Caesarean section for non-medical reasons at term (Review)

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[Intervention Review]

Caesarean section for non-medical reasons at term

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ABSTRACT

Background

Caesarean section rates are progressively rising in many parts of the world. One suggested reason is increasing requests by women for caesarean section in the absence of clear medical indications, such as placenta praevia, HIV infection, contracted pelvis and, arguably, breech presentation or previous caesarean section. The reported benefits of planned caesarean section include greater safety for the baby, less pelvic floor trauma for the mother, avoidance of labour pain and convenience. The potential disadvantages, from observational studies, include increased risk of major morbidity or mortality for the mother, adverse psychological sequelae, and problems in subsequent pregnancies, including uterine scar rupture and a greater risk of stillbirth and neonatal morbidity. The differences in neonatal physiology following vaginal and caesarean births are thought to have implications for the infant, with caesarean section potentially increasing the risk of compromised health in both the short and the long term. An unbiased assessment of advantages and disadvantages would assist discussion of what has become a contentious issue in modern obstetrics.

Objectives

To assess, from randomised trials, the effects on perinatal and maternal morbidity and mortality, and on maternal psychological morbidity, of planned caesarean delivery versus planned vaginal birth in women with no clear clinical indication for caesarean section.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (31 January 2012) and reference lists of relevant studies.

Selection criteria

All comparisons of intention to perform caesarean section and intention for women to give birth vaginally; random allocation to treatment and control groups; adequate allocation concealment; women at term with single fetuses with cephalic presentations and no clear medical indication for caesarean section.

Data collection and analysis

We identified no studies that met the inclusion criteria.

Main results

There were no included trials.

Authors' conclusions

There is no evidence from randomised controlled trials, upon which to base any practice recommendations regarding planned caesarean section for non-medical reasons at term. In the absence of trial data, there is an urgent need for a systematic review of observational studies and a synthesis of qualitative data to better assess the short- and long-term effects of caesarean section and vaginal birth.

PLAIN LANGUAGE SUMMARY

Caesarean section for non-medical reasons at term

Childbirth is a profound and powerful human experience. Women often describe feelings of empowerment, elation and achievement, although other women's experiences include trauma, fear, pain, and loss of control. The way women give birth, either vaginally or by caesarean section, is likely to impact on their feelings. In recent years, caesareans have become safer due to improved anaesthesia and improved surgical techniques, along with the routine use of drugs at surgery to combat the increased risk of infection and blood clots in the mother. However, caesarean section remains a surgical procedure accompanied by abdominal and uterine incisions, scarring and adhesions. There is also evidence of an increased chance of problems in subsequent pregnancies for both women and babies.

This review found no trials to help assess the risks and benefits of caesarean section when undertaken without a conventional medical indication. The authors strongly recommend the use of alternative research methods to gather data on the outcomes associated with different ways of giving birth.

BACKGROUND

Description of the condition

Childbirth is a profound and powerful human experience. Women's accounts of birth often describe feelings of empowerment, elation and achievement, particularly following vaginal birth without medical interventions (Gaskin 2003); whereas other women associate childbirth with trauma, loss of control, fear, pain and anxiety. It is possible that the experience of giving birth may contribute to a woman's ability to adapt to parenthood, although there is only indirect evidence of this. Women giving birth in a supportive environment have been shown to have greater self-esteem, confidence in themselves as mothers, more positive child-rearing practices and less anxiety and depression after birth (Wolman 1993).

Description of the intervention

The term 'caesarean section' refers to the operation of delivering a baby through incisions made in the mother's abdominal wall and uterus. Performed for certain medical indications such as placenta praevia (placenta lying over the opening of the cervix) or transverse lie (the baby lying across the uterus), caesarean section can be a life-saving operation (Neilson 2003). A caesarean section is medically indicated when a significant risk of adverse outcome for mother or baby is present if the operation is not performed at a given time (Penna 2003). However, the use of caesarean section for more vague medical indications (failure to progress, presumed fetal compromise) and non-medical reasons (for example, maternal request) is increasing in many resource-rich health services. Non-medically indicated caesarean sections may be performed for reasons other than the risk of adverse outcome if the person(s) assessing risk feel it is outweighed by the physical or psychological benefits. It has been suggested, for example, that a proportion of women, who request caesarean section for no apparent medical reason, may actually have been influenced by previous or current psychological trauma (Ryding 1993) such as sexual abuse or a previous traumatic birth. These may legitimately be regarded as clinical indications.

In the UK, caesarean section accounted for 2% of all births in 1953, 18% in 1997 (Macfarlane 2000) and 21% in 2001 (Thomas 2001). In 2010, the caesarean section rate (CSR) for England was 24.8% (ICHSC 2010). Statistics for Australia and the United

States of America show almost one in every three pregnant women have a caesarean birth (Laws 2007; MacDorman 2008). Whilst there has been a world-wide trend towards increasing CSRs, the rates vary considerably within and between countries. In Norway, wide variations in CSRs (between 6% and 20%) have been reported between obstetric departments (Bergen 2002). In the United States of America, figures from alternative birth settings show considerably lower CSRs (1.5% - Gaskin 2003) than the national average (24.4% - Martin 2002). Furthermore, marked differences are reported in rates from different healthcare sectors. During a two-year period in an urban area of India, total CSRs in the public, charitable and private sectors were 20%, 38% and 47% respectively (Sreevidya 2003). The authors of this study speculate that physician convenience, preferences and financial incentives (for individuals and healthcare organisations) contribute to high CSRs in the private sector, and suggest that such factors may be important in other healthcare settings.

The extent to which women's request for caesarean section for non-medical reasons has contributed to these rates, and why, is a contentious issue (Goer 2001; Karlstrom 2011; Kingdon 2009; Lowdon 2002; McAleese 2000; Paterson-Brown 1998; Sultan 1996). Existing evidence from both retrospective and prospective studies is limited, utilising different definitions of 'maternal request', and reporting rates of between 1% and 48% in public sector healthcare systems, and 60% in the private sector (Declerq 2002; Thomas 2001). There is insufficient understanding as to why women may request a caesarean section in the absence of a medical reason. Systematic literature reviews have highlighted specific methodological and conceptual issues with existing studies (Gamble 2000; McCourt 2007) as well as identifying personal and cultural reasons for maternal request (Gamble 2007; Kingdon 2006). Moreover, a systematic review and meta-analysis of 38 observational studies reports a higher preference for caesarean section in women with a previous caesarean section versus women without a previous caesarean section (29.4%; 95% confidence interval (CI) 24.4 to 34.8 versus 10.1%; 95% CI 7.5 to 13.1 respectively) (Mazzoni 2011). Women's previous birth experience, fear of vaginal birth, need for choice and control, coupled with the cultural acceptability of caesarean section may all influence women's decision-making surrounding ways of giving birth. Whilst it is likely that the role of the caregiver in data generation, timing of data collection, women's post-hoc rationalisation and recall bias, have led to the over-reporting of maternal request for caesarean section, nonetheless, a percentage of women are now undergoing caesarean section for non-medical reasons. Informed decision-making for both clinicians and women is dependent on accurate information about the consequences of caesarean section compared with vaginal birth.

In countries where the CSR is rising, the incidence of vaginal birth is, as expected, in decline. Intervention in the physiological processes of 'normal' birth varies according to birth setting. In high intervention birth settings where the use of artificial oxytocin, electronic fetal monitoring, epidural analgesia, artificially ruptured membranes, and instrumental deliveries are common, the extent to which adverse outcomes attributed to vaginal birth may also be associated with current obstetric management is an issue. The use of forceps may be particularly relevant to the debate on the possible maternal benefits of caesarean delivery increasingly being cited as including the protection of the pelvic floor to avoid perineal pain, dyspareunia, uterovaginal prolapse and incontinence of urine, flatus and/or faeces (Farrell 2001; Rortveit 2003; Sultan 1993; Sultan 1994; Sultan 1996; Sultan 1997). Conversely, a large, 12-year, postpartum cohort study has reported caesarean section was not protective for urinary incontinence unless all the women's births were exclusively by caesarean section. Moreover, even after women having exclusively caesarean sections, the prevalence of urinary incontinence was high at 40% (MacArthur 2011).

Other possible benefits of elective caesarean section discussed in both the professional and lay press include the convenience of scheduling the time and date of birth (Kirby 1999; Wagner 2000). The extent to which convenience is cited as a maternal benefit may be confounded by the convenience for caregivers. The opportunity to schedule caesarean sections enables caregivers to plan staffing levels accordingly, performing the caesarean sections within daylight hours, and possibly reduce the incidence of litigation associated with vaginal birth or emergency caesareans (Birchard 1999). Avoidance of pain during labour has also been cited as a potential maternal benefit of elective caesarean delivery (Turnbull 1999); as has the avoidance of emergency caesarean sections during labour, which has been associated with increases in morbidity and mortality (Lilford 1990; Paterson-Brown 1998). Precise assessments of the mortality risks associated with elective caesarean section for non-medical reasons are problematic due to multiple definitions of 'elective', and a lack of up-to-date data which distinguishes between outcomes from scheduled or emergency caesarean sections. Nevertheless, Hall and Bewley (Hall 1999) have calculated the case-fatality rate for elective caesarean section in the UK during 1994 to 1996 and estimate it to be almost three times as great as that for vaginal births.

The benefit-risk calculus associated with surgery has evolved, as techniques for surgery, anaesthesia, infection control, and blood banking have improved (Minkoff 2003). Nonetheless, there is evidence to suggest increased maternal risks associated with the surgery, including anaesthetic risks, surgical complications, increased blood loss, need for transfusion, and pulmonary embolism (Kelleher 1994). There may also be restricted activities of daily living (Chippington 2004), breastfeeding difficulties (Francome 1993) and increased maternal problems related to the uterine scar in subsequent pregnancies (Hemminki 1996). A retrospective cohort study of 308,755 Canadian women who had experienced a previous caesarean section found trial of labour is associated with increased risk of uterine rupture (0.65% in the trial of labour group compared with 0.25% in the non-trial of labour group), but elective caesarean section may increase the risk of maternal

death (1.6 per 100,000 in the trial of labour group compared with 5.6 per 100,000 in the elective caesarean section group (Wen 2004). Furthermore new, unexpected long-term risks of caesarean section continue to be reported; these include abnormal placentation (Serena 2005), ectopic pregnancy, haemorrhage and hysterectomy following uterine evacuation, latex allergy, implantation endometriosis, adenomyosis and increased hospital readmission (Bewley 2002). Caesarean section has also been associated with emotional difficulties (Clement 2001) including postpartum depression and negative feelings about the experience of childbirth, but not specifically among women undergoing caesarean delivery by choice (Minkoff 2003). Suggested increased risks for the baby of delivery by caesarean section include, increased admission to neonatal units/separation of the mother and neonate (Treffers 1993), iatrogenic prematurity (Wagner 2000), laceration (Smith 1997), increased neonatal respiratory problems (Madar 1999), increased special educational needs in later life linked to the timing of the caesarean section (Kapellou 2011; MacKay 2010) and stillbirth in the next pregnancy (Smith 2003). A recent literature review suggests that vaginal births involve important physiological changes that are absent or modified in babies born by caesarean section (Hyde 2011). Authors suggest that vaginal birth is an important life programming event for the infant, and that the differences in physiology that arise between vaginal and caesarean births have implications for the infant, with caesarean section increasing the risk of compromised health in both the short and the long term (Hyde 2011).

In a large multi-centre randomised controlled trial of planned caesarean section versus planned vaginal birth for breech presentation, at three months postnatally, women in the planned caesarean delivery group were less likely to report urinary incontinence (Hannah 2002). There was no statistically significant difference regarding incontinence of flatus between groups, but more women reported that it was less of a problem in the planned caesarean delivery group. At three months there were no differences between groups in breastfeeding; infant health; ease of caring for infant and adjusting to being a new mother; sexual relations; pain; depression; and views regarding childbirth experience. The trial reported a significant reduction in adverse perinatal outcomes without an increased risk of immediate maternal morbidity with planned caesarean section compared with planned vaginal birth. The two-year follow up of the same trial (Hannah 2004) showed no differences between groups in breastfeeding; relationship with child or partner; pain; subsequent pregnancy; incontinence; depression; urinary, menstrual or sexual problems; fatigue; or distressing memories of the birth experience. Planned caesarean section was associated with a higher risk of constipation. There was no difference identified between planned caesarean section and planned vaginal birth in risk of death or neurodevelopmental delay in children at two years of age (Whyte 2004). This finding was surprising, given the reduction in the risk of perinatal or neonatal death, or serious neonatal morbidity, with a policy of planned caesarean birth found at three months. The applicability of these findings for cephalic presentation is debatable.

Maternal and neonatal physical health outcomes must also be considered alongside psychosocial influences and the wider cultural context. For example, the trend towards smaller families may be relevant when considering the risks of caesarean section for subsequent pregnancies. The increasingly cited risks of vaginal birth such as placental abruption, cord prolapse, undiagnosed fetal hypoxaemia and shoulder dystocia (Paterson-Brown 1997) must be considered in the context of the medical model within technology-dependent cultures where intervention in the natural processes of reproduction is common. For many healthcare systems, the economic costs associated with different modes of delivery are as pertinent as the social costs. A recent economic model, developed to determine the cost consequence of planned caesarean section in the absence of medical indication to the NHS, estimated it to range from £10.9 to £14.8 million per annum. The mean cost saving of switching from a planned caesarean section to a planned vaginal birth was £1257 per birth (NCCWCH 2004). However, in the USA it would appear the costs of increased intervention in vaginal deliveries, the addition of oxytocin specifically, can nullify any cost differences between delivery mode. If epidural anaesthesia is also used, total costs exceeded the cost of elective caesarean delivery by almost 10% in one study (Bost 2003).

This review is one of a series of Cochrane reviews on planned caesarean section; other reviews focus on elective caesarean section for medical indications ('Planned caesarean section for term breech delivery' (Hofmeyr 2003), 'Planned elective repeat caesarean section versus planned vaginal birth for women with a previous caesarean birth' (Dodd 2004), 'Planned caesarean section for multiple pregnancy' (Dodd 2002).

Why it is important to do this review

Caesarean section for non-medical reasons is a multifaceted complex issue, the implications of which for childbearing women, healthcare professionals and society are unknown. For women, requesting a caesarean section for non-medical reasons is an emotive and very personal decision. For clinicians, performing a caesarean section for non-medical reasons is a professional decision, the ethics of which are being debated without sufficient evidence of the risks, as well as the benefits. The review aims to assist women and clinicians to make informed evidence-based decisions about the way women give birth.

OBJECTIVES

To assess, from randomised trials, the effects on perinatal and maternal morbidity and mortality, and on maternal psychological morbidity, of planned caesarean delivery versus planned vaginal

birth where there is no clear clinical indication for a caesarean section.

METHODS

Criteria for considering studies for this review

Types of studies

All comparisons of intention to perform caesarean section and intention to give birth vaginally; random allocation to treatment and control groups; violations of allocated management and exclusions after allocation not sufficient to materially affect outcomes. Given the nature of the review objective, we planned to include observational and qualitative research in the discussion, to place any trial findings in a social, cultural, organisational, and geographical context.

Types of participants

Pregnant women, singleton pregnancy, cephalic presentation at term, with no conventional medical indication for caesarean section.

Types of interventions

Planned caesarean section compared with planned vaginal birth in the absence of a medical reason for caesarean section (non-medical reason as defined by trial authors).

Types of outcome measures

Primary outcomes

1. Serious maternal morbidity or death (e.g. admission to intensive care unit, septicaemia, organ failure);
2. serious neonatal morbidity or perinatal death, excluding fatal malformations (e.g. seizures, birth asphyxia defined by trialists, neonatal encephalopathy);
3. maternal postnatal depression (as defined by trial authors).

Secondary outcomes

Short-term maternal outcomes

1. Caesarean section (emergency/elective);
2. regional analgesia;
3. general anaesthesia;
4. complications of anaesthesia (anaphylaxis, inhalation of gastric contents, dural tap);
5. instrumental vaginal birth;
6. postpartum haemorrhage (as defined by the trial authors);
7. postpartum anaemia (as defined by the trial authors);
8. blood transfusion;
9. hysterectomy;
10. deep venous thrombosis and pulmonary embolism;
11. postpartum pyrexia (infection, wound, bladder, perineum, genital tract, chest, haematoma: wound, perineum);
12. other operative postpartum interventions (evacuation of retained products of conception, evacuation of haematoma, wound/episiotomy repair);
13. antibiotic use;
14. antithrombotic prophylaxis;
15. experience of childbirth.

Long-term maternal outcomes

1. Breastfeeding failure (as defined by trial authors);
2. perineal pain;
3. abdominal pain;
4. backache;
5. other pain;
6. dyspareunia (as defined by trial authors);
7. uterovaginal prolapse;
8. urinary incontinence;
9. flatus incontinence;
10. faecal incontinence;
11. postnatal self-esteem (as defined by trial authors);
12. postnatal anxiety (as defined by trial authors);
13. post traumatic stress syndrome;
14. relationship with partner;
15. relationship with baby (as defined by trial authors);
16. subsequent pregnancy complications (ectopic pregnancy, abruption, placenta praevia, placenta accreta, decreased fertility, miscarriage, hysterectomy, major obstetric haemorrhage);
17. postpartum rehospitalisation;
18. experience of childbirth.

Outcomes for baby

1. Preterm birth;
2. asthma;
3. behavioural/learning disorders;
4. Apgar score less than seven at five minutes;
5. cord blood pH less than 7.2;
6. neonatal intensive care unit admission;
7. neonatal encephalopathy (as defined by trial authors);
8. brachial plexus injury;
9. transient tachypnea of the newborn; hyaline membrane disease/surfactant/continuous positive airways pressure/ventilation;

10. jaundice;
11. febrile illness/sepsis;
12. physical infant trauma (e.g. cuts and bruises);
13. disability in childhood.

Health services outcomes

1. Caregiver experience;
2. cost: time, financial, staffing, facilities, training.

Outcomes were to be included if considered clinically meaningful by trial authors; 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

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (31 January 2012).

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

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

Details of the search strategies for CENTRAL, MEDLINE and EMBASE, 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.

Searching other resources

We searched for further studies in the reference lists. We did not apply any language restrictions.

For details of searching carried out for the initial version of the review, please see Appendix 1.

Data collection and analysis

The following methodology would have been applied had we identified any studies, and it will be used if studies are identified in future updates.

Selection of studies

Three review authors (Tina Lavender, Carol Kingdon and Gill Gyte) independently assessed for inclusion all the potential studies we identified as a result of the search strategy. There was agreement but had there been any disagreement this would have been resolved through discussion or, if required, we would have consulted our remaining review authors.

Data extraction and management

We designed a form to extract data. In future, for eligible studies, at least two review authors will extract the data using the agreed form. We will resolve discrepancies through discussion or, if required, we will consult a third person. We will enter data into Review Manager software (RevMan 2011) and check for accuracy.

When information regarding any of the above is unclear, we will attempt to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors will independently assess risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreement by discussion or by involving a third assessor.

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

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

We will assess 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 will describe for each included study the method used to conceal allocation to interventions prior to assignment and will assess whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We will assess 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)

It is not possible to blind either participants or personnel in these studies. We will consider the possible impact of this when interpreting the data for relevant outcomes.

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

It will be possible to blind outcome assessors for some outcomes only. Where blinding is not possible, we will consider the possible impact of this when interpreting the data for relevant outcomes.

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

We will describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We will state 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 is reported, or can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake.

We will assess methods as:

- low risk of bias (e.g. 20% or less missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. greater than 20% missing data; 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 will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We will assess the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; 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 will describe for each included study any important concerns we have about other possible sources of bias.

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

- low risk of other bias;
- high risk of other bias;
- unclear whether there is risk of other bias.

(7) Overall risk of bias

We will make explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it is likely to impact on the findings. We will explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data

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

Continuous data

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

Unit of analysis issues

We do not anticipate any cluster- or cross-over trials as we believe these methodologies are unsuitable for our review question.

Dealing with missing data

For included studies, we will note levels of attrition. We will explore 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 will carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we will attempt to include all participants randomised to each group in the analyses, and all participants will be analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We will assess statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if I^2 is greater than 30% and either T^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

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, and use formal tests for funnel plot asymmetry. For continuous outcomes, we will use the test proposed by Egger 1997, and for dichotomous outcomes, we will use the test proposed by Harbord 2006. If asymmetry is detected in any of these tests, or is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using the Review Manager software (RevMan 2011). We will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. The random-effects summary will be treated as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful, we will not combine trials.

If we use random-effects analyses, the results will be presented as the average treatment effect with 95% confidence intervals, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

If we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

We plan to carry out the following subgroup analyses on our primary outcomes only:

1. nulliparous and multiparous;
2. services with low (20 or less per 1000) and high perinatal mortality (more than 20);
3. natural conception and assisted conception;
4. low-level intervention in the first stage of labour in at least 75% versus less than 75% in the planned vaginal birth group;
5. low-level intervention in the first stage of labour, defined as spontaneous onset without regional anaesthesia - epidural, spinal or combination of the two (Birth Choice UK 2001).

We will assess differences between subgroups by carrying out subgroup interaction tests available in RevMan 2011.

Sensitivity analysis

We will perform sensitivity analysis based on trial quality, separating high-quality trials from trials of lower quality. 'High quality' will, for the purposes of this sensitivity analysis, be defined as a trial having adequate sequence generation, allocation concealment and an attrition rate of less than 20%, given the stated importance of attrition as a quality measure (Tierney 2005). We will carry out sensitivity analysis for primary outcomes only.

RESULTS

Description of studies

See: Characteristics of excluded studies.

Results of the search

The search strategies yielded two studies for consideration of inclusion (*see* Characteristics of excluded studies).

Included studies

We found no studies for inclusion in this review.

Excluded studies

Neither of the studies met the basic inclusion criteria and were therefore excluded. One study (European Mode 1999) only included women with a confirmed diagnosis of HIV-1 infection,

which is a medical, as opposed to a 'non-medical', indication for caesarean section. Furthermore, it is unclear from the data how many participants had singleton pregnancies, cephalic presentations, term babies or complications of pregnancy, as the decision to randomise was at the clinician's discretion. The remaining study (Pence 2002) was excluded because of the potential for selection bias; the demography and parity of the sample and method of randomisation was unclear. We attempted to contact the author of this paper, to clarify these issues, without success.

Risk of bias in included studies

No studies met the eligibility criteria for inclusion in this review.

Effects of interventions

No studies met the eligibility criteria for inclusion in this review.

DISCUSSION

There are no randomised controlled trials of planned caesarean section versus planned vaginal birth for non-medical reasons at term, which makes the comparability of the effects on perinatal and maternal morbidity and mortality, and maternal psychological morbidity, for these two different ways of giving birth problematic.

The need for evidence of the effects of caesarean section performed for non-medical reasons at term on perinatal and maternal mortality, and maternal psychological morbidity, is important to women and clinicians. The actual number of women requesting caesarean birth in the absence of clear indications for themselves or their baby is unknown (Klein 2004). Furthermore, women's preferences for birth mode are likely to change as their pregnancies progress (Kingdon 2009). In Kingdon's study, only 2% of women expressed a preference for caesarean birth by late pregnancy. However, a proportion of women are currently undergoing caesarean section performed for non-medical reasons at term, whilst existing evidence concerning the risks and benefits is keenly contested by professionals (Minkoff 2003) and consumer organisations representing maternity service users (Lowdon 2002).

Informed decision-making surrounding vaginal or caesarean birth is considered by some to be aided in specific situations, where randomised controlled trials have been performed and systematically reviewed. For example, planned caesarean section for term breech delivery (Hofmeyr 2003), or planned elective repeat caesarean section versus planned vaginal birth for women with a previous caesarean birth (Dodd 2004).

The findings of existing trials of planned caesarean section performed for medical indications versus planned vaginal birth are not applicable to situations where there are no medical reasons, because caesarean mortality and morbidity is confounded by pre-existing obstetric or general medical conditions (that is, European Mode 1999). The use of data from observational studies of planned caesarean for non-medical reason and planned vaginal birth seems at present inconclusive. For example, in the UK, the most recent data suggest that the estimated case fatality rate per million maternities and risk ratio for elective caesarean section were twice that for vaginal birth. However, this was not statistically significant and "it cannot be concluded that caesarean section is necessarily more dangerous than vaginal birth" (Hall 2001); particularly as the number of elective caesarean sections performed for medical indications was unclear.

The extent to which performing a randomised controlled trial of planned caesarean section for non-medical reasons versus planned vaginal birth would provide sufficient evidence to assess the risks and benefits of all relevant outcomes is debatable (McCourt 2004). Furthermore, to discuss the possibility of such a trial not only raises important methodological questions, but also introduces significant moral concerns about the ethics of undertaking a trial where women randomised to the intervention arm would receive surgery in the absence of a medical indication. Such issues have been raised by health professionals (Lavender 2005) and women (Lavender 2009), in the UK.

AUTHORS' CONCLUSIONS

Implications for practice

There is no evidence from randomised controlled trials upon which to base any practice recommendations regarding planned caesarean section for non-medical reasons at term.

Implications for research

Although a number of trials have assessed the efficacy of planned vaginal birth versus planned caesarean section, sample populations have included women with potential (Barrett 2004; Dodd 2004; Hannah 2000) or actual pregnancy complications (European Mode 1999). Planned caesarean section for non-medical reasons at term is more contentious because it involves a surgical procedure where there is neither a medical problem nor any complications. The lack of existing evidence is likely to be due to the lack of equipoise for such a trial or the highly complex methodological issues which such a trial may generate (Lavender 2005). These include the complexity of following up women throughout their reproductive life; the difficulty of agreeing on a single primary outcome on which to base sample-size calculations; and the prohibitive cost of a trial in relation to more pertinent research questions. The routine collection of good quality prospective morbidity data (short and long term) may provide the best available evidence from which women can make informed decisions. Qual-

itative explorations which contextualise maternal and professional views and experiences would also add to the evidence base. In the absence of trial data, there is an urgent need for a systematic review of observational studies and a synthesis of qualitative data to better assess the short- and long-term outcomes of caesarean section and vaginal birth.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Study	Reason for exclusion
European Mode 1999	Pregnant women with confirmed diagnosis of HIV-1 infection were randomly assigned to planned caesarean section (n = 188) at 38 weeks of pregnancy or vaginal birth (n = 220) 3 of 170 infants born to women assigned caesarean section delivery were infected compared with 21 of 200 born to women assigned vaginal delivery P < 0.001 This study was excluded as confirmed diagnosis of HIV-1 infection is a conventional indication for caesarean section. Furthermore, it is unclear from the data how many participants had singleton pregnancies, cephalic presentations or term babies: "for women with a previous caesarean section twin pregnancy, breech presentation, intrauterine growth retardation or vaginal infection, e.g. active herpes infection, the decision to randomise was at the clinicians discretion"
Pence 2002	Pregnant women between 37 and 42 weeks' gestation were randomly assigned to 1 of 3 groups: group 1 (n = 40) were vaginally delivered, group 2 (n = 26) had caesarean section with epidural anaesthesia, and group 3 (n = 30) had caesarean section under general anaesthesia. The primary outcome measure was umbilical arterial PO2 which was found to be higher in group 3 The study was excluded because of the potential for selection bias; it is unclear whether this is actually a randomised controlled trial. The demography and parity of the sample was not reported therefore findings could not be interpreted

HIV: human immunodeficiency virus
PO2: pressure of oxygen

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. Search methods for previous version of the review

We searched MEDLINE (1974 to April 2005), EMBASE (1974 to April 2005), CINAHL (1982 to April 2005) and PsycINFO (1887 to April 2005) using the subject heading cesarean section and the free-text terms (cesarean or caesarean or caesarian or cesarian) and (birth or delivery) combined with the free-text terms (choice or inclination or behaviour or decision or prefer or request or demand or want or wish or favour or desire or fancy or rather or thoughts or feelings or opinion or view or like or attitude).
We also performed a manual search of the references of all retrieved articles. We sought unpublished papers and abstracts submitted to international conferences and contacted expert informants.

WHAT'S NEW

Last assessed as up-to-date: 7 February 2012.

Date	Event	Description
31 January 2012	New search has been performed	Search updated. Methodology updated. No new trials identified
31 January 2012	New citation required but conclusions have not changed	Updated.

HISTORY

Protocol first published: Issue 1, 2004

Review first published: Issue 3, 2006

Date	Event	Description
28 April 2009	New search has been performed	Search updated. No new trials identified.
10 November 2008	Amended	Contact details updated.
13 August 2008	Amended	Contact details updated

CONTRIBUTIONS OF AUTHORS

T Lavender, C Kingdon and G Gyte reviewed the papers. T Lavender and C Kingdon wrote the first draft of the review. G Gyte, J Neilson and G Hofmeyr commented on review drafts. For this update, T Lavender, C Kingdon and G Gyte updated the review. The final version of the updated review was reviewed and approved by all authors.

DECLARATIONS OF INTEREST

None known.

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Internal sources

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External sources

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- National Institute for Health Research, UK.

NIHR Programme of centrally-managed pregnancy and childbirth systematic reviews of priority to the NHS and users of theNHS: 10/4001/02

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The methods have been updated to reflect the latest Cochrane Handbook (Higgins 2011). Outcomes have been separated into 'Primary' and 'Secondary' outcomes.

INDEX TERMS

Medical Subject Headings (MeSH)

*Cesarean Section [adverse effects; psychology]; *Term Birth

MeSH check words

Female; Humans; Pregnancy