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Treatments for breast engorgement during lactation

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Abstract

Background—Breast engorgement is a painful and unpleasant condition affecting large numbers of women in the early postpartum period. During a time when mothers are coping with the demands of a new baby it may be particularly distressing. Breast engorgement may inhibit the development of successful breastfeeding, lead to early breastfeeding cessation, and is associated with more serious illness, including breast infection.

Objectives—To identify the best forms of treatment for women who experience breast engorgement.

Search methods—We identified studies for inclusion through the Cochrane Pregnancy and Childbirth Group's Trials Register (February 2010).

Selection criteria—Randomised and quasi-randomised controlled trials where treatments for breast engorgement were evaluated.

Data collection and analysis—Two review authors assessed eligibility for inclusion and carried out data extraction.

Main results—We included eight studies with 744 women. Trials examined a range of different treatments for breast engorgement: acupuncture (two studies), cabbage leaves (two studies), cold gel packs (one study), pharmacological treatments (two studies) and ultrasound (one study). For several interventions (ultrasound, cabbage leaves, and oxytocin) there was no statistically significant evidence that interventions were associated with a more rapid resolution of symptoms; in these studies women tended to have improvements in pain and other symptoms over time whether or not they received active treatment. There was evidence from one study that, compared with women receiving routine care, women receiving acupuncture had greater improvements in

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symptoms in the days following treatment, although there was no evidence of a difference between groups by six days, and the study did not have sufficient power to detect meaningful differences for other outcomes (such as breast abscess). A study examining protease complex reported findings favouring intervention groups although it is more than 40 years since the study was carried out, and we are not aware that this preparation is used in current practice. A study looking at cold packs suggested that the application of cold does not cause harm, and may be associated with improvements in symptoms, although differences between control and intervention groups at baseline mean that results are difficult to interpret.

Authors' conclusions—Allthough some interventions may be promising, there is not sufficient evidence from trials on any intervention to justify widespread implementation. More research is needed on treatments for this painful and distressing condition.

Medical Subject Headings (MeSH)

Acupuncture Therapy; Brassica; Breast Diseases [etiology; *therapy]; Cryotherapy [methods]; Lactation Disorders [*therapy]; Oxytocin [therapeutic use]; Peptide Hydrolases [therapeutic use]; Phytotherapy [methods]; Randomized Controlled Trials as Topic; Ultrasonic Therapy [methods]

MeSH check words

Female; Humans; Pregnancy

BACKGROUND

The birth of a baby is an important event in any family. It is therefore important that for a mother to have a healthy baby, she gives her baby the best nutrition. Breast milk is the best food for babies as breastfed babies are generally healthier than formula-fed babies (Chopra 2006). In recognition of the importance of breastfeeding, the Baby-Friendly Hospital Initiative was launched by UNICEF/WHO in 1991 (Schubiger 1997). Breastfeeding results in decreased problems such as infections and other medical problems (Campbell 2000; Cunningham 2005). It has also been associated with enhancement of cognitive development, prevention of obesity, hypertension and insulin dependent diabetes mellitus (Leung 2005). It therefore lowers the rate of illness and consequently the rate of hospital admission. Given the strong evidence of the benefits of breastfeeding for women and babies the WHO recommends that, in all parts of the world, babies should be exclusively breastfed for the first six months "to achieve optimal growth, development and health" (WHO 2003, p.8). Other Cochrane reviews examine interventions to promote breastfeeding and to support breastfeeding mothers (Britton 2007; Dyson 2008).

Breast engorgement

Approximately two days after giving birth the woman's breasts fill with milk; this is a normal physiological process, and as part of this process the breasts become heavy and swollen, but under normal circumstances the breasts should not be painful and hard. Breast engorgement occurs if the baby removes less milk from the breast when feeding than the amount that the mother produces. As well as causing breast engorgement, inadequate emptying of breasts can result in problems such as plugged milk ducts, breast infection and

insufficient milk supply (Giugliani 2004). Breast engorgement is the overfilling of breast milk that causes discomfort and pain to the mother whilst non-infectious mastitis is inflammation of the breast due to milk duct blockage (Clarke 2007).

Breast engorgement usually occurs within a week of the birth, but can occur later. Primary engorgement occurs in the first few days after the baby is born, and it occurs when the mother's body is still trying to adjust to the amount of milk that the baby demands. Secondary engorgement occurs later when the mother is not feeding as frequently as she used to, or the baby removes less milk from the breast. Augmentation mammoplasty has also lately been identified as a cause of breast engorgement when women who have had such operations are breastfeeding (Acarturk 2005).

Breast engorgement is associated with hard, painful, throbbing, aching and tender breasts which may result in women needing analgesia, developing mastitis or temporarily or permanently stopping breastfeeding.The distress associated with breast engorgement may mean that women initiating breastfeeding may not persevere beyond the first few days after the birth (Mass 2004).

Correct breastfeeding technique is important to ensure successful breastfeeding. Incorrect technique may contribute to breast engorgement, and in particular it is important for the baby to latch-on to the breast correctly during feeding so that it can suck effectively. In order to do this the baby needs to be correctly positioned, and new mothers may need advice on this (Mass 2004). Breast engorgement may affect the area around the nipple and areola only or the entire breast, and may affect one breast only, or both. Once engorgement occurs, swelling around the nipple may make it even more difficult for the baby to latch-on and feed successfully, and this may make the engorgement worse. This problem may be compounded if concern that the baby is not getting enough milk, or breast pain and swelling, discourage women from continuing breastfeeding. Women may also receive limited advice and support from health professionals; lack of knowledge in managing this condition could be the reason for limited or inappropriate advice (Hillenbrand 2002).

Support to initiate breastfeeding and on an ongoing basis are important because it has been shown that breastfeeding rates decrease with a decrease in breastfeeding support. Lack of support results in problems of establishment of breastfeeding, breast engorgement, sore or cracked nipples; usually due to poor technique (Stamp 2006). De Oliveira et al also demonstrated in their randomised controlled trial that there was no difference between women who were counselled once in hospital and those who were not counselled on breastfeeding. This suggests that ongoing support is crucial if breastfeeding is to be successful (De Oliveira 2006).

Once engorgement occurs gentle massage, frequent feeding, correct positioning and warm compresses to the breast have been advocated to relieve symptoms along with analgesia to relieve pain. In addition, several pharmacological and non-pharmacological methods of treating breastfeeding engorgement have been introduced. It is not known which ones are effective compared to the others. It is important that this topic be reviewed as the review may have positive public health implications.

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OBJECTIVES

To identify the best forms of treatment for women who experience breast engorgement.

METHODS

Criteria for considering studies for this review

Types of studies—Randomised controlled trials and quasi-randomised trials where treatments for breast engorgement were evaluated.

Types of participants—All women receiving any treatment for breast engorgement during breastfeeding.

Types of interventions

1. Non-medical forms of treatment, e.g. compression binders, support bra, fluid limitation, etc.
2. Medical treatments, e.g. ibuprofen.
3. Medical and non-medical forms of treatment combined.
4. Information and advice on breastfeeding, massage, etc.

Types of outcome measures

Primary outcomes

1. Temporary cessation of breastfeeding.
2. Permanent cessation of breastfeeding.
3. Mastitis.

Secondary outcomes

1. Temperature higher than 38 degrees Celsius.
2. Maternal opinion of treatment.
3. Maternal acceptance of treatment.
4. Analgesic requirement.
5. Hospital admission.
6. Mother’s confidence in continuing to breastfeed.
7. Breast abscess.

Search methods for identification of studies

Electronic searches—We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group’s Trials Register (February 2010).

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

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

Details of the search strategies for CENTRAL and MEDLINE, 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.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies—We assessed all the studies identified as a result of the search strategy to decide whether they met the inclusion criteria. We resolved any disagreements through discussion. We included studies that were published only as abstracts provided that there was sufficient information to allow us to assess eligibility and risk of bias.

Data extraction and management—We designed a form to extract data. Both review authors extracted the data using the agreed form. We resolved discrepancies through discussion. We used the Review Manager software (RevMan 2008) to analyse the data.

Assessment of risk of bias in included studies—Both review authors (L Mangesi and T Dowswell) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2009). We resolved any disagreement by discussion and by involving a third assessor.

(1) Sequence generation (checking for possible selection bias): We have 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:

- adequate (any truly random process, e.g. random number table; computer random number generator);
- inadequate (any non random process, e.g. odd or even date of birth; hospital or clinic record number); or

- unclear.

(2) Allocation concealment (checking for possible selection bias): We have described for each included study the method used to conceal the allocation sequence and judged whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

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

(3) Blinding (checking for possible performance bias): We have 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 judged studies at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results. We assessed blinding separately for different outcomes or classes of outcomes. For some interventions (e.g. the use of cabbage leaves to reduce engorgement) it may not be feasible to blind women or clinical staff to group allocation; however, it may still be possible to blind outcome assessors and we have noted where there has been partial blinding.

We assessed the methods as:

- adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for clinical staff;
- adequate, inadequate or unclear for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations): We have 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 state whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusions where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we have re-included missing data in the analyses. We have assessed methods as:

- adequate (low levels of missing data (less than 10%) and missing data balanced across groups);
- inadequate (high levels of missing data (more than 20%) or;
- unclear.

(5) Selective reporting bias: We did not formally assess outcome reporting bias. Without access to study protocols selective reporting bias may be difficult to assess, but we have noted where we suspected any selective reporting bias: for example, where only statistically significant results were reported or where results were not described for a key outcome that we would have expected to have been reported. We were not able to assess publication bias by producing funnel plots as no comparisons included more than one or two studies.

(6) Other sources of bias: We have described for each included study any important concerns we had about other possible sources of bias.

(7) Overall risk of bias: We have made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2009). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We planned to explore the impact of including studies at high risk of bias through undertaking sensitivity analyses - *see* Sensitivity analysis; however, in view of the few studies included in the review, we did not think sensitivity analysis would throw any further light on findings. If, in updates of the review, more studies are added we will carry out sensitivity analysis for primary outcomes.

Where results from studies were reported in abstracts we had planned to include them provided that there was sufficient information to allow us to assess eligibility and risk of bias; if insufficient information was available in abstracts we planned to contact study authors for more information, or failing that, studies would await assessment until publication of the full trial report. In this version of the review we did not identify any studies only reported in abstracts.

Measures of treatment effect—We carried out statistical analysis using Review Manager (RevMan 2008). In this version of the review we have not combined results from trials, but in updates if more data are available, we plan to use fixed-effect meta-analysis for combining data in the absence of moderate or high levels of heterogeneity.

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

Continuous data: For continuous data, we have used the mean difference. In updates, we will use the standardised mean difference to combine results from trials measuring the same outcome, but using different methods.

Unit of analysis issues

Cluster-randomised trials: We had planned to include cluster-randomised trials but we identified none. If in updates of the review we do identify such trials we plan to include them in the analyses along with individually randomised trials, and adjust their standard errors using the methods described in Gates 2005 and Higgins 2009 using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), or from another source. If ICCs from other sources are used, 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. For more information on data analysis of cluster randomised trials we will consult Ukoumune 1999 andRao 1992 and where further assistance is needed, we will consult the Group's statistician. We will also acknowledge heterogeneity in the randomisation unit and perform a separate meta-analysis; therefore we will perform the meta-analysis in two parts as well.

Crossover trials: We did not identify any crossover trials on this topic, and as breast engorgement is a condition that changes over time, such trials are unlikely to be an appropriate study design for examining interventions in this area. However, if such trials are identified in the future and are deemed eligible for inclusion, they will be included in the analyses with parallel group trials, using methods described in the *Handbook* (Higgins 2009).

Other unit of analysis issues: Several of the studies included in the review used breasts rather than women as the unit of analysis. We are aware that a woman's breasts (engorged or not) are unlikely to be independent of each other and such non-independent data require special methods of analysis. In this version of the review, data were not presented in a way that allowed us to include them in the data tables and so we have presented a brief narrative description of results. If usable data become available in the future we will seek statistical help with analysis.

Dealing with missing data—We have noted levels of attrition for each included study. We planned to explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis, but as we have noted above, too few studies were included in the review to make sensitivity analysis meaningful; as more studies are added in updates we will explore this issue.

For all outcomes we have carried out analyses, as far as possible, on an intention-to-treat basis; i.e. we have attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial being the number randomised minus any participants whose outcomes are known to be missing

We have attempted to analyse data on all participants with available data in the group to which they were allocated, regardless of whether or not they received the allocated intervention. If in the original reports participants were not analysed in the group to which they were randomised, and there is sufficient information in the trial report, we attempted to restore them to the correct group.

Assessment of heterogeneity—In this version of the review, as so few trials contributed data and each examined different interventions, we were unable to combine results in meta-analyses. In future updates of the review if more data are added, we plan to assess heterogeneity among trials. We will visually examine the forest plots from meta-analyses to look for any obvious heterogeneity among trials. We will also examine the I^2,

and T^2 statistics and the P value of the Chi^2 test for heterogeneity. If we identify moderate or high levels of heterogeneity among the trials (I^2 exceeding 30%), we will note this in the text and advise caution in the interpretation of these results.

Subgroup analysis and investigation of heterogeneity—We planned to conduct planned subgroup analyses classifying whole trials by interaction tests as described by Deeks 2001.

We planned to carry out the following subgroup analyses:

1. when breastfeeding was just initiated and when it was already established.

However, in this version of the review data were not available in the included studies to allow us to carry out any subgroup analysis. In updates of the review, if data do become available, we will look at any possible differences between groups. We will carry out subgroup analysis for primary outcomes only.

Sensitivity analysis—We planned to carry out sensitivity analysis to explore the effect of trial quality assessed by concealment of allocation by excluding studies with clearly inadequate allocation concealment. In this version of the review we included too few studies (examining several different types of interventions) to allow meaningful sensitivity analysis. We will carry out sensitivity analysis in future updates if more studies are included.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification.

Results of the search—Using the search strategy, we identified 23 reports, representing 19 studies, examining treatments for breast engorgement for women breastfeeding their babies. After assessing eligibility we included eight studies, and have attempted to contact the author of one trial for further information; Roberts 1998 is awaiting assessment. We excluded 10 studies.

Included studies—We have included eight studies carried out over a period of more than 50 years (Ingelman-Sundberg 1953; Kvist 2007) during which attitudes towards breastfeeding and the types and treatments available to women with breast engorgement have changed considerably.

All of the included studies focused on women with signs and symptoms of breast engorgement. In most of the studies, women with swollen, hard, painful breasts (and sometimes with pyrexia) were generally recruited in the early postnatal period (two to five days postpartum). In the study by Kvist 2007 women were recruited at breastfeeding clinics rather than in hospital postnatal wards, and may have been breastfeeding for some time, although the majority were within two weeks of giving birth. In one study the focus was specifically on women that had had caesarean births (Robson 1990).

The studies we have included in the review examined the effects of a broad range of interventions, and data were sometimes presented in a way that did not allow us to enter them into RevMan tables (Kvist 2004; Roberts 1995; Roberts 1995a; Robson 1990); for these studies we have presented a brief narrative summary of findings. Interventions included:

- acupuncture versus usual care (Kvist 2004; Kvist 2007);
- cabbage leaves (cold versus room temperature leaves (Roberts 1995)); (cabbage leaves versus gel packs (Roberts 1995a);
- cold packs versus routine care (Robson 1990);
- protease complex tablets versus placebo (Murata 1965);
- ultrasound versus sham ultrasound (McLachlan 1991);
- subcutaneous oxytocin versus placebo (Ingelman-Sundberg 1953).

The broad range of interventions examined meant that we were not able to pool data from more than one study in any of the analyses.

One study examined the effects of a cream containing cabbage leaf extract versus a placebo preparation (Roberts 1998). Published results were not presented by randomisation group and so we are attempting to contact the author for more information and hope to include results in future updates of the review. We have provided a description of this study in a table in the Characteristics of studies awaiting classification section of the review.

Further information on the women participating in trials and descriptions of the interventions can be found in the Characteristics of included studies tables.

Excluded studies—We excluded 10 studies identified by the search strategy. The main reasons for exclusion were that studies examined the prevention of breast engorgement in women whose breasts were not yet engorged, or examined interventions to suppress lactation in women who did not intend to breastfeed, rather than examining interventions to treat the symptoms of engorgement in women who were breastfeeding their babies (Booker 1970; Filteau 1999; Garry 1956; King 1958; Phillips 1975; Roser 1966; Ryan 1962). One excluded study included a small number of women intending to breastfeed, but the majority of the sample recruited were not breastfeeding their babies during the intervention period, and results were not reported separately for the former group (Kee 1989). Finally, we excluded one study that was otherwise eligible for inclusion, because not all of the women recruited were receiving an intervention to treat breast engorgement. Approximately half of the women recruited in the Nikodem 1993 study did not have symptoms of breast engorgement and the intervention aimed to prevent rather than treat symptoms in these women. Separate results were not available for women with engorged breasts seeking symptom relief. We have provided further information on these studies in the Characteristics of excluded studies tables.

Risk of bias in included studies

We found it difficult to assess risk of bias in the included studies as methods used in the trials were not generally well described.

Allocation—In two studies we judged that the methods used to conceal group allocation at the point of randomisation were adequate; in these studies group assignments were concealed in sealed opaque sequentially numbered envelopes (Kvist 2004; Kvist 2007). In all of the remaining studies we assessed that methods to conceal allocation were inadequate or unclear. Quasi-randomisation was used in four trials; group allocation was by odd or even case-note number in the Ingelman-Sundberg 1953 trial, by day of the week in theMurata 1965 trial, and in the two studies by Roberts (Roberts 1995; Roberts 1995a) all women received both the experimental and control interventions, as breasts rather than women were randomised. In one study a “balanced block randomisation sequence” was used, but it was not clear what methods were used to conceal group allocation (McLachlan 1991). Finally, in the study byRobson 1990 there were serious problems with the way randomisation was carried out; a table of random numbers was used to decide the randomisation sequence but the allocation sequence was not necessarily observed, so, for example, women with the most distressing symptoms assigned to the control group were moved into the intervention group, and there was no intention-to-treat analysis.

Blinding—In studies where different types of interventions were compared, blinding participants and clinical staff would be difficult and was not attempted (Kvist 2004; Kvist 2007; Roberts 1995; Roberts 1995a; Robson 1990).The lack of blinding (of women, staff and outcome assessors) in these studies may represent a serious source of bias, as many of the outcomes measured (subjective views about treatment and assessment of symptoms) may have been influenced by knowledge of treatment assignment. In the study by McLachlan 1991 comparing ultrasound versus sham ultrasound, it was reported that women and staff were blind to which machine was which. However, in this study breasts rather than women were randomised and one breast may have been randomised to receive ultrasound and the other sham treatment. It was reported that the same machine was always used to treat the same breast. It is not clear how convincing to women and staff this attempt at blinding was, and it is difficult to imagine full compliance with this blinding procedure in the context of busy postnatal wards. Two studies included placebo (protease complex tablets versus placebo (Murata 1965), and subcutaneous oxytocin versus placebo (Ingelman-Sundberg 1953).

Incomplete outcome data—We assessed that levels of attrition were unclear in several of the included studies as information on loss to follow up, or denominators in the results section, may not have been explicit (Ingelman-Sundberg 1953; Kvist 2004; Murata 1965). No attrition was apparent in the studies by Roberts (Roberts 1995; Roberts 1995a), and there appeared to be low levels of attrition (less than 5%) in the studies by Kvist 2007 and McLachlan 1991.

Other potential sources of bias—There was considerable baseline imbalance in the study by Robson 1990. Women in the control group had much lower pre-test pain scores.

There was also some deviation from protocol in this study: three women who were described as having “heightened distress levels” assigned to the intervention group were moved into the control group as this was perceived as being less demanding of their time, and one mother with severe discomfort asked to be assigned to the intervention group. In all, the randomisation schedule was not observed in eight cases. This represents a serious source of bias. There was no intention-to-treat analysis.

In three of the studies included, randomisation and analysis was at the level of breasts rather than women (McLachlan 1991; Roberts 1995; Roberts 1995a). There was no adjustment made for the non-independence of breasts, and we found interpretation of results difficult. This difficulty was exacerbated in the study by Roberts 1995 because the pretest rating of symptoms was for both breasts together (an overall rating), whereas at post-test women provided ratings for separate breasts. It was therefore not possible for us understand possible differences between pre- and post-test scores. We did not formally assess reporting bias as we relied on published reports for data extraction and analysis of risk of bias. We were not able to examine possible publication bias using funnel plots because of the small number of studies included in the review.

Effects of interventions

Interventions to treat breast engorgement: eight studies with 744 women—As we have discussed, we were unable to pool any results from studies in meta-analysis because of the broad range of interventions examined, and the way in which outcomes were assessed and reported in these trials. We have set out separate comparisons for each type of intervention in the text below, and in the data tables; in some studies we were not able to include all outcome data in tables because of the form in which results were presented in research reports; for these outcomes we provide a brief description of findings as reported by the trial authors. Most of the studies did not provide information on the review’s primary outcomes (cessation of breastfeeding and mastitis), and so we have set out findings for both primary and secondary outcomes together.

Acupuncture to treat breast engorgement: two studies with 293 women

Primary and secondary outcomes: Two studies examined the effects of acupuncture on breast engorgement (Kvist 2004; Kvist 2007). In both studies there were three treatment groups: advice and usual care (which might include the use of oxytocin nasal spray at the discretion of the midwife); advice and acupuncture (excluding the SP6 acu-point); and advice and acupuncture including the SP6 point. Results for resolution of symptoms were very similar for women in the two acupuncture groups in the Kvist 2007 study, and we have combined them in the data tables.

We were not able to include data from the Kvist 2004 study in analyses because results were not set out separately for the three randomised groups in the published report and were not available from the author.

Neither study provided information on the review’s primary outcomes (cessation of breastfeeding and mastitis). The number of women prescribed antibiotics may represent a

proxy measure of mastitis; results from Kvist 2007 show that, while women in the acupuncture group were less likely to be prescribed antibiotics, the difference between the acupuncture and control group was not statistically significant (Analysis 1.1).

The number of women with breast abscess was reported in Kvist 2007; women in the acupuncture group were less likely to have abscess compared to women receiving routine care, but the difference between groups did not reach statistical significance (risk ratio (RR) 0.20. 95% confidence interval (CI) 0.04 to 1.01, P = 0.05).

Non pre-specified outcomes: The amount of time taken for symptoms to resolve was reported by Kvist 2007. Findings favoured the acupuncture group, with fewer women having symptoms at three, four, and five days after commencement of treatment; at four and five days the differences between groups reached statistical significance (RR 0.82, 95% CI 0.69 to 0.96) and (RR 0.84, 95% CI 0.70 to 0.99) respectively. The difference between groups for the numbers of women with symptoms lasting more than six days was not statistically significant (Analysis 1.6).

In the Kvist 2004 study it was reported that at three days after the start of treatment there were no significant differences between groups for severity of symptoms or for satisfaction with breast-feeding.

Cabbage leaves to treat breast engorgement: two studies with 62 women

Primary and secondary outcomes: Two studies by the same author examined cabbage leaves to reduce symptoms of breast engorgement, and collected information on pre- and post-treatment pain scores in randomised groups. In both studies breasts rather than women were randomised, and results were not reported in a way that allowed us to enter data intoRevMan 2008. In a study comparing cabbage leaves and gel packs (Roberts 1995a) it was reported that women in both groups had reductions in pain scores following treatment, but that there were no significant differences between groups (data not shown). In a second study comparing chilled versus room temperature cabbage leaves, again authors reported that both groups had less pain following treatment, but that there was no difference between the randomised groups for post-treatment pain scores (Roberts 1995) (data not shown).

Protease complex to treat breast engorgement: one study with 59 women

Primary and secondary outcomes: A study by Murata 1965 examined the effects of protease complex (a plant enzyme) versus placebo in 59 women complaining of painful and tender breasts with symptom assessment at three to five days postpartum. Outcomes measured included improvements in pain and swelling, and overall rating of recovery. Women in the active treatment group were less likely to have no improvement in pain (RR 0.17, 95% CI 0.04 to 0.74) and swelling (RR 0.34, 95% CI 0.15 to 0.79) when symptoms were clinically assessed. Compared with controls, women receiving the active protease complex were also less likely to experience no overall change in their symptoms or worse symptoms (RR 0.26, 95% CI 0.12 to 0.56). It was not clear how many of the women participating in this trial were breastfeeding during the treatment period.

Ultrasound thermal treatment for breast engorgement: one study with 109 women

Primary and secondary outcomes: McLachlan 1991 et al examined ultrasound versus sham ultra-sound in a study where breasts rather than women were randomised (women may have had active treatment on both breasts, sham treatment on both breasts, or one breast receiving active, and one receiving sham ultrasound). No adjustment was made for the non-independence of breasts and most of the results were difficult to interpret. When women who had the same treatment (either active or sham ultrasound) to both breasts were compared the numbers requiring analgesia were very similar (Analysis 3.1). Trial authors report that both sham and active treatment were associated with reductions in ratings of pain, hardness and swelling, but that there were no significant differences between groups at the end of treatment. It was also reported that there were no differences in the duration of breastfeeding for women in the different treatment groups, but actual rates in each group were not reported.

Oxytocin for the treatment of breast engorgement: one study with 45 women

Primary and secondary outcomes: A study carried out in the early 1950s examined the effectiveness of sub-cutaneous oxytocin, which was used daily until symptoms resolved (Ingelman-Sundberg 1953). Participants received either oxytocin or a placebo. The main outcome in this study was duration of treatment. Overall, seven of the 45 women included in the study still had symptoms three days after starting treatment; five of the 20 women in the oxytocin group and two of the 25 in the placebo group still required treatment after three days. Although more women in the oxytocin group had no resolution of symptoms compared with controls, the difference between groups was not statistically significant (RR 3.13, 95% CI 0.63 to 14.44), Analysis 4.1.

Cold packs for breast engorgement: one study with 88 women

Primary and secondary outcomes: In a non-blinded study women who had had caesarean deliveries and who developed symptoms of breast engorgement were randomised to treatment and control groups (breast-shaped cold packs worn in a halter versus routine care) (Robson 1990). Women in the intervention group seemed to experience a reduction in pain intensity at post-test. The author reported a decrease in mean pain intensity score from 1.84 (standard deviation (SD) 0.65) to 1.23 (SD 0.68) compared with an increase in the control group from 1.50 (SD 0.71) to 1.79 (SD 0.72). However, the differences between groups at baseline, and the failure to observe randomisation(women with “heightened distress” were moved into the control group), make results difficult to interpret.

DISCUSSION

Summary of main results

We included eight studies examining six different types of interventions to treat symptoms of breast engorgement. For several interventions (ultrasound, cabbage leaves, and oxytocin) there was no statistically significant evidence that interventions were associated with a more rapid resolution of symptoms; in these studies women tended to have improvements in pain

and other symptoms over time whether or not they received active treatment. The improvement in symptoms may be partly explained by possible placebo effects in those studies with sham or placebo treatments, or, rather, it may be due to the fact that symptoms resolved spontaneously as women continued to breastfeed.

In a study examining acupuncture there was some evidence that, compared with women receiving routine care, women in the acupuncture groups had greater improvements in symptoms in the days following treatment, although symptoms had resolved in most women by six days, and the study did not have sufficient power to detect meaningful differences between groups for other outcomes (such as breast abscess).

The study examining protease complex to treat symptoms reported findings favouring intervention groups. However, it is now more than 40 years since this study was carried out, and we are not aware that this preparation is used in current practice.

Finally, a study looking at cold packs suggested that the application of cold does not cause harm, and may be associated with improvements in symptoms, although differences between control and intervention groups at baseline mean that results are difficult to interpret.

Overall completeness and applicability of evidence

Breast engorgement is a painful and unpleasant condition affecting large numbers of women in the early postpartum period. During a time when mothers are coping with the demands of a new baby, and the physical changes that occur after childbirth, breast engorgement may be particularly distressing. Breast engorgement may inhibit the development of successful breastfeeding, lead to early breastfeeding cessation, and is associated with more serious illness, including breast infection. Despite this, there has been relatively little research in this area. The studies included in the review looked at a broad range of interventions, and we were not able to carry out meta-analysis. For most of the interventions there was insufficient or inconclusive evidence on the effectiveness of interventions. Most of the studies did not report findings on key outcomes such as the impact of interventions on infection, breast-feeding practices and cessation of breastfeeding. It was also not generally clear whether interventions were acceptable to women. Whilst studies did examine improvement in symptoms, and this is certainly an outcome that is likely to be important to women, this outcome is difficult to interpret as symptoms are likely to change over time with or without active intervention. Further, in most studies women in both groups received advice on other interventions (e.g. gentle massage, continued breastfeeding) that may have had an independent effect on outcomes.

One of the studies (Nikodem 1993) which we excluded from this review (as it focused both on the prevention and treatment of engorgement) suggested that the use of cabbage leaves may encourage continued breastfeeding, with women in the intervention group being more likely than those in the usual care group to be exclusively breastfeeding at six weeks. This study produced positive results but findings may be at high risk of bias, and it illustrates the difficulties of carrying out research in this area: it may not be practicable to blind women or care providers to group allocation, symptoms are likely to resolve over time with or without active treatment, women are likely to receive a series of co-interventions, and it is necessary

to follow women up over time to assess the effectiveness of treatment on breastfeeding outcomes.

Quality of the evidence

Overall, the quality of the evidence from studies in the review is not high. The lack of blinding in studies may mean that evidence regarding symptoms (reported by women or assessed by clinicians) may be at high risk of bias. Most of the studies did not have sufficient statistical power to detect differences between groups and so results are not conclusive, and while outcomes that occur relatively infrequently were not generally reported, it is unlikely that these studies would have been large enough to show possible differences. The studies also had relatively short follow-up periods (as outcomes such as symptom improvement are apparent within a few days) which meant that information on longer term outcomes such as duration of breastfeeding, or breastfeeding cessation was not available. Randomisation of breasts in some studies may mean that results are at high risk of bias as breasts are not independent; asking mothers who are not blind to breast assignments to rate individual breasts (when at pre-test they provided a single rating for both breasts) may lead to findings that are at best, difficult to interpret, and at worst, not valid.

Potential biases in the review process

We attempted to minimise bias in the reviewing process by having two review authors assess risk of bias and carry out data extraction. We acknowledge that there is potential for bias in the review process as assessment of risk of bias, for example, is not an exact science.

Agreements and disagreements with other studies or reviews

Clinical practice guidelines in the UK (NICE 2006) broadly agree with this review concluding that cabbage leaves and cold packs may be helpful for symptom relief, but that evidence on the effectiveness of these interventions is not strong. In the absence of evidence from trials the guidelines recommend breast massage, continued breastfeeding and analgesia for symptom relief.

AUTHORS' CONCLUSIONS

Implications for practice

Breast engorgement is a distressing condition for women trying to establish successful breastfeeding. There is insufficient evidence from trials to recommend the widespread implementation of treatments for breast engorgement. At the same time, treatments such as cabbage leaves applied to the breast may be soothing, are unlikely to be harmful, and are cheap. While evidence of effectiveness of interventions is not strong, there is also little information on what women think of particular interventions; cold packs, for example, may be soothing or women may find them unpleasant to use; trials included in the review did not tend to report what women's views and preferences were regarding treatment options.

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Implications for research

There is a paucity of evidence in this important area, and what evidence there is has methodological limitations so that results are at high risk of bias. Studies where individual breasts have been randomised are particularly difficult to interpret. Overcoming problems associated with lack of blinding is a particular problem in this area. Comparing alternative treatment options using a cluster-randomised design rather than randomising individual women may be a possible way forward.

Acknowledgments

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), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

SOURCES OF SUPPORT

Internal sources

- Effective Care Research Unit, East London Hospital Complex, University of Fort Hare, Eastern Cape Department of Health, University of Witwatersrand, South Africa.
- The University of Liverpool, UK.

External sources

- National Institute for Health Research (NIHR), UK.

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CHARACTERISTICS OF STUDIES

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

Ingelman-Sundberg 1953

Methods	Quasi randomised trial. Allocation by folder numbers.
Participants	45 women who showed pronounced signs of engorgement during the second to the fourth day of puerperium
Interventions	Oxytocin 2.5 I.U. given subcutaneously daily to women in the treatment group until breasts became soft; those in the control group were given the same amount of saline In both groups the baby was allowed to breastfeed from the first day after delivery
Outcomes	Amount of breast milk produced. Duration of treatment/symptoms subsided after 1 day, 2 days or not subsided after 3 days
Notes	There were only limited data we were able to use in data tables. The results state that the daily amount of milk produced was the same in both groups, although it was not clear how the amount of milk produced was measured

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Odd or even case note numbers.
Allocation concealment?	No	There was no allocation concealment. Women were allocated into different groups based on their hospital records

Blinding? Women	Yes	"It was concealed from both patient and doctor whether oxytocin or saline was being used."
Blinding? Clinical staff	Yes	
Blinding? Outcome assessors	Unclear	The article does not mention the blinding of the outcome assessors
Incomplete outcome data addressed? All outcomes	Unclear	The study does not mention how incomplete outcome data were addressed

Kvist 2004

Methods	Randomised controlled trial.
Participants	88 women attending breastfeeding clinics with breast inflammation (redness, hardness, pain or pyrexia), half of the women were within 2 weeks of giving birth
Interventions	There were three treatment arms. Group 1 received usual care (advice with oxytocin nasal spray at the discretion of attending midwives); group 2 received advice and acupuncture to points excluding SP6 acupoint; group 3 received advice and acupuncture as group 2 but including SP6 point. Acupuncture was carried out by midwives with acupuncture experience All groups were advised to gently massage breasts, express milk and feed regularly
Outcomes	Severity of symptoms on day 3.
Notes	Published results were not reported in a way that we were able to use in data tables. Results state that there were no differences between groups at day 3 but no original data were presented. We contacted the author for further information; data from the study are no longer available

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Not described.
Allocation concealment?	Yes	Described as sealed opaque envelopes opened by midwives in order
Blinding? Women	No	Not feasible.
Blinding? Clinical staff	No	
Blinding? Outcome assessors	No	
Incomplete outcome data addressed? All outcomes	Unclear	88 women randomised. Denominators for results not clear.

Kvist 2007

Methods	Randomised, non-blinded 3-arm controlled trial. The opaque randomisation envelopes were randomly mixed
Participants	205 mothers with 210 episodes of inflammatory symptoms of breast during lactation

Interventions	Essential care to everyone: breastfeeding advice, manual expression and warm shower. Group 1 was given essential care and oxytocin nasal spray at the discretion of the clinical staff, group 2 was given essential care and acupuncture avoiding the SP6 site which stimulates oxytocin, group 3 was given essential care and acupuncture including the SP6 site. The acupuncture treatment was given by experienced midwives
Outcomes	Pain score, maternal satisfaction with breastfeeding, needs for antipyretics, breast abscess, need for antibiotics
Notes	In the data tables the 2 acupuncture groups have been combined into a single treatment group (140) and compared with the group receiving usual care

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Envelopes prepared in advance. "The sequence of group allocation was not known to anyone."
Allocation concealment?	Yes	Opaque envelopes were used to allocate women into the 3 groups
Blinding? Women	No	Blinding was not possible as women who had no acupuncture would know which group they were in
Blinding? Clinical staff	No	
Blinding? Outcome assessors	No	
Incomplete outcome data addressed? All outcomes	Yes	205 women (210 episodes). 2 women withdrew but were included in the analysis
Free of other bias?	Yes	

McLachlan 1991

Methods	Randomised double-blind, placebo controlled trial. Analysis for breasts rather than women
Participants	197 engorged breasts from 109 women who were referred to the physiotherapist for treatment of breast engorgement
Interventions	A normal ultrasound was used for treatment and for control a crystal was removed and replaced with a resistor to produce surface heat only. In 1 group both breasts received ultrasound, in the second group both breasts received sham treatment and in the third group 1 breast received ultrasound and one group received sham treatment
Outcomes	Pain using a visual analogue scale, hardness using a visual analogue scale, hardness using a digital tonometer
Notes	Each breast, instead of an individual woman was a unit of analysis. The machines were labelled as A and B and were changed weekly by someone blind to allocation of women

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"Balanced block randomisation sequence."
Allocation concealment?	Unclear	There is no mention of allocation concealment.

Blinding? Women	Yes	"Treatment of an individual breast was always be the same machine."
Blinding? Clinical staff	Yes	
Incomplete outcome data addressed? All outcomes	Unclear	4 women were lost to follow up but there is no mention of how lost data were handled
Free of other bias?	Unclear	Results were very difficult to interpret as analysis was by breasts

Murata 1965

Methods	Quasi-randomised trial. Women allocated to different groups on alternate days. Treatment group on even number days and placebo on odd number days
Participants	59 women presenting with breast engorgement on 3rd and 5th day post- delivery with pain and tenderness
Interventions	Women in treatment group were given 2 tablets of protease complex 4 times on day 1 after each meal and before bed time and on second and third day they were given 1 tablet 4 times a day and the placebo group were given placebo
Outcomes	Swelling; pain; maternal opinion of treatment.
Notes	It was not clear that all women were breastfeeding.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	Quasi randomisation, allocation by day of the week.
Allocation concealment?	No	Group allocation could be anticipated in advance.
Blinding? Women	Yes	Placebo controlled trial.
Blinding? Clinical staff	Yes	Placebo controlled trial.
Blinding? Outcome assessors	Yes	2 outcome assessors were recording the change of swelling and pain and were not informed as to which participant belonged to which group
Free of other bias?	Yes	

Roberts 1995

Methods	Random assignment to 2 treatment groups.
Participants	28 lactating women with breast engorgement.
Interventions	Chilled cabbage leaves were placed on the right breast and room temperature cabbage leaves were placed on the left breast, whilst the other group had the leaves placed in reverse order for 2 hours
Outcomes	Pain.
Notes	This was a convenience sample of lactating women with breast engorgement. All women had both treatments and analyses were for individual breasts rather than for women. As breasts are not independent, results are very difficult to interpret.

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	Pre-test assessments were for 28 women whereas post test assessments were for 56 breasts. Data were not in a form in which we were able to enter them into data tables

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Not described.
Allocation concealment?	No	All women had both treatments - 1 on each breast.
Blinding? Women	No	Not feasible.
Blinding? Clinical staff	No	
Blinding? Outcome assessors	No	
Incomplete outcome data addressed? All outcomes	Yes	
Free of other bias?	No	Analysis was by breast rather than by women. Breast are unlikely to be independent

Roberts 1995a

Methods	Quasi-randomised trial (breasts rather than women were the unit of analysis)
Participants	34 lactating women in postnatal wards in 2 Australian hospitals with breast engorgement (hard, warm, painful breasts, difficulty feeding)
Interventions	Cabbage leaves were compared with chilled retaining gel packs. Each woman put cabbage leaves on 1 breast and a cold gel pack on the other
Outcomes	Pre and post-test pain rating for each breast rated on a "pain ruler" (a VAS with numbers from 0-10, labelled with descriptions 0 = no pain, 5 = moderate pain, and 10 = excruciating pain)
Notes	Analysis was at the breast level and results were at high risk of bias and difficult to interpret. We have not included data in the data tables

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Quasi randomisation (by hospital number) of right and left breasts
Allocation concealment?	No	
Blinding? Women	No	Not feasible. This is particularly a problem as women received both treatments (each breast having a different treatment)
Blinding? Clinical staff	No	
Blinding? Outcome assessors	No	
Incomplete outcome data addressed? All outcomes	Yes	None apparent.

Free of other bias?	No	The data were analysed at the breast level with no adjustment for the non-independence of breasts

Robson 1990

Methods	Randomised controlled trial.
Participants	88 breastfeeding mothers with “varying degrees” of breast engorgement, all mothers had had a caesarean section. (Women of oriental ethnic background were excluded as the investigators perceived that these women did not regard cold applications positively; it is not clear how many women were excluded for this reason.)
Interventions	The intervention group received breast shaped cold packs to be worn 15-20 min after 2 consecutive feeds. The control group received routine care
Outcomes	Pre- versus post-test pain scores. Scores were not reported in a way in which we were able to include them in data tables. We have briefly summarised the results in the text of the review
Notes	This study is at high risk of bias. Women who were most distressed who were randomised to the intervention group were moved into the control group, and those in the control group who wanted packs were moved to the intervention group

Risk of bias

Item	Authors’ judgement	Description
Adequate sequence generation?	No	Table of random numbers but the randomisation sequence was not observed in all cases
Allocation concealment?	No	Not described. But the fact that the randomisation sequence was not observed suggests that staff were able to make their own decisions about group allocation. 8/88 women were not allocated according to the randomisation schedule but were allocated because they had distressing symptoms or preferred a different treatment arm
Blinding? Women	No	
Blinding? Clinical staff	No	
Blinding? Outcome assessors	No	
Incomplete outcome data addressed? All outcomes	No	No ITT analysis. Serious protocol deviations.
Free of other bias?	No	There was considerable baseline imbalance. Women in the control groups had much lower pretest pain scores. This may be due to the fact that 3 women with the most severe symptoms were moved out of the control group and into the intervention group. There was no ITT analysis

ITT: intention-to-treat

IU: international units

min: minutes

VAS: visual assessment scale

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

Study	Reason for exclusion
Booker 1970	This study focused on the suppression of lactation in women who did not intend to breastfeed
Filteau 1999	This study was examining interventions to prevent breast engorgement. Women in three villages were assigned three different treatments
Garry 1956	This study focused on an intervention for “drying up breasts” in women who did not intend to breastfeed
Kee 1989	This study was a trial examining the use of serrapeptase (Danzen) including 70 women with symptoms of breast engorgement. The sample included both breastfeeding and non-breastfeeding mothers. Ony 4 patients in the intervention group and 8 in the placebo group were breastfeeding during the study period. There were no separate data available for those women who were breastfeeding
King 1958	This study focused on an intervention to suppress lactation in women who did not intend to breastfeed
Nikodem 1993	This study included 120 women on postnatal wards of a Johannesburg hospital, South Africa. Women were recruited 72 hrs after delivery. Women in the intervention group received cabbage leaves to their breasts versus routine care in the control group. The study was excluded as only approximately half of the sample perceived that they had symptoms of breast engorgement at baseline assessment. Cabbage leaves were therefore used an intervention to prevent, as well as to treat, engorgement. Separate figures were not available for those women that had engorgement at the outset and were treated for symptoms. Results of this study suggested that women in the intervention group were more likely than those in the usual care group to be exclusively breastfeeding at 6 weeks (76 versus 58%)
Phillips 1975	This study only included women who had chosen not to breastfeed
Roser 1966	It was not clear that this study was an RCT. This study focused on an intervention to suppress lactation in women who did not intend to breastfeed; the treatment was commenced during labour, before the onset of any symptoms of breast engorgement
Ryan 1962	In this study women that were breastfeeding were excluded. The study focused on an intervention to suppress lactation in women who did not intend to breastfeed
Stenchever 1962	This study focused on an intervention to suppress lactation in women who did not intend to breastfeed

hrs: hours

RCT: randomised controlled trial

Characteristics of studies awaiting assessment *[ordered by study ID]*

Methods	Quasi-random allocation using coin toss.
Participants	39 postpartum women with breast engorgement from 2 hospitals with women of similar characteristics
Interventions	Treatment group received cream with cabbage extracts and the control group received placebo cream. Cream was applied 2 hours before feeding
Outcomes	Pain, chest circumference, degree of hardness, degree of engorgement
Notes	We have attempted to contact the author as results in the published report are not presented by randomisation group. We have not so far been able to locate the author

DATA AND ANALYSES

Comparison 1

Acupuncture versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Need for antibiotics	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.61 [0.32, 1.16]
2 Breast abscess	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.2 [0.04, 1.01]
3 Symptoms at day three	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.82, 1.08]
4 Symptoms at day four	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.69, 0.96]
5 Symptoms at day five	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.70, 0.99]
6 Women with symptoms lasting more than six days	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.47, 1.10]

Comparison 2

Protease complex versus placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain not improved	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.04, 0.74]
2 Swelling not improved	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.34 [0.15, 0.79]
3 Overall rating of recovery (no change or worse)	1	59	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.12, 0.56]

Comparison 3

Ultrasound versus sham treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Analgesic requirement	1	45	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.63, 1.51]

Comparison 4

Oxytocin versus placebo

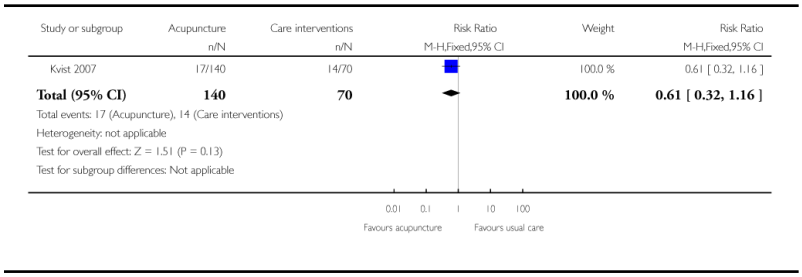
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Symptoms not subsided after three days of treatment	1	45	Risk Ratio (M-H, Fixed, 95% CI)	3.13 [0.68, 14.44]

Analysis 1.1. Comparison 1 Acupuncture versus usual care, Outcome 1 Need for antibiotics

Review: Treatments for breast engorgement during lactation

Comparison: 1 Acupuncture versus usual care

Outcome: 1 Need for antibiotics

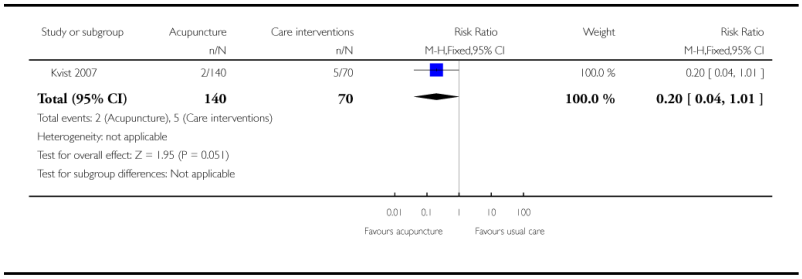


Analysis 1.2. Comparison 1 Acupuncture versus usual care, Outcome 2 Breast abscess

Review: Treatments for breast engorgement during lactation

Comparison: 1 Acupuncture versus usual care

Outcome: 2 Breast abscess

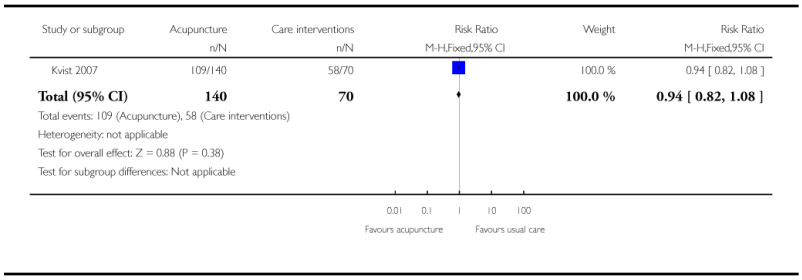


Analysis 1.3. Comparison 1 Acupuncture versus usual care, Outcome 3 Symptoms at day three

Review: Treatments for breast engorgement during lactation

Comparison: 1 Acupuncture versus usual care

Outcome: 3 Symptoms at day three

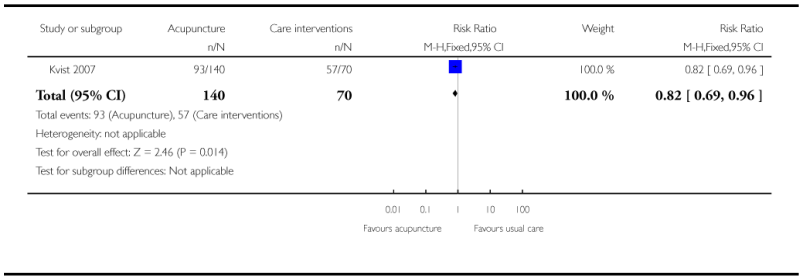


Analysis 1.4. Comparison 1 Acupuncture versus usual care, Outcome 4 Symptoms at day four

Review: Treatments for breast engorgement during lactation

Comparison: 1 Acupuncture versus usual care

Outcome: 4 Symptoms at day four



Analysis 1.5. Comparison 1 Acupuncture versus usual care, Outcome 5 Symptoms at day five

Review: Treatments for breast engorgement during lactation

Comparison: 1 Acupuncture versus usual care

Outcome: 5 Symptoms at day five

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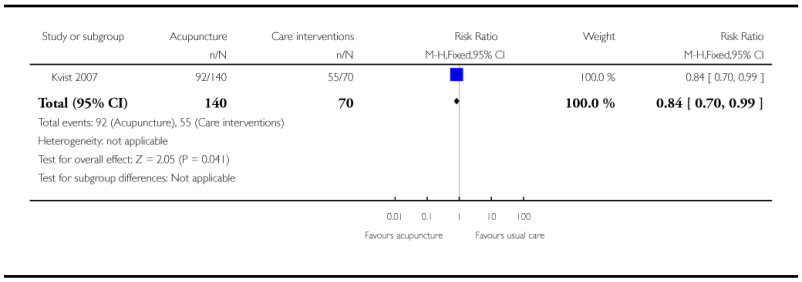
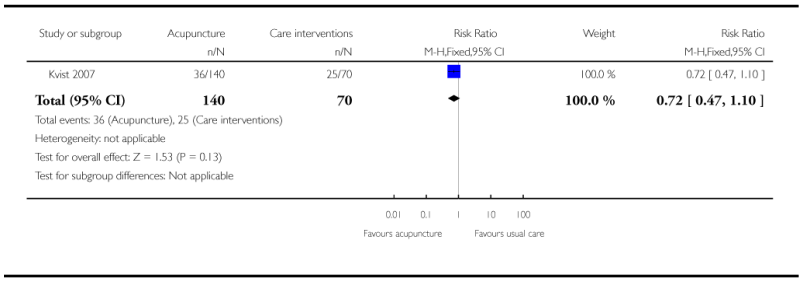


Analysis 1.6. Comparison 1 Acupuncture versus usual care, Outcome 6 Women with symptoms lasting more than six days

Review: Treatments for breast engorgement during lactation

Comparison: 1 Acupuncture versus usual care

Outcome: 6 Women with symptoms lasting more than six days



Analysis 2.1. Comparison 2 Protease complex versus placebo, Outcome 1 Pain not improved

Review: Treatments for breast engorgement during lactation

Comparison: 2 Protease complex versus placebo

Outcome: 1 Pain not improved

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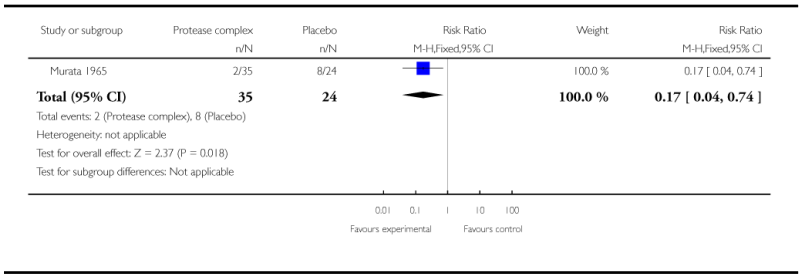
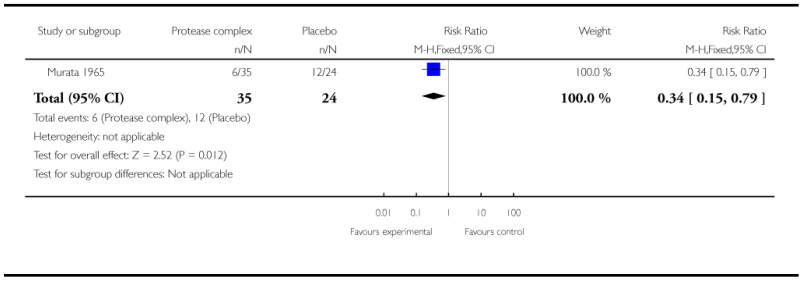


Analysis 2.2. Comparison 2 Protease complex versus placebo, Outcome 2 Swelling not improved

Review: Treatments for breast engorgement during lactation

Comparison: 2 Protease complex versus placebo

Outcome: 2 Swelling not improved



Analysis 2.3. Comparison 2 Protease complex versus placebo, Outcome 3 Overall rating of recovery (no change or worse)

Review: Treatments for breast engorgement during lactation

Comparison: 2 Protease complex versus placebo

Outcome: 3 Overall rating of recovery (no change or worse)

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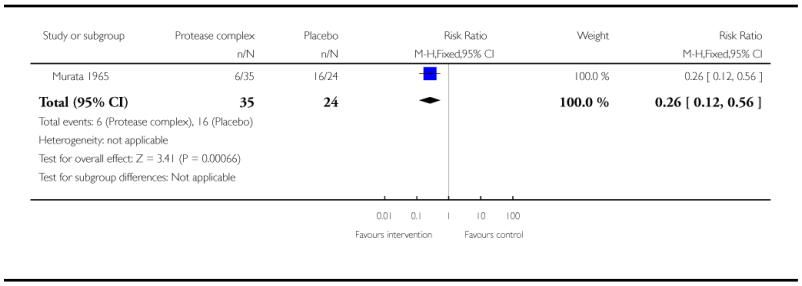
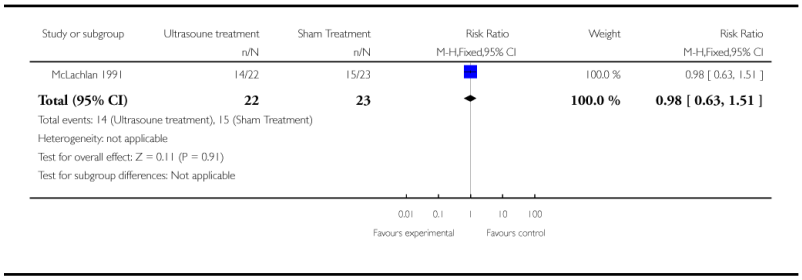


Analysis 3.1. Comparison 3 Ultrasound versus sham treatment, Outcome 1 Analgesic requirement

Review: Treatments for breast engorgement during lactation

Comparison: 3 Ultrasound versus sham treatment

Outcome: 1 Analgesic requirement



Analysis 4.1. Comparison 4 Oxytocin versus placebo, Outcome 1 Symptoms not subsided after three days of treatment

Review: Treatments for breast engorgement during lactation

Comparison: 4 Oxytocin versus placebo

Outcome: 1 Symptoms not subsided after three days of treatment

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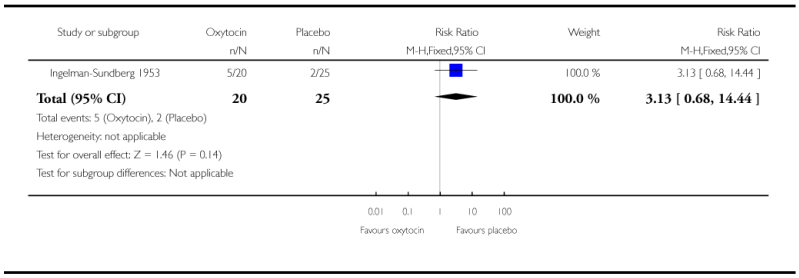

HISTORY

Protocol first published: Issue 1, 2008

Review first published: Issue 9, 2010

Date	Event	Description
23 September 2008	Amended	Converted to new review format.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The protocol Methods section has been updated.

References to studies included in this review

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* *Indicates the major publication for the study*

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PLAIN LANGUAGE SUMMARY

Treatment for breast engorgement in breastfeeding women

Breast engorgement is when the breasts overfill with milk and the breasts become swollen, hard and painful. Large numbers of women experience this, usually in the first few days after giving birth, although it can also occur later on. During a time when mothers are coping with the demands of a new baby it may be particularly distressing. Breast engorgement may mean that women fail to successfully start breastfeeding, cause them to give up breastfeeding, or serious illness can result, including breast infection. The aim of the review was to examine treatments used to relieve the symptoms of breast engorgement. We included eight randomised controlled trials involving 744 women. Studies examined a range of different treatments for breast engorgement including acupuncture, cabbage leaves applied to the breasts, cold gel packs, pharmacological treatments and ultrasound. For some interventions (ultrasound, cabbage leaves, and oxytocin) there was no strong evidence that interventions led to a more rapid resolution of symptoms, as in these studies women tended to have improvements in pain and other symptoms over time whether or not they received active treatment. There was evidence from one study that, compared with women receiving routine care, women receiving acupuncture had greater improvements in symptoms in the days following treatment, although there was no evidence of a difference between groups by six days, and the study was not large enough to be able to detect meaningful differences for other outcomes such as breast abscess. A study looking at cold packs suggested that the application of cold to the breasts does not cause any harm and may be associated with improvements in symptoms, although differences between the control and cold pack groups before treatment started meant that results were difficult to interpret. The overall conclusions of the review are that although some interventions may be promising, there is not sufficient evidence from well designed trials on any intervention to justify widespread uptake of that intervention. More research is needed on treatments for this painful and distressing condition.