

Harms:
We found no RCTs or cohort studies.

Comment:

Clinical guide:
In spite of the lack of evidence, increased fluid intake should be recommended as one of the first measures to relieve constipation in pregnancy. Increasing fluid intake is not expensive, is readily available, and has several other beneficial effects during pregnancy.

OPTION OSMOTIC LAXATIVES FOR CONSTIPATION IN PREGNANT WOMEN New

We found no direct information about osmotic laxatives for the treatment of constipation in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits:

Osmotic laxatives versus placebo:
We found one systematic review (search date 2001), which identified no RCTs of osmotic laxatives for the treatment of constipation in pregnancy. [13] We found no subsequent RCTs.

Harms:

Osmotic laxatives versus placebo:
We found no RCTs.

Comment:

Clinical guide:
A panel of experts has suggested that polyethylene glycol (PEG)-based osmotic laxatives plus electrolytes (PEG+E) may be the ideal laxative for use in pregnancy because absorption is minimal, and because they found no evidence of teratogenicity in animal studies. However, there are insufficient data about the potential effects of PEG+E on the fetus. [1] There is also insufficient evidence about the effects of PEG+E on constipation during pregnancy, and its use cannot therefore be recommended.

OPTION STIMULANT LAXATIVES FOR CONSTIPATION IN PREGNANT WOMEN New

Symptom relief
Compared with bulk-forming laxatives Stimulant laxatives may be more effective at reducing the number of women with unresolved constipation (low-quality evidence).

Note
We found no direct information about whether stimulant laxatives are better than no active treatment for the treatment of constipation in pregnancy. Although both stimulant and bulk-forming laxatives have been associated with high absolute rates of unacceptable adverse effects, stimulant laxatives cause more adverse effects, such as abdominal pain and diarrhoea, compared with bulk-forming laxatives.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits:

Stimulant laxatives versus placebo:
We found one systematic review (search date 2001), which identified no RCTs comparing stimulant laxatives versus placebo for the treatment of constipation in pregnancy. [13] We found no subsequent RCTs.

Stimulant laxatives versus bulk-forming laxatives:
We found one systematic review (search date 2001, 1 RCT, 175 women [data reported for only 140 women]), which compared stimulant laxatives versus bulk-forming laxatives in pregnant women with self-reported constipation (using any definition). [13] The duration of treatment was not reported. The review found that stimulant laxatives significantly decreased the number of women with unresolved constipation compared with bulk-forming laxatives (16/70 [23%] with stimulant laxatives *v* 35/70 [50%] with bulk-forming laxatives; OR 0.30, 95% CI 0.14 to 0.61; P = 0.001). The RCT identified by the review had four intervention arms: two arms assessed the effects of stimulant laxatives (senna 14 mg/day or dioctyl sodium succinate 120 mg plus dihydroxyanthroquinone 100 mg once daily), and two arms assessed the effects of bulk-forming laxatives (60% sterculia plus 8% frangula [10 mL once daily] or 60% sterculia [10 mL once daily]). The review combined the results from the two stimulant-laxative arms and the two bulk-forming-laxative arms to perform the meta-analysis. The RCT was reported to be of moderate quality as the method of randomisation was unclear, although researchers were noted to be blinded to the intervention. Results were reported for only 140 of 175 women, with no reasons given for loss to follow-up. We found no additional or subsequent RCTs. [13]

Harms:

Stimulant laxatives versus placebo:
We found no RCTs.

Stimulant laxatives versus bulk-forming laxatives:
The review found that stimulant laxatives significantly increased the number of women with adverse effects such as abdominal pain and diarrhoea compared with bulk-forming laxatives (total number of adverse effects: 56/210 [27%] with stimulant laxatives *v* 32/210 [15%] with bulk-forming laxatives; OR 2.08, 95% CI 1.27 to 3.41, P = 0.004; abdominal pain: 31/70 [44%] with stimulant laxatives *v* 15/70 [21%] with bulk-forming laxatives; OR 2.91, 95% CI 1.39 to 6.11; P = 0.005; diarrhoea: 21/70 [30%] with stimulant laxatives *v* 9/70 [13%] with bulk-forming laxatives; OR 2.90, 95% CI 1.22 to 6.91; P = 0.02). [13] However, there was no significant difference between groups in the proportion of women with nausea (4/70 [6%] with stimulant laxatives *v* 8/70 [11%] with bulk-forming laxatives;

OR 0.47, 95% CI 0.13 to 1.64, P = 0.2). There was also no significant difference between stimulant and bulk-forming laxatives in the proportion of women who reported that adverse effects of treatment were "unacceptable", which was high for both interventions (33/70 [47%] with stimulant laxatives *v* 35/70 [50%] with bulk-forming laxatives; OR 0.89, 95% CI 0.46 to 1.73; P = 0.7). The criteria for stating that adverse effects of treatment were "unacceptable" were not reported by the review. [13]

Comment: **Clinical guide:**
There is limited evidence of benefit for stimulant laxatives compared with bulk-forming laxatives. However, the adverse effects profile of stimulant laxatives (abdominal pain and diarrhoea) could limit their use in clinical practice, and there are high absolute rates of unacceptable adverse effects both with stimulant laxatives and bulk-forming laxatives.

QUESTION What are the effects of interventions to prevent or treat haemorrhoids in pregnancy?

OPTION RUTOSIDES FOR HAEMORRHOIDS IN PREGNANT WOMEN New

Symptom relief
Compared with placebo Rutosides are more effective at reducing the number of women with worsening or continuing symptoms of haemorrhoids at 4 weeks, but its effects on the fetus are not known (high-quality evidence).

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: **Rutosides versus placebo:**
We found one systematic review with meta-analysis (search date 2004, 2 RCTs, 150 pregnant women at 12–34 weeks' gestation with symptomatic grade 1 to grade 3 haemorrhoids), which compared oral rutosides twice daily versus placebo for 4 weeks. [7] The review found that rutosides significantly reduced the number of women with worsening or continuing symptoms at 4 weeks compared with placebo (no response to treatment: 2 RCTs: 3/75 [4%] with rutosides *v* 50/75 [67%] with placebo; RR 0.07, 95% CI 0.03 to 0.20, P less than 0.0001). [7] The method of randomisation in the RCTs was not described. We found no additional or subsequent RCTs.

Harms: **Rutosides versus placebo:**
The RCTs identified by the review were too small to detect a clinically important difference in adverse effects between groups. [7] The review found no significant difference between rutosides and placebo in maternal adverse effects, which were reported as mild gastrointestinal discomfort, nausea, and dizziness (4/75 [5%] with rutosides *v* 0/75 [0%] with placebo; RR 4.99, 95% CI 0.60 to 41.49, P = 0.1). There was also no significant difference between rutosides and placebo in the rates of fetal death, preterm delivery, or congenital malformations (fetal and perinatal death: 0/75 [0%] with rutosides *v* 1/75 [2%] with placebo; RR 0.34, 95% CI 0.01 to 8.15, P = 0.5; preterm delivery: 1/48 [2.0%] with rutosides *v* 1/49 [2.3%] with placebo; RR 1.02, 95% CI 0.07 to 15.86, P = 1; congenital malformations: 1/75 [2%] with rutosides *v* 0/75 [0%] with placebo; RR 3.06, 95% CI 0.13 to 73.34; P = 0.5). [7] We also searched for systematic reviews, RCTs, cohort studies, and case-control studies assessing adverse effects of rutosides in pregnancy. We found one systematic review (search date 2006), which assessed the effects of rutosides for the treatment of varicose veins and leg oedema in pregnancy. [43] The review identified one small RCT (69 women, at least 28 weeks' gestation), which compared rutosides versus placebo for 8 weeks. The RCT found no significant difference in the number of women with adverse effects between rutosides and placebo (2/37 [5%] with rutosides *v* 2/32 [6%] with placebo; RR 0.86, 95% CI 0.13 to 5.79, P = 0.9). The review did not report details of the specific adverse effects. The authors of the review concluded that there were insufficient data to assess the safety of rutosides in pregnancy. [43] We found another systematic review that assessed the effects of rutosides in people with venous insufficiency (search date 2005); however, the review did not include pregnant women. [44] The review (23 RCTs, 2537 people) did not report the number of people with adverse effects compared with those taking placebo, but reported the number of overall adverse events (210 events with rutosides *v* 165 events with placebo; P value not reported). The review found that the most common adverse effects were gastrointestinal (constipation, dry mouth, epigastric discomfort, vomiting), followed by headache and tiredness (gastrointestinal: 90 events with rutosides *v* 62 with placebo; headache: 23 with rutosides *v* 21 with placebo; tiredness: 17 with rutosides *v* 9 with placebo; P values not reported). [44] We found no cohort studies or case-control studies reporting adverse effects of rutosides in pregnancy. [44]

Comment: **Clinical guide:**
Rutosides seem to relieve the symptoms of haemorrhoids, but safety during pregnancy should be assessed by large, high-quality RCTs. Therefore, rutosides should not be used during the first trimester (14 weeks of gestation), when teratogenesis is more likely.

OPTION ANAESTHETICS (TOPICAL) FOR HAEMORRHOIDS IN PREGNANT WOMEN New

We found no direct information about topical anaesthetic agents to treat symptomatic or complicated haemorrhoids in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found one systematic review (search date 2004), which identified no RCTs of topical anaesthetic agents to treat symptomatic or complicated haemorrhoids in pregnancy. [7] We found no subsequent RCTs.

Harms: We found no RCTs.

Comment: **Clinical guide:**
Pregnant women who have pain because of the complications of haemorrhoids should be offered topical anaesthetic agents unless there are contraindications, despite the absence of RCT evidence.

OPTION BULK-FORMING LAXATIVES FOR HAEMORRHOIDS IN PREGNANT WOMEN New

We found no direct information about bulk-forming laxatives to treat symptomatic or complicated haemorrhoids in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found one systematic review (search date 2004), which identified no RCTs of bulk-forming laxatives to treat symptomatic or complicated haemorrhoids in pregnancy. [7] We found no subsequent RCTs.

Harms: We found no RCTs.

Comment: None.

OPTION COMPOUND CORTICOSTEROIDS PLUS ANAESTHETICS (TOPICAL) FOR HAEMORRHOIDS IN PREGNANT WOMEN New

We found no direct information about compound topical corticosteroid and anaesthetic agents to treat symptomatic or complicated haemorrhoids in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found one systematic review (search date 2004), which identified no RCTs of sufficient quality of compound topical corticosteroid and anaesthetic agents to treat symptomatic or complicated haemorrhoids in pregnancy. [7] We found no subsequent RCTs.

Harms: We found no RCTs.

Comment: None.

OPTION CORTICOSTEROIDS (TOPICAL) FOR HAEMORRHOIDS IN PREGNANT WOMEN New

We found no direct information about topical corticosteroid agents to treat symptomatic or complicated haemorrhoids in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found one systematic review (search date 2004), which identified no RCTs of topical corticosteroid agents to treat symptomatic or complicated haemorrhoids in pregnancy. [7] We found no subsequent RCTs.

Harms: We found no RCTs.

Comment: None.

OPTION INCREASED FIBRE INTAKE FOR HAEMORRHOIDS IN PREGNANT WOMEN New

We found no direct information about increased fibre intake to prevent or treat haemorrhoids in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found one systematic review (search date 2004), which identified no RCTs of increased fibre intake to treat symptomatic or complicated haemorrhoids in pregnancy. [7] We found no subsequent RCTs or cohort studies.

Harms: We found no RCTs or cohort studies.

Comment: **Clinical guide:**
The association of constipation with a low-fibre diet and low fluid intake has been well established in epidemiological studies. [10] It seems reasonable, therefore, to recommend a diet high in fibre and fluids to prevent haemorrhoids in pregnant women, However, the benefit of increased fibre for the relief of symptoms associated with haemorrhoids has not been demonstrated in RCTs.

OPTION INCREASED FLUID INTAKE FOR HAEMORRHOIDS IN PREGNANT WOMEN New

We found no direct information about increased fluid intake to treat symptomatic or complicated haemorrhoids in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found one systematic review (search date 2004), which identified no RCTs of increased fluid intake to treat symptomatic or complicated haemorrhoids in pregnancy. [7] We found no subsequent RCTs or cohort studies.

Harms: We found no RCTs or cohort studies.

Comment: **Clinical guide:**
The association of constipation with a low-fibre diet and low fluid intake has been well established in epidemiological studies. [10] It seems reasonable, therefore, to recommend a diet high in fibre and fluids to prevent haemorrhoids in pregnant women. However, the benefit of increased fluid intake for the relief of symptoms associated with haemorrhoids has not been demonstrated in RCTs.

OPTION OSMOTIC LAXATIVES FOR HAEMORRHOIDS IN PREGNANT WOMEN New

We found no direct information about osmotic laxatives to treat symptomatic or complicated haemorrhoids in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found one systematic review (search date 2004), which identified no RCTs of osmotic laxatives to treat symptomatic or complicated haemorrhoids in pregnancy. [7] We found no additional or subsequent RCTs.

Harms: We found no RCTs.

Comment: None.

OPTION SITZ BATHS FOR HAEMORRHOIDS IN PREGNANT WOMEN New

We found no direct information about Sitz baths to treat symptomatic or complicated haemorrhoids in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found one systematic review (search date 2004), which identified no RCTs of Sitz baths to treat symptomatic or complicated haemorrhoids in pregnancy. [7] We found no additional or subsequent RCTs.

Harms: We found no RCTs.

Comment: **Clinical guide:**
Research on the effect of Sitz baths on haemorrhoids should be conducted only in the context of RCTs, because of the potential risk of cervical and vaginal infections caused by contamination from the perianal region.

OPTION STIMULANT LAXATIVES FOR HAEMORRHOIDS IN PREGNANT WOMEN New

We found no direct information about stimulant laxatives to treat symptomatic or complicated haemorrhoids in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found one systematic review (search date 2004), which identified no RCTs of stimulant laxatives to treat symptomatic or complicated haemorrhoids in pregnancy. [7] We found no subsequent RCTs.

Harms: We found no RCTs.

Comment: None.

QUESTION What are the effects of interventions to prevent or treat heartburn in pregnancy?

OPTION ANTACIDS WITH OR WITHOUT ALGINATES FOR HEARTBURN IN PREGNANT WOMEN New

Symptom relief
Compared with placebo Antacids with or without oxethazaine are more effective at relieving heartburn, but are no more effective at relieving nausea or regurgitation (moderate-quality evidence).

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits:

Antacids versus placebo:
We found no systematic review. We found one RCT (50 women with heartburn), which compared three interventions for 7 days: magnesium hydroxide plus aluminium hydroxide (antacid) plus oxethazaine; magnesium hydroxide plus aluminium hydroxide without oxethazaine; and placebo. [45] The RCT found that antacid with or without oxethazaine both produced similar relief from heartburn, and increased heartburn relief compared with placebo, although the improved relief was of borderline significance (mean heartburn relief score [scale ranging from 1 = mild symptoms to 5 = severe symptoms]: 3.9 with antacid plus oxethazaine *v* 3.3 with antacid alone *v* 2.9 with placebo; P = 0.05 for either active intervention *v* placebo). The RCT found that other antacids were used significantly more frequently in the placebo group compared with both intervention groups (use of other antacids [% of days per participant]: 13% with antacid plus oxethazaine *v* 7% with antacid alone *v* 29% with placebo; P = 0.0003 for either active intervention *v* placebo). The RCT found no significant difference in the relief of nausea and regurgitation over 7 days between antacid with or without oxethazaine and placebo (mean nausea relief score: 3.3 with antacid plus oxethazaine *v* 3.3 with antacid alone *v* 3.4 with placebo; P = 1 for either active intervention *v* placebo; mean regurgitation relief score: 3.5 with antacid plus oxethazaine *v* 3.1 with antacid alone *v* 3.0 with placebo; P = 0.6 for either active intervention *v* placebo). There was no significant difference in the amount of antacid preparations used compared with each other or placebo (28 mL/day with antacid plus oxethazaine *v* 39 mL/day with antacid alone *v* 18 mL/day with placebo; P = 0.2 for either active intervention *v* placebo). [45]

Antacids versus antacids plus ranitidine:
We found no RCTs.

Harms:

Antacids versus placebo:
The RCT comparing antacids versus placebo gave no information on adverse effects. [45]

Antacids versus antacids plus ranitidine:
We found no RCTs.

Comment: **Clinical guide:**
A consensus document has recommended that antacids should be used "on demand" as the first-choice drug treatment for heartburn in pregnancy, because they provide effective and rapid symptom relief. [1] The preferred choice should be calcium-based antacids, because adverse effects are rare, and calcium-based antacids have been shown to be beneficial for the prevention of hypertension and pre-eclampsia. [46] RCTs have shown that magnesium sulphate reduces the risk of eclampsia by more than 50%, and reduces the risk of maternal death. [47] A panel of experts has agreed that, in pregnant women, H_2 receptor antagonists, such as ranitidine, can be combined with antacids when symptoms persist with antacids alone. [1]

OPTION ACID-SUPPRESSING DRUGS FOR HEARTBURN IN PREGNANT WOMEN New

We found no direct information about whether acid-suppressing drugs are better than no active treatment to treat heartburn in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: **Acid-suppressing drugs versus placebo:**
We found no systematic review or RCTs comparing acid-suppressing drugs versus placebo for heartburn in pregnancy.

Acid-suppressing drugs plus antacids versus antacids:
See benefits of antacids with or without alginates, p 10 .

Harms: **Acid-suppressing drugs versus placebo:**
We found no RCTs.

Acid-suppressing drugs plus antacids versus antacids:
See harms of antacids with or without alginates, p 10 .

Comment: **Clinical guide:**
A panel of experts has agreed that, in pregnant women, H_2 receptor antagonists can be combined with antacids when symptoms persist with antacids alone. [1]

OPTION RAISING THE HEAD OF THE BED FOR HEARTBURN IN PREGNANT WOMEN New

We found no direct information about raising the head of the bed to prevent or treat heartburn in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found no systematic review, RCTs, or cohort studies of raising the head of the bed to prevent or treat heartburn in pregnancy.

Harms: We found no RCTs or cohort studies.

Comment: **Clinical guide:**
A consensus document has recommended that lifestyle and dietary modifications should remain first-line treatment for heartburn in pregnancy. [1] The measures include reducing and avoiding intake of reflux-inducing foods (such as greasy and spicy foods, tomatoes, highly acidic citrus products, and carbonated drinks), and substances such as caffeine. NSAIDs should also be avoided. The document also recommends other lifestyle changes to reduce the risk of reflux, such as avoiding lying down within 3 hours after eating. However, if heartburn is severe enough to warrant this action, medication should begin after consultation with a healthcare professional. [1]

OPTION REDUCING CAFFEINE INTAKE FOR HEARTBURN IN PREGNANT WOMEN New

We found no direct information about reducing caffeine intake to prevent or treat heartburn in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see table, p 15 .

Benefits: We found no systematic review, RCTs, or cohort studies of reducing caffeine intake to prevent or treat heartburn in pregnancy.

Harms: We found no RCTs or cohort studies.

Comment: **Clinical guide:**
A consensus document has recommended that lifestyle and dietary modifications should remain first-line treatment for heartburn in pregnancy. [1] The measures include reducing and avoiding intake of reflux-inducing foods (such as greasy and spicy foods, tomatoes, highly acidic citrus products, and carbonated drinks), and substances such as caffeine. NSAIDs should also be avoided. The document also recommends other lifestyle changes to reduce the risk of reflux, such as avoiding lying down within 3 hours after eating. However, if heartburn is severe enough to warrant this action, medication should begin after consultation with a healthcare professional. [1]

OPTION REDUCING THE INTAKE OF FATTY FOODS FOR HEARTBURN IN PREGNANT WOMEN

New

We found no direct information about reducing fatty-food intake to prevent or treat heartburn in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see **table, p 15** .

Benefits: We found no systematic review, RCTs, or cohort studies of reducing fatty-food intake to prevent or treat heartburn in pregnancy.

Harms: We found no RCTs or cohort studies.

Comment: **Clinical guide:**
A consensus document has recommended that lifestyle and dietary modifications should remain first-line treatment for heartburn in pregnancy. [1] The measures include reducing and avoiding intake of reflux-inducing foods (such as greasy and spicy foods, tomatoes, highly acidic citrus products, and carbonated drinks). NSAIDs should also be avoided. The document also recommends other lifestyle changes to reduce the risk of reflux, such as avoiding lying down within 3 hours after eating. However, if heartburn is severe enough to warrant this action, medication should begin after consultation with a healthcare professional. [1]

OPTION REDUCING THE SIZE AND FREQUENCY OF MEALS FOR HEARTBURN IN PREGNANT WOMEN

New

We found no direct information about reducing meal size and frequency to prevent or treat heartburn in pregnancy.

For GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy, see **table, p 15** .

Benefits: We found no systematic review, RCTs, or cohort studies of reducing meal size and frequency to prevent or treat heartburn in pregnancy.

Harms: We found no RCTs or cohort studies.

Comment: **Clinical guide:**
A consensus document has recommended that lifestyle and dietary modifications should remain first-line treatment for heartburn in pregnancy. [1] The measures include reducing and avoiding intake of reflux-inducing foods (such as greasy and spicy foods, tomatoes, highly acidic citrus products, and carbonated drinks), and substances such as caffeine. NSAIDs should also be avoided. The document also recommends other lifestyle changes to reduce the risk of reflux, such as avoiding lying down within 3 hours after eating. However, if heartburn is severe enough to warrant this action, medication should begin after consultation with a healthcare professional. [1]

GLOSSARY

Grade 1 to grade 3 haemorrhoids: Grade 1 haemorrhoids are bleeding haemorrhoids that do not protrude from the anus. Grade 2 haemorrhoids are haemorrhoids that protrude on defecation, but that are reduced spontaneously. Grade 3 haemorrhoids protrude on defecation, but can be replaced digitally.
Sitz bath A warm water bath taken in the sitting position. The water covers only the hips and buttocks.
High-quality evidence Further research is very unlikely to change our confidence in the estimate of effect.
Low-quality evidence Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Moderate-quality evidence Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

SUBSTANTIVE CHANGES

Bulk-forming laxatives New option for which one RCT identified by a systematic review provided insufficient evidence to assess the effects of bulk-forming laxatives in reducing constipation in pregnant women. [13] Categorised as Unknown effectiveness.

Increased fibre intake New option for which one RCT identified by a systematic review provided insufficient evidence to assess the effects of increased fibre intake in reducing consipation in pregnant women. [13] Categorised as Unknown effectiveness.

Increased fluid intake New option for which we identified no RCT evidence assessing the treatment for constipation in pregnant women. Categorised as Unknown effectiveness.

Osmotic laxatives New option for which we identified no RCT evidence assessing the treatment for constipation in pregnant women. Categorised as Unknown effectiveness.

Stimulant laxatives New option for which one RCT identified by a systematic review provided insufficient evidence to assess the effects of stimulant laxatives in reducing constipation in pregnant women. [13] Categorised as Unknown effectiveness.

Rutosides New option for which we found one systematic review suggesting that rutosides reduced symptoms of haemorrhoids in pregnant women. [7] Categorised as Likely to be beneficial, but there are insufficient data about potential adverse effects.

Anaesthetics (topical) New option for which we identified no RCT evidence assessing the treatment for haemorrhoids in pregnant women. Categorised as Unknown effectiveness.

Bulk-forming laxatives New option for which we identified no RCT evidence assessing the treatment for haemorrhoids in pregnant women. Categorised as Unknown effectiveness.

Compound corticosteroids plus anaesthetics (topical) New option for which we identified no RCT evidence assessing the treatment for haemorrhoids in pregnant women. Categorised as Unknown effectiveness.

Corticosteroids (topical) New option for which we identified no RCT evidence assessing the treatment for haemorrhoids in pregnant women. Categorised as Unknown effectiveness.

Increased fibre intake New option for which we identified no RCT evidence assessing the treatment for haemorrhoids in pregnant women. Categorised as Unknown effectiveness.

Increased fluid intake New option for which we identified no RCT evidence assessing the treatment for haemorrhoids in pregnant women. Categorised as Unknown effectiveness.

Osmotic laxatives New option for which we identified no RCT evidence assessing the treatment for haemorrhoids in pregnant women. Categorised as Unknown effectiveness.

Sitz baths New option for which we identified no RCT evidence assessing the treatment for haemorrhoids in pregnant women. Categorised as Unknown effectiveness.

Stimulant laxatives New option for which we identified no RCT evidence assessing the treatment for haemorrhoids in pregnant women. Categorised as Unknown effectiveness.

Antacids with or without alginates New option for which one RCT found that antacids with or without oxethazaine were more effective than placebo at relieving heartburn in pregnant women. [45] Categorised as Likely to be beneficial.

Acid-suppressing drugs New option for which we identified no RCT evidence assessing the treatment for heartburn in pregnant women. Categorised as Unknown effectiveness.

Raising the head of the bed New option for which we identified no RCT evidence assessing the treatment for heartburn in pregnant women. Categorised as Unknown effectiveness.

Reducing caffeine intake New option for which we identified no RCT evidence assessing the treatment for heartburn in pregnant women. Categorised as Unknown effectiveness.

Reducing the intake of fatty foods New option for which we identified no RCT evidence assessing the treatment for heartburn in pregnant women. Categorised as Unknown effectiveness.

Reducing the size and frequency of meals New option for which we identified no RCT evidence assessing the treatment for heartburn in pregnant women. Categorised as Unknown effectiveness.

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Disclaimer

TABLE **GRADE evaluation of interventions for constipation, haemorrhoids, and heartburn in pregnancy**

Important outcomes	**Symptom relief, quality of life, adverse effects**								
Number of studies (participants)	**Outcome**	**Comparison**	**Type of evidence**	**Quality**	**Consistency**	**Directness**	**Effect size**	**GRADE**	**Comment**
What are the effects of interventions to prevent or treat constipation in pregnancy?									
1 (40) [13]	Symptom relief	Increased fibre intake *v* no treatment	4	–1	0	–2	+2	Moderate	Quality point deducted for sparse data. Directness points deducted for unspecific definition of constipation and for few comparators. Effect-size point added for odds ratio less than 0.2
1 (140) [13]	Symptom relief	Stimulant laxatives *v* bulk-forming laxatives	4	–3	0	0	+1	Low	Quality points deducted for sparse data, uncertainty about randomisation, and no clear end-point. Effect-size point added for odds ratio less than 0.5
What are the effects of interventions to prevent or treat haemorrhoids in pregnancy?									
2 (150) [7]	Symptom relief	Rutosides *v* placebo	4	–2	0	0	+2	High	Quality points deducted for sparse data, and for not reporting method of randomisation. Effect-size points added for RR less than 0.2
What are the effects of interventions to prevent or treat heartburn in pregnancy?									
1 (50) [45]	Symptom relief	Antacids *v* placebo	4	–1	0	0	0	Moderate	Quality point deducted for sparse data

Type of evidence: 4 = RCT; 2 = Observational; 1 = Non-analytical/expert opinion. Consistency: similarity of results across studies
Directness: generalisability of population or outcomes
Effect size: based on relative risk or odds ratio