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Fetal scalp stimulation for assessing fetal well-being during labour

Deirdre J Murphy, Declan Devane, Eleanor Molloy, Yulia Shahabuddin

Background
Continuous fetal heart rate monitoring by cardiotocography (CTG) is used in labour for women with complicated pregnancies. Fetal heart rate abnormalities are common and may result in the decision to expedite delivery by caesarean section. Fetal scalp stimulation (FSS) is a second-line test of fetal well-being that may provide reassurance that the labour can continue.

Objectives
To evaluate methods of FSS as second-line tests of intrapartum fetal well-being in cases of non-reassuring CTG. FSS and CTG were compared to CTG alone, and to CTG with fetal blood sampling (FBS).

Search methods
We searched Cochrane Pregnancy and Childbirth's Trials Register (which includes trials from CENTRAL, MEDLINE, Embase, CINAHL, the WHO ICTRP and conference proceedings), ClinicalTrials.gov (18 October 2022), and reference lists of retrieved studies.

Selection criteria
Eligible studies were randomised controlled trials (RCTs) that compared any form of FSS to assess fetal well-being in labour. Quasi-RCTs, cluster-RCTs and studies published in abstract form were also eligible for inclusion, but none were identified.

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Data collection and analysis
Two review authors independently assessed studies for inclusion and risk of bias, extracted data and checked them for accuracy. We assessed the certainty of the evidence using the GRADE approach.

Main results
Two trials, involving 377 women, met the inclusion criteria for this review. Both trials were conducted in hospital settings and included women with singleton, term (37+0 weeks or more) pregnancies, a cephalic presentation, and abnormal CTG. Follow-up was until hospital discharge after the birth. A pilot trial of 50 women in a high-income country (Ireland) compared CTG and digital fetal scalp stimulation (dFSS) with CTG and fetal blood sampling (FBS). A single-centre trial of 327 women in a lower middle-income country (India) compared CTG and manual fetal stimulation (abdominal or vaginal scalp stimulation) with CTG alone. The two included studies were at moderate or unclear risk of bias. Both trials provided clear information on allocation concealment but it was not possible to blind participants or health professionals in relation to the intervention. Although objective outcome measures were reported, outcome assessment was not blinded or blinding was unclear.

dFSS and CTG versus FBS and CTG

There were no perinatal deaths and data were not reported for neurodevelopmental disability at >/= 12 months. The risk of caesarean section (CS) may be lower with dFSS compared to FBS (risk ratio (RR) 0.38, 95% confidence interval (CI) 0.16 to 0.92; 1 pilot trial, 50 women; very low-certainty evidence) but the evidence is very uncertain. There were no cases of neonatal encephalopathy reported. The evidence was also very uncertain between dFSS and FBS for assisted vaginal birth (RR 1.44, 95% CI 0.76 to 2.75; very low-certainty evidence) and for the spontaneous vaginal birth rate (RR 2.33, 95% CI 0.68 to 8.01, very low-certainty evidence). Maternal acceptability of the procedures was not reported.

FSS and CTG versus CTG alone

Manual stimulation of the fetus was performed either abdominally (92/164) or vaginally (72/164). There were no perinatal deaths and data were not reported for neurodevelopmental disability at >/= 12 months. There may be little differences in the risk of CS on comparing manual fetal stimulation and CTG with CTG alone (RR 0.83, 95% CI 0.59 to 1.18; 1 trial, 327 women; very low-certainty evidence), but again the evidence was very uncertain. There were no cases of neonatal encephalopathy reported. There may be no differences in the risk of assisted vaginal birth (RR 1.43, 95% CI 0.78 to 2.60; very low-certainty evidence) or in the rates of spontaneous vaginal birth (RR 1.01, 95% CI 0.85 to 1.21, very low-certainty evidence), but again the evidence is very uncertain. Maternal acceptability of abdominal stimulation/FSS was not reported although 13 women withdrew consent after randomisation due to concerns about fetal well-being.

Authors' conclusions
There is very low-certainty evidence available which makes it unclear whether stimulating the fetal scalp is a safe and effective way to confirm fetal well-being in labour. Evidence was downgraded based on limitations in study design and imprecision. Further high-quality studies of adequate sample size are required to evaluate this research question. In order to be generalisable, these trials should be conducted in different settings, including broad clinical criteria at both preterm and term gestational ages, and standardising the method of stimulation. There is an ongoing study (FIRSST) that will be incorporated into this review in a subsequent update.

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Antenatal dietary supplementation with myo-inositol for preventing gestational diabetes

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Background
Gestational diabetes with onset or first recognition during pregnancy is an increasing problem worldwide. Myo-inositol, an isomer of inositol, is a naturally occurring sugar commonly found in cereals, corn, legumes and meat. Myo-inositol is one of the intracellular mediators of the insulin signal and correlates with insulin sensitivity in type 2 diabetes. The potential beneficial effect of improving insulin sensitivity suggests that myo-inositol may be useful for women in preventing gestational diabetes. This is an update of a review first published in 2015.

Objectives
To assess if antenatal dietary supplementation with myo-inositol is safe and effective, for the mother and fetus, in preventing gestational diabetes.

Search methods
We searched the Cochrane Pregnancy and Childbirth's Trials Register, ClinicalTrials.gov, WHO ICTRP (17 March 2022) and the reference lists of retrieved studies.

Selection criteria
We included published and unpublished randomised controlled trials (RCTs) including cluster-RCTs and conference abstracts, assessing the effects of myo-inositol for the prevention of gestational diabetes in pregnant women. We included studies that compared any dose of myo-inositol, alone or in a combination preparation, with no treatment, placebo or another intervention. Quasi-randomised and cross-over trials were not eligible. We excluded women with pre-existing type 1 or type 2 diabetes.

Data collection and analysis
Two review authors independently assessed studies for inclusion, assessed risk of bias and extracted the data. We checked the data for accuracy. We assessed the certainty of the evidence using the GRADE approach.

Main results
We included seven RCTs (one conducted in Ireland, six conducted in Italy) reporting on 1319 women who were 10 weeks to 24 weeks pregnant at the start of the studies. The studies had relatively small sample sizes and the overall risk of bias was low.

For the primary maternal outcomes, meta-analysis showed that myo-inositol may reduce the incidence of gestational diabetes (risk ratio (RR) 0.53, 95% confidence interval (CI) 0.31 to 0.90; 6 studies, 1140 women) and hypertensive disorders of pregnancy (RR 0.34, 95% CI 0.19 to 0.61; 5 studies, 1052 women). However, the certainty of the evidence was low to very low. For the primary neonatal outcomes, only one study measured the risk of a large-for-gestational-age infant and found myo-inositol was associated with both appreciable benefit and harm (RR 1.40, 95% CI 0.65 to 3.02; 1 study, 234 infants; low-certainty evidence). None of the included studies reported on the other primary neonatal outcomes (perinatal mortality, mortality or morbidity composite).

For the secondary maternal outcomes, we are unclear about the effect of myo-inositol on weight gain during pregnancy (mean difference (MD) -0.25 kilogram (kg), 95% CI -1.26 to 0.75 kg; 4 studies, 831 women) and

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perineal trauma (RR 4.0, 95% CI 0.45 to 35.25; 1 study, 234 women) because the evidence was assessed as being very low-certainty. Further, myo-inositol may result in little to no difference in caesarean section (RR 0.91, 95% CI 0.77 to 1.07; 4 studies, 829 women; low-certainty evidence). None of the included studies reported on the other secondary maternal outcomes (postnatal depression and the development of subsequent type 2 diabetes mellitus). For the secondary neonatal outcomes, meta-analysis showed no neonatal hypoglycaemia (RR 3.07, 95% CI 0.90 to 10.52; 4 studies; 671 infants; very low-certainty evidence). However, myo-inositol may be associated with a reduction in the incidence of preterm birth (RR 0.35, 95% CI 0.17 to 0.70; 4 studies; 829 infants). There were insufficient data for a number of maternal and neonatal secondary outcomes, and no data were reported for any of the long-term childhood or adulthood outcomes, or for health service utilisation outcomes.

Authors' conclusions
Evidence from seven studies shows that antenatal dietary supplementation with myo-inositol during pregnancy may reduce the incidence of gestational diabetes, hypertensive disorders of pregnancy and preterm birth. Limited data suggest that supplementation with myo-inositol may not reduce the risk of a large-for-gestational-age infant.

The current evidence is based on small studies that were not powered to detect differences in outcomes such as perinatal mortality and serious infant morbidity. Six of the included studies were conducted in Italy and one in Ireland, which raises concerns about the lack of generalisability to other settings. There is evidence of inconsistency among doses of myo-inositol, the timing of administration and study population. As a result, we downgraded the certainty of the evidence for many outcomes to low or very low certainty.

Further studies for this promising antenatal intervention for preventing gestational diabetes are encouraged and should include pregnant women of different ethnicities and varying risk factors. Myo-inositol at different doses, frequency and timing of administration, should be compared with placebo, diet and exercise, and pharmacological interventions. Long-term follow-up should be considered and outcomes should include potential harms, including adverse effects.

Mechanical methods for induction of labour

Marieke DT de Vaan, Mieke LG ten Eikelder, Marta Jozwiak, Kirsten R Palmer, Miranda Davies-Tuck, Kitty WM Bloemenkamp, Ben Willem J Mol, Michel Boulvain

Background
Mechanical methods were the first methods developed to ripen the cervix and induce labour. During recent decades they have been substituted by pharmacological methods. Potential advantages of mechanical methods, compared with pharmacological methods may include reduction in side effects that could improve neonatal outcomes. This is an update of a review first published in 2001, last updated in 2012.

Objectives
To determine the effectiveness and safety of mechanical methods for third trimester (> 24 weeks' gestation) induction of labour in comparison with prostaglandin E2 (PGE2) (vaginal and intracervical), low-dose misoprostol (oral and vaginal), amniotomy or oxytocin.

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Search methods
For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register, ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP), and reference lists of retrieved studies (9 January 2018). We updated the search in March 2019 and added the search results to the awaiting classification section of the review.

Selection criteria
Clinical trials comparing mechanical methods used for third trimester cervical ripening or labour induction with pharmacological methods.

Mechanical methods include: (1) the introduction of a catheter through the cervix into the extra-amniotic space with balloon insufflation; (2) introduction of laminaria tents, or their synthetic equivalent (Dilapan), into the cervical canal; (3) use of a catheter to inject fluid into the extra-amniotic space (EASI).

This review includes the following comparisons: (1) specific mechanical methods (balloon catheter, laminaria tents or EASI) compared with prostaglandins (different types, different routes) or with oxytocin; (2) single balloon compared to a double balloon; (3) addition of prostaglandins or oxytocin to mechanical methods compared with prostaglandins or oxytocin alone.

Data collection and analysis
Two review authors independently assessed trials for inclusion and assessed risk of bias. Two review authors independently extracted data and assessed the quality of the evidence using the GRADE approach.

Main results
This review includes a total of 112 trials, with 104 studies contributing data (22,055 women; 21 comparisons). Risk of bias of trials varied. Overall, the evidence was graded from very-low to moderate quality. All evidence was downgraded for lack of blinding and, for many comparisons, the effect estimates were too imprecise to make a valid judgement.

Balloon versus vaginal PGE2: there may be little or no difference in vaginal deliveries not achieved within 24 hours (risk ratio (RR) 1.01, 95% confidence interval (CI) 0.82 to 1.26; 7 studies; 1685 women; low-quality evidence) and there probably is little or no difference in caesarean sections (RR 1.00, 95% CI 0.92 to 1.09; 28 studies; 6619 women; moderate-quality evidence) between induction of labour with a balloon catheter and vaginal PGE2. A balloon catheter probably reduces the risk of uterine hyperstimulation with fetal heart rate (FHR) changes (RR 0.35, 95% CI 0.18 to 0.67; 6 studies; 1966 women; moderate-quality evidence), serious neonatal morbidity or perinatal death (RR 0.48, 95% CI 0.25 to 0.93; 8 studies; 2757 women; moderate-quality evidence) and may slightly reduce the risk of aneonatal intensive care unit (NICU) admission (RR 0.82, 95% CI 0.65 to 1.04; 3647 women; 12 studies; low-quality evidence). It is uncertain whether there is a difference in serious maternal morbidity or death (RR 0.20, 95% CI 0.01 to 4.12; 4 studies; 1481 women) or five-minute Apgar score < 7 (RR 0.74, 95% CI 0.49 to 1.14; 4271 women; 14 studies) because the quality of the evidence was found to be very low and low, respectively.

Balloon versus low-dose vaginal misoprostol: it is uncertain whether there is a difference in vaginal deliveries not achieved within 24 hours between induction of labour with a balloon catheter and vaginal misoprostol (RR 1.09, 95% CI 0.85 to 1.39; 340 women; 2 studies; low-quality evidence). A balloon catheter probably reduces the risk of uterine hyperstimulation with FHR changes (RR 0.39, 95% CI 0.18 to 0.85; 1322 women; 8 studies; moderate-quality evidence) but may increase the risk of a caesarean section (RR 1.28, 95% CI 1.02 to 1.60; 1756

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women; 12 studies; low-quality evidence). It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death (RR 0.58, 95% CI 0.12 to 2.66; 381 women; 3 studies), serious maternal morbidity or death (no events; 4 studies, 464 women), both very low-quality evidence, and five-minute Apgar score < 7 (RR 1.00, 95% CI 0.50 to 1.97; 941 women; 7 studies) and NICU admissions (RR 1.00, 95% CI 0.61 to 1.63; 1302 women; 9 studies) both low-quality evidence.

Balloon versus low-dose oral misoprostol: a balloon catheter probably increases the risk of a vaginal delivery not achieved within 24 hours (RR 1.28, 95% CI 1.13 to 1.46; 782 women, 2 studies, and probably slightly increases the risk of a caesarean section (RR 1.17, 95% CI 1.04 to 1.32; 3178 women; 7 studies; both moderate-quality evidence) when compared to oral misoprostol. It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes (RR 0.81, 95% CI 0.48 to 1.38; 2033 women; 2 studies), serious neonatal morbidity or perinatal death (RR 1.11, 95% CI 0.60 to 2.06; 2627 women; 3 studies), both low-quality evidence, serious maternal morbidity or death (RR 0.50, 95% CI 0.05 to 5.52; 2627 women; 3 studies), very low-quality evidence, five-minute Apgar scores < 7 (RR 0.71, 95% CI 0.38 to 1.32; 2693 women; 4 studies) and NICU admissions (RR 0.82, 95% CI 0.58 to 1.17; 2873 women; 5 studies) both low-quality evidence.

Authors' conclusions
Low- to moderate-quality evidence shows mechanical induction with a balloon is probably as effective as induction of labour with vaginal PGE2. However, a balloon seems to have a more favourable safety profile. More research on this comparison does not seem warranted.

Moderate-quality evidence shows a balloon catheter may be slightly less effective as oral misoprostol, but it remains unclear if there is a difference in safety outcomes for the neonate. When compared to low-dose vaginal misoprostol, low-quality evidence shows a balloon may be less effective, but probably has a better safety profile.

Future research could be focused more on safety aspects for the neonate and maternal satisfaction.

Induction of labour at or near term for suspected fetal macrosomia

Michel Boulvain, Jim G Thornton

Background
Women with a suspected large-for-dates fetus or a fetus with suspected macrosomia (birthweight greater than 4000 g) are at risk of operative birth or caesarean section. The baby is also at increased risk of shoulder dystocia and trauma, in particular fractures and brachial plexus injury. Induction of labour may reduce these risks by decreasing the birthweight, but may also lead to longer labours and an increased risk of caesarean section.

Objectives
To assess the effects of a policy of labour induction at or shortly before term (37 to 40 weeks) for suspected fetal macrosomia on the way of giving birth and maternal or perinatal morbidity.

Search methods
We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 January 2016), contacted trial authors and searched reference lists of retrieved studies.

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Selection criteria
Randomised trials of induction of labour for suspected fetal macrosomia.

Data collection and analysis
Review authors independently assessed trials for inclusion and risk of bias, extracted data and checked them for accuracy. We contacted study authors for additional information. For key outcomes the quality of the evidence was assessed using the GRADE approach.

Main results
We included four trials, involving 1190 women. It was not possible to blind women and staff to the intervention, but for other 'Risk of bias' domains these studies were assessed as being at low or unclear risk of bias.

Compared to expectant management, there was no clear effect of induction of labour for suspected macrosomia on the risk of **caesarean section** (risk ratio (RR) 0.91, 95% confidence interval (CI) 0.76 to 1.09; 1190 women; four trials, *moderate-quality evidence*) or **instrumental delivery** (RR 0.86, 95% CI 0.65 to 1.13; 1190 women; four trials, *low-quality evidence*). **Shoulder dystocia** (RR 0.60, 95% CI 0.37 to 0.98; 1190 women; four trials, *moderate-quality evidence*), and **fracture (any)** (RR 0.20, 95% CI 0.05 to 0.79; 1190 women; four studies, *high-quality evidence*) were reduced in the induction of labour group. There were no clear differences between groups for **brachial plexus injury** (two events were reported in the control group in one trial, *low-quality evidence*). There was no strong evidence of any difference between groups for measures of neonatal asphyxia; **low five-minute infant Apgar scores (less than seven)** or **low arterial cord blood pH** (RR 1.51, 95% CI 0.25 to 9.02; 858 infants; two trials, *low-quality evidence*; and, RR 1.01, 95% CI 0.46 to 2.22; 818 infants; one trial, *moderate-quality evidence*, respectively).

Mean birthweight was lower in the induction group, but there was considerable heterogeneity between studies for this outcome (mean difference (MD) -178.03 g, 95% CI -315.26 to -40.81; 1190 infants; four studies; I^2 = 89%).

For outcomes assessed using GRADE, we based our downgrading decisions on high risk of bias from lack of blinding and imprecision of effect estimates.

Authors' conclusions
Induction of labour for suspected fetal macrosomia has not been shown to alter the risk of brachial plexus injury, but the power of the included studies to show a difference for such a rare event is limited. Also antenatal estimates of fetal weight are often inaccurate so many women may be worried unnecessarily, and many inductions may not be needed. Nevertheless, induction of labour for suspected fetal macrosomia results in a lower mean birthweight, and fewer birth fractures and shoulder dystocia. The observation of increased use of phototherapy in the largest trial, should also be kept in mind.

Findings from trials included in the review suggest that to prevent one fracture it would be necessary to induce labour in 60 women. Since induction of labour does not appear to alter the rate of caesarean delivery or instrumental delivery, it is likely to be popular with many women. In settings where obstetricians can be reasonably confident about their scan assessment of fetal weight, the advantages and disadvantages of induction at or near term for fetuses suspected of being macrosomic should be discussed with parents.

Although some parents and doctors may feel the evidence already justifies induction, others may justifiably disagree. Further trials of induction shortly before term for suspected fetal macrosomia are needed. Such trials

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should concentrate on refining the optimum gestation of induction, and improving the accuracy of the diagnosis of macrosomia.

Planned hospital birth compared with planned home birth for pregnant women at low risk of complications

Ole Olsen, Jette A Clausen

Background
Observational studies of increasingly better quality and in different settings suggest that planned hospital birth in many places does not reduce mortality and morbidity but increases the frequency of interventions and complications. Euro-Peristat (part of the European Union's Health Monitoring Programme) has raised concerns about iatrogenic effects of obstetric interventions, and the World Health Organization (WHO) has raised concern that the increasing medicalisation of childbirth tends to undermine women's own capability to give birth and negatively impacts their childbirth experience. This is an update of a Cochrane Review first published in 1998, and previously updated in 2012.

Objectives
To compare the effects of planned hospital birth with planned home birth attended by a midwife or others with midwifery skills and backed up by a modern hospital system in case a transfer to hospital should turn out to be necessary. The primary focus is on women with an uncomplicated pregnancy and low risk of medical intervention during birth.

Search methods
For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register (which includes trials from CENTRAL, MEDLINE, Embase, CINAHL, WHO ICTRP, and conference proceedings), ClinicalTrials.gov (16 July 2021), and reference lists of retrieved studies.

Selection criteria
Randomised controlled trials (RCTs) comparing planned hospital birth with planned home birth in low-risk women as described in the objectives. Cluster-randomised trials, quasi-randomised trials, and trials published only as an abstract were also eligible.

Data collection and analysis
Two review authors independently assessed trials for inclusion and risk of bias, extracted data, and checked the data for accuracy. We contacted study authors for additional information. We assessed the certainty of the evidence using the GRADE approach.

Main results
We included one trial involving 11 participants. This was a small feasibility study to show that well-informed women - contrary to common beliefs - were prepared to be randomised. This update did not identify any additional studies for inclusion, but excluded one study that had been awaiting assessment. The included study was at high risk of bias for three out of seven risk of bias domains. The trial did not report on five of the seven primary outcomes, and reported zero events for one primary outcome (caesarean section), and non-zero events for the remaining primary outcome (baby not breastfed). Maternal mortality, perinatal mortality (non-malformed), Apgar < 7 at 5 minutes, transfer to neonatal intensive care unit, and maternal satisfaction were not

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reported. The overall certainty of the evidence for the two reported primary outcomes was very low according to our GRADE assessment (downgraded two levels for high overall risk of bias (due to high risk of bias arising from lack of blinding, high risk of selective reporting and lack of ability to check for publication bias) and two levels for very serious imprecision (single study with few events)).

Authors' conclusions
This review shows that for selected, low-risk pregnant women, the evidence from randomised trials to support that planned hospital birth reduces maternal or perinatal mortality, morbidity, or any other critical outcome is uncertain. As the quality of evidence in favour of home birth from observational studies seems to be steadily increasing, it might be just as important to prepare a regularly updated systematic review including observational studies as described in the *Cochrane Handbook for Systematic Reviews of Interventions* as to attempt to set up new RCTs. As women and healthcare practitioners may be aware of evidence from observational studies, and as the International Federation of Gynecology and Obstetrics and the International Confederation of Midwives collaboratively conclude that there is strong evidence that out-of-hospital birth supported by a registered midwife is safe, equipoise may no longer exist, and randomised trials may now thus be considered unethical or hardly feasible.

If you have any questions or comments with regard to the above document please feel free to contact me.

Kind regards

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