Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour (Review)

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This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2010, Issue 6

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[Intervention Review]

Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

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Editorial group: Cochrane Pregnancy and Childbirth Group.
Publication status and date: New, published in Issue 6, 2010.
Review content assessed as up-to-date: 29 March 2010.

Citation: Alexander S, Boulvain M, Ceysens G, Haelterman E, Zhang WH. Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour. *Cochrane Database of Systematic Reviews* 2010, Issue 6. Art. No.: CD005940. DOI: 10.1002/14651858.CD005940.pub2.

ABSTRACT

Background

Repeat digital cervical assessment (RDCA - examination of the cervix with a finger) has been promoted as a routine intervention in the antenatal clinic as a screening test for the risk of preterm birth (that is, birth occurring before 37 weeks of gestation).

Objectives

To assess the effect of repeat digital cervical assessment during pregnancy for the risk of preterm birth and other adverse effects for mother and baby.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (September 2009) and CENTRAL (*The Cochrane Library* 2009, Issue *3*).

Selection criteria

All known randomized clinical trials comparing repeat digital cervical assessment with internal examination limited to clinical indication or no internal examination. We have not included studies where repeat cervical assessment is only a component of complex interventions targeted at decreasing preterm birth.

Data collection and analysis

We evaluated relevant studies for meeting the inclusion criteria and methodological quality without considering their results. Three review authors extracted the data. For all data analyses, we entered data based on the principle of intention to treat. We calculated odds ratios and 95% confidence intervals for dichotomous data.

Main results

We included two trials that enrolled a total of 7163 women. Preterm birth before 37 weeks, was reported in both trials. The odds ratio for birth before 37 weeks was 1.05 (95% confidence interval 0.85 to 1.31; two trials, 6070 women). One trial (involving 5836 women) found no significant difference between the two treatment arms for the following outcomes: preterm birth before 34 weeks; preterm, prelabour rupture of membranes; hospital admission before 37 weeks; caesarean section; use of tocolytic drugs; low birthweight; very low birthweight, stillbirth, neonatal death, neonatal intensive care admissions; use of health services. The other prespecified outcomes were not evaluated in the included studies. We did not conduct the planned subgroup analyses due to insufficient data.

Authors' conclusions

We found no evidence to support the use of RDCA in pregnancy to reduce the prevalence of preterm birth. We have found insufficient evidence to assess adverse effects of the intervention.

PLAIN LANGUAGE SUMMARY

Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Routine digital vaginal examination (examination of the cervix with a finger) during pregnancy, used to reduce the prevalence of preterm birth, is not supported by evidence from randomized controlled trials. Preterm labour is often preceded by changes in the cervix although the woman does not experience any symptoms. Effective detection and appropriate management of risk of preterm birth is key to improved care. Repeat digital cervical assessment is a simple inexpensive technique that uses a disposable glove and takes only one or two minutes to complete. It has been promoted as a routine intervention during pregnancy as a screening test for the risk of preterm birth (that is, birth occurring before 37 weeks of gestation), which can then be managed. It is in standard use in many parts of Europe, Africa and to a lesser extent in the US.

The review included two randomized controlled trials that enrolled a total of 7163 pregnant women. The number of women experiencing preterm birth was similar with and without routine digital vaginal examination when it was not medically indicated. One was a multicentre performed in countries where the intervention was routine and in countries where it was not. Causes for concern included the potential risk of infection and preterm labour from the vaginal examination as well as discomfort and embarrassment for the woman. We have found insufficient evidence to assess adverse effects of the intervention.

BACKGROUND

Rationale for performing vaginal examination before term

The main reason repeat digital cervical assessment (RDCA - examination of the cervix with a finger) has been promoted as a routine intervention in the antenatal clinic is as a screening test for the risk of preterm birth (that is, birth occurring before 37 weeks of gestation).

Preterm birth and treatment of threatened preterm labour

Preterm birth occurs in around 5% to 10% of all pregnancies. Most neonatal deaths (up to 75%) will occur in this group. It is often suggested that effective detection and appropriate management of preterm risk is a key to improved perinatal outcome. Numerous interventions have been used, either for decreasing the risk of preterm birth or for the management of preterm labour. Some of these have been shown to be effective in Cochrane systematic reviews (screening and treating asymptomatic bacteriuria (Smaill 2001)) and some tocolytics (medications intended to reduce uterine contractions), such as betamimetics (Anotayanonth 2004) and calcium channel blockers (King 2003). Others have not been proven useful, such as oxytocin receptor antagonists (Papatsonis 2005), antibiotics (McDonald 2005; Raynes-Greenow 2004), bed rest (Sosa 2004) or magnesium sulphate (Crowther 2002). Two major concerns remain, even with drugs which are effective: side

effects, and the fact that they are only useful for a short time (48 hours), thereby allowing sufficient time to administer steroids to the mother for enhancement of fetal pulmonary maturation (Roberts 2006).

RDCA as a screening test and the geographical distribution of its use

Despite the lack of long-term effective treatment, screening for preterm birth remains an important activity in many parts of the Western world (Goffinet 2005). This attempt at screening includes diverse methods, such as risk scoring, RDCA, home monitoring (Brown 1999) or, more recently, cervical fibronectin (Honest 2002) and ultrasonographic assessment of the cervix (Berghella 2005; Rust 2005). The fact that in normal-term birth the cervix will change before labour starts is the basis for the use of RDCA as screening test. Proponents of RDCA believe that preterm labour will also be regularly preceded by asymptomatic changes in cervical length, consistency, position or dilatation.

Digital cervical assessment or vaginal examination performed on repeated occasions at the antenatal clinic has been adopted at very different levels in the Western world. A *Lancet* editorial in 1988 (Anonymous 1988) dismissed it as being 'probably valueless' even on a single occasion.

On the other side of the channel, Emile Papiernik (Papiernik 1986; Papiernik 2004) introduced a technique for preventing preterm births which involves systematic screening (risk score and RDCA) offered to all pregnant women, leading the caregiver giving advice to make changes to the women's daily work pattern or lifestyle. This policy was evaluated by the French National Institute of Health (INSERM) and showed a progressive reduction from 8.6% to 5.4% in the rates of preterm births from 1972 to 1988 (Papiernik 1999). The reduction was not observed if a major risk factor was present, such as the history of a previous preterm birth or a late spontaneous abortion; not observed for twin pregnancies; and not observed for women who had an episode of bleeding during the index pregnancy. But a significant reduction of preterm births was observed for the women with middle-level risk factors, for example those related to hard, physically demanding jobs. The program involved many different interventions, with RDCA only a single component, hence it is unclear whether the reduction in preterm birth incidence was due to RDCA.

Performing RDCA and characteristics of the test

RDCA is a simple technique using a disposable glove and takes only one or two minutes to complete. The assessment of the cervix is usually made according to the cervical criteria proposed by Bishop in 1964 (Bishop 1964) involving cervical length, position, consistency and dilatation. In Germany, Belgium and France, it is usual to perform digital cervical assessment at each antenatal visit (Langer 1999). More recently, the cervix has also been assessed ultrasonographically. In the preterm setting this may provide some additional information beyond the digital examination, though there is some debate about this (Rozenberg 2004). The ultrasound technique will not be included in this review as it is covered by another Cochrane review (Berghella 2009).

The characteristics of RDCA as a test performed in average-risk pregnancies have been assessed in published studies. The fact that clinicians were not blinded means that some distortion of the predictive properties is possible. Notwithstanding this limitation, these studies show that there is an increased likelihood of preterm delivery in the presence of changes of the cervix (Blondel 1990; Hartmann 1999). Similar predictive values (35% to 37% at 22 to 24 weeks) for fibronectin, ultrasonographic assessment and digital examination were observed by Iams (Iams 2002).

Action on finding an abnormal digital cervical assessment

The rationale for RDCA is that, in some pregnancies, the cervix will efface or dilate, or both, without the woman experiencing any symptoms; the detection by the care provider of asymptomatic cervical change should be followed by further action. These might include further testing, such as assessment of uterine activity with a cardiotocograph, fibronectin testing or ultrasonographic assessment of the cervix. Electromyography and cervical distensibility (cervicotonometer) are being researched. Some intervention will then be offered, starting with leave from work, decreased activity, oral treatment or even hospital admission and tocolytic drugs. French obstetricians report that the global package, which was introduced in the early 1970s and included routine repeat vaginal examination, was instrumental in decreasing preterm birth (Breart 1995). A randomized trial of this global intervention in the March of Dimes project in the US was not able to replicate the French success (Anonymous 1993).

Possible risks and acceptability to women

Causes for concern are multiple. They include the potential risk from the vaginal examination as well as discomfort and embarrassment for the woman. The main concern in relation to the pregnancy is that vaginal examination could, per se, increase the risk of preterm labour or preterm rupture of membranes either directly or by modification of the vaginal flora. The flora of the lower third of the vagina differs from that in the upper part, and contains more organisms from the perineum and rectum. The theoretical concern is that the digital examination might cause colonization of the upper part of the vagina with organisms from the lower part, and that these organisms in turn might cause infection. Observational studies suggest that once membranes are ruptured, digital examination will decrease the time lag to birth (Lewis 1992), but that

this is not the case with intact membranes (Holbrook 1987). No observational studies were found which showed poor outcomes in relation to RDCA.

Regarding women's personal feelings in relation to digital examination, these seem to vary. In the United Kingdom, vaginal examination is perceived as essentially different from other skin-to-skin examinations that a doctor might perform, such as abdominal palpation or inspection of the oropharynx. This presumably is the reason why 68% of male general practitioners (GPs) and 5% of female GPs offer a chaperone (Rosenthal 2005). This does not seem to be the case in continental Europe, where chaperones are uncommon. No studies about women's perception of RDCA were found. The only case study we found was of women in labour from Hong Kong (Ying 2002) who reported that, providing they understood the potential benefit of the examination (in labour), they accepted it without difficulty.

The systematic review

In the context of geographical variation of practice, this review was conducted to address whether this method is useful to identify risk of preterm birth in time for effective interventions. It is important that, however inexpensive the test may be, it is not performed unless it proves to do more good than harm. This review did not explore trials of complex interventions targeted at decreasing preterm birth, in which RDCA was a component.

OBJECTIVES

To assess the effect of repeat digital cervical assessment during pregnancy for the risk of preterm birth and other adverse effects for mother and baby.

METHODS

Criteria for considering studies for this review

Types of studies

All known randomized clinical trials (RCTs) comparing repeat digital cervical assessment with internal examination limited to clinical indication or no internal examination. We have not included studies where repeat cervical assessment is only a component of complex interventions targeted at decreasing preterm birth. We have also included quasi-randomized trials.

Types of participants

All pregnant women.

Types of interventions

Repeat digital cervical assessment all through pregnancy.

Types of outcome measures

Primary outcomes

1. Preterm birth
2. Preterm, prelabour rupture of membranes

Secondary outcomes

Maternal outcomes

1. Maternal satisfaction as defined by trial authors
2. Maternal anxiety as defined by trial authors
3. Chorioamnionitis
4. Hospital admission before 37 weeks
5. Use of health services (number of cardiotocographic recordings, number of ultrasounds)
6. Caesarean delivery
7. Vacuum or forceps delivery
8. Use of tocolytic drugs

Fetal and neonatal outcomes

1. Intrauterine growth restriction
2. Birthweight
3. Five-minute Apgar score less than seven
4. Umbilical arterial pH less than 7.2
5. Stillbirth
6. Neonatal infection*
7. Neonatal death
8. Neonatal intensive care unit admission
9. Ventilation
10. Hypoxic ischaemic encephalopathy
11. Respiratory distress syndrome
12. Length of stay in neonatal intensive care unit

* outcome not prespecified in the protocol.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (September 2009).

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.

In addition, we searched CENTRAL (*The Cochrane Library* 2009, Issue 3) using the search strategy listed in Appendix 1.

Searching other resources

We searched the reference lists of relevant papers.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

Three review authors (Sophie Alexander, Weihong Zhang and Gilles Ceysens) independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We resolved any disagreement through discussion.

Data extraction and management

We designed a form to extract data. For eligible studies, Gilles Ceysens extracted the data using the agreed form. We entered data into Review Manager software (RevMan 2008) and checked for accuracy.

When information regarding any of the above was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Three review authors (Sophie Alexander, Weihong Zhang and Gilles Ceysens) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008). We resolved any disagreement by discussion.

(1) Sequence generation (checking for possible selection bias)

We describe 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);
- unclear.

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

We describe for each included study the method used to conceal the allocation sequence in sufficient detail and determine 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 randomization; 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 describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We have 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 have assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

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

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We describe 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 randomized participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses which we undertook.

We assessed methods as:

- adequate; 10% or less missing data;
- inadequate; greater than 10% missing data;
- unclear.

(5) Selective reporting bias

We describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

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

(6) Other sources of bias

We describe for each included study any important concerns we have about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- yes;
- no;
- unclear.

(7) Overall risk of bias

We made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2008). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we present results as odds ratio with 95% confidence intervals.

Continuous data

For continuous data, we used the mean difference if outcomes are measured in the same way between trials. We used the standardized mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomized trials

If cluster-randomized trials are identified in subsequent updates of this review, we will include these in the analyses along with individually randomized trials. We will adjust their sample sizes using the methods described in the *Handbook* using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), or from another source (Donner 2001). 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-randomized trials and individually-randomized trials, we plan to synthesize 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 randomization unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomization unit and perform a separate meta-analysis.

Dealing with missing data

For included studies, we have noted levels of attrition. We have explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using Sensitivity analysis.

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

Assessment of heterogeneity

We used the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identified substantial heterogeneity (I^2 greater than 50%), we explored it by prespecified subgroup analysis.

Assessment of reporting biases

We were not able to contact Mortensen for further information on the lack of balance between the groups III and IV.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2008). We used fixed-effect inverse variance meta-analysis for combining data where trials are examining the same intervention, and we judged the trials' populations and methods sufficiently similar. Where we suspected clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects may differ between trials, we used random-effects meta-analysis.
If we identified substantial heterogeneity in a fixed-effect meta-analysis, we have noted this and repeated the analysis using a random-effects method.
We have not included outcomes where missing data are greater than 10% in the analysis.

Subgroup analysis and investigation of heterogeneity

In subsequent updates of this review, as data become available, we will carry out subgroup analyses by risk factors for preterm birth and will restrict the outcomes to primary outcomes alone.
For fixed-effect meta-analyses, we will conduct planned subgroup analyses classifying whole trials by interaction tests as described by Deeks 2001. For random-effects meta-analyses, we will assess differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis

We have only included two trials; we performed sensitivity analysis, which did not change the results. In future updates, if additional data become available, we will perform sensitivity analyses where possible to assess the quality of included trials.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.
The search yielded five trials for consideration; we included two and excluded three. Referees identified two additional studies, but these did not meet our inclusion criteria as they were not RCTs (Leveno 1986; Stubbs 1986).

Included studies

Two trials, involving 7163 women, met the inclusion criteria. Buekens 1994 in a multicenter RCT included 2521 women in the intervention group and 2520 in the control group. Mortensen 1987 allocated 1327 women into four groups. Women with obstetrical and/or gynaecological complications or in situations of physical and psychological stress in a previous pregnancy were allocated to group I. Group II consisted of women with complications during the first 24 weeks of gestation in the current pregnancy. The pregnancy was considered complicated in women with haemorrhage, urinary tract infections, painful contractions, or twins. The remainder were randomly divided into a cervically evaluated group (group III) and a control group without cervical screening (group IV). In group I, II and III, evaluation of the cervix was performed at weeks 24, 28 and 32. No cervical screening was done in group IV. We have only included in this review the women of group III (intervention, 581 women) and group IV (control 448 women) because women from the groups I and II were not randomized.
Buekens 1994 included women before 20 weeks of pregnancy. The intervention was to attempt digital cervical examination at every prenatal visit and the controls were to avoid such examinations, except where medically indicated. Mortensen 1987 included women at the first antenatal visit in the first trimester. *See* Characteristics of included studies for further details.

Excluded studies

We excluded three trials (Jenniges 1990; Lenihan 1984; McDuffie 1992; Sivkin 1988) because the intervention started at 37 weeks of pregnancy. *See* Characteristics of excluded studies for further details.

Risk of bias in included studies

We considered generation of the allocation sequence adequate in the trial by Buekens (Buekens 1994) and inadequate in the study by Mortensen (Mortensen 1987), who used the date of birth. Nevertheless, we included the study because it was unlikely that it would introduce a bias in the outcomes evaluated. Additionally, there was 2.9% and 2.7% of miscarriage in the intervention and the control groups respectively.

Allocation

In Buekens 1994, computer-generated randomization sets in individually sealed envelopes of thick paper were prepared for each centre at the central coordinating unit. Mortensen 1987 "randomly divided in accordance to date of birth", a method which precludes allocation concealment.

Blinding

In the context of type of intervention, blinding of the caregiver or the participant was not possible.

Incomplete outcome data

Both included studies included all outcome data because the losses to follow up were low. In the trial by Buekens 1994, there were 4% losses to follow up in both groups. Mortensen 1987 did not report losses to follow up.

Selective reporting

We found no indication of selective reporting as required in the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.0.1 (Higgins 2008).

Other potential sources of bias

Mortensen 1987 had an imbalance in the number of women included in the two groups that was explained by the author by the design of the study. The women in the group "no cervical examination" were given "no special attention" (sic). It is thus possible that some preterm deliveries were not included. To evaluate this possibility, all medical records of preterm birth in the county during the study period were studied retrospectively.

Effects of interventions

The difference in preterm birth rate between the two included studies (2% in Mortensen 1987 versus 6% in Buekens 1994) is probably due to the design of the Mortensen 1987 study, which randomized only low-risk women. We found no substantial heterogeneity. The only outcome that was reported in both trials was preterm birth before 37 weeks. The odds ratio for this outcome was 1.05 (95% confidence interval (CI) 0.85 to 1.31; 2 studies, 6070 women). There was no substantial heterogeneity.

Eleven other prespecified outcomes were evaluated in Buekens 1994 and there was no difference between the two arms: preterm birth at less than 34 weeks; preterm, prelabour premature rupture of the membranes; hospital admission before 37 weeks; caesarean deliveries; use of tocolytic drugs; low birthweight; very low birthweight; stillbirth; neonatal death; neonatal intensive care unit (NICU) admission; and use of health services.

The following prespecified outcomes were not reported in the included studies: maternal satisfaction; maternal anxiety; chorioamnionitis; vacuum or forceps delivery; intrauterine growth restriction; Apgar score less than seven at five minutes; ventilation; hypoxic ischaemic encephalopathy; respiratory distress syndrome; and length of stay in NICU.

DISCUSSION

We found no evidence to support the use of routine digital vaginal examination (RDCA - examination of the cervix with a finger) in pregnancy to reduce the prevalence of preterm birth. In fact, this intervention has not been in use in many parts of the world for many years. However, it is in standard use in many parts of Europe, Africa and to a lesser extent in the US. We have found insufficient evidence to assess adverse effects of the intervention.

All of the outcomes assessed but one (birth before 37 weeks) rely solely on one study (Buekens 1994). The study was multicentric and performed in countries where the intervention was routine and in countries where it was not. In addition, prevalence of prematurity in countries which perform RDCA and those that do not, does not suggest any influence of this intervention (Buitendijk 2003).

AUTHORS' CONCLUSIONS

Implications for practice

The results from this systematic review show that routine digital cervical assessment in the absence of clinical indication is not useful. We have found insufficient evidence to assess adverse effects. Clinicians who are not performing RDCA should not change their practice, whereas those who perform it may consider modifying their practice.

Implications for research

Even though this review relies mainly on one trial, the results are considered to be robust. In addition, prevalence of prematurity among countries which perform RDCA and those which do not, does not suggest any influence of this intervention. As the studies included in this review have been conducted in high-income settings where the prevalence of complications is low, it might be useful to replicate the study in low-income settings where the prevalence of prematurity and complications is higher.

ACKNOWLEDGEMENTS

The authors acknowledge the assistance of the Pregnancy and Childbirth Review Group editorial base in the preparation of this review.

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

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Buekens 1994

Methods	Multicenter randomized controlled trial. Computer-generated randomization sets in individually sealed envelopes of thick paper were prepared for each centre at the central coordinating unit
Participants	All women booked for prenatal care in seven European countries (Belgium, Denmark, Hungary, Ireland, Italy, Portugal, Spain). Reasons for exclusion (before randomization) were: booking after 20 weeks, patient refusal, or clinician's decision not to randomize for medical or other reasons. There was no consensus about medical contraindications to randomization, and the decision to exclude a woman on medical grounds was left to the clinician
Interventions	To attempt digital cervical examination at every prenatal visit (intervention): 2920 women. To avoid such examinations, except where medically indicated (control): 2916 women
Outcomes	Preterm birth (before 37 weeks and before 34 weeks), preterm premature rupture of the membranes (before 37 weeks), hospital admission before 37 weeks, caesarean deliveries, use of tocolytic drugs, use of health services (number of cardiotocographic recordings; number of ultrasound), low birthweight (< 2500 g), very low birth weight (< 1500 g), stillbirth, early neonatal death, neonatal intensive care unit admission
Notes	

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer generated.
Allocation concealment?	Yes	Computer-generated randomization sets in individually sealed envelopes of thick paper were prepared for each centre at the central coordinating unit
Blinding? All outcomes	No	Due to the nature of the intervention.
Incomplete outcome data addressed? All outcomes	Yes	4% were lost to follow up in each group.
Free of selective reporting?	Yes	We found no indication of selective reporting as required in the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.0.1.

Buekens 1994 (*Continued*)

Free of other bias?	Yes	We found no indication of other bias as required in the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.0.1.

Mortensen 1987

Methods	Quasi-randomized controlled trial. Allocation group was according to date of birth.
Participants	All women delivered in the county of Skaraborg in 1982 were recruited during 7 months (1526 women) at their first antenatal clinic in the first trimester. 199 were excluded as they subsequently moved to other areas, had a miscarriage or had an incomplete examination according to the protocol, leaving 1327 women. Women with obstetrical and/or gynaecological complications or in situations of physical and psychological stress in a previous pregnancy were allocated to group I. Group II consisted of women with complications during the first 24 weeks of gestation in the current pregnancy. The pregnancy was considered complicated in women with haemorrhage, urinary tract infections, painful contractions, or twins. The remainder were randomly divided into a cervically evaluated group (group III) and a control group without cervical screening (group IV) . In group I, II and III, evaluation of the cervix was performed at weeks 24, 28 and 32 weeks. No cervical screening was done in group IV We have only included in this review the women of group III (intervention, 581 women) and group IV (control 448 women) because women from the groups I and II were not randomized
Interventions	Group 3: cervical screening. Group 4: no cervical screening.
Outcomes	Preterm birth (< 37 weeks).
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Randomization by date of birth.
Allocation concealment?	No	No concealment of allocation possible when randomization by date of birth
Blinding? All outcomes	No	Due to the nature of the intervention.
Incomplete outcome data addressed? All outcomes	Unclear	No losses to follow up were reported.

Mortensen 1987 (*Continued*)

Free of selective reporting?	Yes	We found no indication of selective reporting as required in the *Cochrane Handbook for Systematic Reviews of Interventions* version 5.0.1.
Free of other bias?	Unclear	The imbalance between the 2 groups was justified by the author by the design of the study

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

Study	Reason for exclusion
Jenniges 1990	The intervention started at 37 weeks of pregnancy.
Lenihan 1984	The intervention started at 37 weeks of pregnancy.
McDuffie 1992	The intervention started at 37 weeks of pregnancy.
Sivkin 1988	The intervention started at 37 weeks of pregnancy.

DATA AND ANALYSES

Comparison 1. Systematic digital cervical examination versus no examination unless medically indicated

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Preterm birth < 37 weeks	2	6070	Odds Ratio (M-H, Fixed, 95% CI)	1.05 [0.85, 1.31]
2 Preterm birth < 34 weeks	1	5041	Odds Ratio (M-H, Fixed, 95% CI)	0.93 [0.65, 1.34]
3 Preterm premature rupture of the membranes	1	5364	Odds Ratio (M-H, Fixed, 95% CI)	1.03 [0.92, 1.17]
4 Maternal satisfaction	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
5 Maternal anxiety	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
6 Chorioamniotitis	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
7 Hospital admission before 37 weeks	1	5440	Odds Ratio (M-H, Fixed, 95% CI)	1.13 [1.00, 1.28]
8 Caesarean deliveries	1	5365	Odds Ratio (M-H, Fixed, 95% CI)	1.10 [0.93, 1.29]
9 Vacuum/forceps	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
10 Use of tocolytic drugs	1	5440	Odds Ratio (M-H, Fixed, 95% CI)	1.08 [0.89, 1.31]
11 IUGR	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
12 Low birthweight	1	5371	Odds Ratio (M-H, Fixed, 95% CI)	0.85 [0.69, 1.04]
13 Very low birthweight	1	5371	Odds Ratio (M-H, Fixed, 95% CI)	0.81 [0.53, 1.24]
14 Apgar score < 7 at 5 minutes	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
15 pHa < 7.20	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
16 Stillbirth	1	5490	Odds Ratio (M-H, Fixed, 95% CI)	1.09 [0.61, 1.95]
17 Neonatal death	1	5444	Odds Ratio (M-H, Fixed, 95% CI)	1.47 [0.76, 2.84]
18 NICU admission	1	5329	Odds Ratio (M-H, Fixed, 95% CI)	1.09 [0.93, 1.27]
19 Ventilation	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
20 Hypoxic ischaemic encephalopathy	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
21 Respiratory distress syndrome	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
22 Length of stay in NICU	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
23 Use of health services	1	5440	Odds Ratio (M-H, Fixed, 95% CI)	1.14 [1.00, 1.30]

Analysis 1.1. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 1 Preterm birth < 37 weeks.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 1 Preterm birth < 37 weeks

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	169/2521	161/2520		93.8 %	1.05 [0.84, 1.32]
Mortensen 1987	12/581	9/448		6.2 %	1.03 [0.43, 2.46]
Total (95% CI)	**3102**	**2968**		**100.0 %**	**1.05 [0.85, 1.31]**

Total events: 181 (Intervention), 170 (Control)

Heterogeneity: $Chi^2 = 0.00$, df = 1 (P = 0.96); $I^2 = 0.0\%$

Test for overall effect: Z = 0.45 (P = 0.65)

Analysis 1.2. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 2 Preterm birth < 34 weeks.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 2 Preterm birth < 34 weeks

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	57/2521	61/2520		100.0 %	0.93 [0.65, 1.34]
Total (95% CI)	**2521**	**2520**		**100.0 %**	**0.93 [0.65, 1.34]**

Total events: 57 (Intervention), 61 (Control)

Heterogeneity: not applicable

Test for overall effect: Z = 0.37 (P = 0.71)

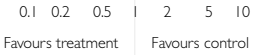
Analysis 1.3. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 3 Preterm premature rupture of the membranes.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 3 Preterm premature rupture of the membranes

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	728/2686	709/2678		100.0 %	1.03 [0.92, 1.17]
Total (95% CI)	**2686**	**2678**		**100.0 %**	**1.03 [0.92, 1.17]**
Total events: 728 (Intervention), 709 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.52 (P = 0.60)					



Analysis 1.7. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 7 Hospital admission before 37 weeks.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 7 Hospital admission before 37 weeks

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	685/2719	626/2721		100.0 %	1.13 [1.00, 1.28]
Total (95% CI)	**2719**	**2721**		**100.0 %**	**1.13 [1.00, 1.28]**
Total events: 685 (Intervention), 626 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.89 (P = 0.059)					

Analysis 1.8. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 8 Caesarean deliveries.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 8 Caesarean deliveries

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	348/2683	321/2682		100.0 %	1.10 [0.93, 1.29]
Total (95% CI)	**2683**	**2682**		**100.0 %**	**1.10 [0.93, 1.29]**
Total events: 348 (Intervention), 321 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.11 (P = 0.27)					

Analysis 1.10. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 10 Use of tocolytic drugs.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 10 Use of tocolytic drugs

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	223/2719	208/2721		100.0 %	1.08 [0.89, 1.31]
Total (95% CI)	**2719**	**2721**		**100.0 %**	**1.08 [0.89, 1.31]**
Total events: 223 (Intervention), 208 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.76 (P = 0.45)					

Analysis 1.12. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 12 Low birthweight.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 12 Low birthweight

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	177/2688	206/2683		100.0 %	0.85 [0.69, 1.04]
Total (95% CI)	**2688**	**2683**		**100.0 %**	**0.85 [0.69, 1.04]**
Total events: 177 (Intervention), 206 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.56 (P = 0.12)					

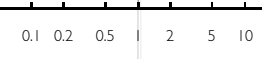
Analysis 1.13. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 13 Very low birthweight.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 13 Very low birthweight

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	39/2688	48/2683		100.0 %	0.81 [0.53, 1.24]
Total (95% CI)	**2688**	**2683**		**100.0 %**	**0.81 [0.53, 1.24]**
Total events: 39 (Intervention), 48 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.98 (P = 0.33)					



Analysis 1.16. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 16 Stillbirth.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 16 Stillbirth

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	24/2744	22/2746		100.0 %	1.09 [0.61, 1.95]
Total (95% CI)	**2744**	**2746**		**100.0 %**	**1.09 [0.61, 1.95]**
Total events: 24 (Intervention), 22 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.30 (P = 0.77)					

Analysis 1.17. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 17 Neonatal death.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 17 Neonatal death

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	22/2720	15/2724		100.0 %	1.47 [0.76, 2.84]
Total (95% CI)	**2720**	**2724**		**100.0 %**	**1.47 [0.76, 2.84]**
Total events: 22 (Intervention), 15 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.15 (P = 0.25)					

Analysis 1.18. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 18 NICU admission.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 18 NICU admission

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	362/2659	338/2670		100.0 %	1.09 [0.93, 1.27]
Total (95% CI)	**2659**	**2670**		**100.0 %**	**1.09 [0.93, 1.27]**
Total events: 362 (Intervention), 338 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.03 (P = 0.30)					

Analysis 1.23. Comparison 1 Systematic digital cervical examination versus no examination unless medically indicated, Outcome 23 Use of health services.

Review: Repeat digital cervical assessment in pregnancy for identifying women at risk of preterm labour

Comparison: 1 Systematic digital cervical examination versus no examination unless medically indicated

Outcome: 23 Use of health services

Study or subgroup	Intervention n/N	Control n/N	Odds Ratio M-H,Fixed,95% CI	Weight	Odds Ratio M-H,Fixed,95% CI
Buekens 1994	2193/2719	2137/2721		100.0 %	1.14 [1.00, 1.30]
Total (95% CI)	**2719**	**2721**		**100.0 %**	**1.14 [1.00, 1.30]**
Total events: 2193 (Intervention), 2137 (Control)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.94 (P = 0.053)					

APPENDICES

Appendix 1. CENTRAL search strategy

#1 (cervi* near exam*) or (cervi* near assess*)
#2 digital near exam*
#3 vagina* near exam*
#4 pelvic near exam*
#5 pregnan* or antenatal* or prenatal* or antepart*
#6 (preterm or premature) near (labor or labour)
#7 pregnancy (explode MeSH)
#8 pregnancy complications (explode MeSH)
#9 (#1 or #2 or #3 or #4)
#10 (#5 or #6 or #7 or #8)
#11 (#9 and #10)

HISTORY

Protocol first published: Issue 2, 2006

Review first published: Issue 6, 2010

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

CONTRIBUTIONS OF AUTHORS

Sophie Alexander (SA) developed the idea and wrote the first draft of the protocol. SA, Gilles Ceysens (GS) and Wei-Hong Zhang (WHZ) worked collaboratively in the development of the protocol, performing a background literature search and making editorial amendments. SA, WHZ and GC independently assessed studies for inclusion and assessed trial quality. Gilles Ceysens performed data extraction. Michel Boulvain and Edwige Haelterman-Breinessen provided general advice on the protocol and the review.

DECLARATIONS OF INTEREST

Sophie Alexander was co-author of the Buekens 1994 included study. Trial assessment and data extraction for this trial was carried out independently by two members of the review team who were not involved in the study.

SOURCES OF SUPPORT

Internal sources

- Université Libre de Bruxelles (ULB) - School of Public Health, Belgium.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The methods section has been updated in accordance with the Cochrane Pregnancy and Childbirth Group's updated methods. We have added 'neonatal infection' as a secondary outcome in response to referee comments and the editor's recommendation. We have added a quasi-randomized study because it was unlikely that it would introduce a bias in the outcomes evaluated.

INDEX TERMS

Medical Subject Headings (MeSH)

*Cervix Uteri; Obstetric Labor, Premature [*diagnosis; prevention & control]; Palpation [*methods]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy