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Interventions for relieving the pain and discomfort of screening mammography (Review)

Miller D, Livingstone V, Herbison GP

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[Intervention Review]

Interventions for relieving the pain and discomfort of screening mammography

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ABSTRACT

Background

The pain of mammography is recognised as a significant deterrent for women considering this examination, and may affect participation in breast screening.

Objectives

To review interventions to reduce or relieve the pain and discomfort of screening mammography.

Search methods

For this update, the Cochrane Breast Cancer Group Specialised Register was searched on the 18th May 2006. Other databases searched were MEDLINE (1966 to November 2006), CINAHL (1982 to December 2006), EMBASE (1988 to 2006) and reference lists of articles. We also searched Current Controlled Trials (www.controlled-trials.com, accessed September 2007) and the UK National Research Register (www.update-software.com/national/, accessed September 2007) for ongoing and completed research projects. Researchers in the field were also contacted.

Selection criteria

Randomised controlled trials and quasi-randomised trials with a comparison group were considered. Studies had to include assessment of pain or discomfort and, if the intervention could have impacted on the quality of the mammograms, an assessment of image quality was also required.

Data collection and analysis

Two authors (DM and VL) reviewed identified studies to determine whether they met the inclusion criteria. Each study was reviewed for quality, including concealment and generation of allocation sequence, comparability between groups at baseline, inclusion of all randomised participants in analysis and blinding after allocation. Data extraction was performed by these two authors.

Main results

Seven RCTs, involving 1671 women were identified for inclusion. The review found that giving women information about the procedure prior to the mammogram may reduce pain and discomfort. Increasing women's control over breast compression could reduce pain experienced during the procedure, though mammogram image quality was only maintained if the technologist controlled the first compression. If the technologist reduced compression force of the mammogram, discomfort experienced was unchanged. The use of

breast cushions reduced pain of mammography; however, image quality was impaired in 2% of women in the intervention group. Acetoaminophen as a premedication did not affect discomfort of mammography. Differences in interventions, and inconsistency in measures, validation of pain scales, and in assessment of mammogram quality, mean that results of these studies cannot be combined. All results are based on single studies. Further research is required.

Authors' conclusions

Currently there are very few proven interventions to reduce pain and discomfort of screening mammography, especially procedures that can be readily introduced to screening programmes. With mammography continuing as the preferred method for breast screening, more research on such interventions is needed.

PLAIN LANGUAGE SUMMARY

Interventions for relieving the pain and discomfort of screening mammography

Breast cancer is the most common cancer affecting women. Screening for breast cancer by means of regular mammograms reduces the death rate from this disease. In the screening process, women who have no symptoms of disease undergo a mammogram, which can identify those who might have breast cancer. Mammography uses X-rays to find early breast cancers. In order to obtain an accurate reading, the mammography machine needs to compress the breasts. This can cause discomfort or pain, and some women decide not to have mammograms because they can be painful. In some mammography studies, up to 35% of women report pain with the procedure.This review tried to identify and assess clinical studies of interventions designed to reduce the pain or discomfort that women can experience during mammography. A set of quality criteria were decided to ensure that only studies that were relevant and well designed were included in this review. Seven studies met these criteria and were included. The studies involved a wide range of interventions to relieve the pain and discomfort of screening mammography, such as providing women with verbal and/or written information before the procedure, or pain relief medication taken before the examination, use of a breast cushion (to pad the surface of the mammography equipment), patient-controlled compression of the breast, and reduced compression by the technician. The studies assessed the pain the women expected, and actually experienced, by means of a range of questionnaires of differing quality.

Each study included in this review looked at a different intervention to reduce pain in mammography. The trial results show that giving women written or verbal information about the procedure prior to the mammogram can reduce pain or discomfort of the examination. Also increasing women's control of breast compression could reduce the pain they experience, though there was no change in the pain women experienced when a mammography-technologist reduced the compression force. Use of breast cushions also reduced the pain; however, it caused a poor quality of X-ray in 2% of women screened, which meant that they would need to have a further mammogram. Paracetamol taken before the procedure did not change the pain the women experienced.

Further research is needed on interventions to relieve the pain and discomfort of screening mammography.

BACKGROUND

Breast cancer is the most common cancer affecting women. The age-standardised incidence rate of breast cancer was 117 per 100, 000 women in Australia in 2002 (Australia Institute) and 145 per 100,000 women in the United Kingdom in 2004 (Cancer Research UK). The age-standardised incidence rate is used to compare groups (for example, countries) with differing age compositions. It is a weighted average of age-specific rates according to a standard distribution of age to eliminate the effect of different age distributions.
More than 80% of breast cancer is diagnosed in women over 50 years of age. Randomised controlled trials of breast cancer screening by mammography have shown a significant reduction in breast cancer mortality in women (Gotzsche 2007; Smith 2004), though the methodology, and hence the results, of some of these trials has been questioned (Gotzsche 2007). This debate is ongoing (Blanks 2000; Lawrence 2002; Nystrom 2000).

The acceptability of the mammography examination is very important for women who are considering participating in breast screening. The pain and discomfort of the mammography procedure, however, makes it unacceptable to some women (McNoe 1996). Frequency of pain varies in reported studies (McNoe 1996; Peipins 2006; Rutter 1992). In New Zealand a collation of five studies of women's experience of the Otago-Southland Breast Screening Programme pilot found that 32% of 611 women having their first mammogram described the experience as painful or very painful (McNoe 1996). Five-hundred and ninety-seven women who attended a mobile breast screening program in South East Thames District, England, were interviewed about discomfort or pain experienced immediately after receiving mammograms. Thirty five percent (209 women) experienced discomfort and 6% (36 women) experienced pain (Rutter 1992). Even 30 months after having a mammogram, 25% of women surveyed in a study in the USA reported the mammogram examination as moderately or very painful (Peipins 2006).

It is important to note that concern has been expressed about the variable and inadequate pain scales used to assess pain of mammography (Elwood 1998).

Although the extent of the problem and its interpretation varies, the perceived and experienced pain of mammography has been shown to be a significant issue, and for some women it is a deterrent to having a mammogram. In a study of 121 women who had their first screening mammogram but had not responded to an invitation for a further mammogram, 46% stated that the pain experienced with their first mammogram had deterred them from further screening (Elwood 1998). For breast screening to be successful the procedure must be acceptable to women. Breast-screening programmes need to develop evidence-based strategies to reduce the pain and discomfort of mammography (Andrews 2001). Therefore, we undertook a systematic search, review and assessment of the literature, both published and unpublished, following the procedures of the Cochrane Collaboration, on strategies to reduce or relieve the pain of mammography.

OBJECTIVES

To review research of interventions to reduce or relieve the pain and discomfort of screening mammography.

Interventions could relate to such issues as the staff and physical environment of the screening facility, any preparation that the woman has before having the mammogram, or the mammogram examination procedure.

The objectives for this systematic review are intentionally broad because the interventions to reduce or relieve the pain of mammography are very diverse. It was anticipated that the search could divulge strategies in areas not contemplated originally.

METHODS

Criteria for considering studies for this review

Types of studies

The initial search was for published and unpublished randomised controlled trials (RCTs) with or without blinding. Quasi-randomised trials were considered but only after careful consideration of possible biases. Non-randomised trials were excluded. RCTs in all languages were included. One study in Swedish and another in Turkish were considered for inclusion in the review after translation. Studies were only included if they had outcome measures for both the intervention and the control group.

Types of participants

Participants included women of any age undergoing screening mammography either as part of an organised screening programme or as opportunistic screening.

Types of interventions

Any intervention to reduce or relieve the pain and discomfort of screening mammography was considered, as stated in the objectives. This could involve the staff or the physical environment of the screening facility, the preparation of the woman undergoing mammography, or the procedure of the mammogram examination.

Types of outcome measures

Measures of pain or discomfort of mammography
Descriptors: the terms 'pain' and 'discomfort' are used to describe degrees of the pain experience. In the protocol for this review 'discomfort' was discounted in pain scales, however, since the included studies have included 'discomfort' as an important pain descriptor, it has been reinstated for this review.
Pain scales: evidence of standardisation or validation of pain or discomfort scales was sought. Care in interpreting and comparing data on pain or discomfort was important in this review.

Quality of mammograms
Strategies to reduce the pain of mammography must also ensure maintenance of quality of mammograms. If an intervention could have any effect on the quality of the image, then the image quality should be assessed. Assessment of quality was determined by achievement of set standards. In the original review, studies were excluded if they did not have an assessment of the quality of the mammogram. The authors of this review update considered that to be too restrictive, and studies that did not have an assessment of quality are now included if the intervention could not have impacted on the quality of the mammogram (e.g. verbal information).

Search methods for identification of studies

For the first full version of this review (Miller 2002), the Specialised Register maintained by the Cochrane Breast Cancer Group was searched on the 29th November 2000. This search was repeated on 18th May 2006 for this update.

The other databases searched for this update were MEDLINE, EMBASE and CINAHL. We also searched Current Controlled Trials (www.controlled-trials.com, accessed September 2007) and the UK National Research Register (www.update-software.com/national/, accessed September 2007) for ongoing and completed research projects. These electronic databases are the ones most likely to identify relevant studies and so are commonly used as sources of material for systematic reviews.

Search strategies applied for this current updated review

(1) The Cochrane Breast Cancer Specialised Register

The Specialised Register maintained by the Cochrane Breast Cancer Group was searched on 18th May 2008 (details of search strategies used by the group for the identification of studies and the procedure used to code references are outlined in the group's module http://www.mrw.interscience.wiley.com/cochrane/clabout/articles/BREASTCA/frame.html). Studies with the keyword 'screen' and text word 'pain' on the Specialised Register were extracted for consideration. Mammography is captured under the key word 'screen'.

(2) Electronic databases

The following databases were searched with no language restrictions. Translations into English were obtained if necessary.
(a) Medline (from 1966 to November week 3 2006) See Appendix 1.
(b) EMBASE (from 1988 to 2006 Week 49).
(c) Cumulative Index to Nursing & Allied Health Literature (CINAHL) (from 1982 to December week 2 2006).

EMBASE and CINAHL were searched using the exploded keywords "Mammography" and "Pain". The searches were limited to human and female subjects.

(3) Trial Registries

(a) Current Controlled Trials (www.controlled-trials.com, accessed September 2007).
(b) UK National Research Register (www.update-software.com/national/, accessed September 2007).

Databases (a) and (b) were searched using the search term "Mammography and Pain".

(4) Contacting authors

Information about studies/trials/conferences/ published or unpublished information or other contacts was also requested from authors of identified studies. All suggestions for other contacts (individuals, organisations or websites), articles, or studies were checked and followed up if relevant to the review.

Search strategies applied for original review only (Miller 2002)

The following databases and websites were searched for the initial review (Miller 2002). Searching of these was not conducted for the updated review as they did not reveal any relevant studies for the initial review.

Hand searching was done for the initial review but not repeated in the update as this did not yield any relevant studies.

(1) Electronic databases

The following databases were searched when this review was first published in 2002:

MEDLINE - 1966-2001(please see Additional Table 1 for the search strategy used in the original review).
EBM Reviews - Best Evidence (1991 to January/February 2001).
EBM Reviews - Cochrane Database of Systematic Reviews (The Cochrane Library, 2001, issue 1).
EBM Reviews - Database of Abstracts of Reviews of Effectiveness (The Cochrane Library, 2001, issue 1).
AMED (Allied and Complementary Medicine) (1985 to February 2001).
CANCERLIT (1975 to November 2000).
Current Contents/All Editions (1993 Week 26 to 2001 Week 10).
HealthSTAR (1975 to December 2000).
PREMEDLINE (March 6, 2001).
PsycINFO (1967 to February Week 3 2001).

The above databases were searched using the exploded keywords "Mammography" and "Pain". The searches were limited to human and female subjects. The abstracts of the identified articles were then searched manually for relevance and possible inclusion in the review. This considered particularly whether the mammography was part of a screening programme, and whether an intervention was used to relieve pain. Bibliographies from all retrieved articles were then searched for other possible references. Authors of relevant articles were contacted for further information wherever possible.

Initial searches of the databases were conducted with the following limits: Clinical Trial (including Clinical Trials Phase 1 to 4), Controlled Clinical Trial, Interview, MetaAnalysis, Multicentre Study, RCT, and Twin Study, with the Current Contents database also being limited to Clinical Med, and Social and Behavioural Science. These limits however were found to be too restrictive so the searches were repeated using only "Humans" and "Female" as limits. Initial searches also included the keyword "screening" but this was also found to be too restrictive for locating articles. Articles located from the broader search were checked for relevance to screening mammography.

(2) Other databases and electronic theses/dissertation websites searched

The following were searched to June 2002:

UMI ProQuest Digital Dissertations.
Index to Theses (Universities of Great Britain and Ireland).
University Theses Online Group (UK).
Networked Digital Library of Theses and Dissertations (NDLTD) (Mostly USA University libraries, some European Universities).
Dissertations Online.com.
PENN State ETD.
Dissertation.com.

The above databases/websites were searched using the keywords "Mammography" and "Pain".

(3) Hand searching

A total of 43 issues were hand searched for articles from the following five journals:

Pain (eight issues)

May 2000 to Dec 2000 (inclusive).

Synergy (16 issues)
Feb, Mar, Apr, May, Jun 1996
Jan, Jul, Aug, Sept 1997
Jan, Feb, Sept 1998
Apr, Dec 1999
Feb, Mar 2000.

Radiology (seven issues)
Jan, Mar, Apr, May, Jun, Jul, Aug 2000.

Australasian Radiology (seven issues)
Feb, May, Aug 1999
Feb, May, Aug, Nov 1998.

The Radiographer (five issues)
Sept 1992
Jun, Dec 1991
Mar, Sept 1990.

Data collection and analysis

Selecting trials for inclusion

All studies identified by the search strategy were reviewed by two of the authors (DM and VL) to determine if the studies met the inclusion criteria. The studies were not masked. Any disagreement about any particular study was resolved by discussion or by referring to a third person (PH).

Assessing the methodological quality

Two of the authors (DM and VL) independently reviewed the methodological quality of each study identified to assess any bias arising from its design or the way in which it was conducted. Randomised, and non-randomised trials that included a control or normal treatment group, were assessed.
The checklist for quality of randomised controlled trials included (Table 1):

- concealment of the allocation sequence;
- generation of the allocation sequence;
- comparability between groups at baseline;
- inclusion of all randomised participants in the analysis;
- double-blinding after allocation if possible.

Allocation concealment is regarded as particularly important in protecting against bias, and was graded using the Cochrane approach as follows:
Grade A - Clearly adequate concealment.
Grade B - Possibly adequate/unclear.
Grade C - Clearly inadequate concealment.

Each study was appraised with regard to recruitment procedures, number and characteristics of participants, comparability of the intervention and control groups, effect modifiers and drop-outs from the study. Studies were checked to see if intention-to-treat analysis was considered. The intervention and nature of outcomes measured, including quality of mammograms, were assessed. The reasons for exclusion of any trial are documented in the 'Characteristics of excluded studies' table.

Data collection

Two of the authors (DM and VL) independently extracted the data from the original paper using a data extraction form. Differences in data extraction were discussed, and, if necessary, a third person (PH) arbitrated. The authors of the studies were contacted if relevant data were missing.
Descriptors of significant pain or discomfort of mammography with screening mammography included the terms 'painful', 'very painful' or 'discomfort'. Originally, in the protocol for this review, it was decided that the descriptor 'discomfort' would be disregarded because it might indicate very low levels of pain, however, some scales for assessing pain of mammography referred only to level of 'discomfort,' not pain, and so 'discomfort' has been included as an outcome in this review update.

Data analysis

In the protocol for this review, it was planned that dichotomous outcomes would be reported as relative risks with 95% confidence intervals, and continuous outcomes would be reported as mean differences and combined using a weighted mean difference. It was also planned that if the continuous outcomes measured the same outcome but in a different manner or on a different scale then consideration would be given to combining them using the standardised mean difference. Absolute measures such as Absolute Risk Reduction were also considered. However, the studies in this review were not combined as no two studies were sufficiently similar. As the studies were not combined, statistical heterogeneity between the studies was not examined.
No subgroup analysis was considered in the review update.

RESULTS

Description of studies

Seventeen potential studies were identified by the search strategy. Seven of the studies were included in the review; seven were excluded. One is awaiting assessment, and two are on-going studies.

Updating the search from June 2002 resulted in the identification of 12 new studies. Three of these studies (Alimoglum 2004; Dibble 2005; Shrestha 2001) were included in this update and six studies (Domar 2005; Everett 2005; Hendrick 2002; Markle 2004; Poulos 2003; Tabar 2004) were excluded for reasons outlined in the 'Characteristics of excluded studies' table. Of the remaining three, one is awaiting assessment (Hagen 2008), and the other two are on-going studies (Lambertz 2006; Morrow 2005). One study that was previously excluded because it did not include assessment of image quality (Sjolin 1994), is now included. This is as a result of changing the inclusion criteria so that studies that did not have an assessment of quality of the mammogram are now included if the intervention could not impact on quality. This was the case for the Sjolin study which assessed the effect of written information and/or reflection on the women prior to the mammogram on their experience of pain.

Included studies

Seven studies met the inclusion criteria for this review. Details of the studies are given in the 'Characteristics of Included Studies' table.

The studies included in this review involved a wide range of interventions to relieve the pain and discomfort of screening mammography. Three studies examined the effect of giving the

patient information prior to the mammogram. One of these studies investigated the effect of verbal information (Shrestha 2001), while the other two investigated the effect of written information prior to the mammogram (Alimoglum 2004; Sjolin 1994). Sjolin et al also investigated the effect of the technologist 'reflecting' on the experience of mammography with the woman undergoing the examination. The Sjolin paper was translated from Swedish. The paper by Alimoglum et al was translated from Turkish. Two studies (Kornguth 1993; Poulos 1997) examined interventions related to breast compression. One of these studies (Kornguth 1993), investigated the effect of allowing the participant to perform her own breast compression, and the other study investigated the effect of the technologist reducing the compression (Poulos 1997). Only one study investigated the effect of medication (acetoaminophen) on relieving the pain and discomfort of mammography (Lambertz 1998), and one study investigated the effect of breast cushions (Dibble 2005).

Types of intervention

Information provided before the mammogram

Verbal information

The purpose of the Shrestha 2001 study was to determine the effect of giving verbal information on women's expectations of discomfort prior to the mammogram on the actual discomfort experienced. A secondary objective was to determine whether the effect of the intervention differed according to whether it was a woman's first time of attending, or not.

In this randomised controlled trial women were assigned to either the control group (standard care), or the treatment group (verbal information given prior to the mammogram), through a matching process that involved the random assignment of a pair of women with similar characteristics. A total of 181 women were invited to participate in the study and 167 agreed to participate. Prior to the examination, each woman in the treatment group was given standardised verbal information comprising an explanation of the procedure, the importance of breast compression and assurance that slight discomfort may be experienced. The women in the control group received standard care and hence did not get the verbal information. Participants filled out two questionnaires. In the first questionnaire, filled out before the mammogram, the participants rated their expected level of discomfort. The second questionnaire was filled out after the mammogram, and on it the participants rated the actual level of discomfort that they experienced. Discomfort was rated on a five point scale: none, slight, moderate, considerable and severe discomfort.

Written information

The aim of the Alimoglum 2004 study was to investigate the effect of written information given prior to the mammogram on women's anxiety and perceived pain.

In this randomised controlled trial women were assigned to either the control group (standard care) or the treatment group (written information given prior to the mammogram). A total of 501 women were included in the study; 257 in the treatment group and 244 in the control group. The written information outlined the procedure, and informed the women about the reasons for any pain that they might experience from compression during the mammogram. After the mammogram the participants rated their perceived level of pain using a 100 mm visual analogue scale (VAS).

Written information and 'reflection'

The objective of the Sjolin 1994 study was to establish the effect that written information prior to the mammogram, and/or the reflection method (the authors state that "the reflection method means that the woman feels that the radiology nurse can put herself in her situation and can appreciate her experience of it"), had on the women's experience of pain at the time of mammography. This randomised controlled trial, had a 2 by 2 factorial design where the women were randomly assigned to one of four groups: (1) both written information and reflection (2) reflection method only (3) written information only (4) control - no intervention. Of the 108 women invited to participate in the study, 76 agreed (22 in Group 1, 20 in Group 2, 17 in Group 3 and 17 in Group 4). The women in the study were aged between 40 to 79 years. The women in Groups 1 and 3 received an information letter which described why the radiological examination was being carried out and what would happen. It also explained why the breast had to be compressed during the taking of the X-ray picture, and that it could cause some discomfort. Women in Groups 1 and 2 were given reflection. This entailed making the patient feel that she was understood by the nurse, and was done through verbal expressions and body language. Participants filled out a questionnaire, rating the pain they experienced on a four point scale (graded numerically 1 to 4): no pain, slight pain, painful and unbearable pain.

Premedication with acetoaminophen (paracetamol)

The Lambertz 1998 study was a thesis for a Masters degree. It considered the effect of premedication with acetoaminophen (paracetamol) on patients' perception of the pain of mammography screening, and their overall satisfaction with the screening experience. This study was a placebo-controlled RCT with three groups: (1) intervention, (2) placebo and (3) usual care. Only 48% of the 541 women invited participated in the study (265 women). The patient questionnaire was completed after the mammogram. It included questions on the woman's preconception of discomfort as well as her actual experience of discomfort of mammography. Discomfort was rated on a 100 mm VAS.

Breast cushion

The aim of the Dibble 2005 study was to determine the impact on pain and image quality when radiolucent breast cushions were used to pad the surfaces of the mammography equipment during film-screen mammography. This was a randomised trial with a cross-over design. Radiolucent cushions were attached to the compression paddle and film cassette holder when imaging one breast. No cushions were used when imaging the other breast. The breast to receive the cushion and the breast to image first were both randomised. Four standard views were taken. These were one craniocaudal (CC) view and one mediolateral oblique (MLO) view of each breast. The subject rated her breast pain using two pain scales (an 11-point numeric rating scale and a 10 cm VAS) after each mammographic view was taken. A total of 415 women were invited to participate in the study; 21 refused to participate, with the primary reason being time constraints. The remaining 394 women were included in the study (305 from the university site and 89 from the community site). The average age of the subjects was 55.41 years (SD 10.8) and the majority of them were of white/non-Hispanic origin (75.3%).

Breast compression

Patient- controlled compression of the breast

The Kornguth 1993 study investigated the impact of patient-controlled versus technologist-controlled compression of the breast on the pain of mammography. This was a cross-over trial with the technologist compressing one breast and the patient compressing the other. The order of the two procedures was randomly assigned. After each compression, the technologist asked the woman to rate her pain on a six-item scale that ranged from very comfortable to painful and intolerable. Of the 138 women invited to participate, 109 women aged 32 to 71 years were included in the study. Two women were excluded because they were found to have a breast lump, but no details were given of the point during the proceedings at which a breast examination took place.

Reduction in breast compression force by the technologist
The aim of the Poulos 1997 study was to examine the effect of reducing the breast compression force on the woman's actual experience of discomfort, compared to her preconception of discomfort. The intervention involved applying normal breast compression, described as blanching and tautness of the skin, for one craniocaudal view then, for the same view in the other breast, applying the same compression but then releasing the foot pedal which controls compression for approximately one second before taking that view. Only women having their first mammogram were included in the study. Prior to the mammogram, the participants were given a questionnaire that asked them to rate their preconception of discomfort on a five-point Likert scale that ranged from no discomfort to severe discomfort. After the mammogram, the participants were given a questionnaire and asked to rate the actual discomfort that they experienced on the same five-point scale and to note whether they had perceived any difference in discomfort between the two craniocaudal films.

Excluded studies
Seven studies were excluded from the review as they did not meet the inclusion criteria. Descriptions of these studies, and their reasons for non-inclusion, are given in the 'Characteristics of excluded studies' table.

Studies awaiting assessment
One study is awaiting assessment (Hagen 2008). This was a randomised controlled trial that investigated the effect of a sitting position versus a standing positioning on pain and discomfort during mammography. The study has been accepted for publication in the journal Radiologic Technology (personal correspondence with study author, September 2007).

Ongoing studies
Two studies have been classified as ongoing: their details are given below:

Morrow 2005: this trial has been registered as completed in the UK National Research Register. It was a randomised controlled trial that evaluated the effect of a computerised intervention to reduce discomfort during mammography. No further information is available at present, and no response has been obtained from the study authors.

Lambertz 2006: this trial has been registered as completed in the Current Controlled Trials Register. It was a randomised controlled trial that evaluated the effect of premedication with acetaminophen, ibuprofen, and topical lidocaine gel (Topicaine) on the perception of discomfort and overall satisfaction with the mammography experience. No further information is available at present, and no response has been obtained from the study authors.

The authors of this report would be pleased to receive any additional information about the studies that are included in this review.

Risk of bias in included studies

In general, the studies were not well designed and, important information about study methodology was not reported. A summary of the quality of the studies is given in Table 1.

Information provided before the mammogram
Verbal information
In the Shrestha 2001 trial, pairs of women with similar characteristics were randomly assigned to the control or the treatment group. The authors did not state the characteristics on which the women were matched. Fourteen women declined to participate in the study, but the authors did not give any information about the reasons for their decision. It was not possible to blind the participants, and it was not clear from the article whether or not the providers (technologists) were blinded. In order to rate discomfort, the authors used a scale that they had used in a previous study, which had been adapted from Frank et al (Frank 1982). The authors did not provide any information about whether this scale had been validated. As the intervention would not have any effect on the quality of the image from the mammography, image quality was not assessed.

Written information
The authors of Alimoglum 2004 stated that the women were assigned to the treatment or control group, but no information about how the randomisation was done was given. No information was given about the number of women who declined to participate in the study. It was not possible to blind the participants, and it was not clear from the article whether the providers (technologists) were blinded. Perceived level of pain was assessed using a VAS, which is a validated tool for assessing pain. As the intervention could not have any effect on the quality of the mammogram imaging, image quality was not assessed.

Written information and 'reflection'
The Sjolin 1994 study was not well designed. Randomisation was performed prior to the study participants giving their consent to take part in the study. Women were randomised (27 per group) when the invitations were sent to attend screening mammography. This meant that a large number of women that had already been randomised into groups did not participate in the study, and there was subsequently a discrepancy between the size of the intervention and control groups. The authors stated that, of those women who declined to participate, 11 rebooked for another time, four declined to be in the study and 17 gave no reason for not participating. One woman who agreed to participate did not fill in the questionnaire due to an "asthma problem". Consequently, the results were presented for 75 women. The three radiology nurses who were responsible for implementing the reflection intervention were trained in reflection methods by means of role-playing before the study. It was not possible to blind the participants and it was not possible to blind the nurses as to whether or not the women were given reflection. The nurses could have been blinded as to whether the women received the written information or not, but the journal article did not make it clear whether they were. The authors did

not give any information about whether the scale that they used for rating pain had been validated. As the intervention would not have any effect on the quality of the image from the mammography, image quality was not assessed.

Premedication with acetoaminophen (paracetamol)
Both the intervention group and placebo group in the Lambertz 1998 trial were blinded, however, blinding was not possible for the third, usual care (no treatment) group. Only 48% of the 541 women invited, participated in the study (a total of 265), raising the possibility of response bias. These 265 women were randomised into three groups. The study did include twenty women (7.8% of participants) who had a breast lump detected immediately before the mammogram was taken. It was not stated whether these women were told of the presence of the breast lump before the mammogram examination, and we have yet to have this clarified by the researchers. In the Kornguth study women with a breast lump detected at the time of the study were excluded (Kornguth 1993). In the presence of a breast lump the mammogram becomes a diagnostic assessment, not screening, and should, therefore, involve a different approach to the examination and assessment. The patient questionnaire was completed after the mammogram. It included questions on the woman's preconception of pain as well as her actual experience of pain of mammography, raising the possibility of recall bias. The pain scales and criteria for quality of mammograms used were well validated tools. The questionnaire for patients had been "carefully thought through by an expert panel" of consultants and researchers, however, there was no input from lay persons into this.

Breast cushion
The Dibble 2005 trial was a well conducted study and was the only one of the three studies using breast cushions, that we identified, that was eligible to be included in the review. The other studies were excluded due to non-randomisation. The cross-over design allowed each subject to act as her own control, thus eliminating inter-subject variability. The breast to receive the breast cushion was randomly assigned, as was the order in which the breasts were imaged. Randomisation was done using computer-generated random numbers with permutated blocking procedures (correspondence with author). The authors gave information about the number of women who refused to participate and the reason for their non-participation: 394 participants were included in the statistical analysis that compared the pain scores between the breasts with a cushion and those without. The article stated that the total number of participants was 391, but we established that this was a typographical error through correspondence with the author. Neither the subject nor the provider (technologist) could be blinded, but the radiologists who assessed the image quality of the mammograms were. The technologists performing the mammograms each had over 10 years of experience, and were certified in mammography examination by the American Registry of Radiologic Technologists. They also received one day of training on how to position the breast correctly when using breast cushions. This was deemed necessary because the use of a cushion on the breast compression paddle obscures the usual visual landmarks and therefore the technologists had to learn how to position by touch. Research assistants were involved in recruitment, randomisation assignments and data collection. They were trained by the study project manager. The radiologists that assessed the quality of the mammograms were Board-certified, Mammography Quality Standards Act (MQSA) accredited radiologists specialising in breast imaging. Participants rated their breast pain using both an 11-point numeric rating scale (NRS) and a 10 cm horizontal line VAS. The VAS has been studied extensively as a tool for assessing pain and has been found to be reliable (Joyce 1975); it had also been shown to have a strong positive correlation with the NRS in a previous study of pain (Kremer 1981).

Breast compression
Patient-controlled compression of the breast
The cross-over design of the Kornguth 1993 study meant that each woman acted as her own control, thus eliminating inter-subject variability. Although the order of the two procedures was randomly assigned, details of allocation concealment were not given. Neither the subject nor the provider (technologist) could be blinded, but the two radiologists who read the mammograms were. No information was provided regarding the training given to the women on the compression required. The pain scales used had been validated through previous research into force applied during mammography (Sullivan 1991), and criteria to assess quality of the mammograms were as used in the accreditation programme of the American College of Radiologists.

Reduction in breast compression by the provider
The Poulos 1997 study of 200 women was not well designed. It was unclear whether there was randomisation of the breast side having reduced compression, or of the sequence of normal or reduced compression. It was also unclear whether the patient and the radiologist were blinded. Two radiologists reported each mammogram, however, a total of seven radiologists were involved in reading the mammograms in this study. The article reported on the quality of the mammograms only in relation to any differences between the standard compressed film and the less compressed film. There was no validation of the tools used for assessing discomfort, or quality of mammograms. Of the 200 original participants, 198 were included in the reporting of perception of discomfort of the mammogram, and 184 reports on image quality were included. There was no explanation offered for the women lost to follow up.

Effects of interventions

The results of the seven studies suitable for inclusion are as follows. A summary of results can be found in Table 2.

Information provided before the mammogram
Verbal information
Only one study investigated the effect of verbal information on the experience of discomfort in mammography (Shrestha 2001). Although 167 women participated in the study, the authors report the results for a subgroup of 136 women. The authors stated that "a t-test of independent groups indicated a significant difference between the control and the experimental groups in reporting of the levels of actual discomfort relative to their reported expectation (P value 0.007)". It was not clear, however, what analysis the authors performed. Perhaps they calculated the difference between the actual and expected discomfort for each participant and then used this as their outcome measure in the statistical analysis. In further analyses, the authors categorised the study participants into three change groups: (1) lower actual discomfort than expectation; (2) same actual discomfort as expectation and (3) higher actual discomfort than expectation. They found that in the control group, 24% of the women experienced less discomfort than they had expected, 47% experienced the same amount of discomfort as

expected, and 29% experienced more discomfort than expected. In the treatment group 44% of the women experienced less discomfort than expected, 44% experienced the same amount of discomfort as expected, and 12% experienced more discomfort than expected. A chi-squared test performed by the review authors found that there was a statistically significant association between the group a person was in (treatment or control) and the change category (P value 0.009).

The authors performed a subgroup analysis investigating the differential effect of information on first time attendees and subsequent attendees. For first time attendees (n=12 per group), 75% in the treatment group and 8% in the control group experienced discomfort lower than expected. For subsequent attendees (n=56 per group), 38% in the treatment group compared to 27% in the control group experienced discomfort lower than expected. The study authors report that there was a statistically significant difference between the control and the treatment group (P value 0.002) for first time attendees, but not for subsequent attendees (P value not given). However, the readers of this review should be aware that the P values quoted are the results of a subgroup analysis, and therefore do not actually test whether there is a differential effect of information on first time attendees and subsequent attendees. If the authors wanted to test that, they should have combined the data from first time and subsequent attendees and included an interaction term in the model. The P value associated with that interaction would test whether information had a differential effect on first time, and subsequent, attendees. The study authors recommended that verbal information be provided routinely prior to the procedure, especially for first time attendees.

Written information

One study investigated the effect of written information on mammography-related pain and anxiety (Alimoglum 2004). This study used a VAS that ran from 0 to 100, with 0 indicating no pain. The mean value was 16.5 (standard deviation (SD) 22.4) for the treatment group, and 24.5 (SD 28.1) for the control group. There was a statistically significant difference in the perceived pain between the two groups (P value less than 0.05 stated by the study authors; weighted mean difference (WMD): 8.0; 95% confidence interval (CI) 3.6 to 12.4 calculated by the review authors). The authors concluded that providing written information about mammography lowers the perceived pain, and that informing the patient is an important ethical duty of practitioners.

Written information and 'reflection'

One trial investigated the effect of information and/or 'reflection' on the pain of mammography experienced by women (Sjolin 1994). Of the 75 women included in the study, 41 women reported "slight pain", one woman rated the experience as "painful" and the remaining 33 women reported not experiencing any pain. This trial used a four-point scale of: no pain, slight pain, painful, and unbearable pain, that were graded numerically from one to four. The mean pain scores in treatment Groups 1(written information about the procedure and reflection), 2 (reflection), 3 (written information) and 4 (usual care) were 1.56, 1.63, 1.63 and 1.50, respectively. Hence the control group had the lowest mean score, followed by the group that received the written information and reflection. The authors reported that they performed an analysis of variance and no significant differences were found between the groups. They did not report the P value associated with this test. The authors concluded that the most important result of their study was that the women in all four groups considered that they had experienced little pain and that the differences between the groups in terms of their ratings were small.

Premedication with acetoaminophen (paracetamol)

The effect of acetoaminophen as a premedication on the pain of mammography was investigated in one trial (Lambertz 1998). This trial used a VAS from 0-100, with 0 indicating no discomfort or pain. Overall, 93% of participants reported some level of discomfort, 7% (18 women) reported no discomfort, and 15% of participants rated discomfort of mammography as above 50 on the VAS. The mean values on the VAS were 23.7 (SD 20.8), 22.8 (SD 21.8) and 24.4 (SD 22.2) for the acetaminophen, placebo and control groups, respectively. This was not statistically significant (P value 0.896). Therefore, acetoaminophen, taken as a premedication, was not found to be effective in reducing the pain of mammography. No mammograms were judged as inadequate in any of the groups.

Breast cushion

Mammography with radiolucent breast cushions was investigated in one trial (Dibble 2005). For the 394 women included in the analysis, there was statistically significantly less pain in the breast that received the cushion, compared to the breast that did not (from paired t-tests). This was the case for both the CC and MLO views using either the NRS or VAS pain rating scales (pain CC view (NRS): cushion mean 2.26 (SD 2.21), no cushion mean 3.82 (SD 2.80), difference in means: 1.56 (95% CI 1.37 to 1.75), P value less than 0.001; pain CC view (VAS): cushion mean 20.34 (SD 21.27), no cushion mean 34.94 (SD 26.84), difference in means: 14.60 (95% CI 12.67 to 16.61), P value less than 0.0001; pain MLO view (NRS): cushion mean 3.02 (SD 2.33), no cushion mean 4.59 (SD 2.82), difference in means: 1.57 (95% CI 1.37 to 1.77), P value less than 0.0001; pain MLO view (VAS): cushion mean 26.42 (SD 23.04), no cushion mean 42.55 (SD 28.83), difference in means: 16.13 (95% CI 14.07 to 18.20), P value less than 0.0001). For 98% of women there was either no difference, or a clinically insignificant difference, in image quality between the mammograms taken with and without the use of cushions. However, for 2% of the women, image quality was impaired when a breast cushion was used. The authors suggested that the most likely reason for this is that the breast cushion can obscure the usual visual positioning clues that technologists use for correct breast placement on the mammography machine plate. This could also result in a less effective compression, despite the delivery of slightly more force. The authors believed that the slight possibility of reduction in image quality might limit the clinical acceptability of using breast cushions routinely during mammography. This is because, at present, an overall repeat rate of 2% or less is considered ideal (American College), and the use of cushions would increase this repeat percentage to some extent. The authors of the study stated that the acceptability of an increased repeat rate is not clear and requires further study. Additional research is required to study the effect of breast cushions on mammogram image quality. In a recent correspondence with the lead author, she reiterated that she believed a follow-up study was necessary, but had been unable to obtain funding for one.

Breast compression

Patient-controlled compression of the breast

The impact of patient-controlled compression versus technologist-controlled compression on the pain of mammography was

investigated in one trial (Kornguth 1993). There was significantly less discomfort for 31% (34 women) of the 109 women included in the study when participants controlled compression of their breast, compared to when the technologist controlled compression, regardless of who compressed the breast first (P value 0.003). For 56% of patients (61 women) there was no difference in pain experienced from these two compressions, and for the remaining 13% (14 women) self-compression was more painful than technologist-compression. A significant difference was determined only when the pain scales were collapsed to 'comfortable' versus 'uncomfortable'. The effect of the intervention on the image quality depended on whether the technologist or the patient performed the first compression. Where the technologist performed the first compression, self-compression produced as good a mammogram as technologist-controlled compression. However, when the participant compressed her breast first, the overall quality of mammograms was significantly reduced (P value 0.016).

Reduction in breast compression by the provider

There was no significant difference in discomfort experienced in the study that compared normal breast compression level with one second of reduced compression (Poulos 1997). While 23% (45 women) perceived the manipulated view (one second of reduced compression) to be less uncomfortable, 20% (39 women) rated it as more uncomfortable than the normally compressed view, and 57% (114 women) perceived no difference in discomfort. The experience was rated as 'moderate', 'considerable' or 'severe discomfort' by 29% of participants (58 women) and overall 83% (162 women) experienced some level of discomfort. The reporting radiologists did not identify any significant difference in image quality between the mammography views of the control and intervention groups.

These seven studies are all different. In three studies the intervention involved providing women with information about mammography prior to the examination. Written information was given in two studies (one of these studies also included 'reflection') and verbal information in one. The studies providing written information could not be combined in a meta-analysis as one study assessed the effect of information on pain and the other the effect on discomfort. Another study investigated the role of analgesia in reducing the pain of mammography, and a further study considered the effect of breast cushions placed on the examination plates of the mammography machine, on the pain and discomfort experienced. Two studies assessed the effect of different interventions related to breast compression on the pain of mammography. As none of the studies had a common outcome measure or a common intervention, it was not possible to combine them in a meta-analysis.

DISCUSSION

Mammography continues to be the best method available to screen for early breast cancer, and regular mammography screening is associated with a reduction in breast cancer mortality (Gotzsche 2007; Smith 2004). The pain and discomfort of the examination, however, makes mammography unacceptable to some women (Elwood 1998; McNoe 1996; Rutter 1992). Acceptability of any screening method is vital in determining the success or failure of that method. Breast screening programmes need to develop evidence-based strategies to reduce the pain and discomfort of mammography (Andrews 2001). The current evidence is as follows.

Seventeen studies were identified, of which seven were suitable for inclusion in this review. Two of the three studies that investigated the effect of providing women with information prior to the mammogram found that this significantly reduced the pain or discomfort that the women experienced during the examination. One of these studies investigated the effect of verbal information on actual discomfort compared to expected discomfort (Shrestha 2001), and the other investigated the effect of written information on perceived pain (Alimoglum 2004). The third study identified no statistically significant reduction in pain for the women who received written information and/or reflection prior to having a mammogram (Sjolin 1994); however, very few women in this study recorded the mammogram as a painful experience. Providing written and verbal information is an easy and inexpensive intervention, which may reduce the pain and discomfort of having a mammogram.

Patient-controlled compression significantly reduced the pain and discomfort of mammography, though the quality of mammograms was maintained only if the technologist controlled the first compression (Kornguth 1993). This suggests that the woman has a better idea of the compression pressure required if she has recent experience of it. Any education about the required compression was not outlined in this study, but perhaps, with a well planned and tested educational programme, women could be trained to participate actively in the mammogram examination. Giving women more control of the procedure could be the more important finding here, and, if women had more control over other aspects of the mammography process, their experience might also be improved. It is interesting to note that in Poulos' study (Poulos 1997) when the technician reduced the compression force, there was no change in women's experience of discomfort of the mammogram examination. This reduction in compression, though brief, was when the compressed breast was taut and blanched, just prior to the mammogram being taken. Any relieving of compression at this point could be expected to ease any pain or discomfort of the procedure.
However it did not. This suggests that there is more to the pain or discomfort experienced with a mammogram than just the force of the compression applied.

Use of a breast cushion significantly reduced the pain experienced in the breast that received the cushion compared to the breast that did not (Dibble 2005). For 98% of women the quality of the mammogram image was maintained when the breast cushion was used, though for 2% of the women studied image quality was impaired. The authors of the original study suggested that the impaired image quality in this 2% of participants was probably due to the lack of visual positioning clues that occasionally lead to poor positioning of the breast on the examination plate by the technologist. These authors believe that the slight possibility of reduction in image quality may limit the clinical acceptability of using the breast cushions routinely during mammography. This is because, at present, an overall repeat rate of 2% or less is considered ideal and the use of cushions would increase this repeat percentage to some extent. The authors also suggested that further research is required on the effect of breast cushions on mammogram image quality, and to identify any factors that might predispose women to cushion-induced image-quality impairment. In a recent correspondence with the lead author, she reiterated that she believed a follow-up study is necessary but she has been unable to obtain funding for such a study. Two other published studies

that investigated the effect of breast cushions were identified in our search (Markle 2004; Tabar 2004) but they were excluded because they were not randomised trials. These studies also showed a significant reduction in pain when the breast cushion was used, but their results should be interpreted with caution due to design limitations. The authors of this review believe that further studies should be carried out to investigate the effect of breast cushions on the pain and discomfort of mammography, and on the quality of the mammograms.

The study of acetoaminophen (paracetamol) as a premedication did not show any effect on the pain of mammography (Lambertz 1998), so a readily accessible analgesic, such as paracetamol, does not seem to be the answer. The preliminary results of the study of propranolol (see 'Characteristics of excluded studies table') also showed no improvement in pain or discomfort experienced, though, as it contained a small number of participants and had not been completed, the results should be interpreted carefully. A study of other readily available, over-the-counter, anti-inflammatory analgesics such as aspirin and the non-steroidal anti-inflammatories would be interesting.

Currently, there are no RCTs available that investigate the impact of the physical environment of the screening facility on the pain of mammography. In addition, interventions in the studies included in this review did not include any complementary treatments.

All of these conclusions are based on the results of single studies, some with a small number of participants, and so further studies are required to confirm the results observed.

AUTHORS' CONCLUSIONS

Implications for practice

Provision of verbal or written information about the procedure prior to a mammogram can reduce the pain and discomfort of the procedure. These are easy and inexpensive interventions to include in mammography screening.

While use of a breast cushion was shown to reduce the pain of screening mammography, a possible adverse effect on image quality for a small proportion of those women studied was concerning. Mammograms may be less painful with a breast cushion; however, their use could lead to a breast cancer being missed, or to tests needing to be repeated, because they affected image quality. The Food and Drug Administration (FDA) has approved the use of breast cushions for mammography screening in the USA. However, considering the current evidence, the authors believe that breast cushions should not be recommended for use in screening mammography programmes.

Increasing women's control over mammogram compression can reduce the pain and discomfort of this examination. More studies are required to investigate this further. If the findings were replicated, and a suitable and tested educational programme developed, women could be given the option of having more control of their own breast compression. It is unlikely that all women would choose this option; however, having the choice could improve any experience of pain or discomfort. Quality control measures to ensure quality of mammograms would, as always, be an important part of such a programme. This does raise the question about who would be answerable if breast cancers were missed, i.e. if the interval breast cancer rate rose.

The review also suggests that the use of acetoaminophen (paracetamol), a readily available over-the-counter medication, as a premedication has no effect on the pain of mammography.

All of these conclusions are based on the results of single studies and further studies are required to test the results observed.

Implications for research

More research into interventions to reduce the pain of mammography is needed if this examination is to continue as the preferred screening method in the detection of breast cancer, as the possible pain associated with it is a deterrent for many women.

Further studies on the use of breast cushions, including possible effects on image quality, are needed before breast cushions are recommended for use in screening mammography.

Patient control of breast compression can improve a woman's experience of pain of mammography. More research to test these findings is required. Research into other aspects of breast screening, particularly increasing patient input into, and control of, the process could identify further areas where a woman's experience of breast screening could be improved.

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CHARACTERISTICS OF STUDIES

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

Alimoglum 2004

Methods	Trial design: RCT. Randomisation procedure: not stated. Allocation concealment: not stated. Blinding: not stated. Drop-outs: not stated. Intention-to-treat analysis: not stated Country: Turkey
Participants	No information given about the number of women asked to participate in the study. 501 women (257 in treatment group, 244 in control group) reported on in the journal article. No information on how the groups were randomised or of any drop-outs. Mean age in the treatment group was 50.1 (SD 6.5)

Alimoglum 2004 *(Continued)*

	years and in the control group was 49.5 (SD 6.5) years. 61.8% of the participants were educated to high school level or higher.
Interventions	Group 1: an information letter given prior to the mammogram, informing the women of the necessity of compression and the reasons for the pain that they may experience during the procedure (n = 257). Group 2: usual care (n = 244).
Outcomes	1) Perceived pain marked on a 100 mm VAS with the two extremes being 0 = no pain and 100 = worst pain imaginable.
Notes	We contacted the author via email but have not yet heard back from him.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Dibble 2005

Methods	Trial design: cross-over study. Randomisation procedure: breast to receive the breast cushion and the order in which breasts were to be imaged were randomised by computer-generated random numbers with permutated blocking procedures. Allocation concealment: sealed envelopes. Blinding: subject and technologist could not be blinded, but radiologist assessing image quality was blinded. Drop-outs: nil. Intention-to-treat analysis: yes. Country: USA
Participants	415 women were invited to participate, of whom 394 agreed. The main reason given for non-participation was time constraints. 394 women were randomised; no drop-outs. The mean age of the women was 55.4 (SD 10.8) years and the majority were white/non-Hispanic (75.3%).
Interventions	Radiolucent cushions were attached to the compression paddle and film cassette holder when imaging one breast. No cushions were used when imaging the other breast. The breast to receive the cushion and the breast to image first were both randomised. Two views were taken of each breast - CC and MLO. Thus, 4 images were taken for each woman. The results for the CC and MLO views were presented separately.
Outcomes	1) Pain using an 11-point NRS. 2) Pain marked on a 10 cm VAS with the two extremes being 0 = no pain and 10 = severe pain. 3) Image quality: the radiologist directly compared the mammogram views obtained from the same woman with and without the use of cushions.
Notes	This study was of good quality and is the only study on breast cushions included in this review.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Kornguth 1993

Methods	Trial design: cross-over study. Randomisation procedure: randomised order of application of the two procedures, though the breast to be examined first was not randomised. Allocation concealment: unclear. Blinding: subject and technologist could not be blinded, but the outcome assessor (radiologist) was. Drop-outs: accounted for. Intention-to-treat analysis: yes. Country: USA
Participants	138 women invited of whom 109 women, aged 32-71 years, agreed to participate. 2 women regarded as ineligible for the study because breast lumps detected, presumably at the time of recruitment. 109 women were randomised. Women who had taken analgesics or tranquillizers on the day of the mammogram (n = 24) were included in the study. Data from one participant were not used in the results because of a 'mixed assessment of views'. Therefore 108 women completed the study. Of these 72% were 'white' and 24% 'black', 80% were employed and 52% had a college (university) education. Women were evenly distributed between pre- and post-menopausal groups.
Interventions	2-view mammogram with compression of 1 breast controlled by the technologist and compression of the other controlled by the woman being examined. The left breast was always examined first; however, the order of breast self-compression and technologist-controlled compression was determined by random assignment.
Outcomes	1) Pain of mammography assessed for each patient for self-compression and when the technologist applied the compression. Patients rated their pain on a 6-item scale that ranged from 'very comfortable' to 'painful and intolerable'. This had been used in a previous study of compression force in mammography. (Sullivan 1991). 2) Quality of the mammogram was assessed by adequacy of compression according to American College of Radiology criteria.
Notes	A very educated population of women, 24% black. 2 regarded as ineligible for the study because of breast lumps. No information given on training of the women in e.g. placement of the breast on the mammography machine plates, criteria for an adequate mammogram, compression required etc. The machine was adapted so that compression could be controlled by a handheld button instead of a foot pedal.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Lambertz 1998

Methods	Trial design: randomised, double-blind, placebo and normal care controlled study. Randomisation procedure: acetoaminophen, placebo or nothing was packaged in numbered envelopes, the numbers generated by a computer random number generator. Patients were assigned a number and attached envelope. Allocation concealment: good. Blinding: adequate for the intervention and placebo groups, but not possible for the usual care group who received no 'medication'. The outcome assessors (radiologists) were blinded. Drop-outs: accounted for. Intention-to-treat analysis: none. Analysis was on the 259 of the 265 who completed the study. 6 participants did not complete a questionnaire. Country: USA
Participants	A consecutive sample of 541 women attending Breast Cancer Detection Centre for screening mammography were invited to participate in the study, 325 agreed to do so, but 60 had a change of appointment time so were ineligible. A total of 265 women participated in the study and were randomised. However,

Lambertz 1998 *(Continued)*

	6 of those who completed the study were ineligible because of failing to complete the questionnaire, uncertain analgesic intake, or withdrawal from the study. 258 of the 259 women were accounted for at the end of the study. No explanation was given for the withdrawal. 7.8% (n = 20) of women had breast lump detected by registered nurse before the mammogram was taken and these women were still included in the study. No information was given on whether these women were aware of the presence of a breast lump at the time of the screening mammogram. In the study population: age range 29-90 years; mean age 53 years; 98% Caucasian; 80% College (university) educated. This sample believed to be representative of women scheduled at any time of year but not representative of the general USA population. Women were excluded from the study if they had difficulty understanding or communicating in English, a history of breast cancer, sensitivity to acetoaminophen, liver dysfunction, were pregnant or had taken pain relief in the previous 24 hours.
Interventions	Group 1: acetoaminophen (n = 88). Group 2: placebo (n = 85). Group 3: no intervention - usual care (n = 86). Women received acetoaminophen or placebo 42 to 103 minutes (mean 62 minutes) before mammogram.
Outcomes	1) Discomfort expected and discomfort experienced with the mammogram. Discomfort was marked on a 100 mm VAS with 0 indicating no discomfort. 2) The authors stated that none of the mammograms was judged as inadequate in any of the groups but did not give any information about whether the image quality was actually assessed.
Notes	A well educated population, 98% Caucasian, so not representative of the USA general population. Less than 50% of those initially invited participated in the study, raising the possibility of non-response bias. Inclusion of 20 women with breast lumps could affect this study, especially if these women were aware of this finding before their mammogram, when it might increase anxiety and pain levels during the examination. Furthermore, these mammograms would be more diagnostic than screening mammograms, which could affect the radiologists' approach and the criteria used in assessing these mammograms.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Poulos 1997

Methods	Trial design: cross-over study. Randomisation procedure: not stated. The only information given was: "The breast side having the manipulated view, as well as the sequence of films, was varied across subjects..." Allocation concealment: not stated. Blinding: not stated. Drop-outs: total of 200 participants; 4 did not complete the questionnaire, but only 198 accounted for in data presented. No explanation given for this. Intention-to-treat analysis: none. Country: Australia
Participants	205 women invited, 200 participated, aged 40 to 70+ years, median age 59 years, 62.5% English speaking, 37.5% non-English speaking backgrounds, attending mobile mammography unit for their first screening mammogram. No information on randomisation or drop-outs.

Poulos 1997 *(Continued)*

Interventions	2-view mammogram with normal compression to mediolateral views of both breasts and then reduced compression to the craniocaudal view for one breast (achieved by releasing the foot pedal controlling compression for approximately one second) and normal compression to the same view in the other breast.
Outcomes	Discomfort of mammography was assessed by completion of a questionnaire after the mammogram. Questionnaire included a 5-point scale of discomfort, from 'no discomfort' to severe discomfort'. Participants were asked whether they had perceived any difference in discomfort between the two craniocaudal views, i.e. the normal and manipulated views.
Notes	The intervention was vague and not standardised in any way. Measurement tools for pain and quality of mammograms were not validated. A total of 7 radiologists were involved in reading the mammograms, with 2 reading each one. It is unclear if they were blinded. Data from 198 of the original 200 participants were included for the reporting of perception of discomfort of the mammogram, together with 184 reports on image quality. There was no explanation for women lost to follow up.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Shrestha 2001

Methods	Trial design: RCT. Randomisation procedure: unclear, "Women were assigned to either the control or the experimental groups through a matching process, which involved randomly assigning a pair of women having similar characteristics." No details about these similar characteristics, or how the matched pairs were randomised were given. Allocation concealment: not stated. Blinding: not possible to blind the participants. Not clear whether technologists were blinded. Drop-outs: nil from matched pairs. Intention-to-treat analysis: yes. Country: Australia
Participants	181 women invited, 167 participated. Randomisation unclear. No drop-outs. Age range: 40-86 years. The results presented here are for a subgroup of 136 women.
Interventions	Group 1: verbal information explaining the procedure, the importance of breast compression, and assurance that only slight discomfort may be experienced (n = 68). Group 2: usual care (n = 68).
Outcomes	Actual discomfort compared to expected discomfort. Discomfort was rated on a 5-point scale: none, slight, moderate, considerable and severe discomfort. The participants rated their level of discomfort on a questionnaire - the expected level of discomfort was rated before the mammogram and the actual discomfort experienced was rated after the mammogram.
Notes	The scale that the authors used in this study was used by them in a previous study and is a scale that was adapted from Frank et al. The authors did not give any information about whether or not this scale had been validated.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Sjolin 1994

Methods	Trial design: 2 by 2 factorial design. Randomisation procedure: participants were allocated a number 1-4 in the appointment book. No information given about the method of randomisation, however, the randomisation was done before the women agreed to participate in the study and this is considered a major flaw in this study. Allocation concealment: unclear. Blinding: not possible to blind participants or technologists for the women who received reflection, as the technologists delivered that intervention. Possible to blind technologists to whether or not the women received written information, but it was not clear whether this was done. Drop-outs: described and reasons given. Intention-to-treat analysis: none. Country: Sweden
Participants	108 women randomly assigned to one of the 4 groups (n = 27 per group). 32 women did not consent to participate, and one woman who agreed to participate could not fill out the questionnaire at the end due to "asthma problems". Consequently, 75 women included in the analysis of data from this study.
Interventions	Group 1: written information about the procedure and reflection (where the nurse used words and body language to "put herself in the situation of the patient and appreciate the patient's experience of the mammogram") Group 2: reflection. Group 3: written information. Group 4: usual care.
Outcomes	Pain experienced on a 4-point scale: no pain, slight pain, painful and unbearable pain.
Notes	The randomisation of patients before they consented was a major flaw of this study. There was no information about whether or not the pain scale used by the authors had been validated.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Abbreviations
CC = craniocaudal
MLO = mediolateral oblique
n = number in experimental group
NRS = numeric rating scale
RCT = randomized controlled trial
SD = standard deviation
VAS = visual analogue scale

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

Study	Reason for exclusion
Domar 2005	This study was excluded as there was no assessment of image quality. We, the authors of this review, believe that it is possible that the quality of the image could be compromised by the wearing of headphones while undergoing mammogram examination. This is because the patient can be asked to change position, hold a position, to gain best placement of the breast on the photographic plate in order to get the best image. The aim of this study was to determine whether listening to a relaxation audiotape before and during mammography decreases subjective reports of pain and anxiety. This was a randomised controlled trial of 143 participants. The participants were randomly assigned to a group that listened

Study	Reason for exclusion
	to a relaxation tape, a group that listened to music, or to a group that listened to a blank tape (control group). Though there were no statistically significant differences among the groups on any of the assessed measures of pain and anxiety, the authors concluded that the mean levels of anxiety and pain reported by the subjects were so low that it would have been difficult for any intervention to show an effect.
Everett 2005	This study was excluded as it did not have measurements on pain or discomfort in the control group, only the intervention group. The main aim of this study was to investigate if there was an increase in breast tissue acquisition following positioning training and the use of the Mammopad, the radiolucent breast cushion. The authors believed that the comfort provided by the pad would help women relax and co-operate so that additional tissue could be acquired. Since their main focus was not on pain and discomfort, they only measured expected discomfort and experienced discomfort for the breast cushion group and not for the control group (no breast cushion).
Hendrick 2002	This study was excluded as the only available results were those from an interim analysis, and important information regarding randomisation was missing. We contacted the study author for further information, but have received no response to date. This study evaluated the effects of using radiolucent breast cushions on image quality, breast dose, positioning ease, tissue inclusion, and patient comfort. The only information available to us was an abstract detailing the results of an interim analysis with 29 subjects that was presented as a poster at a conference. This abstract reported that there was a statistically significant difference in comfort experienced with and without the breast cushion. Participants were imaged with and without breast cushions and, on a comfort scale of 1 (least) to 10 (most), the mean subject rating without breast cushions was reported as 4.2 (1.7) and with breast cushions was reported as 8.6 (1.5), P<0.00001). It was not clear from the abstract whether the numbers in brackets were standard deviations or standard errors and what statistical test was performed. It was also not evident whether the trialists randomised the breast that got the pad and, if so, how the randomisation was conducted.
Markle 2004	The main aim of this study was to determine if the use of a radiolucent cushioning pad on the mammography machine plate reduced the level of discomfort during screening mammography. This study was excluded because the first breast to be examined was always with the non-padded plate, i.e. the allocation of the use of the breast cushion was not randomised. Other outcomes that were considered included any correlation between the reduction in discomfort and clinical factors, and the pad's impact on image quality, compression force, and radiation dose. The pads were randomly placed on the left or right breast but, as stated, the non-padded images were always taken first. The mammogram consisted of images taken of the padded and non-padded breasts in both CC and MLO views. The participants were asked to rate their level of discomfort after completion of the mammogram.
Nemergut 2001	This study investigated the effect of premedication with 10 mg or 30 mg propranolol, or placebo, on pain of mammography and associated anxiety. The researchers stated that they required a sample size of 360 to acheive sufficient power for this study. The research team had difficulty with recruitment of women and were unable to complete the study. They did provide us with a preliminary report of their findings. As the study was never completed, and included only 71 women rather than the 360 required for sufficient power, it was excluded.
Poulos 2003	The aim of this study was to determine the effect of reducing compression on breast thickness, reported discomfort and image quality. Each participant had an extra film taken, in addition to their normal routine films, with a compression force reduction of 10, 20 or 30 N compared to the normal film. The selection of the breast to receive the film was determined with reference to any evidence of breast problems, pathology or soreness. If any of these were present in one breast, then that breast did not receive the extra film. The participants were only asked about their level of discomfort once and not separately for the normal film and the extra film which makes it impossible to distinguish between discomfort experienced at the normal level of compression and that experienced at the reduced level of compression. This study was excluded as the selection of the breast to re-

Study	Reason for exclusion
	ceive the extra film was not randomly assigned and separate measurements of discomfort were not obtained for the normal film and the extra film.
Tabar 2004	The aim of this study was to determine whether the use of a radiolucent cushion could significantly decrease the pain experienced during screening mammography without compromising image quality or other technical factors. This study was excluded because it was not a randomised trial, since the intervention (radiolucent cushion) was always applied when the right breast was imaged. This study had 838 participants. The radiolucent cushions were placed on the compression surfaces of the mammographic equipment and were used while imaging the right breast. No pads were used while imaging the left breast.

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

Hagen 2008

Methods	Unknown
Participants	
Interventions	
Outcomes	
Notes	

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

Lambertz 2006

Trial name or title	Premedication to reduce discomfort with screening mammography.
Methods	
Participants	
Interventions	
Outcomes	
Starting date	
Contact information	
Notes	This trial is registered as completed in the Current Controlled Trials Register. It was a randomised controlled trial that evaluated the effect of premedication with acetaminophen, ibuprofen, and topical lidocaine gel (Topicaine) on the perception of discomfort and overall satisfaction with the mammography experience. No further information is available and no response has been obtained from the study authors.

Morrow 2005

Trial name or title	Effect of a computerised intervention to reduce discomfort during mammography.
Methods	
Participants	
Interventions	
Outcomes	
Starting date	
Contact information	
Notes	This trial is registered as completed in the UK National Research Register. It was a randomised controlled trial that evaluated the effect of a computerised intervention to reduce discomfort during mammography. No further information is available and no response has been obtained from the study authors.

ADDITIONAL TABLES

Table 1. Checklist for study quality

Study	Trial design	At baseline	Randomisation	Allocation concealed	Intention-to-treat	Assessor blinding	Losses accounted for
Shrestha 2001	placebo-controlled RCT	yes - 'matched'	unclear	not stated	yes	not stated	yes - no drop-outs
Alimoglum 2004	placebo-controlled RCT	similar	not stated	not stated	not stated	not stated	not stated
Sjolin 1994	2 by 2 factorial design	unclear	yes but flawed	unclear	no	not stated	yes
Lambertz 1998	placebo-controlled RCT with normal care group	similar	yes	yes	no	yes	yes
Dibble 2005	cross-over study	same woman	yes	yes	yes	yes	yes - no drop-outs
Kornguth 1993	cross-over study	same woman	yes	unclear	yes	yes	yes
Poulos 1997	cross-over study	same woman	not stated	not stated	no	not stated	no

Table 2. Summary of results

Study	Intervention	Outcome	Scale	Result	Comments
Shrestha 2001	Verbal information prior to mammogram.	Expectation and experience of discomfort.	5-point scale; not validated.	Group that was given verbal information more likely to have lower actual discomfort than expectation compared to the control group (statistically significant).	Significant difference for first time attendees, not subsequent attendees (analysis performed separately for the two groups).
Alimoglum 2004	Written information prior to mammogram.	Pain.	VAS; validated.	Significant reduction in pain with written information.	
Sjolin 1994	Written information prior to mammogram and/or reflective comments during the procedure.	Pain.	4-point scale; not validated.	No significant difference with written information and reflection.	All women in the study experienced very little pain with mammography.
Lambertz 1998	Premedication with acetoaminophen.	Pain.	VAS and Likert scale; validated.	No significant difference.	
Dibble 2005	Breast cushion.	Pain and quality of mammogram.	VAS and 11-point scale for pain; validated. Board-certified radiologist assessors.	Significant pain reduction with breast cushion, but image quality affected in 2% of mammograms taken with breast cushion.	
Kornguth 1993	Patient-controlled compression.	Pain and quality of mammogram.	6-point scale for pain; validated. Board-certified radiologist assessors.	Mammogram with patient-controlled compression significantly less painful.	Quality of mammogram only maintained if technologist performed first compression.
Poulos 1993	Reduction in compression force of mammography machine.	Pain and quality of mammogram.	5-point scale for pain. No validation of scale. No reporting of radiologists' experience.	No significant difference in pain experienced or image quality between groups.	

APPENDICES

Appendix 1. Medline (1966 to November week 3 2006)(OVID)

1. exp Mammography/
2. mammogram.mp.

3. mammography.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
4. mammogr$.mp. [mp=title, original title, abstract, name of substance word, subject heading word]
5. breastscreen$.mp.
6. "breast screen$".mp.
7. or/1-6
8. exp Pain/
9. pain$.mp.
10. Pain Measurement/
11. (ache$ or hurt$ or sore$ or tender$ or discomfort).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
12. 8 or 9 or 11
13. 7 and 10 and 12
14. 7 and 12
15. 10 or 12
16. 7 and 15
17. limit 16 to (clinical trial or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or meta analysis or randomized controlled trial or twin study or validation studies)
18. limit 16 to yr="2004 - 2006"
19. from 18 keep 1-78
20. or/8-10
21. 7 and 20
22. breast neoplasms/
23. 21 not 22

WHAT'S NEW

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

HISTORY

Protocol first published: Issue 1, 2001
Review first published: Issue 4, 2002

Date	Event	Description
14 November 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Dawn Miller developed the project. She was joined by Isobel Martin in working on the protocol, overseeing the literature search and selection, then data collection and analysis for the original review. Peter Herbison also assisted with development of the protocol, was the arbiter on questions of selection, and advised on data analysis. Dawn Miller wrote the original review with editorial assistance from both Isobel and Peter. For this, the first update, Dawn Miller and Vicki Livingstone completed the literature search, critiqued the identified studies, and selected and analysed those that met the inclusion criteria. Peter Herbison acted as arbiter. Composition of this updated review was done by Vicki Livingstone with editorial assistance from Dawn Miller and Peter Herbison.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

- Dunedin School of Medicine, University of Otago, New Zealand.

External sources

- No sources of support supplied

NOTES

This review was updated for Issue 1, 2008. The main changes are that:
(1) The search has been updated to May 2006.
(2) Three newly-identified studies have been included (Alimoglum 2004; Dibble 2005; Shrestha 2001).
(3) One study has been added to 'Studies awaiting assessment' (Hagen 2008).
(4) Two studies have been added to 'Ongoing studies' (Lambertz 2006, Morrow 2005).
(5) In the original review, studies were excluded if they did not have an assessment of the quality of the mammogram. The authors of this review update considered that to be too restrictive, and so now, and in the future, studies that did not have an assessment of quality will be included if the intervention could not have impacted on the quality of the mammogram (e.g. verbal or written information). Consequently, one study that was excluded previously, due to non-assessment of image quality, is now included (Sjolin 1994). The intervention in this trial was written information, which could not have impacted on the quality of the mammograms.

INDEX TERMS

Medical Subject Headings (MeSH)

Acetaminophen [therapeutic use]; Analgesics, Non-Narcotic [therapeutic use]; Mammography [*adverse effects] [standards]; Pain [*prevention & control]; Patient Education as Topic; Premedication; Pressure; Quality Control; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans