

Interventions to help external cephalic version for breech presentation at term (Review)

Hofmeyr GJ, Gyte G



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This record should be cited as:

Hofmeyr GJ, Gyte G. Interventions to help external cephalic version for breech presentation at term. *Cochrane Database of Systematic Reviews* 2004, Issue 1. Art. No.: CD000184. DOI: 10.1002/14651858.CD000184.pub2.

This version first published online: 26 January 2004 in Issue 1, 2004.

Date of most recent substantive amendment: 13 September 2003

ABSTRACT

Background

Breech presentation places a fetus at increased risk. The outcome for the baby is improved by planned caesarean section compared with current medical practice for planned vaginal birth. External cephalic version (turning the fetus to the vertex position by external manipulation) attempts to reduce the chances of breech presentation at birth, and thus reduce the adverse effects of caesarean section, but is not always successful. Tocolytic drugs to relax the uterus, as well as other methods, have been used in an attempt to facilitate external cephalic version at term.

Objectives

To assess the effects of routine tocolysis, fetal acoustic stimulation, epidural or spinal analgesia and transabdominal amnioinfusion for external cephalic version at term on successful version and measures of pregnancy outcome.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group trials register (March 2004) and the Cochrane Central Register of Controlled Trials (*The Cochrane Library*, Issue 2, 2004).

Selection criteria

Randomised and quasi-randomised trials comparing routine tocolysis; selective tocolysis; fetal acoustic stimulation in midline fetal spine positions; epidural or spinal analgesia; or transabdominal amnioinfusion; with alternative methods or no intervention to facilitate external cephalic version at term.

Data collection and analysis

We assessed eligibility and trial quality.

Main results

Sixteen studies were included. Routine tocolysis with beta-stimulants was associated with fewer failures of external cephalic version (6 trials, 617 women, relative risk (RR) 0.74, 95% confidence interval (CI) 0.64 to 0.87). The reduction in non-cephalic presentations at birth was not statistically significant. Caesarean sections were reduced (3 trials, 444 women, RR 0.85, 95% CI 0.72 to 0.99). In four small trials, sublingual nitroglycerine was associated with significant side-effects, and was not found to be effective. Fetal acoustic stimulation in midline fetal spine positions was associated with fewer failures of external cephalic version at term (1 trial, 26 women, RR 0.17, 95% CI 0.05 to 0.60). External cephalic version failure, non-cephalic births and caesarean sections were reduced in two trials with epidural but not in three with spinal analgesia. We postulate that large volume preloading with epidural may have increased the amniotic fluid volume. No randomised trials of transabdominal amnioinfusion for external cephalic version at term were located.

Authors' conclusions

Although the methodological quality of the trials was not ideal, routine tocolysis appears to increase the success rate of external cephalic version at term. There is not enough evidence to evaluate the use of fetal acoustic stimulation in midline fetal spine positions, nor of epidural or spinal analgesia.

PLAIN LANGUAGE SUMMARY

Babies in the bottom first position are more likely to change position to head first during external cephalic version if women receive tocolytic drugs

Babies born in the breech position (bottom first) are at increased risk. During external cephalic version (ECV) practitioners use their hands on the woman's abdomen to gently try to turn the baby from the breech position. The review of trials found that babies are more likely to turn head first during ECV if women receive tocolytic drugs (to relax womb muscles). There is too little evidence to show whether an injection into the lower back for pain relief (epidural or spinal), increasing the fluid surrounding the baby (transabdominal amnioinfusion), or sound stimulation of the baby help the baby to turn.

BACKGROUND

Breech presentation

Breech presentation is where the fetus is lying bottom first. Breech presentation may be caused by an underlying fetal or maternal abnormality, or may be an apparently chance occurrence, or may be related to an otherwise benign variant such as cornual placental position (the placenta situated in an upper lateral corner of the uterus). In the latter instances, breech presentation places a healthy fetus and mother at increased risk of a complicated vaginal birth or caesarean section. It is not surprising that, over the years, the possibility of turning the baby from the breech to the cephalic presentation (ECV) has intrigued some obstetric caregivers.

Considerable disagreement surrounds the management of breech (bottom first) presentation, both with respect to the place of external cephalic version (ECV) and the type of birth. The interpretation of non-randomised trials is confounded by the fact that breech presentation per se appears to be a marker for poor perinatal outcome. For example, the incidence of childhood handicap following breech presentation has been found to be high (16%) both for those babies delivered vaginally and those delivered by caesarean section (Danielian 1996). Randomised trials of current medical practice for vaginal breech birth have shown clear benefits for the breech presenting baby delivered by caesarean section compared with planned vaginal birth, although long-term follow up and impact on future pregnancies remains uncertain (Hofmeyr 2002e). These results have had a profound effect on clinical practice, and in many institutions caesarean section for breech presentation has become routine. Under these circumstances, the impact of ECV on caesarean section rates would be expected to be greater than was the case in previous trials in institutions where vaginal breech birth was common.

There are three basic types of breech presentation: (1) frank breech where the fetus' legs are extended up to its head; (2) complete breech where the fetus' legs are flexed back to the bottom; (3) footling breech where one or both legs are extended below the fetus' bottom. Although there may be underlying reasons for the breech presentation, the baby is considered to have a more difficult

vaginal birth because of concern that the head may be delayed in being born.

External cephalic version (ECV)

During an external cephalic version, practitioners use their hands on the woman's abdomen to gently try to turn the baby from the breech position.

ECV before term 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 before 1980 (Brosset 1956). The popularity of ECV before term waned after the mid-1970s, partly because of reports of an increase in perinatal mortality associated with the procedure (Bradley-Watson 1975) which, in retrospect, may have been due to undue force being applied, and the increasing perception of caesarean section as a safer option than ECV or breech birth.

Before 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, ECV could be achieved in a substantial proportion of women with breech presentation at term (37 completed weeks of pregnancy or more). Predictors of unsuccessful version include engaged presenting part, fetal head not easily palpable and tense uterus (Lau 1997).

Initially, successful external cephalic version at a late stage of pregnancy was considered to have become possible only because of the use of tocolytic drugs to relax the uterus. However, later studies showed that external cephalic version at term was frequently possible without tocolysis. The overall success rate was 60% in a systematic review of RCTs where some trials included facilitation and others did not (Hofmeyr 2002b).

The question therefore arose as to whether tocolysis should be used routinely for external cephalic version at term, or only in those cases in which difficulty is anticipated or initial attempts fail.

Tocolysis to facilitate ECV at term

The most widely used tocolytics have been beta-adrenergic (beta-mimetic) drugs such as salbutamol, ritodrine, hexoprenaline or

terbutaline These are given intravenously or by inhalation. The possible side-effects on the mother and baby include tachycardia (increase in heart rate). Intravenous nitroglycerine (Belfort 1993) or sublingual glyceryl trinitrate/nitroglycerine spray (Reddick 1997; Yanny 2000) have been suggested as alternative tocolytics, which might have fewer side-effects than the betastimulants. A retrospective study found no benefit from nitroglycerine spray (Bujold 2003b).

Vibroacoustic stimulation for midline fetal spine position to facilitate ECV at term

This procedure is where the fetus is stimulated using sound applied to the mother's abdomen to stimulate the baby to move out of the midline position. It has been studied in one small trial, included in this review (Johnson 1995).

Epidural or spinal analgesia to facilitate ECV at term

Epidural analgesia is where an anaesthetic drug is infused into the epidural space around the mother's spinal column. Spinal analgesia is when an anaesthetic drug is injected into the spinal column. In a retrospective cohort study, ECV at term was successful in 59% of 32 women with epidural analgesia, and 24% of 37 women without (Carlan 1994). In an uncontrolled study, ECV under epidural analgesia was successful in nine (56%) of 16 women in whom initial attempts had failed (Neiger 1998a; Neiger 1998b). The potential adverse effects of these analgesics include a fall in blood pressure, and headache. Also it may be that the caregiver does not undertake the ECV as gently because the mother feels no pain and hence the chance of damaging the baby may be increased.

Amnioinfusion to facilitate ECV at term

Amnioinfusion is where saline is infused into the amniotic sac to increase the volume of fluid there to enable the fetus to turn more easily. In an uncontrolled study, six women with failed ECV had a successful repeat attempt following transabdominal amnioinfusion with 700 to 900 ml warmed saline (Benifla 1995). To our knowledge, no randomised trials to determine the effectiveness of this intervention have been reported. Potential adverse effects include infection.

It is important to assess whether these various interventions do increase the effectiveness of ECV or not. Readers are referred to previous reviews of the topic (Hofmeyr 1989; Hofmeyr 1991; Hofmeyr 1992; Hofmeyr 1993; Zhang 1993). See also related Cochrane reviews: 'Cephalic version by postural management for breech presentation' (Hofmeyr 2002a); 'External cephalic version for breech presentation at term' (Hofmeyr 2002b); 'External cephalic version for breech presentation before term' (Hofmeyr 2002c).

OBJECTIVES

To assess, from the best evidence available, the effects of the routine use of tocolysis, acoustic stimulation for midline spine position, epidural or spinal analgesia or amnioinfusion for external cephalic

version at term on successful version, presentation at and method of delivery, and perinatal and maternal morbidity and mortality.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Clinical trials comparing routine tocolysis versus selective or no use of tocolysis, or different tocolytics, epidural or spinal analgesia, amnioinfusion or fetal acoustic stimulation in midline fetal spine positions, on clinically meaningful outcomes; random or quasi-random allocation to a treatment and control group; violations of allocated management and exclusions after allocation not sufficient to materially affect outcomes.

Types of participants

Routine tocolysis for external cephalic version at term

Women with breech presentation at term and no contraindications to external cephalic version (ECV) or tocolytic drugs.

Fetal acoustic stimulation in midline fetal spine positions

Women with breech presentation at term, no contraindication to external cephalic version attempt, and the fetal spine in a midline position.

Epidural or spinal analgesia

Women with breech presentation at term and no contraindications to ECV, with or without previous failed ECV attempt.

Amnioinfusion

Women with breech presentation at term and no contraindications to ECV, with or without previous failed ECV attempt.

Types of intervention

Routine tocolysis for external cephalic version at term

Tocolysis used routinely versus selectively or not at all, or comparison of different tocolytic agents, for attempted external cephalic version.

Fetal acoustic stimulation in midline fetal spine positions

Acoustic stimulation applied over the fetal head, versus dummy or no stimulation.

Epidural analgesia

Epidural or spinal analgesia versus no regional analgesia.

Amnioinfusion

Amnioinfusion versus no amnioinfusion.

Types of outcome measures

Failed external cephalic version; difficult external cephalic version; maternal side-effects such as palpitations, chest pain (retrosternal pain), headaches and hypotension (low blood pressure); and fetal side-effects such as bradycardia (slow heart rate); perinatal outcomes including presentation at delivery, method of delivery and perinatal and maternal morbidity and mortality.

Outcomes included if clinically meaningful; reasonable measures taken to minimise observer bias; missing data insufficient to materially influence conclusions; data available for analysis according to original allocation, irrespective of protocol violations; data available in format suitable for analysis.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

We searched the Cochrane Pregnancy and Childbirth Group trials register (March 2004).

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

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. monthly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness search of a further 37 journals.

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

Trials identified through the searching activities described above are given a code (or codes) depending on the topic. The codes are linked to review topics. The Trials Search Co-ordinator searches the register for each review using these codes rather than keywords.

In addition, CENTRAL (*The Cochrane Library*, Issue 3, 2003) was searched with the terms 'external cephalic version or ECV'.

METHODS OF THE REVIEW

The original protocol was modified in November 2001 to include comparisons of nitric oxide donors with placebo, no treatment or other tocolytics. We evaluated trials under consideration for methodological quality and appropriateness for inclusion according to the prestated selection criteria, without consideration of their results. We included individual outcome data in the analysis if they met the prestated criteria in 'Types of outcome measures'. We processed included trial data as described in Clarke 2000.

We extracted data from the sources and entered them onto the Review Manager (RevMan 2000) computer software, checked the

data for accuracy, and analysed them as above using the RevMan software. We calculated relative risks and 95% confidence intervals for dichotomous data, and in the absence of heterogeneity, we pooled results using a fixed effects model. We pooled continuous data using weighted mean differences and 95% confidence intervals.

DESCRIPTION OF STUDIES

See 'Characteristics of included studies'.

METHODOLOGICAL QUALITY

See table of 'Characteristics of included studies', particularly the 'Methods' and 'Notes' sections.

Routine tocolysis for external cephalic version at term:

In the study of Robertson et al (Robertson 1987), allocation was according to social security number. In other respects the study was methodologically sound. Although not blinded, the measures of outcome analysed were not subject to observer bias.

In the study of Tan et al (Tan 1989), predetermined numbers of women were allocated to each group by means of a 'stack' of cards, stratified for parity and gestational age. The management was made blind by dummy intravenous lines, and the outcome variables were not subject to observer bias. In each group, nine of the 30 pregnancies were of less than 36 weeks' gestational age.

In the study of Stock et al (Stock 1993), 63 women suitable for external cephalic version (ECV) between 36 and 42 weeks' gestation were "randomised" in sets of three, stratified for parity and investigator, to receive dextrose only (A), ritodrine 0.3 mg per minute for 30 minutes (B), or hexoprenaline 10 micrograms by intravenous infusion (C). Blinding was achieved by the use of "dummy" infusions and injections.

Marquette 1996 do not account for a discrepancy in numbers (ritodrine 138 versus control 145), which should not occur using balanced blocks of 10 (283 women: maximum difference in numbers should be three).

Chung 1996 allocated women in pairs, using computer randomisation and a closed sequential plan. One author, who attended the women throughout but did not participate in the ECV procedure, knew the randomisation. It is not clear whether allocation in pairs may have unblinded the next allocation in some cases, which could introduce selection bias.

Fernandez 1997 used randomised unlabelled syringes randomly prepared by the pharmacy, containing terbutaline or placebo.

Yanny 2000 used opaque sealed envelopes in computer-generated random sequence to allocate use of spray 'A' or spray 'B'.

For the study of Andarsio 2000, only a brief abstract has been reviewed. It is described as a “randomized prospective study”.

The studies of Bujold et al (Bujold 2002; Bujold 2003) used double-blind, placebo-controlled random allocation.

Overall, therefore, methodological quality was not ideal.

Fetal acoustic stimulation in midline fetal spine positions

The one small trial (Johnson 1995) used randomised envelopes for allocation, and the physician was blinded by leaving the room during fetal or dummy acoustic stimulation. Sufficient data were given on three exclusions after allocation, for inclusion of the data in this review. To increase numbers a crossover study design was used. Only data from the primary intervention are included in this review.

Epidural or spinal analgesia

Operator bias could not be excluded as blinding was not possible in these three trials.

In the reports of Delisle 2001 and Hollard 2003, the method of random allocation was not specified.

RESULTS

Sixteen studies were included.

Routine tocolysis for external cephalic version at term

Betamimetics

Overall, tocolysis was associated with reduced risk of failed external cephalic version (ECV) in both nulliparous and multiparous women (six trials, 617 women, relative risk (RR) 0.74, 95% confidence interval (CI) 0.64 to 0.87). Caesarean section rates, reported according to group allocation in only three studies, were reduced with tocolysis (3 trials, 444 women, RR 0.85, 95% CI 0.72 to 0.99).

In the study of Robertson et al (Robertson 1987), external cephalic version was successful at the first attempt in 20/30 women using tocolysis and 19/28 without. In the latter failures, external cephalic version was attempted again using tocolysis, and was successful in 1/9. Subsequent comparisons were therefore between the routine compared with the selective use of tocolysis, and revealed no significant differences between the groups, though the numbers of participants is likely to have been insufficient to show a difference.

In the study of Tan et al (Tan 1989), the immediate version success rate was 14/30 following oral salbutamol 4 mg three times daily for at least one day, 15/30 following salbutamol infusion to produce maternal tachycardia of 100 beats per minute for 30 minutes, and 14/30 in the control group. For consistency, only the latter two groups are considered in this review. Pregnancy outcomes are unfortunately not given for the individual drug treatments.

In the study of Stock et al (Stock 1993), external cephalic version was significantly more successful with hexoprenaline than with

placebo (16/21 versus 9/21). The difference between ritodrine (14/21) and placebo was not statistically significant. For the purpose of this review, the hexoprenaline and ritodrine groups have been combined as the primary objective is to compare tocolysis with placebo. Failure to achieve external cephalic version within one minute, and fetal bradycardia were also less frequent in the tocolysis groups.

Nitric oxide donors

Two small trials comparing sublingual glyceryl trinitrate/nitroglycerine with placebo showed a trend to fewer successful ECV attempts in multiparous women (Bujold 2002) and more in women with mixed parity (Yanny 2000), and overall no effect (2 trials, 156 women, RR 1.06, 95% CI 0.82 to 1.37). In one trial (Bujold 2002), headaches and symptomatic hypotension were more common with nitroglycerine.

One study comparing sublingual nitroglycerine with intravenous ritodrine in nulliparous women (Bujold 2003) found more headaches and hypotension, and a trend to fewer successful ECV attempts, with nitroglycerine. Another study comparing nitroglycerin with terbutaline in women of mixed parity (Andarsio 2000) was too small to draw conclusions from. Overall, there was no difference in failed ECV (2 trials, 109 women, RR 1.31, 95% CI 0.96 to 1.77).

Fetal acoustic stimulation in midline fetal spine positions

In one small trial, the rate of failed external cephalic version was greatly reduced (26 women, RR 0.17, 95% CI 0.05 to 0.60).

Epidural or spinal analgesia

There was a discordance between the five trials included in this review. External cephalic version failure was significantly reduced in the two trials using epidural analgesia (Mancuso 2000 and Schorr 1997), but no difference was found in the three trials of spinal analgesia (Delisle 2001, Dugoff 1999 and Hollard 2003). Non-cephalic births and caesarean sections were significantly reduced in the two epidural trials (Schorr 1997; Mancuso 2000), but not the other trial which reported these outcomes (Dugoff 1999), and there was significant heterogeneity of these results. The overall differences (using a random effects model because of heterogeneity) were not statistically significant, except for failure rate with and without regional analgesia which was of borderline significance (5 trials, 456 women, RR 0.79, 95% CI 0.63 to 1.00). In the two studies which reported these results, there was less maternal discomfort with spinal analgesia (Dugoff 1999, Hollard 2003). There were no differences in fetal heart rate changes, and maternal hypotension occurred too infrequently for evaluation.

Amnioinfusion

No randomised trials were found.

DISCUSSION

Routine tocolysis for external cephalic version at term

In the study of Stock et al (Stock 1993), one woman in the ritodrine and one in the hexoprenaline group complained of palpitations. One in the hexoprenaline group complained of retrosternal pain, with no sequelae. The authors therefore recommend that hexoprenaline be given as two five microgram boluses two minutes apart, checking blood pressure and pulse during the interval to identify those women who are unusually sensitive to the cardiovascular side-effects.

There is reasonable agreement between trials. While two trials show no effect of tocolysis, the numbers studied were small, and the confidence intervals include the point estimate of reduced failure of external cephalic version (ECV) in the other studies. Differences might be due to differences in the type and dose of tocolytic used. In the two studies which showed a significant difference (Stock 1993; Chung 1996), hexoprenaline or a relatively high dose of ritodrine (300 to 400 micrograms per minute) were used. In the other studies salbutamol or a lower dose of ritodrine (111 to 200 micrograms per minute) were used. The study of Tan et al (Tan 1989) also differed from the others in that 27/90 of the women enrolled were at 33 to 35 weeks' gestation.

The small trials of sublingual glyceryl trinitrate show increased side-effects, no evidence of effectiveness compared with placebo, and a trend to lower effectiveness than with beta-stimulants. Nitroglycerine should not be used for ECV.

Fetal acoustic stimulation in midline fetal spine positions

Results, while encouraging in terms of immediate ECV success, are available from only one trial of this intervention. There were no data on follow up to delivery.

Epidural or spinal analgesia

There is no reason to expect that the effect of epidural analgesia should differ from that of spinal analgesia per se. However, in the two studies using epidural analgesia (Schorr 1997; Mancuso 2000), preloading was with 2000 and 1500 ml lactated Ringer's solution respectively. In the studies of spinal analgesia, preloading was with 500 ml (Dugoff 1999), 1000 ml (Hollard 2003) and not stated (Delisle 2001). This difference, together with the longer time usually taken for epidural analgesia, may have resulted in an increase in the volume of amniotic fluid in the former study (*see* Cochrane review of hydration for increasing amniotic fluid volume (Hofmeyr 2002d)). This may have contributed to the improved results with epidural analgesia in this study. In the study of Mancuso 2000, 1500 ml Ringer's lactate was also administered to the control group, but without the intervening epidural procedure, the time for this to affect amniotic fluid volume may have been insufficient.

Another possible reason for the conflicting results is the use of vaginal displacement of the presenting part, which might be facilitated by regional analgesia, in only one of the studies (Schorr 1997). The latter study also differed in that 13% of the women had transverse lies.

AUTHORS' CONCLUSIONS

Implications for practice

Routine tocolysis for external cephalic version at term

There is evidence from this review to support the use of tocolysis in clinical practice to reduce the failure rate of external cephalic version (ECV) at term. Whether tocolysis should be used routinely, or selectively when initial ECV attempts fail, has not been adequately addressed. In the one trial which used tocolysis selectively in the control group (Robertson 1987), the numbers were too small for meaningful deductions.

There is no evidence to support the use of glyceryl trinitrate in clinical practice.

Fetal acoustic stimulation in midline fetal spine positions

Confirmation of the findings in further trials with substantive outcomes (particularly potential adverse effects) should be awaited before incorporation of this new procedure into routine clinical practice.

Epidural or spinal analgesia

Because of conflicting results, use of regional analgesia for facilitating external cephalic version cannot be recommended at this stage.

Implications for research

Routine tocolysis for external cephalic version at term

There is scope for further controlled trials of routine tocolysis for external cephalic version (ECV) at term. In particular, the possible benefits of routine tocolysis use to reduce the force required for successful ECV, and the possible risks of maternal cardiovascular side-effects, need to be addressed further. Further trials are also needed to compare the effectiveness of routine versus selective use of tocolysis, and should include short-term and long-term outcome measures which assess morbidity from the type of birth.

Although the randomised trials of nitroglycerine are small, the results are sufficiently negative to discourage further trials.

Fetal acoustic stimulation in midline fetal spine positions

The results presented in this review are sufficiently encouraging to justify further trials of this procedure. Short-term and long-term outcomes need to be assessed.

Epidural or spinal analgesia

Further trials are needed. The effect of vaginal displacement of the presenting part should be assessed. The fluid received by the regional analgesia group and the control group should be similar. The possible effect of intravenous hydration prior to ECV attempt, to increase amniotic fluid volume, should be investigated as a separate intervention.

POTENTIAL CONFLICT OF INTEREST

None known.

ACKNOWLEDGEMENTS

None.

SOURCES OF SUPPORT

External sources of support

- South African Medical Research Council SOUTH AFRICA
- UNDP/UNFPA/WHO/World Bank (HRP) SWITZERLAND

Internal sources of support

- University of the Witwatersrand SOUTH AFRICA
- University of Fort Hare SOUTH AFRICA

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T A B L E S**Characteristics of included studies**

| Study | Andarsio 2000 |
|------------------------|--|
| Methods | 'Randomized prospective study'. |
| Participants | Women undergoing ECV attempt. |
| Interventions | Nitroglycerine versus terbutaline for tocolysis. |
| Outcomes | ECV success. |
| Notes | Preliminary abstract report only reviewed. |
| Allocation concealment | B – Unclear |

| Study | Bujold 2002 |
|--------------|---|
| Methods | Double-blind, randomised study using computerised randomisation table. |
| Participants | Women with parity 1 or more, 36 to 40 weeks' gestation; singleton breech presentation eligible for ECV. Exclusion criteria: intrauterine growth restriction; oligohydramnios; placenta praevia, abruptio placenta, uterine scar other than low transverse; active labour; rupture of membranes; fetal anomalies incompatible with life; non-mobile breech; contraindication to vaginal delivery ; contraindication to nitroglycerin. All underwent cardiotocography and ultrasound examination. |

Characteristics of included studies (Continued)

| | |
|------------------------|--|
| Interventions | Two 400 mcg sublingual sprays of nitroglycerin 400 micrograms, versus placebo. Up to four ECV attempts |
| Outcomes | ECV success; side-effects (headaches nitroglycerine 42% vs 4%; symptomatic hypotension 12% vs 2%); obstetrical outcomes. |
| Notes | Sainte-Justine Hospital, April 1999 to August 2002. |
| Allocation concealment | A – Adequate |

Study Bujold 2003

| | |
|------------------------|---|
| Methods | Double-blind, placebo-controlled randomised trial. Allocation by computerised table in balanced blocks of 6. |
| Participants | Women with singleton breech pregnancy at 36–40 weeks' gestation. Exclusion criteria: intrauterine growth restriction; oligohydramnios; placenta praevia; placenta abruptio; uterine scar other than low transverse caesarean section; active labour; ruptured membranes; fetal anomalies incompatible with life, any contraindication to vaginal birth; contraindications to trial medications; non-reactive cardiotocography. Cardiotocography and ultrasound performed. |
| Interventions | Two sublingual sprays of 400 micrograms nitroglycerine plus intravenous placebo, versus ritodrine 15 mg in 1.5 mL plus 20 mL 5% dextrose water by intravenous infusion at 111 micrograms per minute, plus placebo sublingual spray. Maximum 4 ECV attempts with ultrasound control. |
| Outcomes | Cardiotocograph results (prolonged fetal heart rate decelerations, 2 in each group); maternal blood pressure (lower in nitroglycerine group); hypotensive episodes (nitroglycerine 3/36 vs ritodrine 1/38); maternal pulse (higher in ritodrine group); headaches (10/36 vs 3/38); palpitations (2/36 vs 4/38); ECV success; presentation at delivery; and mode of delivery. |
| Notes | Sainte-Justine Hospital April 1999 to August 2001. |
| Allocation concealment | A – Adequate |

Study Chung 1996

| | |
|---------------|---|
| Methods | Nulliparous and parous women randomised separately. Allocated in pairs, using computer randomisation. One author knew the randomisation, who attended the woman but did not participate in the ECV procedure. Not clear whether allocation in pairs may have enabled the unblinded author to know the next allocation in some cases, which could introduce selection bias. Of 51 women recruited, 1 was excluded before commencement of the procedure because of absent umbilical artery end-diastolic flow. |
| Participants | Women with singleton breech presentation, confirmed by ultrasound, at 36 to 38 weeks' gestation. Exclusion criteria: contraindication to tocolytic therapy; scarred uterus; antepartum haemorrhage, hypertension, impaired fetal growth, oligohydramnios; vaginal delivery contraindicated; abnormal umbilical artery Doppler flow pattern. |
| Interventions | Intravenous infusion of ritodrine 0.4 mg/ml in 5% dextrose at 1.5 ml/minute via an infusion pump, for 15 minutes before and during ECV attempt. If uterine contractions appeared to be preventing successful version, the infusion rate was increased in steps of 0.75 ml/minute. Compared with matching 5% dextrose infusion. ECV attempted by 2 investigators, followed by repeat ultrasound scan and cardiotocography. |
| Outcomes | Failed ECV attempt. Other data presented according to successful or failed ECV attempt: non-cephalic presentation at delivery (1/24 vs 23/26); caesarean section (5/24 vs 19/26). One intrauterine death occurred 4 weeks after successful ECV (group not stated). Subgroup analysis showed that statistically significant benefit was limited to nulliparous women. |
| Notes | Paired sequential analysis reached significance after 10 pairs. Trial continued because of erroneous statistical calculations. Thereafter little benefit was seen from tocolysis. The authors suggest that tocolysis is helpful only during the learning phase of the technique. A subsequent trial (published earlier) from the same group showed no benefit of tocolysis [Stock 1993]. |

Characteristics of included studies (Continued)

Allocation concealment C – Inadequate

| | |
|------------------------|---|
| Study | Delisle 2001 |
| Methods | 'Randomized controlled trial'. |
| Participants | Singleton non-vertex; age 18 or more; gestational age 36 weeks or more; intact membranes; reactive cardiotocography. |
| Interventions | Spinal analgesia with bupivacaine 0.25% 1 ml plus 20 mcg fentanyl versus control; four ECV attempts; nitroglycerin tocolysis used as per operator's preference. |
| Outcomes | ECV failure; non-re-assuring cardiotocography (1/73 versus 0/68) |
| Notes | August 1998 to June 2001 |
| Allocation concealment | B – Unclear |

| | |
|------------------------|--|
| Study | Dugoff 1999 |
| Methods | Allocation by cards in sealed envelopes in computer-generated random sequence. |
| Participants | Inclusion criteria: breech presentation; 36 weeks or more; reactive cardiotocography; intact membranes; minimum 2 x 2 cm pocket of amniotic fluid. Exclusion criteria: gross fetal anomaly; uterine malformation; estimated fetal weight > 4000 g; fetal growth restriction; placenta praevia; third trimester vaginal bleeding; labour; contraindications to spinal analgesia or terbutaline. Ultrasonography, cardiotocography and digital cervical examination were performed before the procedure. |
| Interventions | Spinal analgesia with 10 mcg sufentanil and 1 ml 0.25% bupivacaine and 500 ml lactated Ringer's prehydration (n = 50), compared with no spinal (n = 52). ECV with terbutaline 0.25 mg was attempted usually by two operators, and stopped for fetal bradycardia, maternal discomfort or 4 failed attempts. Vaginal elevation of the presenting part not used. |
| Outcomes | Successful ECV; breech delivery; caesarean section. |
| Notes | University of Colorado Health Sciences Centre and Denver Health Medical Centre, USA. October 1993 to August 1997. |
| Allocation concealment | B – Unclear |

| | |
|------------------------|--|
| Study | Fernandez 1997 |
| Methods | Randomisation by pharmacy using computer-generated random sequence. |
| Participants | Inclusion criteria: singleton, non-cephalic pregnancy; > 36 weeks gestation. Exclusion criteria: under 17 years old; prior uterine surgery; ruptured membranes; placenta praevia; anomalous fetus; multiple gestation; sensitivity to terbutaline; other maternal medical complications. |
| Interventions | Terbutaline 0.25 mg (n = 52) or placebo (n = 51) in unlabelled insulin syringe given subcutaneously 15 to 30 minutes before ECV attempts. Forward then backward roll attempted. |
| Outcomes | Successful version; caesarean section. |
| Notes | Parkland Memorial Hospital, Dallas, Texas, USA. January 1994 to June 1995. |
| Allocation concealment | A – Adequate |

| | |
|---------------|---|
| Study | Hollard 2003 |
| Methods | 'Randomly assigned'. |
| Participants | Normal singleton breech pregnancy; gestational age 36 weeks or more; intact membranes; not in labour. |
| Interventions | 1000 ml IVI prehydration and intrathecal injection of 6 mg 2% lidocaine with 15 mcg fentanyl; versus control. All received .25 mg SQ terbutaline and ECV attempted. |

Characteristics of included studies (Continued)

| | |
|------------------------|--|
| Outcomes | Maternal pain (reduced in spinal analgesia group) and satisfaction (no difference) on visual scale; ECV success. |
| Notes | January 1998 to January 2003. |
| Allocation concealment | B – Unclear |

Study Johnson 1995

| | |
|------------------------|--|
| Methods | Allocation by sequential envelopes generated by a table of random numbers. |
| Participants | <p>Women scheduled for attempted external cephalic version with the fetal spine in the midline (either back-up or back-down) on ultrasound examination.</p> <p>Exclusion criteria: oligohydramnios (amniotic fluid index < 5 cm); fetal or uterine anomalies; ruptured amniotic membranes; active labour; engagement of presenting part; fetal heart rate decelerations.</p> <p>All 26 women approached agreed to participate.</p> |
| Interventions | Fetal acoustic stimulation for 1-3 seconds with a Western Electric Division AT & T (Phoenix) model 5C electrolarynx over the fetal head, or over the nurse's upper arm (dummy). Physician blinded by leaving the room during the intervention. |
| Outcomes | Persistent midline spine position on ultrasound (stimulation 1/13, control 13/13); failed external cephalic version attempt. Data on method of delivery not included because followed crossover treatment. |
| Notes | <p>2 hospitals in Arizona, USA, 1 Jan 1993 to 31 December 1994.</p> <p>After randomisation, 1 from the treatment and 2 from the control group were excluded because the breech was found to be deeply engaged in the pelvis during the initial external cephalic version attempt. None had changed position to the spine lateral position, and no further attempts at external cephalic version were made. In keeping with the prestated protocol for this review, these women have been included in the outcomes as originally allocated.</p> <p>Those women in whom external cephalic version failed, were crossed over to the other intervention arm. This review considers only data from the first intervention, according to the original allocation. Results of the 'crossover' part of the study are not included.</p> |
| Allocation concealment | B – Unclear |

Study Mancuso 2000

| | |
|------------------------|--|
| Methods | Allocation by sealed, sequentially numbered opaque envelopes in computer-generated random sequence. |
| Participants | <p>Women undergoing ECV attempt. Inclusion criteria: age 18 years or more; singleton pregnancy; 37 weeks or more; breech or transverse presentation; intact membranes; estimated fetal weight 2000 to 4000 g; reassuring fetal heart rate testing. Exclusion criteria: placenta praevia; prior classical caesarean section; third trimester bleeding; amniotic fluid index < 5 or > 25 cm; known uterine malformation; suspected major fetal anomaly; active-phase labour.</p> |
| Interventions | Lumbar epidural analgesia with 3 + 10 ml 2% lidocaine, with epinephrine test dose and fentanyl 100 micrograms, versus no epidural. All received Ringer's Lactate 1500 ml intravenously, and terbutaline 0.25 mg subcutaneously. |
| Outcomes | Presentation after ECV attempt; presentation at delivery; fetal bradycardia causing cessation of ECV attempts; method of delivery. |
| Notes | Tripler Army Medical Centre, Honolulu, Hawaii, December 1994 to June 1998. |
| Allocation concealment | A – Adequate |

Study Marquette 1996

| | |
|---------|--|
| Methods | Allocation by identical vials of ritodrine or placebo prepared by the pharmacy, in balanced blocks of 10. Investigators blind to allocation. Authors do not account for a discrepancy in numbers (ritodrine 138 vs |
|---------|--|

Characteristics of included studies (Continued)

| | |
|------------------------|---|
| | control 145), which should not occur using balanced blocks of 10 (283 women: maximum difference in numbers should be 3). |
| Participants | Women with singleton breech presentation; 36-41 weeks' gestation; reactive cardiotocography; breech mobile on abdominal palpation. Exclusion criteria: impaired fetal growth (estimated weight < 10 th percentile); oligohydramnios (amniotic fluid index < 5); placenta praevia; placental abruption; uterine scar other than low transverse caesarean section; active labour; ruptured membranes; fetal anomalies incompatible with life; contraindication to vaginal delivery; contraindication to tocolysis. |
| Interventions | Intravenous infusion for 20 minutes before, and during ECV attempt, of ritodrine 111 micrograms/minute or placebo. Maximum of 3 ECV attempts as forward or backward flip. Cardiotocography was repeated. |
| Outcomes | Duration of infusion (tocolysis mean 32.1 (SD 1.04) vs control 31.7 (1.12) minutes); unsuccessful ECV; cardiotocography results (all reactive); time from ECV to delivery (average 2 weeks); maternal and fetal complications (maternal complications < 4%, similar between groups); mode of delivery; birthweight (3370 (39) vs 3382 (44) grams). |
| Notes | Groups differed in terms of frank breech (tocolysis 59/138 vs control 43/145) and nulliparity (58/138 vs 49/145). Parity (nulliparous 34% vs parous 61%), but not type of breech, affected ECV success rate, therefore results controlled for parity. |
| Allocation concealment | A – Adequate |

Study **Robertson 1987**

| | |
|------------------------|--|
| Methods | Allocated according to social security number. |
| Participants | Breech presentation suitable for external cephalic version at term (37 to 41 weeks). |
| Interventions | Use of tocolysis (ritodrine infusion 200 micrograms per minute for 20 minutes) compared with no tocolysis. All women had intravenous lines. Repeat version attempt with tocolysis was successful in 1/9 with initial failure in the control group (for immediate success rate, this review considered only the initial attempt, ie tocolysis versus no tocolysis). |
| Outcomes | Non-cephalic presentation at birth; caesarean section; immediate ECV success. |
| Notes | Tacoma, Washington, USA. July 1984 to May 1987. |
| Allocation concealment | C – Inadequate |

Study **Schorr 1997**

| | |
|------------------------|--|
| Methods | Allocation by computer-generated random sequence cards in sealed envelopes, using permuted blocks of 10. |
| Participants | Inclusion criteria: breech presentation or transverse lie. Exclusion criteria: placenta praevia; fetal compromise; fetal growth restriction; ruptured membranes. |
| Interventions | Epidural analgesia with 2% lidocaine with 1:200 000 epinephrine (n = 35); prehydration with 2000 ml lactated Ringer's solution; versus no epidural (n = 34). All women received 0.25 mg terbutaline subcutaneously. External cephalic version attempted up to 3 times, with vaginal elevation of the presenting part when necessary. |
| Outcomes | Successful ECV, complications, mode of delivery, presentation at delivery. |
| Notes | University of Mississippi Medical Centre Hospital, USA. 1 December 1993 to 31 July 1996. |
| Allocation concealment | D – Not used |

Study **Stock 1993**

| | |
|--------------|---|
| Methods | 'Randomised' in sets of 3 to the 3 groups, stratified for parity and practitioner. Method not specified. Practitioner was blind to the group allocation. |
| Participants | Breech presentation between 36 and 42 weeks with no contraindication to external cephalic version. |

| | |
|------------------------|--|
| | Exclusion criteria: diabetes; heart disease; thyrotoxicosis; ruptured membranes; multiple pregnancy; uterine scar; placenta praevia; oligohydramnios; impaired fetal growth; nuchal cord; placenta praevia. |
| Interventions | Group A: placebo infusion and bolus injection. Group B: ritodrine 0.3 mg per minute infusion for 30 minutes and during the procedure, and placebo bolus injection. Group C: placebo infusion and hexoprenaline 10 micrograms bolus injection. For the purposes of this review, which addresses the effectiveness of intravenous tocolysis for external cephalic version rather than the evaluation of specific tocolytic agents, Groups B and C have been combined. |
| Outcomes | Immediate ECV success; ECV completed < 1 minute; fetal bradycardia during ECV. |
| Notes | The improved external cephalic version success rate with tocolysis reached statistical significance for hexoprenaline but not for ritodrine. The authors decided not to continue the ritodrine/placebo arm of the trial to completion. |
| Allocation concealment | C – Inadequate |

| | |
|------------------------|--|
| Study | Tan 1989 |
| Methods | Allocated by stacks of cards stratified for parity and gestational age less than or greater than 36 weeks. |
| Participants | Breech presentation beyond 33 weeks' gestation without contraindication to external cephalic version. |
| Interventions | Group 1 received salbutamol 4 mg orally three times a day for at least one day. Group 2 received an intravenous infusion of salbutamol until the maternal heart rate exceeded 100 beats per minute for 30 minutes. Group 3 received no salbutamol. Groups 1 and 3 received dummy intravenous lines. For consistency in this review only groups 2 and 3 are compared. |
| Outcomes | Immediate ECV success. |
| Notes | Singapore. |
| Allocation concealment | C – Inadequate |

| | |
|---------------|--|
| Study | Yanny 2000 |
| Methods | Allocation by sealed, opaque envelopes, in computer-generated random sequence. |
| Participants | Women with breech presentation choosing ECV; cardiotocograph and ultrasound examination acceptable; failed initial ECV attempt without tocolysis. |
| Interventions | Glycerol trinitrate sublingual spray 800 micrograms (n = 31) versus placebo (n = 26) (labelled spray A and B); repeat ECV attempt; if unsuccessful and uterus not relaxed, salbutamol infusion and repeat ECV attempt. |
| Outcomes | Side-effects: maternal discomfort; blood pressure; pulse, after spray administration; ECV success; uterine relaxation (poor 8/30 nitroglycerine vs 9/25 placebo, reasonable 11/30 vs 8/25, good 7/30 vs 8/25/ excellent 4/30 vs 0/25); salbutamol required (13/31 vs 14/26); dose of salbutamol. |
| Notes | |

Allocation concealment A – Adequate

ECV: external cephalic version;

IVI: intravenous infusion;

SD: standard deviation;

SQ: subcutaneous;

vs: versus.

Characteristics of excluded studies

| | |
|---------------|---|
| Study | Reason for exclusion |
| El-Sayed 1998 | Ongoing study, published as abstract. Because of cross-over to other arm, success rate with original randomisation not available. |

Characteristics of excluded studies (Continued)

Wallace 1984 Non-randomised follow-up study after randomised trial of ECV with tocolysis (see review 'External cephalic version for breech presentation at term').

ECV: external cephalic version

ANALYSES**Comparison 01. Routine betamimetic tocolysis for external cephalic version at term**

| Outcome title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|------------------------------|-------------------|
| 01 Failed external cephalic version | 6 | 617 | Relative Risk (Fixed) 95% CI | 0.74 [0.64, 0.87] |
| 02 Failed external cephalic version by parity | 6 | 396 | Relative Risk (Fixed) 95% CI | 0.70 [0.57, 0.84] |
| 03 Failed external cephalic version in < 1 minute | 1 | 63 | Relative Risk (Fixed) 95% CI | 0.56 [0.39, 0.80] |
| 04 Fetal bradycardia during external cephalic version | 1 | 63 | Relative Risk (Fixed) 95% CI | 0.13 [0.03, 0.54] |
| 05 Non-cephalic presentation at birth | 2 | 161 | Relative Risk (Fixed) 95% CI | 0.80 [0.60, 1.07] |
| 06 Caesarean section | 3 | 444 | Relative Risk (Fixed) 95% CI | 0.85 [0.72, 0.99] |

Comparison 02. Acoustic stimulation for external cephalic version with midline fetal spine

| Outcome title | No. of studies | No. of participants | Statistical method | Effect size |
|---------------------------------------|----------------|---------------------|------------------------------|-------------------|
| 01 Failed external cephalic version | 1 | 26 | Relative Risk (Fixed) 95% CI | 0.17 [0.05, 0.60] |
| 02 Non-cephalic presentation at birth | 0 | 0 | Relative Risk (Fixed) 95% CI | Not estimable |
| 03 Caesarean section | 0 | 0 | Relative Risk (Fixed) 95% CI | Not estimable |

Comparison 03. Epidural or spinal analgesia for external cephalic version at term

| Outcome title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|-------------------------------|---------------------|
| 01 Failed external cephalic version | 5 | 456 | Relative Risk (Random) 95% CI | 0.79 [0.63, 1.00] |
| 02 Fetal bradycardia during external cephalic version | 2 | 210 | Relative Risk (Random) 95% CI | 1.48 [0.62, 3.57] |
| 03 Maternal hypotension | 2 | 210 | Relative Risk (Random) 95% CI | 9.35 [0.52, 169.36] |
| 04 Placental abruption | 2 | 138 | Relative Risk (Random) 95% CI | 1.09 [0.12, 10.16] |
| 05 Maternal discomfort | 2 | 171 | Relative Risk (Random) 95% CI | 0.19 [0.03, 1.04] |
| 06 Non-cephalic presentation at birth | 3 | 279 | Relative Risk (Random) 95% CI | 0.73 [0.42, 1.27] |
| 07 Caesarean section | 3 | 279 | Relative Risk (Random) 95% CI | 0.73 [0.39, 1.37] |

Comparison 04. Nitric oxide donor for external cephalic version at term

| Outcome title | No. of studies | No. of participants | Statistical method | Effect size |
|---|----------------|---------------------|------------------------------|-------------------|
| 01 Failed external cephalic version | 2 | 156 | Relative Risk (Fixed) 95% CI | 1.06 [0.82, 1.37] |
| 02 Fetal bradycardia during external cephalic version | 1 | 99 | Relative Risk (Fixed) 95% CI | 0.39 [0.08, 1.93] |

| | | | | |
|--|---|----|------------------------------|-------------------|
| 03 Difficult external cephalic version as defined by trial authors | 0 | 0 | Relative Risk (Fixed) 95% CI | Not estimable |
| 04 Maternal discomfort during external cephalic version | 1 | 51 | Relative Risk (Fixed) 95% CI | 0.90 [0.40, 2.03] |
| 05 Non-cephalic presentation at birth | 1 | 99 | Relative Risk (Fixed) 95% CI | 1.50 [0.94, 2.39] |
| 06 Caesarean section | 0 | 0 | Relative Risk (Fixed) 95% CI | Not estimable |

Comparison 05. Nitric oxide donor versus betamimetic for external cephalic version at term

| Outcome title | No. of studies | No. of participants | Statistical method | Effect size |
|--|----------------|---------------------|------------------------------|-------------------|
| 01 Failed external cephalic version | 2 | 109 | Relative Risk (Fixed) 95% CI | 1.31 [0.96, 1.77] |
| 02 Fetal bradycardia during external cephalic version | 1 | 74 | Relative Risk (Fixed) 95% CI | 1.06 [0.16, 7.10] |
| 03 Difficult external cephalic version as defined by trial authors | 0 | 0 | Relative Risk (Fixed) 95% CI | Not estimable |
| 04 Maternal discomfort during external cephalic version | 0 | 0 | Relative Risk (Fixed) 95% CI | Not estimable |
| 05 Non-cephalic presentation at birth | 1 | 74 | Relative Risk (Fixed) 95% CI | 1.36 [0.96, 1.91] |
| 06 Caesarean section | 0 | 0 | Relative Risk (Fixed) 95% CI | Not estimable |

INDEX TERMS

Medical Subject Headings (MeSH)

Analgesia, Obstetrical; *Breech Presentation; Delivery, Obstetric; Tocolysis [*methods]; Version, Fetal [*methods]

MeSH check words

Female; Humans; Pregnancy

COVER SHEET

| | |
|--|---|
| Title | Interventions to help external cephalic version for breech presentation at term |
| Authors | Hofmeyr GJ, Gyte G |
| Contribution of author(s) | Justus Hofmeyr prepared the original version of the review. Gill Gyte and Justus Hofmeyr revised the review in 2004, and are responsible for maintaining the review. |
| Issue protocol first published | 1996/3 |
| Review first published | 1996/3 |
| Date of most recent amendment | 27 October 2004 |
| Date of most recent SUBSTANTIVE amendment | 13 September 2003 |
| What's New | September 2003: Two new trials included (Bujold 2002; Bujold 2003) and the recommendation regarding nitroglycerine has changed. March 2004: One new trial included (Hollard 2003). |

Date new studies sought but none found Information not supplied by author

Date new studies found but not yet included/excluded Information not supplied by author

Date new studies found and included/excluded 31 March 2004

Date authors' conclusions section amended Information not supplied by author

Contact address Prof G Justus Hofmeyr
Director/Hon. Professor, Effective Care Research Unit
Department of Obstetrics and Gynaecology, East London Hospital Complex
University of the Witwatersrand, University of Fort Hare, Eastern Cape Department of Health
Frere and Cecilia Makiwane Hospitals
Private Bag X 9047
East London
Eastern Cape
5200
SOUTH AFRICA
E-mail: gjh@global.co.za
Tel: +27 43 7092483
Fax: +27 43 7092483

DOI 10.1002/14651858.CD000184.pub2

Cochrane Library number CD000184

Editorial group Cochrane Pregnancy and Childbirth Group

Editorial group code HM-PREG

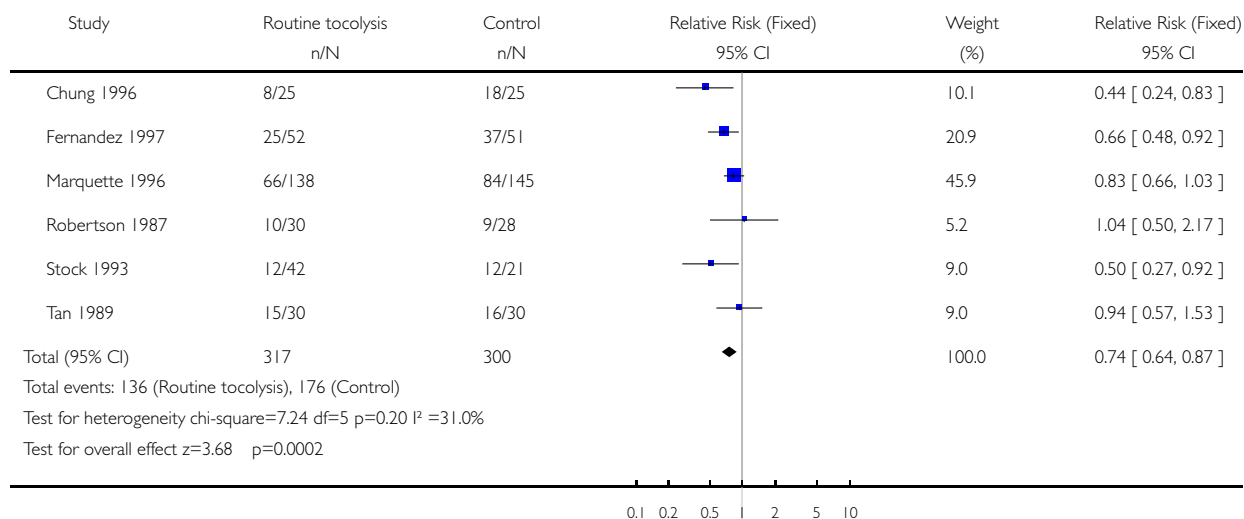
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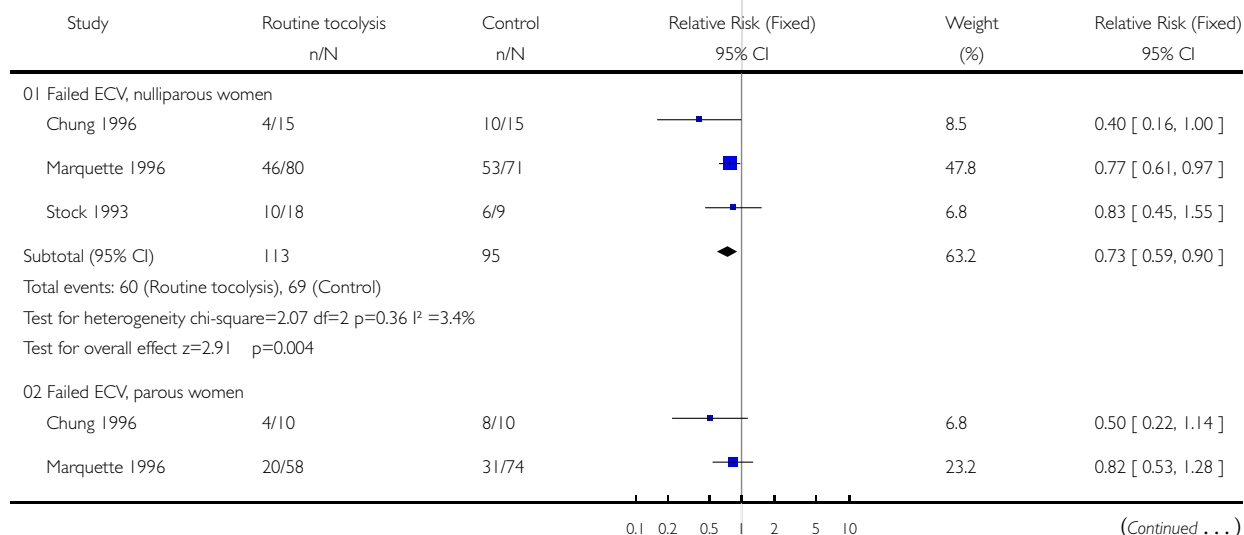


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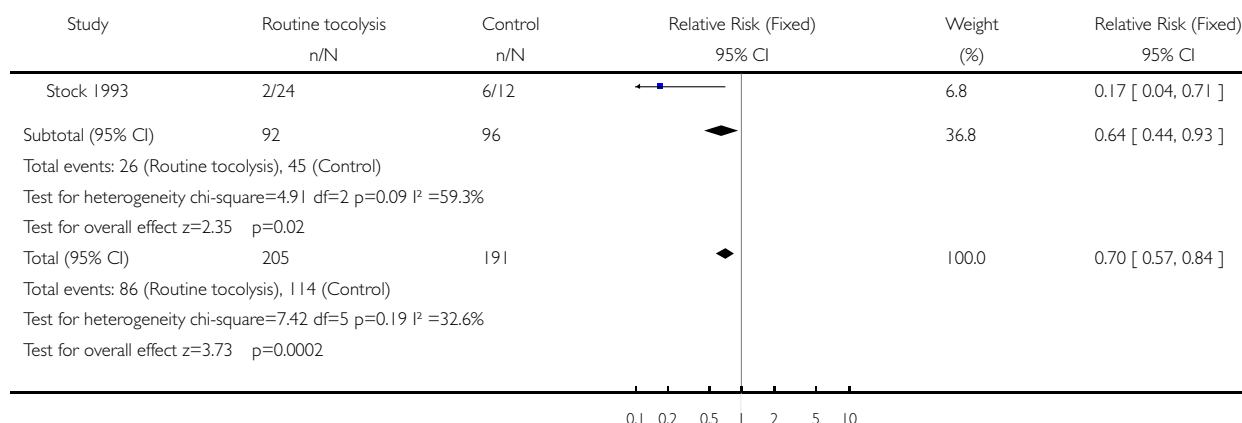
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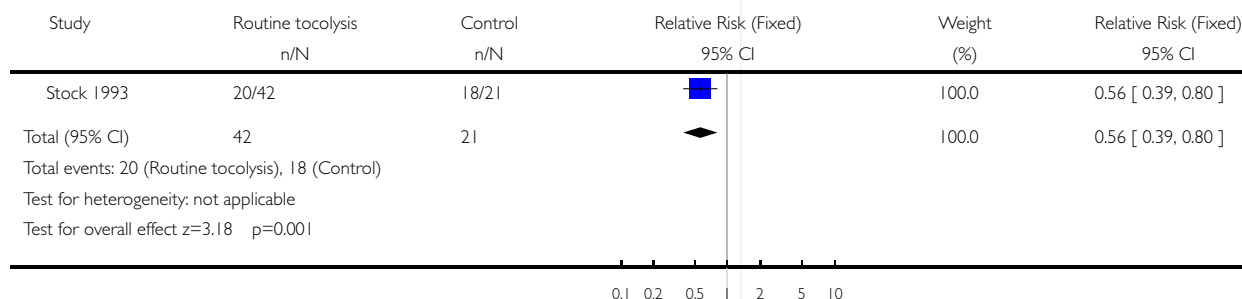


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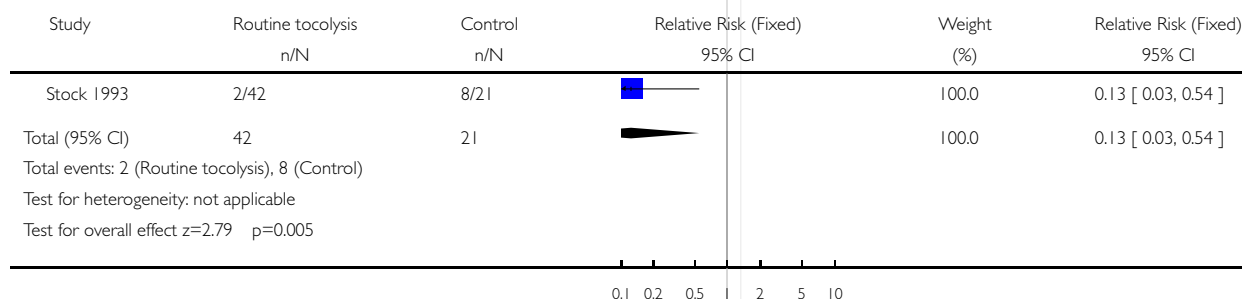


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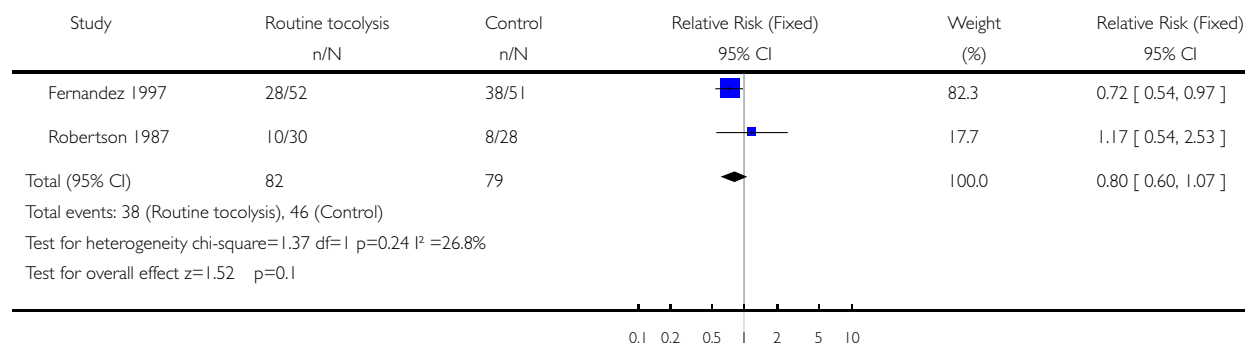


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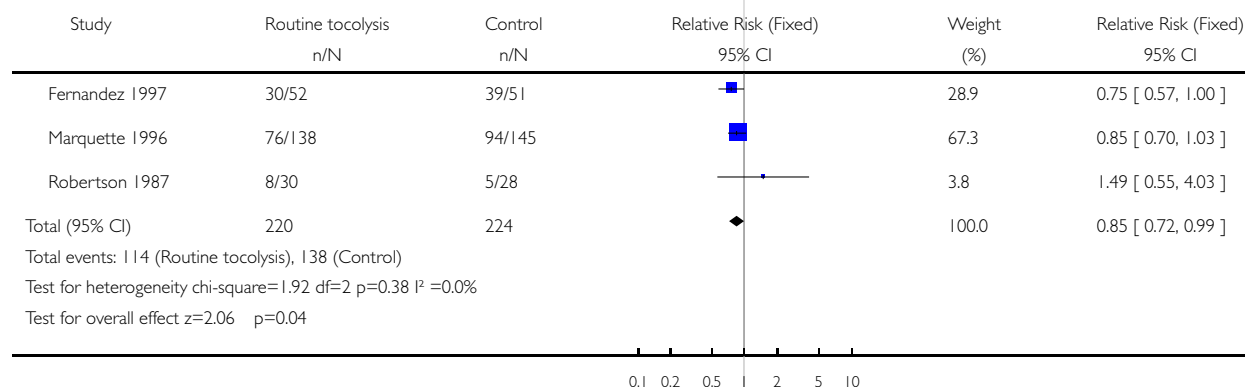


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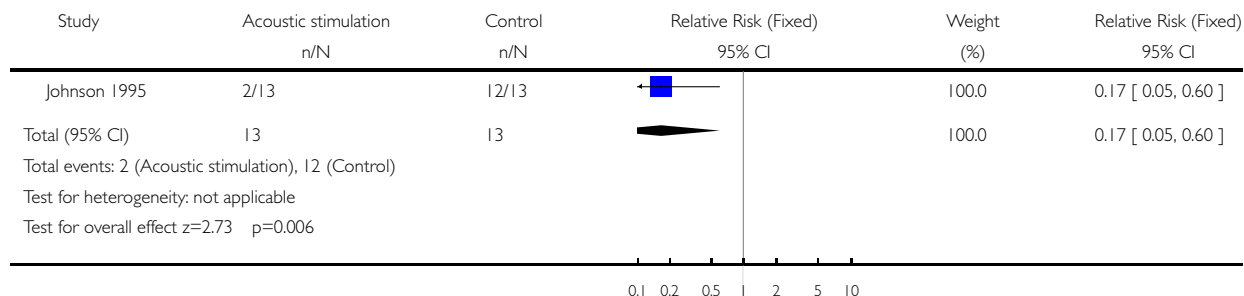


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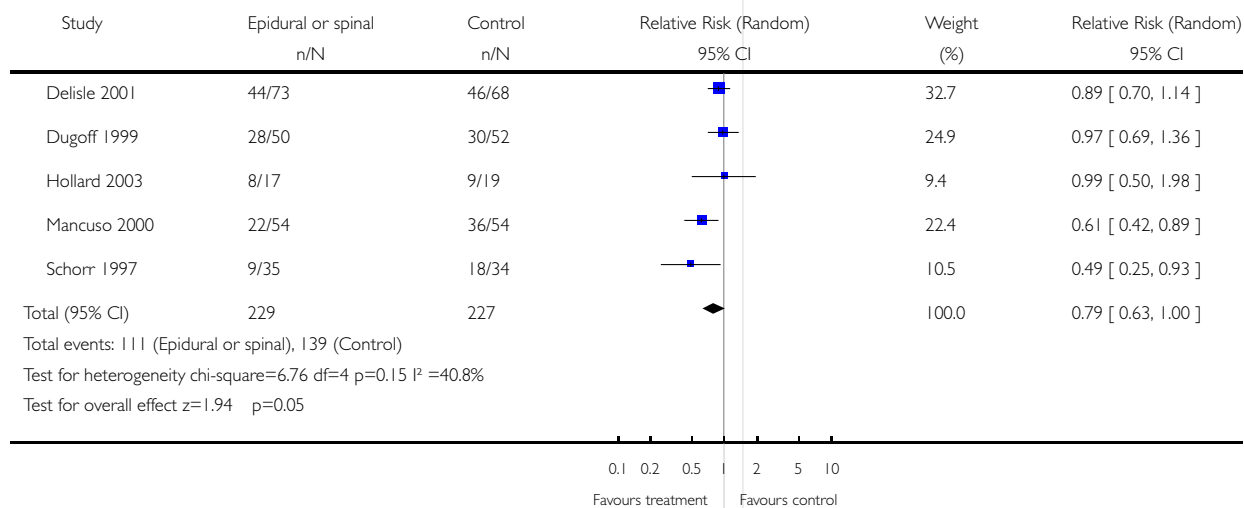


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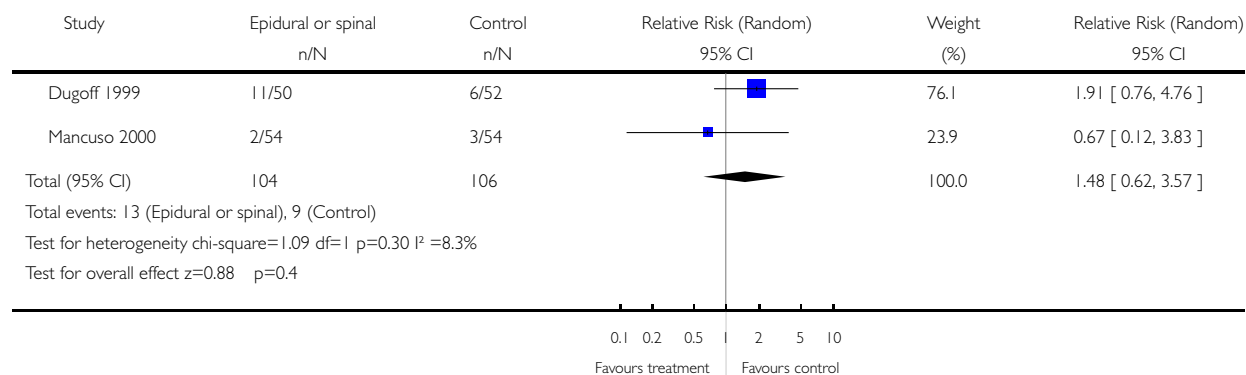


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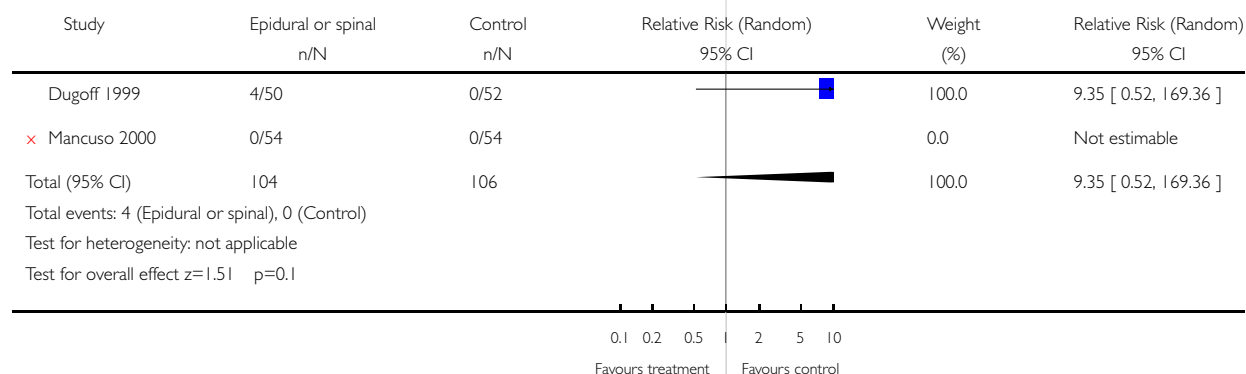


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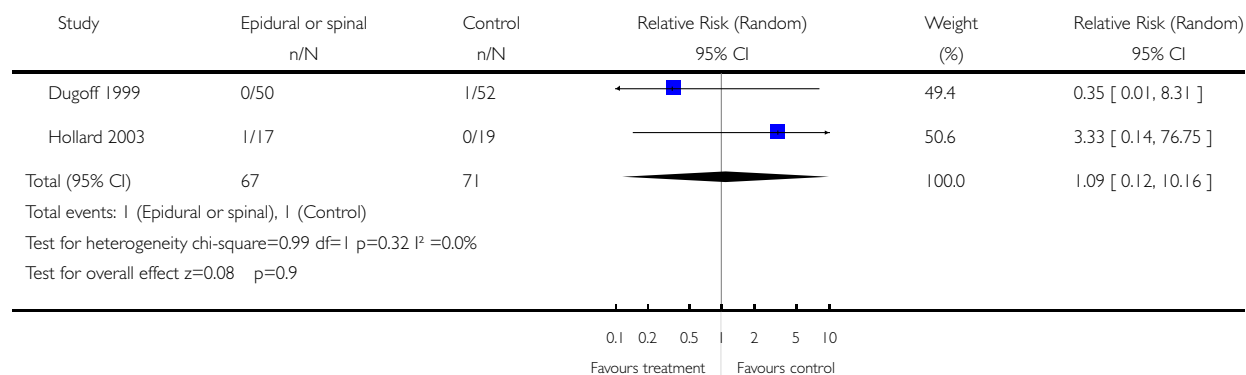


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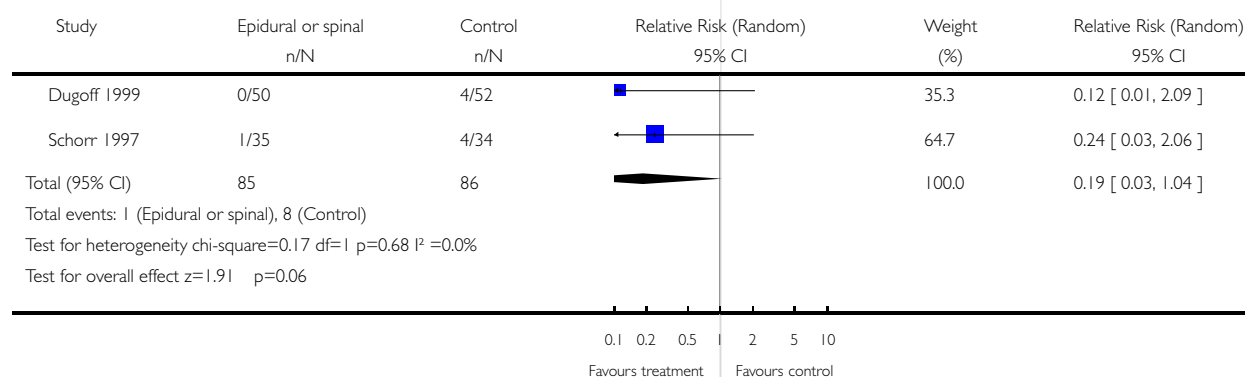


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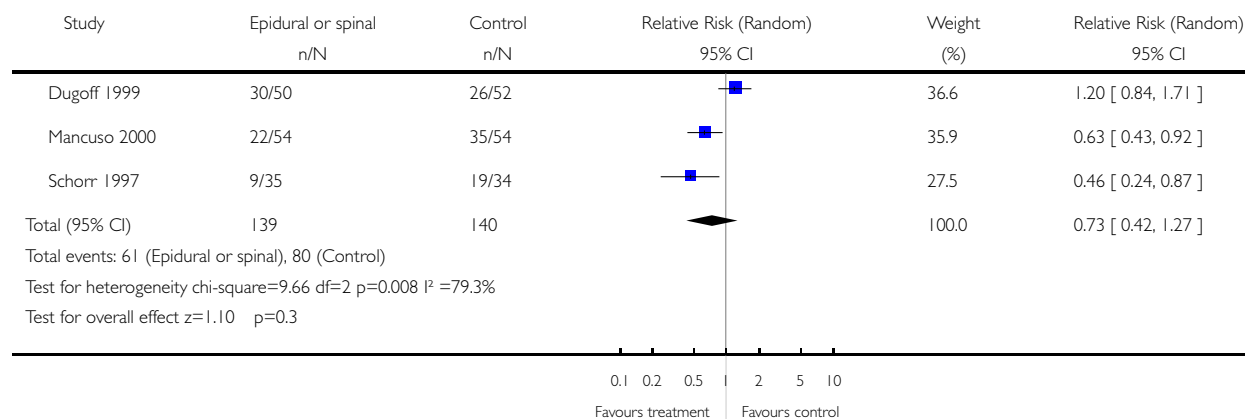


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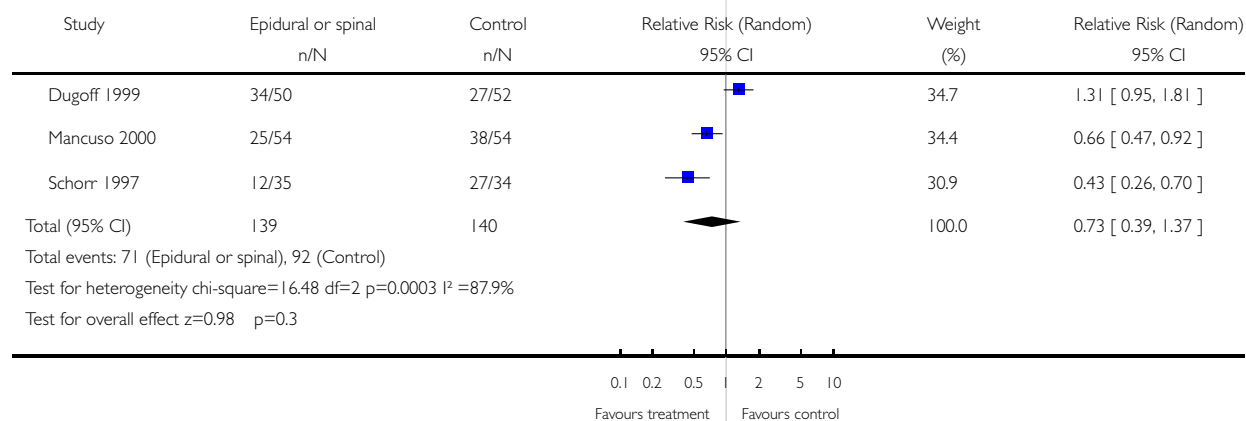


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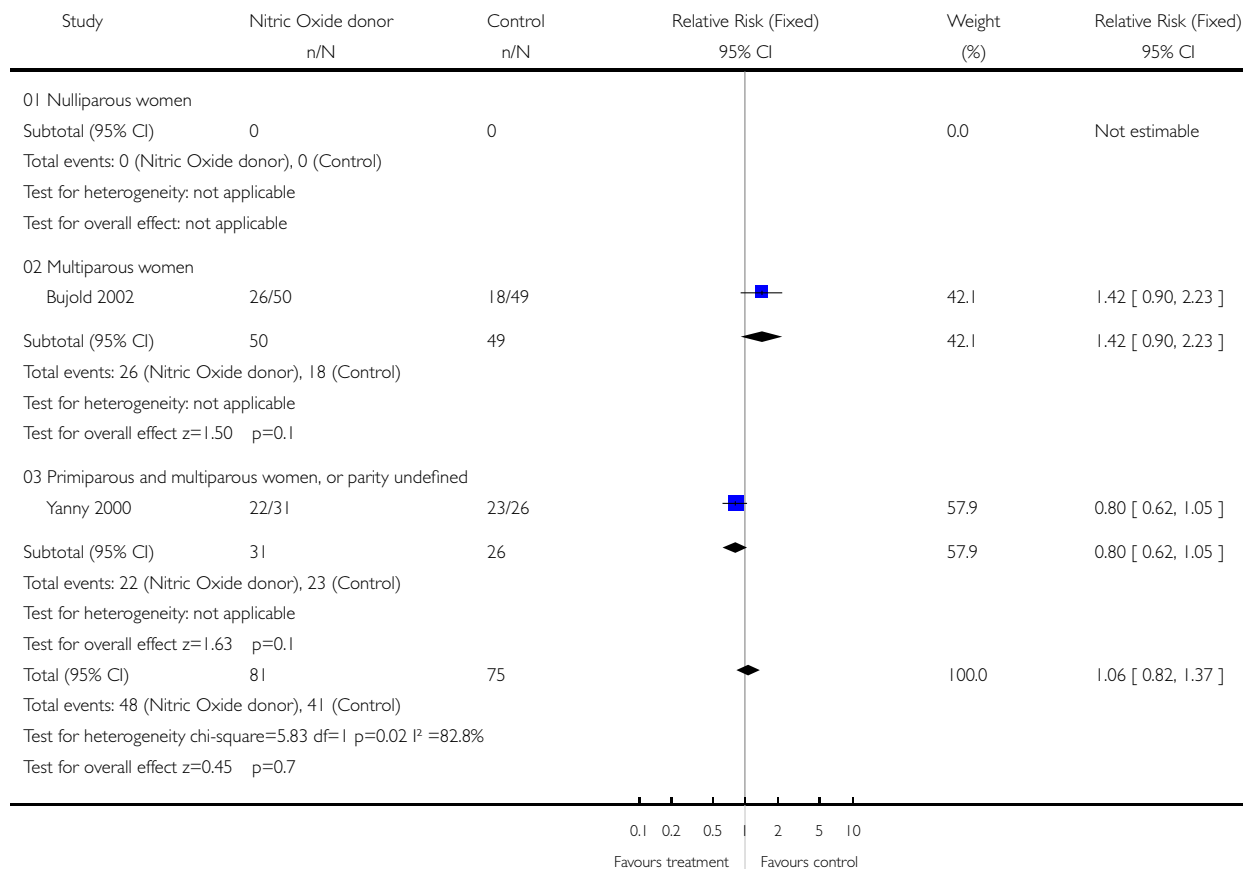


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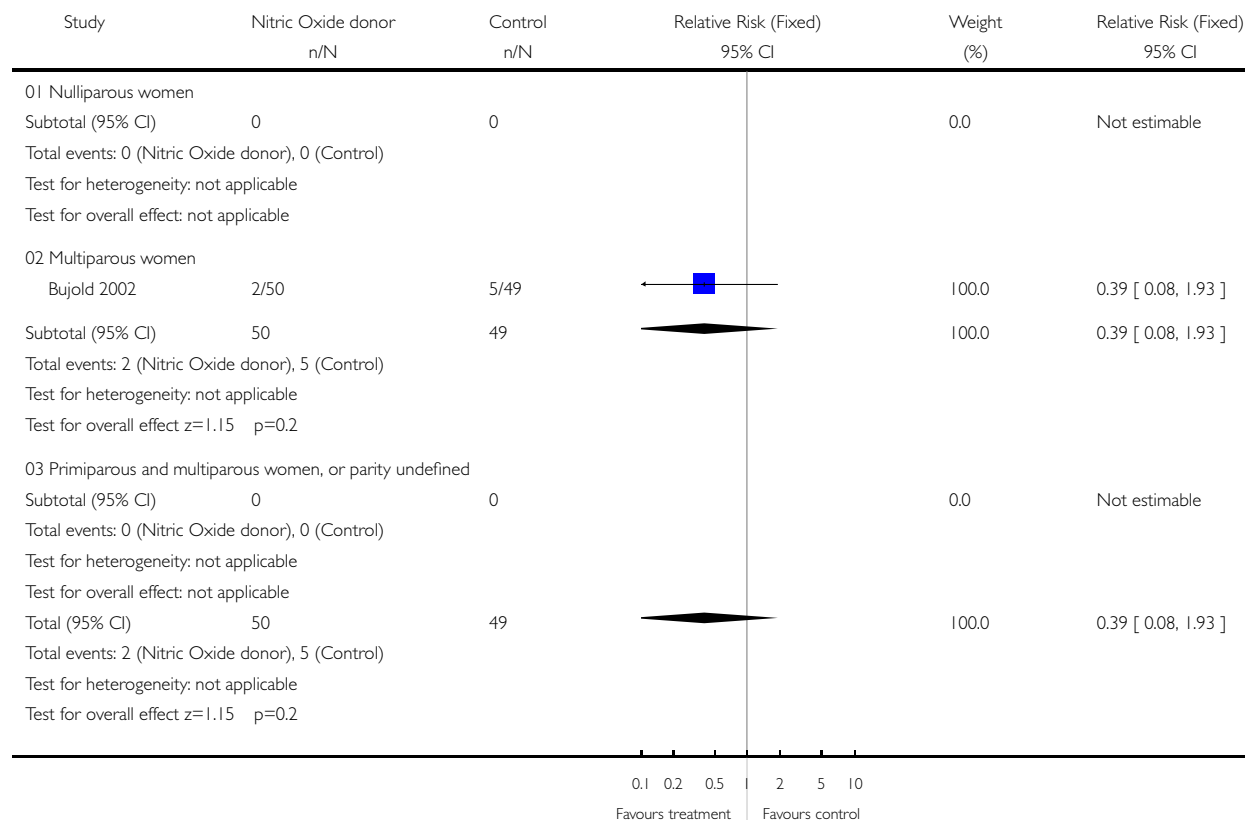


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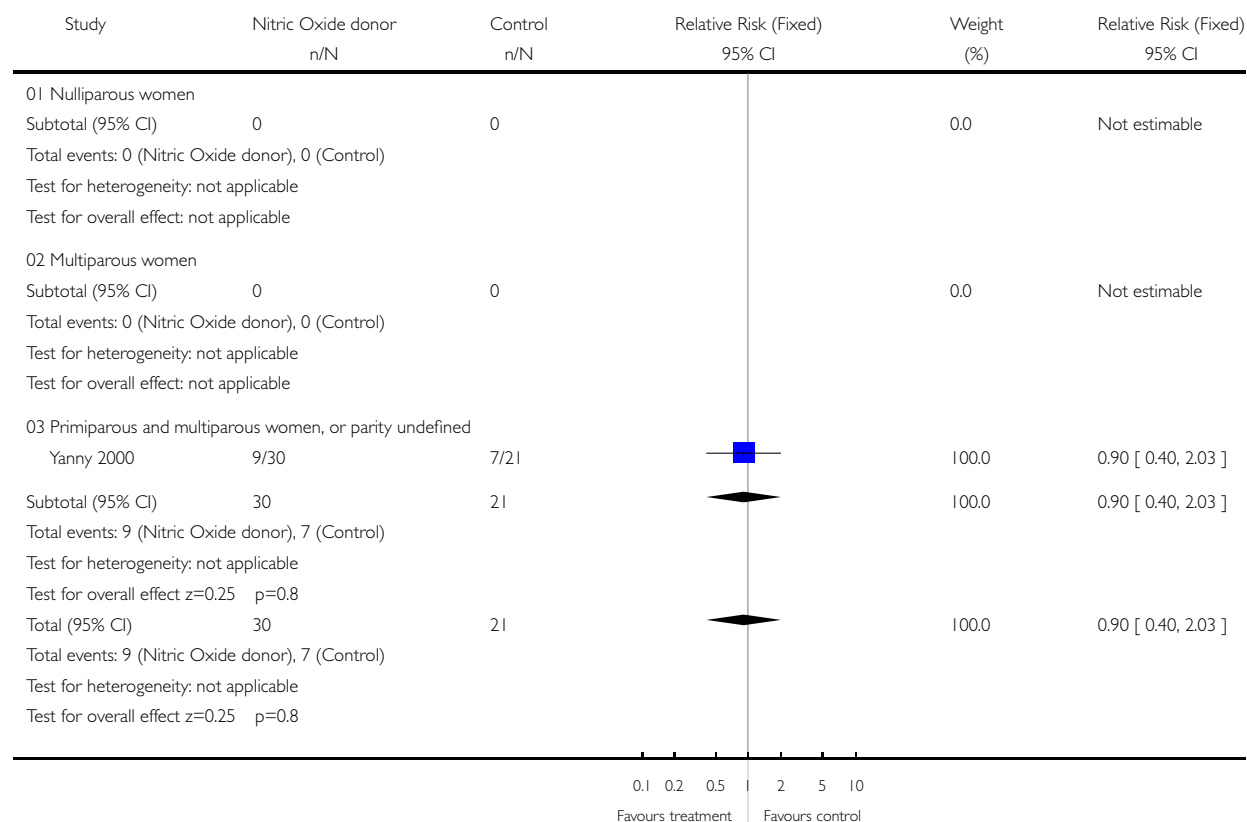


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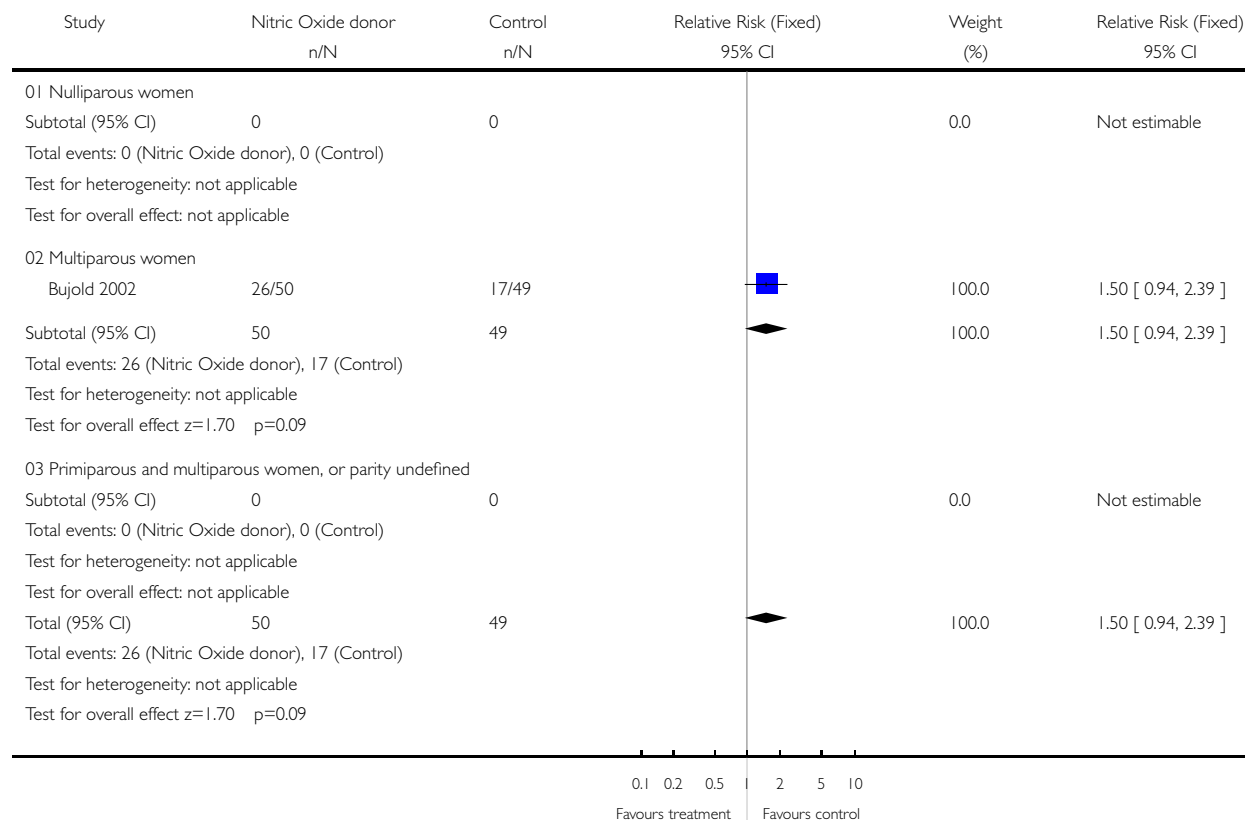


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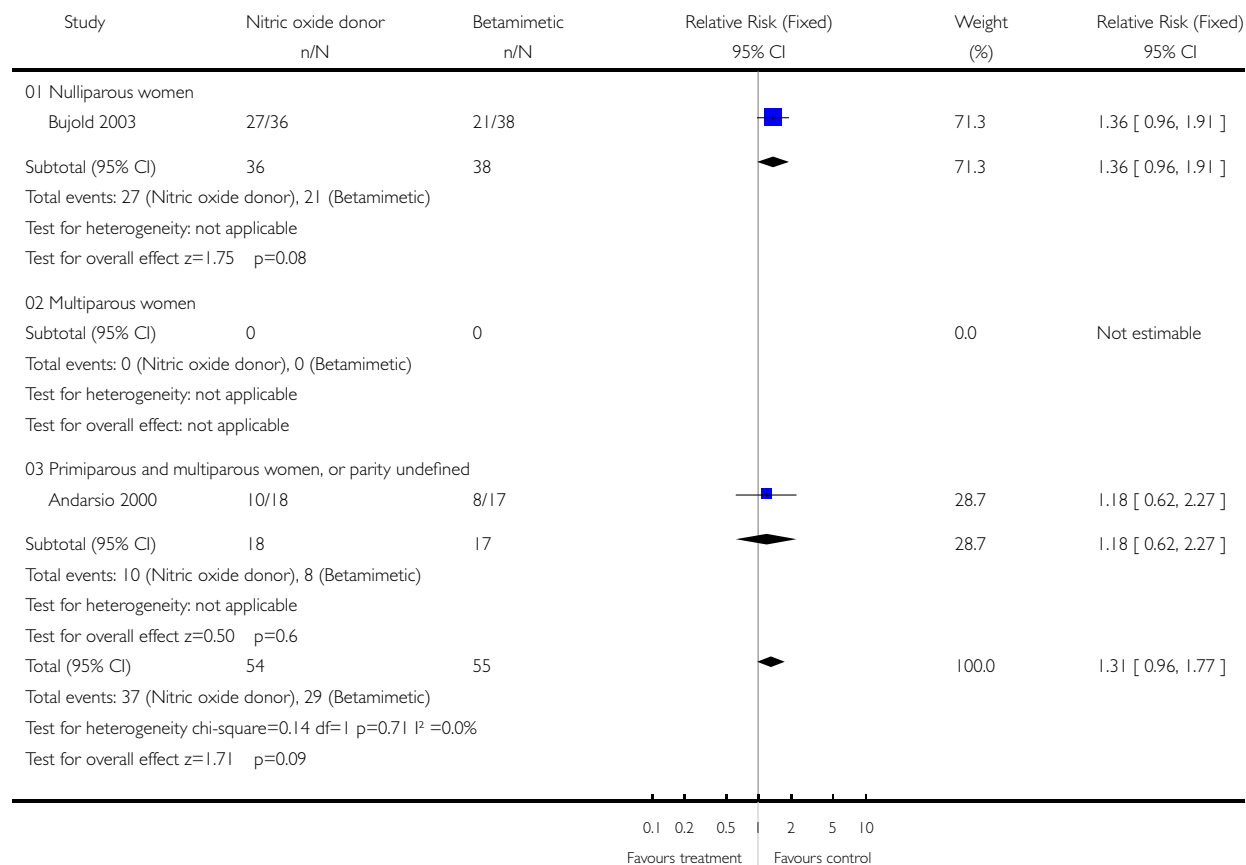


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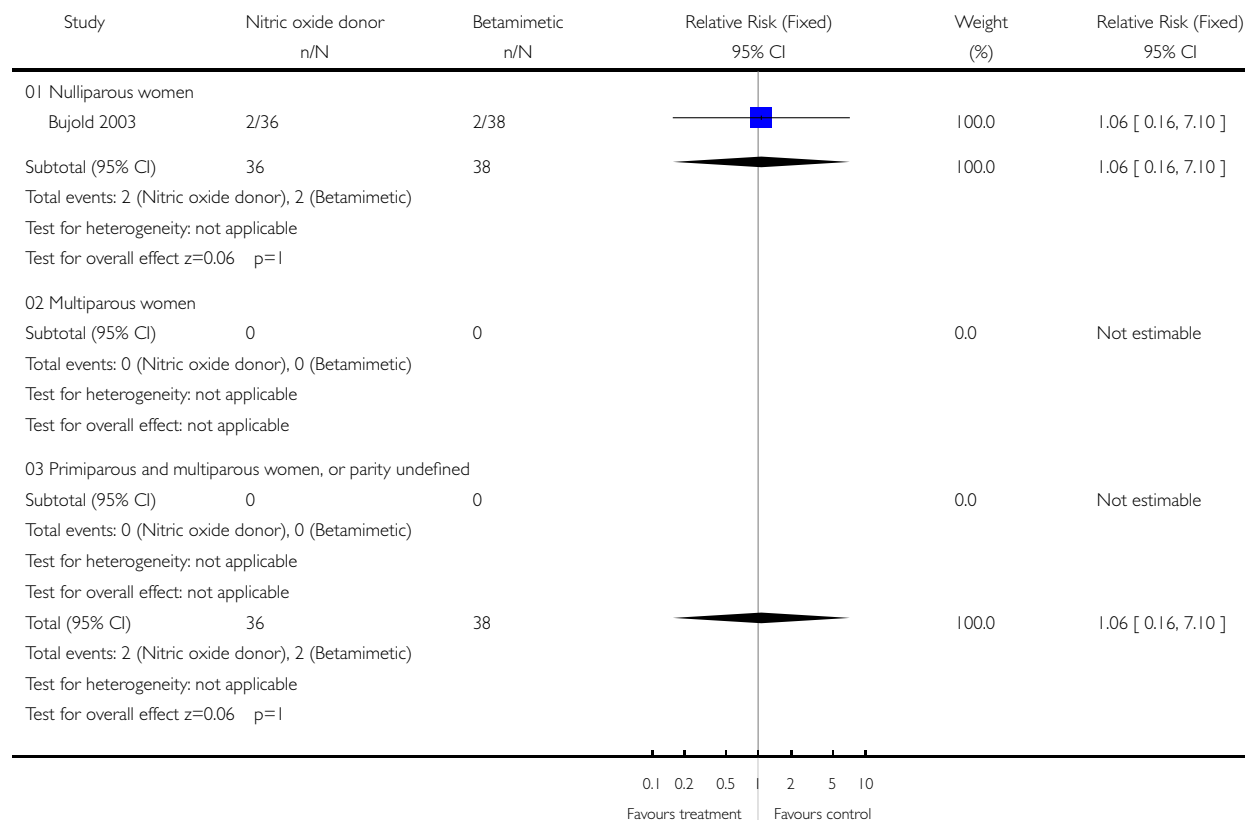


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