External cephalic version for breech presentation at term (Review)

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TABLE OF CONTENTS

[Intervention Review]

External cephalic version for breech presentation at term

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ABSTRACT

Background

Management of breech presentation is controversial, particularly in regard to manipulation of the position of the fetus by external cephalic version (ECV). ECV may reduce the number of breech presentations and caesarean sections, but there also have been reports of complications with the procedure.

Objectives

The objective of this review was to assess the effects of ECV at or near term on measures of pregnancy outcome. Methods of facilitating ECV, and ECV before term are reviewed separately.

Search methods

We searched the Cochrane Pregnancy and Childbirth Trials Register (28 February 2015) and reference lists of retrieved studies.

Selection criteria

Randomised trials of ECV at or near term (with or without tocolysis) compared with no attempt at ECV in women with breech presentation.

Data collection and analysis

Two review authors assessed eligibility and trial quality, and extracted the data.

Main results

We included eight studies, with a total of 1308 women randomised. The pooled data from these studies show a statistically significant and clinically meaningful reduction in non-cephalic presentation at birth (average risk ratio (RR) 0.42, 95% confidence interval (CI) 0.29 to 0.61, eight trials, 1305 women); vaginal cephalic birth not achieved (average RR 0.46, 95% CI 0.33 to 0.62, seven trials, 1253 women, evidence graded very low); and caesarean section (average RR 0.57, 95% CI 0.40 to 0.82, eight trials, 1305 women, evidence graded very low) when ECV was attempted in comparison to no ECV attempted. There were no significant differences in the incidence of Apgar score ratings below seven at one minute (average RR 0.67, 95% CI 0.32 to 1.37, three trials, 168 infants) or five minutes (RR 0.63, 95% CI 0.29 to 1.36, five trials, 428 infants, evidence graded very low), low umbilical vein pH levels (RR 0.65, 95% CI 0.17

to 2.44, one trial, 52 infants, evidence graded very low), neonatal admission (RR 0.80, 95% CI 0.48 to 1.34, four trials, 368 infants, evidence graded very low), perinatal death (RR 0.39, 95% CI 0.09 to 1.64, eight trials, 1305 infants, evidence graded low), nor time from enrolment to delivery (mean difference -0.25 days, 95% CI -2.81 to 2.31, two trials, 256 women).

All of the trials included in this review had design limitations, and the level of evidence was graded low or very low. No studies attempted to blind the intervention, and the process of random allocation was suboptimal in several studies. Three of the eight trials had serious design limitations, however excluding these studies in a sensitivity analysis for outcomes with substantial heterogeneity did not alter the results.

Authors' conclusions

Attempting cephalic version at term reduces the chance of non-cephalic presentation at birth, vaginal cephalic birth not achieved and caesarean section. There is not enough evidence from randomised trials to assess complications of ECV at term. Large observational studies suggest that complications are rare.

PLAIN LANGUAGE SUMMARY

External cephalic version for breech presentation at term

External cephalic version (ECV) from 36 weeks reduces the chance of breech presentation at birth and caesarean section.

There is less risk to the baby and mother when the baby is head-down at the time of birth. ECV is a procedure by which the baby, who is lying bottom first, is manipulated through the mother's abdominal wall to the head-down position. The review of eight studies, involving 1308 women, found that If the baby is not head down after about 36 weeks of pregnancy, ECV reduces the chance that the baby will present as breech at the time of birth, reduces the chance of caesarean birth, and increases the chance that a head-first vaginal delivery will be achieved

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

External cephalic version at term for breech presentation

Patient or population: women with breech presentation
Settings: 8 studies (one each in Denmark, India, Jordan, The Netherlands, South Africa, Sudan, USA, and Zimbabwe)
Intervention: external cephalic version at term

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	External cephalic version at term				
Vaginal cephalic birth not achieved	Study population		RR 0.46 (0.33 to 0.62)	1253 (7 studies)	⊕◯◯◯ very low[1,2]	
	795 per 1000	366 per 1000 (262 to 493)				
	Moderate					
	848 per 1000	390 per 1000 (280 to 526)				
Caesarean section	Study population		RR 0.57 (0.4 to 0.82)	1305 (8 studies)	⊕◯◯◯ very low[1,3]	
	316 per 1000	180 per 1000 (126 to 259)				
	Moderate					
	393 per 1000	224 per 1000 (157 to 322)				
Apgar score <7 at 5 minutes	Study population		RR 0.63 (0.29 to 1.36)	428 (5 studies)	⊕◯◯◯ very low[4,5]	

	70 per 1000	**44 per 1000** (20 to 95)			
	Moderate				
	37 per 1000	**23 per 1000** (11 to 50)			
Umbilical vein pH <7.20	**Study population**		**RR 0.65** (0.17 to 2.44)	52 (1 study)	⊕○○○ **very low**[6,7]
	185 per 1000	**120 per 1000** (31 to 452)			
	Moderate				
	185 per 1000	**120 per 1000** (31 to 451)			
Neonatal admission	**Study population**		**RR 0.8** (0.48 to 1.34)	368 (4 studies)	⊕○○○ **very low**[4,5]
	151 per 1000	**121 per 1000** (73 to 203)			
	Moderate				
	146 per 1000	**117 per 1000** (70 to 196)			
Perinatal death	**Study population**		**RR 0.39** (0.09 to 1.64)	1305 (8 studies)	⊕⊕○○ **low**[4,8]
	9 per 1000	**4 per 1000** (1 to 15)			
	Moderate				
	0 per 1000	**0 per 1000** (0 to 0)			

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Most studies contributing data had design limitations, with more than 40% of weight from a study with serious design limitations.
[2] Statistical heterogeneity ($I^2 > 30\%$). Variation in size of effect.
[3] Statistical heterogeneity ($I^2 > 30\%$). Variation in size and direction of effect.
[4] Most studies contributing data had design limitations.
[5] Wide confidence interval crossing the line of no effect and few events.
[6] One study with design limitations.
[7] Wide confidence interval crossing the line of no effect, few events and small sample size.
[8] Wide confidence interval crossing the line of no effect.

BACKGROUND

Description of the condition

Approximately 3% to 4% of all pregnant women who reach full term will have a fetus in breech presentation. This may be caused by an underlying fetal or maternal abnormality, or could be an apparently chance occurrence, or related to an otherwise benign variant such as cornual placental position. In the latter instance, breech presentation places a healthy fetus and mother at increased risk of a complicated vaginal delivery or caesarean section.

Breech delivery, whether vaginally or by caesarean section, has a higher incidence of poor perinatal outcomes than cephalic birth. For example, the incidence of minor childhood handicap following breech presentation has been found to be high (19.4%) and similar for those delivered following trial of labour and those following an elective caesarean section (Danielian 1996).

The majority of women with a breech presenting baby would prefer a vaginal birth although most would choose caesarean section if there is a medical indication (Gamble 2000; Geary 1997; Hildingsson 2002; Turnbull 1999). For the singleton fetus in breech presentation, caesarean section has been shown to be safer for the fetus than vaginal birth in many settings (Hofmeyr 2005), although a large prospective study suggested that vaginal breech delivery may be safe under certain conditions with experienced practitioners (Goffinet 2006).

The risks associated with caesarean section are low, however caesarean section is not without maternal risk and in developed countries remains the largest contributing factor to the incidence of maternal mortality and morbidity following childbirth (Minkoff 2003). A Cochrane review of planned caesarean section versus planned vaginal delivery for breech pregnancy at term, reported that even though 45% of women in the planned vaginal delivery group were delivered by caesarean section, planned caesarean section was associated with an increase in maternal morbidity (risk ratio (RR) 1.29, 95% confidence interval (CI) 1.03 to 1.61) (Hofmeyr 2003). Furthermore, although the overall risk is very small, recent estimates of the incidence of mortality associated with elective caesarean section were nearly tripled compared to vaginal birth (Cooper 2002; Hall 1999). In addition to the increase in immediate morbidity following caesarean section, intra-abdominal adhesions may occur after caesarean section resulting in subsequent infertility (LaSala 1987). The presence of the uterine scar puts future pregnancies at increased risk of complications such as ectopic pregnancy, placenta previa, accreta and abruption, and uterine rupture (Dashe 2002; Gilliam 2002; Lydon-Rochelle 2001; Minkoff 2003). A further deterrent to caesarean section is that the procedure requires the expertise of an obstetrician or other health worker with surgical training, and limits the role for low-risk obstetrical care providers such as midwives and family practitioners. A review of strategies to reduce caesarean section rates identified external cephalic version (ECV) as the only clinical intervention with demonstrated Level 1 evidence for reducing primary caesarean section rates overall (Walker 2002).

Description of the intervention

Considering the complications that can arise from breech delivery, it is not surprising that, over the years, the possibility of manipulating the baby from the breech to the cephalic presentation has intrigued obstetric caregivers. ECV is a procedure in which the baby is manipulated by pressure through the mother's abdominal wall into a cephalic (head-down) position.

ECV before term (usually before 34 weeks' gestation) came into routine obstetric practice on the basis of the self-evident immediate effectiveness of the procedure as well as reassuring results from several non-randomised trials, and in spite of the negative results of the only randomised trial reported prior to 1980 (Brosset 1956). The popularity of ECV before term waned after the mid-1970s, partly because of reports of a substantial perinatal mortality associated with the procedure (Bradley-Watson 1975), and the increasing perception of caesarean section as a safer option than ECV or breech delivery.

Prior to the mid-1970s, ECV was usually attempted before term because of the belief that the procedure would seldom be successful at term. Subsequent studies showed that with the use of tocolysis (medication to relax the uterus), ECV could be achieved in a substantial proportion of women with breech presentation at term. ECV at term differs in many fundamental ways from that performed before term. These include the fact that the fetus is mature and may be delivered more readily in the event of complications, and that spontaneous versions without ECV attempt, or reversion after successful ECV, are less common at term. ECV before term is therefore evaluated as a separate procedure (*see 'External cephalic version for breech presentation before term'* (Hutton 2006)). The current review includes studies in which the intention was to include pregnant women at or near term (i.e. from 36 weeks' gestation).

External cephalic version at term has been shown to be feasible in two small uncontrolled trials in women with previous caesarean section (Flamm 1991; Schachter 1994), and in two in women in labour (Ferguson 1985; Fortunato 1988). El-Muzaini 2008a and El-Muzaini 2008b are abstract reports of prospective controlled studies of ECV in labour and with previous caesarean section respectively, with results in favour of ECV, but it is not clear whether these studies were randomised. To our knowledge, no randomised trials of these interventions have been reported.

Several authors have investigated which factors are associated with an increased chance of successful external cephalic version (Boucher 2003; Fortunato 1988; Guyer 2001; Lau 1997; Le Bret 2004). Factors which have been found to predict failure of ECV attempt include engagement of the presenting part, difficulty in palpating the fetal head and a tense uterus on palpation (Lau 1997), and increased amniotic fluid volume (Boucher 2003). However,

a prediction model based on clinical parameters was found to be insufficiently accurate to be useful in predicting the outcome of ECV attempts (Chan 2004).

The majority of women prefer vaginal birth over caesarean birth (Hildingsson 2002). As ECV is the primary intervention to achieve a vaginal delivery when the baby is in breech presentation, it would seem logical that women would be highly motivated to try it. The preferences of women with breech presentation regarding their care appear to have changed over the past couple of decades, and vary by location. In an Israeli study in 1995, 54% were willing to consider ECV and 65% preferred planned caesarean section if the breech presentation persisted, compared with 24% and 97% respectively in 2001 (Yogev 2002). In an Australian study in 2001, 39% of women attending antenatal clinic would choose ECV if needed, and 22% were undecided (Raynes-Greenow 2004). In another Australian study, Nassar 2007 evaluated a decision aid for women with breech presentation at term. The decision aid was not intended to increase or decrease intervention rates, but rather aim to support informed decision-making that is consistent with personal values. Seventy-four per cent of women who were randomised to receive the decision aid expressed an intention to have ECV if needed, while 66% of women who received normal care would choose ECV. A higher proportion of women who received the additional information reported that they had enough information to make a decision (95.7%, compared with 73.6%, at first follow-up). The women who received the decision aid experienced lower decisional conflict, increased knowledge, and greater satisfaction with their decision. Murray-Davis 2012 reported that women participating in a trial comparing the timing of ECV preferred the procedure to be carried out at 34 to 36 weeks' gestation rather than after 37 weeks, as it was perceived to have physiological and practical advantages. However, their sample is likely to have over-estimated preferences for early ECV as that option was only available to trial participants.

Complications reported following ECV at term include fracture of the baby's femur (Papp 2004), prolonged tachycardia (rapid heartbeat) of the baby (Nzewi 1999), sinusoidal baby's heart rate pattern (a fluctuating pattern sometimes indicating compromise) (Ferber 1999), and fetal-maternal haemorrhage (bleeding from the baby's to the mother's circulation in the placenta) (Shankar 2004). The rate of caesarean section during labour has been found to be greater following successful ECV than in spontaneous cephalic presentation: 20% versus 6.3%, RR 3.2 (Ben-Haroush 2002); 27.6% versus 12.5%, RR 2.04; 95% CI 1.43 to 2.91 (Chan 2004b); odds ratio 2.04 for nulliparous women, 4.30 for multiparous (Vezina 2004). This is not surprising, given that women with persistent breech presentation in the first instance are a high-risk group. Cord blood gases at delivery were no different (Chan 2004c).

However, series of cases have reported very low complication rates with ECV (Boucher 2003; Impey 1999; Impey 2005; Tong 2012). A review of 44 studies of ECV (7377 participants) from 1990 to 2002 found the most frequently reported complication to be transient abnormal baby's heart rate patterns (5.7%). Less frequent complications were persisting pathological baby's heart rate patterns (0.37%); vaginal bleeding (0.47%); placental abruption (0.12%); emergency caesarean section (0.43%); and perinatal mortality (0.16%) (Collaris 2004). Because of the risk of alloimmunisation, anti-D prophylaxis is recommended for non-sensitised D-negative women following ECV attempts (Fung Kee Fung 2003).

Contra-indications to ECV include: multiple pregnancy, severe abnormality, unsatisfactory condition or death of the baby, caesarean section necessary irrespective of the presentation (e.g. major placenta praevia), and ruptured membranes. Relative contraindications include previous caesarean section, poor growth of the baby, and bleeding from the uterus.

The question of whether ECV might increase the risk of mother-to-child transmission of viral infections such as HIV is important and, in the absence of direct evidence, we have reviewed the relevant biological evidence and concluded that, unlike fetal-maternal transfusion (bleeding from the baby's to the mother's circulation in the placenta), maternal-fetal transfusion is extremely rare, and unlikely to be precipitated by ECV (Holmes 2004). It is also reassuring that in a randomised trial of fundal pressure to expel the baby during caesarean section, no evidence of maternal-fetal transfusion was found (Owens 2003).

Several authors have reported success rates for ECV at term in routine clinical practice in the region of 40% to 50%: 53% (Hughes 1997); 39% (Williams 1999); 55% (Guyer 2001); 45% (Devendra 2002); 43% (Lojacono 2003); 51% (Skupski 2003); 42% to 65% (depending on amniotic fluid volume (Boucher 2003)); and 51% (Le Bret 2004).

Readers are referred to previous reviews of the topic (Hofmeyr 1989; Hofmeyr 1991; Hofmeyr 1992; Hofmeyr 1993; Zhang 1993). *See* also related Cochrane systematic reviews: '*External cephalic version for breech presentation before term*', '*Cephalic version by postural management for breech presentation*' and '*Interventions for helping to turn term breech babies to head first presentation when using external cephalic version*.' (Hutton 2006; Hofmeyr 2000; Cluver 2012).

Why it is important to do this review

There is a higher risk of complications when delivering a baby presenting in the breech rather than in the cephalic position. Caesarean section appears to be safer for the baby, but presents a higher level of maternal morbidity. Achieving a cephalic vaginal delivery by successfully rotating the baby in utero therefore, potentially offers a way to reduce the caesarean section rate, and improve perinatal and maternal outcomes. It may be of particular importance in resource-poor situations in which women may be unable to reach health services during labour, and caesarean sections are unavailable or unsafe (Hofmeyr 2004).

OBJECTIVES

To assess, using the best available evidence, the effects of external cephalic version (ECV) at or near term for breech presentation on: presentation at and method of delivery; and perinatal and maternal morbidity and mortality.

METHODS

Criteria for considering studies for this review

Types of studies

Clinical trials comparing the effects of external cephalic version (ECV) at or near term, with or without tocolysis, with a control group (no ECV attempt). Cluster-randomised studies and cross-over studies were eligible for inclusion, as mentioned in Unit of analysis issues. Quasi-randomised controlled trials were not eligible for inclusion.

Types of participants

Pregnant women with babies in the breech presentation at or near term and no contraindications to ECV.

Types of interventions

ECV attempt at term, with or without the use of tocolysis, compared with no ECV attempt.

Types of outcome measures

Outcomes were included if:

- they were determined to be clinically meaningful;
- reasonable measures were taken to minimise observer bias;
- missing data were insufficient to materially influence conclusions;
- data were available for analysis according to original allocation, irrespective of protocol violations;
- and data were available in a format suitable for analysis.

Primary outcomes

1. Vaginal cephalic birth not achieved (not prespecified)
2. Caesarean section

Secondary outcomes

1. Non cephalic presentation at delivery
2. Vaginal breech birth (not prespecified)
3. Apgar score less than seven at one minute (not prespecified)
4. Apgar score less than seven at five minutes
5. Umbilical vessel pH below 7.2
6. Perinatal death
7. Neonatal admission
8. Enrolment-delivery interval (not prespecified)

Search methods for identification of studies

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

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (28 February 2015).

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

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

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

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

[For details of additional searches we carried out for the previous version of this review (Hofmeyr 2012), see Appendix 1.]

Searching other resources

We searched the reference lists of retrieved studies.

We did not apply any language or date restrictions.

Data collection and analysis

For methods used when assessing the trials identified in the previous version of this review (*see* Hofmeyr 2012). For this update, the following methods were used for assessing the trial identified by the updated search (Rita 2012).

Selection of studies

Two review authors independently assessed for inclusion all the potential studies identified as a result of the search strategy. We resolved any disagreement through discussion and, if required, would have consulted a third assessor.

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We entered data into Review Manager software (RevMan 2014) and checked for accuracy.
When information was unclear, we attempted to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed the risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement through discussion and, if required, would have consulted R Kulier.

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

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

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

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

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

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

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

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

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

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

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

- low, high or unclear risk of bias.

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

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

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

(5) Selective reporting (checking for reporting bias)

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

We assessed the methods as:

- low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (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 risk of bias.

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

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

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we planned to assess the likely magnitude and direction of the bias and whether we considered it is likely to impact on the findings. In future updates, we will explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

For this update the quality of the evidence was assessed using the GRADE approach (Schunemann 2009) in order to assess the quality of the body of evidence relating to the following outcomes for the main comparisons.

1. Vaginal cephalic birth not achieved
2. Caesarean section
3. Apgar score less than seven at five minutes
4. Umbilical pH below 7.2
5. Perinatal death
6. Neonatal admission

The GRADE profiler (Grade 2008) was used to import data from Review Manager 5.3 (RevMan 2014) in order to create a 'Summary of findings' table. A summary of the intervention effect and a measure of quality for each of the above outcomes was produced using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

Measures of treatment effect

Dichotomous data

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

Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We planned to use the standardised mean difference to combine trials that measured the same outcome, but used different methods, if required.

Unit of analysis issues

Cluster-randomised trials

We would have included cluster-randomised trials in the analyses along with individually-randomised trials had there been any. We would have adjusted their sample sizes or standard errors using the methods described in the *Handbook* in Section 16.3.4 and 16.3.6 (Higgins 2011) using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. In future updates of the review, if we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. Had we identified both cluster-randomised trials and individually-randomised trials, we planned to synthesise the relevant information. We would consider it reasonable to combine the results from both if there was little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit was considered to be unlikely.

We would also acknowledge heterogeneity in the randomisation unit and perform a sensitivity or subgroup analysis to investigate the effects of the randomisation unit.

Cross-over trials

We identified no cross-over trials on this topic for the update, but if such trials were identified and deemed eligible for inclusion, we would include them in the analyses with parallel group trials, using methods described by Elbourne 2002.

Dealing with missing data

For included studies, we noted levels of attrition. We 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 randomised to each group in the analyses. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the Tau², I² and Chi² statistics. We regarded heterogeneity as substantial if an I² was greater than 30% and either a Tau² was greater than zero, or there was a low P value (less than 0.10) in the Chi² test for heterogeneity. Had we identified substantial heterogeneity (above 30%), we planned to explore it by prespecified subgroup analysis.

Assessment of reporting biases

Where we suspected reporting bias (*see* 'Selective reporting bias' above), we attempted to contact study authors, asking them to provide missing outcome data. Where this was not possible, and the missing data were thought to introduce serious bias, we explored the impact of including such studies in the overall assessment of results by a sensitivity analysis.

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

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2014). We used fixed-effect meta-analysis for combining data where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar.

If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average of the range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we would not have combined trials. Where we used random-effects analyses, the results were presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau² and I².

Subgroup analysis and investigation of heterogeneity

We did not perform any subgroup analyses in the original review or this update (2015). If we identified substantial heterogeneity in a fixed-effect meta-analysis, we noted this and repeated the analysis using a random-effects method. In future updates, if sufficient data become available, we will conduct the following subgroup analyses on primary outcomes.

1. Nulliparous women versus multiparous women versus parity mixed or not stated.
2. Frank breech presentation versus non-frank breech presentation versus presentation mixed or not stated
3. Studies recruiting mainly black African women versus studies recruiting mainly Caucasian women versus other studies.

We will assess subgroup differences by interaction tests available within RevMan (RevMan 2014) and report the results of subgroup analyses quoting the Chi² statistic and P value, and the interaction test I² value.

Sensitivity analysis

Due to the potentially high risk of bias in three of the studies (Brocks 1984; Dafallah 2004; Hindawi 2005) and our lack of success in contacting the latter two trial authors, we undertook the meta-analyses of included studies twice: first, including all the studies and second, excluding the studies at high risk of bias. When sensitivity analyses showed that the overall results and conclusions from primary outcomes were not affected by their inclusion, we regarded the results of the review with a higher degree of certainty. If both or either of these studies had greatly influenced the findings of the review, we would have recommended an appropriate degree of caution.

It has been suggested that ECV may be more successful (and spontaneous version more common) in black African than Caucasian women, possibly because of the tendency for the presenting part to remain high until the onset of labour (Hofmeyr 1986). Ethnicity was not a pre-defined subgroup analysis for the original review. However for this update (2015), post-hoc sensitivity analysis excluding the three studies in black African women (Dafallah 2004; Hofmeyr 1983; Mahomed 1991) was conducted.

RESULTS

Description of studies

Results of the search

Eight studies were included in the review (one from an updated search: Rita 2012).

Included studies

See Characteristics of included studies.

Design

All eight studies were two-arm randomised controlled trials, in which women were randomised to either receive attempted ECV or no attempt at ECV.

Sample sizes

The total number of women included in the eight included studies was 1308. Five of the studies included 65 or fewer women (Brocks 1984; Hofmeyr 1983; Rita 2012; Van de Pavert 1990; Van Dorsten 1981), two recruited around 200 women (Hindawi 2005; Mahomed 1991), and one included over 600 women (Dafallah 2004).

Setting

Studies were carried out in Denmark, India, Jordan, the Netherlands, South Africa, Sudan, the USA and Zimbabwe. The recruitment and any intervention happened in an outpatient clinic in Brocks 1984; Dafallah 2004; Hindawi 2005; Van Dorsten 1981, women in Hofmeyr 1983 were recruited when admitted to hospital from antenatal clinics and subsequently referred back to the antenatal clinic, and the setting was not described in the other studies (Mahomed 1991; Rita 2012; Van de Pavert 1990).

Participants

Pregnant women with a breech presentation baby were included in all studies. Women were recruited during the 37th week of pregnancy (Brocks 1984), 36 to 38 weeks' gestation (Dafallah 2004), from 37 weeks' gestation (Hindawi 2005; Mahomed 1991; Rita 2012) after 36 weeks' gestation (Hofmeyr 1983; Van de Pavert 1990), and 37 to 39 weeks' gestation (Van Dorsten 1981). Several reports explicitly stated that only women with singleton pregnancies were eligible (Brocks 1984; Hindawi 2005; Mahomed 1991; Rita 2012). The women included in these studies had low-risk pregnancies and medical histories, with no contra-indications to vaginal delivery or external version. Women with a previous caesarean section or uterine scar were excluded from all studies except Rita 2012, which excluded those with two or more previous caesarean sections.

Interventions

A variety of different techniques and maternal positions were used to perform ECV (classic forward roll technique (Dafallah 2004, Van de Pavert 1990), forward roll or back flip (Hofmeyr 1983; Mahomed 1991; Van Dorsten 1981), woman lying in left lateral tilt (Brocks 1984; Rita 2012), in the Trendelberg position (Dafallah 2004). lying with left or right lateral tilt (Hofmeyr 1983). An ultrasound scan confirming breech presentation was carried out prior to ECV in all studies (Brocks 1984; Dafallah 2004; Hindawi 2005; Hofmeyr 1983; Mahomed 1991; Rita 2012; Van de Pavert 1990; Van Dorsten 1981), and a reactive non-stress test/unstressed cardiotocogram was often recorded (Brocks 1984; Mahomed 1991; Van de Pavert 1990; Van Dorsten 1981).

A single attempt at ECV was carried out in Brocks 1984; Hindawi 2005; Mahomed 1991; and Rita 2012. Repeat attempts were allowed in Dafallah 2004 (up to three attempts), Hofmeyr 1983 and Van Dorsten 1981 (in the opposite direction to the initial attempt if it failed), and in Van de Pavert 1990 if the first attempt without tocolysis was unsuccessful, ritodrine was administered and ECV was attempted again.

No analgesia was used in these studies. This review included trials with and without tocolysis. Four trials used tocolysis routinely for ECV (ritodrine: Brocks 1984 and Hindawi 2005; hexaprenaline: Mahomed 1991; terbutaline sulphate: Van Dorsten 1981). In two trials, tocolysis was used if the initial ECV attempt was unsuccessful (hexaprenaline: Hofmeyr 1983; ritodrine: Van de Pavert 1990). No tocolysis was used in Dafallah 2004 and Rita 2012.

Outcomes

All studies reported caesarean section and perinatal death. Outcomes regarding presentation at delivery were not reported in a consistent way, however in most reports the information was available to impute the outcomes of interest (e.g. vaginal cephalic birth not achieved by adding caesarean section and breech vaginal delivery).

Excluded studies

Six studies identified by the search strategy were excluded from this review (see Characteristics of excluded studies). They were excluded because group allocation was not randomised (Besio 1994; El-Muzaini 2008a; El-Muzaini 2008b; Stine 1985), compared early with late ECV (Rust 2005), and ECV attempts started at 33 weeks' gestation (Van Veelen 1989).

Risk of bias in included studies

See Characteristics of included studies, Figure 1 and Figure 2.

Figure 1. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

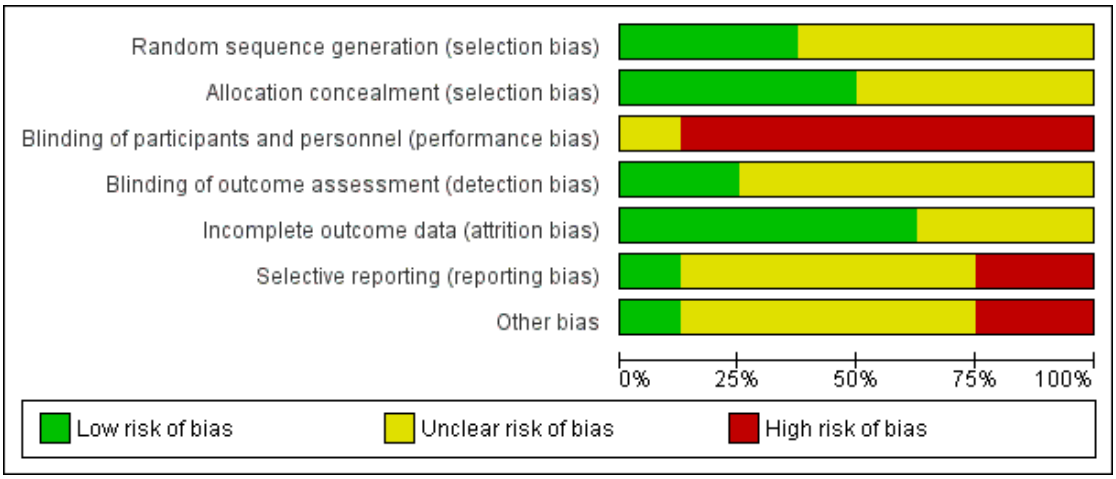
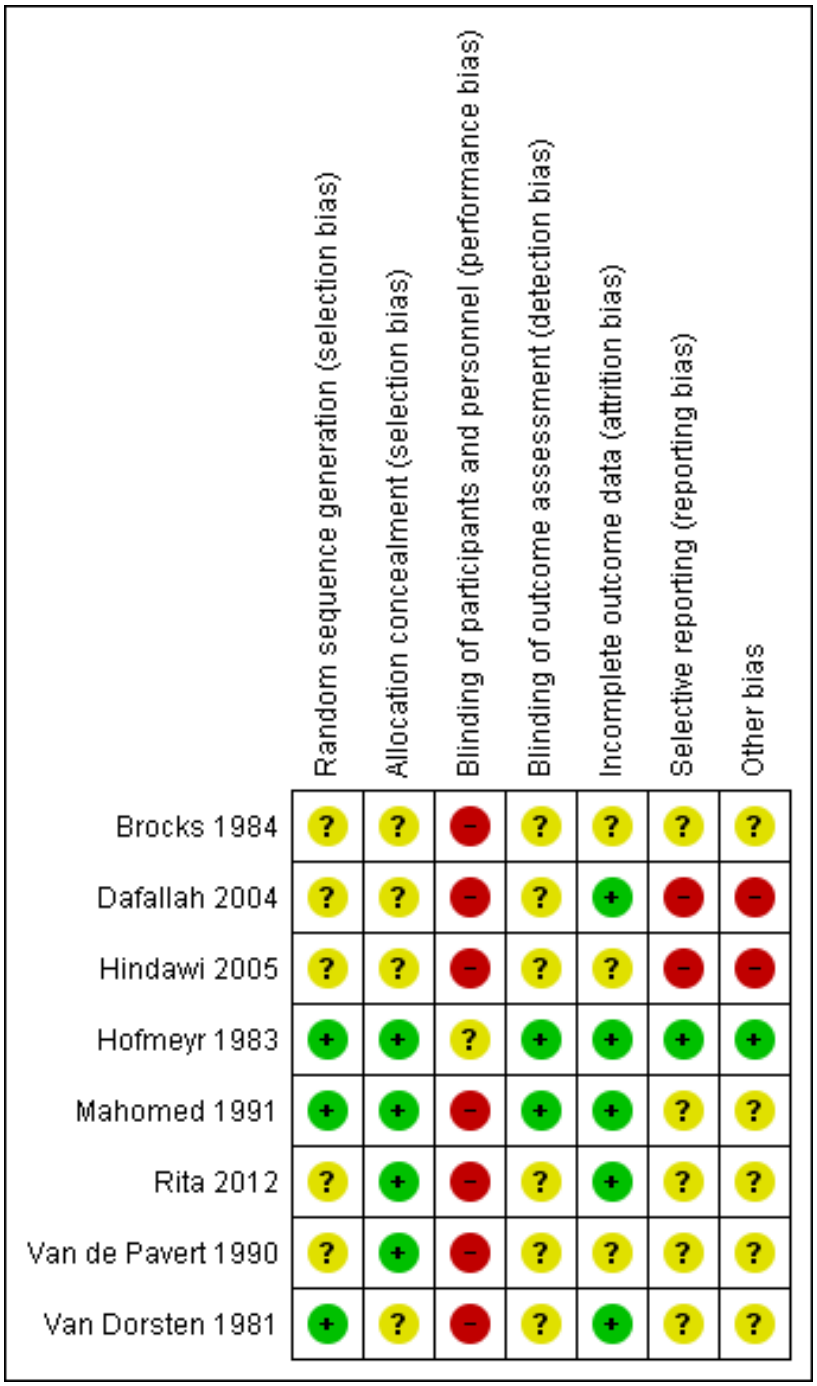


Figure 2. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.



Allocation

In four trials, randomly ordered sealed envelopes or cards were used for allocation (Hofmeyr 1983; Mahomed 1991; Rita 2012; Van de Pavert 1990), but only two (Mahomed 1991; Rita 2012) specified that the cards were sequentially numbered. Van Dorsten 1981 used a random number table and Brocks 1984 used 'random' allocation without specifying the mechanism. Concealment of allocation was thus not optimal.

Dafallah 2004 and Hindawi 2005 did not describe the methods of randomisation and allocation concealment at all. Attempts to contact the respective authors for more information failed. *See* Sensitivity analysis.

Blinding

Due to the nature of the intervention, no studies attempted to blind participants or clinicians to group allocation. Women would have been aware of the intervention and this may have affected decisions regarding care in later pregnancy and at the birth. Staff would be aware of the intervention and this may have affected other aspects of care and decision-making at the birth. This may have had an impact on outcomes such as caesarean section. In one study (Van de Pavert 1990), it was much more likely that women would have a caesarean section if external cephalic version (ECV) had been attempted and failed than in women where ECV had never been attempted, so it is possible than attempt and failure of ECV affects decision-making about caesarean section.

One study (Mahomed 1991) described blinding assessors to some outcomes (Apgar scores, admission to neonatal unit, stillbirth, neonatal death). In one study (Hofmeyr 1983), outcome assessment was from records (it was not clear whether attempted ECV or randomisation group was stated in the records). It states that "there was no subsequent intervention in their management by the investigator". In all other studies, it was not clear whether outcome assessment was carried out by staff who were involved in women's care. It is unlikely that lack of blinding of outcome assessors could have influenced most of the outcomes measured, but assessment of the infant may have been affected by knowledge of randomisation group.

Incomplete outcome data

Brocks 1984 studied 65 women who agreed to randomisation and a further 65 who either specifically requested or refused an ECV attempt. Since factors that may have a bearing on the outcome of pregnancy may influence the decision to accept ECV, we have limited this review to an analysis of the 65 randomised cases.

Hindawi 2005 gives no explanation for the large difference in group size (90 versus 102).

The exclusion of three women after enrolment in Van Dorsten 1981 is unlikely to have affected the results materially. Van de Pavert 1990 attempted ECV without tocolysis in 21/25 of the study group, and with tocolysis in 16/20 initial failures. Thus 8/25 (32%) received no ECV attempt (4) or incomplete ECV protocol (4). ECV was attempted on request in 5/27 of the control group, tocolysis being used in the three which were successful. While the analysis was appropriate according to intention-to-treat, the rate of non-compliance with the allocated treatment reduces the power of the study to detect differences resulting from ECV attempt.

Selective reporting

Neonatal outcomes were given according to presentation not allocation in Brocks 1984, so were not included in this review. Dafallah 2004 did not report on all prespecified outcomes, e.g. Apgar scores, or other key outcomes of interest, e.g. morbidity. In Hindawi 2005, outcomes are not clearly prespecified. Studies were generally assessed from published reports, without access to the protocols, so it was unclear whether all prespecified outcomes had been reported (Brocks 1984; Mahomed 1991; Rita 2012; Van de Pavert 1990; Van Dorsten 1981).

Other potential sources of bias

In two trials, higher numbers of women in the ECV group had fundal placentas (Mahomed 1991; Rita 2012), however the clinical implications are unclear.

Group sizes differ by 13% and outcomes are not clearly prespecified in Hindawi 2005.

Overall, all studies had some design limitations. It was judged that three studies had serious design limitations and were at high risk of bias (Brocks 1984; Dafallah 2004; Hindawi 2005). A sensitivity analysis was carried out to assess the effect of these limitations on the results.

Effects of interventions

See: **Summary of findings for the main comparison** External cephalic version at term for breech presentation

External cephalic version at term versus no ECV attempt

There was significant heterogeneity in the results for the outcomes vaginal cephalic birth not achieved, caesarean section, non-cephalic presentation at birth, vaginal breech birth, and Apgar score less than seven at one minute, therefore these were pooled using the random-effects model. For all other data we used the fixed-effect model.

Primary outcomes: Vaginal cephalic birth not achieved and caesarean section

Overall, the pooled data from included studies show a statistically significant and clinically meaningful reduction in vaginal cephalic birth not being achieved (average risk ratio (RR) 0.46, 95% confidence interval (CI) 0.33 to 0.62, seven trials, 1253 women, evidence graded very low, Analysis 1.1), and caesarean section (average RR 0.57, 95% CI 0.40 to 0.82, eight trials, 1305 women, evidence graded very low, Analysis 1.2) when ECV was attempted.

Secondary outcomes: Perinatal and maternal morbidity and mortality

The pooled data from included studies show a statistically significant and clinically meaningful reduction in non-cephalic presentation at birth (average RR 0.42, 95% CI 0.29 to 0.61, eight trials, 1305 women, Analysis 1.3), and vaginal breech delivery (not prespecified, average RR 0.35, 95% CI 0.24 to 0.50, seven trials, 685 women, Analysis 1.4).

Data were not available from all the trials for the remaining outcomes. There were no significant differences in the incidence of Apgar score ratings below seven at one minute (not prespecified, random-effects model: average RR 0.67, 95% CI 0.32 to 1.37; three trials, 168 infants, Analysis 1.5) or five minutes (RR 0.63, 95% CI 0.29 to 1.36, five trials, 428 infants, evidence graded very low, Analysis 1.6), low umbilical vein pH levels (RR 0.65, 95% CI 0.17 to 2.44, one trial, 52 infants, evidence graded very low, Analysis 1.7), neonatal admission (RR 0.80, 95% CI 0.48 to 1.34, four trials, 368 infants, evidence graded very low, Analysis 1.9), perinatal death (RR 0.39, 95% CI 0.09 to 1.64, eight trials, 1305 infants, evidence graded low, Analysis 1.8), nor time from enrolment to delivery (not prespecified, mean difference -0.25 days, 95% CI -2.81 to 2.31, two trials, 256 women, Analysis 1.10).

Sensitivity analyses

Three studies were judged to have serious design limitations and were at high risk of bias (Brocks 1984; Dafallah 2004; Hindawi 2005). However, a sensitivity analysis excluding these studies from the analyses showed that the overall results were not greatly influenced by their inclusion (random-effect model) (vaginal cephalic birth not being achieved: average RR 0.32, 95% CI 0.25 to 0.41, four trials, 376 women, Analysis 2.1; caesarean section: average RR 0.46, 95% CI 0.27 to 0.79, five trials, 428 women, Analysis 2.2; non-cephalic presentation at birth: average RR 0.29, 95% CI 0.12 to 0.68, five trials, 428 women, Analysis 2.3; and vaginal breech delivery: average RR 0.38, 95% CI 0.21 to 0.69, five trials, 428 women, Analysis 2.4).

It has been suggested that ECV may be more successful (and spontaneous version more common) in black African than Caucasian women, possibly because of the tendency for the presenting part to remain high until the onset of labour (Hofmeyr 1986). Ethnicity was not a pre-defined subgroup analysis for the original review. However, post-hoc sensitivity analysis excluding the three studies in black African women (Dafallah 2004; Hofmeyr 1983; Mahomed 1991) produced the following results (fixed-effect model): vaginal cephalic birth not achieved: RR 0.49, 95% CI 0.41 to 0.58, 4 trials, 365 women, Analysis 3.1; caesarean section: RR 0.57, 95% CI 0.45 to 0.73, five trials, 417 women, Analysis 3.2, non-cephalic presentation at birth: RR 0.46, 95% CI 0.39 to 0.55, five trials, 417 women Analysis 3.3; vaginal breech birth: RR 0.38, 95% CI 0.27 to 0.54, five trials, 417 women, Analysis 3.4.

DISCUSSION

Summary of main results

The evidence from randomised trials shows that attempting external cephalic version at term increases the chance of vaginal cephalic birth, and reduces the chance of caesarean section and vaginal breech delivery. There is not enough evidence from randomised trials to assess complications of external cephalic version at term, however large observational studies suggest that complications are rare (Boucher 2003; Impey 1999; Impey 2005).

Overall completeness and applicability of evidence

The absolute numbers of non-cephalic births and caesarean sections vary considerably between trials. This probably reflects differences in study populations and caesarean section policies. The direction of effects is, however, consistent, with the exception of the rates of caesarean section in the study of Van de Pavert 1990. Considerable cross-over between groups in the latter study may have reduced the power of the study to show differences related to external cephalic version (ECV). The study authors suggest that against a background of low caesarean section rates for breech presentation, the negative experience of failed ECV may render the woman or doctors more likely to opt for caesarean section.

The women included in these studies had low-risk pregnancies and medical histories. Women with previous caesarean sections were excluded, for example. This limits the applicability of the evidence to other populations of women.

The recent trend to routine caesarean section for persistent breech presentation may result in a greater impact of ECV on caesarean section rates than was apparent in the studies reviewed.

The trials reviewed do not give information on women's views.

No analgesia was used in these studies. This review included trials with and without tocolysis. Four trials used tocolysis routinely for ECV (ritodrine: Brocks 1984 and Hindawi 2005, hexaprenaline:

Mahomed 1991, terbutaline sulphate: Van Dorsten 1981). In two trials tocolysis was used if the initial ECV attempt was unsuccessful (hexaprenaline: Hofmeyr 1983, ritodrine: Van de Pavert 1990). No tocolysis was used in Dafallah 2004 and Rita 2012. The use of tocolytic drugs and other interventions to help ECV is covered by a separate Cochrane review (Cluver 2012).

Quality of the evidence

All of the trials included in this review had design limitations. Due to the nature of the intervention, no studies attempted to blind participants or clinicians to group allocation. Women would have been aware of the intervention and this may have affected decisions regarding care in later pregnancy and at the birth. Staff would be aware of intervention and this may have affected other aspects of care and decision-making at the birth. This may have had an impact on outcomes such as caesarean section. In one study (Van de Pavert 1990), it was much more likely that women would have a caesarean section if ECV had been attempted and failed than in women where ECV had never been attempted, so it is possible than attempt and failure of ECV affects decision-making about caesarean section.

The descriptions of randomisation and allocation procedures were not optimal in several studies (Brocks 1984; Dafallah 2004; Hindawi 2005; Rita 2012; Van de Pavert 1990; Van Dorsten 1981). It is unclear whether this is due to omissions in the reporting of the studies, or limitations of study design.

The level of evidence was graded low (perinatal death) or very low (vaginal cephalic birth not achieved, caesarean section, Apgar score < 7 at five minutes, umbilical vein pH < 7.20, neonatal admission) (Summary of findings for the main comparison). The two graded outcomes addressing mode of delivery (vaginal cephalic birth not achieved, caesarean section) were downgraded for quality of evidence due to design limitations in the studies, and inconsistency due to statistical heterogeneity. The four graded outcomes addressing perinatal outcomes (Apgar score < 7 at five minutes, umbilical vein pH < 7.20, neonatal admission, perinatal death) were downgraded for quality evidence due to design limitations in the studies, and imprecision due to wide confidence intervals and few events.

Potential biases in the review process

The assessment of risk of bias involves subjective judgements. This potential limitation is minimised by following the procedures in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), with review authors independently assessing studies and resolving any disagreement through discussion, and if required involving a third assessor in the decision.

Agreements and disagreements with other studies or reviews

No recent systematic reviews of randomised trials were found. A systematic review of cohort studies (three) and case-control studies (eight), found an increased caesarean delivery rate for women with a successful external cephalic version (21%; odds ratio 2.2, 95% confidence interval 1.6 to 3.0) (De Hundt 2014).

AUTHORS' CONCLUSIONS

Implications for practice

The studies in this review provide convincing evidence that the chance of breech birth and caesarean section may be substantially reduced by attempting external cephalic version (ECV) at or near term. The numbers studied are too small to give an accurate assessment of the risks of ECV, though data from observation studies are reassuring. There is sound reason for the clinical use of ECV at term, with the appropriate precautions, in any woman in whom the value of an improved chance of a cephalic birth outweighs the risk of the procedure.

Implications for research

Future research should be directed towards refining the selection of women suitable for ECV attempt at term. For example, previous caesarean section has been regarded as a contraindication to ECV. In an uncontrolled series, ECV was found to be successful in 82% of 56 women with one or two previous caesarean sections (Flamm 1991).

The place of ECV during labour requires further study. This procedure was reported to be successful in 11 (73%) out of 15 women in labour considered unsuitable for vaginal breech delivery. Caesarean section was avoided in 10 (67%) of the women (Ferguson 1985).

Further research is needed to define more accurately the effect of ECV on perinatal outcome, and the place of ECV in non-longitudinal lies.

Future studies should include an assessment of women's views.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Brocks 1984

Methods	65 women who agreed to enter the trial were "randomly allocated" to ECV or control group. A further 65 women who had ECV or no ECV according to request are not included in this review as they were not randomised
Participants	Inclusion criteria: singleton breech presentation on ultrasound in 37th week. Agree to enter study. Exclusion criteria: contraindication to ECV
Interventions	Single ECV attempt following ritodrine 15 μg/minute for 15 minutes (31 women). ECV repeated successfully in 2 women in whom reversion to breech occurred. Compared with no ECV attempt (34 women)
Outcomes	Presentation at delivery; method of delivery.
Notes	Neonatal outcomes given according to presentation rather than allocation and therefore not included in the review. Location: outpatient clinic, Denmark

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomly allocated."
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women were selected for the study if they had specified that they wanted a vaginal birth. Women would have been aware of the intervention and this may have affected decisions regarding care in later pregnancy and at the birth. Staff would be aware of intervention and this may have affected other aspects of care and decision-making at the birth. This may have had an impact on outcomes such as CS
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not clear whether outcome assessment was carried out by staff who were involved in care. It is unlikely that lack of blinding of outcome assessors could have influenced some of the outcomes measured, but assessment of the infant may have been affected by knowledge of randomisation group

Brocks 1984 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Neonatal outcomes given according to presentation not allocation, and include non-randomised participants. They are therefore not included in the review
Selective reporting (reporting bias)	Unclear risk	Neonatal outcomes given according to presentation not allocation. Unclear whether all prespecified outcomes were reported
Other bias	Unclear risk	Neonatal outcomes given according to presentation rather than allocation and therefore not included in the review. No information on whether the intervention and control groups were comparable

Dafallah 2004

Methods	Women were "randomly allocated" to the study group or the control group. Randomisation was stratified by parity (nulliparas and multiparas)
Participants	620 healthy women with uncomplicated breech pregnancy at 36-38 weeks in Sudan from 1995-2001 (135 nulliparas and 175 multiparas in the study group compared to 125 nulliparas and 185 multiparas in the control group). Ultrasound examination before randomisation excluded congenital malformation, oligohydramnios, placenta praevia, uterine abnormality. Other exclusions were previous CS, APH, hypertensive disorders, IUGR
Interventions	ECV attempt of up to 5 minutes without tocolysis versus no ECV attempt. If the procedure failed or when reversion occurred, the manoeuvre was repeated up to 3 times at subsequent antenatal visits
Outcomes	Mode of delivery, Apgar scores at 1, 5, 10 min, fetal weight
Notes	Baseline characteristics were similar except for maternal age (multiparas in control group older than study group). There were 750 ECV attempts in 310 women: 196/750 successful (26%) with greater success in multiparas. Apgar scores not reported. Additional information requested but not obtained from authors. Location: antenatal care clinic at Wad Medani Teaching Hospital, Sudan

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'Randomly allocated.'
Allocation concealment (selection bias)	Unclear risk	Not described.

Dafallah 2004 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Women would have been aware of the intervention and this may have affected decisions re care in later pregnancy and at the birth. It was stated that ECV was carried out by a single obstetrician. It is not clear if this same obstetrician cared for women in the control group or was involved in other aspects of care. Staff would be aware of intervention and this may have affected other aspects of care and decision-making at the birth. This may have had an impact on outcomes such as CS
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not clear whether outcome assessment was carried out by staff who were involved in care. It is unlikely that lack of blinding of outcome assessors would have influenced some of the outcomes measured
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up reported.
Selective reporting (reporting bias)	High risk	The authors do not report on all prespecified outcomes, e.g. Apgar scores, or other key outcomes of interest, e.g. morbidity
Other bias	High risk	Potentially high risk of bias.

Hindawi 2005

Methods	Stated 'randomised controlled trial'. No details of randomisation or allocation concealment are given.
Participants	192 singleton breech pregnancies > 37 weeks' gestation at King Hussein Medical Center in Amman, Jordan (Jan 1999-Dec 2001). Included if: reactive CTG and fetal movements, known Rhesus group, fasted for 6 hours prior to procedure. Excluded if: fetal abnormality, abnormal CTG, placenta praevia, established labour, ruptured membranes, gestational diabetes requiring insulin, IUGR, proteinuric hypertension disorders, previous CS, oligohydramnios, polyhydramnios
Interventions	ECV (90) with tocolysis vs no ECV (102).
Outcomes	'All clinical details concerning the pregnancy, ECV and delivery were recorded and reviewed.'
Notes	No explanation given for the large difference in group size (90 vs 102). Baseline characteristics similar except for fetal weight (3350 in ECV group vs 3120 in control group). Outcomes not clearly prespecified. High risk of bias. Additional information requested

Hindawi 2005 (*Continued*)

	but not obtained from author. Location: outpatient clinic, King Hussein Medical Centre, Jordan

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated 'randomised'. No other details provided.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women would have been aware of the intervention and this may have affected decisions re care in later pregnancy and at the birth. Staff would be aware of intervention and this may have affected other aspects of care and decision-making at the birth. This may have had an impact on outcomes such as CS/elective CS
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was not clear whether outcome assessment was carried out by staff who were involved in care. It is unlikely that lack of blinding of outcome assessors would have influenced some of the outcomes measured
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear whether there were protocol deviations, post randomisation exclusions or missing data
Selective reporting (reporting bias)	High risk	Outcomes are not clearly prespecified.
Other bias	High risk	Baseline difference in fetal weight; large unexplained difference in group size (control group 13% bigger than treatment group). Potentially high risk of bias

Hofmeyr 1983

Methods	2-arm randomised trial. Women were allocated to the intervention or control group by randomly ordered, concealed cards
Participants	Inclusion criteria: singleton breech presentation on ultrasound examination at 36 or more weeks' gestation; consent to participate. Exclusion criteria: contraindication to ECV.

Hofmeyr 1983 (*Continued*)

Interventions	ECV attempt initially without tocolysis (30 women). If unsuccessful (7 cases), attempt repeated following hexoprenaline 10 μg by slow IVI injection. Compared with no ECV attempt (30 women)
Outcomes	Presentation at delivery; method of delivery; Apgar score < 7 at 1 and 5 minutes; perinatal mortality
Notes	Location: Baragwanath Hospital, South Africa (admitted from hospital antenatal clinic & district clinics in Soweto)

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Previously shuffled cards marked 'V' or 'C'.
Allocation concealment (selection bias)	Low risk	Concealed cards.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Women would have been aware of allocation and may have discussed it with staff providing care. It was stated that the staff carrying out the ECV were not involved in the subsequent care of women
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessment was from records (it was not clear whether attempted ECV or randomisation group was stated in the records). It is unlikely that those collecting information could have influenced maternal and infant outcomes reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up reported.
Selective reporting (reporting bias)	Low risk	All prespecified outcomes reported.
Other bias	Low risk	

Mahomed 1991

Methods	2-arm randomised trial. Allocation by consecutively numbered sealed opaque envelopes, randomised in blocks of 6
Participants	Inclusion criteria: singleton breech presentation at 37 weeks or more; consent to participate. Exclusion criteria: contraindication to ECV; non-reactive nonstress test

Mahomed 1991 (*Continued*)

Interventions	ECV attempt following hexoprenaline 10 μg intravenously over 1 minute (103 women) , compared with no ECV attempt (105 women)
Outcomes	Presentation at delivery; CS rate; 5 minute Apgar score < 7 and < 5; perinatal mortality; enrolment-labour interval; gestation at delivery
Notes	Factors affecting ECV success rate evaluated in the 103 women in the trial together with another 104 non-trial ECV attempts. In the latter group 1 stillbirth occurred 17 days after successful ECV. The baby was born with the cord tightly around the neck. In the randomised to ECV group, a baby born vaginally 23 days after successful version was severely asphyxiated and died at 3 days old. 2 perinatal deaths occurred in the control group following vaginal breech delivery. Location: Harare maternity hospital, Harare, Zimbabwe

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomised in blocks of 6.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women would have been aware of the intervention and this may have affected decisions re care in later pregnancy and at the birth. Staff would be aware of intervention and this may have affected other aspects of care and decision-making at the birth. This may have had an impact on outcomes such as CS/elective CS
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessment was from records It was stated that those collecting data on condition of the newborn were blind to allocation. It is unlikely that those collecting information could have influenced other outcomes reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals or loss to follow-up.
Selective reporting (reporting bias)	Unclear risk	Assessed from published report, unclear whether all prespecified outcomes were reported
Other bias	Unclear risk	The ECV group contained higher numbers of women with fundal placentas, the clini-

		cal implications of this are unclear

Rita 2012

Methods	2-arm randomised trial of ECV after 37 weeks' gestation. 60 women were recruited after a routine ultrasound at 37 weeks had shown breech presentation, and were randomised using consecutively numbered opaque envelopes. Women were seen weekly for routine antenatal care
Participants	Inclusion criteria: ≥ 37 weeks' GA (ultrasound confirmed), singleton, breech presentation Exclusion criteria: APH, placenta praevia, uterine anomalies, severe proteinuric hypertension, diabetes, cardiac disease, conditions favouring premature labour, rhesus negative mother, ruptured membranes, previous 2 or more CSs
Interventions	ECV (single attempt, over a maximum of 5 minutes) (30 women), compared with no ECV attempt (30 women)
Outcomes	Cephalic presentation during labour, fetal heart rate abnormality during and after procedure, mode of delivery, perinatal mortality and morbidity (Apgar score, NICU admission)
Notes	Location: India.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Stated 'randomised'. No other details provided.
Allocation concealment (selection bias)	Low risk	Consecutively numbered sealed opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding. Women would have been aware of the intervention and this may have affected decisions re care in later pregnancy and at the birth. Staff would be aware of intervention and this may have affected other aspects of care and decision-making at the birth. This may have had an impact on outcomes such as CS/elective CS
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No blinding described. Not clear if the same staff assessed outcomes and were involved in care. It is possible that lack of blinding could affect assessment of fetal and neonatal outcomes

Rita 2012 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	All women appear to be included in the analysis.
Selective reporting (reporting bias)	Unclear risk	Assessed from published report, unclear whether all prespecified outcomes were reported
Other bias	Unclear risk	The ECV group contained higher numbers of women with fundal placentas, the clinical implications of this are unclear

Van de Pavert 1990

Methods	2-arm randomised trial. Randomisation by sealed envelope. Analysis was according to intention-to-treat
Participants	Inclusion criteria: singleton breech presentation at more than 36 weeks' gestation; agree to participate. Exclusion criteria: contraindication to ECV
Interventions	ECV without tocolysis (25 women), followed by ECV attempt with ritodrine infusion, compared with no ECV attempt (27 women)
Outcomes	Presentation at delivery; CS rate.
Notes	4 in the ECV group refused ECV attempt, while 5 in the control group had ECV attempt on request. Analysis was according to intention-to-treat. Location: The Netherlands

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Stated 'randomised'. No other details provided.
Allocation concealment (selection bias)	Low risk	Sealed envelope.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women would have been aware of the intervention and this may have affected decisions regarding care in later pregnancy and at the birth. Staff would be aware of intervention and this may have affected other aspects of care and decision-making at the birth. This may have had an impact on outcomes such as CS/elective CS (In this study it was much more likely that women would have a CS if ECV had been attempted and failed than in women where

Van de Pavert 1990 (*Continued*)

		ECV had never been attempted, so it is possible than attempt and failure of ECV affects decision-making regarding CS.)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if the same staff assessed outcomes and were involved in care. It is possible that lack of blinding could affect assessment of fetal and neonatal outcomes
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	4 in the ECV group refused ECV attempt, while 5 in the control group had ECV attempt on request. Analysis was according to intention-to-treat. Outcomes reported for all participants
Selective reporting (reporting bias)	Unclear risk	Assessed from published report, unclear whether all prespecified outcomes were reported
Other bias	Unclear risk	4 in the ECV group refused ECV attempt, while 5 in the control group had ECV attempt on request. Analysis was according to intention-to-treat

Van Dorsten 1981

Methods	2-arm randomised trial. Allocation by random number table.
Participants	Inclusion criteria: low-risk pregnant women; breech presentation at 37 to 39 weeks' gestation; normal ultrasound examination; reactive nonstress test. Exclusion criteria: medical conditions; hypertension; premature labour; premature rupture of membranes; suspected impaired fetal growth; previous uterine surgery; multiple gestation; third trimester bleeding
Interventions	ECV attempt following terbutaline sulphate infusion at 5 μg per minute for 10 to 15 minutes (25 women), compared with no ECV attempt (23 women)
Outcomes	Presentation at delivery; CS rate; Apgar score < 7 at 1 and 5 minutes; enrolment-delivery interval; birthweight; meconium during labour or at delivery
Notes	There were 3 exclusions after selection because of oligohydramnios, placenta praevia and non-reactive nonstress test. Location: outpatient clinic at Los Angeles County/University of Southern Calfornia Medical Center, USA

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Van Dorsten 1981 (*Continued*)

Random sequence generation (selection bias)	Low risk	Random number table.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women would have been aware of the intervention and this may have affected decisions regarding care in later pregnancy and at the birth. Staff would be aware of intervention and this may have affected other aspects of care and decision-making at the birth. This may have had an impact on outcomes such as CS/elective CS
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not clear if the same staff assessed outcomes and were involved in care. It is possible that lack of blinding could affect assessment of fetal and neonatal outcomes
Incomplete outcome data (attrition bias) All outcomes	Low risk	3 post-randomisation exclusions. All women accounted for.
Selective reporting (reporting bias)	Unclear risk	Assessed from published report, unclear whether all prespecified outcomes were reported
Other bias	Unclear risk	3 post-randomisation exclusions.

APH: antepartum haemorrhage
CS: caesarean section
CTG: cardiotocograph
ECV: external cephalic version
GA: gestational age
IUGR: intrauterine growth restriction
IVI: intravenous

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

Study	Reason for exclusion
Besio 1994	Controlled trial of ECV at term, not randomised. Cephalic presentation at term in 32/45 versus 4/45 in the control group. Caesarean sections 22/45 versus 39/45 respectively

(*Continued*)

El-Muzaini 2008a	This is an abstract from a conference presentation of intrapartum ECV (30 women) without tocolysis compared to no ECV attempt (30 women). No mention of whether randomisation was used in group allocation. Attempts to contact authors for clarification failed
El-Muzaini 2008b	This is an abstract from a conference presentation of outpatient ECV without tocolysis (40 women) compared to no ECV attempt (47 women) in women with a singleton breech and 1 previous lower segment caesarean section. No mention of whether randomisation was used in group allocation. Attempts to contact authors for clarification failed
Rust 2005	This randomised trial compares late ECV with early ECV.
Stine 1985	Non-randomised follow-on study after completion of the Van Dorsten randomised trial. ECV was successful in 108/148 women. 6 were lost to follow-up and 7 reverted to abnormal lies. Of the remaining 95, 23 underwent caesarean section. 1 unexplained intrauterine death occurred 3 weeks after successful ECV. 1 maternal death occurred at caesarean section 4 days after successful ECV, from amnionitis, septicaemia, intravascular coagulation and amniotic fluid embolus
Van Veelen 1989	Excluded because ECV attempts commenced at 33 weeks, and continued up to term. See review '*External cephalic version for ECV before term*' (Hutton 2006).

ECV: external cephalic version

DATA AND ANALYSES

Comparison 1. External cephalic version at term versus no ECV attempt

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal cephalic birth not achieved (CS + breech vaginal birth) (not prespecified)	7	1253	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.33, 0.62]
2 Caesarean section	8	1305	Risk Ratio (M-H, Random, 95% CI)	0.57 [0.40, 0.82]
3 Non-cephalic presentation at birth	8	1305	Risk Ratio (M-H, Random, 95% CI)	0.42 [0.29, 0.61]
4 Vaginal breech birth (not prespecified)	7	685	Risk Ratio (M-H, Random, 95% CI)	0.35 [0.24, 0.50]
5 Apgar score < 7 at 1 minute (not prespecified)	3	168	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.32, 1.37]
6 Apgar score < 7 at 5 minutes	5	428	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.29, 1.36]
7 Umbilical vein pH < 7.20	1	52	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.17, 2.44]
8 Perinatal death	8	1305	Risk Ratio (M-H, Fixed, 95% CI)	0.39 [0.09, 1.64]
9 Neonatal admission	4	368	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.48, 1.34]
10 Enrolment-delivery interval (not prespecified)	2	256	Mean Difference (IV, Fixed, 95% CI)	-0.25 [-2.81, 2.31]

Comparison 2. Sensitivity analysis (excluding studies with high risk of bias)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal cephalic birth not achieved (CS + breech vaginal birth)	4	376	Risk Ratio (M-H, Random, 95% CI)	0.32 [0.25, 0.41]
2 Caesarean section	5	428	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.27, 0.79]
3 Non cephalic presentation at birth	5	428	Risk Ratio (M-H, Random, 95% CI)	0.29 [0.12, 0.68]
4 Vaginal breech birth	5	428	Risk Ratio (M-H, Random, 95% CI)	0.38 [0.21, 0.69]

Comparison 3. Sensitivity analysis (excluding studies in Africa)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal cephalic birth not achieved (CS + breech vaginal birth)	4	365	Risk Ratio (M-H, Fixed, 95% CI)	0.49 [0.41, 0.58]
2 Caesarean section	5	417	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.45, 0.73]
3 Non cephalic presentation at birth	5	417	Risk Ratio (M-H, Fixed, 95% CI)	0.46 [0.39, 0.55]
4 Vaginal breech birth	5	417	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.27, 0.54]

Analysis 1.1. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 1 Vaginal cephalic birth not achieved (CS + breech vaginal birth) (not prespecified).

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 1 Vaginal cephalic birth not achieved (CS + breech vaginal birth) (not prespecified)

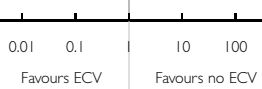
Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Hofmeyr 1983	6/30	21/30		9.0 %	0.29 [0.13, 0.61]
Van Dorsten 1981	9/25	19/23		11.9 %	0.44 [0.25, 0.76]
Rita 2012	9/30	28/30		11.9 %	0.32 [0.18, 0.56]
Brocks 1984	17/31	29/34		15.5 %	0.64 [0.45, 0.91]
Mahomed 1991	26/103	89/105		15.6 %	0.30 [0.21, 0.42]
Hindawi 2005	41/90	93/102		17.4 %	0.50 [0.40, 0.63]
Dafallah 2004	161/310	225/310		18.7 %	0.72 [0.63, 0.81]
Total (95% CI)	**619**	**634**		**100.0 %**	**0.46 [0.33, 0.62]**

Total events: 269 (ECV), 504 (no ECV)

Heterogeneity: $Tau^2 = 0.13$; $Chi^2 = 37.63$, df = 6 (P<0.00001); $I^2 = 84\%$

Test for overall effect: Z = 5.00 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 1.2. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 2 Caesarean section.

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 2 Caesarean section

Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Brocks 1984	7/31	12/34		10.5 %	0.64 [0.29, 1.42]
Dafallah 2004	44/310	45/310		17.2 %	0.98 [0.67, 1.44]
Hindawi 2005	35/90	62/102		18.6 %	0.64 [0.47, 0.87]
Hofmeyr 1983	6/30	13/30		10.1 %	0.46 [0.20, 1.05]
Mahomed 1991	13/103	35/105		13.9 %	0.38 [0.21, 0.67]
Rita 2012	6/30	22/30		11.2 %	0.27 [0.13, 0.58]
Van de Pavert 1990	7/25	3/27		6.1 %	2.52 [0.73, 8.69]
Van Dorsten 1981	7/25	17/23		12.3 %	0.38 [0.19, 0.74]
Total (95% CI)	**644**	**661**		**100.0 %**	**0.57 [0.40, 0.82]**

Total events: 125 (ECV), 209 (no ECV)

Heterogeneity: $Tau^2 = 0.16$; $Chi^2 = 20.37$, df = 7 (P = 0.005); $I^2 = 66\%$

Test for overall effect: Z = 3.01 (P = 0.0026)

Test for subgroup differences: Not applicable

Analysis 1.3. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 3 Non-cephalic presentation at birth.

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 3 Non-cephalic presentation at birth

Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Brocks 1984	17/31	28/34		14.6 %	0.67 [0.47, 0.95]
Dafallah 2004	135/310	210/310		16.4 %	0.64 [0.55, 0.75]
Hindawi 2005	33/90	92/102		15.4 %	0.41 [0.31, 0.54]
Hofmeyr 1983	1/30	20/30		3.1 %	0.05 [0.01, 0.35]
Mahomed 1991	18/103	87/105		13.8 %	0.21 [0.14, 0.32]
Rita 2012	6/30	28/30		10.4 %	0.21 [0.10, 0.44]
Van de Pavert 1990	16/25	20/27		14.5 %	0.86 [0.60, 1.25]
Van Dorsten 1981	8/25	19/23		11.8 %	0.39 [0.21, 0.71]
Total (95% CI)	**644**	**661**		**100.0 %**	**0.42 [0.29, 0.61]**

Total events: 234 (ECV), 504 (no ECV)

Heterogeneity: $Tau^2 = 0.22$; $Chi^2 = 54.22$, df = 7 ($P<0.00001$); $I^2 = 87\%$

Test for overall effect: $Z = 4.52$ ($P < 0.00001$)

Test for subgroup differences: Not applicable

Analysis 1.4. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 4 Vaginal breech birth (not prespecified).

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 4 Vaginal breech birth (not prespecified)

Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Brocks 1984	10/31	29/34		25.4 %	0.38 [0.22, 0.64]
Hindawi 2005	6/90	31/102		14.6 %	0.22 [0.10, 0.50]
Hofmeyr 1983	0/30	8/30		1.7 %	0.06 [0.00, 0.98]
Mahomed 1991	13/103	54/105		24.8 %	0.25 [0.14, 0.42]
Rita 2012	3/30	6/30		7.2 %	0.50 [0.14, 1.82]
Van de Pavert 1990	9/25	18/27		22.7 %	0.54 [0.30, 0.97]
Van Dorsten 1981	2/25	2/23		3.7 %	0.92 [0.14, 6.01]
Total (95% CI)	**334**	**351**		**100.0 %**	**0.35 [0.24, 0.50]**

Total events: 43 (ECV), 148 (no ECV)

Heterogeneity: $Tau^2 = 0.07$; $Chi^2 = 8.52$, df = 6 (P = 0.20); $I^2 = 30\%$

Test for overall effect: Z = 5.57 (P < 0.00001)

Test for subgroup differences: Not applicable

Analysis 1.5. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 5 Apgar score < 7 at 1 minute (not prespecified).

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 5 Apgar score < 7 at 1 minute (not prespecified)

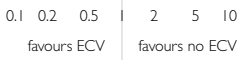
Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Hofmeyr 1983	3/30	5/30		21.2 %	0.60 [0.16, 2.29]
Rita 2012	6/30	15/30		39.6 %	0.40 [0.18, 0.89]
Van Dorsten 1981	9/25	7/23		39.2 %	1.18 [0.53, 2.66]
Total (95% CI)	**85**	**83**		**100.0 %**	**0.67 [0.32, 1.37]**

Total events: 18 (ECV), 27 (no ECV)

Heterogeneity: $Tau^2 = 0.18$; $Chi^2 = 3.54$, df = 2 (P = 0.17); $I^2 = 43\%$

Test for overall effect: Z = 1.10 (P = 0.27)

Test for subgroup differences: Not applicable



Analysis 1.6. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 6 Apgar score < 7 at 5 minutes.

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 6 Apgar score < 7 at 5 minutes

Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Van Dorsten 1981	0/25	0/23			Not estimable
Hofmeyr 1983	0/30	0/30			Not estimable
Van de Pavert 1990	0/25	1/27		9.4 %	0.36 [0.02, 8.43]
Rita 2012	1/30	4/30		26.1 %	0.25 [0.03, 2.11]
Mahomed 1991	8/103	10/105		64.5 %	0.82 [0.34, 1.98]
Total (95% CI)	**213**	**215**		**100.0 %**	**0.63 [0.29, 1.36]**

Total events: 9 (ECV), 15 (no ECV)

Heterogeneity: Chi^2 = 1.17, df = 2 (P = 0.56); I^2 =0.0%

Test for overall effect: Z = 1.19 (P = 0.24)

Test for subgroup differences: Not applicable

Analysis 1.7. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 7 Umbilical vein pH < 7.20.

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 7 Umbilical vein pH < 7.20

Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Van de Pavert 1990	3/25	5/27		100.0 %	0.65 [0.17, 2.44]
Total (95% CI)	**25**	**27**		**100.0 %**	**0.65 [0.17, 2.44]**

Total events: 3 (ECV), 5 (no ECV)

Heterogeneity: not applicable

Test for overall effect: Z = 0.64 (P = 0.52)

Test for subgroup differences: Not applicable

Analysis 1.8. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 8 Perinatal death.

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 8 Perinatal death

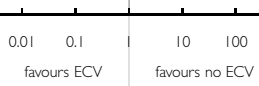
Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Brocks 1984	0/31	0/34			Not estimable
Van Dorsten 1981	0/25	0/23			Not estimable
Van de Pavert 1990	0/25	0/27			Not estimable
Hofmeyr 1983	0/30	0/30			Not estimable
Hindawi 2005	0/90	0/102			Not estimable
Mahomed 1991	1/103	2/105		30.6 %	0.51 [0.05, 5.54]
Rita 2012	1/30	2/30		30.9 %	0.50 [0.05, 5.22]
Dafallah 2004	0/310	2/310		38.6 %	0.20 [0.01, 4.15]
Total (95% CI)	**644**	**661**		**100.0 %**	**0.39 [0.09, 1.64]**

Total events: 2 (ECV), 6 (no ECV)

Heterogeneity: $Chi^2 = 0.28$, df = 2 (P = 0.87); $I^2 = 0.0\%$

Test for overall effect: Z = 1.29 (P = 0.20)

Test for subgroup differences: Not applicable



Analysis 1.9. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 9 Neonatal admission.

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 9 Neonatal admission

Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Van Dorsten 1981	0/25	0/23			Not estimable
Van de Pavert 1990	1/25	3/27		10.4 %	0.36 [0.04, 3.24]
Rita 2012	3/30	6/30		21.7 %	0.50 [0.14, 1.82]
Mahomed 1991	18/103	19/105		67.9 %	0.97 [0.54, 1.73]
Total (95% CI)	**183**	**185**		**100.0 %**	**0.80 [0.48, 1.34]**

Total events: 22 (ECV), 28 (no ECV)

Heterogeneity: $Chi^2 = 1.41$, df = 2 (P = 0.49); $I^2 = 0.0\%$

Test for overall effect: Z = 0.85 (P = 0.40)

Test for subgroup differences: Not applicable

Analysis 1.10. Comparison 1 External cephalic version at term versus no ECV attempt, Outcome 10 Enrolment-delivery interval (not prespecified).

Review: External cephalic version for breech presentation at term

Comparison: 1 External cephalic version at term versus no ECV attempt

Outcome: 10 Enrolment-delivery interval (not prespecified)

Study or subgroup	ECV N	Mean(SD)	no ECV N	Mean(SD)	Mean Difference IV,Fixed,95% CI	Weight	Mean Difference IV,Fixed,95% CI
Mahomed 1991	103	14 (11)	105	14 (9)		87.6 %	0.0 [-2.73, 2.73]
Van Dorsten 1981	25	15.6 (11.5)	23	17.6 (13.9)		12.4 %	-2.00 [-9.25, 5.25]
Total (95% CI)	**128**		**128**			**100.0 %**	**-0.25 [-2.81, 2.31]**

Heterogeneity: $Chi^2 = 0.26$, df = 1 (P = 0.61); $I^2 = 0.0\%$

Test for overall effect: Z = 0.19 (P = 0.85)

Test for subgroup differences: Not applicable

Analysis 2.1. Comparison 2 Sensitivity analysis (excluding studies with high risk of bias), Outcome 1 Vaginal cephalic birth not achieved (CS + breech vaginal birth).

Review: External cephalic version for breech presentation at term

Comparison: 2 Sensitivity analysis (excluding studies with high risk of bias)

Outcome: 1 Vaginal cephalic birth not achieved (CS + breech vaginal birth)

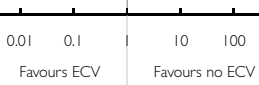
Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Hofmeyr 1983	6/30	21/30		10.5 %	0.29 [0.13, 0.61]
Van Dorsten 1981	9/25	19/23		19.3 %	0.44 [0.25, 0.76]
Rita 2012	9/30	28/30		19.3 %	0.32 [0.18, 0.56]
Mahomed 1991	26/103	89/105		50.9 %	0.30 [0.21, 0.42]
Total (95% CI)	**188**	**188**		**100.0 %**	**0.32 [0.25, 0.41]**

Total events: 50 (ECV), 157 (no ECV)

Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 1.46$, df = 3 (P = 0.69); $I^2 = 0.0\%$

Test for overall effect: Z = 9.06 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 2.2. Comparison 2 Sensitivity analysis (excluding studies with high risk of bias), Outcome 2 Caesarean section.

Review: External cephalic version for breech presentation at term

Comparison: 2 Sensitivity analysis (excluding studies with high risk of bias)

Outcome: 2 Caesarean section

Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Van de Pavert 1990	7/25	3/27		12.2 %	2.52 [0.73, 8.69]
Hofmeyr 1983	6/30	13/30		19.2 %	0.46 [0.20, 1.05]
Rita 2012	6/30	22/30		20.9 %	0.27 [0.13, 0.58]
Van Dorsten 1981	7/25	17/23		22.6 %	0.38 [0.19, 0.74]
Mahomed 1991	13/103	35/105		25.1 %	0.38 [0.21, 0.67]
Total (95% CI)	**213**	**215**		**100.0 %**	**0.46 [0.27, 0.79]**

Total events: 39 (ECV), 90 (no ECV)

Heterogeneity: $Tau^2 = 0.21$; $Chi^2 = 9.62$, df = 4 (P = 0.05); $I^2 = 58\%$

Test for overall effect: Z = 2.83 (P = 0.0047)

Test for subgroup differences: Not applicable

Analysis 2.3. Comparison 2 Sensitivity analysis (excluding studies with high risk of bias), Outcome 3 Non cephalic presentation at birth.

Review: External cephalic version for breech presentation at term

Comparison: 2 Sensitivity analysis (excluding studies with high risk of bias)

Outcome: 3 Non cephalic presentation at birth

Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Hofmeyr 1983	1/30	20/30		10.8 %	0.05 [0.01, 0.35]
Mahomed 1991	18/103	87/105		23.1 %	0.21 [0.14, 0.32]
Rita 2012	6/30	28/30		20.9 %	0.21 [0.10, 0.44]
Van de Pavert 1990	16/25	20/27		23.4 %	0.86 [0.60, 1.25]
Van Dorsten 1981	8/25	19/23		21.8 %	0.39 [0.21, 0.71]
Total (95% CI)	**213**	**215**		**100.0 %**	**0.29 [0.12, 0.68]**

Total events: 49 (ECV), 174 (no ECV)

Heterogeneity: $Tau^2 = 0.78$; $Chi^2 = 41.17$, df = 4 ($P<0.00001$); $I^2 = 90\%$

Test for overall effect: Z = 2.85 (P = 0.0044)

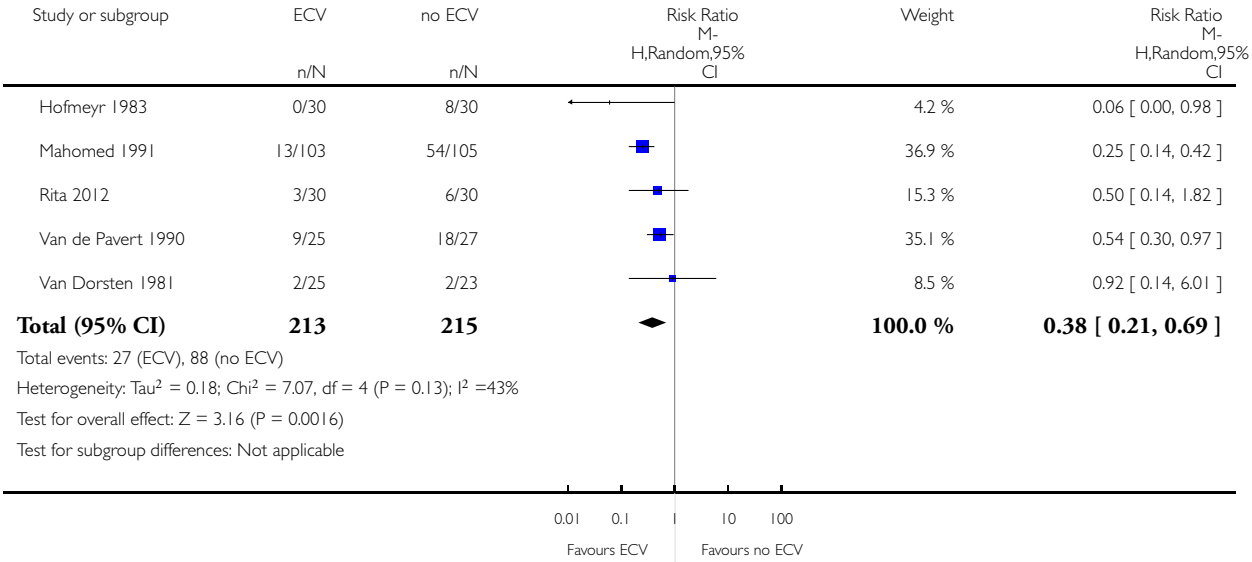
Test for subgroup differences: Not applicable

Analysis 2.4. Comparison 2 Sensitivity analysis (excluding studies with high risk of bias), Outcome 4 Vaginal breech birth.

Review: External cephalic version for breech presentation at term

Comparison: 2 Sensitivity analysis (excluding studies with high risk of bias)

Outcome: 4 Vaginal breech birth



Analysis 3.1. Comparison 3 Sensitivity analysis (excluding studies in Africa), Outcome 1 Vaginal cephalic birth not achieved (CS + breech vaginal birth).

Review: External cephalic version for breech presentation at term

Comparison: 3 Sensitivity analysis (excluding studies in Africa)

Outcome: 1 Vaginal cephalic birth not achieved (CS + breech vaginal birth)

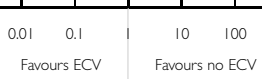
Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Van Dorsten 1981	9/25	19/23		12.2 %	0.44 [0.25, 0.76]
Brocks 1984	17/31	29/34		17.0 %	0.64 [0.45, 0.91]
Rita 2012	9/30	28/30		17.2 %	0.32 [0.18, 0.56]
Hindawi 2005	41/90	93/102		53.6 %	0.50 [0.40, 0.63]
Total (95% CI)	**176**	**189**		**100.0 %**	**0.49 [0.41, 0.58]**

Total events: 76 (ECV), 169 (no ECV)

Heterogeneity: $Chi^2 = 4.82$, df = 3 (P = 0.19); $I^2 = 38\%$

Test for overall effect: Z = 8.05 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 3.2. Comparison 3 Sensitivity analysis (excluding studies in Africa), Outcome 2 Caesarean section.

Review: External cephalic version for breech presentation at term

Comparison: 3 Sensitivity analysis (excluding studies in Africa)

Outcome: 2 Caesarean section

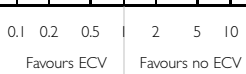
Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Van de Pavert 1990	7/25	3/27		2.6 %	2.52 [0.73, 8.69]
Brocks 1984	7/31	12/34		10.2 %	0.64 [0.29, 1.42]
Van Dorsten 1981	7/25	17/23		15.8 %	0.38 [0.19, 0.74]
Rita 2012	6/30	22/30		19.6 %	0.27 [0.13, 0.58]
Hindawi 2005	35/90	62/102		51.8 %	0.64 [0.47, 0.87]
Total (95% CI)	**201**	**216**		**100.0 %**	**0.57 [0.45, 0.73]**

Total events: 62 (ECV), 116 (no ECV)

Heterogeneity: Chi^2 = 11.32, df = 4 (P = 0.02); I^2 =65%

Test for overall effect: Z = 4.55 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 3.3. Comparison 3 Sensitivity analysis (excluding studies in Africa), Outcome 3 Non cephalic presentation at birth.

Review: External cephalic version for breech presentation at term

Comparison: 3 Sensitivity analysis (excluding studies in Africa)

Outcome: 3 Non cephalic presentation at birth

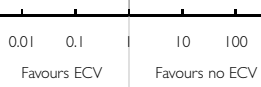
Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Van de Pavert 1990	16/25	20/27		10.7 %	0.86 [0.60, 1.25]
Van Dorsten 1981	8/25	19/23		11.0 %	0.39 [0.21, 0.71]
Brocks 1984	17/31	28/34		14.8 %	0.67 [0.47, 0.95]
Rita 2012	6/30	28/30		15.6 %	0.21 [0.10, 0.44]
Hindawi 2005	33/90	92/102		47.9 %	0.41 [0.31, 0.54]
Total (95% CI)	**201**	**216**		**100.0 %**	**0.46 [0.39, 0.55]**

Total events: 80 (ECV), 187 (no ECV)

Heterogeneity: Chi^2 = 20.61, df = 4 (P = 0.00038); I^2 =81%

Test for overall effect: Z = 8.44 (P < 0.00001)

Test for subgroup differences: Not applicable



Analysis 3.4. Comparison 3 Sensitivity analysis (excluding studies in Africa), Outcome 4 Vaginal breech birth.

Review: External cephalic version for breech presentation at term

Comparison: 3 Sensitivity analysis (excluding studies in Africa)

Outcome: 4 Vaginal breech birth

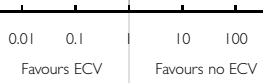
Study or subgroup	ECV n/N	no ECV n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Van Dorsten 1981	2/25	2/23		2.5 %	0.92 [0.14, 6.01]
Rita 2012	3/30	6/30		7.3 %	0.50 [0.14, 1.82]
Van de Pavert 1990	9/25	18/27		21.1 %	0.54 [0.30, 0.97]
Brocks 1984	10/31	29/34		33.7 %	0.38 [0.22, 0.64]
Hindawi 2005	6/90	31/102		35.4 %	0.22 [0.10, 0.50]
Total (95% CI)	**201**	**216**		**100.0 %**	**0.38 [0.27, 0.54]**

Total events: 30 (ECV), 86 (no ECV)

Heterogeneity: $Chi^2 = 4.12$, df = 4 (P = 0.39); $I^2 = 3\%$

Test for overall effect: Z = 5.49 (P < 0.00001)

Test for subgroup differences: Not applicable



APPENDICES

Appendix 1. Previous searches conducted by authors

CENTRAL (*The Cochrane Library,* 2010, Issue 3) and PubMed (1966 to September 2010) using the terms external cephalic version OR ECV.

WHAT'S NEW

Last assessed as up-to-date: 28 February 2015.

Date	Event	Description
9 March 2015	New citation required but conclusions have not changed	Review updated. The review now includes eight trials.
28 February 2015	New search has been performed	Search updated, one new trial identified and included (Rita 2012), methods updated. A 'Summary of findings' table has been added

HISTORY

Protocol first published: Issue 2, 1996

Review first published: Issue 2, 1996

Date	Event	Description
7 August 2012	New search has been performed	Search updated. No new trial reports identified.
31 July 2012	New citation required but conclusions have not changed	Review updated with new search date.
10 September 2010	New search has been performed	Search updated. Two new studies included (Dafallah 2004; Hindawi 2005) and three studies excluded (Rust 2005; El-Muzaini 2008a; El-Muzaini 2008b). Conclusions not changed.
2 July 2010	Amended	Contact details edited.
2 September 2008	Amended	Converted to new review format.
1 April 2005	Amended	Revised to be consistent with revision of review 'External cephalic version for breech presentation before term' (Hutton 2006). Van Veelen 1989 trial reassigned to the latter review. Search updated. No new trials identified.
31 December 2004	New search has been performed	Literature search revised. No new data identified.

CONTRIBUTIONS OF AUTHORS

GJ Hofmeyr prepared the original version, maintains the review and reviewed the updated version. H West revised the text, assessed studies, extracted and analysed data for the updated version of the review. R Kulier assessed studies and extracted data for the updated version of the review, and revised and quality-checked the previous version of the review.

DECLARATIONS OF INTEREST

GJ Hofmeyr is an author of one of the papers included in this review (Hofmeyr 1983) but he was not involved in assessing this study for inclusion, assessing trial quality, or data extraction. GJ Hofmeyr receives royalties for two chapters in UpToDate.

SOURCES OF SUPPORT

Internal sources

- (GJH) Effective Care Research Unit, University of the Witwatersrand/Fort Hare, Eastern Cape Department of Health, South Africa.
- Department of Obstetrics and Gynaecology, Geneva University Hospital, Switzerland.
- (HW) Cochrane Pregnancy and Childbirth Group, Department of Women's and Children's Health, The University of Liverpool, Liverpool, UK.

External sources

- (GJH) South African Medical Research Council, South Africa.
- (GJH) HRP-UNDP/UNFPA/WHO/World Bank Special Programme in Human Reproduction, Geneva, Switzerland.
- Rockefeller Foundation, USA.
- (HW) National Institute for Health Research (NIHR), UKNIHR Cochrane Programme Grant Project: 13/89/05 - Pregnancy and childbirth systematic reviews to support clinical guidelines, UK.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The outcomes vaginal cephalic delivery not achieved and vaginal breech delivery were added for this 2015 update. Outcomes that were not prespecified in the original protocol include: vaginal cephalic delivery not achieved, vaginal breech delivery, Apgar score less than seven at one minute, and enrolment-delivery interval.

Methods for subgroup analysis for future updates were added. It has been suggested that ECV may be more successful (and spontaneous version more common) in black African than Caucasian women, possibly because of the tendency for the presenting part to remain high until the onset of labour (Hofmeyr 1986). Post-hoc sensitivity analysis excluding the three studies in black African women (Dafallah 2004; Hofmeyr 1983; Mahomed 1991) was conducted.

INDEX TERMS

Medical Subject Headings (MeSH)

*Breech Presentation; *Term Birth; Cesarean Section; Pregnancy Outcome; Randomized Controlled Trials as Topic; Version, Fetal [*methods]

MeSH check words

Female; Humans; Pregnancy